Ultrasound Imaging System

LX Series (LX128LC, LX192LC)

Ver_02
LK_UI-LX-01 **(EUA)**

Revision history

Revision	Date
User Manual Ver_01 1. First edition	2024/4/24
User Manual Ver_02	2025/07/24

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I. Using the Leltek Ultrasound Imaging System

A、 About this manual

This document contains the following information:

- About Leltek Ultrasound Imaging System: Describes the product, lists the technical specifications, and its intended use.
- A quick tour: shows you how to get started and start scanning.
- Using the Leltek Ultrasound Imaging System: Introduces the features and concepts, helps you set up your system, and explains the tasks you can perform.
- Cleaning and Disinfecting: Explains how to clean and disinfect your system.
- Security: Outlines important security standards, principles, and policies to follow when using the product.
- References: Provides 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 the user's Leltek ultrasound imaging system. It contains instructions and reference material related to the use and maintenance of the product.

B、 Indications for use

The Ultrasound Imaging System is a software-based imaging system and accessories intended for use by qualified physicians and healthcare professionals who have the ability to perform the ultrasound scanning process for evaluation by ultrasound imaging system or fluid flow analysis of the human body. Operating modes include B-mode, M-mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, Tissue Doppler mode (TD: TVI/TDI), and combined mode (B+M, B+CD/TVI, B+PWD/TDI). Specific clinical applications and types of examinations, including:

Dual-head probe

LX128LC

Linear Transducer: Abdominal, Adult Cephalic, Pediatric Cephalic, Neonatal Cephalic, Carotid, Musculoskeletal, Muscle Injuries, Nerve, Ophthalmic, Pediatric, Peripheral Vessel, Blockage, Lesion Identification, Fast Examination for Internal Bleeding, Pulmonary, Pleural Effusion, Small Parts (Breast, Testicles, Thyroid), Fluid Punctures.
Convex Transducer: Abdominal, Renal, Adult Cardiac, Pediatric Cardiac, Neonatal, Fetal, Gynecology, Musculoskeletal, Nerve, Obstetric, Pediatric, Peripheral Vessel, Small Parts, (Breast, Testicles, Thyroid), Prenatal, Pulmonary, Blockage.

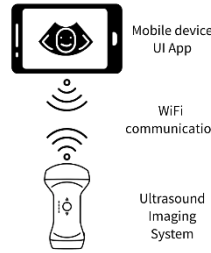
LX192LC

Linear Transducer: Abdominal, Adult Cephalic, Pediatric Cephalic, Neonatal Cephalic, Carotid, Musculoskeletal, Muscle Injuries, Nerve, Ophthalmic, Pediatric, Peripheral Vessel, Blockage, Lesion Identification, Fast Examination for Internal Bleeding, Pulmonary, Pleural Effusion, Small Parts (Breast, Testicles, Thyroid), Fluid Punctures.
Convex Transducer: Abdominal, Renal, Adult Cardiac, Pediatric Cardiac, Neonatal, Fetal, Gynecology, Musculoskeletal, Nerve, Obstetric, Pediatric, Peripheral Vessel, Small Parts, (Breast, Testicles, Thyroid), Prenatal, Pulmonary, Blockage.

The device is intended for use in settings where healthcare is provided by trained healthcare workers.

The Leltek Ultrasound Imaging System (Model: LX Series) is a portable, software-controlled, portable ultrasound system used to acquire and display high-resolution, real-time ultrasound

data via a commercial off-the-shelf (COTS) mobile device.

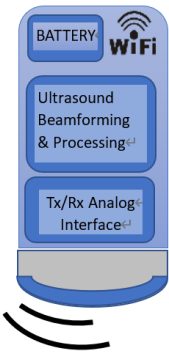


1. The imaging system software runs as an application on a mobile device.
2. The imaging system software can be downloaded to a commercial mobile off-the-shelf (COTS) device and utilizes an icon touch-based user interface.
3. The imaging system consists of a series of wireless transducers that employ Wi-Fi-based technology to communicate with traditional tablet/smartphone devices via direct Wi-Fi. This allows the user to export ultrasound images and display them on a portable personal device.
4. The imaging system houses a built-in battery, multi-channel beamformer, pre-scan converter, and Wi-Fi components

C、 Description of the ultrasound imaging system.

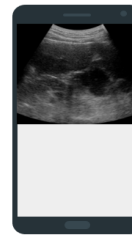
Get started with the LX Series Ultrasound System, which includes:

i. Ultrasound probe
ii. Ultrasound Application
iii. User tablet/smartphone/PC



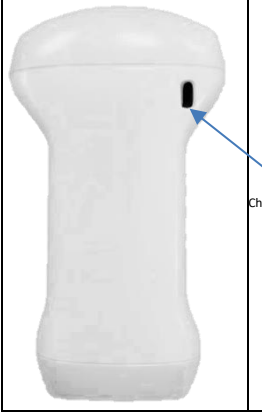
Ultrasound Probe

Wi-Fi Enable User's Tablet
/Smart phone
/PC



User Interface (APP) for Display

D、 Ultrasound probe

LX Series	Part Name	Meaning and purpose
	Probe cover	Protects acoustic lens.
	Power button/ Freeze Button/	When not connected: - Press and hold the button: Turn on the probe. - Short Push Button: Displays the current battery level. - Purple light is always on: indicates that the probe is in the ON state. When connected: - White light is solid: WiFi has been successfully connected. - Short press the button: Pause the image or resume the image paused during scanning.
	Battery indicator	– Flashing orange light: Charging (the indicator light will turn off when the battery is fully charged). - Solid Orange Light: Displays the current battery level (4 indicators show a full charge, 1 indicator shows a low battery level).
	Operation Indicator	- Solid Blue Light: Active transducer at this location
	Probe cover	Protects acoustic lens.
	Charging port	To charge.

E、 System requirements for mobile devices

Android	Android: OS 7.0 or higher Processor: 2 GHz ARM-based CPU architecture with 2 or more cores processor or higher. Memory: 2G or higher. Supported smart devices: Wi-Fi 802.11 a/b/g/n Display: Resolution (in pixels) of 960 X 640 pixels or higher.
Ios	iOS: 11.0 or higher Processor: 2 GHz ARM-based CPU architecture with 2 or more cores processor or higher. Memory: 2G or higher. Supported smart devices: Wi-Fi 802.11 a/b/g/n Display: Resolution (in pixels) of 960 X 640 pixels or higher.
Personal computer	Windows: Windows10 or higher Processor: 1.6 GHz ARM-based CPU architecture with 2-core processor or higher, or Bigger. Memory: 8G or higher. Supported devices: Wi-Fi 802.11 a/b/g/n Display: Resolution (in pixels) of 1024X768 pixels or higher.

Regularly charge your mobile device to ensure it is fully powered up

F、 Ultrasound Application

Download the app
Nome do software: "LELTEK Ultrasound – LeSono" "
Software version: 1.25.XX.X

1. in the Android app store. Link: https://play.google.com/store/apps/details?id=com.leltek.leltekultrasound

2. in the iOS app store. Connection: https://apps.apple.com/gb/app/leltek-ultrasound-lesono/id1474760019

3. "LELTEK Ultrasound – LeSono" from Download the Windows app directly from the official website: https://www.leltek.com/leltek/

G、 Probe Specifications

Model	Number of Items	Matrix Type	Mode
LX128LC	Linear: 128 Convex: 128	Linear, Convex + Cardiac 3 in 1	B-mode, M Mode, CF Mode, Color Flow Doppler (CF), PW Doppler, Tissue Doppler (TD: TVI/TDI)
*LX128LP	Linear: 128 Phased Array: 64	Linear, Phased Array	
LX192LC	Linear: 192 Convex: 192	Linear, Convex + Cardiac 3 in 1	

*(*Some probe type may not be supported due to reginal regulatory registration).*

Template features

The LX Series supports a transducer of up to **192 elements in linear and convex models**.
The system also supports **384** scan lines and has a proprietary octal beam line beamformer , capable of processing eight beams simultaneously.
Powered by a **5,000 mAh** battery, it can provide up to **3 hours** of continuous operation.
In turbo mode (linear model), the frame rate can reach **30** fps.

H、 Transducer Specifications:

ID (1st number)	Models	Transducer
H	LX128LC	L12-5 Linear, C5-2 Convexo
Had	LX128LP	L12-5 Linear, P4-2 Phased Array
G	LX192LC	L12-5 Linear, C5-2 Convexo

I、 System Dimension

*(*Some probe type may not be supported due to reginal regulatory registration).*

Model	Length (mm) x Width (mm) x Height (mm)	Weight (g) (with battery)
LX128LC	145x74x34	274
*LX128LP	154x74x34	268
LX192LC	145x74x34	276

J、 RF Power Specification

2.4G:	5G :
- Tx Frequency: 2412Mhz-2462Mhz - TX Modulation: DSSS/CCK/OFDM - Tx Power: ■ 16dbm @1DSSS ■ 12.5dBm @54OFDM - Rx Frequency: 2412Mhz-	- Tx Frequency: 5180Mhz-5825Mhz - TX Modulation: OFDM - Tx Power: ■ 12dbm @54OFDM ■ Rx Frequency: 5180Mhz-5825Mhz - Rx Sensitivity:

2462Mhz - Rx Sensitivity: 2.4 GHz: – 94.5 dBm a 1 DSSS	- 5 GHz: –89 dBm a 6 OFDM

K、 Battery Specification

Item	Specification
Description	Rechargeable lithium-ion battery
Ability	3000 or 5000mAh
Battery life	300 discharge cycles
Battery manufacturing	PROPELLER CO., Ltd
Battery Model	703590
Cell Type	Prismatic cell
Battery Dimensions	93 mm * 35,5 mm * 7,2 mm
Safety	UN38.3, EN IEC 62133

L、 Storage limits


Storage Restrictions

Refer to the user's equipment instructions for use for more information on the environmental specifications of the user's equipment.

The probes shall be operated, stored and transported according to the following parameters: A room free of corrosive gases.

project	operate	Inventory	transport
pressure	700 hPa (525 mmHg) to 1060 hPa (795 mmHg)	700 hPa (525 mmHg) to 1060 hPa (795 mmHg)	700 hPa (525 mmHg) e 1060 hPa (795mmHg)
humidity	Non-condensing humidity 15% to 95%	Relative turbidity from 0% to 95%	Relative temperature≤90%
temperature	0°C to 35°C	-20°C to 50°C/	-20°C to 50°C

_____

About Ultrasound Imaging System

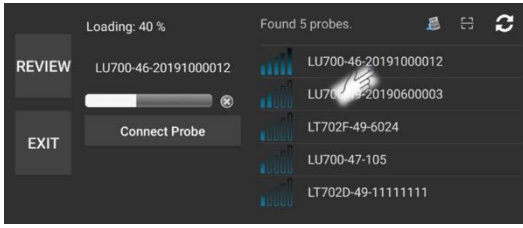
II. About Ultrasound Imaging System

A. Get Started With Ultrasound App

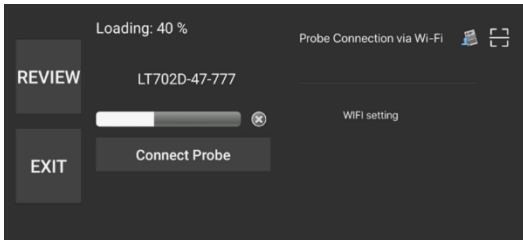
1. Ultrasound gel is a type of conductive medium that allows a close bond between the skin and the probe or transducer, causing the waves to be transmitted directly to the underlying tissues and areas to be visualized. It is formulated to reduce static and act as a coupling agent.

B. Starting new exams

Home -Android:



Home - iOS



2. Step 1: After launching the LELEEK app, select the SSID or scan the QR code of the probe to be connected.
   - a When the user enters the home page, the system automatically scans the ultrasound probe that can be connected via encrypted Wi-Fi.
   - b The system lists the names, signal strength, and quantities of the
   - c ultrasound probes automatically.
   - d Select and connect an ultrasound probe SSID manually from the Probe List.
   - e The system automatically does the decryption and authentication process.
   - f Check the progress and status of the connection. The connection successfully entered the ultrasonic scan page.

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

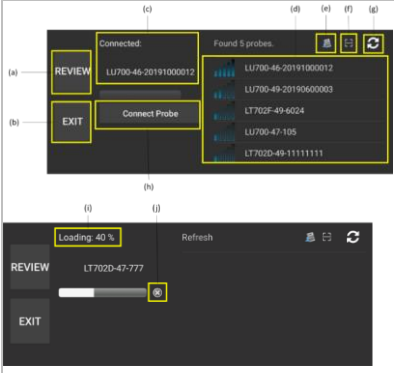
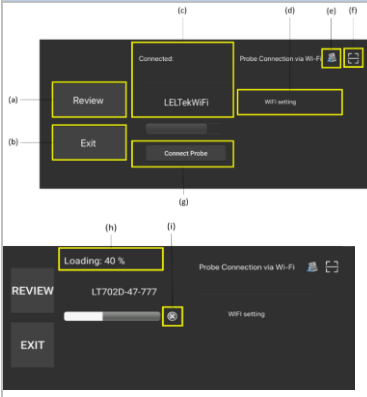
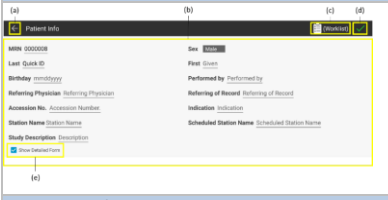
   <u>Functions on the home page</u>

   - a REVIEW: The user taps this button; the system will link to the "Saved Exam" page and will be able to review previously saved test data.
   - b EXIT: The user taps the function button to exit the app.
   - c  : The transducers that will be automatically detected to be connected via Wi-Fi. (Android or iOS only)
   - d Probes found: The transducers that will be automatically detected to be connected via Wi-Fi; The user can then select the corresponding transducer. (Android or iOS only)
   - e Wi-Fi Configuration Button: The user can manually select an ultrasound probe from the Wi-Fi settings page. (iOS only)
   - f  : QR code reader. Scan the QR code on the probe to connect it via Wi-Fi.
   - g Connect the probe: The user can tap the "Connect Probe" button to enter the main scanning page without reconnecting the probe via Wi-Fi.
   - h  : Suspend the charging progress and cancel the

connection.

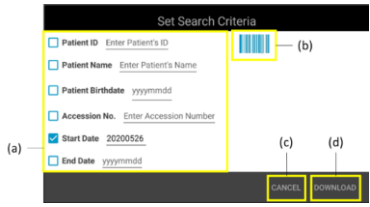
i  : Enter the Edit Patient Information page with the Worklist button 

. The user can download the server's worklist or the most recent records. If the user wants to download the data, they must first define the worklist server. If there is an existing server, the user can edit, delete, or connect it.

App Interface Design	
Home - Android	
	a. View Button b. Exit Button c. Current Ultrasound Probe d. List of ultrasonic probes e. Patient information button f. QR code scan button g. Investigation list reorder button h. Probe connection button i. Connection percentage j. Disconnect button
Home - iOS	
	a. View Button b. Exit Button c. Current Ultrasound Probe d. Wi-Fi settings button e. Patient information button f. QR code scan button g. Probe connection button h. Connection Progress Percentage i. Disconnect button
Home, Patient Information	
	a. Back Button b. Edit patient information c. Download Worklist button (displayed only when the user enters this page from the home page) d. Save button e. Show detailed table checkbox
Home, Patient Information: DICOM Worklist	

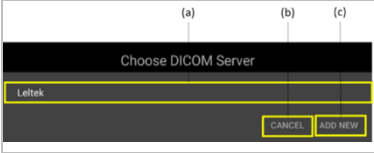
a. Back Button
b. Initialize Server Button
c. Edit server settings
d. Set search criteria button
e. Patient information downloaded from the server

Home, Patient Information: DICOM Worklist



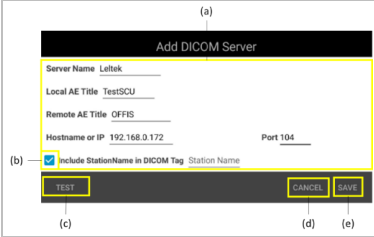
a. Select and enter search criteria
b. Barcode Scan Button
c. Cancel button
d. Download Button

Home, Patient Information: DICOM Worklist, DICOM Server Settings



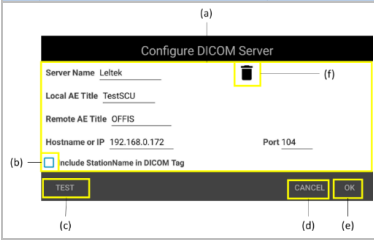
a. List of existing servers
b. Cancel button
c. Add Server Button

Home, Patient Information: DICOM Worklist, DICOM Server Settings



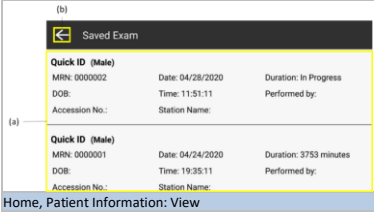
a. Edit server information
b. Shows a check box for the station name field
c. Test Server Response Button
d. Cancel button
e. Save Server Settings button

Home, Patient Information: DICOM Worklist, DICOM Server Settings



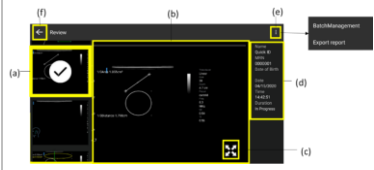
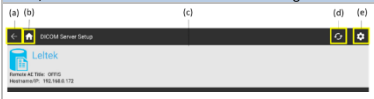
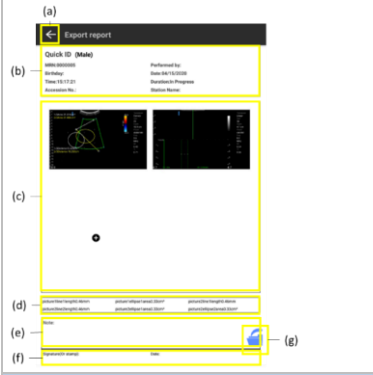
a. Edit server information
b. Shows a check box for the station name field
c. Test Server Response Button
d. Cancel button
e. Save Server Settings button
f. Delete Server Button

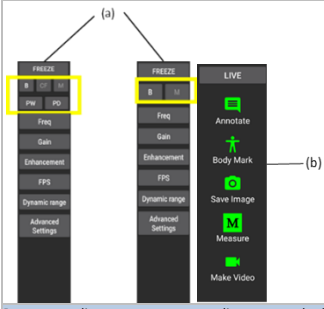
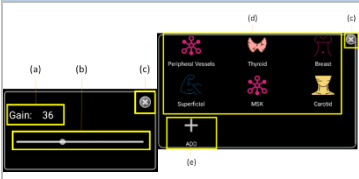
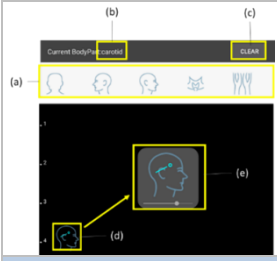
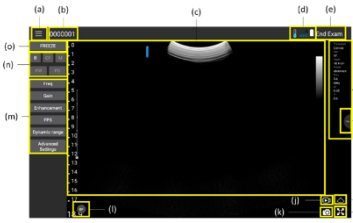
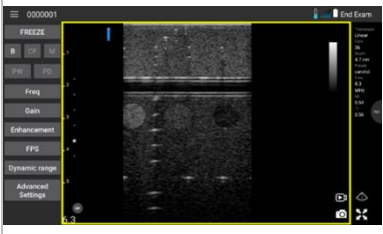
Home, Patient Information: Stored Test



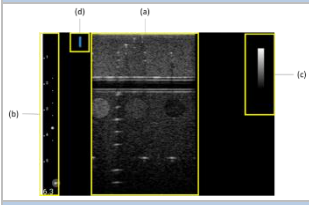
a. Patient Information Record
b. Back Button

Home, Patient Information: View

	a. Saved images and videos b. View selected saved image or video c. full screen d. Current settings e. Batch management of images and videos, export of images and videos/export of reports f. Back Button
Home, Patient Information: Batch Management	
	a. Back Button b. Saved images (DICOM: optional), saved images and videos c. Export button (including DICOM: optional) d. Toolbar
Home, Patient Information: DICOM Server Settings	
	a. Back Button b. Back button to homepage c. Initialize Server Button d. Edit server settings
Home Page, Patient Information: Export Report	
	a. Back Button b. Patient Information c. Selected image d. Measurement Information e. annotation f. Signature and date g. Export button
Home, Patient Information: Export Report (Selected Image)	
	a. Back Button b. Saved image c. Toolbar

Annotate & Measure, Save, Resume, and Playback: Pause/Scan	
	a. Scanning: Combination of mode buttons in the scan state (optional) b. pause
Parameter adjustment: parameter adjustment and selection of human body parts to be scanned	
	a. Parameter names and values b. Adjust the progress bar c. Cancel button d. Parts of the human body e. Add custom preset
Annotations and Measurements: Human Markings	
	a. Labeled images of human body parts b. Parts of the human body c. Buttons to close windows (d) and (e) d. Brand image of human body containing position mark e. Adjust Position Mark
Parameter adjustment, image display and gestures: scanning	
	a. Menu Button b. Patient Information c. image d. Ultrasound Probe Status e. Final detection button f. Current settings g. TGC Button h. Middle row i. Full-screen button j. Video Button k. Save Image Button l. Select Human Body Part button m. Parameters n. Mode button o. Pause button
Parameter adjustment, image display, and gestures: mode	
	

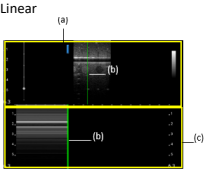
B-mode



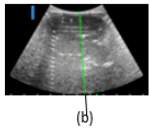
a. image
b. Depth gauge
c. Shades of gray
d. Mirror Mark

M Mode

Linear



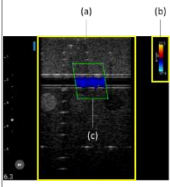
Convex



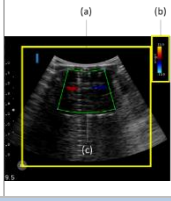
a. B-mode images
b. M Line
c. Basic Time Degree

CF/TVI mode (optional)When TD mode is turned on (ON), it is the TVI mode in the cardiac app.

Linear



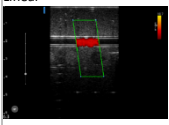
Convex



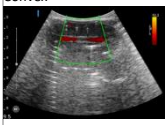
a. image
b. Color Code
c. Area of Local Interest (ROI)

D-mode (Power Doppler) (optional)

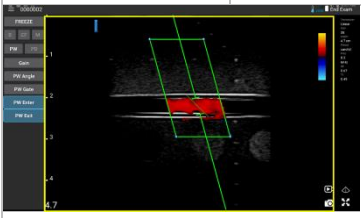
Linear

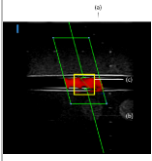
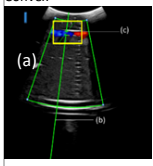
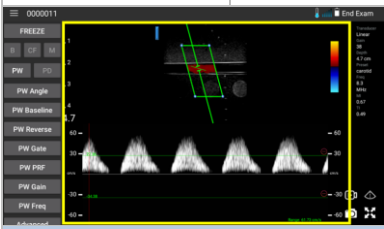
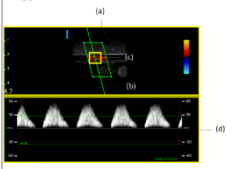
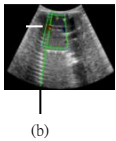


Convex

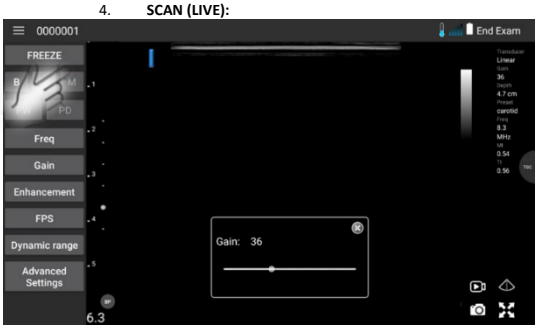


a. Except for a certain color used to represent the intensity of blood flow, everything else is the same as the CF mode.



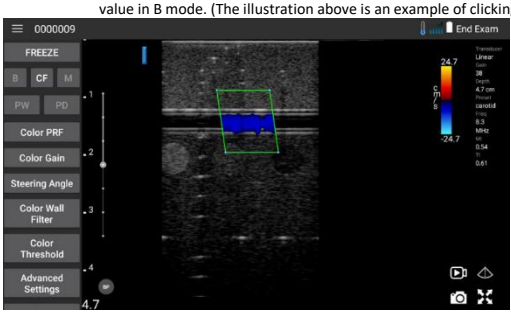
Preset PW gate location (optional) Default TDI gate location (optional when TD is enabled)		
Linear 	Convex 	a. Image in CF/TVI mode paused b. LOI (line of interest) c. Spacing, beam/flux angle differences
		
PW (pulsed ultrassom) mode (optional) TDI (Pulsed Ultrasound) mode (optional when TD is on)		
Linear 	Convex 	a. Image in CF/TVI mode paused b. LOI (line of interest) c. Spacing, beam/flux angle differences d. Time grid, baseline, blood flow value, and interval between two blood flow values

4. **SCAN (LIVE):**



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

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



D. Step 5: Switch to CF mode (optional) or TVI mode (optional when TD is

enabled)

1. Functions in **SCAN (LIVE) mode selection:**
   - a Touch B, the system would be selected for mode B, which means a two-dimensional ultrasound image display composed of bright dots representing the ultrasound echoes.
   - b Touch CF (optional), the system would be selected for CF mode, the speed and direction of blood flows are represented on a color map overlaid on the 2D image. The color flow is shown in ROI. Its size and location are adjustable.

     (TD on) Tap TD to activate TVI (optional). The system will be selected for TVI mode. The velocity and direction of the heart tissue are represented on a color map superimposed on the 2D image. The movement of the tissue is displayed in the ROI. Its size and location are adjustable.
   - c Touch M, the system would be selected for M mode, a diagnostic ultrasound presentation of the temporal changes in the echoes in which the depth of the echo-producing interfaces is displayed along one axis and the time is displayed along the second axis, recording the movement of the interfaces to and away from the transducer.
   - d Tap PW to enter PW mode sample port placement (optional). Select the port position and adjust the port size, port angle, and image gain base in CF mode.

     (TD On) Touch TDI to enter the TDI mode of sample port placement (optional when TD is turned on as 'ON'). Select the door position and adjust the size, angle, and gain of the image based on the TVI mode.
   - e Tap PW Enter (optional), the system would be selected for Doppler PW (pulsed wave) mode, if moving objects changed the characteristic of the sound waves. By sending short, rapid pulses of sound, it becomes possible to accurately measure blood velocity in a precise location and in real time.

     (TD on) Tap Enter for TDI (optional when TD is enabled) and the system will be selected for Tissue Doppler Imaging (TDI) mode. Moving objects alter the characteristics of sound waves. By sending short, fast sound pulses, it is possible to accurately measure the velocity of heart tissue in a precise location and in real time.
   - f 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 located within organs.
2. Turning parameters:
   - a Depth: Depth of penetration is related to the frequency of the ultrasound wave. Higher frequencies have a shorter depth of penetration. Lower frequencies have a greater depth of penetration.
   - b THI: (Tissue harmonic image). It is a signal processing technique also called native harmonic imaging. It provides special focusing methods to collect ultrasonic waves to achieve the focus that meets the requirements.
   - c Freq: The carrier frequency of the ultrasound wave transmitted and received by the transducer.
   - d Gain: Digital gain is used to adjust the brightness of the image.
   - e Persistence: It is a type of temporal smoothing used in ultrasound imaging. Successive frames are calculated as they are displayed to reduce variations in the image between frames, thereby decreasing the temporal resolution of the image. This function can be used to adjust different levels of image processing to reduce image noise and make it more delicate. 0 means that this function is disabled.
   - f Enhancement: Image Enhancement Processing
   - g FPS: Frames per second. Provides three modes, including power saving, normal, and high performance, representing different image smoothness.
   - h TGC: (Time Gain Compensation). Ability to compensate for the attenuation of the transmission beam as the sound wave travels through the body tissue. The goal of the TGC is to make the entire image appear evenly lit from top to bottom.
   - i Advanced settings: When the user taps this button, other

buttons are listed and depend on the mode the user has selected.

j Dynamic Range: When the user taps this button, it allows the user to tell the transducer how they want the echo intensity to be displayed in grayscale. A wider range will display more shades of gray and a smoother overall image. A narrow range will display fewer shades of gray and appear as a higher contrast with a more black-and-white image.

k Gray Map: When the user taps this button, they are adjusting the gray maps in the ultrasonic image which has a similar effect on an ultrasound image as changing the dynamic range, but they are different. While Dynamic Range adjusts the total number of shades of gray, a gray map determines how dark or light you prefer to show each level of white/gray/black based on the strength of the ultrasound signal.

l Freeze Timer: When the user touches this button, the system can be selected how many seconds in static situation.

m Mirror: Flip the image horizontally.

n 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.

o Color PRF: When the user taps this button, the time is between the start of one pulse and the start of the next pulse. It is measured in units of time. This parameter includes the time when 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.

p Color gain: Number of Doppler pulses per line of color Doppler information.

q Steering angle: The scanning angle of the ultrasound.

r Color Wall Filter: Filter low- or high-frequency Doppler signals.

s Color Limit: Remove parts of the image that fall within a specified color range.

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

u PW (TDI) Enter: When the user touches this button, it will enter PW (TDI) mode. Maintain the position of the LOI and parameter values. (PW Port, Gain, PW Angle)

v PW Output (TDI): When the user touches this button, it switches back to CF (TVI) mode.

w PW Angle: It is used in the CF mode image to align the angle correction cursor along the vessel wall for speed measurement.

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

y PW Reverse: Flip the PW mode image vertically according to the baseline position of the value "0".

z PW Port: Adjust the port size to try the flow measurements, the whole vessel should be insonated. A large gate may include signs of adjacent vessels.

aa PW PRF: When the user taps this button, the time is between the start of one pulse and the start of the next pulse. It is measured in units of time. This parameter includes the time when 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.

bb PW Gain: Remove or reinforce parts of the pulse wave image that fall within a specified brightness range.

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

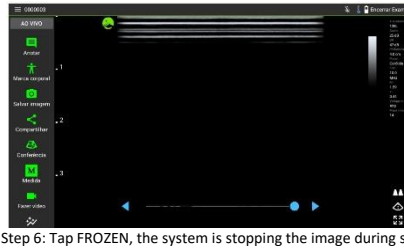
dd : Select the scanned part of the human body. The user can directly touch the scanned part of the human body in the BP to get the current scanned part of the human body. Users can also add custom presets.

3. Multimedia:

a  A: To make the ultrasonic images which are in the area of ultrasound imaging as video.

b  : To save an ultrasonic image that is in the ultrasonic image area.

FREEZE:



E. Step 6: Tap FROZEN, the system is stopping the image during scanning; or by reactivating the interrupted image. When the image is frozen, the last 200 frames can be shown. The annotation can be added. The freeze image can be saved for later review. The measuring function also allows you to measure the length and area.

1. Functions in FREEZE

a Annotate: Tap Annotate, the user can fill in one or more text notes and move anywhere in the ultrasonic image and can also be removed by long-pressing.

b Body Mark For the user to mark which parts of the human body by scanning.

c Save Image: To save an ultrasonic image that is in the ultrasonic image area. Save the image that can be exported in DICOM format (optional).

d Measure: Tap Measure, the user can select the Ellipse, Distance, Arrow, Mark and Clear All element. Tap Ellipse, is used to measure the area and perimeter of an ellipse. Tap Distance, the user can draw a length range anywhere on the ultrasound screen as the distance emphasized on the screen. Tap Arrow, which is used to clearly mark the position and orientation next to the annotation. Tap Mark, clearly mark the position. All of them can be removed by long-pressing. Tap Clear All, the user can clear all ellipses, distances, arrows, and marks on the ultrasound screen.

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

f Conferência: To hold the call conference it is necessary to start a meeting in the Zoom app with ID and password, this data needs to be linked within the LELTEK app settings. It is also possible to hold the conference via Whatsapp, through screen sharing in the video call.

Note: This function needs to be enabled in the settings menu.

g Step 7: Tap End Exam, the diagnosis is terminated and the system will return to the home page automatically.

2. General Functions

a Menu:

b : To tap on the user can select the item Review, Edit patient information, Current exam and About.

c Review: After entering Review in the current diagnostic, the user can choose to view an ultrasonic image or video in Cine Graphic to review. By tapping , the user can choose "Batch Management" or "Export Report". Tap Batch Management, the user can select, delete, export multiple stored images (available format: .jpg, .png, .bmp and.dcm.. dcm file is optional) or videos (available format: .mp4) to local storage, and upload DICOM files (optional) to the server. Tap Export Report, the user can export the diagnosis to pdf with the patient's information, selected images, measurement information, annotation, signature, and date.

d Edit Patient Information: This is used to enter or modify patient information stored in the local database. The default name of the current patient is "Quick ID". Images and videos are saved in each patient study record. The default values for the items on the current patient information edit screen are the values stored in the local database. Press the "Save" button that is on

the screen in the upper right corner to update new data to the local database.

e Current examination: Select the scanned part of the human body. The user can directly touch the scanned part of the human body in the Current Exam to get the current scanned part of the human body. Users can also add custom presets.

f About: The user can review the company name, app version, website, credit, OpenCV license agreement, copyright announcement... and so on.

g Other:

h  : An ultrasonic image can be added with a center dotted line, in Freeze or Live mode.

i  : The ultrasound image part can be enlarged for full-screen viewing. Whether it is Freeze or Live status or viewing historical records, this function can be used if the ultrasound image is displayed.

j Finalize Scan: When the user presses Finalize Scan, a diagnostic is terminated and the time spent on that diagnostic is calculated and the value is displayed under Saved Scan. Then, updating the list of previous diagnostics causes the status of that diagnostic to no longer be in progress. Create a new exam automatically after returning to the home page.

3. * Additional Features

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

b The combination of mode buttons in the scan state (optional):

c Case 1: B-mode and M-mode without Live status

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

C. Ultrasound gels

4. 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 be transmitted directly to the underlying tissues and areas to be visualized. It is formulated to reduce static and act as a coupling agent.
5. Ultrasonic gel is usually composed of propylene glycol, water, and occasionally a dye. The dye is mainly for aesthetic purposes. The gel is usually clear and thick and slightly sticky. This means that the gel does not drip or run off after application to the skin. After the procedure, the gel can be cleaned easily.
6. DO NOT use gels (lubricants) that are not recommended. Doing so may damage the probe and void the warranty.
7. Ultrasound gels should NOT contain any of the following ingredients, which may damage the probe.
   a Olive oil
   b Methyl or ethyl parabens (parahydroxybenzoic acid)
   c Dimetyl silicone
   d Iodine
   e Lotions
   f Lanolina
   g Aloe vera
   h Mineral oils
   i Methanol, ethanol, isopropanol alcohol, or any other alcohol-based gel
8. During the ultrasound imaging procedure, the examiner must wear "patient examination gloves." Patient examination gloves are disposable devices intended for medical purposes and are worn on the examiner's hand or fingers to prevent contamination between the patient and the examiner.

I. SAFETY

All contraindications and warnings are well concerned in following the regulation of EN ISO 14971:2019 with the related report. Read this information before operating your ultrasound system. Applies to the device, transducers, and software. This section covers general safety information that applies only to a specific task and is included in the procedure for that task.

A. Contraindications and warnings

1. Battery Safety:
   - a DO NOT ignore the specified instructions for use of lithium-ion batteries in medical diagnostic equipment. Failure to comply with specifications can result in accidents and the manufacturer is not responsible.
   - b DO NOT leave a battery unused for long periods of time, as it may leak and damage the electronics. If the equipment remains unused for more than one week, charge the battery using an IEC 60601-1 compliant power supply for a two-MOPP insulation system. Regularly check or replace the charging power supply.
   - c DO NOT charge the battery near sources of fire or heat.
   - d DO NOT use the equipment if the battery leaks or emits an odor. Turn off the equipment and contact your local representative.
   - e If the battery is not used for more than one month, store it between -20°C (-4°F) and 20°C (68°F).
   - f DO NOT attempt to disassemble the device yourself. The lithium battery may explode due to a short circuit. If abnormal behavior is noticed, turn off the equipment and contact your local representative.
   - g DO NOT charge the battery near sources of fire or heat.

2. Mechanical safety:
   - a DO NOT use on a patient who would be harmed by the application of ultrasound.
   - b DO NOT drop the probe or subject it to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the case may occur.
   - c DO NOT use the probe with high-frequency surgical equipment. Doing so may damage the equipment.
   - d DO NOT use the product near strong electromagnetic fields, electromagnetic waves, and magnetic environments. There is a possibility of measurement errors or damage to the product.
   - e DO NOT operate this system in the presence of flammable gases. Explosion may occur. The system is not supported in AP/APG environments as defined by IEC 60601-1.
   - f To avoid the risk of electric shock, always inspect the transducer before use. Check the face, housing, and cable before use. DO NOT use if face is cracked, chipped, or torn; the carcass is damaged; or the cable is frayed.

   - g DO NOT take the probe into an MRI environment. Unsafe MRI items should not enter the MRI room and patients with unsafe MRI devices should not be examined
   - h NO The operating temperature of the ultrasound probe should remain below 43°C.
   - i DO NOT allow the transducer to contact the patient if the transducer temperature is higher than 43°C (109°F).
   - j DO NOT leave children unattended with the system. Transducers pose a choking hazard due to small, detachable parts and the transducer cable is a strangulation hazard.

3. Waring Image Quality:

   - a When administering to patients undergoing surgery that may have altered the composition of the tissue being examined, as this may distort or alter the measured density.
   - b In patients whose bodies contain foreign artifacts (e.g., implants) in the examining tissue, image distortion may occur.
   - c When using for intraoperative purposes (e.g., defined as introducing a system into a surgical incision or burr hole), ensure the equipment is protected by the sterile bag and gel.
   - d Use for ophthalmic purposes must be carried out by a specialized Ophthalmologist.
   - e DO NOT attempt to perform imaging on an open wound

without being protected with a sterile bag and gel.

4. Software Security
   a DO NOT allow potential damage to the product that could void your warranty or service contract, or result in the loss of patient or system data.
   b DO NOT use the system if any parts are known or suspected to be defective or incorrectly installed. Discontinue use until repairs are made. Operating the system with defective or incorrectly adjusted components may expose you and/or the patient to safety hazards.
   c DO NOT attempt to remove, modify, replace, or disable any security device on the system under any circumstances. Interfering with safety devices can cause serious injury or death.
   d DO NOT misuse the system; use it only for its intended purpose. DO NOT use the system with any product not designated by the manufacturer as compatible with the system. Operating the product for unintended purposes or with incompatible products may result in serious injury or death.
   e DO NOT continue using the system if the system or transducer appears to be defective. Immediately discontinue use and contact your local representative.
   f DO NOT configure the device without adhering to your institution's security policies. Notifications and alerts from third-party apps can interfere with exams.
   g DO NOT use the system for any application until you are properly trained in its safe and effective operation. If you are unsure of your ability to operate the system safely and effectively, avoid using it. Operating the system without proper training can cause fatal or serious injury.
   h DO NOT use the system with patients unless you have a proper understanding of its capabilities and functions. Using the system without this understanding can compromise its effectiveness and compromise the safety of the patient, you, and others.
   i DO NOT ignore revealed or undisclosed vulnerabilities, as they may cause the system to function abnormally. DO NOT allow data breaches, as they may result in OTS data sabotage.

5. Cybersecurity:
   a DO NOT neglect to protect your credentials and patient information (e.g., names).
   b DO NOT assume that the scanner stores patient identification data.
   c DO NOT transfer data between the device and the ultrasound app unless it is encrypted.
   d DO NOT forget that the image data, while not encrypted, does not contain identifiable information. To encrypt:
   e DO NOT use an untrusted Wi-Fi network.
   f DO NOT neglect to use Wi-Fi Direct, which encrypts image data.
   g DO NOT use unsecured networks; ensure WPA protection and provide adequate training for users.
   h DO NOT ignore the risks associated with network changes, new connections, or equipment upgrades. Managing these risks is your organization's responsibility.
   i DO NOT use untrusted networks that may expose data.
   j DO NOT use weak passwords or outdated wireless equipment.
   k DO NOT leave devices unlocked.
   l DO NOT compromise data integrity.
   m DO NOT avoid unauthenticated encryption, integrity checks, or TCP channels.
   n DO NOT allow more than one device to connect to the ultrasound system simultaneously.

6. Waterproof warning
   a DO NOT immerse the probe in any liquid beyond the immersion level. Never immerse the probe connector in any liquid

7. Electrical compatibility
   a DO NOT use your system in combination with other products or components unless expressly acknowledged by the manufacturer as compatible.
   b DO NOT hesitate to contact your local representative for

information on these products and components.

c DO NOT make changes or additions to the system unless they are made by the manufacturer or by a third party expressly authorized by the manufacturer. DO NOT allow such changes and additions unless they comply with best engineering practices and all applicable laws and regulations in the jurisdictions concerned.

d DO NOT operate the system near pacemakers, as ultrasound equipment, like other medical electronic diagnostic equipment, uses high-frequency electrical signals that can interfere with the operation of the pacemaker. Although the possibility of interference is small, DO NOT ignore this potential hazard and stop system operation immediately if you notice interference with a pacemaker.

e DO NOT use additional peripheral equipment interconnected by functional connection without considering it as part of a medical electrical system. DO NOT fail to comply with IEC 60601-1 and test the system according to these requirements. If you have questions, DO NOT hesitate to contact your local representative.

f DO NOT use patient-applied parts that do NOT meet the IEC 60601-1 standard. DO NOT exceed applied voltage standards as this may result in electric shock to the patient or operator, although this is unlikely.

8. Acoustic Safety

a DO NOT exceed the acoustic output limit:

1. ISPTA.3 = 720 mW/cm^2 (50 for ophthalmology) for Band 3; Ophthalmic Track 3,
2. TI ≤ 6.0 (Maximum TIS as ICT ≤1)
3. MI ≤ 1.9 (0.23 for ophthalmic) for band 3;

9. FCC RF Radiation Exposure Statement

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

10. Information Security

a DO NOT operate this system without having read, understood, and familiarized yourself with all of the emergency safety information, procedures, and protocols contained in the "Safety" section. Operating the system without proper knowledge of safety protocols can result in fatal or serious injury.

11. Biological Safety

a DO NOT use probes in secondary areas (including, but not limited to, surgery, rectum, or vaginal procedures) without confirming that the probe is approved by the appropriate authorities and covered with an aseptic probe sheath. The FDA's recommendations to healthcare professionals regarding latex awareness are as follows:

b Be sure to ask about latex sensitivity when taking patient history, especially for surgical, radiological, or spina bifida patients and healthcare professionals. DON'T forget to include questions about symptoms such as itching, rash, or wheezing after exposure to latex products, such as gloves or balloons, and mark charts for patients with a positive history.

c DO NOT use latex-containing devices if latex sensitivity is suspected. Instead, consider alternatives like plastic. For example, DO NOT expose sensitive patients to direct contact with latex; Wear latex-free gloves over latex ones. If the healthcare provider and patient are sensitive, DO NOT rely solely on hypoallergenic latex gloves as they may not prevent reactions.

d DO NOT ignore the potential for allergic reactions when using latex-containing medical devices, especially when the latex comes into contact with mucous membranes.

e DO NOT rule out signs of an allergic reaction if latex is suspected as a cause. Advise the patient of possible latex sensitivity and consider an immunologic evaluation.

f Be sure to advise patients with latex sensitivity to inform healthcare professionals and emergency personnel prior to

medical procedures. DO NOT neglect the recommendation that patients with severe sensitivity wear a medical ID bracelet.

12. Storage limits
    a DO NOT neglect to ensure that the room is ventilated and free of corrosive gases.
    b DO NOT operate, store, or transport probes outside of the parameters

Item	Operational	Storage/Transportation
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% relative humidity
Temperature	0°C to 35°C	-20 °C to 50 °C /-20 °C to 50 °C

13. Maintenance and troubleshooting
    a DO NOT use this product if it is not working properly. Contact your local dealer or contact the manufacturer via email at info@leltek.com.

    b Follow the troubleshooting guide:

Question	Solution
No abnormal images or displays once connected	When the probe is connected normally, but no ultrasonic image on the screen or abnormal lines in the image, check for electromagnetic interference (e.g.: other Wi-Fi signals) around and restart the scan. After the above operation, if the situation persists, please contact the Customer Service Center.
Failed to connect to mobile device	- The probe uses Wi-Fi for data transmission and automatically detects and selects the best Wi-Fi channel when it's on. - When the image is found stationary, it may conflict with other Wi-Fi devices in the environment, or the mobile device itself runs too many apps. Try restarting the probe and plugging it in. - Overcharging apps or low battery can also cause the image to get stuck, check the battery level or close other apps on mobile devices to improve the situation

14. Disinfectants and cleaning method
    a DO NOT use your compatible smart device unless it has been properly cleaned and disinfected in accordance with the device manufacturer's instructions and your institution's medical device cleaning and disinfection policies.
    b DO NOT ignore the internal contamination of the compatible smart device with pathogen-containing body fluids. You must immediately notify the manufacturer's service representative. The components inside the device cannot be disinfected. In such cases, DO NOT attempt to disinfect the device and dispose of it as biohazardous material in accordance with local or federal laws.
    c DO NOT fail to wear protective goggles and gloves when cleaning, disinfecting, or sterilizing any equipment.
    d DO NOT use protective covers that are not qualified for transrectal and intravaginal procedures. In some regions, these coverages are mandatory. Always be sure to wear qualified protective covers recommended by the manufacturer.
15. Rework
    a DO NOT attempt to open a transducer or transducer connector.
    b DO NOT modify this device without authorization.
16. Product Disposal
    a DO NOT mix electrical and electronic equipment with general waste. Separate collection is required in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive.
    b DO NOT dispose of devices containing lead or mercury in regular waste. Components containing these materials must be recycled or disposed of in accordance with local, state, and federal laws. The backlight lamps in LCD system monitors contain mercury.
    c DO NOT dispose of electrical and electronic equipment unless it meets the Restriction of Hazardous Substances Directive (RoHS) 2011/65/EU.

d DO NOT dispose of items marked as recyclable material in the regular trash. These items or their materials must be processed through recovery or recycling.

B. Benefits and risks

1. Ultrasound is widely used because it offers many clinical benefits to the patient and has an excellent safety record. In more than three decades of use, there have been no long-term negative side effects associated with this technology.
2. More safety issues are being discussed because more applications are being discovered and the industry is producing technically sophisticated scanners that provide more diagnostic information. Dialogue between the medical community, manufacturers, and the FDA has resulted in a standard that allows for higher results for greater diagnostic capability.
3. Benefits of ultrasound:
    - a Multiple Diagnostic Uses
    - b Immediate results with high-quality information
    - c Replacement or courtesy or used with other procedures
    - d Custo-benefit
    - e Portability
    - f Patient acceptance
    - g Safety Record

4. Risks of ultrasound:
    - a The potential for adverse bioeffects caused by heating or cavitation. … The benefits to patients of prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

A. Acoustic output and measurement

1. The system limits the patient's contact temperature to 43°C (109°F) and the acoustic output values to the respective U.S. Food and Drug Administration limits. A power protection circuit protects against overcurrent conditions. If the power monitor protection circuit detects an overcurrent condition, the transducer drive voltage will be shut off immediately, preventing overheating of the transducer surface and limiting acoustic output. The validation of the power protection circuit is done in normal system operation.
2. Since the initial use of diagnostic ultrasound, the possible human bioeffects of 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 Committee on Bioeffects ("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 the 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 was measured and calculated in accordance with the "Standard for Measurement of Acoustic Output for Diagnostic Ultrasound Equipment" (Revision 3, AIUM, NEMA, 2004), the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices in Diagnostic Ultrasound Equipment" (Revision 2, AIUM, NEMA, 2004) and the September 2008 FDA document "Information for Manufacturers Seeking Marketing Authorization for Diagnostic Ultrasound Systems and Transducers."

3. MI & IT & Ultrasound Bioeffects
   a The biological effects of ultrasound are the potential biological consequences due to the interaction between the ultrasound wave and the scanned tissues. Concern about ultrasound safety has led several agencies to set regulatory limits for machine output intensities. The visual display of thermal and mechanical indices during ultrasound imaging provides an aid to limit machine output. Ultrasound evaluation of the human body, including potentially sensitive tissues such as the developing fetus and eye, has been performed in millions of patients with no documentation of serious adverse events. However, ultrasonic waves have the potential to cause significant biological effects, depending on the characteristics of the ultrasonic waves and the sensitivity of the scanned tissues. Physicians and sonographers should be aware of these potential biological effects when evaluating the overall safety of the procedure. The biological effects of ultrasound depend on the total energy applied to a given region. Thus, the variation of the exposure time to the wave emission, intensity and frequency of the ultrasound beam, pulsed or continuous emission modality, and acoustic power, can lead to significant biological effects, which are commonly divided into thermal and mechanical (non-thermal) effects.
   b Acoustic Output Limit:
      1. ISPTA.3 = 720 mW/cm^2 (50 for ophthalmology) for Band 3; Ophthalmic Track 3,
      2. TI ≤ 6.0 (Maximum TIS as ICT ≤1)
      3. MI ≤ 1.9 (0.23 for ophthalmic) for band 3;

4. Mechanical Index (MI) (Non-Thermal)
   a Ultrasound energy also creates mechanical forces independent of thermal effects, causing biological effects that are not only related to temperature increase, such as cavitation, torque forces, oscillatory shear, radiation, pressure, and microflow.
   b Scientific evidence suggests that mechanical bioeffects are threshold phenomena that occur when a certain level of production is exceeded. The threshold level varies depending on the tissue. The potential for mechanical bioeffects varies with the peak pressure between rare factions and the frequency of ultrasound. The higher the reading of the MI value, the greater the potential. There is no specific MI value, which means that a mechanical effect is occurring. The impact assessment should be used as a guide for the application of the ALARA principle.
   c Accuracy and precision of mechanical index display
      1. It is estimated that 90% of the IM values will be within +/– 15% of the displayed value, or +/– 0.14 of the

displayed MI value, whichever is greater. It approaches +/–1.2 dB. The IM is displayed with an accuracy of 0.01.

5. Thermal Index (TI)
   a The biological effects of ultrasound energy are mainly related to heat production. Heat is generated whenever ultrasound energy is absorbed, and the amount of heat produced depends on the intensity of the ultrasound, the exposure time, and the specific absorption characteristics of the tissue. Up to 70% of the total temperature increase associated with ultrasound occurs within the first minute of exposure [2], but the temperature continues to increase as the exposure time is extended. Minimizing exposure time is probably the most important factor in ensuring patient safety from thermal injury [3]. Other important parameters to consider are:
      1. The relative protein content of each tissue, since the absorption coefficients of the tissues are directly related to the protein content; absorption coefficients vary between 1 (skin, tendon, spinal cord) and 10 (bone) dB/cm MHz
      2. Tissue perfusion, which has a dampening effect on heat generation and physically allows heat to be carried away from the energy transfer point.
      3. Emission modality, since pulsed-wave ultrasound is extremely unlikely to significantly heat tissues.
      4. Beam width, since a larger beam width reduces the rate and extent of temperature rise, allowing energy to be distributed over a larger perfusion territory.
   b It informs the user of existing conditions that can lead to an increase in temperature at the surface of the body, within the body tissue, or at the focus point of the ultrasound beam on the bone. That is, it informs the user about the potential for temperature increase in body tissue. It is an estimate of the increase in temperature 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. IT should be used as a guide for the implementation of the ALARA principle. The thermal bone index (TIB) informs the user of potential heating at or near the focus after the ultrasound beam has passed through the soft tissue or fluid; for example, in or near the fetal bone of the second or third trimester. The cranial bone thermal index (TIC) informs the user of the potential heating of the bone at or near the surface; for example, cranial bone. The soft tissue thermal index (TIS) informs the user of the heating potential within homogeneous soft tissues. You can choose to view TIS, TIC, or TIB.
   c The application software has real-time display of the thermal (TI) and mechanical (MI) index, according to IEC62359. These two indices are intended to estimate the potential for ultrasound-induced thermal and mechanical bioeffects. Both TI and MI are displayed in increments of 0.01, and the indexes displayed are nominal values.
   d Output display indexes are calculated with the accuracy described below. The stated display accuracy values are determined against the MI and TI models, equations, and measurement methods specified in the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices in Diagnostic Ultrasound Equipment, Revision 2" (NEMA UD3). TI and MI are relative indicators for the probability of tissue thermal increase and mechanical bioeffects, respectively. The statements of accuracy listed here are not linked to deviation from the displayed indices of the actual increase in temperature or pressure levels in the body. TI and MI values are determined from measurements in water and reduced for tissue attenuation using an assumed homogeneous tissue model with 0.3 dB/cm/MHz attenuation and the sound propagation properties of water. Most tissues attenuate ultrasound at a higher rate. Fluids such as amniotic fluid attenuate less. In addition, ultrasound propagation is non-linear in most cases, to varying degrees in water and in various tissues, with varying resultant effects on actual MI or TI values. The IM is a relative indicator for the probability of a mechanical bioeffect, such as cavitation, and its model assumes the presence of nucleation sites required for cavitation. The TI models assume a blood perfusion length of 1 cm. Tissue perfusion lengths and rates depend on vasculature and blood

flow and the thermal properties of the surrounding tissue, which vary greatly. The TI bone shunt assumes that all ultrasound energy is absorbed by the impacted bone.

e Accuracy and precision of the thermal index display
1. It is estimated that 90% of the IT values will be +/– 40% of the displayed IT value or +/– 0.4 of the displayed value, whichever is greater. Approaches +/–3 dB. The TI is displayed with an accuracy of 0.01.

f There are three ITs that are used for different combinations of soft tissue and bone in the area to be examined. IT aims to keep us aware of the conditions that cause increased temperature, no matter on the surface, within the tissue, or at the point where the ultrasound is focusing on the bone.

Thermal Index (TI)	Scan Mode	Unverified Mode
Soft tissue	TIS on the surface	TIS Small opening Large opening
Bone in focus	TIS on the surface	TIB
Bone on the surface (Cranial bone)	TIC	TIC

6. Cavitation
a The interaction of ultrasound with gas bubbles or contrast agents causes rapid and potentially large changes in bubble size. This process, called cavitation, can increase the temperature and pressure inside the bubble and thus cause mechanical stress on the surrounding tissues, precipitate the formation of fluid microbes, and generate free radicals [5]. Gas-containing structures (e.g., lungs, intestines) are more susceptible to the effects of acoustic cavitation. The wavelength of ultrasound has an important role in the formation and growth of bubbles: short-wavelength ultrasound (observed at higher frequencies) does not provide enough time for significant bubble growth; therefore, cavitation is less likely under these circumstances compared to 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 intensity of the threshold for cavitation. However, due to the relatively high viscosity of blood and soft tissues, significant cavitation is unlikely, and cavitation has not been shown to occur with exposure to commonly used ultrasound during a diagnostic examination. Note: *Cavitation depends on:*
1. Frequency
2. Pressure
3. Focused/Blurred Beams
4. Pulsed/continuous ultrasound
5. Degree of standing waves
6. Nature and condition of materials
7. Limits

7. Other effects
a A variety of other physical forces can 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 have a significant biological effect on patients.
b Ensure that the scanning time is kept to a minimum and that only clinically necessary verification is performed. Never compromise on quality by rushing an exam. A bad exam may require a follow-up, which ends up increasing the exposure time. Diagnostic ultrasound is an important tool in medicine, and like any tool, it must be used efficiently and effectively.
c B-mode depth: An increase in 2D depth will automatically decrease the 2D frame rate. This will decrease IT. The system can also automatically choose a deeper 2D focal depth. A change in focal depth can change the IM. The displayed IM is the zone with the highest IM value.
d Application: Acoustic output defaults are set when you select an application. Factory defaults vary by transducer, application, and mode. The patterns were chosen below the intended use.
e Picture Mode Controls: When a new picture mode is selected, TI and MI can switch to the default settings. Each mode has a

corresponding pulse repetition frequency and a maximum intensity point. In combined or concurrent modes, the TI is the sum of the contribution of the enabled modes, and the displayed MI is the greater of the MI values associated with each enabled mode and focal zone. The system returns to the previously selected state if a mode is disabled and selected again.

f Transducer: Each type of transducer has unique specifications for contact area, beam shape, and center frequency. The defaults are initialized when you select a transducer. Factory defaults vary depending on the transducer, application, and mode selected. The patterns were chosen below the intended use.

8. ALARA Principles

a The guiding principle for the use of diagnostic ultrasound is defined by ALARA (meaning that we keep total ultrasound exposure as low as possible by optimizing diagnostic information). The decision on what is reasonable has been left to the judgment and perception of qualified personnel. According to AIUM Medical Ultrasound Safety (Third Edition), there is the following description: "With the new ultrasound equipment, the on-screen output display (thermal index [TI] and mechanical index [MI]) allows us to determine the level of exposure in terms of the potential for biological effects. For equipment that does not have an output display, we rely on any output information, such as intensity, decibels, or percentage of power that the system provides. Because the threshold, if any, for the diagnostic bioeffects of ultrasound is indeterminate, it becomes our responsibility to control the total exposure to the patient. The control of the total exposure depends on the output level and the exposure time. The level of output required for an exam depends on the patient and the clinical need. Not all diagnostic tests can be performed at very low levels. In fact, using a level that is too low can result in poor data and the need to repeat the exam. Using too high a level may not necessarily increase the quality of the information, but it will expose the patient to unnecessary ultrasound energy. The use of ALARA is a way to implement the security guarantee. The threshold for diagnostic bioeffects of ultrasound is indeterminate. Ultimately, the exposure time depends on the person performing the exam. Primarily, it is our training, education, and experience that determine how quickly we can obtain a useful image, and therefore the duration of the examination and the amount of exposure. So, the question is, "How long do we need to get the diagnostic information you want?" But there are also some other factors that can affect the length of time that any particular tissue is exposed to. One is the mode, whether it is a moving or stationary beam; and another is the choice of transducer. Other factors include the patient's body characteristics, the operator's understanding of the system's controls and how they affect output levels, and particularly whether continuous or pulsed wave Doppler or color flow Doppler are used. To achieve ALARA, we need an in-depth knowledge of imaging mode, transducer capabilities, system configuration, and operator scanning techniques.

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

c First, the mode that we select, such as M-mode, B-mode, or Doppler, depends on what we're looking for. B-mode imaging provides anatomical information, while color flow Doppler and Doppler modes provide information about blood flow through vessels. The M-mode provides information about how anatomical structures move in time. If one wishes to use 3D/4D ultrasound, one should remember that 3D/4D image sets consist of a series of two-dimensional (2D) B-mode acquisitions, which are then constructed by the computer into 3D/4D representations. So whatever the settings are for 2D images in B-mode, it will be what determines the output. Time will be the most important variable because, on the one hand, a 2D scan will be fast and time-limited, but prolonged exposure can result from trying to get the "best" set of images. Secondly, the capabilities of the transducer are related to the depth of penetration of the ultrasound into the tissue at the chosen frequency, resolution, and field of view that we can achieve with the selected transducer. Third, the system configuration

and control settings depend on where we start in the output scale and our knowledge of which combination of controls gets the best results. Fourthly, the scanning technique we use is based on our knowledge of anatomy and pathology, ultrasound physics, and signal processing capabilities of the equipment, as well as our experience with a specific scanning modality, such as sector, linear, and so on. The recording and playback capabilities of a system allow us to reduce exposure time to just the time it takes to get a useful image. Analysis and diagnosis can be performed with recorded images, rather than long live imaging sessions. The same can be said about 3D volumes, obtained by an examiner and analyzed by that examiner or by someone else, without exposure to the patient, at the bedside, in the reading room, throughout the city or across the country. Without an output display pattern, we must rely on this knowledge to estimate a patient's ultrasound exposure. With an output display pattern, we have a real-time indication of the exposure in terms of bioeffects potential. Either way, we implemented ALARA by minimizing the level and duration of exposure, while still getting the necessary diagnostic information."

d No set of rules can be formulated that is sufficiently complete to dictate the correct answer for each circumstance. Qualified personnel can adjust to improve image quality and minimize output intensity. There are several variables that affect the way that output display indexes can be used to implement the ALARA principle. These variables involve:

1. Index values
2. Body Size
3. Location of the bone in relation to the focal point
4. Attenuation in the body
5. Ultrasound exposure time. Exposure time is an especially useful variable, because it is controlled by users.

9. Applying ALARA

a The system image mode of the selected operator, i.e. depends on the user information required. Understanding the nature of the imaging mode used, transducer frequency, system configuration values, scanning techniques, and operator expertise allows the sonographer to meet the definition of the ALARA principle. The amount of acoustic output is the responsibility of the system operator. This decision should be based on the following factors: type of patient, type of examination, patient history, ease or difficulty of obtaining useful information for diagnosis, potential localized warming of the patient due to the surface temperature of the transducer. Prudent use of the system occurs when patient exposure is limited to reading the lowest index for the shortest amount of time necessary to obtain acceptable diagnostic results. A high index reading does not necessarily indicate the occurrence of a bioeffect; however, it should be taken seriously. It is the operator's responsibility to make every effort to reduce the possible effects of a high index reading by limiting the exposure time.

b Limiting exposure time is an effective way to achieve 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 can use to implement ALARA. These controls can be divided into three categories: direct, indirect, and receiver controls.

10. Using System Controls to Implement ALARA

a Direct controls: The system has no direct control for output, so the sonographer must control the 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 the output. The system does not exceed an average spatial peak temporal intensity (I SPTA) of 720 mW/cm2 for all imaging modes. The mechanical index (MI) of the equipment does not exceed values greater than 1.9 and the thermal index (TI) does not exceed values greater than 6.0.

b Indirect controls: 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 mode of scanning; Doppler is either a stationary or non-digitized mode. A stationary ultrasound beam concentrates energy in a single location. A mobile or scanned ultrasound beam disperses energy over an area and the beam is concentrated in the same area for a fraction of the time in an unscanned manner.

c Receiver Controls: Receiver controls are used by the operator to improve image quality. These controls have no effect on the output. The 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, regarding output, is that the receiver controls must be optimized before the output is increased. For example, before increasing the output, optimize the gain to improve the image quality.

d An example of the application of the ALARA principle: An ultrasound of a patient's liver begins with the selection of the appropriate transducer frequency. After selecting the transducer and application, which are based on the patient's anatomy, adjustments to the output power should be made to ensure that the lowest possible setting is used to acquire an image. If a suitable image can be obtained with increasing gain, a decrease in output should be made. Only after making these adjustments do you increase production to the next level. Having acquired the 2D display of the liver, Color can be used to locate blood flow. As with displaying 2D images, the gain and image processing controls must be optimized before increasing the 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 image controls.

e Disturbances in heart rhythm were observed during perfusion studies with gaseous ultrasonographic contrast agents in the diagnostic range of Mechanical Index (MI) values. For details, refer to the specific package insert of the contrast agent used.

11. Output Display

a There are two types of indexes that can be displayed: one is the mechanical index (MI) and the other is the thermal index (TI). The mechanical index (MI) provides an indication of the risk due to mechanical or non-thermal mechanisms. The thermal index (TI) provides an indication of the risk of damage due to thermal mechanisms. The mechanical index (MI) is displayed continuously in the range of 0.0 to 1.9, in increments of 0.1.

b The thermal index also consists of the following indices: soft tissue (TIS), bone (TIB), and cranial bone (TIC). Only one of them is displayed at any given time. Each transducer application has a standard selection appropriate for this combination. The TIB, TIS, or TIC is displayed continuously in the range of 0.0 up to the maximum output, based on the transducer and application. The application-specific nature of the default configuration is also an important factor of index behavior. A default setting is a system control state predefined by the manufacturer or operator. The system has default index settings for the transducer application. The default settings are automatically invoked by the ultrasound system when the power is turned on, when new patient data is entered into the system database, or when a change occurs in the application. The decision on which of the three thermal indices to display should be based on the following criteria:

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

d Mitigating factors that can create artificially high or low thermal index readings: location of fluids or bones or blood flow. For example, is there a highly attenuating fabric path so that the actual warming potential of the local zone is less than the thermal index exhibits?

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

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

sensitivity.

12. Display Accuracy
    a MI and IT have an accuracy of 0.01 units in the system.
    b Estimates of the MI and IT display accuracies are shown in the Acoustic Output Tables. Many factors are considered when estimating the accuracy of the displayed values:
    c Hardware variations, such as piezoelectric crystal efficiencies, process-related impedance differences, and variations in sensitive lens focus parameters.
    d Accuracy of the estimation algorithm, including variations in pulsator voltage control, operating conditions, and efficiencies.
    e Measurement variability, such as inaccuracies in laboratory measurements caused by hydrophone calibration and performance, positioning, alignment and scan tolerances, and variability of test operations.
    f Controls Affecting Indexes
        1. B-mode controls
        2. Transducer Frequency
        3. Color Controls
    g Color sector width: The narrower width of the color sector will increase the color frame rate and IT will increase. The system can automatically decrease the pulse voltage to be below the system maximum. A decrease in pulse voltage will decrease the IM.
    h Color Sector Depth: The deeper color sector depth can automatically decrease the 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, IT will decrease with increasing depth of the color sector. The IM will correspond to the IM of the dominant pulse type, which is a colored pulse.
    i Measurement accuracy and uncertainty of acoustic output values: The measurement accuracy of quantities is listed in the table below. They are measured as part of the determination of the IM or TI values. Quantities are listed as a standard deviation, in percentage.

Parameter	Description	Uncertainty
Pulse Intensity Integral (PII)	Energy density (mJoules/cm2) in an ultrasonic pressure wave. Used in the determination of IT, Ispta.0 and Ispta.3.	+/-25.10%
Peak Pressure Filtration (Pr)	Largest pressure range (MPa) of negative pressure semicycles in an ultrasonic pressure wave. Used in the determination of the MI.	+/-12.55%
Spatial Average	Spatial mean correction factor	+/-10.00% for intensity, +/-5.00% for pressure
Center Frequency (Fc)	Center frequency (MHz) of an ultrasonic pressure wave. Used in the determination of the MI.	+/-0.012%

III. Specifications

A. PCBA

1. There are some of the technical aspects of the system as listed:
   - a Receiving frequency and/or bandwidth and bandwidth of the receiving section.
   - b Frequency band and/or transmission, modulation and ERP
   - c Functions: Image data transmission and control data communications
   - d FPGA High Performance Computing Technology
   - e Unique "Ultra Image Block Algorithm" (UIBA) technology solution for B-mode, color mode, M-mode, Power Doppler and PW Doppler block imaging
   - f High frame rate
   - g High contrast
   - h High resolution
   - i Harmonic Tissue Image
   - j Support Imaging Mode
   - k B-mode
   - l Color Doppler
   - m M Mode
   - n PW Doppler
   - o Power Doppler
2. Built-in continuous-use battery
   a. Approximately 2 hours of continuous scanning under default settings.
   b. Battery life may vary depending on the mode and settings.
3. Three examples of IEC 60601-1 compliant adapter for two MOPP insulation systems:
   - a Tripp Lite Healthcare Product Group
     Model Name: U280-001-W2-HG
   - b Good Opportunity Electronic Co., Ltd.
     Model Name: 10W Medical Power Adapter
   - c MEDIUM WELL ENTERPRISES CO., LTD.
     Model Name: GSM12U USB Connection

4. Description of Radio Frequency Wireless Technology
   - a The technical aspects of the system's 2.4 GHz and 5 GHz wireless communication as listed below

Parameter	Specification	Comment
IEEE 802.11 Level	IEEE 802.11a/b/g/n	802.11b Chapter 1-11 802.11g Chapter 1-11 802.11n 20 million 802.11a 5150-5250 (UNII-1) 802.11a 5725-5850 (UNII-3)
Wireless Signal Rate	1 - 11 Mbps (IEEE 802.11b) 6 - 54 Mbps (IEEE 802.11g) 6 - 54 Mbps (IEEE 802.11a)	The actual data transfer rate is lower and is affected by device distance and packet error rates, network condition, environmental factors, etc.
Security type	WPA2. 128 works as AP mode connection with SSID and password selection required; Only one authenticated connection at a time.	Encryption for added security and authentication for secure connection.
Redundancy mechanism	CRC	Verifying the integrity of metadata
Distance between 128 and mobile device	<3 meters; <1 meter if in crowded environment	In most tests See Wi-Fi Coexistence Test.
Error rate	<5%	See Wi-Fi Coexistence Test.
Data frame rate (relative to latency and data throughput)	8 fps	See Wi-Fi Coexistence Test. By default, the frame time of the normal condition is about 0.128s, a sigma is about 0.009s.

B. Clinical measurement range and accuracies

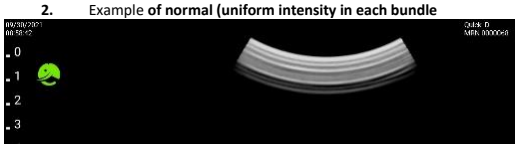
Measurement	Units	Useful Range	Reported accuracy	Limitations or Conditions	
				Probe	Mode of operations
Distance:					
Vertical	millimeter	Full screen	Maximum error.2.17 % Maximum error. 1.81 % Maximum error. 1.9% Maximum error. -3.35% Maximum error. -3.30%	LX128L LX128C LX128PA LX192L LX192C	■B
Horizontal	millimeter	Full screen	Maximum error. 1.67 % Maximum error. 2.9% Maximum error. 0.7% Maximum error. 1.92% Maximum error. 0.69%	LX128L LX128C LX128PA LX192L LX192C	■B
Area:					
Circle	mm2	Full screen	Maximum error 2.15% Maximum error 2.3% Maximum error 3.47% Maximum error 3.04% Maximum error 4.50%	LX128L LX128C LX128PA LX192L LX192C	■B
Dead zone					
Dead zone	mm2	-	0 mm 0 mm 2mm 0 mm 0 mm	LX128L LX128C LX128PA LX192L LX192C	■B
Doppler					
Speed	mm/s	Full screen	Maximum error 4.48% Maximum error 3.00% Maximum error. 3.6% Maximum error. 1.19% Maximum error. 0.72%	LX128L LX128C LX128PA LX192L LX192C	■PWD

1. * Run translation element check

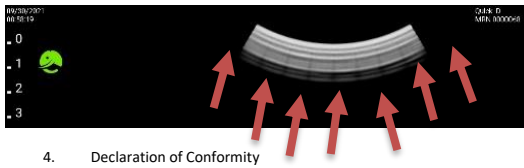
To perform the transducer element test, we have added the following function and description to the user manual. Operators can therefore check the transducer on their own.

Press the button Advanced settings in the menu to the left of the main view. The user can Transducer Check use it to determine if the element is working as expected. The system transmits and receives through a projected sequence and forms the image. Abnormal variations in intensity (e.g., dark lines) near the surface should be considered as a possible element failure. Contact the service for guidance on other necessary actions.

2. Example **of normal (uniform intensity in each bundle**



3. Example of a probmatic element or channel failure.



4. Declaration of Conformity
   The products comply with international and national standards and laws. Users are responsible for ensuring that the smart device and scanner they choose complies with the law of the jurisdiction where the product is used. Leltek meets all regulatory standards listed in this chapter.
5. Product Classification
   The device with transducers: Internally powered Class IIa/ME equipment.
   Transducers: Applied parts type BF, IPX68
   Ordinary Equipment/Continuous Operation
   Non-AP/APG
6. Electromechanical safety standards met
   The transducers and software comply with the requirements of IEC 60601-1 Medical Electrical Equipment, General Safety Requirements, including all applicable warranties and specific standards, as well as all applicable deviations. Users of the system are responsible for ensuring that the device they choose complies with the law of the jurisdiction in which the product is used.
7. System Specifications
   Grayscale: 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 runs the Imaging System application. It is the user's responsibility to select a compatible device that meets the needs of the user's clinical environment.
   For information about the environmental specifications of the user's device, refer to the documentation that came with the user's device.

C. Acoustic output tables

[C5-2 Convex] Acoustic Output Reporting Table

Acoustic output reporting table for band 3
Transducer Model: C5-2 Convex
Operating Mode: B Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			1.69	0.72			0.72			IN	
Index Component Value			1.69	0.72	IN	IN	0.72	IN	IN	IN	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		2.33								
	P (mW)			323.20	IN		323.20	IN		IN	IN
	P1x1 (mW)			79.18	IN		79.18	IN			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	e.g., (cm)								IN		
	ZPI (cm)		6.22			IN			IN		
	zMI (cm)		4.16								
	D in ZB (cm)								IN		
	fawf (MHz)		1.91	1.91	IN		1.91	IN		IN	IN
	Dimof Aaprt	X (cm		3.14	IN		3.14	IN		IN	IN
		Y (cm		1.30	IN		1.30	IN		IN	IN
Other information	Mode Components		B	B	IN		B	IN		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		2368.50								
	srr (Hz)		14.13								
	pr in zpii (MPa)		3.06								
	Deq for ZPII (cm								IN		
	Ipa,α em zpii,α (W/cm2)		405.00								
	Focal length	FLX(c	6.40			IN			IN		
		FLY (cm)	4.20			IN			IN		
Operational control conditions	Focus (cm)		6.4	6.4	IN	IN	6.4	IN	IN	IN	IN
	Depth (cm)		12.6	12.6	IN	IN	12.6	IN	IN	IN	IN
	POETRY		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MH		3.6	3.6	IN	IN	3.6	IN	IN	IN	IN

NA indicates that there is no corresponding intended use or no data reported.

Acoustic output reporting table for band 3
Transducer Model: C5-2 Convex
Operation Mode: B+M Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			1.69	0.79			1.09			IN	
Index Component Value			1.69	0.70	0.03	0.09	0.70	0.16	0.39	IN	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		2.33								
	P (mW)			312.20	14.87		312.20	14.87		IN	IN
	P1x1 (mW)			76.48	3.64		76.48	3.64			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					9.30					
	zS (cm)					3.42					
	ZBP (cm)					3.41			3.41		
	e.g., (cm)								4.16		
	ZPI (cm)		6.22			6.22			6.22		
	zMI (cm)		4.16								
	d em zb (cm)								0.49		
	fawf (MHz)		1.91	1.91	1.91		1.91	1.91		IN	IN
	Dimof Aaprt	X (cm		3.14	3.14		3.14	3.14		IN	IN
		Y (cm		1.30	1.30		1.30	1.30		IN	IN
Other information	Mode Components		B + M	B	M		B	M		IN	IN
	TD (USEC)		1.05								
	prr (Hz)		B: 2288.16 Phone: 108.99								
	srr (Hz)		13.62								
	pr in zpii (MPa)		3.06								
	Deq for ZPII (cm								0.48		
	Ipa,α em zpii,α		405.00								

	(W/cm2)										
	Focal length	FLX (cm)	6.40			6.40			6.40		
		FLY (cm)	4.20			4.20			4.20		
Operational control conditions	Focus (cm)		6.4	6.4	6.4	6.4	6.4	6.4	6.4	IN	IN
	Depth (cm)		12.6	12.6	12.6	12.6	12.6	12.6	12.6	IN	IN
	POETRY		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MH		3.6	3.6	3.6	3.6	3.6	3.6	3.6	IN	IN
	M PRF (Hz)		114.0	--	114.0	114.0	--	114.0	114.0	IN	IN
NA indicates that there is no corresponding intended use or no data reported.											

Acoustic output reporting table for band 3
Transducer Model: C5-2 Convex
Operating Mode: B+CF/B+PD/B+TVI/B+TEI (TD) Mode

Index Label			MI	TIS			TIB			TICK	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			1.69	0.75			0.75			IN	
Index Component Value			1.69	B: 0.40 CF: 0.35	IN	IN	B: 0.40 CF:0.35	IN	IN	IN	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		2.33								
	P (mW)			B: 178.60 CF: 94.30	IN		B: 178.60 CF: 94.30	IN		IN	IN
	P1x1 (mW)			B: 43.75 CF: 23.10	IN		B: 43.75 CF: 23.10	IN			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	e.g., (cm)								IN		
	ZPI (cm)		6.22			IN			IN		
	zMI (cm)		4.16								
	D in ZB (cm)								IN		
	fawf (MHz)		B: 1.91	B: 1.91 CF: 3.17	IN		B: 1.91 CF: 3.17	IN		IN	IN
	Dimof Aaprt	X (cm		3.14	IN		3.14	IN		IN	IN
		Y (cm		1.30	IN		1.30	IN		IN	IN
Other information	Mode Components		B+CF	B+CF	IN		B+CF	IN		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		B: 1308.72 CF: 3600.0								
	srr (Hz)		7.79								
	pr in zpii (MPa)		3.06								
	Deq for ZPII (cm								IN		
	Ipa,α em zpii,α (W/cm2)		405.00								
	Focal length	FLX(c	6.40			IN			IN		
		FLY (cm)	4.20			IN			IN		
Operational control conditions	Focus (cm)		6.4	6.4	IN	IN	6.4	IN	IN	IN	IN
	Depth (cm)		12.6	12.6	IN	IN	12.6	EM	EM	IN	EM
	POETRY		EM	EM	EM	EM	EM	EM	EM	EM	IN
	Frequency (MH		B: 3.6 CF: 3.1	B: 3.6 CF: 3.1	IN	IN	B: 3.6 CF: 3.1	IN	IN	IN	IN
	Cor PRF (kHz)		3.6	3.6	IN	IN	3.6	IN	IN	IN	IN
NA indicates that there is no corresponding intended use or no data reported.											

Acoustic output reporting table for band 3
Transducer Model: C5-2 Convex
Operating Mode: PW/TDI (TD) Mode

Index Label			MI	TIS			TIB			TICK	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			1.04	0.69			1.60			IN	
Index Component Value			1.04	IN	0.30	0.69	IN	1.16	1.60	IN	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		1.62								
	P (mW)			IN	105.53		IN	105.53		IN	IN
	P1x1 (mW)			IN	25.85		IN	25.85			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					59.30					
	zS (cm)					3.42					
	ZBP (cm)					3.41			3.41		
	e.g., (cm)								4.16		
	ZPI (cm)		5.52			5.52			5.52		
	zMI (cm)		5.52								
	D in ZB (cm)								0.65		
	fawf (MHz)		2.45	IN	IN		IN	2.45		IN	IN
	Dimof Aaprt	X (cm		IN	3.14		IN	3.14		IN	IN
		Y (cm		IN	1.30		IN	1.30		IN	IN
Other	Mode		Prisone	IN	Prisoner of war		IN	Prisoner of war		IN	IN

informati on	Component s		of war								
	TD (USEC)		1.58								
	PRR (Hz)		4170.00								
	srr (Hz)		IN								
	pr in zpii (MPa)		1.78								
	Deq for ZPII (cn								0.65		
	Ipa,α em zpii,α (W/cm2)		75.33								
	Foc al len gth	FLX(c	6.40			6.40			6.40		
		FLY (cm)	4.20			4.20			4.20		
Operatio nal control conditio ns	Focus (cm)		6.4	IN	6.4	6.4	IN	6.4	6.4	IN	IN
	Depth (cm)		12.6	IN	12.6	12.6	IN	12.6	12.6	IN	IN
	Frequency (MH		2.6	IN	2.6	2.6	IN	2.6	2.6	IN	IN
	PRF (kHz)		4.17	IN	4.17	4.17	IN	4.17	4.17	IN	IN
	Gate (mm)		0.5	IN	0.5	0.5	IN	0.5	0.5	IN	IN

NA indicates that there is no corresponding intended use or no data reported.

[L12-5 Linear] Acoustic Output Reporting Table

Acoustic output reporting table for band 3
Transducer Model: L12-5 Linear
Operating Mode: B Mode

Index Label			MI	TIS			TIB			TICK	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surfa ce	In Surfa ce	Belo w the surfa ce	In Surfa ce	In Surfa ce	Belo w the surfa ce	In Surfac e	In Surfac e
Maximum index value			1.59	0.44			0.44			0.93	
Index Component Value			1.59	0.44	IN	IN	0.44	IN	IN	0.93	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		3.46								
	P (mW)			37.42	IN		37.42	IN		37.42	IN
	P1x1 (mW)			19.49	IN		19.49	IN			
	Min de [Pa(zs), Ita,α(zs)x1c m2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	ZB (cm)								IN		
	ZPI (cm)		1.20			IN			IN		
	zMI (cm)		1.00								
	d em zb (cm)								IN		
	fawf (MHz)		4.74	4.74	IN		4.74	IN		4.74	IN
	Di mo f Aa prt	X (cn		1.92	IN		1.92	IN		1.92	IN
		Y (cn		0.42	IN		0.42	IN		0.42	IN
Other informati on	Mode Component s		B	B	IN		B	IN		B	IN
	TD (USEC)		0.52								
	prr (Hz)		3203.00								
	srr (Hz)		11.30								
	pr in zpii (MPa)		4.08								
	Deq for ZPII (cn								IN		
	Ipa,α em zpii,α (W/cm2)		391.30								
	Foc al len gth	FLX(c	1.20			IN			IN		
		FLY (cm)	1.00			IN			IN		
Operatio nal control conditio ns	Focus (cm)		1.2	1.2	IN	IN	1.2	IN	IN	1.2	IN
	Depth (cm)		3.0	3.0	IN	IN	3.0	IN	IN	3.0	IN
	THI		EM	EM	IN	IN	EM	IN	IN	EM	IN
	Frequency (MH		10	10	IN	IN	10	IN	IN	10	IN

NA indicates that there is no corresponding intended use or no data reported.

Acoustic output reporting table for band 3
Transducer Model: L12-5 Linear
Operation Mode: B+M Mode

Index Label			MI	TIS			TIB			TICK	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surfa ce	In Surfa ce	Belo w the surfa ce	In Surfa ce	In Surfa ce	Belo w the surfa ce	In Surfac e	In Surfac e
Maximum index value			1.59	0.44			0.48			0.94	
Index Component Value			1.59	0.43	0.01	0.01	0.43	0.03	0.05	0.91	0.03
Associate Acoustic Parameters	pr,α em zMI (MPa)		3.46								
	P (mW)			36.93	1.02		36.93	1.02		36.93	1.02
	P1x1 (mW)			19.23	0.53		19.23	0.53			
	Min de [Pa(zs), Ita,α(zs)x1c m2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					1.52			1.52		
	e.g., (cm)								1.52		
	ZPI (cm)		1.20			1.20			1.20		
	zMI (cm)		1.00								
	d em zb (cm)								0.26		
	fawf (MHz)		4.74	4.74	4.74		4.74	4.74		4.74	4.74
	Di mo	X (cn		1.92	1.92		1.92	1.92		1.92	1.92
		Y (cn		0.42	0.42		0.42	0.42		0.42	0.42

	f Aa prt										
Other information	Mode Components		B + M	B	M		B	M		B	M
	TD (USEC)		0.52								
	prr (Hz)		B: 3161,00 M: 87,1								
	srr (Hz)		10.90								
	pr in zpii (MPa)		4.08								
	Deq for ZPII (cm								0.23		
	Ipa,α em zpii,α (W/cm2)		391.30								
	Focal length	FLX (cm)	1.20			1.20			1.20		
		FLY (cm)	1.00			1.00			1.00		
Operational control conditions	Focus (cm)		1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
	Depth (cm)		3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
	POETRY		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MH		10	10	10	10	10	10	10	10	10
	M PRF (Hz)		89.38	--	89.38	89.38	--	89.38	89.38	--	89.38
NA indicates that there is no corresponding intended use or no data reported.											

Acoustic output reporting table for band 3
Transducer Model: L12-5 Linear
Operation Mode: B+CF/B+PD Mode

Index Label			MI	TIS			TIB			TICK	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			1.59	0.38			0.38			0.79	
Index Component Value			1.59	B: 0.25 CF: 0.13	IN	IN	B: 0.25 CF: 0.13	IN	IN	B: 0.52 CF: 0.27	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		3.46								
	P (mW)			B: 21,11 CF: 11.06	IN		B: 21,11 CF: 11.06	IN		B: 21,11 CF: 11.06	IN
	P1x1 (mW)			B: 10,99 CF: 5,76	IN		B: 10,99 CF: 5,76	IN			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	e.g., (cm)								IN		
	ZPI (cm)		1.20			IN			IN		
	zMI (cm)		1.00								
	d em zb (cm)								IN		
	fawf (MHz)		B: 4,74	B: 4,74 CF: 4,83	IN		B: 4,74 CF: 4,83	IN		B: 4,74 CF: 4,83	IN
	Dimof Aa prt	X (cm		1.92	IN		1.92	IN		1.92	IN
		Y (cm		0.42	IN		0.42	IN		0.42	IN
Other information	Mode Components		B+CF	B+CF	IN		B+CF	IN		B+CF	IN
	TD (USEC)		0.52								
	prr (Hz)		B: 1806,70 CF: 4940.0								
	srr (Hz)		6.23								
	pr in zpii (MPa)		4.08								
	Deq for ZPII (cm								IN		
	Ipa,α em zpii,α (W/cm2)		391.30								
	Focal length	FLX(c	1.20			IN			IN		
		FLY (cm)	1.00			IN			IN		
Operational control conditions	Focus (cm)		1.2	1.2	IN	IN	1.2	IN	IN	1.2	IN
	Depth (cm)		3.0	3.0	IN	IN	3.0	IN	IN	3.0	IN
	THI		EM	EM	IN	IN	EM	IN	IN	EM	IN
	Frequency (MH		B: 10 CF: 5	B: 10 CF: 5	IN	IN	B: 10 CF: 5	IN	IN	B: 10 CF: 5	IN
	Cor PRF (kHz)		4.94	4.94	IN	IN	4.94	IN	IN	4.94	IN
NA indicates that there is no corresponding intended use or no data reported.											

Acoustic output reporting table for band 3
Transducer Model: L12-5 Linear
Operation Mode: PW Mode

Index Label			MI	TIS			TIB			TICK	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			1.07	0.43			1.71			0.82	
Index Component Value			1.07	IN	0.36	0.43	IN	0.82	1.71	IN	0.82
Associate Acoustic Parameters	pr,α em zMI (MPa)		2.22								
	P (mW)			IN	33.14		IN	33.14		IN	33.14
	P1x1 (mW)			IN	17.26		IN	17.26			
	Min de [Pa(zs),					IN					

	lta,α(zs)x1cm2] (mW)										
	zS (cm)					IN					
	ZBP (cm)					1.52			1.52		
	e.g., (cm)								1.52		
	ZPI (cm)		0.88			0.88			0.88		
	zMI (cm)		0.86								
	d em zb (cm)								0.28		
	fawf (MHz)		4.31	IN	4.31		IN	4.31		IN	4.31
	Dimof Aaprt	X (cm		IN	1.92		1.92	1.92		IN	1.92
		Y (cm		IN	0.42		0.42	0.42		IN	0.42
	Mode Components		Prisoneof war	IN	Prisoner of war		IN	Prisoner of war		IN	Prisoner o war
	TD (USEC)		0.89								
	prr (Hz)		3920.00								
	srr (Hz)		IN								
Other information	pr in zpii (MPa)		2.52								
	Deq for ZPII (cm								0.23		
	Ipa,α em zpii,α (W/cm2)		161.50								
	Focal length	FLX (cm)	1.20			1.20			1.20		
		FLY (cm)	1.00			1.00			1.00		
Operational control conditions	Focus (cm)		1.2	IN	1.2	1.2	IN	1.2	6.4	IN	1.2
	Depth (cm)		3.0	IN	3.0	3.0	IN	3.0	12.6	IN	3.0
	Frequency (MH		4.2	IN	4.2	4.2	IN	4.2	2.6	IN	4.2
	PRF (kHz)		3.92	IN	3.92	3.92	IN	3.92	4.17	IN	3.92
	Gate (mm)		0.3	IN	0.3	0.3	IN	0.3	0.5	IN	0.3

NA indicates that there is no corresponding intended use or no data reported.

[P4-2 Phased Array] Acoustic Output Reporting Table

Acoustic output reporting table for band 3
Transducer Model: P4-2 Phased Array
Operating Mode: B Mode

Index Label			MI	TIS			TIB			TICK	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			1.61	0.75			0.75			IN	
Index Component Value			1.61	0.75	IN	IN	0.75	IN	IN	IN	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		2.12								
	P (mW)			214.40	IN		214.40	IN		IN	IN
	P1x1 (mW)			90.94	IN		90.94	IN			
	Min de [Pa(zs), lta,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	e.g., (cm)								IN		
	ZPI (cm)		3.92			IN			IN		
	zMI (cm)		2.96								
	D in ZB (cm)								IN		
	fawf (MHz)		1.74	1.74	IN		1.74	IN		IN	IN
	Dimof Aaprt	X (cm		2.05	IN		2.05	IN		IN	IN
		Y (cm		1.15	IN		1.15	IN		IN	IN
Other information	Mode Components		B	B	IN		B	IN		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		2368.00								
	srr (Hz)		14.13								
	pr in zpii (MPa)		2.54								
	Deq for ZPII (cm								IN		
	Ipa,α em zpii,α (W/cm2)		233.80								
	Focal length	FLX(c	3.20			IN			IN		
		FLY (cm)	3.00			IN			IN		
Operational control conditions	Focus (cm)		3.2	3.2	IN	IN	3.2	IN	IN	IN	IN
	Depth (cm)		6.3	6.3	IN	IN	6.3	IN	EM	IN	IN
	THI		EM	EM	IN	IN	EM	IN	IN	IN	IN
	Frequency (MH		3.6	3.6	IN	IN	3.6	IN	IN	IN	IN

NA indicates that there is no corresponding intended use or no data reported.

Acoustic output reporting table for band 3
Transducer Model: P4-2 Phased Array
Operation Mode: B+M Mode

Index Label			ME	TIS			TIB			SUMMARY	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			1.61	0.79			0.93			IN	
Index Component Value			1.61	0.73	0.04	0.06	0.73	0.14	0.20	IN	IN
Associate Acoustic	pr,α em zMI (MPa)		2.12								

Parameters	P (mW)			207.20	9.87		207.20	9.87		IN	IN
	P1x1 (mW)			87.89	4.18		87.89	4.18			
	Min de [Pa(zs), Ita,α(zs)x1c m2] (mW)					7.18					
	zS (cm)					2.60					
	ZBP (cm)					2.60			2.60		
	e.g., (cm)								2.96		
	ZPI (cm)		3.92			3.92			3.92		
	zMI (cm)		2.96								
	d em zb (cm)								0.79		
	fawf (MHz)		1.74	1.74	1.74		1.74	1.74		IN	IN
	Di mo f Aa prt	X (cm		2.05	2.05		2.05	2.05		IN	IN
		Y (cm		1.15	1.15		1.15	1.15		IN	IN
Other informati on	Mode Component s		B + M	B	M		B	M		IN	IN
	TD (USEC)		1.05								
	prr (Hz)		B: 2288.16 Phone: 108.99								
	srr (Hz)		13.62								
	pr in zpii (MPa)		2.54								
	Deq for ZPII (cm								0.78		
	Ipa,α em zpii,α (W/cm2)		233.80								
	Foc al len gth	FLX (cm)	3.20			3.20			3.20		
		FLY (cm)	3.00			3.00			3.00		
Operatio nal control conditio ns	Focus (cm)		3.2	3.2	3.2	3.2	3.2	3.2	3.2	IN	IN
	Depth (cm)		6.3	6.3	6.3	6.3	6.3	6.3	6.3	IN	IN
	POETRY		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MH		3.6	3.6	3.6	3.6	3.6	3.6	3.6	IN	IN
	M PRF (Hz)		114.0	--	114.0	114.0	--	114.0	114.0	IN	IN

NA indicates that there is no corresponding intended use or no data reported.

Acoustic output reporting table for band 3
Transducer Model: P4-2 Phased Array
Operating Mode: B+CF/B+PD/B+TVI/B+TEI (TD) Mode

Index Label			MI	TIS			TIB			TICK	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surfa ce	In Surfa ce	Belo w the surfa ce	In Surfa ce	In Surfa ce	Belo w the surfa ce	In Surfac e	In Surfac e
Maximum index value			1.61	1.66			1.66			IN	
Index Component Value			1.61	B: 0.76 CF: 0.90	IN	IN	B: 0.76 CF: 0.90	IN	IN	IN	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		2.12								
	P (mW)			B: 214.90 CF: 173.9	IN		B: 214.90 CF: 173.9	IN		IN	IN
	P1x1 (mW)			B: 91,16 CF: 73.76	IN		B: 91.16 CF: 73.76	IN			
	Min de [Pa(zs), Ita,α(zs)x1c m2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	e.g., (cm)								IN		
	ZPI (cm)		3.92			IN			IN		
	zMI (cm)		2.96								
	D in ZB (cm)								IN		
	fawf (MHz)		B: 1.74	B: 1.74 CF: 2.56	IN		B: 1.74 CF: 2.56	IN		IN	IN
	Di mo f Aa prt	X (cm		2.04	IN		2.04	IN		IN	IN
		Y (cm		1.15	IN		1.15	IN		IN	IN
Other informati on	Mode Component s		B+CF	B+CF	IN		B+CF	IN		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		B: 2373 CF: 3600.0								
	srr (Hz)		14.13								
	pr in zpii (MPa)		2.54								
	Deq for ZPII (cm								IN		
	Ipa,α em zpii,α (W/cm2)		238.80								
	Foc al len gth	FLX(c	3.20			IN			IN		
		FLY (cm)	3.00			IN			IN		
Operatio nal control conditio ns	Focus (cm)		3.2	3.2	IN	IN	3.2	IN	IN	IN	IN
	Depth (cm)		6.3	6.3	IN	IN	6.3	IN	IN	IN	IN
	POETRY		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MH		B: 3.6 CF: 2.6	B: 3.6 CF: 2.6	IN	IN	B: 3.6 CF: 2.6	IN	IN	IN	IN
	Cor PRF (kHz)		3.6	3.6	IN	IN	3.6	IN	IN	IN	IN

NA indicates that there is no corresponding intended use or no data reported.

Acoustic output reporting table for band 3
Transducer Model: P4-2 Phased Array
Operating Mode: PW/TDI (TD) Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	Do not scan		Scan	Do not scan		Scan	Do not scan
				In Surface	In Surface	Below the surface	In Surface	In Surface	Below the surface	In Surface	In Surface
Maximum index value			0.76	1.28			3.87			IN	
Index Component Value			0.76	IN	0.79	1.28	IN	2.70	3.87	IN	IN
Associate Acoustic Parameters	pr,α em zMI (MPa)		1.10								
	P (mW)			IN	186.53		IN	186.53		IN	IN
	P1x1 (mW)			IN	79.12		IN	79.12			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					127.80					
	zS (cm)					2.60					
	ZBP (cm)					2.60			2.60		
	e.g., (cm)								2.62		
	ZPI (cm)		3.08			3.08			3.08		
	zMI (cm)		2.62								
	d em zb (cm)								0.74		
	fawf (MHz)		2.09	IN	2.09		IN	2.09		IN	IN
	Dimof Aaprt	X (cm		IN	2.05		IN	2.05		IN	IN
		Y (cm		IN	1.15		IN	1.15		IN	IN
Other information	Mode Components		Prisoner of war	IN	Prisoner of war		IN	Prisoner of war		IN	IN
	TD (USEC)		1.83								
	PRR (Hz)		4170.00								
	srr (Hz)		IN								
	pr in zpii (MPa)		1.33								
	Deq for ZPII (cm								0.73		
	Ipa,α em zpii,α (W/cm2)		33.17								
	Focal length	FLX(c	3.20			3.20			3.20		
		FLY (cm)	3.00			3.00			3.00		
Operational control conditions	Focus (cm)		3.2	IN	3.2	3.2	IN	3.2	3.2	IN	IN
	Depth (cm)		6.3	IN	6.3	6.3	IN	6.3	6.3	IN	IN
	Frequency (MH		2.1	IN	2.1	2.1	IN	2.1	2.1	IN	IN
	PRF (kHz)		4.17	IN	4.17	4.17	IN	4.17	4.17	IN	IN
	Gate (mm)		0.5	IN	0.5	0.5	IN	0.5	0.5	IN	IN
NA indicates that there is no corresponding intended use or no data reported.											

D. Manufacturer's Guidance and Declaration

1. The LX Series requires special precautions regarding EMC.
2. The LX Series should not be used adjacent to or stacked with other equipment.
3. Using the wrong cables and accessories can negatively impact EMC's performance
4. Do not use accessories that are not supplied or recommended by the manufacturer. Other accessories may adversely affect EMC's performance.
5. Household electronic devices such as humidifiers, heaters, or microwaves, and so on, may be susceptible to causing interference with the device.
6. Do not expose the device to strong electrostatic fields or strong magnetic fields to avoid inaccurate results.
7. If abnormal behavior is observed due to electromagnetic disturbances, reposition the device accordingly.
8. Use of this device adjacent to or stacked with other devices should be avoided as it may result in improper operation.
9. Any part of the monitor should not be used within 30 cm (12 inches) of wireless communication devices, such as network devices, mobile phones, and walkie-talkies, or may result in errors or display of inaccurate results.
10. The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is required, the device should be observed to verify normal operation in the configuration in which it will be used.
11. It is not recommended to use accessories (e.g., cables, humidifiers) other than those specified for the device. They can result in increased emissions or decreased immunity from the device.

E. Electromagnetic emissions

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

Manufacturer's declaration - electromagnetic emissions		
The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP is intended for use in the electromagnetic environment (for home and professional health care) specified below. The customer or user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP LV128LP must ensure that it is used in such an environment.		
Emissions Testing	Compliance	Electromagnetic orientation of the environment (for home and professional health setting)
RF emissions CISPR 11	Group 1	The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP uses RF energy only for its internal function. Therefore, their RF emissions are very low and are unlikely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/scintillation emissions IEC 61000-3-3	Not applicable	

Manufacturer's Declaration – Electromagnetic Immunity The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP is intended for use in the electromagnetic environment (for home and professional health care) specified below. The customer or user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP LV128LP must ensure that it is used in such an environment.			
Immunity test	IEC 60601 Test Level	Level of compliance	Electromagnetic Orientation of the Environment (for home and

			professional health environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Com: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ± 8 kV Com: ±2 kV, ±4 kV, ±8 kV, ±15 kV	The floors must be made of wood, concrete or ceramic. If the floors are covered with synthetic material, the relative humidity should be at least 30%
Transient/rapid electrical explosion IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input/output lines	2kV ± for power lines Not applicable	The quality of the electricity should be that of a typical home and professional health environment.
Outbreak IEC 61000-4-5	± 0.5 kV, ±1 kV line(s) to line(s) ± 0.5 kV, ±1 kV, ± 2 kV linha(s) à terra	± 0.5 kV, ±1 kV line(s) to line(s) Not applicable	The quality of the electricity should be that of a typical home and professional health environment.
Voltage drops, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Voltage Drops: 0% TU; 0.5 cycle0 % TU; 1 cycle70% UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 Cycle	Voltage Drops: 0% TU; 0.5 cycle0 % TU; 1 cycle70% UT; 30 cycles Voltage interruptions: 0% TU; 300 cycles	The quality of the electricity should be that of a typical home and professional health environment. If the user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP needs continuous operation during outages in the power grid, it is recommended that the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP be powered by an uninterruptible power supply or battery.
Magnetic field energy frequency (50, 60 Hz) IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The magnetic fields of energy frequency LX192LC, LV192LC, LX128LC, LV128LC LX128LP LV128LP should be at levels characteristic of a typical location in a typical home and healthcare professional environment.
Note: UT is the AC mains voltage before the test level is applied.			

Manufacturer's Declaration – Electromagnetic Immunity			
The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP is intended for use in the electromagnetic environment (for home and professional health care) specified below. The customer or user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP LV128LP must ensure that it is used in such an environment.			
Immunity test	IEC 60601 Test Level	Level of compliance	Electromagnetic Orientation of the Environment (for home and professional health environment)
RF Led IEC 61000-4-6	3 Vrms: 0.15 MHz - 80 MHz 6 Vrms: in ISM and amateur radio bands between 0.15 MHz and	3 Vrms: 0.15 MHz - 80 MHz 6 Vrms: in ISM and amateur radio bands between 0.15 MHz and 80	Portable and mobile RF communications The equipment shall not be used closer to any part of the LX192LC, LV192LC, LX128LC, LV128LC LX128LP LV128LP including cables, than the recommended separation distance

Radiated RF IEC	80 MHz 80% AM at 1 kHz 10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	MHz 80% AM at 1 kHz 10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	calculated from the applicable transmitter frequency equation. Recommended separation distance: $d = 1.2\sqrt{P}$ d = 1.2 80MHz to 800 MHz$\sqrt{P}$ d = 2.3 800 MHz to 2.7 GHz $\sqrt{P}$ Where P is the maximum output power 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: 
IEC 61000-4-39 Proximity Magnetic Field	8 A/m to 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	8 A/m to 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	
NOTE1 At 80 MHz and 800 MHz, the highest frequency range applies. NOTE2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects, and people.			

Recommended separation distance between
portable and mobile RF communication equipments and LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP

The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP is intended for use in an electromagnetic environment (for home and professional health care) in which radiated RF disturbances are controlled. The customer or user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP can help avoid electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication equipment (transmitters) and the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP as recommended below, according to the maximum output power of the communication equipment.

Maximum Rated Transmitter Output Power In	Separation distance according to transmitter frequency m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz up to 2.7 GHz $d = 2.3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated with a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the transmitter frequency, where p is the maximum transmitter output power in watts (W) according to the transmitter manufacturer.

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

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

Manufacturer's Declaration – Electromagnetic Immunity

Test Specifications for CABINET DOOR IMMUNITY for RF Wireless Communication Equipment

The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP is intended for use in the electromagnetic environment (for home and professional health care) specified below.

The customer or user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP LV128LP must ensure 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** (m/m)	**LEVEL OF COMPLIANCE** (m/m) (for home and professional health care)
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 senoidal	2	0,3	28	28
710	704 – 787	Banda LTE 13, 17	Pulse Modulation (B) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation (B) 18 Hz	2	0,3	28	28
870							
930							
1 720	1,700 – 1,990	GSM 1800; CDMA 1900; GSM 1900; DECT; Banda LTE 1, 3, 4, 25; UMTS	Pulse Modulation (B) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2,400 – 2,570	Bluetooth, WIRELESS 802.11 b/g/n, RFID 2450, LTE band 7	Pulse Modulation (B) 217 Hz	2	0,3	28	28
5 240	5,100 – 5,800	Wi-Fi 802.11 A/N	Pulse Modulation (B) 217 Hz	0,2	0,3	9	9
5 500							

5 785							

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

a) For some services, only 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 can be used at 18 Hz because, although it does not represent the actual modulation, it would be the worst case.

Manufacturer's Declaration – Electromagnetic Immunity

Test Specifications for CABINET DOOR IMMUNITY to proximity magnetic fields

The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP is intended for use in the electromagnetic environment (for home and professional health care) specified below. The customer or user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP LV128LP must ensure that it is used in such an environment.

Frequencies	Test Level [A/m]	Modulation	Length of stay [s]	LEVEL OF COMPLIANCE [A/m] (for home and professional health care)
30 kHz (a)	8	CW	3	8
134,2 kHz	65	Pulse modulation (b) 2,1 kHz	3	65 (c)
13.56 MHz	7,5	Pulse modulation (b) 50 kHz	3	7.5 c)

Note:

(a) This test is applicable only to EM EQUIPMENT and EM SYSTEMS intended for use in the HOME AND PROFESSIONAL HEALTH CARE SETTING.

(b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) R.M.S., before the application of the modulation.

F. Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the party 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 reposition the receiving antenna.

•Increase the separation between the equipment and the receiver.

-Connect the equipment to 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. The 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 specific operating instructions to satisfy RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

A、 Maintenance

If this product is not working properly, you can contact your local dealer or contact the manufacturer by email: info@leltek.com

B、 Troubleshooting

Question	Solution
LED indicator flashing and unable to turn off the device.	When the battery is low, plug in the adapter to charge the device and turn it off.
Unable to connect to Wi-Fi.	a. When the LED indicator of the device (transducer) is purple, the device (transducer) may be low on battery and needs to be charged by an adapter. b. When the LED indicator of the device (transducer) is white, the device (transducer) may need to reset the power and reconnect the device (transducer) via Wi-Fi. c. Make sure there is no background on the screen or that other apps have been activated.
The app was activated, but it could not display an image.	Make sure there is no background on the screen or that other apps have been activated first. It should turn the device (transducer) back on and reconnect the device (transducer) via Wi-Fi and then re-enable the app.
The app is on the image page, but it would immediately switch to the Wi-Fi connected selection page.	Disconnect Wi-Fi first and delete the current app, then reinstall and activate the app.
The screen can display an unclear white image in a very short time when the product has been used long-term in the high static environment.	The status is normal condition and would not affect the essential performance, it would interfere with the diagnosis also without basic safety consideration, please set up the product in the environment without high static.

Manufacturer's Address

CGRX INDÚSTRIA COMÉRCIO IMPORTAÇÃO EXPORTAÇÃO LTDA
Av. Hiroshima, 2034 - Bosque do Carandá - Campo Grande - Mato Grosso do Sul - 79036-360

IV. References

A、 Acoustic

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

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

iii. AIUM/NEMA UD 3- 2004 2009 Publication of the NEMA UD 3-2004 (R2009) standard for real-time display of thermal and mechanical acoustic output indices in diagnostic ultrasound equipment

B、 Biocompatibility

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

ii. EN ISO 10993-5:2009 - Biological evaluation of medical devices - In vitro cytotoxicity tests

iii. ISO 10993-10:2010 - Biological evaluation of medical devices. Skin irritation and sensitization tests

C、 Chemist

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

ii. 128 The ultrasound imaging system meets the minimum requirements for compliance with the European Union's Restriction of Hazardous Substances Directive (RoHS) 2011/65/EU and its amendments.

D、 Battery

i. UN 38.3 - Transport of lithium batteries

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

E、 Wireless

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

ii. EN 300 328 V2.1.1; 2016 - Broadband transmission by wireless radio frequency);

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

F、 Raincoat

i. IEC 60529 edition 2.2:2013 - Degrees of protection provided by enclosures

G、 Safety and performance

i. IEC 60601-1 Edition 3.2 2020-08 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

ii. IEC 60601-1-2 Edition 4.1 2020-09 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Capability - Requirements and Tests

iii. IEC 60601-1-6 Edition 3.2 2020-07 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability

iv. IEC 60601-2-37 Edition 2.1 2015 Medical Electrical Equipment - Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Medical Monitoring Equipment

v. EN IEC 62304:2006 Medical Device Software - Software Lifecycle Processes

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

vii. ISO 15223-1 2016 Medical Devices - Symbols to be used with medical device labels, labeling and information to be provided

H、 Quality management

i. ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

ii. ISO 14971:2019 Medical devices – Application of risk

management to medical devices

I、 Labelling

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

Symbols

Symbol	Description
	This icon indicates useful information or tips.
	Indicates the need for the user to refer to the instructions for use for important information on warnings, such as warnings, warnings, and precautions that cannot, for various reasons, be presented on the medical device itself.
	Refer to the Operator's Manual
	Electrical protection. Isolated application with IEC60601-1 (type BF applied part)
	Wi-Fi. This symbol means wireless communication
	Non-ionizing radiation
	This way up. Indicates this correct vertical position of the transport package.
	Manufacturer. Indicates the manufacturer of the medical device as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
	Batch code. Indicates the manufacturer's lot code so that the lot can be identified
	Serial number. This means that the manufacturer's serial number and medical device can be identified.
	Model name. This means that the model name and the manufacturer's medical device can be identified.

	It appoints the representative in the European Community.
	Fragile and handled with care. Indicates a medical device that can be broken or damaged if not handled with care.
	Non-sterile
	Keep dry. It means a medical device that needs to be protected from moisture.
	Indicates medical device that should not be used if the package is damaged or opened.
	Atmospheric pressure limitation
	For indoor use only. Identify electrical equipment that is primarily designed for indoor use.
	Requires separate collection for Waste Electrical and Electronic Equipment (WEEE) compliant electrical and electronic equipment. Directive. When accompanied by or, device components may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local state federal laws. The backlight lamps on an LCD system monitor contain mercury.
	Identify electrical and electronic equipment that meets the Restriction of Hazardous Substances Directive (RoHS) 2011/65/EU.
	European compliance. In accordance with European Council Directive 93/42/EEC.
	Recyclable material. To indicate that the labeled item or its material is part of a recovery or recycling process.
Rx Only	Federal law restricts this device to sale by or on the order of a licensed (USA) healthcare professional.

	MR Insecure an item that poses unacceptable risks to the patient, medical staff, or others within the MR setting.
	Medical device Indicates that the item is a medical device
	Unique device identifier Indicates a carrier that contains Unique Device Identifier information The use of this symbol is optional, but it can be used when multiple media are present in the label. If used, this symbol should be placed next to the device's unique identifier holder. NOTE: Used to identify what information is associated with the Unique Device Identifier
	Model Number To identify a product's model number or type number This symbol must be accompanied by the model number or catalogue number of the product, adjacent to the symbol.
	importer Indicate the entity importing the medical device to the location This symbol must be accompanied by the name and address of the importing entity, adjacent to the symbol
	Distributor To indicate the entity distributing the medical device on site This symbol must be accompanied by the name and address of the distributor, next to the symbol

A. Label ID

No.	Templates	Label Current Version
1	LX128LC	
2	*LX128LP	
3	LX192LC	

*(*Some probe type may not be supported due to reginal regulatory registration).*

Problem	Possible cause	Solution
The probe has no power.	When the battery is discharged.	Charge the probe for at least 10 minutes and turn it on.
Battery defect or end of life.	.	Contact your local dealer or manufacturer
The probe is not charging.	Faulty battery or probe hardware problem	Contact your local dealer or manufacturer
	Faulty AC adapter.	Contact your local dealer or manufacturer
	Faulty wireless charger pad.	Contact your local dealer or manufacturer
	Faulty USB cable.	Contact your local dealer or manufacturer
	The power to the power grid is off.	Contact your local dealer or manufacturer
	The temperature is outside the specified limits.	Make sure the ambient temperature is within the specified limits
The display screen is blank when the device is turned on.	Connection interrupted during software load.	Contact your local dealer or manufacturer
Parts of the image are missing during scanning.	The channels are missing.	Contact your local dealer or manufacturer
No images are displayed during scanning.	Defective probe.	Contact your local dealer or manufacturer
The scan screen is not displayed.	The battery may not have enough charge.	Charge the probe for at least 60 minutes.
How to download the CE Declaration of Conformity from Leltek website?	1. Access to Leltek website. Move the page to the bottom and click the [Global] icon.	For more information, please refer to the following link (https://www.leltek.com/support/)
Failed to connect to mobile device	1. The probe uses the overcrowded Wi-Fi channel for data transmission, 2. Overcharging apps or low battery can also cause the image to get stuck, check the battery level 3. Close other apps on mobile devices to improve the situation	Try restarting the probe and plugging it in, as it may conflict with other Wi-Fi devices in the environment, For more information, please refer to the following link (https://www.leltek.com/support/)
Any serious incident that occurs in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established		

V. DEVICE MAINTENANCE

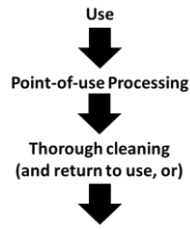
B. NOTICE

1. It is your responsibility to properly clean and disinfect your compatible smart device in accordance with the device manufacturer's instructions and your institution's medical device cleaning and disinfection policies.
2. If the compatible smart device is internally contaminated with pathogen-containing body fluids, you should immediately notify the manufacturer's service representative. The components inside the device cannot be disinfected. In this case, the device must be disposed of as biohazardous material in accordance with local or federal laws.
3. Always wear protective goggles and gloves when cleaning, disinfecting, or sterilizing any equipment.
4. Protective covers are recommended for transrectal and intravaginal procedures; In some regions, coverage is mandatory. The manufacturer recommends the use of qualified covers.

C. Reprocessing Equipment

1. Cleaning and Disinfection

2. Proper reprocessing instructions are essential to ensure effective device performance and prevent microbial transmission or patient infections. The compatible smart device is an undisassembled device. A reprocessing flowchart is presented below. Each detailed step of the reprocessing is listed in the following sections.



3. Point-of-use processing
   - a Items to use: Disposable paper towel.
   - b Please note that the item mentioned above must not include abrasive parts or abrasive cleaners.
   - c Turn off the device.
   - d Use a gentle wiping motion to remove any visible dirt or particulate matter from the surface of the transducer using a clean, disposable paper towel.
   - e Visually inspect and confirm the entire surface of the transducer without visible residual dirt or particulate matter. If some debris or contaminants dry on the surface of the transducer, follow the cleaning instructions (section below) to remove it.
   - f Confirm that the compatible smart device does not have cracks or other damage. If so, contact your local distributor or manufacturer's service representative immediately.
4. Complete cleaning
   - a Transducers should be cleaned before each use and it is suggested that the parts that can be cleaned with isopropyl alcohol are the transducer housing and the lens (acoustic window). Inspect all transducer parts carefully before each use. Check for cracks or other damage that could harm
   - b transducer integrity. Report any damage to the manufacturer's agent and discontinue use of the transducer.
   - c Use of disinfectants not recommended, use of incorrect dosages of solution, or immersion of a transducer deeper or longer than recommended may damage or discolor the transducer and void the transducer warranty.
5. Disinfection
   - a Spaulding ratings are a tool to help reduce cross-contamination and infection by specifying the level of cleaning and disinfection required for medical equipment. Based on these criteria, the

compatible smart device is classified as a "non-critical" or "semi-critical" device, because the device must scan the surface of the skin or mucous membranes and not penetrate it. Therefore, "low-level cleaning" and "disinfection" for non-critical devices and "high-level cleaning" and "high-level disinfection" for semi-critical devices are required for the next use.

Class	Use	Method	Example
Non-critical	Touches intact skin	Cleaning followed by low-level disinfection.	convex, linear, phase, microconvex
Semi-critical	Touches mucous membranes or non-intact skin	Cleaning followed by high-level disinfection.	Endocavity

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

When cleaning and disinfecting:

- Follow the procedures in the order they are described in this guide, without skipping steps.
- Use only 70% isopropyl alcohol on the device. Other solutions may be incompatible with the system and may damage the scanner.
- Follow the manufacturer's instructions, recommendations, and guidelines for cleaners and disinfectants, as well as regional regulations.
- Check the expiration dates, concentration, and effectiveness of the chemicals used.
- Wear the appropriate personal protective equipment (PPE), such as goggles and gloves, as recommended by the chemical manufacturer.
- Repeated use and cleaning over the life of the scanner can 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 disinfection processes (including repetitive processes) specified in this manual and may damage or deteriorate its safety arrangements.
- Cleaning or disinfecting the scanner while the battery is charging may cause the battery to short circuit and overheat, causing electric shock or burns.
- Cleaning or disinfecting the scanner with **isopropyl alcohol other than** IPA 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 disinfection among patients can spread infections to other patients and users.

- Recommendations for cleaning the ultrasound probe according to the following step:
- Turn off your devices before wiping them.
- To ensure that all coupling gel and other visible substances from the probe are removed with a clean paper towel. If necessary, to remove the dry material from the surface, the cloth can be moistened with warm water.
- Should inspect the lens and probe housing after each use. To check for any damage that allows liquid to enter the probe. If the user encounters a probe damage, the probe should not be placed in any liquid (e.g., for disinfection) and should not be used until it has been inspected and repaired/replaced by Leltek or a local distributor for service.

Recommendations for disinfecting the ultrasound probe (after cleaning):

- Spray 70% isopropyl alcohol on the surface of the probe head.
- Repeat step one two or three times.
- Wipe the sanitizer with a clean paper towel.

Pictures

Model	Photography
LX128LC	
*LX128LP	
LX192LC	

*(*Some probe type may not be supported due to reginal regulatory registration).*