LELTEK

Leltek Ultrasound Imaging System
(MODEL:LU700 Series)

LK_UI-LU700-01

USER MAUNAL REV. 0.1

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Revision History

Revision	Date
User Manual(LK_UI-LU700-01) Revision 0.1 Initial release	2017-08-18

Contents

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.

Document Conventions

Icons

Icon	Description
 Note	This icon indicates information material or helpful suggestions.
 Caution	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.

Symbols

Symbols	Description/Function
	Consult Operators Manual
	Electrical protection. Insulated application with IEC60601-1 (Type BF applied part)
	WiFi. 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.

EC REP	Indicates the Authorized representative in the European Community.
	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 s 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, or 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	For prescription devices.

Chapter 1 About Leltek Ultrasound Imaging System

About This User Manual

Product Name	Leltek Ultrasound Imaging System
Trademark	Leltek ULTRASOUND IMAGING SYSTEM
Model	LU700

- Please read and understand all instructions in this User Manual before attempting to operate the LU700 equipment.
- Keep this User Manual with the product for future reference.
- Some options or features may not be available in some countries.
- The screen graphics and illustrations in this User Manual are for illustrative purposes only, and may different from what is displayed on the screen.
- All references to standards and regulations, and their revisions are valid as of the date of publication of this User Manual.

About Leltek Ultrasound Imaging System

Install, operate, and maintain this product according to the safety and operating procedures in this manual, and only for its intended purpose. Always use the information in this document with sound clinical judgment and best clinical procedures.
This product is subject to the law in the jurisdiction that the product is used. Install, use, and operate the product only in ways that adhere to applicable laws or regulations, which have the force of law.

- Using the product incorrectly, or for purposes other than those intended and expressly stated by Leltek, may relieve Leltek or its agents from all or some responsibility for resultant noncompliance, damage, or injury.
- Using portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment.
- Operating this system in the presence of flammable gases or anesthetics can cause an explosion.
- Install and operate medical equipment according to electromagnetic compatibility (EMC) guidelines.
- Users are responsible for image quality and diagnosis.
- This product has demonstrated EMC compliance under conditions that included the use of compliant peripheral devices. It is important that you use compliant peripheral devices to reduce the possibility of causing interference to radios, televisions, and other electronic devices.

- Never attempt to open a transducer or a transducer connector. This will avoid the warranty.
- Probes are not delivered sterile before the first us, it's MANDATORY to clean and disinfect probes to avoid infections or disease transmissions.
- Probes must be cleaned and disinfected before they are replaced or disposed of.
- If an user lost him/her tablet／smart phone, the stored data cannot be recovered.
- Do NOT touch the patient with Android mobile device when a user uses the LU700.
- Must comply with Operation condition. (Max 30-min with 10-min resting time.)
- The user should carefully be managed a patient information and key security information because LU700 is used with personal mobile device.
- If the probe dropped to ground or on any other hard surface, Do Not use the probe anymore. That may increase the risk of electric shock due to damaged electrical insulation.
- Electrical leakage checks should be performed on a routine basis by qualified hospital personnel.
- This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

Ultrasound Gels

Ultrasound gel is a type of conductive medium that enables a tight bond between the skin and the probe or transducer, letting the waves transmit directly to the tissues beneath and to the parts that need to be imaged. It is formulated to act as a coupling agent and reduce static.
Ultrasonic gel is usually composed of propylene glycol, water and occasionally a dye. The dye is more for looks than making it work better. It is usually clear and thick, and a little bit sticky. That way, when it is applied to the skin it doesn't drip or run off. At the end of the procedure it can be wiped off easily.

- Do NOT use non-recommended gels(lubricants) which may damage the probe and void the warranty.

- Ultrasound Gels should NOT contain any of the following ingredients, in which would cause the probe damage.

  - Mineral oils
  - Methanol, ethanol, isopropanol alcohol, or any other alcohol-based
  - Iodine
  - Lotions
  - Lanolin
  - Aloe Vera
  - Olive oil
  - Methyl or ethyl parabens (para hydroxybenzoic acid)
  - Dimethyl silicone

- When the examiner does the ultrasound Imaging diagnostic, the examiner shall wear "patient examination gloves". A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

LU700 Ultrasound Imaging System Description

The LU700 Ultrasound Imaging System is a portable, general purpose, software controlled, handheld ultrasound system used to acquire and display hi-resolution, real-time ultrasound data through a commercial off-the-shelf (COTS) Android mobile device.

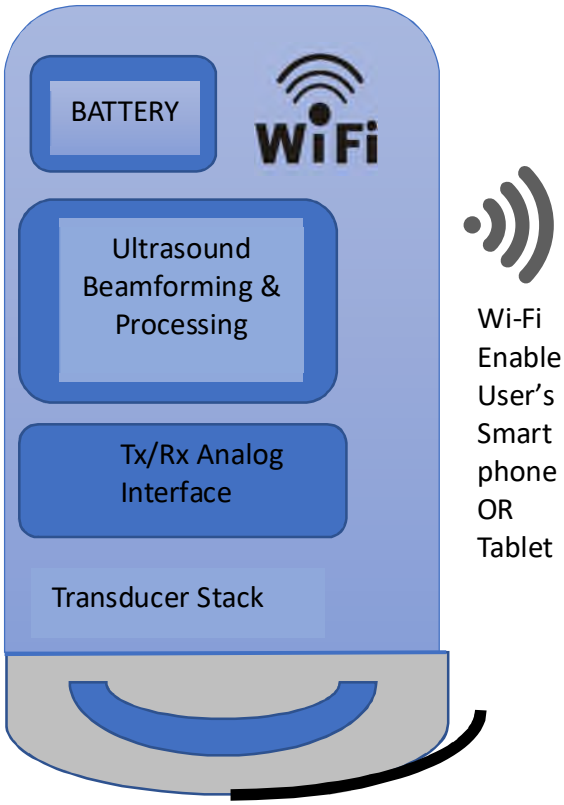
I. The imaging system software runs as an app on a mobile device.

II. The imaging system software can be download to a commercial off-the-shelf (COTS) Android mobile device and utilizes an icon touch-based user interface.

III. The imaging system consists of a series of wireless transducers employing Wi-Fi-based technology to communicate with traditional tablet/smartphone devices via direct Wi-Fi. This allows the user to export ultrasound images and display them across a range portable personal device.

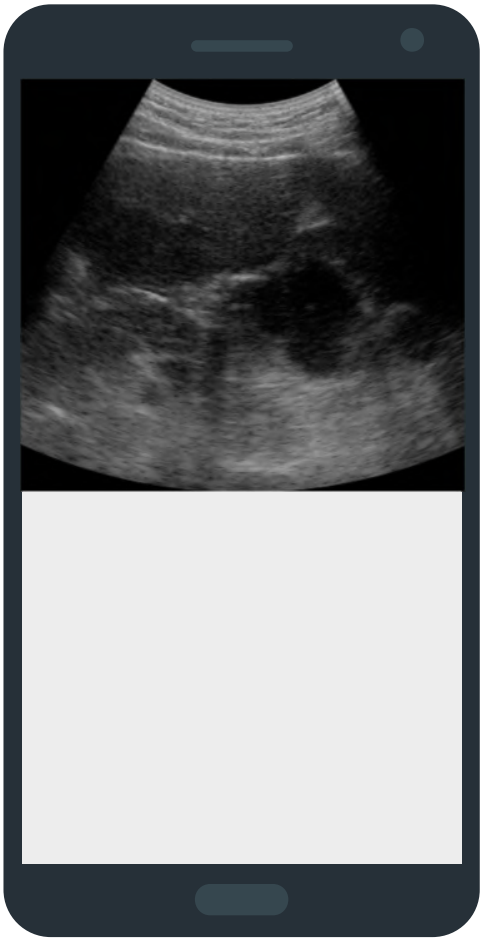
IV. The imaging system houses a built-in battery, multichannel beamformer, prescan converter and Wi-Fi components

The LU700 Ultrasound System included



Ultrasound Probe

Wi-Fi Enable User's Smart phone OR Tablet



User Interface(APP) for Display

Battery Specification

Item	Specification
Description	Rechargeable Li-ion Battery Pack
Capacity	6000mAh
Battery Life	300 discharge cycle
Manufacture	DongGuan Alpha Energy Technology Co.,Ltd.
Model	1036B7
Cell Type	Prismatic cell
Dimensions	120mm*36mm*10.5mm
Safety	UN38.3

System Dimension

Item	Length (mm)	Width (mm)	Height(mm)	Weight(g)
System (with L10-5 front piece, a battery)	177	72	40	320
System (with C5-2 front piece, a battery)	187	72	40	340

Leltek Ultrasound Imaging App

Probe

L10-5 Linear

- Array type: Linear
- Number of element: 128
- Depth(cm): 6.0
- Frequency bandwidth(MHz): 5.0 – 10.0
- Center Frequency: 7.5MHz
- B mode, M mode, Color Doppler, PW Doppler

C5-2 Convex

- Array type: Curvilinear
- Number of element: 128
- Depth(cm): 18.0
- Frequency bandwidth(MHz): 2.0 – 5.0
- Center Frequency: 3.5MHz
- Field of view: 60°
- B mode, M mode, Color Doppler, Power Doppler

Chapter 2 Product Usage

Indication for Use

The LU700 Ultrasound Imaging System is a software-based imaging system and accessories intended for use by qualitied physicians and healthcare professionals who has the ability to conduct ultrasound scan process for evaluation by ultrasound imaging system or fluid flow analysis of the human body. Specific clinical applications and exam types including: General abdominal imaging, musculoskeletal (conventional), musculoskeletal (superficial), peripheral vessel, OB/Gyn.

System: Leltek LU700
Ultrasound Pulsed Echo System
Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other*
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N		
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculoskeletal (conventional)	N	N	N		N		
	Musculoskeletal (superficial)	N	N	N		N		
	Intravascular							
	Other (OB/Gyn.)	N	N	N		N		
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Fetal Echo)							
Peripheral	Peripheral Vessel	N	N	N		N		
Vessel	Other(Carotid)							

N = new indication P = previously cleared by FDA E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

System: Leltek LU700

Transducer: C2-5 Convex 3.6MHz Curved Linear Array Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other*
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N		
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculoskeletal (conventional)	N	N	N		N		
	Musculoskeletal (superficial)	N	N	N		N		
	Intravascular							
	Other (OB/Gyn.)	N	N	N		N		
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral Vessel	N	N	N		N		
	Other(Carotid)							

N = new indication P = previously cleared by FDA E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.

System: Leltek LU700

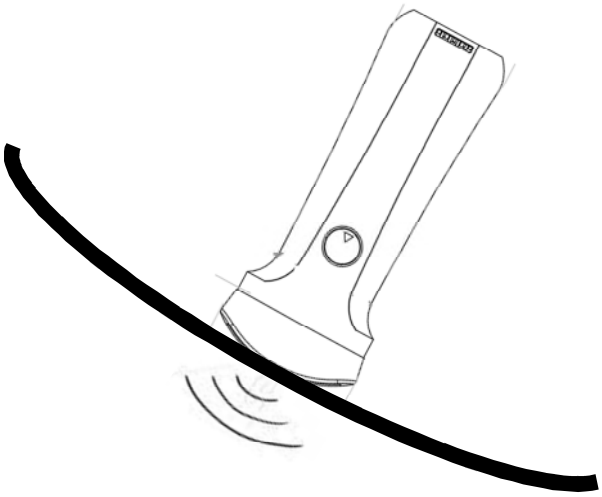
Transducer: L10-5 7.1MH Linear Array Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		**Mode of Operation**						
General (Track 1)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other*
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N		
	Intra-operative(Specify)							
	Intra-operative(Neuro)							
	Laparoscopic							
	Pediatric							
	Small organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card.)							
	Musculoskeletal (conventional)	N	N	N		N		
	Musculoskeletal (superficial)	N	N	N		N		
	Intravascular							
	Other (OB/Gyn.)	N	N	N		N		
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral Vessel	N	N	N		N		
	Other(Carotid)							

N = new indication P = previously cleared by FDA E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging.



- The patient's diagnostic environment in circumstances may negatively impact the system and the exam. For example: (1) Chemicals and gases in the operating room. (2) Altitudes below -382 m or above 4000 m.
- Biological incompatibility may exist between the system materials used and the biological tissues, cells, and body fluids of the patient/user, taking account of the intended purpose of this system.
- Using this system in the patient environment may be unsafe if the following conditions exist: (1) Extremes in humidity (RH<15% and RH>90%). (2) Ambient temperatures that are excessively high (35°C / 95°F) or excessively low (0°C / 32°F).
- Fragile patients, such as children and pregnant/nursing women, may be more prone to the exposure of acoustic energy when this system is used for prolonged periods.
- Do not use in a patient who would be harmed caused by applying ultrasound (example: implanted pace-maker)
- The patients are not the users (not relevant) only used by related experts. Users will be trained medical professionals (e.g., doctors, nurses, technicians) with previous training in ultrasound. Images produced by this system are transmitted wirelessly to the user’s smart device (tablet or smart phone).
- Untrained/unqualified users purchasing and using this system may unable to measure up quality images.

Contraindications

Do not use the Leltek Ultrasound Imaging System to do following situations then result in the that produce images with inaccurate results:

- Patients who have had surgery, which may have changed the composition of the examining tissue, as this could skew or alter the measured density.
- Patients whose bodies contain foreign artifacts (for example, implants), in the examining tissue.
- Intra-operative use (e.g., defined as introducing a System into a surgical incision or burr hole).
- Ophthalmic use or any use causing the acoustic beam to pass through the eye.
- At the scene of an emergency outside of a professional healthcare facility.
- During transportation of a patient to a professional healthcare facility, or between professional healthcare facilities.
- Endocavity use or imaging an open wound.

Hardware

Purchases and Upgrades

- The equipment has a lifetime of 3 years.
- To order additional supplies and accessories, go to www.leltek.com and contact Leltek.

Warranty

- This equipment includes a one-year warranty. To purchase extended warranty programs, go to www.leltek.com and contact Leltek.

Disposal

- Leltek has been supporting and protecting the natural environment. The equipment is designed and manufactured according to environmental protection guidelines. This equipment is designed and manufactured according to environment protection.
  Due to improper disposal of the equipment (like the battery is no longer working or the scanner has exceeded its shelf life) adds hazardous materials to our landfills. For proper disposal of this equipment or any of its parts, please contact the manufacturer or an authorized disposal company to decommission your equipment according to local regulations.

Security

Information security

- When using Leltek 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).

Network Security

- 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 smart device (tablet or smart phone). ◦

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:

- Changing network configurations.
- Connecting to additional networks or disconnecting from existing networks.
- Upgrading to new equipment or updating existing equipment.

Confidentiality

The confidential information is assured as follows:

- The scanner contains no patient-identifiable information.
- When the scanner connects to a wireless network, it encrypts and stores the Wi-Fi password.
- The data transferred between the smart device and the Leltek Ultrasound App is encrypted.
- Image data contains no patient or user identifiable information and is transmitted in unencrypted form. If you want this data encrypted, connect to a:
    * Wi-Fi network where only trusted parties are permitted. The Wi-Fi network encrypts all image data sent from other Wi-Fi networks.
    * 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.
- The smart device stores no patient or user data on disk.

Integrity constrains

Integrity of the data transmitted between the smart device and the Leltek Ultrasound App is assured as follows:

- Authenticated encryption prevents malicious users from intercepting and modifying data.
- Integrity checks ensure completion and validity of data received. If any data is incomplete or invalid, it is discarded.
- TCP channels used over Wi-Fi ensures that data is delivered correctly. For transmitting image data, a UDP channel is used.

Technical Features

There are some of the technical aspects of the system as following list:

- Wi-Fi 802.11b/g wireless connect
  - Receive frequency and/or band and bandwidth of receiving section.
  - Transmit frequency and/or band, modulation, and ERP
- USB 3.0, Micro B connector as output port
- Leltek high performance computing technology of FPGA
- Leltek unique technology “Ultra Image Block Algorithm” (UIBA) solution for B mode, Color mode, M mode, Power Doppler and PW Doppler block image
- High frame rate
- High contrast
- High resolution
- Support Image Mode
- B mode
- Color Doppler
- M mode
- PW Doppler
- Power Doppler
- Internal battery continuous use of time
  - B mode (approx.) 4.5 hours
  - Color Doppler(approx.) 3.5 hours
  - M mode(approx.) 4.5 hours
  - PW Doppler(approx.) 2.5 hours.
  - Power Doppler(approx.) 3.5 hours

- The micro USB connector connected to a mobile power supply for the charging, it could extend the power to 5-8 hours.
- Charging power supply by micro USB(DC: 5.0V, 2A(Max))
- Weight(g): 320 (with battery)

System Requirements

Product /Package Components:

1. Software:
   - The Ultrasound App named as LU700 App for Android
   - Android: OS 5.0 or above
   - iOS: 11 or above

2. Transducers:
   - LU700 Transducer C5-2 Convex probe, or
   - LU700 Transducer L10-5 Linear probe

Chapter 3 Safety

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:

Product Safety

Leltek takes the responsible for the safety of the equipment. To keep a safety of the smart device is a user responsibility. Always follow the safety guidelines provided with your smart device before, during and after use.

Product Caution

- Warnings indicated information important to the safety of you, the operator, and the patient.
- Be care of focus possible damages to the product that may void your warranty or service contract or lose patient or system data.
- 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.
- 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.
- 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.
- Use the system only for its intended purposes and do not misuse the system. Do not use the system with any product that Leltek 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.
- Stop use immediately if the system or the transducer appear to be malfunctioning. Contact your Leltek representative immediately.

- 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.

- 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.
- 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.
- 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.

Product Compatibility

Do not use your system in combination with other products or components, unless Leltek expressly recognizes those other products or components as compatible.
For information about such products and components, contact Leltek agent Changes and additions to the system should be made only by Leltek or by third parties expressly authorized by Leltek 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.

Equipment Protection

Follow these warnings to protect your system:

- DO NOT immerse the probe into any liquid beyond the immersion level. Never immerse the probe connector into any liquid.
- 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.
- Do NOT modify this device without authorization of the Leltek.
- Do NOT use the probe with high frequency surgical equipment. Doing so may damage the equipment.
- 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.
- When the device LU700 is charged with a mobile charging power supply, do NOT use it to work for diagnostic.
- The device LU700 should be charged with the mobile charging power supply and charging cable of medical products comply with IEC 60601-1 for two MOPP insulation system. The mobile charging power supply should be checked or replaced regularly.
- If the system or transducers have been in an environment above 35°C (95°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 the transducer to cool as possible as you can. If the transducers were only briefly exposed to temperatures above 35°C (95°F), then the time required for the devices to return to operating temperature may be less.
- 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 the transducers to warm to operating temperature as possible as you can. 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 may be less.
- If the probe reached it maximum surface temperature, the system would get into the idle mode until it back to the operating temperature.

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

♦ 根據 NCC 低功率電波輻射性電機管理辦法規定：
第十二條 經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。
第十四條 低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。前項合法通信，指依電信法規定作業之無線電通信。低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

♦ 減少電磁波影響，請妥適使用。

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

- The sing 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.
- 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.

Battery Safety

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, Letek will not accept any responsibility.
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 LU700 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.

- Do Not charge the battery near a fire or heater.
- If the battery leaks or emits an odor, turn-off the equipment and contact with local agent.
- If the battery will remain unused for over a month, keep it between-20°C (-4°F) and 20°C (68°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 LU700, please turn-off the equipment and contact with Leltek's local agent.

Thermal safety

Keep a safety thermal environment for the patient always been a design priority at Leltek. The operating temperature of the ultrasound probe must remain below 43°C

Biological Safety

This section contains information about biological safety and a discussion of the prudent use of the system.

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.

Latex

Leltek ultrasound equipment 's transducers do not contain natural rubber latex that contacts humans.

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

- 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.
- 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.)
- 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.
- 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.

Bioeffects

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 human 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.

Thermal

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:

- 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.
- 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.
- Emission modality, since pulsed-wave ultrasound is extremely unlikely to significantly heat tissues.
- 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

Mechanical(Non-Thermal)

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.

Cavitation

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 microjet 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:*

- *Frequency*
- *Pressure*
- *Focused/unfocused beams*
- *Pulsed/continuous ultrasound*
- *Degree of standing waves*
- *Nature and state of material*
- *Boundaries*

Other effects

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.

ALARA Principles

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, that 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.

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

- Index values
- Body size
- Location of the bone relative to the focal point
- Attenuation in the body

- Ultrasound exposure time. Exposure time is an especially useful variable, because it is controlled by the users.

Acoustic Output Limits

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

Applying ALARA

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.
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.

Using System Controls to Implement ALARA

Direct Controls

The system LU700 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 LU700 is designed to automatically adjust output. The system does not exceed a spatial peak temporal average intensity (I SPTA) of 720 mW/cm for 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.

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.

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.

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.

Additional Considerations

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.

Output Display

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.
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:

- 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 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.
- 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.

Mechanical Index (MI) Display

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.

Thermal Index (TI) Displays

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 (Cranial bone)	TIS at Surface	TIB
Bone at Surface	TIC	TIC

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. For details on changing the TI display, see

Controls Affecting the Indices

B mode Controls

- Transducer Frequency

Color Controls

- 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.
- 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 •

- 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.

- 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.

Related Guidance Documents

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

- "Bioeffects and Safety of Diagnostic Ultrasound." AIUM Report, January 28, 1993.
- "American Institute of Ultrasound in Medicine Bioeffects Consensus Report." Journal of Ultrasound in Medicine, Vol. 27, Issue 4, April 2008.
- Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. (AIUM, NEMA, 2004)
- Third Edition of the AIUM Medical Ultrasound Safety brochure, 2014. (A copy of this document is provided with each system.)
- Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. FDA, September 2008.
- Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. (AIUM, NEMA, 2004)
- 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.

Acoustics

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.

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 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."

Chapter 4 Device Maintenance

It is your responsibility to appropriately clean and disinfect your LU700-compatible smart device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices.
If the LU700-compatible smart device becomes contaminated internally with bodily fluids containing pathogens, you must immediately notify your Leltek 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.

Turning the Device ON and OFF

- If battery power is unavailable, or if the battery charge level is critically low, disconnect the transducer and charge the transducer.
- We strongly recommend that transducer LU700 shall be fully charged before user start imaging. To avoid unexpected battery discharging, charge your device at regular intervals, or when the device displays the low-battery warning.
- Before turning on transducer LU700, please disconnect the transducer and all peripheral device. Before turning off transducer LU700, please end the current exam.

Transducer Care

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

the integrity of the transducer. Report any damage to the leltek's agent and discontinue use of the transducer.

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.

Cleaning & Disinfecting

It is important to clean and disinfect the ultrasound probe 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 solutions approved by Leltek . 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 installed may cause the battery to short-circuit and overheat, causing an electric shock or burn.
- Cleaning or disinfecting the scanner using 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:

- It shall remove all coupling gel and other visible substances from the probe by wiping with a soft dry cloth. 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 must not be placed into any liquid (e.g., for disinfection) and must not be used until it has been inspected and repaired/replaced by a Leltek 's agent for service.

Recommendations for disinfecting the ultrasound probe (After cleaning):

- Spray disinfect onto the surface of probe head.
- Repeat step one for two or three times.
- Let stand for about 1 minute.
- Wipe out the disinfectant with a clean cloth.

Recommended disinfectants:

To provide users with options in choosing a disinfectant, Lelte routinely reviews new medical disinfectants for compatibility with the system. Although a necessary step in protecting patients and employees from disease transmission, liquid chemical disinfectants must also be selected to minimize potential damage to the transducer.

The following disinfectants can be used on the system:

Name	Manufacture
Bleach Germicidal Cleaner	Clorox
Transeptic Cleaning Sol.	Parker

Chapter 5 Regarding Diagnostic Ultrasounds

Interactions of Ultrasound with Matter

As an ultrasound pulse passes through matter, such as human tissue, it interacts in several different ways. Some of these interactions are necessary to form an ultrasound image, whereas others absorb much of the ultrasound energy or produce artifacts and are generally undesirable in diagnostic examinations. The ability to conduct and interpret the results of an ultrasound examination depends on a thorough understanding of these ultrasound interactions.

The History

The use of ultrasound in medicine began during and shortly after the 2nd World War in various centers around the world. The work of Dr.Karl Theodore Dussik in Austria in 1942 on transmission ultrasound investigation of the brain provides the first published work on medical ultrasonic. Although other workers in the USA, Japan and Europe have also been cited as pioneers, the work of Professor Ian Donald and his colleagues in Glasgow, in the mid-1950s, did much to facilitate the development of practical technology and applications. This lead to the wider use of ultrasound in medical practice in the subsequent decades.

LU700 Device Operation

Overview of the Interface

- Please make sure to have full battery power on your smart device by charging it regularly.
- Please download the Leltek LU700 App as "**LELTEK**" from Android App store.
- Start app "LELTEK".

LELTEK

- The software version will be displayed on the right upper corner of the screen as below figure.

Status Lights

For the equipment's status lights, please refer to following table:

Color	Display	Meaning
White	Solid	Wi-Fi connection
Purple	Solid	Power-On
Blue	Solid	Battery Charging

Equipment 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
5. Power Charging Port
6. Probe

Device Operation

Power On

(1). Press the power button for 3 seconds.
(2). The power LED is purple.
(3). When the power LED is changed from purple to white, Wi-Fi is connected ready.

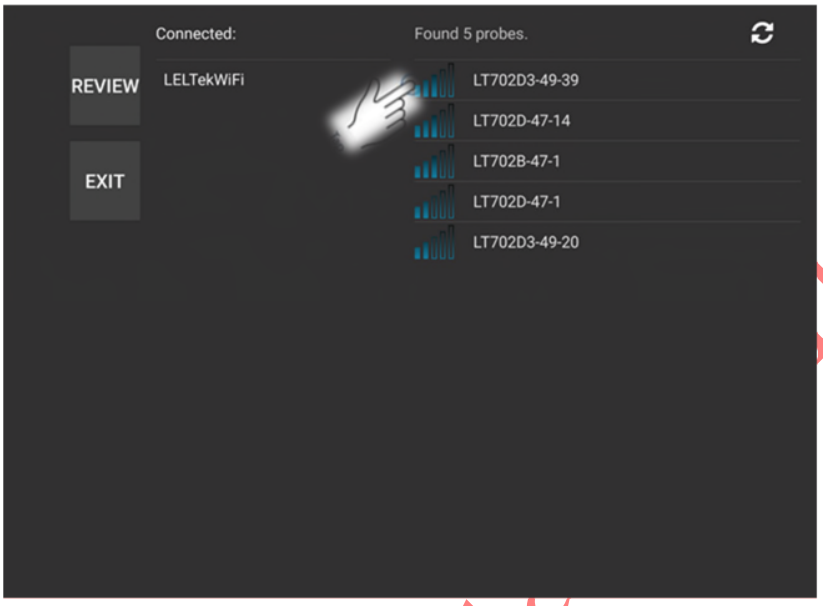
Power Down

When press power button for 3 seconds, the system will be turned off.

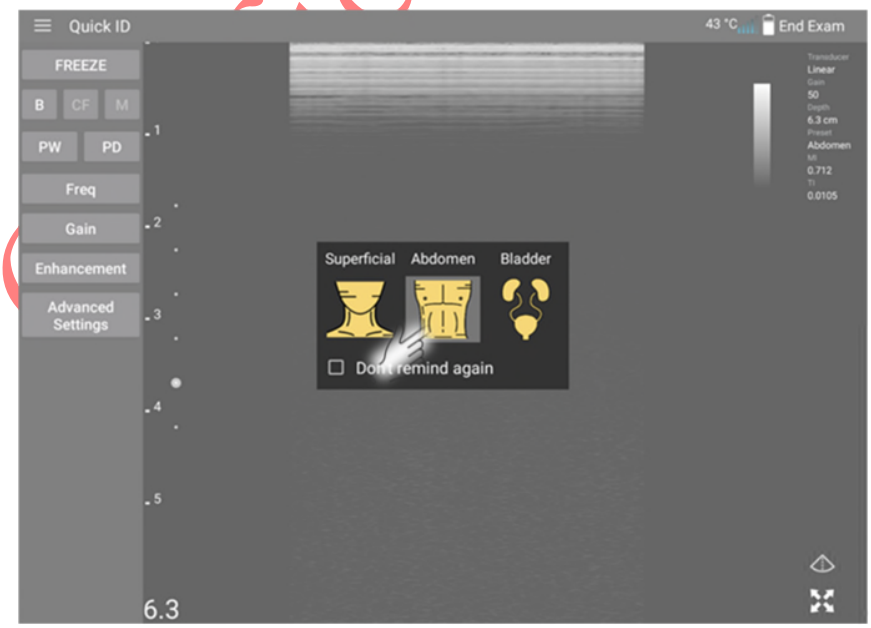
Idle Mode

If the scanner does NOT move for approx., 25 seconds, the LU700 App screen will be freeze and the LED is still white.

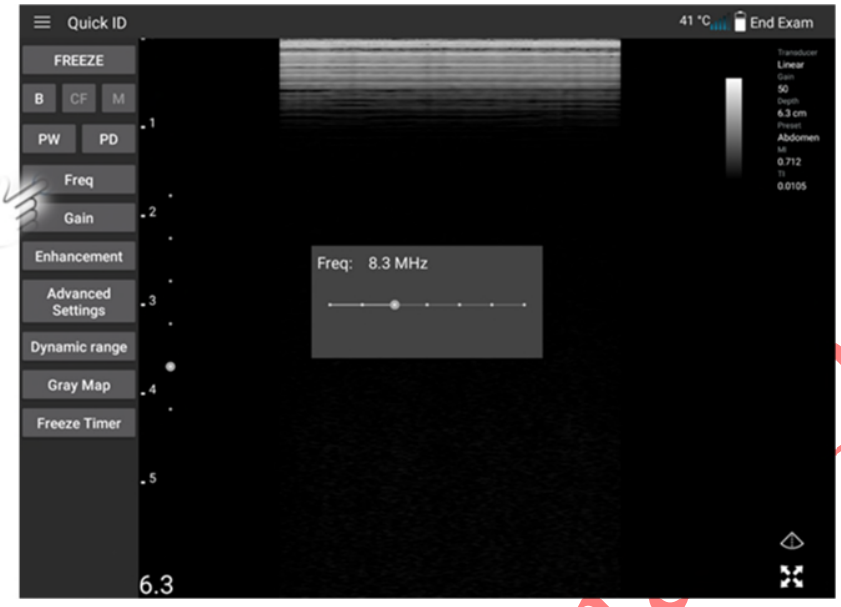
Starting New Exams

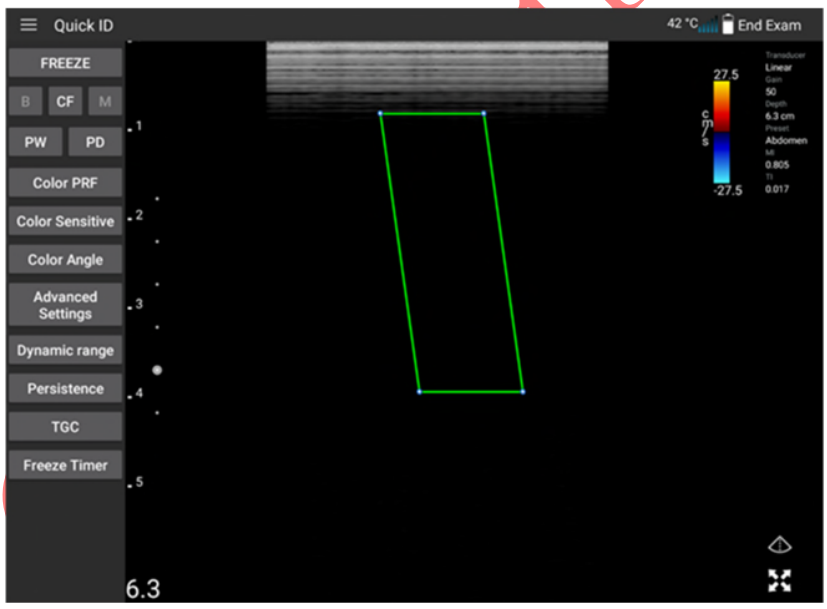


1. REVIEW: The user touches this button, the system will link to page "Saved Exam" and could be reviewing previously saved test data.
2. EXIT: The user touches the function button to exit from App "LELTEK".
3. : The transducers that will be re-auto detected to be connected via Wi-Fi.
4. Found probes: The transducers that will be auto detected to be connected via Wi-Fi; then the user can select the transducer that is corresponding.



In this scanning page of ultrasonic image, the user must be manual selected the scanned position of a body.





1. To create a temporary **Quick ID** and start scanning immediately, touch **SCAN**. The imaging display appears, and you can begin scanning.
2. To touch **Quick ID** manually enter patient information before you begin scanning, touch and present a screen for **Edition Parent Info**".
3. By the page of "**Edition Patient Info**", it would edit a patient related information then press the button "**Save**" which is on the screen of the right upper corner to do save.
4. Touch **FREEZE**, the system is stopping the image during the scanning; or re-activating the stopped image. When the image is frozen, the latest 50 frames could be showed. The annotate could be added. The frozen image could be saved for later review. The measure function is also enabling to measure for the length and

the area.

5. Touch **B**, the system would be selected for B mode which means a two-dimensional ultrasound image display composed of bright dots representing the ultrasound echoes.
6. Touch **CF**, the system would be selected for CF mode, the velocity and direction of blood flows are depicted in a color map superimposed on the 2-D image. Color flow is showed in ROI. Its size and location are adjustable.
7. Touch **M**, the system would be selected for M mode, a diagnostic ultrasound presentation of the temporal changes in echoes in which the depth of echo-producing interfaces is displayed along one axis and time is displayed along the second axis, recording motion of the interfaces toward and away from the transducer.
8. Touch **PW**, the system would be selected for PW (Pulsed wave) Doppler mode, it is moving objects change the characteristic of sound waves. By sending short and quick pulses of sound, it becomes possible to accurately measure the velocity of blood in a precise location and in real time.
9. Touch **PD,** the system would be selected for PD (Power Doppler) mode, it is used to obtain images that are difficult or impossible to obtain using standard color Doppler and to provide greater detail of blood flow, especially in vessels that are located inside organs.
10. **Depth:** The depth of penetration is related to the frequency of the ultrasound wave. Higher frequencies have a shorter depth of penetration. Lower frequencies have a longer depth of penetration.
11. **Freq:** Th carrier frequency of the ultrasound wave transmitted and received by the transducer.
12. **Gain:** The digital gain is used to adjust the brightness of the image.
13. **Persistence:** It is a type of temporal smoothing used in ultrasound imaging. Successive frames are averaged as they are displayed to reduce the variations in the image between frames, hence lowering the temporal resolution of the image.
14. **Enhancement:** Imagine enhancement processing
15. **C mode TGC:** C mode with analogy TGC (Time Gain Compensation). Ability to compensate for the attenuation of the transmittal beam as the sound wave travels through tissue in the body. The goal of TGC is to make the entire image look evenly lit from top to bottom.
16. **Advanced Settings:** When the user touches this button, there would be listed other buttons which depended the mode that user selected.
17. **Dynamic range:** When the user touches this button, it allows the user to tell the transducer how does want the echo intensity displayed as shades of gray. A broad range will display more shades of gray and an overall smoother image. A narrow range will display fewer shades of gray and appear as a higher contrast with a more black-and-white image.
18. **Gray Map**: When the user touches this button, it is adjusting gray maps on ultrasonic image has a similar effect on an ultrasound image as changing the dynamic range., but they are different. While Dynamic Range adjusts the overall number of shades of gray, a gray map determines how dark or light you prefer to show each level of white/gray/black based upon the strength of the ultrasound signal.
19. **Freeze Timer**: When the user touches this button, the system could be selected how many second in static situation.
20. **Color PRF**: When the user touches this button, the time is between the onset of one pulse till the onset of the next pulse. It is measured in units of time. This parameter includes the time the pulse is “on” and the listening time when the transducer is “off”. It can be changed by the sonographer by varying the depth to which the signal is send.
21. **Color Sensitive**: Number of doppler pulses per line of color doppler information.
22. **Color Angle**: The ultrasound scanning angle.

Chapter 6 References

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.

Leltek Ultrasound Imaging System

Authorized Representative

European Authorized Representative (AR) Name:
(Reserved)

Product Classification

Classification:

- The device with transducers: Class IIa/internally powered ME equipment.
- Transducers: Type BF applied parts, IPX1
- Ordinary Equipment/Continuous Operation
- Non-AP/APG

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.

Product Serial Number

(Reserved below)

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 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.

Probes must be operated, stored, or transported with the parameter outline as following:

Item	Operational	Storage/Transport
Pressure	700 hPa (525 mmHg) to 1060 hPa (795 mmHg)	700 hPa (525 mmHg) to 1060 hPa (795 mmHg)
Humidity	15% to 95% non-condensing	0% to 95% relative humidity/ ≤90% RH
Temperature	0°C (32°F) to 35°C (95°F)	-20°C (-4°F) to 50°C (122°F)/ -40°C to + 55°C

Storage Limits

- Ventilate room without corrosive gases.

Standards

Acoustic

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

Biocompatibility

ANSI/ISO 10993-1:2009 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
ANSI/ISO 10993-1:2009 - Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
ANSI/ISO 10993-1:2010 -Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Chemical

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. LU700 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.

Labeling

ISO 60417:2014 - Graphical symbols for use on equipment.

Wireless

ETSI EN 300 328 V2.1.1(2016-11)

Safety Conformance

Conforms to the following safety standards

Performance

IEC 60601-1:2005+AMD1:2012 CSV Medical electrical equipment- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 2014 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic Capability- Requirements and tests
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
ISO 10993-1 2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
AIUM/NEMA UD 2- 2004 2009 NEMA Standards Publication UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3. (Radiology)
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

Product Specification, Design Review, Verification/Validation and Risk,

IEC 62304 2006 Medical device software- Software life cycle processes
IEC 62366 2014 Medical devices- Application of usability engineering to medical devices
IEC 60601-1-6 Usability
ISO 15223-1 2016 Medical devices- Symbols to be used with medical device labels, labeling and information to be supplied
ISO 13485 2003 Medical Devices- Quality Management Systems- Requirements for Regulatory Purposes
ISO 14971 2007 Medical Devices- Application of Risk Management to Medical Devices
MDD 1993 Medical Device Directive 93/42/EEC ANNEX II

Acoustic Output Tables

C2-5 Transducer

Acoustic Output Reporting Table for Track 3 : Transducer Model C2-5, B-Mode Operation, Probe with 3.6MHz

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm^2	$A_{aprt} > 1$ cm^2		
Global Maximum Index Value			0.727	0.011	-	-	-	
Associated Acoustic Parameter	$P_{r.a}$	(MPa)	1.417					
	P	(mW)		2.93	-		-	
	$P_\alpha(z_s)$min and $I_{ta,\alpha}(z_s)$min	(mW)				-		
	z_s	(cm)				-		
	z_{bp}	(cm)				-		
	z_b	(cm)					-	
	z_{max} of $I_{pi,\alpha}$	(cm)	4.75				-	
	$d_{ep}(z_b)$	(cm)			-	-	-	
	f_{awf}	(MHz)	3.8	3.8				
	Dim. of A_{aprt}	X (cm)		1.3	-	-	-	
		Y (cm)		6	-	-	-	
Other Information	t_d	(µsec)	1.164					
	prr	(Hz)	1000					
	$p_r@I_{pi}max$	(MPa)	1.455					
	$d_{eq}@I_{pi}max$	(cm)					-	
	$I_{pa,\alpha}@MI_{max}$	(W/cm^2)	63.9					
Operating Control Conditions	Frequency	(MHz)	3.6					
	Number of focus	(point)	)1					
	Power	(mW)	10					

Note

1. No TIS formula information is required for the maximum TIS value in this mode.
2. No information about TIC is required for any transducer assembly that is not used for the head of a transcranial or neonatal
3. If the device meets the 51.2aa) and 51.2dd) exemptions, no MI or TI information is required.

(a) The intended use does not include the head, so the TIC is not calculated.

No data report

L10-5 Transducer

Acoustic Output Reporting Table for Track 3 : Transducer Model L10-5, B-Mode Operation, Probe with 7.1MHz

			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm^2	$A_{aprt} > 1$ cm^2		
Global Maximum Index Value			0.712	0.0105				
Associated Acoustic Parameter	$P_{r.a}$	(MPa)	1.93					
	P	(mW)		1.46	-		-	
	$P_\alpha(z_s)$ min and $I_{ta,\alpha}(z_s)$min	(mW)				-		
	z_s	(cm)						
	z_{bp}	(cm)				-		
	z_b	(cm)				-		
	z_{max} of $I_{pi,\alpha}$	(cm)	2.279				-	
	$d_{ep}(z_b)$	(cm)					-	
	f_{awf}	(MHz)	7.35	7.35				
	Dim. of A_{aprt}	X (cm)		0.44	-	-	-	
		Y (cm)		3.84	-	-	-	
Other Information	t_d	(μsec)	1334					
	prr	(Hz)	1000					
	$p_r@I_{pi}$ max	(MPa)	2.888					
	$d_{eq}@I_{pi}$ max	(cm)					-	
	$I_{pa,\alpha}$@MImax	(W/cm^2)						
Operating Control Conditions	Frequency	(MHz)	7.1					
	Number of focus	(point)	1					
	Power	(mW)	10					

Note

1. No TIS formula information is required for the maximum TIS value in this mode.
2. No information about TIC is required for any transducer assembly that is not used for the head of a transcranial or neonatal
3. If the device meets the 51.2aa) and 51.2dd) exemptions, no MI or TI information is required

(a) The intended use does not include the head, so the TIC is not calculated.

No data report

ID Label

Guidance and Manufacture's Declaration

- LU700 requires special precautions regarding EMC.
- LU700 should not be used adjacent to or stacked with other equipment.
- Using the wrong cable and accessories may adversely affect the EMC performance

Electromagnetic Emissions

The LU700 is intended for use in electromagnetic environments, as specified below. The customer or the user of the LU700 should ensure that it is used in such an environment.

Manufacturer's declaration-electromagnetic emissions		
The LU700C, LU700L is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU700C, LU700L 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 LU700C, LU700L 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 LU700C, LU700L 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	

Electromagnetic immunity

All LU700 series product are in compliance with the regulation of

Manufacturer's declaration-electromagnetic immunity			
The LU700C, LU700L is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU700C, LU700L 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 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 30 cycles Voltage interruptions: 0 % U_T; 300 cycle	Mains power quality should be that of a typical professional healthcare environment. If the user of the LU700C, LU700L requires continued operation during power mains interruptions, it is recommended that the LU700C, LU700L 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 LU700C, LU700L 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.			

immunity test, and the detail and declaration as below:

Manufacturer's declaration-electromagnetic immunity			
The LU700C, LU700L is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU700C, LU700L 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** LU700C, LU700L 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.			

Recommended separation distance between portable and mobile RF communications equipment and the LU700C, LU700L

The LU700C, LU700L 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 LU700C, LU700L can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LU700C, LU700L 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.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The LU700C, LU700L is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the LU700C, LU700L should assure that it is used in such an environment.

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 healthcare)
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) 抄±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; LTE Band 1, 3	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.

Trouble Shooting:

Issue	Solution	Note
LED indicator flashing and could not turn off device.	When low battery state, please does use adapter to charge device then could turn off the device.	
Wi-Fi could not be connected.	a. When LED indicator of the device(transducer) is purple, the device(transducer) may be low battery state and need to be charged by an adapter. b. When LED indicator of the device(transducer) is white, the device(transducer) maybe need to do power reset and reconnect the device(transducer) via Wi-Fi. c. Please check is there no any background in screen or other apps had been enabled.	
App has been enabled but could not be display an image.	Please check there is no background in the screen or other apps had been enabled first. It should do repower on the device(transducer) and reconnect the device(transducer) via Wi-Fi then reenable App.	
App has been into image page, but it would be immediately swapped to Wi-Fi connected selection page.	Please disconnect Wi-Fi first and delete the current App, then reinstall and enable the App.	
The screen may display unclearly white image in very short time when the product has been used long-term in the environment of high static.	The status is normal condition, and would not affect essential performance, interfere with diagnosis also without basic safety consideration, please set up the product in the environment without high static.	

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.