ASUS Ultrasound Imaging System

LU700 Series for Vet

(LU700C, LU700L)

USER MAUNAL REV. A

LK_UI-LU700-01(E)

Contents

ABOUT THIS MANUAL

	This document contains the following information: • About the ASUS 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 ASUS 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 ASUS Ultrasound Imaging System. It contains instructions and reference material pertaining to the usage and maintenance of the product.

Disclaimer

This disclaimer extends to all printed matter accompanying the ASUS Ultrasound Imaging System.

This manual is licensed under the ASUSsoftware and maintenance agreement. All use of this manual must be in compliance with the license. The information within these materials is proprietary and confidential to ASUSTeK Computer Inc. ("ASUS") and is provided for the sole use of the individual or entity to whom it is addressed. Therefore, these materials must be held in the strictest confidence. Without the prior written permission of ASUS, no part of this manual may be copied, reproduced, republished, modified, sold, disclosed, or distributed. Unauthorized copying or distribution of this manual, as well as an infringement of copyright, may impair the ability of ASUS to provide updates and current information to users.

ASUS has taken care to ensure the accuracy of this document, however, revisions are not always possible. ASUS assumes no liability for errors or omissions and information in this document may be subject to change without notice. ASUS reserves the right to make changes to any products herein without further notice to improve reliability, function, or design. ASUS reserves the right to make improvements or changes in the products or programs described in this document at any time.

These materials may contain third-party copyright and/or trademark materials, the use of which has not always been specifically authorized by the intellectual property owner. All copyrights and/or trademarks contained in these materials are the sole and exclusive property of their respective owners.

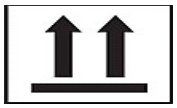
The ASUS logo is a registered trademark and is the sole and exclusive property of ASUS.

All names used in ASUS (whether online, in print, or any other media) are fictitious and are used herein for the purposes of example and demonstration on how to use the ASUS Ultrasound System. Any similarity to real people is a coincidence.

Revision History

Revision	Date
User Manual Revision A Initial release	2018-07-18
User Manual Revision B - Add TI/MI related information - Add company contact info	2018-08-16
User Manual Revision C - Update the battery supplier - Add LU710C/ LU710M/LU710PA/LU710E probe contents - Update App introduction	2020-12-27

Symbols

Symbols	Description/Function
 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.
	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.
	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 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.

CHAPTER 1 ABOUT ASUS ULTRASOUND IMAGING SYSTEM

Install, operate, and maintain this product according to the safety and operating procedures set out in this manual, and only for its intended purpose. Always use the information in this document alongside sound clinical judgment and best clinical procedures.

This product is subject to the law of the jurisdiction in which the product is used. Install, use, and operate the product only in ways in adherence to applicable laws or regulations, and which are in legal force.

Incorrect use of the product, or use for purposes other than those intended and expressly stated by ASUS, may relieve ASUS or its agents from some or all responsibility for any 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 inflammable gases or anesthetics can induce an explosion.

Medical equipment should be installed and operated according to electromagnetic compatibility (EMC) guidelines.

Responsibility for image quality and diagnosis is with users.

This product has demonstrated EMC compliance under conditions that included the use of compliant peripheral devices. The use of compliant peripheral devices is important to reduce the possibility of interference to radios, televisions, and other electronic devices.

- Never attempt to open a transducer or a transducer connector as this will void the warranty.
- As probes are not delivered sterile before first use, it's MANDATORY to clean and disinfect probes to avoid infections or transmission of disease.
- Probes must be cleaned and disinfected before replacement or disposal.
- If a user loses his/her tablet/smart phone, the stored data is not recoverable.
- Do NOT touch patients with Android mobile device during use of the LU700 series.
- Comply with Operation conditions (i.e. max 30-min use with 10-min resting time.)
- As LU700 series is used in conjunction with personal mobile devices, users should carefully manage patient data and key security information.

- If the probe falls to the floor or on any other hard surface, CEASE further use. Damage caused by impact to electrical insulation may increase the risk of electrical shock due to damaged.
- Electrical leakage checks should be routinely performed 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 allows a close bond between the skin and the probe or transducer, causing the waves to transmit directly to the underlying tissues and the areas to be imaged. It is formulated to reduce static and act as a coupling agent.

Ultrasonic gel is usually composed of propylene glycol, water and occasionally a dye. The dye is mostly for aesthetic purposes. The gel is usually clear and thick, and a slightly sticky. This means the gel doesn't drip or run off after application to the skin. Post procedure, the gel can be wiped off with ease.

- Do NOT use non-recommended gels (lubricants). These may damage the probe and void the warranty.
- Ultrasound Gels should NOT contain any of the following ingredients, which have the potential to damage the probe.
    - Olive oil
    - Methyl or ethyl parabens (para hydroxybenzoic acid)
    - Dimethyl silicone
    - Iodine
    - Lotions
    - Lanolin
    - Aloe Vera
    - Mineral oils
    - Methanol, ethanol, isopropanol alcohol, or any other alcohol-based gels
- During the ultrasound Imaging diagnostic procedure, the examiner shall wear "patient examination gloves". A patient examination gloves are disposable devices intended for medical purposes and are worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

LU700 Series Ultrasound Imaging System Description

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

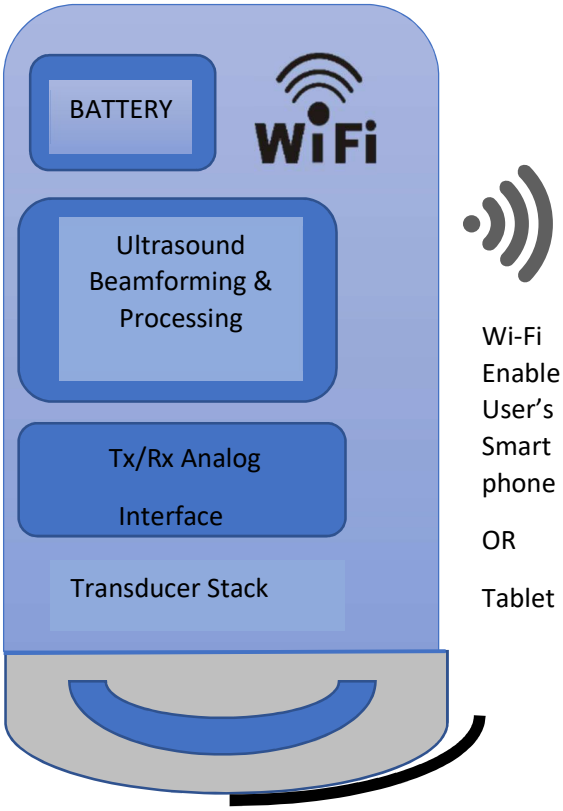
I. The imaging system software runs as an app on a mobile device.

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

III. The imaging system comprises a series of wireless transducers employing Wi-Fi-based technology to communicate with conventional tablet/smartphone devices via Wi-Fi directly. This allows users to export ultrasound images and display them across a range of portable personal devices.

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

The LU700 Series Ultrasound System included

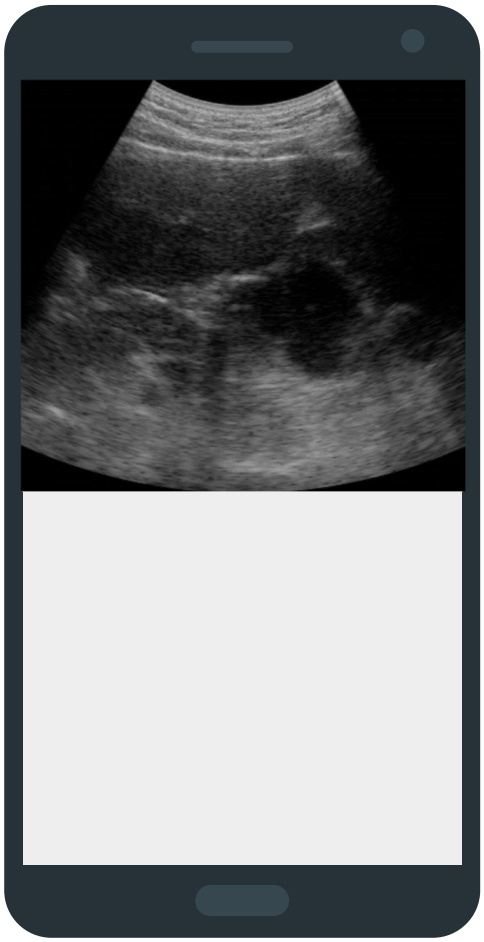


Ultrasound Probe

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	Shen Zhen Yu Xin Technology Co., Ltd.
Model	SZYX1036B7
Cell Type	Prismatic cell
Dimensions	120mm*36mm*10.5mm
Safety	UN38.3, EN IEC 62133

System Dimension

Item	Length (mm)	Width (mm)	Height(mm)	Weight(g)
LU700L System	178	74	40	357
LU700C System	187	74	40	388
LU710M System	190	74	40	340
LU710C System	187	74	40	388
LU710PA System	194	74	40	350
LU710E System	370	74	40	412

Probe

LU700L

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

LU700C

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

LU710C

- Array type: Curvilinear
- Number of elements: 128
- Depth(cm): 18.0
- Frequency bandwidth (MHz): 2.0-5.0
- Center Frequency: 3.2MHz
- Field of view: 60°
- B mode, M mode, CF mode, Color Doppler, Power Doppler

LU710M

- Array type: Micro convex
- Number of elements: 128
- Depth(cm): 12.0
- Frequency bandwidth (MHz): 4.0-8.5
- Center Frequency: 6.2MHz
- Field of view: 100°
- B mode, M mode, CF mode, Color Doppler, Power Doppler

LU710PA

- Array type: Phased array
- Number of elements: 64
- Depth(cm): 18.0
- Frequency bandwidth (MHz): 1.7-3.7
- Center Frequency: 2.7MHz
- Field of view: 90°
- B mode, M mode, CF mode, Color Doppler, Power Doppler

LU710E

- Array type: Endocavity
- Number of elements: 128
- Depth(cm): 15.0
- Frequency bandwidth (MHz): 4.0-8.5
- Center Frequency: 6.2MHz
- Field of view: 151°

- B mode, M mode, CF mode, Color Doppler, Power Doppler

RF energy spec

- Tx frequency: 2412Mhz-2462Mhz
- TX modulation: DSSS/CCK/OFDM
- Tx Power:
    - 18dbm @1DSSS
    - 14.5dbm @54OFDM
- Rx frequency: 2412Mhz-2462Mhz
- Rx Sensitivity:
    - -95.7dbm @1DSSS
    - -74.0dbm @54OFDM

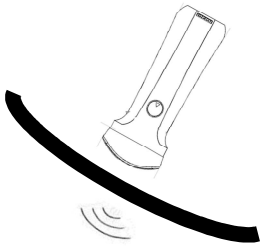
CHAPTER 2 PRODUCT USAGE

Intended Use

The ASUS Ultrasound Imaging System is a software-based imaging system and accessories intended for use by qualified 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.

The device is intended for use in environments where healthcare is provided by trained healthcare professionals, but not intended for use in emergency medical service, ambulance, or aircraft.

The modes of operation include B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and the combined mode (B+M, B+CD, B+PWD).



LU700C

General abdominal imaging, musculoskeletal (conventional), musculoskeletal (superficial), peripheral vessel and OB/Gyn.

LU700L

General abdominal imaging, small organ (breast, thyroid), musculoskeletal (conventional), musculoskeletal (superficial) and peripheral vessel.

LU710C

Fetal, abdominal, pediatric, small organ (thyroid, prostate, scrotum, breast), musculoskeletal (conventional), urology, gynecology, cardiac adult, cardiac pediatric and peripheral vessel.

LU710M

Fetal, abdominal, pediatric, small organ (thyroid, prostate, scrotum, breast), musculoskeletal (conventional), urology, gynecology, cardiac adult, cardiac pediatric and peripheral vessel.

LU710PA

Fetal, abdominal, pediatric, cardiac adult, cardiac pediatric.

LU710E

Fetal, abdominal, pediatric, small organ (thyroid, prostate, scrotum, breast), trans-rectal, trans-vaginal, urology, gynecology.

- 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 and Warnings

Contraindications

(1) Do NOT use the ASUS Ultrasound Imaging System to do following situations then result in the 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.
- Try imaging on an open wound.

- 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.

Warnings

(1) DO NOT immerse the probe into any liquid beyond the immersion level. Never immerse the probe connector into any liquid.

(2) Do NOT use in a patient who would be harmed caused by applying ultrasound.

(3) 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.

(4) Do NOT modify this device without authorization of the ASUS.

(5) Do NOT use the probe with high frequency surgical equipment. Doing so may damage the equipment.

(6) 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.

(7) When the device LU700 is charged with a mobile charging power supply, do NOT use it to work for diagnostic.

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

(9) Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result.

(10) Do not use if the face is cracked, chipped, or torn; the housing is damaged; or the cable is abraded. Electric shock can result.

(11) Do Not charge the battery near a fire or heater.

(12) Never attempt to open a transducer or a transducer connector.

All the contraindications and warning are well concerned by following the regulation of EN ISO 14971:2012 with related report.

Hardware

Purchases and Upgrades

- The equipment has a lifetime of 300 battery charging cycle.
- To order additional supplies and accessories, go to www.asus.com and contact Leltek.

Warranty

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

Disposal

- ASUSsupports and protects the natural environment. This equipment is designed and manufactured according to environmental protection guidelines.

  Improper disposal of this equipment (e.g. if the battery is no longer functioning or the scanner has exceeded its shelf life) can add hazardous materials to landfills. For information on the proper disposal of this equipment or any of its parts, please contact the manufacturer or an authorized disposal company to decommission your equipment in accordance with local regulations.

Security

Information security

- When using ASUSUltrasound 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.
- The data transferred between the smart device and the ASUSUltrasound 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.

Integrity constrains

Integrity of the data transmitted between the smart device and the ASUSUltrasound 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 TCP 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
- ASUShigh performance computing technology of FPGA
- ASUSunique 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
- Tissue Harmonic Imaging
- 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
- Charging power supply by micro USB(DC: 5.0V, 2A(Max))
- Weight(g): 357g(LU700L)/388g(LU700C)/340g(LU710M)/388g (LU710C)/ 350g(LU710PA)/412g(LU710E) (with battery)

System Requirements

Product /Package Components:

1. Software:
    - The Ultrasound App named as “LELTEK” for Android, “ASUSUltrasound” for iOS
    - Android: OS 7.0 or above
    - iOS: 11.0 or above

2. Transducers:
    - LU700C Transducer C5-2 Convex probe, or
    - LU700L Transducer L10-5 Linear probe, or
    - LU710M Transducer M8-4 Micro Convex probe, or
    - LU710PA Transducer P4-2 Phased Array probe, or
    - LU710E Transducer E8-4 Endocavity probe, or
    - LU710C Transducer Convex 3.2MHz 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

ASUStakes 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 contain information important for the safety of both you the operator, and the patient.
- Be aware of possible damage to the product that may void your warranty or service contract or lose patient or system data.
- 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.
- 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.
- 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.
- 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 ASUSas compatible with the system. Operation of the product for unintended purposes, or with incompatible products, could lead serious injury or death.
- If the system or the transducer appears to be malfunctioning, immediately cease use and contact your ASUSrepresentative.
- 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.
- 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.
- 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.

- 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.

Product Compatibility

Do not use your system in combination with other products or components, unless expressly recognized by ASUSas compatible.

For information about such products and components, contact your ASUSrepresentative.

Changes or additions to the system should be made only by either ASUSor third parties expressly authorized by ASUSto 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...

Equipment Protection

Follow these warnings to protect your system:

- DO NOT immerse the probe into any liquid beyond the immersion level. In no circumstances immerse the probe connector into any liquid.
- DO NOT drop the probe or subject it to any type of physical shock or impact. Impaired performance or damage such as housing cracks or chips could result.
- Do NOT modify this device without the authorization of Leltek.
- Do NOT use the probe with high frequency surgical equipment. Such use may damage the device.
- Do Not use the product in proximity to a strong electromagnetic field, electromagnetic wave or in a magnetic environment. Such use may lead to a possibility of measurement errors or product damage.
- While the LU700 Series device is being charged using a mobile charging power supply, do NOT use for diagnostic work.
- The LU700 Series device should be charged using the mobile charging power supply and medical product charging cable in compliance with IEC 60601-1 for two MOPP insulation system. The mobile charging power supply should be checked and replaced regularly.
- If the system or transducers have been in an environment in excess of 35°C (95°F), allow them to cool to operating temperature before initiating 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), the transducer will automatically shut down. Please let the transducer to cool the extent possible. If the transducers

were only briefly exposed to temperatures in excess of 35°C (95°F), then the time required for to return to operating temperature may be shortened.

- If the system or transducers have been in an environment below 0°C (32°F), allow them to return to operating temperature before initiating the system or connecting the transducers. As condensation inside the devices could cause damage, allow the transducers to warm to operating temperature to the extent possible. 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 reduced.
- If the probe reaches it maximum surface temperature, the system will enter idle mode until it returns to 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:

- 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 ASUSrepresentative.
- 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, ASUSwill 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 Series, 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

ASUSultrasound 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 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:*

- *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, 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.

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 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."

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^2 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^{2}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.

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 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 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 series-compatible smart device becomes contaminated internally with bodily fluids containing pathogens, you must immediately notify your ASUSservice 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 series 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 series, please disconnect the transducer and all peripheral device. Before turning off transducer LU700 series, 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 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 ASUSor 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.

Maintenance

If this device is not functional, you may contact local distributor or contact ASUS by email: ServiceCenter@asus.com

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.

LU700 Series 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 ASUSLU700 App as
  A. " ASUS MediConnect " from Android App store. Link: https://play.google.com/store/apps/details?id=com.asus.medical.ultrasound
  B. " ASUS MediConnect " from iOS App store. Link: https://apps.apple.com/tw/app/asus-mediconnect/id1545553946
- Start app " ASUS MediConnect " on your device.

ASUS MediConnect

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
Purple/Blue	Flash	Low battery

The light goes off when the battery is full.

Equipment description

LU700L: L10-5 Linear Probe

LU700C: C5-2 Convex Probe

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 case

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.

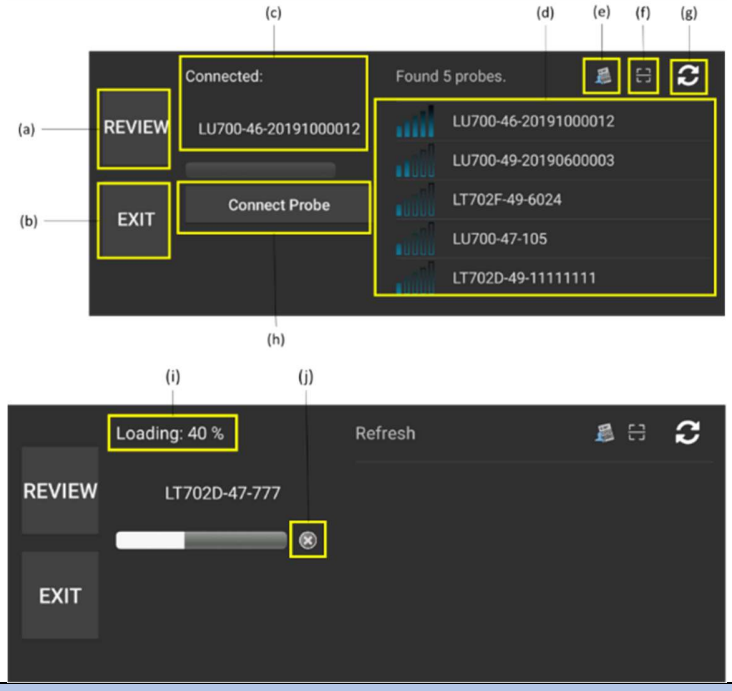
Idle Mode

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

App Introduction

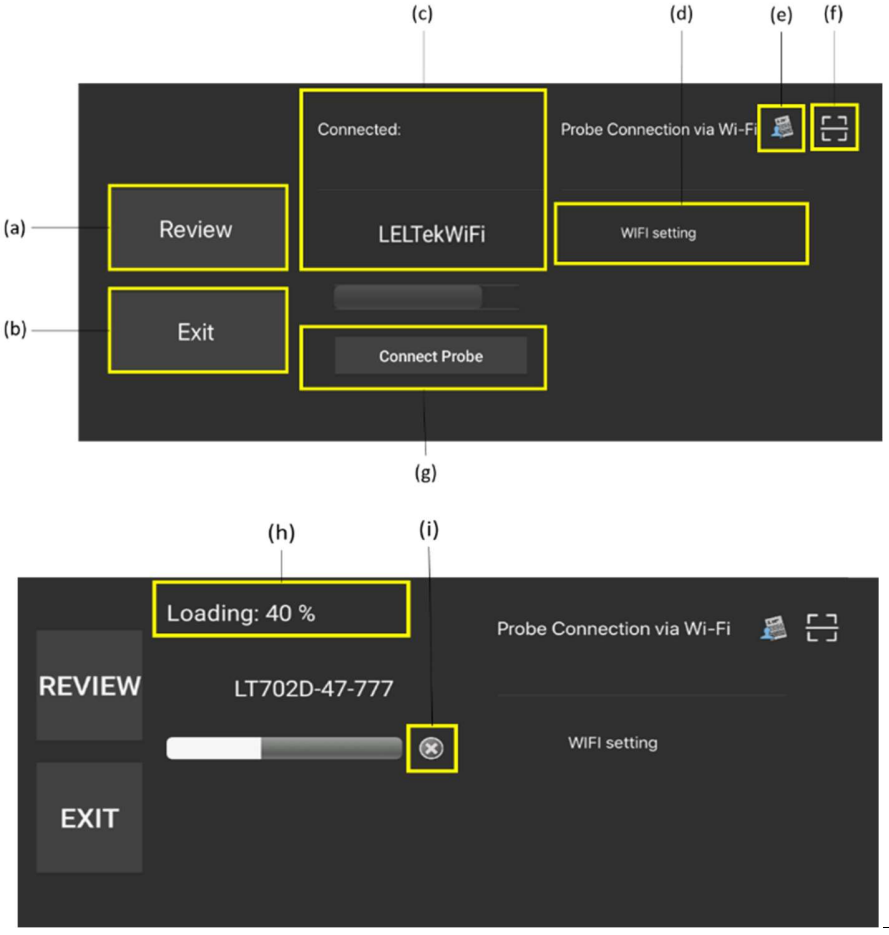
App Interface Design

Home Page- Android



(a) Review Button
(b) Exit Button
(c) Current ultrasound probe
(d) Ultrasound probe List
(e) Patient info button
(f) QRcode scan button
(g) Refresh Button
(h) Connect button
(i) Connect percentage
(j) Cancel Connection button

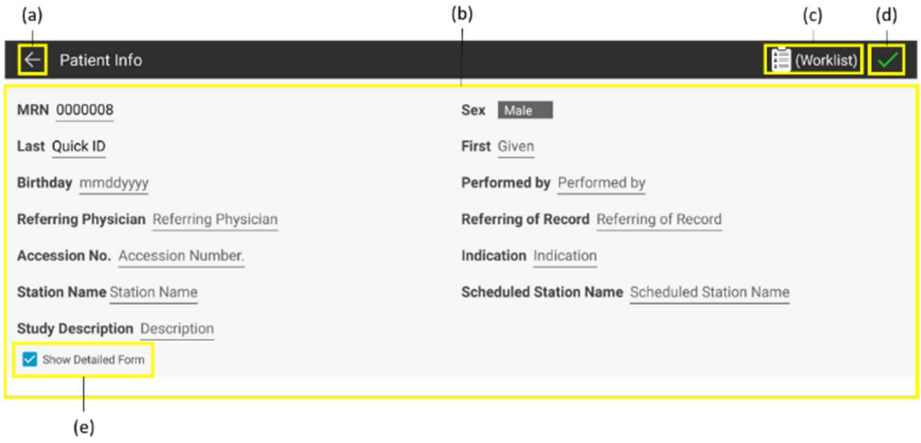
Home Page- iOS



(a) Review Button
(b) Exit Button
(c) Current ultrasound probe
(d) Wi-Fi setting button
(e) Patient info button
(f) QRcode scan button
(g) Connect button
(h) Connect percentage
(i) Cancel Connection button

App Interface Design

Home Page, Patient Info

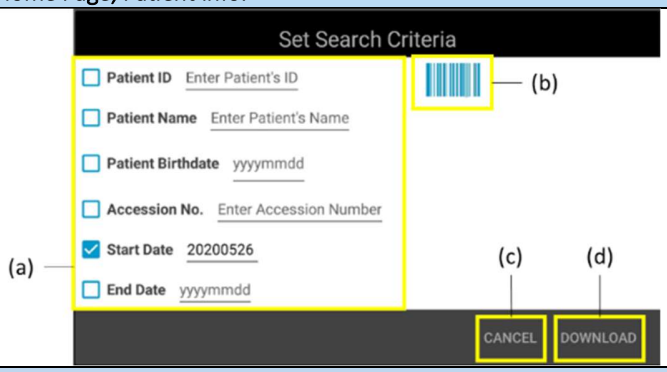


(a) Back Button
(b) Patient Info Edit
(c) Download worklist button (it only appears when the user enters the page from **Home Page**)
(d) Save Button
(e) Checkbox for detailed form

Home Page, Patient Info: DICOM Worklist

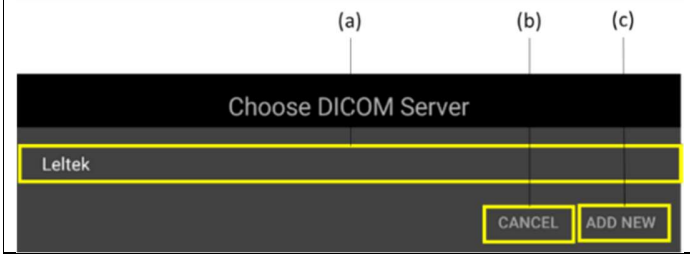
(a) Back Button
(b) Initial the server button
(c) Edit the server setting
(d) Set search criteria button
(e) Patient info downloaded from the server

Home Page, Patient Info: DICOM Worklist



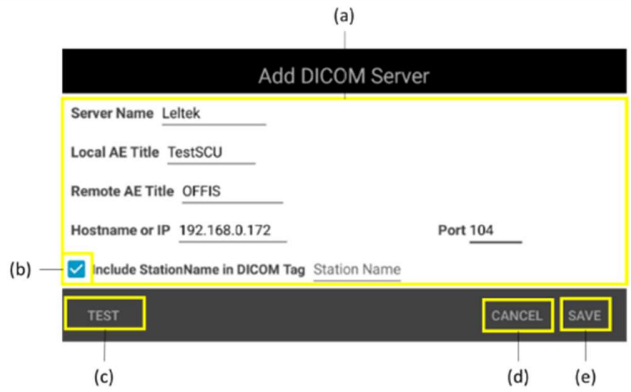
(a) Select and input search criteria
(b) Barcode scan button
(c) Cancel button
(d) Download button

Home Page, Patient Info: DICOM Worklist, DICOM Server Setup



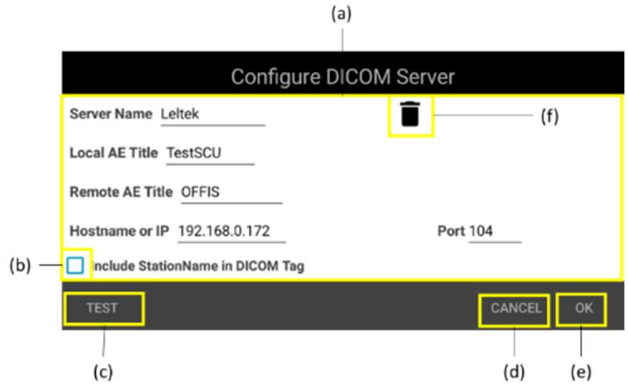
(a) Existing server list
(b) Cancel button
(c) Add server button

Home Page, Patient Info: DICOM Worklist, DICOM Server Setup



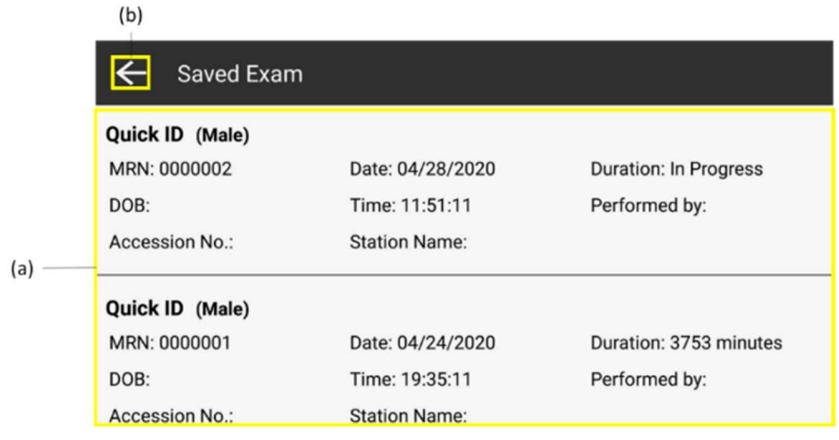
(a) Server info edit
(b) Check box for showing the input box of station name
(c) Test the server response button
(d) Cancel button
(e) Save the server setting button

Home Page, Patient Info: DICOM Worklist, DICOM Server Setup



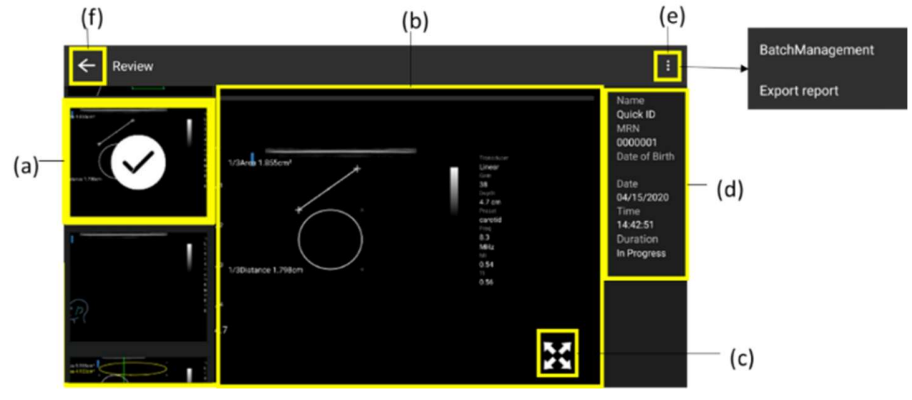
(a) Server info edit
(b) Check box for showing the input box of station name
(c) Test the server response button
(d) Cancel button
(e) Save the server setting button
(f) Delete server button

Home Page, Patient Info: Saved Exam

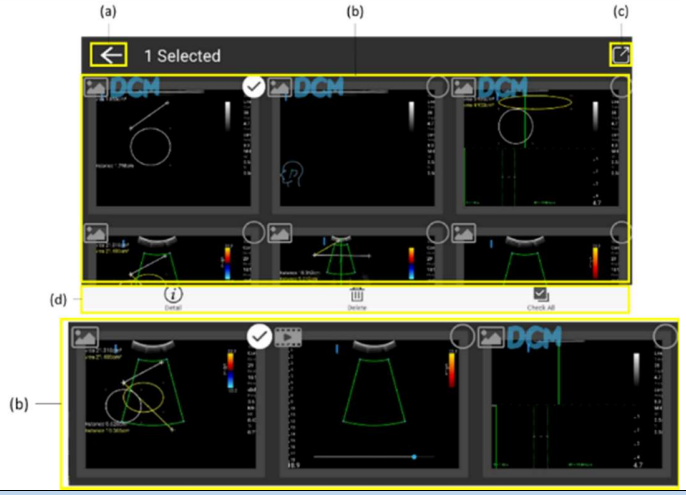
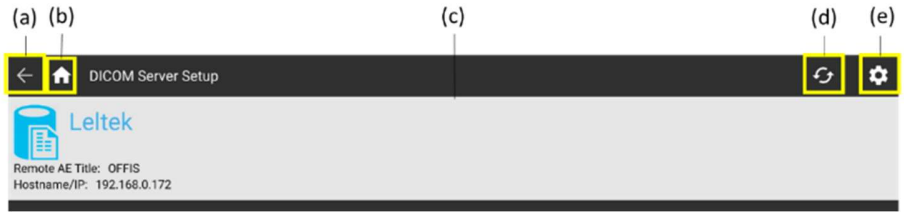
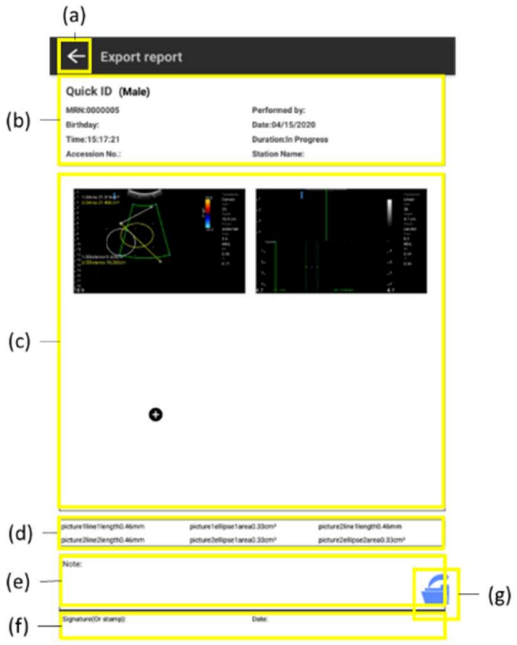


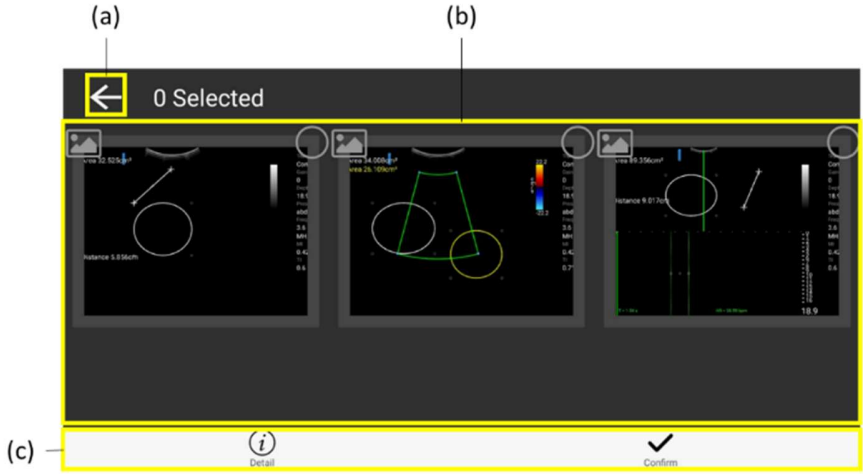
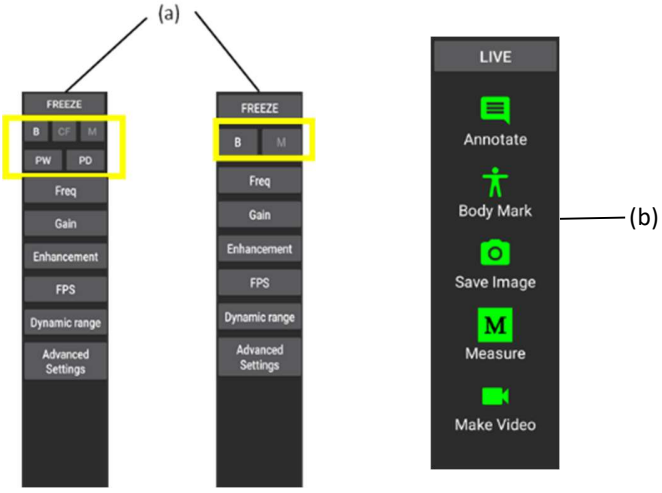
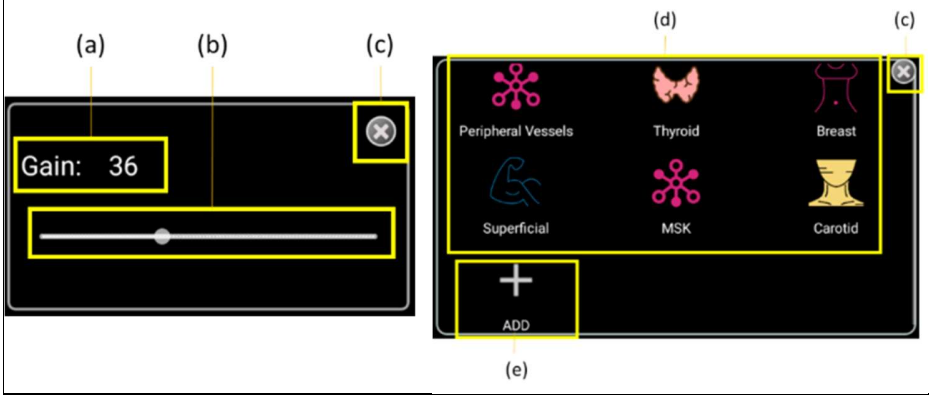
(a) Patient Info Record
(b) Back Button

Home Page, Patient Info: Review

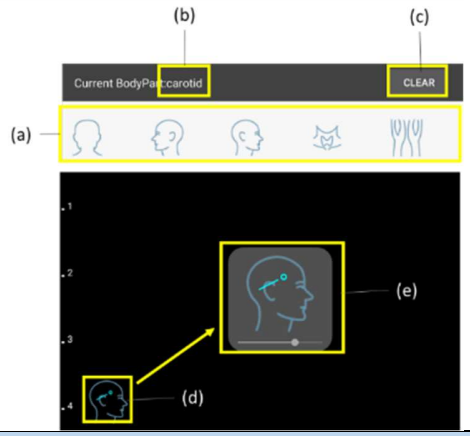


(a) Saved Image and Video
(b) View selected saved Image and Video
(c) Full Screen
(d) Current Setting
(e) Batch management of image and video, export viewed image and video /Export report

	(f) Back Button
Home Page, Patient Info: Batch Management	
	(a) Back Button (b) Saved Image (**DICOM: Optional**), Saved Image and Video (c) Export Button (Including **DICOM: Optional**) (d) Tool Bar
Home Page, Patient Info: DICOM Server Setup	
	(a) Back Button (b) Return to Home Page button (c) Initial the server button (d) Edit the server setting
Home Page, Patient Info: Export Report	
	(a) Back Button (b) Patient info (c) Selected images (d) Measure info (e) Note (f) Signature and date (g) Export Button

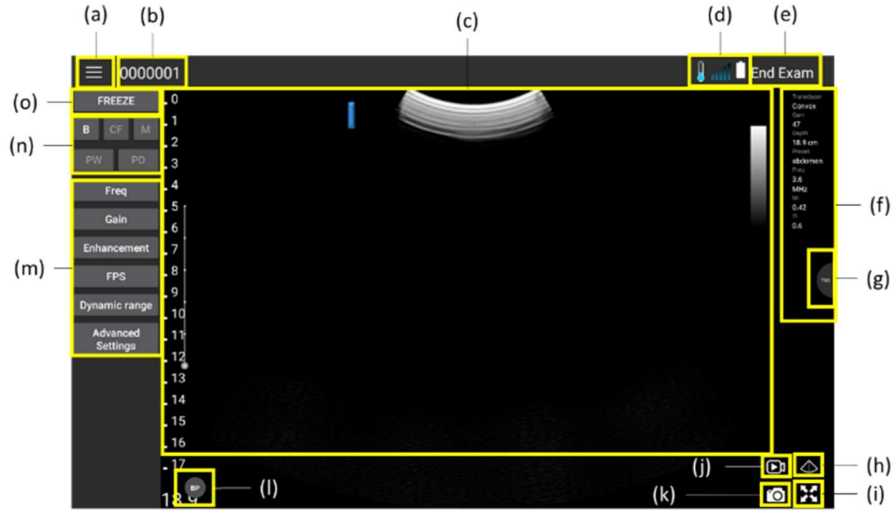
Home Page, Patient Info: Export Report (Select images)	
	(a) Back Button (b) Saved Image (c) Tool Bar
Annotation and Measurement, Save , Restore and PlayBack : Freeze/Live	
	(a) Live: **The combination of mode buttons in scanning state (Optional)** (b) Freeze
Parameter Tuning: Parameter Tuning & Select the scanned position of a body	
	(a) Parameter name and value (b) SeekBar for tuning (c) Cancel button (d) Position of a body (e) Add customized preset

Annotation and Measurement: Body Mark



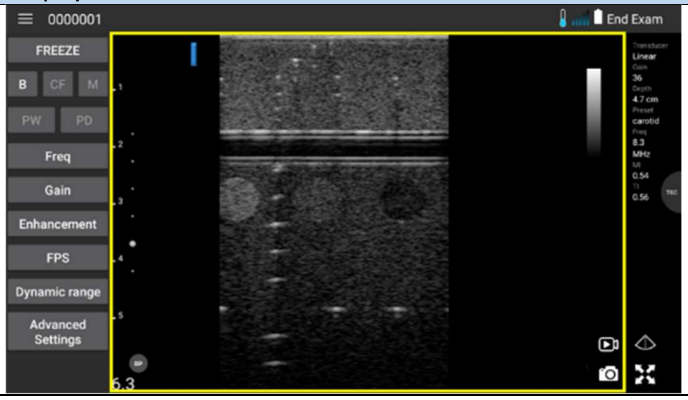
(a) Body mark icons of the body part
(b) Body part
(c) Button to close (d) and (e)
(d) Body Mark with degree mark
(e) Turning degree mark

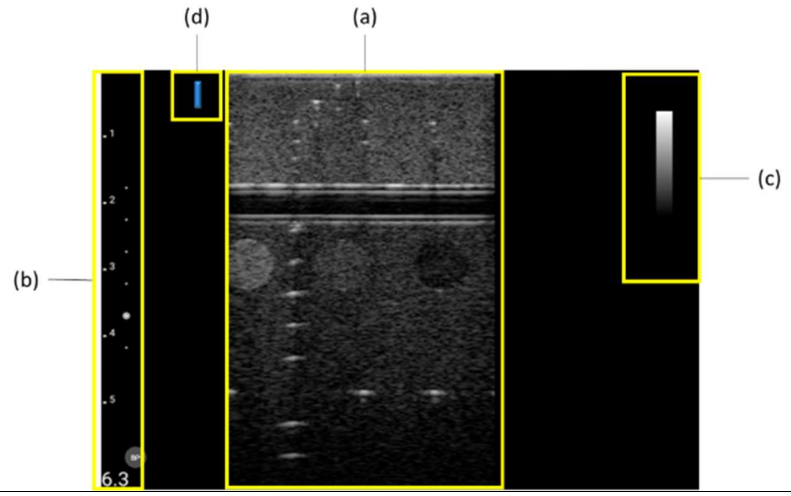
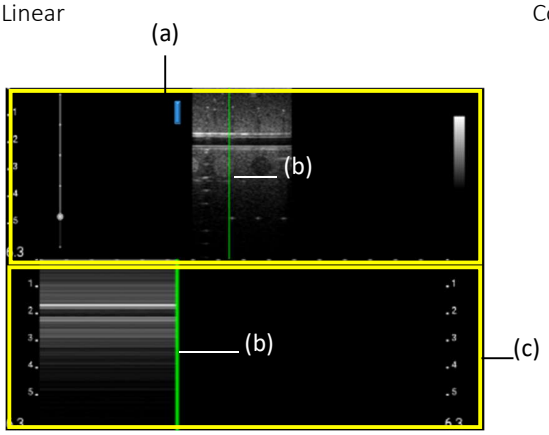
Parameter Tuning, Image Display and Gesture: Scan

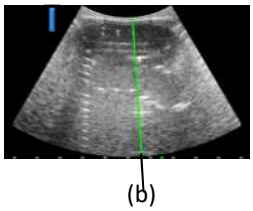
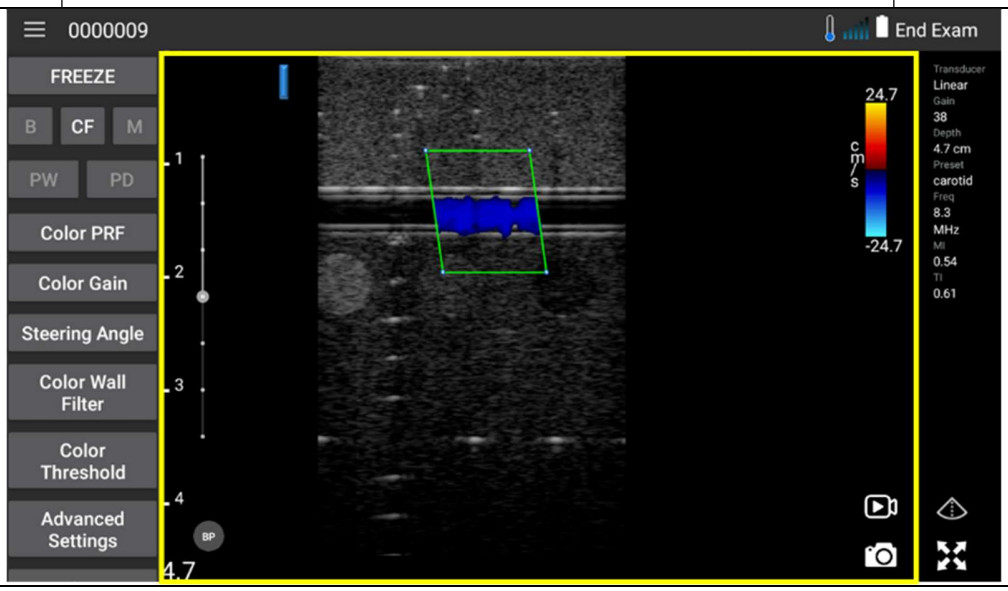


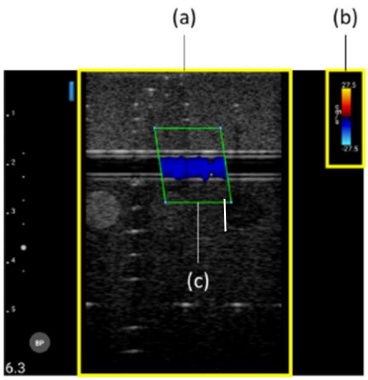
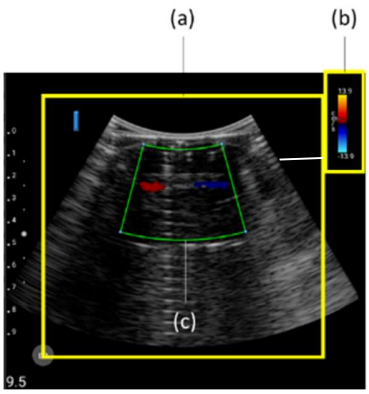
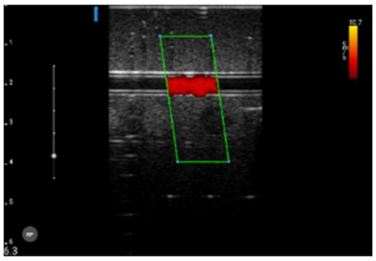
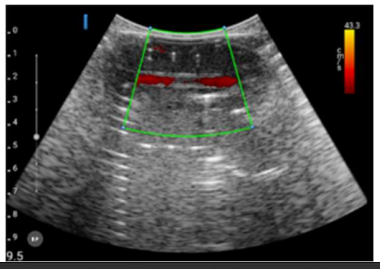
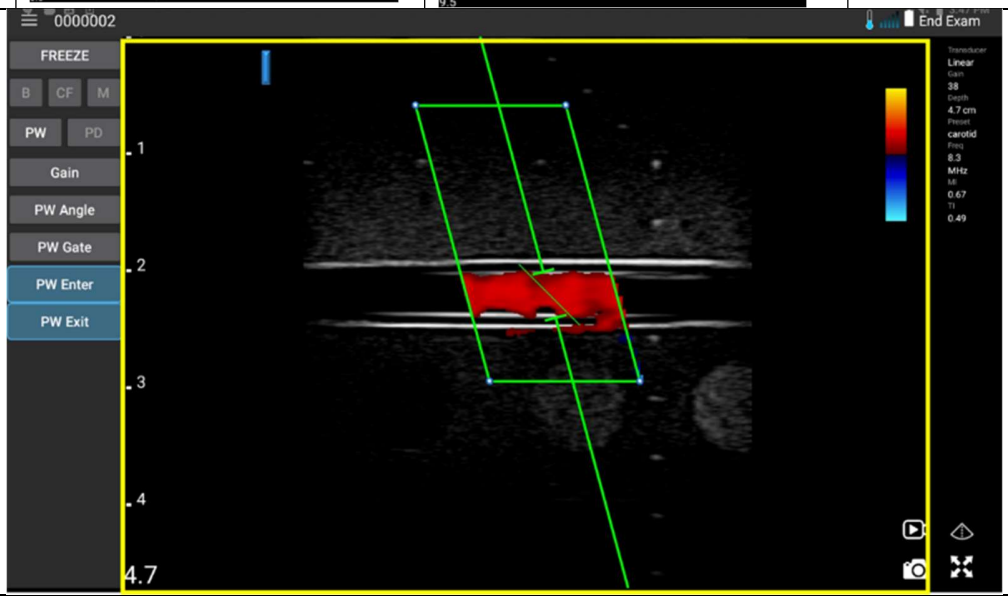
(a) Menu Button
(b) Patient Info
(c) Image
(d) Ultrasound Probe Status
(e) End exam button
(f) Current Settings
(g) TGC button
(h) Needle Guide
(i) Full Screen Button
(j) Make video button
(k) Save image button
(l) Preset Button
(m) Parameters
(n) Mode Button
(o) Freeze Button

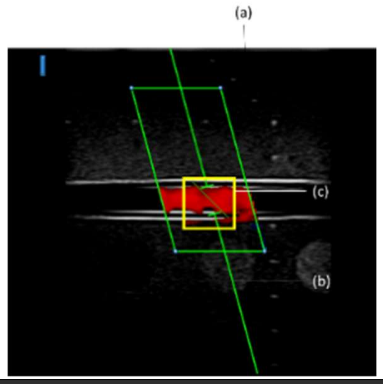
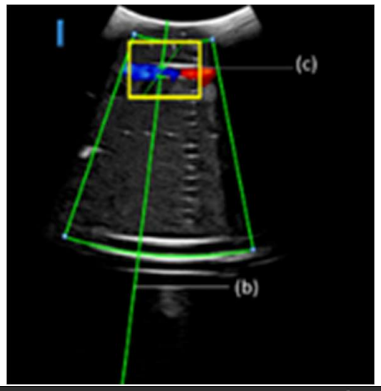
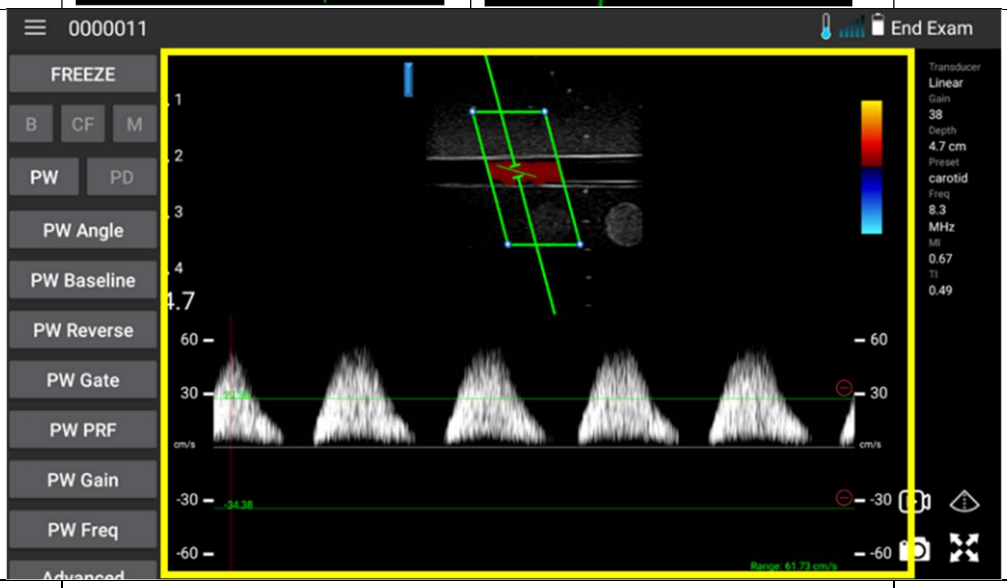
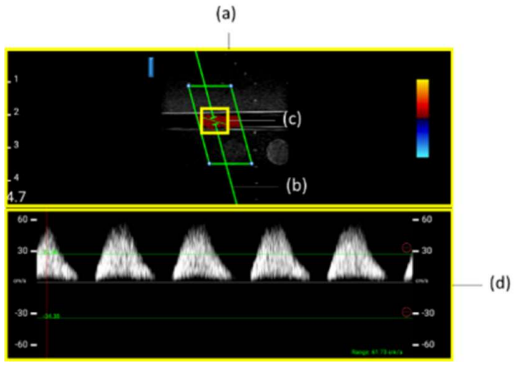
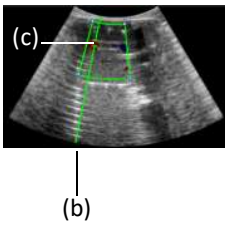
Parameter Tuning, Image Display and Gesture: Mode



<table>
<tr>
<td>B mode</td>
<td> 
</td>
<td>(a) Image
(b) Depth Ruler
(c) Gray Scale
(d) Mirror Mark</td>
</tr>
<tr>
<td>M mode</td>
<td>Linear
 

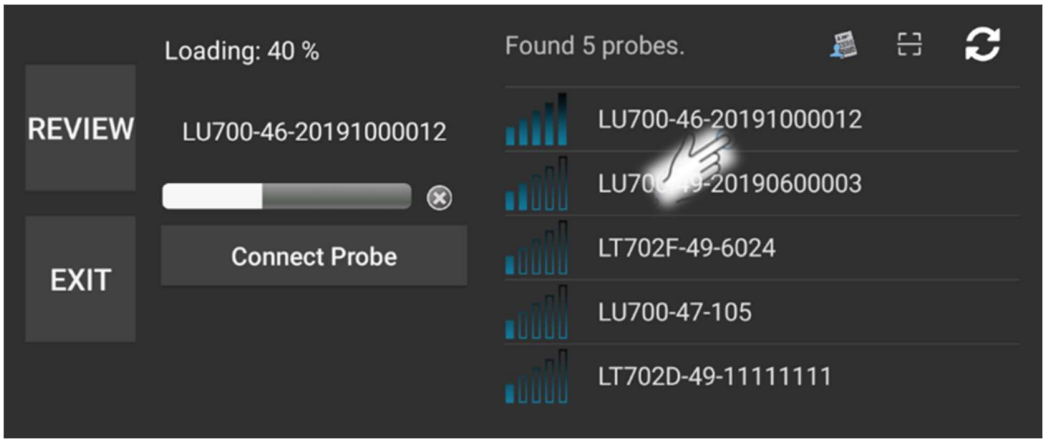
Convex
 
</td>
<td>(a) Area with B mode
(b) M Line
(c) Time-Base Graticule</td>
</tr>
<tr>
<td colspan="3"> 
</td>
</tr>
</table>

<table>
<tr>
<td>CF mode
(Optional)</td>
<td>Linear
 
</td>
<td>Convex
 
</td>
<td>(a) Image
(b) Color Scale
(c) ROI (Region of Interest)</td>
</tr>
<tr>
<td rowspan="2">PD (Power Doppler) mode
(Optional)</td>
<td colspan="2">Except that only one color is used to indicate blood flow intensity, the other is the same as CF mode.</td>
<td rowspan="2"></td>
</tr>
<tr>
<td>Linear
  </td>
<td>Convex
  </td>
</tr>
<tr>
<td colspan="3"> 
</td>
</tr>
</table>

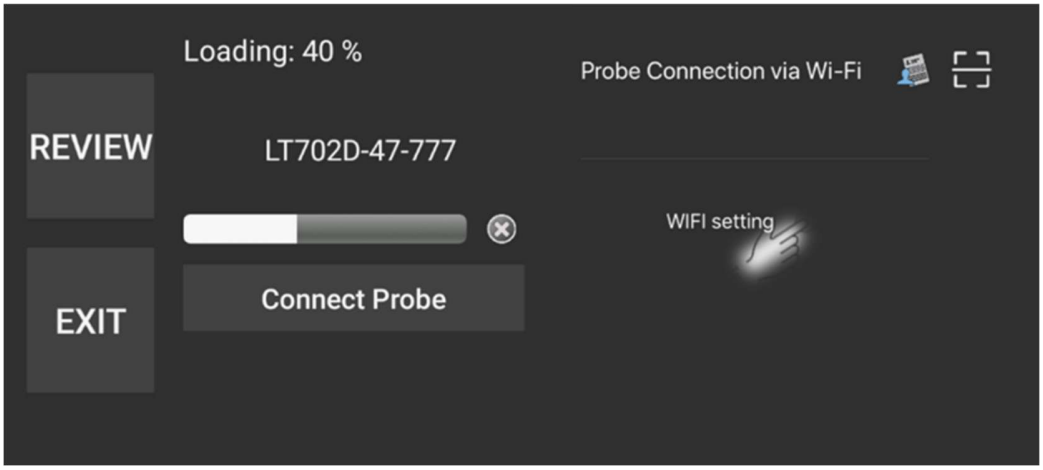
<table>
<tr>
<td>PW mode sample gate positioning (Optional)</td>
<td>Linear
 
</td>
<td>Convex
 
</td>
<td>(a) Area with suspended CF mode
(b) LOI (Line of Interest)
(c) Gap, beam/flow angle</td>
</tr>
<tr>
<td colspan="4"> 
</td>
</tr>
<tr>
<td>PW (Pulsed wave) mode (Optional)</td>
<td>Linear
 
</td>
<td>Convex
 
</td>
<td>(a) Area with suspended CF mode
(b) LOI (Line of Interest)
(c) Gap, beam/ flow angle difference
(d) Time-Base Graticule, baseline, blood velocity value and the range between blood velocity values</td>
</tr>
</table>

Starting New Exams

Home Page -Android:



Home Page - iOS:



Step 1: After starting ASUSapp, please select the SSID or scan the QR code of the probe to be connected.

Step 2: When the selected probe is connected, the loading progress will appear.

Functions in Home Page

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. (Android Only)
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. (Android Only)
5. Wi-Fi setting button: The user can manually select an ultrasound probe in the Wi-Fi settings page. (iOS Only)
6.  : QR code scanner. Scan the QR code on the probe to connect it via Wi-Fi.

7. **Connect Probe**: The user can tap "Connect Probe" button to enter the main scanning page without re-connecting the probe via Wi-Fi.

8.  : Suspend the loading progress and cancel connection.

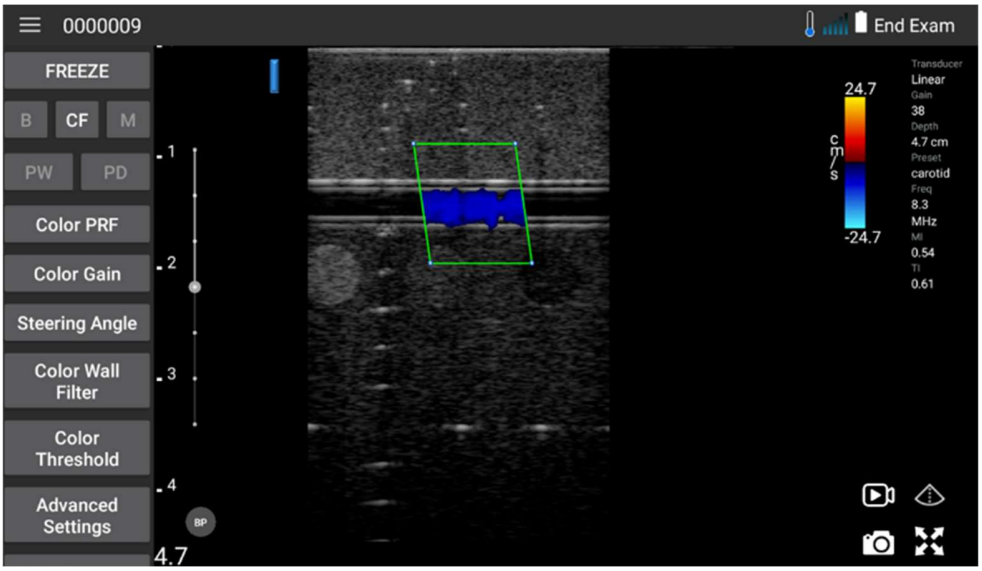
9.  : Enter **Edit Patient Info** page with worklist 

button. The user can download the worklist from the server or the latest records. If the user would like to download the data, he should set the worklist server first. If there is an existing server, the user can edit, delete or connect it.

SCAN (LIVE):

Step 3: Start scanning immediately in LIVE. The ultrasound images appear, and you can begin scanning.

Step 4: Select a parameter button on the left side to tune the parameter value in the B mode. (The illustration above is an example of clicking “Gain”)



Step 5: Switch to CF mode (Optional)

Functions in SCAN (LIVE)

Mode selection:

1. 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.

2. Touch **CF (Optional)**, 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.

3. 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.

4. Touch **PW** to enter **PW mode sample gate positioning (Optional).** Select the gate position and adjust gate size, gate angle and image gain base on CF mode.

5. Touch **PW Enter (Optional)**, 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.

6. Touch **PD (Optional),** 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.

Parameter Turning:

7. **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.

8. **THI**: **(Tissue harmonic imaging)**. It is a signal processing technique also termed native harmonic imaging. It provides special focusing methods to gather ultrasonic waves to get the focus that meets the requirements.

9. **Freq:** The carrier frequency of the ultrasound wave transmitted and received by the transducer.

10. **Gain:** The digital gain is used to adjust the brightness of the image.

11. **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. This function can be used to adjust different image processing levels to reduce image noise and make the image more delicate. 0 means this function is off.

12. **Enhancement:** Imagine enhancement processing

13. **FPS:** Frames per second. Provides three modes including energy saving, normal and high performance, representing different image smoothness.

14. **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.

15. **Advanced Settings:** When the user touches this button, there would be listed other buttons which depended the mode that user selected.

16. **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.

17. **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.

18. **Freeze Timer**: When the user touches this button, the system could be selected how many second in static situation.

19. **Mirror:** Flip the image horizontally.

20. **Line Density:** Adjusts the number of scan lines in your ultrasound image. A higher level provides better resolution in the image (more scan lines), but reduces the frame rate.

21. **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.

22. **Color Gain**: Number of Doppler pulses per line of color Doppler information.

23. **Steering Angle**: The ultrasound scanning angle.

24. **Color Wall Filter:** Filter out low or high frequency Doppler signals.

25. **Color Threshold:** Remove parts of the image that fall within a specified color range.

26. **LOI Angle:** LOI (Line of Interest) angle with visualized UI corresponding to the steering angle in CF mode.

27. **PW Enter:** When the user taps this button, it will enter PW mode. Keep LOI position and parameter values. (PW Gate, Gain, PW Angle)

28. **PW Exit:** When the user taps this button, it will go back to CF mode.

29. **PW Angle:** It is used in the CF mode image to line up the angle correction cursor along the vessel wall for velocity measurement.

30. **PW Baseline:** The PW mode image is levelly shifted up and down according to the baseline position corresponding to "0".

31. **PW Reverse:** Flip the PW mode image vertically according to the position of the value “0” baseline.

32. **PW Gate:** Adjust the gate size to attempted the flow measurements, the whole vessel should be insonated. A large gate may include signals from adjacent vessels.

33. **PW PRF:** When the user taps 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 sent.

34. **PW Gain:** Remove or strengthen parts of the pulse wave image that fall within a specified brightness range.

35. **PW Freq:** The carrier frequency of the ultrasound wave transmitted and received by the transducer in PW mode.

36. 

: Select the scanned part of human body.The user can directly tap the scanned part of human body in **BP** to obtain current scanned part of human body. Users can also add customized preset.

Multimedia:

37. 
: To make the ultrasonic images which is in the ultrasound image area as the video.

38. 
: To save an ultrasonic image which is in the ultrasound image area.

FREEZE:

Step 6: Touch FREEZE, the system is stopping the image during the scanning; or re-activating the stopped image. When the image is frozen, the latest 200 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.

Functions in FREEZE

1. 

: Tap **Annotate**, the user can fill in one or more text notes and move to anywhere on the ultrasonic image and can also be removed by long press.

2. 

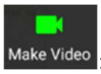
: For the user to mark which parts of human body scanning.

3. 

: To save an ultrasonic image which is in the ultrasound image area. Save the image which can be exported by DICOM **(Optional)** format.

4. 

: Tap **Measure**, the user can select element **Ellipse**, **Distance, Arrow, Mark** and **Clear all**. Tap **Ellipse**, is used to measure the area and perimeter of an ellipse. Tap **Distance**, the user can pull out a range of length anywhere on the ultrasound screen as the emphasized distance on the screen. Tap **Arrow**, is used to clearly mark the position and the orientation beside annotation. Tap **Mark**, clearly mark the position. All of them can be removed by long press. Tap **Clear all**, the user can clear all **Ellipse, Distance, Arrow and Mark** on the ultrasound screen.

5. 

: To make the ultrasonic images which is in the saved 200 ultrasound images as the video. And the user can adjust the seek bar to set the video time (the default is 3 seconds).

General:

Step 7: Touch End Exam, the diagnosis is ended and the system will back to Home Page automatically.

Functions in General

Menu:

1. 
: To touch 
the user can select item **Review**, **Edit Patient Info, Current Exam** and **About.**

2. **Review:** After entering **Review** in current diagnosis, the user can choose to display an ultrasonic image or video in Cine Graphic to review. When tapping 
, user can choose "**Batch Management**" or "**Export report**". Tap **Batch Management**, the user can multiple select, delete, export stored images (Available Format: .jpg, .png, .bmp and .dcm, .dcm is **Optional**) or videos (Available Format: .mp4) to local storage and upload DICOM **(Optional)** files to the server. Tap **Export report,** the user can export the diagnosis to pdf with the patient info, selected images, measurement info, annotation, signature and date.

3. **Edit Patient Info**: It is used to enter or modify patient information that is stored in the local database. The default current patient name is "Quick ID". Images and videos are saved under each patient study record. The default values for the items in the current edit patient information screen are the values stored in the local database. Press the button "**Save**" which is on the screen of the right upper corner to do update new data to local database.

4. **Current Exam:** Select the scanned part of human body.The user can directly tap the scanned part of human body in **Current Exam** to obtain current scanned part of human body. Users can also add customized preset.

5. **About:** The user can review company name, application version, website, credit, OpenCV license agreement, copyright announcement…etc.

Others:

6.  : An ultrasonic image can be added with a center dotted line, whether it is in **Freeze** or **Live** mode.

7.  : The part of the ultrasound image can be enlarged to full-screen viewing. Whether it is **Freeze** or **Live** status or historical record viewing, this function can be used if the ultrasound image is displayed.

8. **End Exam:** When the user presses **End Exam**, a diagnosis is ended and the time spent on this diagnosis will be calculated and the value will be displayed in **Saved Exam**. Then updating the previous diagnosis list makes the status of this diagnosis no longer in progress. Create a new exam automatically after back to Home Page.

* Additional features

1. **DICOM(Optional):** When capturing images, it can be saved as a medical image format (.dcm). This format will add more complete image-related information and can be uploaded to the DICOM server.

2. **The combination of mode buttons in scanning state (Optional):**

   Case 1: B mode and M mode in Live status

   Case 2: B mode, M mode, CF mode, PD mode, PW mode sample gate positioning and PW mode in Live status.

CHAPTER 6 REFERENCES

Compliance Statement

ASUSproducts 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. ASUSmeets all regulatory standards listed in this chapter.

Authorized Representative

European Authorized Representative (AR)
Name: MedNet GmbH
Address: Borkstrasse 10 • 48163 Muenster • Germany
Phone +49 25132266-61 • Fax +49 251 32266-22

Product 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

ASUShas assigned a unique serial number on each ultrasound device. This serial number, displayed in the format X –YY –M-XXXXXX, is used to track quality control.

X

ASUSserial product model name.

X	A	B
Model Name	LU700C	LU700L

YY

2-digit year of manufacture.

M

Month of manufacture, 1~9 means January to September, A is for Oct., B is for Nov. and C for Dec.

XXXXXX
Manufactured in this batch of production.
6-digit numerical counter starting from 01.

System Specifications

- Gray shades: 256 in B-Mode
- Pressure, humidity, and temperature limits: These limits apply only to the ASUStransducer, not to the Android device on which the user run the ASUSimaging 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 to 35°C	-20°C to 50°C / -20°C to 50°C

Storage Limits

- Ventilate room without corrosive gases.

Standards

Acoustic

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

Biocompatibility

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

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

ISO 10993-10:2010-Biological evaluation of medical devices. 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 15223-1:2016 (Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - General requirements)

Battery

UN 38.3 -Lithium Battery Transportation

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

Wireless

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

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

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

Waterproof

IEC 60529 edition2.2:2013 -Degrees of protection provided by enclosures (IP Code

Safety Conformance

Conforms to the following safety standards

Performance

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

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

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

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

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

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

IEC 60601-1-6 / EN 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 2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

EN ISO 14971:2012-Medical devices. Application of risk management to medical devices

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

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

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

Acoustic Output Tables

Acoustic output reporting table

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

Transducer Model: LU700C SN:LT702D-47-00001

Operating Model: B Mode

Index Lebel			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			0.42	0.60		0.60		N/A
Index component value				0.60	0.60	N/A	0.60	
Associated Parameter	$P_{r.a}$ at Z_{MI}	(MPa)	0.77					
	P	(mW)		101.10		101.10		N/A
	P_{1x1}	(mW)		38.82		38.82		
	Z_S	(cm)			N/A			
	Z_b	(cm)					N/A	
	Z_{MI}	(cm)	0.50					
	$Z_{PII\,\alpha}$	(cm)	0.50					
	f_{awf}	(MHz)	3.27	3.27		3.27		N/A
Other Information	prr	(Hz)	5063.8					
	srr	(Hz)	7.47					
	n_{pps}		1.00					
	$I_{pa.\,\alpha}$ at $Z_{PII\,\alpha}$	(W/cm^2)	15.97				-	
	$I_{spta.\,\alpha}$ at $Z_{PII\,\alpha}$ or $Z_{SII\,\alpha}$	(mW/cm^2)	5.80					
	$I_{spta.}$ at Z_{PII} or Z_{SII}	(mW/cm^2)	21.68				-	
	$P_{r.}$ at Z_{PII}	(MPa)	0.81					
Operating Control Conditions	Display focus	(cm)	3.00	3.00	3.00	N/A	3.00	N/A
	Display depth	(cm)	9.50	9.50	9.50	N/A	9.50	N/A
	Working frequency	(MHz)	3.60	3.60	3.60	N/A	3.60	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: LU700L 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.								

Acoustic output reporting table

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

Transducer Model: LU700C SN:LT702D-47-00001

Operating Model: PW Mode

Index Lebel			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum Index Value			1.09	0.72		3.13		N/A
Index component value				N/A	0.72	N/A	3.13	
Associated Parameter	$P_{r.a}$ at Z_{MI}	(MPa)	1.81					
	P	(mW)		92.74		92.74		N/A
	P_{1x1}	(mW)		N/A		N/A		
	Z_S	(cm)			2.75			
	Z_b	(cm)					4.42	
	Z_{MI}	(cm)	4.43					
	$Z_{PII\,\alpha}$	(cm)	4.43					
	f_{awf}	(MHz)	2.76	2.76		2.76		N/A
Other Information	prr	(Hz)	2000.00					
	srr	(Hz)	N/A					
	n_{pps}		1					
	$I_{pa.\,\alpha}$ at $Z_{PII\,\alpha}$	(W/cm^2)	182.1				-	
	$I_{spta.\,\alpha}$ at $Z_{PII\,\alpha}$ or $Z_{SII\,\alpha}$	(mW/cm^2)	634.3					
	$I_{spta.}$ at Z_{PII} or Z_{SII}	(mW/cm^2)	1474.00				-	
	$P_{r.}$ at Z_{PII}	(MPa)	2.76					
Operating Control Conditions	Display focus	(cm)	3.0	N/A	3.0	N/A	3.0	N/A
	Display depth	(cm)	9.5	N/A	9.5	N/A	9.5	N/A
	Working frequency	(MHz)	2.8	N/A	2.8	N/A	2.8	N/A
	Display focus number		1	N/A	1	N/A	1	N/A
	PRF	(KHz)	2.0	N/A	2.0	N/A	2.0	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: LU700L 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: LU700L 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.								

Acoustic output reporting table

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

Transducer Model: LU700L 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.								

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

<table>
<tr><th colspan="3">Manufacturer’s declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The LU700 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the LU700 Series should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment-guidance

(for professional healthcare environment)</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The LU700 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">The LU700 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.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations

/flicker emissions IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Manufacturer's declaration-electromagnetic immunity

The LU700 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU700 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 % 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.			

Electromagnetic immunity

All LU700 series products are in compliance with the regulation of immunity test, and the detail and declaration as below:

<table>
<tr><th colspan="4">Manufacturer's declaration-electromagnetic immunity</th></tr>
<tr><td colspan="4">The LU700 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the LU700 Series should assure that it is used in such and environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment-guidance
(for professional healthcare environment)</th></tr>
<tr><td>Conducted RF

IEC 61000-4-6</td><td>3 Vrms:

0,15 MHz – 80 MHz

6 Vrms:

in ISM bands between

0,15 MHz and 80 MHz

80 % AM at 1 kHz</td><td>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)</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the LU700 Series including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

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 meters (m).

Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td>Radiated RF

IEC 61000-4-3</td><td>3 V/m

80 MHz – 2,7 GHz

80 % AM at 1 kHz</td><td>3 V/m

80 MHz – 2,7 GHz

80 % AM at 1 kHz</td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

Recommended separation distance between

portable and mobile RF communications equipment and the LU700 Series

The LU700C,LU700L,LU710C,LU710M,LU710PA,LU710E 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 LU700 Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LU700 Series as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter** **m**		
W	**150 kHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2,7 GHz**
	$d = 1{,}2\sqrt{P}$	$d = 1{,}2\sqrt{P}$	$d = 2{,}3\sqrt{P}$
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 LU700 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the LU700 Series 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) ±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							
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT;	Pulse modulation b) 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5500							
5785							

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
LED indicator flashing and could not turn off device.	When low battery state, please plug in the 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 re-enable 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.

Manufacturer’s address

ASUSTeK Computer Inc.

6F-3., No. 293, Sec. 1, Beixin Rd., Xindian Dist.,

New Taipei City 23147,

Taiwan, R.O.C

www.asus.com

CE 0598

EC REP

MedNet GmbH

Borkstrasse 10, 48163 Muenster, Germany

Phone +49 25132266-61, Fax +49 251 32266-22