Asus LU800 Series User Manual

Ultrasound imaging system

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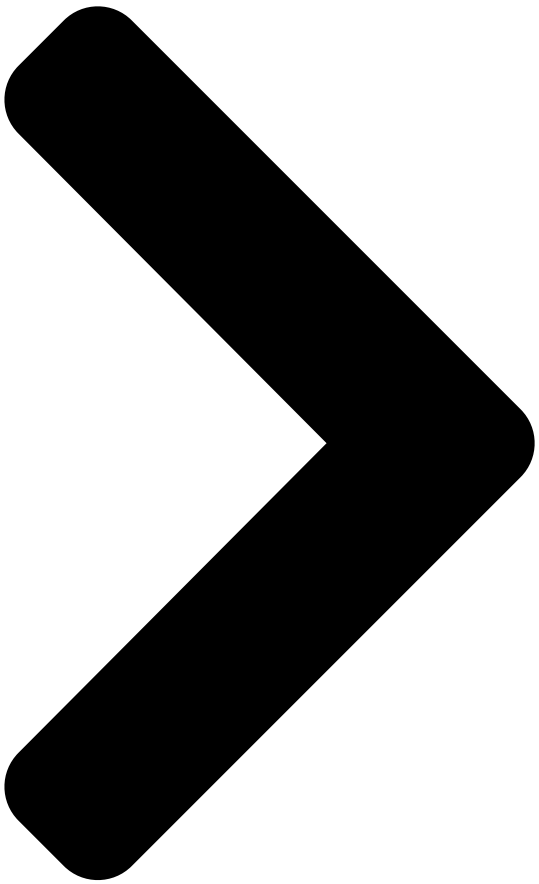
Bookmarks



ASUS Ultrasound Imaging System

USER MANUAL

LU800 Series (LU800C, LU800L, LU800M,
LU800PA, LU800E)

Ver_01

AS_UI-LU800-01

2024-10-01

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Related Manuals for Asus LU800 Series

All in One Printer Asus LU700 Series Manual

Ultrasound imaging system (77 pages)

Summary of Contents for Asus LU800 Series

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Page 2 ABOUT THIS MANUAL .....4 B INDICATIONS FOR USE .....4 C ULTRASOUND IMAGING SYSTEM DESCRIPTION..... 5 START TO USE THE LU800 SERIES ULTRASOUND SYSTEM WHICH INCLUDE: ..... 5 ULTRASOUND PROBE ..... 5 ULTRASOUND APP .....5 III. USER'S TABLET/SMART PHONE/PC ....5 D...

Page 4 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 any other media) are fictitious and are used herein for the purposes of example and demonstration on how to use the ASUS Ultrasound System.

Page 5 Indications for B The ASUS Ultrasound Imaging System (Model: LU800 Series) 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.

Page 6 The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients. The ASUS Ultrasound Imaging System (Model: LU800 Series) is a portable, software controlled, handheld ultrasound system used to acquire and display hi-resolution, real-time ultrasound data through a commercial off-the-shelf (COTS) mobile device.

Page 7 ASUS App screen will be freeze and the LED is still white. Ultrasound App E Please download the App 1. The Android Play Store download name is "ASUS MediConnect". Links: https://play.google.com/store/apps/details?i d=com.asus.medical.ultrasound64 2. The iOS App Store download name is "ASUS...

Page 8 System Requirements F Using the ASUS Ultrasound Imaging System with a mobile device that does not meet the minimum requirements may result in low-quality images, unexpected anomalies, and possible inaccurate results. The minimum specifications of the mobile...

Page 9 LU800E E8-4 Endocavity System Dimension I Weight(with Model Length x Width x Height (mm) battery) LU800C 177×71×34mm 305(g) LU800L 168x58x34 mm 270(g) LU800M 176x58x34mm 265(g) LU800PA 174x58x34mm 280(g) LU800E 345x58x34mm 295(g)

Page 10 RF Energy Specification J 2.4G : 5G : Tx frequency: 2412Mhz- Tx frequency: 5180Mhz- 2462Mhz 5825Mhz TX modulation: TX modulation: OFDM DSSS/CCK/OFDM Tx Power: Tx Power: 12dbm 16dbm @54OFDM @1DSSS 12.5dbm frequency: @54OFDM 5180Mhz- 5825Mhz Rx frequency: 2412Mhz- 2462Mhz Rx Sensitivity: Rx Sensitivity:...

Page 11 Temperature 0°C to 35°C Maintenance M If this product is not functioning properly, you can contact your local dealer or reach out to the manufacturer via email: info@ASUS.com Trouble Shooting N Issue Solution LED indicator flashing and could When low battery state, please plug in the adapter to charge device not turn off device.

Page 12 About the Ultrasound Imaging System...

Page 13 About the Ultrasound Imaging System Start to use ultrasound app 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.

Page 14 (a) Back button (b) Edit patient information (c) Download Worklist button (only appears when a user enters this page from the homepage) (d) Save button (e) Show detailed table check Homepage, Patient Information: DICOM Worklist (a) Back button (b) Edit the server settings (c) Set search criteria...

Page 15 (a) Edit the server information (b) Option: Institution Name and Station Name (c) Storage server settings (d) Test the server response button (e) Back button Homepage, Patient Information: Stored Tests (a) Patient information records (b) Back button Home, Patient Information: View Patient testing information...

Page 16 (a) Select Export Stored Images (DICOM: Optional). (b) Return button for saved images and videos (c) Export button (with DICOM: optional). (d) Delete Home, Patient Information: DICOM Server Settings (a) Back button (b) Add a new server (c) Connect to a server (d) Edit server settings...

Page 17 Opt-in imagery Select All Confirm the selection Delete Cancel the return Annotation & Measurement, Storage, Recovery & Playback: Pause/Scan Scan: A group of buttons in the scan state Time out Parameter Adjustment: Adjust the parameters and select the body part to be scanned Function keys The name of the...

Page 18 Patient Information Median line Record button Save Image button image Depth selection Focus marking Pause button Choice of features Mode selection Advanced settings Select the body part (m) Image parameters Dual-screen display TGC button Full screen button Probe status inspection Parameter adjustment, image display and gestures: mode Model B image...

Page 19 Pre-select Linear Convex (a) CF mode image PW Gate (b) LOI (Line of Location Interest) (optional). (c) Differences in spacing, beam/stream angles (Enter PW) (a) Paused PW pulse mode image ultrasonic (b) LOI (Line of mode Interest) (Optional) (c) Differences in spacing, beam/stream angles...

Page 20 Start a new inspection Home Step 1: After enabling ASUS MediConnect, select "Probe List" to select the probe, or "Continue to Scan" / or "Start to Scan" to scan the probe's QR code to wire the probe. Step 2: When the selected probe is connected, the reading progress will be displayed.

Page 21 and the user can start scanning. Step 4: Select the function button below in mode B and adjust the parameter value. (Above is a diagram of clicking "Gain") Step 5: Switch to CF mode Scan (activate) the function Mode Selection: Press B to select B mode, which is a 2D ultrasound image display that highlights the ultrasonic echo.

Page 22 image noise and make the image more detailed, and 0 means that this function is off. Enhancement: Image enhancement processing Image update rate: frames per second. There are three different modes including Energy Saving, Normal, and High Efficiency, and you can choose different image smoothness through the modes.

Page 23 PW Gate: Adjust the interval size for flow measurement, and the acoustic processing should cover the full vascular width. Larger intervals may contain signals from adjacent blood vessels. PW PRF: When the user presses this button, it represents the time between two pulses, which is calculated in units of time.

Page 24 the user can pull out a certain length anywhere on the ultrasound image, mark and measure the distance. Click on the indication and the annotation will clearly point to the marker's location. Click on the marker location. They can be deleted individually by long-pressing.

Page 25 information. Mode button combination in scan state (optional): □ Case 1 (when CF, PD, and PW are not selected): B mode and M mode are available in scanning mode Situation 2 (when CF, PD and PW are optional): B mode, M mode, CF mode, PD mode are available in

scanning mode, and PW Gate position and PW mode are pre-selected Ultrasound Gels...

Page 26 III. SAFETY Contraindications and Warnings Do NOT use the 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.

Page 27 When the scanner connects to a wireless network. The data transferred between the smart device and the ASUS Ultrasound App is encrypted. Image data contains no patient or user identifiable information and is transmitted in unencrypted form. If you want this data...

Page 28 This Ultrasound imaging system only one device connection to it at a time. When a smart device directly connects to the system. it disallows other user from connecting, and reduce DoS (Denial of Service) attacks. If the communication is disrupted, the device continues to monitor itself and shuts down after a period of inactivity.

Page 29 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.

Page 30 heater. If the battery leaks or emits an odor, turn-off the equipment and contact with Local representative. 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.

Page 31 Acoustic Output and Measurement 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.

Page 32 Mechanical(non-thermal) effects. Acoustic output limit: ISPTA.3 = 720 mW/cm^2 (50 for ophthalmic) for Track 3; for Track 3 ophthalmic, TI ≤ 6.0(Max TIS as TIC ≤1) MI ≤ 1.9 (0.23 for ophthalmic) for track 3; Mechanical Index (MI) (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...

Page 33 width reduces the rate and extent of temperature rise by permitting the energy to be distributed over a larger perfusion territory. 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.

Page 34 vasculature and blood flow and the thermal properties of the surrounding tissue, which vary greatly. The bone TI derivation assumes all ultrasound energy is absorbed by the impinged bone. Thermal Index Display Accuracy and Precision It is estimated that 90% of TI values will be +/–...

Page 35 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. Ensure that scanning time is kept to a minimum and that only medically required scanning is performed.

Page 36 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.

Page 37 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...

Page 38 divided into three categories: direct, indirect, and receiver controls. Using System Controls to Implement ALARA Direct Controls: The system has no direct control for output, therefore the sonographer must control exposure time and scanning technique to implement the ALARA principle. To ensure that acoustic and thermal limits are not exceeded for all imaging modes, the system is designed to automatically adjust output.

Page 39 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).

Page 40 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...

Page 41 Technical Features PCBA There are some of the technical aspects of the system as following list: Receive frequency and/or band and bandwidth of receiving section. Transmit frequency and/or band, modulation, and ERP Functions: Image data transmit and control data communications High performance computing technology of FPGA unique technology “Ultra Image Block...

Page 42 and password required; only one authenticated connection at a time. Redundancy Metadata checking for mechanism integrity Distance <3 meter; In most tests between the <1 meter if in See Wi-Fi coexistence LU800 and the crowded testing. mobile device environment Error rate <5% See Wi-Fi coexistence testing.

Page 43 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. ASUS meets all regulatory standards listed in this chapter. Product Classification The device with transducers: Class IIa/internally powered ME equipment.

Page 44 which the product is used. System Specifications Gray shades: 256 in B-Mode Pressure, humidity, and temperature limits: These limits apply only to the transducer, not to the Android or iOS device on which the user run the imaging System app. It is the user's responsibility to select a compatible device that meets the needs of the user's clinical environment.

Page 45 Acoustic Output Tables [LU800C] Acoustic output reporting table...

Page 47 [LU800L] Acoustic output reporting table...

Page 49 [LU800M] Acoustic output reporting table...

Page 51 [LU800PA] Acoustic output reporting table...

Page 53 [LU800E] Acoustic output reporting table...

Page 55 Manufacturer’s declaration-electromagnetic emissions The LU800 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU800 Series should assure that it is used in such an environment. Emission test Compliance...

Page 56 The LU800 Series is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU800 Series should assure that it is used in such and environment. Immunity IEC 60601 test level...

Page 57 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment The LU800Series is intended for use in the electromagnetic environment (for professional healthcare) specified below. The customer or the user of the LU800 Series should assure that it is used in such an environment. Complianc Test...

Page 58 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.

Page 59 * _____ * References A 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 AIUM/NEMA UD 2- 2004 2009 NEMA Standards Publication UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3.

Page 60 ISO 13485 2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes ISO 14971:2019 Medical devices — Application of risk management to medical devices I Labeling ISO 15223-1:2016 (Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - General requirements) Symbols Symbol...

Page 61 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.

Page 62 Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner (USA). MR Unsafe an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment. Medical device Indicates the item is a medical device Unique Device Identifier Indicates a carrier that contains Unique Device Identifier information...

Page 63 Label ID Models Label LU800C LU800L LU800M LU800PA LU800E...

Page 64 DEVICE MAINTENANCE WARNING It is your responsibility to appropriately clean and disinfect your compatible smart device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices. If the compatible smart device becomes contaminated internally with bodily fluids containing pathogens, you must immediately notify your Manufacturer service representative.

Page 65 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 ASUS or a local distributor for service. Recommendations for disinfecting the ultrasound probe (After cleaning): ...

Page 66 Model Photo Immerse area LU800 Wiping Range Immerse point Immerse area LU800 Wiping Range Immerse point Immerse area LU800 Wiping Range Immerse point LU800 Immerse area LU800 Wiping Range Immerse point...

This manual is also suitable for:

Lu800cLu800lLu800mLu800paLu800e