LELTEK

Ultrasound Imaging System

LX Series (LX128LC, LX128LP, LX192LC)

Ver_01
LK_UI-LX-01**(US)**

Revision History

Revision	Date
User Manual Ver_01 1. First Edition	2024/4/24

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I. Using the Leltek Ultrasound Imaging System

A、 About This Manual

This document contains the following information:

- About the Leltek Ultrasound Imaging System: Describes the product, lists technical specifications, and its intended use.
- A Quick Tour: Shows you how to get started and begin scanning.
- Using the Leltek Ultrasound Imaging System: Introduces you to the features and concepts, helps you set up your system, and explains the tasks you can perform.
- Cleaning & Disinfecting: Explains how to clean and disinfect your System.
- Safety: Outlines important safety standards, principles, and policies to follow when using the product.
- References: Offers information such as product standards, regulatory requirements, terms and conditions, glossary of terms, and acoustic output data.

Target Audience	This document is written for trained medical professionals who operate and maintain user's Leltek Ultrasound Imaging System. It contains instructions and reference material pertaining to the usage and maintenance of the product.

B、 Indications for use

The Ultrasound Imaging System is a software-based imaging system and accessories intended for use by qualified physicians and healthcare professionals who has the ability to conduct ultrasound scan process for evaluation by ultrasound imaging system or fluid flow analysis of the human body.
The modes of operation include B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and the combined mode (B+M, B+CD, B+PWD). Specific clinical applications and exam types including:

Dual headed probe

LX128LC
Linear transducer: Abdominal, Adult Cephalic, Carotid, Musculoskeletal, Nerve, Ophthalmic, Pediatric, Peripheral Vessel, Pulmonary, Small Organ(Breast, Testes, Thyroid)
Convex transducer: Abdominal, Cardiac Adult, Cardiac Pediatric, Fetal, Gynecology, Musculoskeletal, Nerve, Obstetric, Pediatric, Peripheral Vessel, Small Organ (Breast, Testes, Thyroid)

LX128LP
Linear transducer: Abdominal, Adult Cephalic, Carotid, Musculoskeletal, Nerve, Ophthalmic, Pediatric, Peripheral Vessel, Pulmonary, Small Organ(Breast, Testes, Thyroid)
Phased Array transducer: Cardiac (adult),Cardiac (pediatric),FAST/EFAST,Fetal,General abdominal imaging,Nerve,Pediatric,Pulmonary

LX192LC
Linear transducer: Abdominal, Adult Cephalic, Carotid, Musculoskeletal, Nerve, Ophthalmic, Pediatric, Peripheral Vessel, Pulmonary, Small Organ(Breast, Testes, Thyroid)
Convex transducer: Abdominal, Cardiac Adult, Cardiac Pediatric, Fetal, Gynecology, Musculoskeletal, Nerve, Obstetric, Pediatric, Peripheral Vessel, Small Organ (Breast, Testes, Thyroid)

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

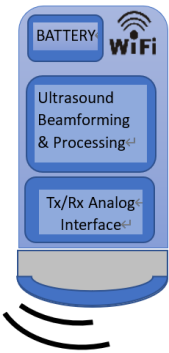
The Leltek Ultrasound Imaging System (Model: LX Series) is a portable, software controlled, handheld ultrasound system used to acquire and display hi-resolution, real-time ultrasound data through a commercial off-the-shelf (COTS) mobile device.

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

C、 Ultrasound Imaging System Description.

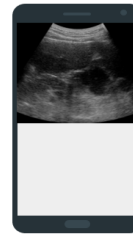
Start to use the LX Series Ultrasound System which include:

i. Ultrasound Probe
ii. Ultrasound App
iii. User's Tablet/Smart phone/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 the acoustic lens.
	Power Button/ Freeze button/	When Not Connected: - Press and hold the button: Powers on the probe. - Short press the button: Displays the current battery level. - Blue light is flashing: Indicates the probe is in the ON state. When Connected: - The Blue light is solid: WiFi is successfully connected. - Short press the button: Pauses the image or resumes the paused image 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).
	Operating indicator	- Solid blue light: Transducer active at this site
	Probe Cover	Protects the acoustic lens.

E、 Mobile device System Requirements

Android	Android: OS 7.0 or above Processor: 2GHz ARM-based CPU architecture with 2 or more core 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 pixel or higher.
iOS	iOS: 11.0 or above Processor: 2GHz ARM-based CPU architecture with 2 or more core 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 pixel or higher.
PC	Windows: Windows10 or above Processor: 1.6 GHz ARM-based CPU architecture with 2 or more core processor or higher. Memory: 8G or higher. Supported devices: Wi-Fi 802.11 a/b/g/n Display: Resolution (in pixels) of 1024X768 pixel or higher.

Regularly charge your mobile device to ensure it is fully powered

F、 Ultrasound App

Please download the App
Software name: "LELTEK Ultrasound – LeSono" "
Software Version:1.25.XX.X

1. from Android App store. Link: https://play.google.com/store/apps/details?id=com.leltek.leltekultrasound

2. from iOS App store. Link: https://apps.apple.com/gb/app/leltek-ultrasound-lesono/id1474760019

3. "LELTEK Ultrasound – LeSono" from Windows App directly download from official website:
https://www.leltek.com/support/release-notes-installer-windows/

G、 Probe Specifications

Model	Number of elements	Array type	Mode
LX128LC	Linear: 128 Convex:128	Linear, Convex	B mode, M mode, CF mode, Color Flow Doppler(CF), PW Doppler
LX128LP	Linear: 128 Phased Array: 64	Linear, Phased Array	
LX192LC	Linear:192 Convex: 192	Linear, Convex	

H、 Transducer Specifications：

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

I、 System Dimension

Model	Length (mm) x Width (mm) x Height (mm)	Weight(g)(with battery)
LX128LC	145x70x34	231(g)
LX128LP	145x70x34	241(g)
LX192LC	145x70x34	231(g)

J、 RF Energy Specification

2.4G :	5G :
- Tx frequency: 2412Mhz-2462Mhz - TX modulation: DSSS/CCK/OFDM - Tx Power: ■ 16dbm @1DSSS ■ 12.5dbm @54OFDM - Rx frequency: 2412Mhz-2462Mhz - Rx Sensitivity: 2.4 GHz: – 94.5 dBm at 1 DSSS	- Tx frequency: 5180Mhz-5825Mhz - TX modulation: OFDM - Tx Power: ■ 12dbm @54OFDM ■ Rx frequency: 5180Mhz-5825Mhz - Rx Sensitivity: - 5 GHz: –89 dBm at 6 OFDM

K、 Battery Specification

Item	Specification
Description	Rechargeable Li-ion Battery Pack
Capacity	3000mAh
Battery Life	300 discharge cycle
Battery Manufacture	HELIX CO., Ltd
Battery Model	703590
Cell Type	Prismatic cell
Battery Dimensions	93mm*35.5mm*7.2mm
Safety	UN38.3, EN IEC 62133

L、 Storage Limits


Storage Restrictions

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

Probes must be operated, stored, and transported in accordance with the following parameters:

A room free of corrosive gases.

project	operate	inventory	transport
pressure	700 hPa (525 mmHg) to 1060hPa (795 mmHg)	700 hPa (525 mmHg) to1060 hPa (795mmHg)	700 hPa (525 mmHg) to 1060 hPa (795mmHg)
humidity	Non-condensing humidity 15% to 95%	Relative turbidity 0% to 95%	Relative Temperatures≤90%
temperature	0°C to 35°C	-20°C to 50°C/	-20°C to 50°C

_____

About the Ultrasound Imaging System

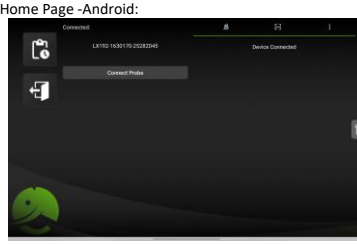
II. About the Ultrasound Imaging System

A. Start to use 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 transmit directly to the underlying tissues and the areas to be imaged. It is formulated to reduce static and act as a coupling agent.

B. Starting New Exams

Home Page -Android:



Home Page - iOS

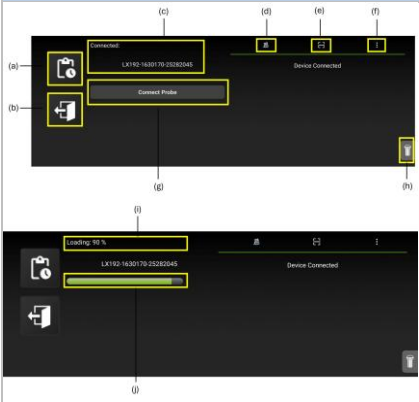
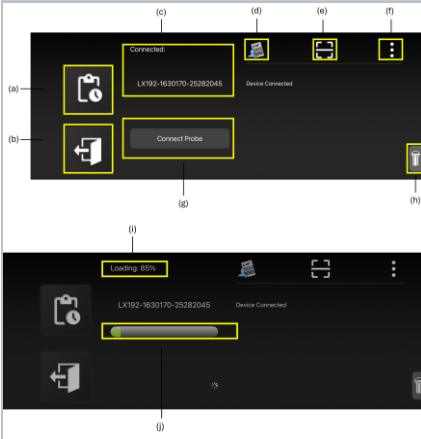
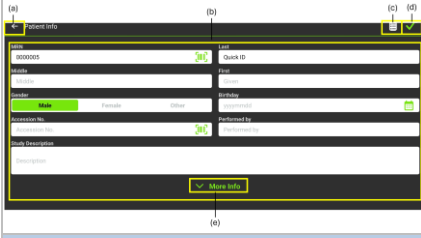
2. Step 1: After starting LELTEK app, please scan the QR code of the probe to be connected.
   - a When the user enters the Home Page, the system automatically scans the ultrasound probe which can be connected via the encrypted Wi-Fi.
   - b System lists the names, signal strength and quantities of the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

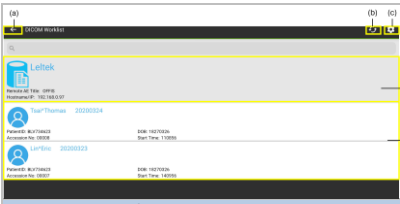
3. Step 2: When the selected probe is connected, the loading progress will appear.

Functions in Home Page

- a REVIEW: The user touches this button; the system will link to page "Saved Exam" and could be reviewing previously saved test data.
- b EXIT: The user touches the function button to exit from App.
- c : QR code scanner. Scan the QR code on the probe to connect it via Wi-Fi.
- d Connect Probe: The user can tap "Connect Probe" button to enter the main scanning page without re-connecting the probe via Wi-Fi.

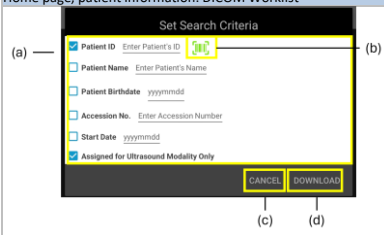
e : Enter Edit Patient Info page with worklist button. The user can download the worklist from the server or the latest records. If the user would like to download the data, he should set the worklist server first. If there is an existing server, the user can edit, delete or connect it.

Application interface design	
Home - Android	
	a. View button b. Leave button c. Current ultrasound probe d. Patient information button e. QR code scan button f. More information g. Connect probe button h. Probe list button i. & j. Connection percentage
Home - iOS	
	a. View button b. Leave button c. Current ultrasound probe d. Patient information button e. QR code scan button f. More information g. Connect probe button h. Probe list button i. & j. Connection percentage progress
Home page, patient information	
	a. back button b. Edit patient information c. Download Worklist button (only displayed when the user enters this page from the home page) d. save button e. Show detailed table checkbox
Home page, patient information: DICOM Worklist	



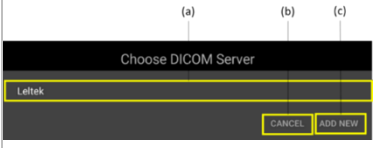
a. back button
b. Refresh server button
c. Edit server settings
d. Set search criteria button
e. Patient information downloaded from server

Home page, patient information: DICOM Worklist



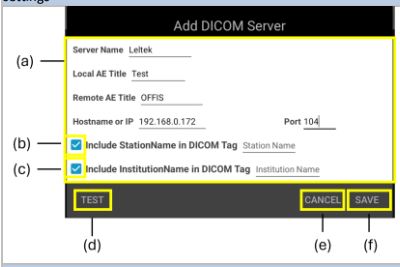
a. Select and enter search criteria
b. Scan barcode button
c. Cancel button
d. download button

Home page, patient information: DICOM Worklist, DICOM server settings



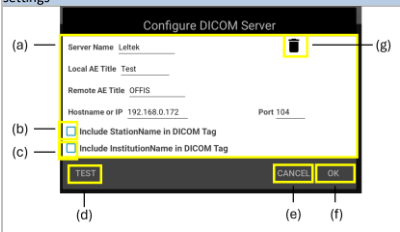
a. List of existing servers
b. Cancel button
c. Add server button

Home page, patient information: DICOM Worklist, DICOM server settings



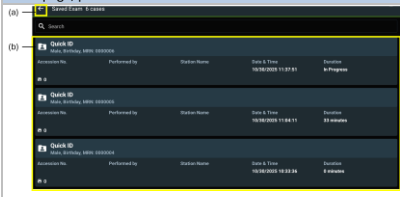
a. Edit server information
b. Shows a checkbox for the station name field
c. Shows a checkbox for the institution name field
d. Test server response button
e. Cancel button
f. Save server settings button

Home page, patient information: DICOM Worklist, DICOM server settings

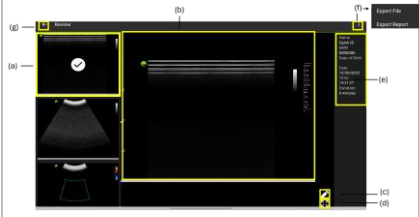
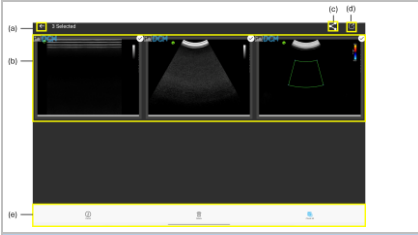
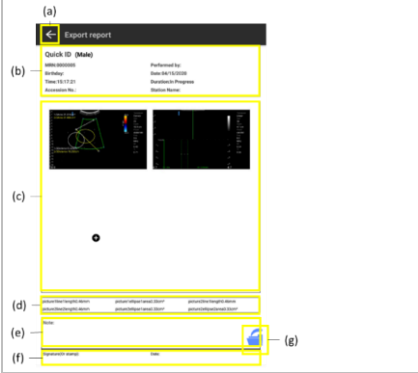
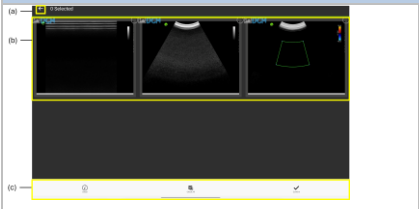


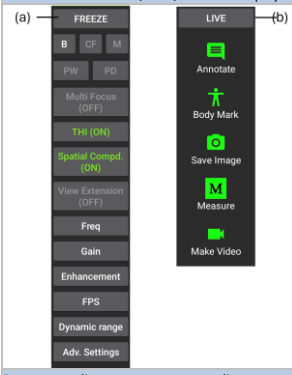
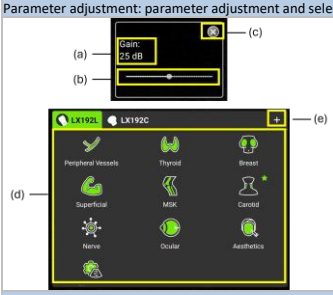
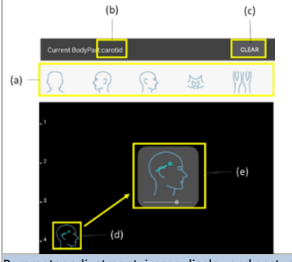
a. Edit server information
b. Shows a checkbox for the station name field
c. Shows a checkbox for the institution name field
d. Test server response button
e. Cancel button
f. Save server settings button
g. Delete server button

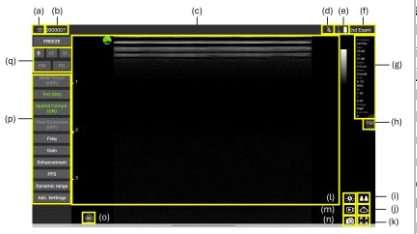
Home page, patient information: stored test



a. Patient information record
b. back button

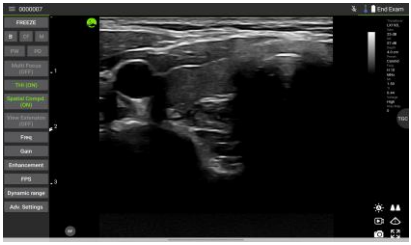
Home Page, Patient Information: View	
	a. Saved images and videos b. View selected saved image or video c. Re-Edit d. full screen e. Current settings f. Batch management of images and videos, export of images and videos/export reports g. back button
Home page, patient information: batch management	
	a. back button b. Saved images (DICOM: optional), saved images and videos c. Share button d. Export button (including DICOM: optional) e. Toolbar
Home Page, Patient Information: DICOM Server Settings	
	a. back button b. Refresh server button c. 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 Page, Patient Information: Export Report (Selected Image)	
	a. back button b. Saved image c. Toolbar

Annotate and measure, save, resume and playback: pause/scan	
	a. Scan: Mode button combination in scanning state (optional) b. pause
Parameter adjustment: parameter adjustment and selection of human body parts to be scanned	
	a. Parameter names and values b. Adjust progress bar c. Cancel button d. human body parts e. Add custom preset
Annotations and Measurements: Human Markings	
	a. Labeled images of human body parts b. human body parts c. Buttons to close windows (d) and (e) d. Human body mark image containing position mark e. Adjust position mark
Parameter adjustment, image display and gestures: scanning	

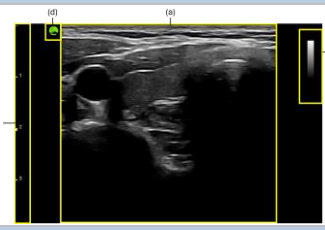


a. Menu button
b. Patient information
c. image
d. Voice control status
e. Ultrasound probe status
f. End detection button
g. Current settings
h. TGC button
i. Dual screen mode
j. Middle line
k. Full screen button
l. IQ Scan button
m. Video button
n. Save image button
o. Select human body part button
p. Parameters
q. Mode button

Parameter adjustment, image display and gestures: mode

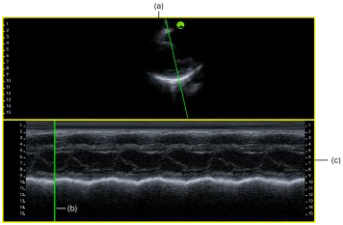


B mode

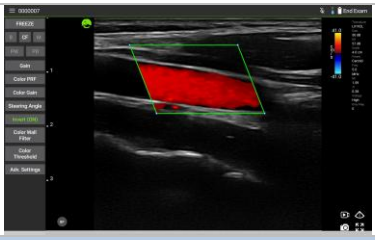


a. Image
b. Depth gauge
c. Grayscale
d. Mirror mark

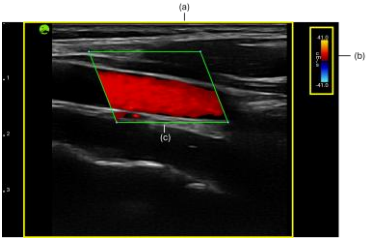
M mode



a. B mode images
b. M line
c. Time base grid

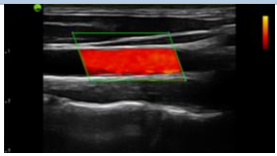


CF mode (optional)

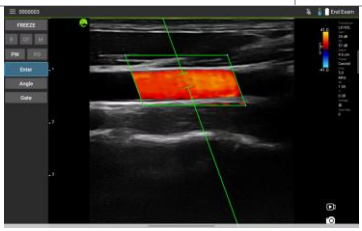


a. Image
b. Color code
c. Local area of interest (ROI)

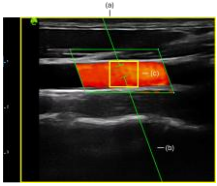
D (Power Doppler) mode (optional)



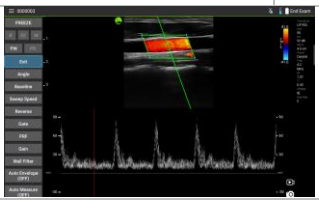
a. Except for a certain color used to represent blood flow intensity, everything else is the same as CF mode.

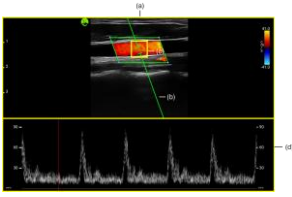


Pre-set PW Gate location (optional)



a. Paused CF mode image
b. LOI(line of interest)
c. Spacing, beam/stream angle differences

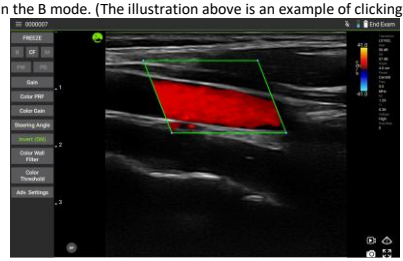


PW (pulsed ultrasound) mode (optional)	
	a. Paused CF mode image b. LOI (line of interest) c. Spacing, beam/stream angle differences d. Time grid, baseline, blood flow value and range between two blood flow values

4. **SCAN (LIVE):**

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

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



D. Step 5: Switch to CF mode (Optional)

1. Functions in SCAN (LIVE) **Mode selection:**
   - a Touch B, the system would be selected for B mode which means a two-dimensional ultrasound image display composed of bright dots representing the ultrasound echoes.
   - b Touch CF (Optional), the system would be selected for CF mode, the velocity and direction of blood flows are depicted in a color map superimposed on the 2-D image. Color flow is showed in ROI. Its size and location are adjustable.
   - c Touch M, the system would be selected for M mode, a diagnostic ultrasound presentation of the temporal changes in echoes in which the depth of echo-producing interfaces is displayed along one axis and time is displayed along the second axis, recording motion of the interfaces toward and away from the transducer.
   - d Touch PW to enter PW mode sample gate positioning (Optional). Select the gate position and adjust gate size, gate angle and image gain base on CF mode.
   - e Touch PW Enter (Optional), the system would be selected for PW (Pulsed wave) Doppler mode, it is moving objects change the characteristic of sound waves. By sending short and quick pulses of sound, it becomes possible to accurately measure the velocity of blood in a precise location and in real time.
   - 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 that are located inside organs.
2. Parameter Turning:
   - a Depth: The depth of penetration is related to the frequency of

the ultrasound wave. Higher frequencies have a shorter depth of penetration. Lower frequencies have a longer depth of penetration.

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

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

d Gain: The 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 averaged as they are displayed to reduce the variations in the image between frames, hence lowering the temporal resolution of the image. This function can be used to adjust different image processing levels to reduce image noise and make the image more delicate. 0 means this function is off.

f Enhancement: Imagine enhancement processing

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

h TGC: (Time Gain Compensation). Ability to compensate for the attenuation of the transmittal beam as the sound wave travels through tissue in the body. The goal of TGC is to make the entire image look evenly lit from top to bottom.

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

j Dynamic range: When the user touches this button, it allows the user to tell the transducer how does want the echo intensity displayed as shades of gray. A broad range will display more shades of gray and an overall smoother image. A narrow range will display fewer shades of gray and appear as a higher contrast with a more black-and-white image.

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

l Freeze Timer: When the user touches this button, the system could be selected how many second 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 touches this button, the time is between the onset of one pulse till the onset of the next pulse. It is measured in units of time. This parameter includes the time the pulse is “on” and the listening time when the transducer is “off”. It can be changed by the sonographer by varying the depth to which the signal is send.

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

q Steering Angle: The ultrasound scanning angle.

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

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

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

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

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

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

z PW Gate: Adjust the gate size to attempted the flow

measurements, the whole vessel should be insonated. A large gate may include signals from adjacent vessels.

aa PW PRF: When the user taps this button, the time is between the onset of one pulse till the onset of the next pulse. It is measured in units of time. This parameter includes the time the pulse is "on" and the listening time when the transducer is "off". It can be changed by the sonographer by varying the depth to which the signal is sent.

bb PW Gain: Remove or strengthen 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 human body. The user can directly tap the scanned part of human body in BP to obtain current scanned part of human body. Users can also add customized preset.

3. Multimedia:

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

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

FREEZE:

E. Step 6: Touch FREEZE, the system is stopping the image during the scanning; or re-activating the stopped image. When the image is frozen, the latest 200 frames could be showed. The annotate could be added. The frozen image could be saved for later review. The measure function is also enabling to measure for the length and the area.

1. Functions in FREEZE

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

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

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

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

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

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

1. Functions in General

a Menu:

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

c Review: After entering Review in current diagnosis, the user can choose to display an ultrasonic image or video in Cine

Graphic to review. When tapping  , user can choose “Batch Management” or “Export report”. Tap Batch Management, the user can multiple select, delete, export stored images (Available Format: .jpg, .png, .bmp and.dcm,.dcm is Optional) or videos (Available Format: .mp4) to local storage and upload DICOM (Optional) files to the server. Tap Export report, the user can export the diagnosis to pdf with the patient info, selected images, measurement info, annotation, signature and date.

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

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

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

g Others:

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

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

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

2. * Additional features

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

b The combination of mode buttons in scanning state (Optional):

c Case 1: B mode and M mode in Live status

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

C. Ultrasound Gels

3. Ultrasound gel is a type of conductive medium that allows a close bond between the skin and the probe or transducer, causing the waves to transmit directly to the underlying tissues and the areas to be imaged. It is formulated to reduce static and act as a coupling agent.
4. Ultrasonic gel is usually composed of propylene glycol, water and occasionally a dye. The dye is mostly for aesthetic purposes. The gel is usually clear and thick, and a slightly sticky. This means the gel does not drip or run off after application to the skin. Post procedure, the gel can be wiped off with ease.
5. Do NOT use non-recommended gels (lubricants). These may damage the probe and void the warranty.
6. Ultrasound Gels should NOT contain any of the following ingredients, which have the potential to damage the probe.
   a Olive oil
   b Methyl or ethyl parabens (para hydroxybenzoic acid)
   c Dimethyl silicone
   d Iodine
   e Lotions
   f Lanolin
   g Aloe Vera
   h Mineral oils
   i Methanol, ethanol, isopropanol alcohol, or any other alcohol-based gels

7. During the ultrasound Imaging diagnostic procedure, the examiner shall wear ""patient examination gloves"". A patient examination gloves are disposable devices intended for medical purposes and are worn on the examiner's hand or fingers to prevent contamination between patient and examiner.

I. SAFETY

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

A. Contraindications and Warnings

1. Battery Safety:
   - a DO NOT ignore the specified usage instructions for lithium-ion batteries in medical diagnostic equipment. Failure to follow the specifications may result in accidents, and the manufacturer will not accept responsibility.
   - b DO NOT leave a battery unused for long periods, as it can leak and damage electronics. If the equipment remains unused for more than a week, charge the battery using a power supply compliant with IEC 60601-1 for a two MOPP insulation system. Regularly check or replace the charging power supply.
   - c DO NOT charge the battery near fire or heat sources.
   - d DO NOT use the equipment if the battery leaks or emits an odor. Turn off the equipment and contact the local representative.
   - e If the battery will be unused for more than a 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 the local representative.
   - g DO NOT charge the battery near fire or heat sources.

2. Mechanical Safety:
   - a DO NOT use in a patient who would be harmed caused by applying ultrasound.
   - b DO NOT drop the probe or subject them to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the housing may result.
   - c DO NOT use the probe with high frequency surgical equipment. Doing so may damage the equipment.
   - d DO NOT use the product close to strong electromagnetic field, electromagnetic wave and magnetic environment. There is possibility of measurement errors or damage to the product.
   - e DO NOT operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is not compliant in AP/APG environments as defined by IEC 60601-1.
   - f To avoid risk of electrical shock hazards, always inspect the transducer before use. Check the face, housing, and cable before use. DO NOT use if the face is cracked, chipped, or torn; the housing is damaged; or the cable is abraded.
   - g DO NOT take the probe into an MR environment. MR Unsafe items should not enter the MRI scanner room, and patients with MR Unsafe devices should not be scanned
   - h DO NOT The operating temperature of the ultrasound probe must remain below 43°C.
   - i DO NOT allow the transducer to contact the patient if the temperature of the transducer is higher than 43°C (109°F).
   - j DO NOT leave children unattended with the system. The transducers pose a choking hazard due to small, detachable parts and the transducer cable is a strangulation hazard.

3. Image Quality Waring:
   - a DO NOT use on patients who have had surgery that may have changed the composition of the examining tissue, as this could skew or alter the measured density.
   - b DO NOT use on patients whose bodies contain foreign artifacts (e.g., implants) in the examining tissue.
   - c DO NOT use for intra-operative purposes (e.g., defined as introducing a system into a surgical incision or burr hole).
   - d DO NOT use for ophthalmic purposes or any use that causes

the acoustic beam to pass through the eye.

e DO NOT attempt imaging on an open wound.

4. Software Safety
   a DO NOT allow potential damage to the product that may void your warranty or service contract, or result in the loss of patient or system data.
   b DO NOT use the system if any part is known or suspected to be defective or incorrectly adjusted. Cease use until repairs are made. Operating the system with defective or incorrectly adjusted components could expose you and/or the patient to safety hazards.
   c DO NOT attempt to remove, modify, override, or disable any safety device on the system under any circumstances. Interfering with safety devices could lead to serious personal injury or death.
   d DO NOT misuse the system; use it only for its intended purposes. 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, could result in serious injury or death.
   e DO NOT continue using the system if the system or the transducer appears to be malfunctioning. Immediately cease 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 applications may 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, refrain from use. Operating the system without proper training could lead to fatal or other serious personal injury.
   h DO NOT use the system with patients unless you have an adequate understanding of its capabilities and functions. Using the system without such understanding may compromise its effectiveness and jeopardize the safety of the patient, yourself, and others.
   i DO NOT ignore revealed or unrevealed vulnerabilities, as they may cause the system to function abnormally. DO NOT allow data breaches, as they may result in sabotage of OTS data.

5. Cybersecurity:
   a DO NOT neglect securing your credentials and patient information (e.g., names).
   b DO NOT assume the scanner stores patient-identifiable data.
   c DO NOT transfer data between the device and Ultrasound App unless it is encrypted.
   d DO NOT forget that image data, although unencrypted, does not contain identifiable information. To encrypt:
   e DO NOT use an untrusted Wi-Fi network.
   f DO NOT neglect using Wi-Fi Direct, which encrypts image data.
   g DO NOT use unsecured networks; ensure WPA protection and provide proper training for users.
   h DO NOT ignore 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 into any liquid beyond the immersion level. Never immerse the probe connector into any liquid

7. Electrical Compatibility
   a DO NOT use your system in combination with other products or components unless expressly recognized by the manufacturer

as compatible.

b DO NOT hesitate to contact your local representative for information about such products and components.

c DO NOT make changes or additions to the system unless done by the manufacturer or third parties 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 within 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 pacemaker operation. Though the possibility of interference is slight, 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 those 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 the applied voltage standards, as this could result in electrical shock to the patient or operator, though this is unlikely.

8. Environment Compatibility

a DO NOT use at the scene of an emergency outside of a professional healthcare facility.

b DO NOT use during the transportation of a patient to a professional healthcare facility, or between professional healthcare facilities.

9. Acoustic Safety

a DO NOT exceed the acoustic output limit:

1. ISPTA.3 = 720 mW/cm^2 (50 for ophthalmic) for Track 3; for Track 3 ophthalmic,
2. TI ≤ 6.0(Max TIS as TIC ≤1)
3. MI ≤ 1.9 (0.23 for ophthalmic) for track 3;

10. FCC RF Radiation Exposure Statement

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

11. Information Safety

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

12. 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 competent authorities and covered with an aseptic probe sheath. The FDA’s recommendations to health professionals concerning latex awareness are as follows:

b DO NOT neglect to ask about latex sensitivity when taking patient histories, especially for surgical, radiology, or spina bifida patients and healthcare workers. DO NOT forget to include questions about symptoms like itching, rash, or wheezing after exposure to latex products, such as gloves or balloons, and mark charts for patients with positive histories.

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 latex contact; use non-latex gloves over latex ones. If both the healthcare professional 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 latex comes into contact with mucous membranes.

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

f DO NOT fail to advise patients with latex sensitivity to inform healthcare professionals and emergency personnel before medical procedures. DO NOT overlook recommending that patients with severe sensitivity wear a medical identification bracelet.

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

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

14. Maintenance and Trouble Shooting
    a DO NOT use this product if it is not functioning properly. Please Contact your local dealer or reach out to the manufacturer via email at info@leltek.com.

    b Follow the guide for troubleshooting:

Issue	Solution
No image or abnormal display after connected	When probe is connected normally but without ultrasonic image on screen or abnormal lines on the image, please check if there's electromagnetic interference (e.g.: other Wi-Fi signals) around and restart the scan. After operation of the above, if the situation remains, please contact the Customer Service Center.
Fail to connect with the mobile device	- Probe uses Wi-Fi for data transmission, and will automatically detect and select the best Wi-Fi channel when it's turned on. - When it is found that the picture is stalling, it may conflict with other Wi Fi devices in the environment, or the mobile device itself runs too many applications. Try to restart the probe and connect it. - Overloading Apps or low battery may also cause the picture to get stuck, please check the battery level or close other apps in the mobile devices to improve the situation

15. Disinfectants and Cleaning method
    a DO NOT use your compatible smart device unless it has been properly cleaned and disinfected according to the device manufacturer's instructions and your institution's policies for cleaning and disinfecting medical devices.
    b DO NOT ignore internal contamination of the compatible smart device with bodily fluids containing pathogens. You must notify the manufacturer's service representative immediately. 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 skip the use of protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.
    d DO NOT use unqualified protective covers for transrectal and intravaginal procedures. In some regions, these covers are mandatory. Always ensure the use of qualified protective covers recommended by the manufacturer.
16. Rework
    a DO NOT attempt to open a transducer or a transducer connector.
    b DO NOT modify this device without authorization.
17. 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 that contain lead or mercury in regular waste. Components containing these materials must be recycled or disposed of in accordance with local, state, and federal laws. 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 (RoHS) Directive

2011/65/EU.

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

B. Benefits & Risks

1. Ultrasound is widely used because it provides many clinical benefits to the patient and has an outstanding safety record. In more than three decades of use, there has been no known long-term negative side-effects associated to this technology.
2. More questions of safety are being discussed because more applications are being discovered, and the industry is producing technically sophisticated scanners that provide more diagnostic information. Dialogue among the medical community, manufacturers, and the FDA has resulted in a standard that allows higher outputs for greater diagnostic capability.
3. Ultrasound benefits:
    - a Multiple diagnostic uses
    - b Immediate results with high-quality information
    - c Replacement or complimentary or used with other procedures
    - d Cost-effectiveness
    - e Portability
    - f Patient acceptance
    - g Safety record

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

A. Acoustic Output and Measurement

1. The system limits patient contact temperature to 43°C (109°F), and acoustic output values to their respective U.S. Food and Drug Administration limits. A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive voltage to the transducer is shut off immediately, preventing overheating of the transducer surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.
2. Since the initial use of diagnostic ultrasound, the possible human bioeffects from ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, the American Institute of Ultrasound in Medicine (AIUM) ratified a report prepared by its Bioeffects Committee ("Bioeffects Considerations for the Safety of Diagnostic Ultrasound." Journal of Ultrasound in Medicine, Vol. 7, No. 9 Supplement, September 1988), sometimes referred to as the Stowe Report, which reviewed available data on possible effects of ultrasound exposure. Another report, “Bioeffects and Safety of Diagnostic Ultrasound,” dated January 28, 1993, provides more-current information. The acoustic output for this system has been measured and calculated in accordance with the “Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment” (Revision 3, AIUM, NEMA, 2004), the “Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment” (Revision 2, AIUM, NEMA, 2004), and the September 2008 FDA document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

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

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

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

5. Thermal Index (TI)

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

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

b The TI informs the user about the conditions that exist that might lead to an increase in temperature at the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. That is, the TI informs the user of the potential for temperature rise in body tissue. It is an estimate of temperature increase in body tissue with specific properties. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, mode of operation, and others. The TI should be used as a guide for implementing the ALARA principle. The bone thermal index (TIB) informs the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid; for example, at or near second- or third-trimester fetal bone. The cranial bone thermal index (TIC) informs the user about the potential heating of bone at or near the surface; for example, cranial bone. The soft tissue thermal index (TIS) informs the user about the potential for heating within soft homogeneous tissue. You can choose to display TIS, TIC, or TIB.

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

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

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

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

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

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

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

7. Other Effects
a A variety of other physical forces may also be produced by ultrasound energy. Although each of these effects can be demonstrated in vitro, there is no evidence that any of these physical phenomena has a significant biological effect on patients.
b Ensure that scanning time is kept to a minimum and that only medically required scanning is performed. Never compromise quality by rushing through an exam. A poor exam may require a follow‑up, which ultimately increases exposure time. Diagnostic ultrasound is an important tool in medicine, and like any tool, it should be used efficiently and effectively.
c B mode Depth: An increase in 2D depth will automatically decrease the 2D frame rate. This will decrease the TI. The system may also automatically choose a deeper 2D focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest MI value.
d Application: Acoustic output defaults are set when you select an application. Factory defaults vary with transducer,

application, and mode. Defaults have been chosen below the Intended use.

e Imaging Mode Controls: When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the TI is the sum of the contribution from the modes enabled, and the displayed MI is the largest of the MI values associated with each mode and focal zone enabled. The system will return to the previously selected state if a mode is turned off and then reselected.

f Transducer: Each transducer type has unique specifications for contact area, beam shape, and center frequency. Defaults are initialized when you select a transducer. Factory defaults vary with transducer, application, and selected mode. Defaults have been chosen below the Intended use.

8. ALARA Principles

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

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

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

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

d No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. The qualified personnel can adjust to improve image quality and minimize output intensity. There are several variables which affect the way in which the output display indices can be used to implement the ALARA principle. These variables involve:

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

9. Applying ALARA

a The system imaging mode of the operator selected that is depends on the user information needed. Understanding the nature of the imaging mode used, the transducer frequency, system setup values, scanning techniques, and operator experience allow the sonographer to meet the definition of the ALARA principle. The amount of acoustic output is up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, the potential localized heating of the patient due to transducer surface temperatures. Prudent use of the system occurs when patient exposure is limited to the lowest index reading for the shortest amount of time necessary to achieve acceptable diagnostic results. A high index reading does not necessarily indicate the occurrence of a bioeffect; however, it must be taken seriously. It is the operator responsibility to make every effort to reduce the possible effects of a high index reading by limiting exposure time.

b Limiting exposure time is an effective way to accomplish this goal. There are several system controls that the operator can use to adjust the image quality and limit the acoustic intensity. These controls are related to the techniques that an operator might use to implement ALARA. These controls can be divided into three categories: direct, indirect, and receiver controls.

10. Using System Controls to Implement ALARA

a Direct Controls: The system has no direct control for output, therefore the sonographer must control exposure time and scanning technique to implement the ALARA principle. To ensure that acoustic and thermal limits are not exceeded for all imaging modes, the system is designed to automatically adjust output. The system does not exceed a spatial peak temporal average intensity (I SPTA) of 720 mW/cm2for all imaging modes. The equipment's mechanical index (MI) does not exceed values greater than 1.9 and thermal index (TI) does not exceed values greater than 6.0.

b Indirect Controls: The indirect controls are those that have an

indirect effect on acoustic intensity. These controls affect imaging mode, pulse repetition frequency (PRF), pulse length. The choice of imaging mode determines the nature of the ultrasound beam. 2D is a scanning mode; Doppler is a stationary or un-scanned mode. A stationary ultrasound beam concentrates energy in a single location. A moving or scanned ultrasound beam disperses the energy over an area and the beam is concentrated on the same area for a fraction of the time as that of an un-scanned mode.

c Receiver Controls: Receiver controls are used by the operator to improve image quality. These controls have no effect on output. Receiver controls only affect how the ultrasound echo is received. These controls include gain, time gain compensation (TGC), dynamic range, and image processing. The important thing to remember, relative to output, is that receiver controls should be optimized before output is increased. For example, before increasing output, optimize gain to improve image quality.

d An Example of Applying the ALARA Principle: An ultrasound scan of a patient's liver begins with selecting the appropriate transducer frequency. After selecting the transducer and the application, which are based on patient anatomy, adjustments to output power should be made to ensure that the lowest possible setting is used to acquire an image. If an adequate image can be obtained with the increase in gain, then a decrease in output should be made. Only after making these adjustments should, you increase output to the next level. Having acquired the 2D display of the liver, Color can be used to localize blood flow. As with the 2D image display, gain and image processing controls must be optimized before increasing output. In summary: Select the correct transducer frequency and application for the job; start with a low output level; and optimize the image by receiver gain, and other imaging controls.

e Disturbances in cardiac rhythm during perfusion studies using gas ultrasound contrast agents have been observed in the diagnostic range of Mechanical Index (MI) values. For details, see the specific package insert of the contrast agent used.

11. Output Display

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

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

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

d Mitigating factors that might create artificially high or low thermal index readings: location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the thermal index displays?

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

f Always limit ultrasound exposure time. Do not rush the exam.

Ensure that the indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

12. Display Accuracy
    a The MI and TI have a precision of 0.01 unit on the system.
    b Estimates of the MI and TI display accuracies are shown in the Acoustic Output Tables. Many factors are considered when estimating the accuracy of the displayed values:
    c Hardware variations, such as piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations.
    d Estimation algorithm accuracy, including variations in pulser voltage control, operation conditions, and efficiencies.
    e Measurement variability, such as inaccuracies in laboratory measurements caused by hydrophone calibration and performance, positioning, alignment, and digitization tolerances, and variability of test operations.
    f Controls Affecting the Indices
        1. B mode Controls
        2. Transducer Frequency
        3. Color Controls
    g Color Sector Width: Narrower color sector width will increase color frame rate and the TI will increase. The system may automatically decrease pulse voltage to stay below the system maximum. A decrease in pulse voltage will decrease the MI.
    h Color Sector Depth: Deeper color sector depth may automatically decrease color frame rate or select a new color focal zone or color pulse length. The TI will change due to the combination of these effects. Generally, the TI will decrease with increased color sector depth. MI will correspond to the MI of the dominant pulse type which is a color pulse.
    i Measurement Precision and Uncertainty of Acoustic Output Values: The measurement precision of quantities is listed in the table below. They are measured as part of determining MI or TI values. Quantities are listed as one standard deviation, in percentage.

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

III. Technical Features

A. PCBA

1. There are some of the technical aspects of the system as following list:
   - a Receive frequency and/or band and bandwidth of receiving section.
   - b Transmit frequency and/or band, modulation, and ERP
   - c Functions: Image data transmit and control data communications
   - d High performance computing technology of FPGA
   - e unique technology "Ultra Image Block Algorithm" (UIBA) solution for B mode, Color mode, M mode, Power Doppler and PW Doppler block image
   - f High frame rate
   - g High contrast
   - h High resolution
   - i Tissue Harmonic Imaging
   - j Support Image Mode
   - k B mode
   - l Color Doppler
   - m M mode
   - n PW Doppler
   - o Power Doppler
2. Internal battery continuous use of time
   - a B mode (approx.) 1.5 hours
   - b Color Doppler(approx.) 1 hours
   - c M mode(approx.) 1.5 hours
   - d PW Doppler(approx.) 1hours.
   - e Power Doppler(approx.) 1hours

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

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

Parameter	Specification	Comment
IEEE 802.11 Level	IEEE 802.11a/b/g/n	802.11b ch 1-11 802.11g ch 1-11 802.11n 20M 802.11a 5150-5250 (UNII-1) 802.11a 5725-5850 (UNII-3)
Wireless Signal Rate	1 - 11 Mbps (IEEE 802.11b) 6 - 54 Mbps (IEEE 802.11g) 6 - 54 Mbps (IEEE 802.11a)	Actual data throughput is lower and is affected by distance from the device and packet error rates network condition, environment factors, etc.
Security Type	WPA2. 128 works as AP mode connection with SSID selection and password required; only one authenticated connection at a time.	Encryption for improved security and authentication for secured connection.
Redundancy mechanism	CRC	Metadata checking for integrity
Distance between the 128 and the mobile device	<3 meter; <1 meter if in crowded environment	In most tests See Wi-Fi coexistence testing.
Error rate	<5%	See Wi-Fi coexistence testing.
Data frame rate (regarding data latency and throughput)	8 fps	See Wi-Fi coexistence testing. By default the normal condition frame time is about 0.128s, one sigma is about 0.009s.

B. Clinical measurement range and accuracies

Measurement	Units	Useful Range	Reported Accuracy	Limitations or Conditions	
				Probe	Mode of operations
Distance:					
Vertical	mm	Full screen	Max error. 2.17 % Max error. 2.5% Max error. 2.8% Max error. 1.81 % Max error. 2.5% Max error. 3.6% Max error. 1.9% Max error. 2.8%	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■B
Horizontal	mm	Full screen	Max error. 1.67 % Max error. 0.7% Max error. 3.0% Max error. 1.67 % Max error. 2.9% Max error. 2.8% Max error. 3.5% Max error. 2.8%	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■B
Area:					
Circle	mm^2	Full screen	Max error 2.15% Max error 3.45% Max error 3.47% Max error 1.81% Max error 2.3% Max error. 3.9% Max error. 3.5% Max error. 2.5%	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■B
Dead Zone					
Dead Zone	mm^2	-	0 mm 0 mm 1mm 0 mm 0 mm 0 mm 2 mm 0 mm	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■B
Doppler					
Velocity	mm/s	Full screen	Max error 3.81% Max error 4.48% Max error6.31% Max error 3.00% Max error 4.1% Max error. 2.8% Max error. 3.6% Max error. 2.7%	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■PWD

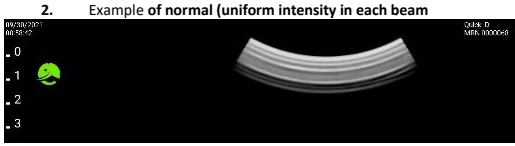
1. * Perform Traducer Element Check

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

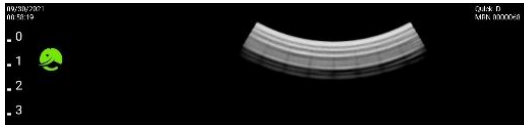
Press the button Advanced Settings in the left menu of the main view . the user can

use Transducer Check to determine if the element working as intended. The system transmits and receive by a designed sequence and form the image. The abnormal intensity variations (e.g. dark lines) near the surface shall be considered the possible element failure. Contact the service for guide on further actions needed.

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



3. Example of probmatic element or channel failure.



4. Compliance Statement
   The products comply with international and national standards and laws. Users are responsible for ensuring that the chosen smart device and scanner are compliant with the law in the jurisdiction where the product is used. Leltek meets all regulatory standards listed in this chapter.
5. Product Classification
   The device with transducers: Class IIa/internally powered ME equipment.
   Transducers: Type BF applied parts, 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 Requirements for Safety, including all applicable collateral and particular standards, as well as all applicable deviations. System users are responsible for ensuring that the chosen device is compliant with the law in the jurisdiction in which the product is used.
7. System Specifications
   Gray shades: 256 in B-Mode
   Pressure, humidity, and temperature limits: These limits apply only to the transducer, not to the Android or iOS device on which the user run the imaging System app. It is the user's responsibility to select a compatible device that meets the needs of the user's clinical environment.
   For information about the user's device's environmental specifications, consult the documentation that accompanies users' device.

C. Acoustic Output Tables

[C5-2 Convex] Acoustic output reporting table

Acoustic Output Reporting Table for Track 3
Transducer Model: C5-2 Convex
Operating mode: B Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.69	0.72			0.72			NA	
Index Component Value			1.69	0.72	NA	NA	0.72	NA	NA	NA	NA
Associated Acoustic Parameters	$p_{r,a}$ at z_{MI} (MPa)		2.33								
	P (mW)			323.20	NA		323.20	NA		NA	NA
	P_{1x1} (mW)			79.18	NA		79.18	NA			
	Min of $[P_a(z_i), I_{ta,a}(z_i)x1cm^2]$ (mW)					NA					
	z_1 (cm)					NA					
	z_{bp} (cm)					NA			NA		
	z_b (cm)								NA		
	z_{sp} (cm)		6.22			NA			NA		
	z_{sw} (cm)		4.16								
	d at z_b (cm)								NA		
	f_{awf} (MHz)		1.91	1.91	NA		1.91	NA		NA	NA
	Dimof A_{aprt}	X(cm		3.14	NA		3.14	NA		NA	NA
		Y(cm		1.30	NA		1.30	NA		NA	NA
Other information	Mode Components		B	B	NA		B	NA		NA	NA
	t_d (usec)		1.05								
	prr (Hz)		2368.50								
	srr (Hz)		14.13								
	p_r at z_{pii} (MPa)		3.06								
	d_{eq} at z_{pii} (cm)								NA		
	$I_{pa,a}$ at $z_{pii,a}$ (W/cm^2)		405.00								
	Focal Length	FLX(c	6.40			NA			NA		
		FLY(c	4.20			NA			NA		
Operating Control Conditions	Focus (cm)		6.4	6.4	NA	NA	6.4	NA	NA	NA	NA
	Depth (cm)		12.6	12.6	NA	NA	12.6	NA	NA	NA	NA
	THI		ON	ON	NA	NA	ON	NA	NA	NA	NA
	Frequency (MH		3.6	3.6	NA	NA	3.6	NA	NA	NA	NA

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

Acoustic Output Reporting Table for Track 3
Transducer Model: C5-2 Convex
Operating mode: B+M Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.69	0.79			1.09			NA	
Index Component Value			1.69	0.70	0.03	0.09	0.70	0.16	0.39	NA	NA
Associated Acoustic Parameters	$p_{r,a}$ at z_{MI} (MPa)		2.33								
	P (mW)			312.20	14.87		312.20	14.87		NA	NA
	P_{1x1} (mW)			76.48	3.64		76.48	3.64			
	Min of $[P_a(z_i), I_{ta,a}(z_i)x1cm^2]$ (mW)					9.30					
	z_1 (cm)					3.42					
	z_{bp} (cm)					3.41			3.41		
	z_b (cm)								4.16		
	z_{sp} (cm)		6.22			6.22			6.22		
	z_{sw} (cm)		4.16								
	d at z_b (cm)								0.49		
	f_{awf} (MHz)		1.91	1.91	1.91		1.91	1.91		NA	NA
	Dimof A_{aprt}	X(cm		3.14	3.14		3.14	3.14		NA	NA
		Y(cm		1.30	1.30		1.30	1.30		NA	NA
Other information	Mode Components		B+M	B	M		B	M		NA	NA
	t_d (usec)		1.05								
	prr (Hz)		B:2288. M:108.5								
	srr (Hz)		13.62								
	p_r at z_{pii} (MPa)		3.06								
	d_{eq} at z_{pii}(cm)								0.48		
	$I_{pa,a}$ at $z_{pii,a}$ (W/cm^2)		405.00								
	Focal Length	FLX(c	6.40			6.40			6.40		
		FLY(c	4.20			4.20			4.20		

	gh										
Operating Control Conditions	Focus (cm)	6.4	6.4	6.4	6.4	6.4	6.4	6.4	NA	NA
	Depth (cm)	12.6	12.6	12.6	12.6	12.6	12.6	12.6	NA	NA
	THI	ON	ON	ON	ON	ON	ON	ON	NA	NA
	Frequency (MH	3.6	3.6	3.6	3.6	3.6	3.6	3.6	NA	NA
	M PRF(Hz)	114.0	--	114.0	114.0	--	114.0	114.0	NA	NA

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

Acoustic Output Reporting Table for Track 3
Transducer Model: C5-2 Convex
Operating mode: B+CF/B+PD Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.69	0.75			0.75			NA	
Index Component Value			1.69	B:0.40 CF: 0.35	NA	NA	B:0.40 CF:0.35	NA	NA	NA	NA
Associated Acoustic Parameters	$p_{r.a}$ at z_{MI} (MPa)		2.33								
	P (mW)			B: 178.60 CF: 94.30	NA		B: 178.60 CF: 94.30	NA		NA	NA
	P_{1x1} (mW)			B: 43.75 CF: 23.10	NA		B: 43.75 CF: 23.10	NA			
	Min of $[P_a(z_1), I_{ta,a}(z_1)x1cm^2]$ (mW)					NA					
	z_1 (cm)					NA					
	z_{bp} (cm)					NA			NA		
	z_b (cm)								NA		
	z_{sp} (cm)		6.22			NA			NA		
	z_{MI} (cm)		4.16								
	d at z_b (cm)								NA		
	f_{awf} (MHz)		B: 1.91	B: 1.91 CF: 3.17	NA		B: 1.91 CF: 3.17	NA		NA	NA
	Dimof A_{aprt}	X(cm		3.14	NA		3.14	NA		NA	NA
		Y(cm		1.30	NA		1.30	NA		NA	NA
Other information	Mode Components		B+CF	B+CF	NA		B+CF	NA		NA	NA
	t_d (usec)		1.05								
	prr (Hz)		B:1308. CF:3600								
	srr (Hz)		7.79								
	p_r at z_{pii} (MPa)		3.06								
	d_{eq} at z_{pii}(cm)								NA		
	$I_{pa,a}$ at $z_{pii,a}$ (W/cm²)		405.00								
	Focal Length	FLX(c	6.40			NA			NA		
		FLY(c	4.20			NA			NA		
Operating Control Conditions	Focus (cm)		6.4	6.4	NA	NA	6.4	NA	NA	NA	NA
	Depth (cm)		12.6	12.6	NA	NA	12.6	NA	NA	NA	NA
	THI		ON	ON	NA	NA	ON	NA	NA	NA	NA
	Frequency (MH		B:3.6 CF: 3.1	B:3.6 CF: 3.1	NA	NA	B:3.6 CF: 3.1	NA	NA	NA	NA
	Color PRF(kHz)		3.6	3.6	NA	NA	3.6	NA	NA	NA	NA

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

Acoustic Output Reporting Table for Track 3
Transducer Model: C5-2 Convex
Operating mode: PW Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.04	0.69			1.60			NA	
Index Component Value			1.04	NA	0.30	0.69	NA	1.16	1.60	NA	NA
Associated Acoustic Parameters	$p_{r.a}$ at z_{MI} (MPa)		1.62								
	P (mW)			NA	105.53		NA	105.53		NA	NA
	P_{1x1} (mW)			NA	25.85		NA	25.85			
	Min of $[P_a(z_1), I_{ta,a}(z_1)x1cm^2]$ (mW)					59.30					
	z_1 (cm)					3.42					
	z_{bp} (cm)					3.41			3.41		
	z_b (cm)								4.16		
	z_{sp} (cm)		5.52			5.52			5.52		
	z_{MI} (cm)		5.52								
	d at z_b (cm)								0.65		
	f_{awf} (MHz)		2.45	NA	NA		NA	2.45		NA	NA
	Dimof A_{aprt}	X(cm		NA	3.14		NA	3.14		NA	NA
		Y(cm		NA	1.30		NA	1.30		NA	NA
Other information	Mode Components		PW	NA	PW		NA	PW		NA	NA
	t_d (usec)		1.58								
	prr (Hz)		4170.00								
	srr (Hz)		NA								
	p_r at z_{pii} (MPa)		1.78								

	d_{eq} at z_{pii}(cm)								0.65		
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm²)		75.33								
	Focal Length	FLX(c	6.40			6.40			6.40		
		FLY(c	4.20			4.20			4.20		
Operating Control Conditions	Focus (cm)		6.4	NA	6.4	6.4	NA	6.4	6.4	NA	NA
	Depth (cm)		12.6	NA	12.6	12.6	NA	12.6	12.6	NA	NA
	Frequency (MH		2.6	NA	2.6	2.6	NA	2.6	2.6	NA	NA
	PRF(kHz)		4.17	NA	4.17	4.17	NA	4.17	4.17	NA	NA
	Gate(mm)		0.5	NA	0.5	0.5	NA	0.5	0.5	NA	NA

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

[L12-5 Linear] Acoustic output reporting table

Acoustic Output Reporting Table for Track 3
Transducer Model: L12-5 Linear
Operating mode: B Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.59	0.44			0.44			0.93	
Index Component Value			1.59	0.44	NA	NA	0.44	NA	NA	0.93	NA
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)		3.46								
	P (mW)			37.42	NA		37.42	NA		37.42	NA
	P_{1x1} (mW)			19.49	NA		19.49	NA			
	Min of $[P_a(z_i), I_{ta,\alpha}(z_i)x1cm^2]$ (mW)					NA					
	z_1 (cm)					NA					
	z_{bp} (cm)					NA			NA		
	z_b (cm)								NA		
	z_{sp} (cm)		1.20			NA			NA		
	z_{sw} (cm)		1.00								
	d at z_b (cm)								NA		
	f_{awf} (MHz)		4.74	4.74	NA		4.74	NA		4.74	NA
	Dimof A_{aprt}	X(cm		1.92	NA		1.92	NA		1.92	NA
		Y(cm		0.42	NA		0.42	NA		0.42	NA
Other information	Mode Components		B	B	NA		B	NA		B	NA
	t_d (usec)		0.52								
	prr (Hz)		3203.00								
	srr (Hz)		11.30								
	p_i at z_{pii} (MPa)		4.08								
	d_{eq} at z_{pii}(cm)								NA		
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm²)		391.30								
	Focal Length	FLX(c	1.20			NA			NA		
		FLY(c	1.00			NA			NA		
Operating Control Conditions	Focus (cm)		1.2	1.2	NA	NA	1.2	NA	NA	1.2	NA
	Depth (cm)		3.0	3.0	NA	NA	3.0	NA	NA	3.0	NA
	THI		ON	ON	NA	NA	ON	NA	NA	ON	NA
	Frequency (MH		10	10	NA	NA	10	NA	NA	10	NA

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

Acoustic Output Reporting Table for Track 3
Transducer Model: L12-5 Linear
Operating mode: B+M Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
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
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)		3.46								
	P (mW)			36.93	1.02		36.93	1.02		36.93	1.02
	P_{1x1} (mW)			19.23	0.53		19.23	0.53			
	Min of $[P_a(z_i), I_{ta,\alpha}(z_i)x1cm^2]$ (mW)					NA					
	z_1 (cm)					NA					
	z_{bp} (cm)					1.52			1.52		
	z_b (cm)								1.52		
	z_{sp} (cm)		1.20			1.20			1.20		
	z_{sw} (cm)		1.00								
	d at z_b (cm)								0.26		
	f_{awf} (MHz)		4.74	4.74	4.74		4.74	4.74		4.74	4.74
	Dimof A_{aprt}	X(cm		1.92	1.92		1.92	1.92		1.92	1.92
		Y(cm		0.42	0.42		0.42	0.42		0.42	0.42
Other information	Mode Components		B+M	B	M		B	M		B	M
	t_d (usec)		0.52								
	prr (Hz)		B: 3161.00								

			M:87.19								
	srr (Hz)		10.90								
	p_r at z_{pii} (MPa)		4.08								
	d_{eq} at z_{pii}(cm)								0.23		
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm²)		391.30								
	Focal Length	FLX(c	1.20			1.20			1.20		
		FLY(c	1.00			1.00			1.00		
Operating 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
	THI		ON	ON	ON	ON	ON	ON	ON	ON	ON
	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's no corresponding intended use or no data reported.											

Acoustic Output Reporting Table for Track 3
Transducer Model: L12-5 Linear
Operating mode: B+CF/B+PD Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.59	0.38			0.38			0.79	
Index Component Value			1.59	B:0.25 CF: 0.13	NA	NA	B:0.25 CF:0.13	NA	NA	B:0.52 CF:0.27	NA
Associated Acoustic Parameters	$p_{r\alpha}$ at z_{MI} (MPa)		3.46								
	P (mW)			B: 21.11 CF: 11.06	NA		B: 21.11 CF: 11.06	NA		B: 21.11 CF: 11.06	NA
	P_{1x1} (mW)			B: 10.99 CF: 5.76	NA		B: 10.99 CF: 5.76	NA			
	Min of $[P_r(z_i), I_{ta,\alpha}(z_i)x1cm^2]$ (mW)					NA					
	z_1 (cm)					NA					
	z_{bp} (cm)					NA			NA		
	z_b (cm)								NA		
	z_{pi} (cm)		1.20			NA			NA		
	z_{sp} (cm)		1.00								
	d at z_b (cm)								NA		
	f_{awf} (MHz)		B: 4.74	B: 4.74 CF: 4.83	NA		B: 4.74 CF: 4.83	NA		B: 4.74 CF: 4.83	NA
	Dimof A_{aprt}	X(cm		1.92	NA		1.92	NA		1.92	NA
		Y(cm		0.42	NA		0.42	NA		0.42	NA
Other information	Mode Components		B+CF	B+CF	NA		B+CF	NA		B+CF	NA
	t_d (usec)		0.52								
	prr (Hz)		B:1806.2 CF:4940								
	srr (Hz)		6.23								
	p_r at z_{pii} (MPa)		4.08								
	d_{eq} at z_{pii}(cm)								NA		
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm²)		391.30								
	Focal Length	FLX(c	1.20			NA			NA		
		FLY(c	1.00			NA			NA		
Operating Control Conditions	Focus (cm)		1.2	1.2	NA	NA	1.2	NA	NA	1.2	NA
	Depth (cm)		3.0	3.0	NA	NA	3.0	NA	NA	3.0	NA
	THI		ON	ON	NA	NA	ON	NA	NA	ON	NA
	Frequency (MH		B:10 CF: 5	B:10 CF: 5	NA	NA	B:10 CF: 5	NA	NA	B:10 CF: 5	NA
	Color PRF(kHz)		4.94	4.94	NA	NA	4.94	NA	NA	4.94	NA
NA indicates that there's no corresponding intended use or no data reported.											

Acoustic Output Reporting Table for Track 3
Transducer Model: L12-5 Linear
Operating mode: PW Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.07	0.43			1.71			0.82	
Index Component Value			1.07	NA	0.36	0.43	NA	0.82	1.71	NA	0.82
Associated Acoustic Parameters	$p_{r\alpha}$ at z_{MI} (MPa)		2.22								
	P (mW)			NA	33.14		NA	33.14		NA	33.14
	P_{1x1} (mW)			NA	17.26		NA	17.26			
	Min of $[P_r(z_i), I_{ta,\alpha}(z_i)x1cm^2]$ (mW)					NA					
	z_1 (cm)					NA					
	z_{bp} (cm)					1.52			1.52		
	z_b (cm)								1.52		
	z_{pi} (cm)		0.88			0.88			0.88		
	z_{sp} (cm)		0.86								
	d at z_b (cm)								0.28		
	f_{awf} (MHz)		4.31	NA	4.31		NA	4.31		NA	4.31
	Dimof	X(cm		NA	1.92		1.92	1.92		NA	1.92
		Y(cm		NA	0.42		0.42	0.42		NA	0.42

	A_{aprt}										
Other information	Mode Components		PW	NA	PW		NA	PW		NA	PW
	t_d (usec)		0.89								
	prr (Hz)		3920.00								
	srr (Hz)		NA								
	p_r at z_{pii} (MPa)		2.52								
	d_{eq} at z_{pii}(cm)								0.23		
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm²)		161.50								
	Focal Length	FLX(c	1.20			1.20			1.20		
		FLY(c	1.00			1.00			1.00		
Operating Control Conditions	Focus (cm)		1.2	NA	1.2	1.2	NA	1.2	6.4	NA	1.2
	Depth (cm)		3.0	NA	3.0	3.0	NA	3.0	12.6	NA	3.0
	Frequency (MH		4.2	NA	4.2	4.2	NA	4.2	2.6	NA	4.2
	PRF(kHz)		3.92	NA	3.92	3.92	NA	3.92	4.17	NA	3.92
	Gate(mm)		0.3	NA	0.3	0.3	NA	0.3	0.5	NA	0.3
NA indicates that there's no corresponding intended use or no data reported.											

[P4-2 Phased array] Acoustic output reporting table

Acoustic Output Reporting Table for Track 3
Transducer Model: P4-2 Phased array
Operating mode: B Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.61	0.75			0.75			NA	
Index Component Value			1.61	0.75	NA	NA	0.75	NA	NA	NA	NA
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)		2.12								
	P (mW)			214.40	NA		214.40	NA		NA	NA
	P_{1x1} (mW)			90.94	NA		90.94	NA			
	Min of $[P_a(z_1), I_{ta,\alpha}(z_1)x1cm^2]$ (mW)					NA					
	z_1 (cm)					NA					
	z_{bp} (cm)					NA			NA		
	z_b (cm)								NA		
	z_{pii} (cm)		3.92			NA			NA		
	z_{sii} (cm)		2.96								
	d at z_b (cm)								NA		
	f_{awf} (MHz)		1.74	1.74	NA		1.74	NA		NA	NA
	Dimof A_{aprt}	X(cm		2.05	NA		2.05	NA		NA	NA
		Y(cm		1.15	NA		1.15	NA		NA	NA
Other information	Mode Components		B	B	NA		B	NA		NA	NA
	t_d (usec)		1.05								
	prr (Hz)		2368.00								
	srr (Hz)		14.13								
	p_r at z_{pii} (MPa)		2.54								
	d_{eq} at z_{pii}(cm)								NA		
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$ (W/cm²)		233.80								
	Focal Length	FLX(c	3.20			NA			NA		
		FLY(c	3.00			NA			NA		
Operating Control Conditions	Focus (cm)		3.2	3.2	NA	NA	3.2	NA	NA	NA	NA
	Depth (cm)		6.3	6.3	NA	NA	6.3	NA	NA	NA	NA
	THI		ON	ON	NA	NA	ON	NA	NA	NA	NA
	Frequency (MH		3.6	3.6	NA	NA	3.6	NA	NA	NA	NA
NA indicates that there's no corresponding intended use or no data reported.											

Acoustic Output Reporting Table for Track 3
Transducer Model: P4-2 Phased array
Operating mode: B+M Mode

Index Label		MI	TIS			TIB			TIC	
			Scan	NonScan		Scan	NonScan		Scan	NonScan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.61	0.79			0.93			NA	
Index Component Value		1.61	0.73	0.04	0.06	0.73	0.14	0.20	NA	NA
Associated Acoustic Parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	2.12								
	P (mW)		207.20	9.87		207.20	9.87		NA	NA
	P_{1x1} (mW)		87.89	4.18		87.89	4.18			
	Min of $[P_a(z_1), I_{ta,\alpha}(z_1)x1cm^2]$ (mW)				7.18					
	z_1 (cm)				2.60					
	z_{bp} (cm)				2.60			2.60		
	z_b (cm)							2.96		
	z_{pii} (cm)	3.92			3.92			3.92		
	z_{sii} (cm)	2.96								
	d at z_b (cm)							0.79		
	f_{awf} (MHz)	1.74	1.74	1.74		1.74	1.74		NA	NA

	Dimof A_{aprt}	X(cm		2.05	2.05		2.05	2.05		NA	NA
		Y(cm		1.15	1.15		1.15	1.15		NA	NA
Other information	Mode Components		B+M	B	M		B	M		NA	NA
	t_d (usec)		1.05								
	prr (Hz)		B: 2288.16 M:108.9								
	srr (Hz)		13.62								
	p_r at z_{pii} (MPa)		2.54								
	d_{eq} at z_{pii}(cm)								0.78		
	$I_{pa.a}$ at $z_{pii,a}$ (W/cm²)		233.80								
	Focal Lengh	FLX(c	3.20			3.20			3.20		
		FLY(c	3.00			3.00			3.00		
Operating Control Conditions	Focus (cm)		3.2	3.2	3.2	3.2	3.2	3.2	3.2	NA	NA
	Depth (cm)		6.3	6.3	6.3	6.3	6.3	6.3	6.3	NA	NA
	THI		ON	ON	ON	ON	ON	ON	ON	NA	NA
	Frequency (MH		3.6	3.6	3.6	3.6	3.6	3.6	3.6	NA	NA
	M PRF(Hz)		114.0	--	114.0	114.0	--	114.0	114.0	NA	NA
NA indicates that there's no corresponding intended use or no data reported.											

Acoustic Output Reporting Table for Track 3
Transducer Model: P4-2 Phased array
Operating mode: B+CF/B+PD Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.61	1.66			1.66			NA	
Index Component Value			1.61	B:0.76 CF: 0.90	NA	NA	B:0.76 CF: 0.90	NA	NA	NA	NA
Associated Acoustic Parameters	$p_{r.a}$ at z_{MI} (MPa)		2.12								
	P (mW)			B: 214.90 CF: 173.9	NA		B: 214.90 CF: 173.9	NA		NA	NA
	P_{1x1} (mW)			B: 91.16 CF: 73.76	NA		B: 91.16 CF: 73.76	NA			
	Min of $[P_a(z_1), I_{ta.a}(z_1)x1cm^2]$ (mW)					NA					
	z_1 (cm)					NA					
	z_{bp} (cm)					NA			NA		
	z_b (cm)								NA		
	z_{sp} (cm)		3.92			NA			NA		
	z_{ss} (cm)		2.96								
	d at z_1 (cm)								NA		
	f_{awf} (MHz)		B: 1.74	B: 1.74 CF: 2.56	NA		B: 1.74 CF: 2.56	NA		NA	NA
	Dimof A_{aprt}	X(cm		2.04	NA		2.04	NA		NA	NA
		Y(cm		1.15	NA		1.15	NA		NA	NA
Other information	Mode Components		B+CF	B+CF	NA		B+CF	NA		NA	NA
	t_d (usec)		1.05								
	prr (Hz)		B:2373. CF:3600								
	srr (Hz)		14.13								
	p_r at z_{pii} (MPa)		2.54								
	d_{eq} at z_{pii}(cm)								NA		
	$I_{pa.a}$ at $z_{pii,a}$ (W/cm²)		238.80								
	Focal Lengh	FLX(c	3.20			NA			NA		
		FLY(c	3.00			NA			NA		
Operating Control Conditions	Focus (cm)		3.2	3.2	NA	NA	3.2	NA	NA	NA	NA
	Depth (cm)		6.3	6.3	NA	NA	6.3	NA	NA	NA	NA
	THI		ON	ON	NA	NA	ON	NA	NA	NA	NA
	Frequency (MH		B:3.6 CF: 2.6	B:3.6 CF: 2.6	NA	NA	B:3.6 CF: 2.6	NA	NA	NA	NA
	Color PRF(kHz)		3.6	3.6	NA	NA	3.6	NA	NA	NA	NA
NA indicates that there's no corresponding intended use or no data reported.											

Acoustic Output Reporting Table for Track 3
Transducer Model: P4-2 Phased array
Operating mode: PW Mode

Index Label			MI	TIS			TIB			TIC	
				Scan	NonScan		Scan	NonScan		Scan	NonScan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.76	1.28			3.87			NA	
Index Component Value			0.76	NA	0.79	1.28	NA	2.70	3.87	NA	NA
Associated Acoustic Parameters	$p_{r.a}$ at z_{MI} (MPa)		1.10								
	P (mW)			NA	186.53		NA	186.53		NA	NA
	P_{1x1} (mW)			NA	79.12		NA	79.12			
	Min of $[P_a(z_1), I_{ta.a}(z_1)x1cm$					127.80					

	^{2}] (mW)										
	z_s (cm)					2.60					
	z_{bp} (cm)					2.60			2.60		
	z_b (cm)								2.62		
	z_{pi} (cm)		3.08			3.08			3.08		
	z_{MI} (cm)		2.62								
	d at z_b (cm)								0.74		
	f_{awf} (MHz)		2.09	NA	2.09		NA	2.09		NA	NA
	Dimof A_{aprt}	X(cm		NA	2.05		NA	2.05		NA	NA
		Y(cm		NA	1.15		NA	1.15		NA	NA
	Mode Components		PW	NA	PW		NA	PW		NA	NA
	t_d (usec)		1.83								
	prr (Hz)		4170.00								
	srr (Hz)		NA								
Other information	p_r at z_{pi} (MPa)		1.33								
	d_{eq} at z_{pi}(cm)								0.73		
	$I_{pa,\alpha}$ at $z_{pi,\alpha}$ (W/cm^2)		33.17								
	Focal Lengh	FLX(c	3.20			3.20			3.20		
		FLY(c	3.00			3.00			3.00		
Operating Control Conditions	Focus (cm)		3.2	NA	3.2	3.2	NA	3.2	3.2	NA	NA
	Depth (cm)		6.3	NA	6.3	6.3	NA	6.3	6.3	NA	NA
	Frequency (MH		2.1	NA	2.1	2.1	NA	2.1	2.1	NA	NA
	PRF(kHz)		4.17	NA	4.17	4.17	NA	4.17	4.17	NA	NA
	Gate(mm)		0.5	NA	0.5	0.5	NA	0.5	0.5	NA	NA

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

D. Guidance and Manufacture's Declaration

1. LX Series requires special precautions regarding EMC.
2. LX Series should not be used adjacent to or stacked with other equipment.
3. Using the wrong cable and accessories may adversely affect the EMC performance
4. Do not use accessories which are not supplied or recommended by the manufacturer. Other accessories may negatively affect EMC performance.
5. Household electronic devices such as humidifiers, heaters or microwaves, and so on may be susceptible to cause 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 EM disturbances, please relocate the device accordingly.
8. Use of this device adjacent to or stacked with other devices should be avoided as it could result in improper operation.
9. Any part of the monitor should be used no closer than 30 cm (12 inches) to wireless communication devices, such as networking devices, mobile phones, and walkie-talkies, or it can result in error display or inaccurate results.
10. The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
11. The use of accessories (eg, cables, humidifiers) other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.

E. Electromagnetic Emissions

The LX Series is intended for use in electromagnetic environments, as specified below. The customer or the user of the LX Series should 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 healthcare) specified below. The customer or the user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance (for home and professional healthcare environment)
RF emissions CISPR 11	Group 1	The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class 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/flicker 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 healthcare) specified below. The customer or the user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare

			environment)
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ± 8 kV Air: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV line(s) to line(s) ± 0.5 kV, ±1 kV, ± 2 kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 25/30 cycles Voltage interruptions: 0 % UT; 250/300 cycle	Voltage dips: 0 % UT; 0,5 cycle 0 % UT; 1 cycle 70 % UT; 30 cycles Voltage interruptions: 0 % UT; 300 cycle	Mains power quality should be that of a typical home and professional healthcare environment. If the user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP requires continued operation during power mains interruptions, it is recommended that the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Manufacturer's declaration-electromagnetic immunity			
The LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance (for home and professional healthcare environment)
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP including cables, than the recommended separation distance calculated from

Radiated RF IEC	80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	80 % AM at 1 kHz 10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Interference may occur in the vicinity of equipment marked with the following symbol:
Proximity magnetic field IEC 61000-4-39	8 A/m at 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	8 A/m at 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 higher frequency range applies.

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

Recommended separation distance between
portable and mobile RF communications equipment and the 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 healthcare) in which radiated RF disturbances are controlled. The customer or the user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

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

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

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

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

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

The customer or the user of the LX192LC, LV192LC, LX128LC, LV128LC, LX128LP, LV128LP should assure that it is used in such an environment.

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

5 785							

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

a) For some services, only the uplink frequencies are included.

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

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

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

Frequencies	Test Level [A/m]	Modulation	Dwell time [s]	Compliance LEVEL [A/m] (for home and professional healthcare)
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 ME EQUIPMENT and ME SYSTEMS intended for use in the HOME AND PROFESSIONAL HEALTHCARE ENVIRONMENT.

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

(c) r.m.s., before modulation is applied.

F. Federal Communications Commission (FCC) Statement

15.21

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

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1) this device may not cause harmful interference and

2) this device must accept any interference received, including interference that may cause undesired operation of the device.

FCC RF Radiation Exposure Statement

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

A、 Maintenance

If this product is not functioning properly, you can contact your local dealer or reach out to the manufacturer via email: info@leltek.com

B、 Trouble Shooting

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

Manufacturer's address

LELTEK INC.
6F-3., No. 293, Sec. 1, Beixin Rd., Xindian Dist., New Taipei City 23147,
Taiwan, R.O.C

LeSONO www.leltek.com

Authorized Representative

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

IV. References

A、 Acoustic

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

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

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

B、 Biocompatibility

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

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

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

C、 Chemical

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

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

D、 Battery

i. UN 38.3 -Lithium Battery Transportation

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

E、 Wireless

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

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

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

F、 Waterproof

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

G、 Safety and Performance

i. IEC 60601-1 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 monitoring equipment

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

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

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

H、 Quality management

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

ii. ISO 14971:2019 Medical devices — Application of risk management to medical devices

I、 Labeling

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

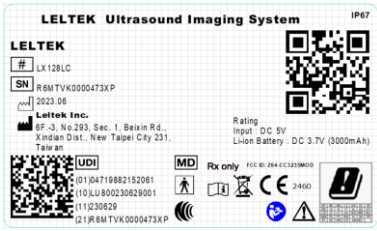
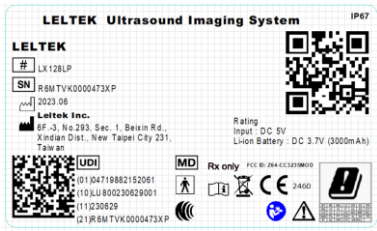
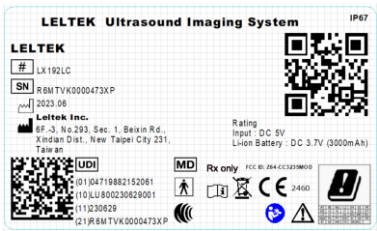
Symbols

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

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

	MR Unsafe an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	Medical device Indicates the item is a medical device
	Unique Device Identifier Indicates a carrier that contains Unique Device Identifier information The use of this symbol is optional, but may be used when multiple data carriers are present on the label. If used, this symbol shall be placed adjacent to the Unique Device Identifier carrier. NOTE Used to identify which information is associated with Unique Device Identifier
	Model number To identify the model number or type number of a product This symbol shall be accompanied by the model number or catalogue number of the product, adjacent to the symbol.
	importer To indicate the entity importing the medical device into the locale This symbol shall be accompanied by the name and address of the importing entity, adjacent to the symbol
	distributer To indicate the entity distributing the medical device into the locale This symbol shall be accompanied by the name and address of the distributing entity, adjacent to the symbol

A. Label ID

No.	Models	Label Current Version
1	LX128LC	
2	LX128LP	
3	LX192LC	

Problem	Possible cause	Solution
Probe has no power.	When battery is discharged.	Charge the probe for at least 10 minutes and then power on.
Battery defect or end of life.	.	Please Contact your local dealer or the manufacturer
Probe is not charging.	Defective battery or probe hardware issue	Please Contact your local dealer or the manufacturer
	Defective AC adapter.	Please Contact your local dealer or the manufacturer
	Defective wireless charger pad.	Please Contact your local dealer or the manufacturer
	Defective USB cable.	Please Contact your local dealer or the manufacturer
	Mains power is down.	Please Contact your local dealer or the manufacturer
	Temperature is outside the specified limits.	Ensure the ambient temperature is within the specified limits
Display screen is blank when the device is powered on.	Connection broken during software loading.	Please Contact your local dealer or the manufacturer
Parts of the image is missing when scanning.	Channels are missing.	Please Contact your local dealer or the manufacturer
No image displayed when scanning.	Defective probe.	Please Contact your local dealer or the manufacturer

Scan screen is not displayed.	Battery may not have sufficient charge.	Charge the probe for at least 60 minutes.
How to download the CE Declaration of Conformity on Leltek Website?	1. Access to Leltek Website. Move the page to the very bottom a click [Global/English] icon.	For more information, please refer to the following link (https://www.leltek.com/support/)
Fail to connect with the mobile device	1. Probe uses Overcrowded Wi-Fi channel for data transmission, 2.Overloading Apps or low battery may also cause the picture to get stuck, please check the battery level 3. Close other apps in the mobile devices to improve the situation	Try to restart the probe and connect it 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 has occurred in relation to the device should 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

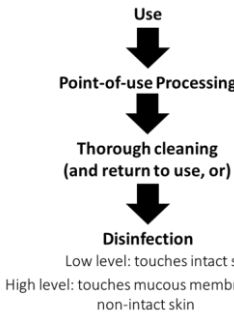
B. WARNING

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

C. Reprocessing Equipment

1. Cleaning & Disinfecting

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



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

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

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

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

When cleaning and disinfecting:

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

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

Recommendations for disinfecting the ultrasound probe (After cleaning):

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

Photos

Model	Photo
LX128LC	
LX128LP	
LX192LC