Ultrasound Imaging System

128 Series (LK128C, LK128L, LK128LH, LK128M, LK128PA, LK128E)

Ver_02

LK_UI-128-01 (USA)

Revision history

Revision	Date
User Manual Ver_01 First edition	2024/4/24
User Manual Ver_02 Add TDI	2025/07/24

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I. Using the Leltek Ultrasound Imaging System

A、About this manual

This document contains the following information:

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

Target audience	This document is written for trained medical professionals who operate and maintain the user's Leltek ultrasound imaging system. It contains instructions and reference material relating to the use and maintenance of the product.

B、Indications for use

The Leltek Ultrasound Imaging System (Model: Series 128) is a software-based imaging system and accessories intended for use by qualified physicians and healthcare professionals who have the ability to perform the ultrasound scanning process for evaluation by ultrasound imaging system or fluid flow analysis of the human body. Operating modes include B mode, M mode, PWD mode, Color Doppler (CD) mode, Power Doppler mode, and combined mode (B+M, B+CD, B+PWD, TD/TVI). Specific clinical applications and types of examinations, including:

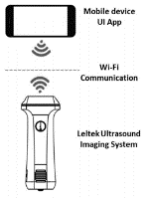
128 Series	LK128L	LK128LH	LK128C	LK128M	LK128PA	LK128E
Ophthalmic	●	●				
Fetal			●	●	●	●
Abdominal	●	●	●	●	●	●
Renal			●	●	●	
Cephalic Adult	●	●			●	
Pediatric Cephalic	△	△				
Carotid	●	●				
Musculoskeletal	●	●				
Muscle injuries	●	●				
Nerve	●	●	●	●		
Blockade	●	●	●			
Injury Identification	●	●				
Fast exam for Identification of bleeding internal	●	●				
Pleural effusion	●	●				
General abdominal imaging	●	●	●	●	●	●
Pediatric	△	△	△	△	△	△
Small Parts Small organ (**thyroid**, prostate, scrotum, **breast**,	●	●	●	●		●

128 Series	LK128L	LK128LH	LK128C	LK128M	LK128PA	LK128E
Testicles)						
Neonatal Cephalic	△	△		△		
Transrectal						•
Neonatal			△	△	△	
Transvaginal						•
Urology			•	•		•
Musculoskeletal (conventional)	•	•	•	•		
Musculoskeletal (superficial)	•	•				
Prenatal			△	△		△
Obstetrician			△	△		△
Obstetrician Gynaecologist			•	•		•
Cardiac, Adult			•	•	•	
Pediatric Cardiac	△	△	△	△	△	
Peripheral vessel	•	•	•	•		
Other (Carotid)	•	•				
Pulmonary	•	•	•	•	•	
interventionist orientation (freehand needle/catheter)	•	•	•	•		•
Punches Liquids.	•	•				

△: Intended to be used in fetuses, neonetal, pediatric
• : Intended for use in adults

The Leltek Ultrasound Imaging System (Model: Series 128) is a portable, software-controlled, portable ultrasound system used to acquire and display high-resolution, real-time ultrasound data via a commercial off-the-shelf (COTS) mobile device.

1.The imaging system software runs as an app on a mobile device.
2.The imaging system software can be downloaded to a commercial mobile device ready to use (COTS) and utilizes an icon touch-based user interface.
3.The imaging system consists of a series of wireless transducers that employ Wi-Fi-based technology to communicate with traditional tablet/smartphone devices via direct Wi-Fi. This allows the user to export ultrasound images and display them on a portable personal device.

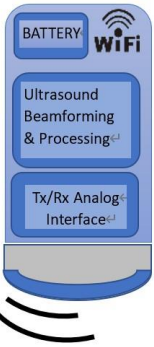


4.The imaging system houses a built-in battery, multi-channel beamformer, pre-scan converter, and Wi-Fi components

C、 Description of ultrasound imaging system.

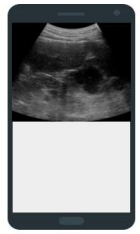
Get started with the 128 Series Ultrasound System, which includes:

i. Ultrasound Probe
ii. Ultrasound Application
iii. User Tablet/Smart phone/PC



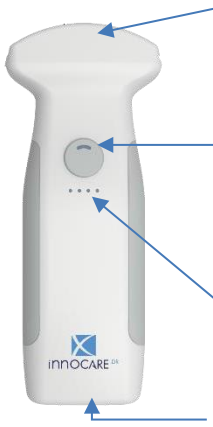
Ultrasound Probe

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



User Interface (APP) for Display

D、Ultrasound Probe

128 Series	Part Name	Meaning and purpose
	Probe cover	Protects the acoustic lens.
	Power button/ Freeze button	When not connected: - Press and hold the button: Turn on the probe. - Short press button: Displays the current battery level. - The purple light is always on: indicates that the probe is in the ON state. When connected: - The white light is solid: the WiFi has been successfully connected. - Short press the button: Pause the image or resume the paused image during scanning.
	Battery Indicator	- Flashing white light: Charging (the indicator light will turn off when the battery is fully charged). - Solid white light: Displays the current battery level (4 indicators show a full charge, 1 indicator shows a full charge). ow battery).
	Type-C charging port	To charge.

E、System Requirements for Mobile Devices

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

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

F、Ultrasound App

Download the app

Software name: "LELTEK Ultrasound – LeSono" "

Software version: 1.25.XX.X

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

2. "LELTEK Ultrasound – LeSono" from the iOS app store. Connection:
https://apps.apple.com/gb/app/leltek-ultrasound-lesono/id1474760019

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

G、Probe Specifications

Model	Number of Elements	Array Type	Mode
LK128C	128	Convex + Cardiac	B-mode, M Mode, CF Mode, Power Doppler (PD), PW Doppler (PWD), Tissue Doppler (TD: TVI/TDI) to cardiac application
LK128L	128	Linear	
LK128LH	128	Linear	
LK128M	128	Micro Convex	
LK128PA	64	Phased Array (Sectoral)	
LK128E	128	Endocavitary	

Template features

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

H、Power Specifications: Power Input

Interface: USB Type-C Input Voltage: 5V

I、Transducer Specifications:

Model	Bandwidth	Depth of	Array Type	Number of elements	Mode
LK128C	2.0~5.0	30cm	C5-2 Convex + Sectoral (Cardiac)	128	B-mode, M Mode, CF Mode, Power Doppler (PD), PW Doppler (PWD), Tissue Doppler (TD: TVI/TDI) to cardiac application
LK128L	4.2~12.5	12.6 cm	L10-5 Linear	128	
LK128LH	4~17	12.6 cm	L12-5 Linear	128	
LK128M	3.6~8.5	12.6 cm	M8-4 Micro Convex	128	
LK128PA	1.3~3.7	30cm	P4-2 Phased Array (Sectoral)	64	
LK128E	3.6~8.5	15cm	E8-4 Endocavitary	128	

J、System Dimension

Model	Length (mm) x Width (mm) x Height (mm)	Weight (g) (with battery)
LK128C	175x57x31	253
LK128L	167x57x31	223
LK128LH	170x57x31	238
LK128M	178x57x31	224
LK128PA	177x57x31	236
LK128E	344x57x31	266

K、RF Power Specification

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

L、Battery Specification

Item	Pecification
Description	Rechargeable lithium-ion battery
Ability	3000 or 5000 mAh
Battery life	300 discharge cycles
Battery manufacturing	PROPELLER CO., Ltd
Battery Model	703590
Cell Type	Prismatic cell
Battery Dimensions	93mm*35.5mm*7.2mm
Safety	UN38.3, EN IEC 62133

M、Storage Limits


Storage Restrictions

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

The probes shall be operated, stored and transported according to the following parameters:

A room free of corrosive gases.

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

_____

About Ultrasound Imaging System

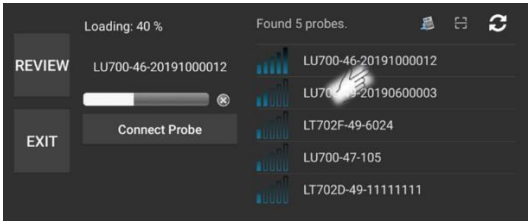
II. About Ultrasound Imaging System

A. Get Started With Ultrasound App

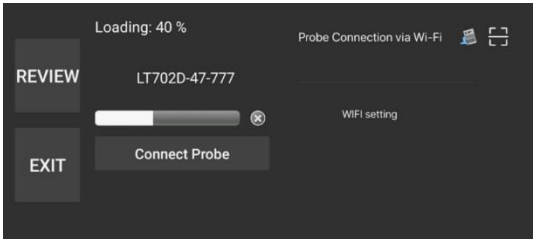
1.Ultrasound gel is a type of conductive medium that allows a close bond between the skin and the probe or transducer, causing the waves to be transmitted directly to the underlying tissues and areas to be viewed. It is formulated to reduce static and act as a coupling agent.

B. Starting new exams

Home -Android:



Home - iOS



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

3. Step 2: When the selected probe is connected, the charging progress will appear.
Functions on the home page
aREVIEW: The user taps this button; the system will link to the "Saved Exam" page and will be able to review previously saved test data.
bEXIT: The user taps the function button to exit the app.

c  : The transducers that will be automatically detected to be connected via Wi-Fi. (Android or iOS only)
dProbes found: The transducers that will be automatically detected to be connected via Wi-Fi; The user can then select the corresponding transducer. (Android or iOS only)
eWi-Fi Configuration Button: The user can manually select an ultrasound probe on the Wi-Fi settings page. (iOS only)

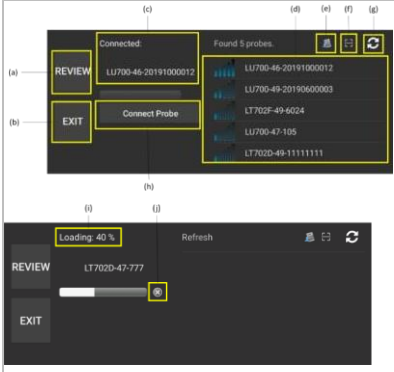
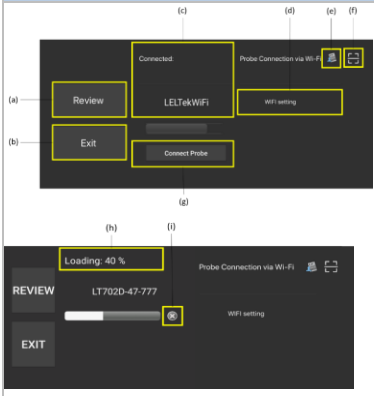
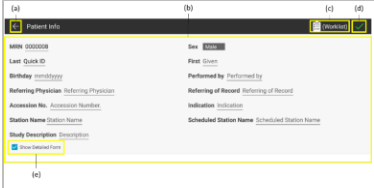
f  : QR code reader. Scan the QR code on the probe to connect it via Wi-Fi. gConnect the probe: The user can tap the "Connect Probe" button to enter the main scanning page without reconnecting the probe via Wi-Fi.

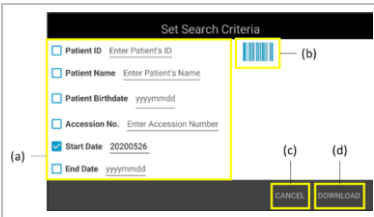
h  : Suspend the charging progress and cancel the connection.

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

. The user can download the worklist from the server or

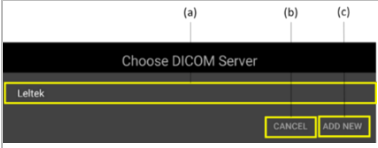
of the most recent records. If the user wants to download the data, they must first define the worklist server. If there is an existing server, the user can edit, delete, or connect it.

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



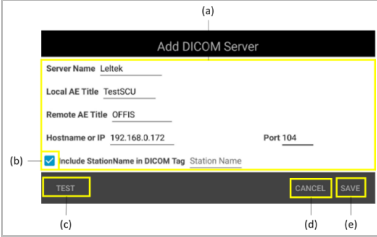
a. Select and enter search criteria
b. Barcode Scan Button
c. Cancel button
d. Download Button

Home, Patient Information: DICOM Worklist, DICOM Server Settings



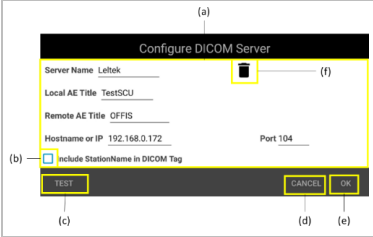
a. List of existing servers
b. Cancel button
c. Add Server Button

Home, Patient Information: DICOM Worklist, DICOM Server Settings



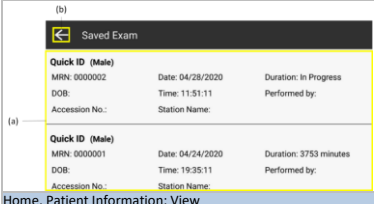
a. Edit server information
b. Shows a check box for the station name field
c. Test Server Response Button
d. Cancel button
e. Save Server Settings button

Home, Patient Information: DICOM Worklist, DICOM Server Settings



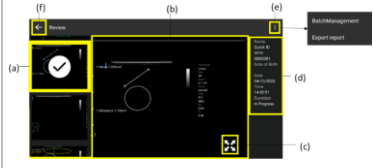
a. Edit server information
b. Shows a check box for the station name field
c. Test Server Response Button
d. Cancel button
e. Save Server Settings button
f. Delete Server Button

Home, Patient Information: Stored Test



a. Patient Information Record
b. Back button

Home, Patient Information: View

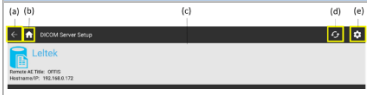


a. Saved images and videos
b. View selected saved image or video
c. full screen
d. Current settings
e. Batch management of images and videos, export of images and videos/export of reports
f. Back button

Home, Patient Information: Batch Management

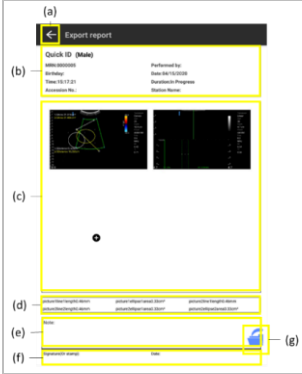
a. Back button
b. Saved images (DICOM: optional), saved images and videos
c. Export button (including DICOM: optional)
d. Toolbar

Home, Patient Information: DICOM Server Settings



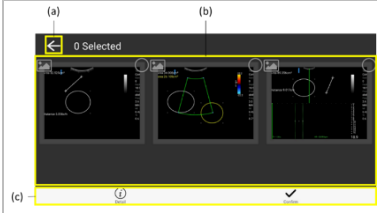
a. Back button
b. Back button to homepage
c. Initialize Server Button
d. Edit server settings

Home Page, Patient Information: Export Report



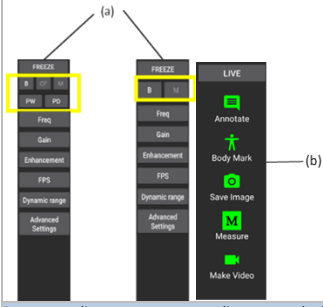
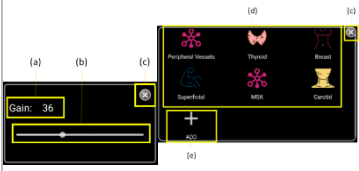
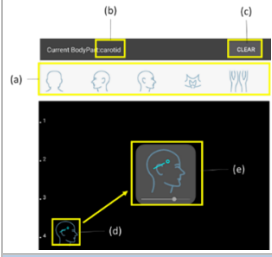
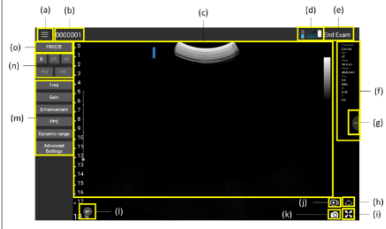
a. Back button
b. Patient Information
c. Selected image
d. Measurement Information
e. annotation
f. Signature and date
g. Export button

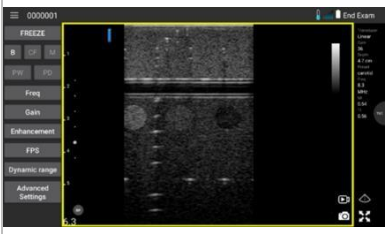
Home, Patient Information: Export Report (Selected Image)



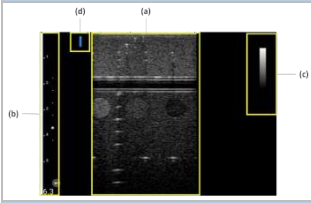
a. Back button
b. Saved image
c. Toolbar

Annotate & Measure, Save, Resume, and Playback: Pause/Scan

	a. Scanning: Combination of mode buttons in the scan state (optional) b. pause
Parameter adjustment: parameter adjustment and selection of human body parts to be Scanned	
	a. Parameter names and values b. Adjust the progress bar c. Cancel button d. 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. Brand image of human body containing position mark e. Adjust Position Mark
Parameter adjustment, image display and gestures: scanning	
	a. Menu Button b. Patient Information c. image d. Ultrasound Probe Status e. Final detection button f. Current settings g. TGC Button h. middle row i. Full-screen button j. Video Button k. Save Image Button l. Select Human Body Part button m. Parameters n. Mode Button o. Pause button
Parameter adjustment, image display, and gestures: mode	



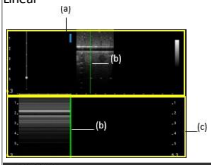
B-mode



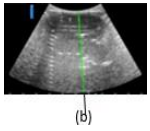
a. image
b. Depth gauge
c. Shades of gray
d. Mirror Mark

M Mode

Linear



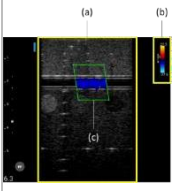
Convex



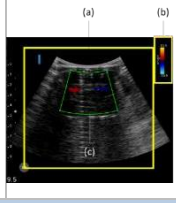
a. B-mode images
b. M Line
c. Time Base Grid

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

Linear



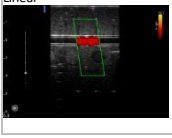
Convex



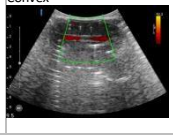
a. image
b. Color Code
c. Area of Local Interest (ROI)

D (Power Doppler) mode (optional)

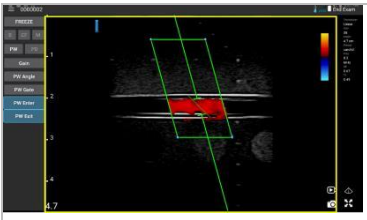
Linear

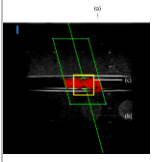
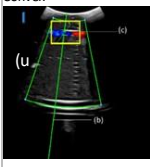


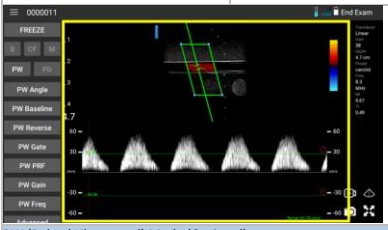
Convex

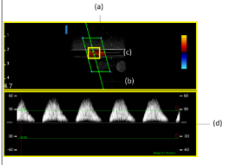
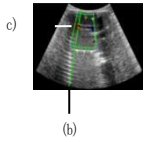


a. Except for a certain color used to represent the intensity of blood flow, everything else is the same as the CF mode.



Default PW Gate Location (Optional) Default TDI gate location (optional when TD is enabled)		
Linear 	Convex 	a. Image in CF/TVI mode paused b. LOI (line of interest) c. Spacing, beam/flow angle differences

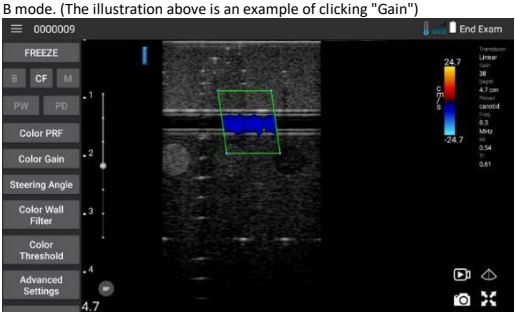


PW (Pulsed Ultrasound) Mode (Optional) TDI (Pulsed Ultrasound) mode (optional when TD is on)		
Linear 	Convex 	a. Image in CF/TVI mode paused b. LOI (line of interest) c. Spacing, beam/flow angle differences d. Time grid, baseline, blood flow value, and interval between two blood flow values

4. **SCAN (LIVE):**

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

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



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

1. Functions in **SCAN (LIVE) mode selection:**

aTouch B, the system would be selected for mode B, which means a two-dimensional ultrasound image display composed of bright dots representing the ultrasound echoes.

bTouch CF (optional), the system would be selected for CF mode, the speed and direction of blood flows are represented on a color map overlaid on the 2D image. The color flow is shown in the ROI. Its size and location are adjustable. (TD on) Tap TD to turn on TVI (optional). The system will switch to TVI mode. The velocity and direction of the heart tissue are represented on a color map overlaid on the 2D image. The movement of the tissue is displayed in the ROI. Its size and location are adjustable.

cTouch M, the system would be selected for M mode, a diagnostic ultrasound presentation of the temporal changes in the echoes in which the depth of the echo-producing interfaces is displayed along one axis and the time is displayed along the second axis, recording the movement of the interfaces towards and away from the transducer. dTap PW to enter PW mode sample port placement (optional).

Select the gate position and adjust the gate size, gate angle, and image gain base in CF mode.

(TD in) Tap TDI to enter TDI sample port placement mode (optional when TD is set to 'ON'). Select the gate position and adjust the size, angle, and gain of the image based on the TVI mode.

eTouch PW Enter (optional), the system would be selected for Doppler PW (pulsed wave) mode, if moving objects changed the characteristic of sound waves. By sending short, rapid pulses of sound, it becomes possible to accurately measure blood velocity in a precise location and in real time.

(TD in) Tap Enter for TDI (optional when TD is enabled) and the system will switch to Tissue Doppler Imaging (TDI) mode. Moving objects alter the characteristics of sound waves. By sending short, fast sound pulses, it is possible to accurately measure the velocity of heart tissue in a precise location and in real time.

fTouch PD (Optional), the system would be selected for PD (Power Doppler) mode, it is used to obtain images that are difficult or impossible to obtain using standard color Doppler, and to provide greater detail of blood flow, especially in vessels located within organs.

2. Turning parameters:

aDepth: 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 greater depth of penetration.

bTHI: (Tissue harmonic image). It is a signal processing technique also called native harmonic imaging. It provides special focusing methods to collect ultrasonic waves to achieve the focus that meets the requirements.

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

dGain: Digital gain is used to adjust the brightness of the image.

ePersistence: It is a type of temporal smoothing used in ultrasound imaging. Successive frames are calculated as they are displayed to reduce variations in the image between frames, thereby decreasing the temporal resolution of the image. This function can be used to adjust different levels of image processing to reduce image noise and make it more delicate. 0 means that this function is disabled. Enhancement: Imagine Enhancement Processing

gFPS: Frames per second. Provides three modes, including power saving, normal, and high performance, representing different image smoothness.

hTGC: (Time Gain Compensation). Ability to compensate for the attenuation of the transmission beam as the sound wave travels through the body tissue. The goal of the TGC is to make the entire image appear evenly lit from top to bottom. iAdvanced settings: When the user taps this button, other buttons are listed

that depend on the mode that the user has selected.
jDynamic Range: When the user taps this button, it allows the user to tell the transducer how they want the echo strength to be displayed in grayscale. A wider gamut will display more shades of gray and a smoother overall image. A narrow range will display fewer shades of gray and appear as a higher contrast with a more black-and-white image.
kGray Map: When the user taps this button, it is adjusting gray maps in the ultrasonic image has a similar effect on an ultrasound image as changing the dynamic range, but they are different. While Dynamic Range adjusts the total number of shades of gray, a gray map determines how dark or light you prefer to show each level of white/gray/black based on the strength of the ultrasound signal.
l Freeze timer: When the user touches this button, the system can be selected how many seconds in static situation.
mMirror: Flip the image horizontally.
nLine 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.
The colored PRF: When the user taps this button, the time is between the start of one pulse and the start of the next pulse. It is measured in units of time. This parameter includes the time when the pulse is "on" and the listening time when the transducer is "off". It can be changed by the sonographer by varying the depth to which the signal is sent.
Color gain: Number of Doppler pulses per line of color Doppler information. Steering angle: The ultrasound scanning angle.
aColor Wall Filter: Filter out low- or high-frequency Doppler signals.
sColor Threshold: Remove parts of the image that fall within a specified color range.
tLOI Angle: LOI (Line of Interest) angle with visualized UI corresponding to the steering angle in CF mode.
uPW Enter: When the user taps this button, it will enter PW mode. Maintain the position of the LOI and parameter values. (PW Port, Gain, PW Angle)
vPW output: When the user touches this button, it will switch back to CF mode.
w PW Angle: It is used in the CF mode image to align the angle correction cursor along the vessel wall for speed measurement.
xPW Baseline: The PW mode image is shifted levelly up and down according to the baseline position corresponding to "0".
yPW Reverse: Flip the PW mode image vertically according to the baseline position of the value "0".
zPW Port: Adjust the port size to try the flow measurements, the whole vessel should be insonated. A large gate may include signs of adjacent vessels.
aaPW PRF: When the user touches this button, the time is between the start of one pulse to the start of the next pulse. It is measured in units of time. This parameter includes the time when the pulse is "on" and the listening time when the transducer is "off". It can be changed by the sonographer by varying the depth to which the signal is sent.
bbPW Gain: Remove or reinforce portions of the pulse wave image that fall within a specified brightness range.
ccPW Freq: The carrier frequency of the ultrasound wave transmitted and received by the transducer in PW mode.

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

3. Multimedia:

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

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

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

and the area.

1. Functions in FREEZE

a 

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

b 

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

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

d 

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

e 

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

f 

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

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

2. General functions aMenu:

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

cReview: After entering Review in the current diagnostic, the user can choose to view an ultrasonic image or video in Cine Graphic to review. By tapping 
, the user can choose "Batch Management" or "Export Report". Tap Batch Management, the user can select, delete, export multiple stored images (available format: .jpg, .png, .bmp and.dcm.. dcm file is optional) or videos (available format: .mp4) for local storage and uploading DICOM files (optional) to the server.

Tap Export Report, the user can export the diagnosis to pdf with the patient's information, selected images, measurement information, annotation, signature, and date.

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

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

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

gOthers:

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

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

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

3. * Additional Features

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

image and can be uploaded to the DICOM server.
bThe combination of mode buttons in the scan state (optional): cCase 1: B mode and M mode in Live status
dCase 2: B mode, M mode, CF mode, PD mode, PW sample gate mode positioning, and PW mode in Live status.

C. Ultrasound gels

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

I.SECURITY

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

A. Contraindications and warnings

1. Battery Safety:

a. DO NOT ignore the specified instructions for use for lithium-ion batteries in medical diagnostic equipment. Failure to comply with specifications may result in accidents and the manufacturer will not accept liability.

b. DO NOT leave a battery unused for long periods of time, as it may leak and damage the electronics. If the equipment remains unused for more than one week, charge the battery using an IEC 60601-1 compliant power supply for a two-MOPP insulation system. Regularly check or replace the charging power supply.

c. DO NOT charge the battery near sources of fire or heat.

d. DO NOT use the equipment if the battery leaks or emits an odor. Turn off the equipment and contact your local representative.

e. If the battery is not used for more than one month, store it between -20°C (-4°F) and 20°C (68°F).

f. DO NOT attempt to disassemble the device yourself. The lithium battery may explode due to a short circuit. If abnormal behavior is noticed, turn off the equipment and contact your local representative.

g. DO NOT charge the battery near sources of fire or heat.

2. Mechanical safety:

a. DO NOT use on a patient who would be harmed by the application of ultrasound.

b. DO NOT drop the probe or subject it to other types of mechanical shock or impact. Degraded performance or damage such as cracks or chips in the case may occur.

c.DO NOT use the product near strong electromagnetic fields, electromagnetic waves, and magnetic environments. There is a possibility of measurement errors or damage to the product. d.DO NOT operate this system in the presence of flammable gases. Explosion may occur. The system is not supported in AP/APG environments as defined by IEC 60601-1.

e.To avoid the risk of electric shock, always inspect the transducer before use. Check the face, housing, and cable before use. DO NOT use if face is cracked, chipped, or torn; the carcass is damaged; or the cable is frayed.

f. DO NOT take the probe into an MRI environment. MRI-unsafe items should not enter the MRI scanner room and patients with MRI-unsafe devices should not be examined

g. NO The operating temperature of the ultrasound probe should remain below 43°C.

h. DO NOT allow the transducer to contact the patient if the transducer temperature is higher than 43°C (109°F).

i. DO NOT leave children unattended with the system. Transducers pose a choking hazard due to small, detachable parts and the transducer cable is a strangulation hazard.

3. Waring Image Quality:

a When administering to patients undergoing surgery that may have altered the composition of the examining tissue, as this may distort or alter the measured density.

b In patients whose bodies contain foreign artifacts (e.g., implants) in the examining tissue, image distortion may occur.

c When using for intraoperative purposes (e.g., defined as introducing a system into a surgical incision or burr hole), verify that the equipment is protected by the sterile gel bag.

d Use for ophthalmic purposes needs to be performed by a specialized ophthalmologist. and DO NOT attempt imaging on an open wound without being protected with a bag, and

sterile gel.

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

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

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

7. Electrical compatibility
aDO NOT use your system in combination with other products or components unless expressly recognized by the manufacturer as compatible.
bDO NOT hesitate to contact your local representative for information on these products and components.
cDO NOT make changes or additions to the system unless made by the manufacturer or by a third party expressly authorized by the manufacturer. DO NOT allow such changes and additions unless they comply with best engineering practices and all applicable laws and regulations in the jurisdictions concerned.
dDO NOT operate the system near pacemakers, as ultrasound equipment, like other medical electronic diagnostic equipment, uses high-frequency electrical signals that can interfere with the operation of the pacemaker. Although the possibility of interference is small, DO NOT ignore this potential hazard and stop system operation immediately if you notice interference with a pacemaker.
eDO NOT use additional peripheral equipment interconnected by functional connection without considering it as part of a medical electrical system. DO NOT fail to comply with IEC 60601-1 and test the system according to these requirements. If you have questions, DO NOT hesitate to contact your local representative.

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

8. Acoustic Safety

a. DO NOT exceed the acoustic output limit:

1.ISPTA.3 = 720 mW/cm^2 (50 for ophthalmics) for Band 3; ophthalmic Track 3,

2. TI ≤ 6.0 (TIS maximum as TIC ≤1)

3. MI ≤ 1.9 (0.23 for ophthalmic) for band 3;

9. FCC RF Radiation Exposure Statement

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

10. Information Security

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

11. Biological Safety

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

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

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

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

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

fBE sure to advise patients with latex sensitivity to inform healthcare professionals and emergency personnel prior to medical procedures. DO NOT neglect the recommendation that patients with severe sensitivity wear a medical ID bracelet.

12. Storage limits

aDO NOT neglect to ensure that the room is ventilated and free of corrosive gases. bDO NOT operate, store, or transport probes outside the parameters

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

13. Maintenance and troubleshooting

aDO NOT use this product if it is not working properly. Contact your local dealer or contact the manufacturer via email at info@leltek.com.

bFollow the troubleshooting guide:

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

14. Disinfectants and cleaning method

aDO NOT use your compatible smart device unless it has been properly cleaned and disinfected in accordance with the device manufacturer's instructions and your institution's medical device cleaning and disinfection policies.

bDO NOT ignore the internal contamination of the compatible smart device with pathogen-containing body fluids. You must immediately notify the manufacturer's service representative. The components inside the device cannot be disinfected. In such cases, DO NOT attempt to disinfect the device and dispose of it as biohazardous material in accordance with local or federal laws.

cDO NOT skip wearing protective goggles and gloves when cleaning, disinfecting, or sterilizing any equipment.

dDO NOT use protective covers that are not qualified for transrectal and intravaginal procedures. In some regions, these coverages are mandatory. Always be sure to use qualified protective covers recommended by the manufacturer.

15. Rework

a. DO NOT attempt to open a transducer or transducer connector.

b. DO NOT modify this device without authorization.

16. Product Disposal

aDO NOT mix electrical and electronic equipment with general waste. Separate collection is required in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive.

bDO NOT dispose of devices containing lead or mercury in ordinary waste. Components containing these materials must be recycled or disposed of in accordance with local, state, and federal laws. The backlight lamps in LCD system monitors contain mercury.

cDO NOT dispose of electrical and electronic equipment unless it meets the Restriction of Hazardous Substances Directive (RoHS) 2011/65/EU.

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

B. Benefits and risks

1. Ultrasound is widely used because it offers many clinical benefits to the patient and has an excellent safety record. In more than three decades of use, there has been no

long-term negative side effects associated with this technology.

2. More safety issues are being discussed because more applications are being discovered and the industry is producing technically sophisticated scanners that provide more diagnostic information. Dialogue between the medical community, manufacturers, and the FDA has resulted in a standard that allows for higher results for greater diagnostic capability.

3. Benefits of ultrasound:

a. Multiple diagnostic uses

b. Immediate results with high-quality information

c. Replacement or courtesy or used with other procedures

d. Cost-effective

e. Portability

f. Patient acceptance

g. Safety Record

4. Risks of ultrasound:

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

A. Acoustic output and measurement

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

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

4. Mechanical Index (MI) (Non-Thermal)
Ultrasound energy also creates mechanical forces independent of thermal effects, causing biological effects that are not only related to temperature rise, such as cavitation, torque forces, oscillatory shear, radiation, pressure, and microflow. Scientific evidence suggests that mechanical bioeffects are threshold phenomena that occur when a certain level of production is exceeded. The threshold level varies depending on the tissue. The potential for mechanical bioeffects varies with the peak pressure between rare factions and the frequency of ultrasound. The higher the reading of the MI value, the greater the potential. There is no specific MI value, which means that a mechanical effect is actually occurring. The IA should be used as a guide for the implementation of the ALARA principle. cAccuracy and precision of mechanical index display
1. It is estimated that 90% of the MI values will be within +/– 15% of the displayed value, or +/–0.14 of the displayed IM value, whichever is greater. It approaches +/–1.2 dB. The IM is displayed with an accuracy of 0.01.

5. Thermal Index (TI)
The biological effects of ultrasound energy are mainly related to heat production. Heat is generated whenever ultrasound energy is absorbed, and the amount of heat produced depends on the intensity of the ultrasound, the exposure time, and the specific absorption characteristics of the tissue. Up to 70% of the total temperature increase associated with ultrasound occurs within the first minute of exposure [2], but the temperature continues to increase as the exposure time is extended.
Minimizing exposure time is probably the most important factor in ensuring patient safety from thermal injury [3]. Other important parameters to consider are:
1. The relative protein content of each tissue, since the absorption coefficients of the tissues are directly related to the protein content; absorption coefficients vary between 1 (skin, tendon, spinal cord) and 10 (bone) dB/cm MHz
2. The perfusion of the fabric, which has a cushioning effect on heat generation and

Physically allows heat to be carried away from the power transfer point.
3. Emission modality, since pulsed-wave ultrasound is extremely unlikely to significantly heat tissues.
4. Beam width, since a larger beam width reduces the rate and extent of temperature rise, allowing energy to be distributed over a larger perfusion territory.
bIT informs the user of existing conditions that can lead to an increase in temperature on the surface of the body, within body tissue, or at the focus point of the ultrasound beam on the bone. That is, IT informs the user about the potential for temperature increase in body tissue. It is an estimate of the increase in temperature in body tissue with specific properties. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, mode of operation, and others. IT should be used as a guide for the implementation of the ALARA principle. The thermal bone index (TIB) informs the user of potential heating at or near the focus after the ultrasound beam has passed through the soft tissue or fluid; for example, in or near the fetal bone of the second or third trimester. The cranial bone thermal index (TIC) informs the user of the potential heating of the bone at or near the surface; for example, cranial bone. The soft tissue thermal index (TIS) informs the user of the heating potential within homogeneous soft tissues. You can choose to view TIS, TIC, or TIB.
cThe application software has real-time display of thermal (TI) and mechanical (MI) index, according to IEC62359. These two indices are intended to estimate the potential for ultrasound-induced thermal and mechanical bioeffects. Both TI and MI are displayed in increments of 0.01, and the key figures displayed are nominal values.
dOutput display indexes are calculated with the precision described below. The stated display accuracy values are determined against the MI and TI models, equations, and measurement methods specified in the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices in Diagnostic Ultrasound Equipment, Revision 2" (NEMA UD3). TI and MI are relative indicators for the probability of tissue thermal increase and mechanical bioeffects, respectively. The statements of accuracy listed here are not linked to deviation from the displayed indices of the actual increase in temperature or pressure levels in the body. The TI and MI values are determined from measurements in water and reduced for tissue attenuation using an assumed homogeneous tissue model with attenuation of 0.3 dB/cm/MHz and the sound propagation properties of water. Most tissues attenuate ultrasound at a higher rate. Fluids such as amniotic fluid attenuate less. In addition, ultrasound propagation is nonlinear in most cases, to varying degrees in water and in various tissues, with varying resultant effects on actual MI or TI values. The IM is a relative indicator for the probability of a mechanical bioeffect, such as cavitation, and its model assumes the presence of nucleation sites required for cavitation. The TI models assume a blood perfusion length of 1 cm. Tissue perfusion lengths and rates depend on vasculature and blood flow and the thermal properties of the surrounding tissue, which vary greatly. TI bone shunt assumes that all ultrasound energy is absorbed by the impacted bone.

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

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

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

6. Cavitation
The interaction of ultrasound with gas bubbles or contrast agents causes rapid and potentially large changes in bubble size. This process, called cavitation, can increase the temperature and pressure inside the bubble and thus cause mechanical stress on the surrounding tissues, precipitate the formation of fluid microbes, and generate free radicals [5]. Gas-containing structures (e.g., lungs, intestines) are more susceptible to the effects of acoustic cavitation. The wavelength of ultrasound has an important role in the formation and growth of bubbles: short-wavelength ultrasound (observed at higher frequencies) does not provide enough time for significant bubble growth; therefore, cavitation is less likely under these circumstances compared to long wavelengths. The short half-life of cavitation nuclei prevents most cavitation-related biological effects unless

that ultrasound contrast agents are also present. Contrast agents markedly reduce the intensity of the threshold for cavitation. However, due to the relatively high viscosity of blood and soft tissues, significant cavitation is unlikely, and cavitation has not been shown to occur with exposure to ultrasound commonly used during a diagnostic examination.
Note: *Cavitation depends on:*

1. Frequency
2. Pressure
3. Focused/Blurred Beams
4. Pulsed/continuous ultrasound
5. Degree of standing waves
6. Nature and condition of materials
7. Limits
7. Other effects

A variety of other physical forces can also be produced by ultrasound energy. Although each of these effects can be demonstrated in vitro, there is no evidence that any of these physical phenomena have a significant biological effect on patients.
bEnsure that the scanning time is kept to a minimum and that only clinically necessary verification is performed. Never compromise on quality by rushing through an exam. A bad exam may require a follow-up, which ends up increasing the exposure time. Diagnostic ultrasound is an important tool in medicine, and like any tool, it must be used efficiently and effectively.
cB-mode depth: An increase in 2D depth will automatically decrease the 2D frame rate. This will decrease IT. The system can also automatically choose a deeper 2D focal depth. A change in focal depth can change the IM. The IM displayed is the zone with the highest IM value.
dApplication: Acoustic output defaults are set when you select an application. Factory defaults vary by transducer, application, and mode. The patterns were chosen below the intended use.
ePicture Mode Controls: When a new picture mode is selected, both TI and MI can switch to the default settings. Each mode has a corresponding pulse repetition frequency and a maximum intensity point. In combined or concurrent modes, the TI is the sum of the contribution of the enabled modes, and the displayed MI is the greater of the MI values associated with each mode and enabled focal zone. The system returns to the previously selected state if a mode is disabled and selected again.
fTransducer: Each type of transducer has unique specifications for contact area, beam shape, and center frequency. The defaults are initialized when you select a transducer. Factory defaults vary depending on the transducer, application, and mode selected. The patterns were chosen below the intended use.

8. ALARA Principles

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

Color flow Doppler and Doppler modes provide information about blood flow through the vessels. The M-mode provides information about how anatomical structures move in time. If one wishes to use 3D/4D ultrasound, one must remember that 3D/4D image sets consist of a series of two-dimensional (2D) B-mode acquisitions, which are then constructed by the computer into 3D/4D representations. So whatever the settings are for 2D images in B-mode, it will be what determines the output. Time will be the most important variable because, on the one hand, a 2D scan will be fast and time-limited, but prolonged exposure can result from trying to get the "best" set of images. Secondly, the capabilities of the transducer are related to the depth of penetration of the ultrasound into the tissue at the chosen frequency, resolution, and field of view that we can achieve with the selected transducer. Third, the system setup and control settings depend on where we start on the output scale and 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, ultrasound physics, and the signal processing capabilities of the equipment, as well as our experience with a particular scanning modality, such as sector, linear, and so on. The recording and playback capabilities of a system allow us to reduce exposure time to just the time it takes to get a useful image. Analysis and diagnosis can be performed with recorded images, rather than long live imaging sessions. The same can be said about 3D volumes, obtained by an examiner and analyzed by that examiner or by another person, without exposure to the patient, at the bedside, in the reading room, across town or across country. Without an output display pattern, we must rely on this knowledge to estimate a patient's ultrasound exposure. With an output display pattern, we have a real-time indication of the exposure in terms of bioeffects potential. Either way, we implemented ALARA by minimizing the level and duration of exposure, while still getting the necessary diagnostic information."

dNo set of rules can be formulated that is sufficiently complete to dictate the correct answer to each circumstance. Qualified personnel can adjust to improve image quality and minimize output intensity. There are several variables that affect the way that output display indexes can be used to implement the ALARA principle. These variables involve:

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

9. Applying ALARA

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

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

10. Using System Controls to Implement ALARA

Direct controls: The system has no direct control for output, so the sonographer must control the exposure time and scanning technique to implement the ALARA principle. To ensure that acoustic and thermal limits are not exceeded for all imaging modes, the system is designed to automatically adjust the output. The system does not exceed a mean temporal intensity of spatial peak (I SPTA) of 720 mW/cm2 for all imaging modes. The mechanical index (MI) of the equipment does not exceed values greater than 1.9 and the thermal index (TI) does not exceed values greater than 6.0.

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

cReceiver Controls: Receiver controls are used by the operator to improve image quality. These controls have no effect on the output. The receiver controls only affect how the ultrasound echo is received. These controls include gain, time gain compensation (TGC), dynamic range, and image processing. The important thing to remember, regarding output, is that the receiver controls must be optimized before the output is increased. For example, before increasing the output, optimize the gain to improve the image quality.
dAn example of application of the ALARA principle: An ultrasound of a patient's liver begins with the selection of the appropriate transducer frequency. After selecting the transducer and application, which are based on the patient's anatomy, adjustments to the output power should be made to ensure that the lowest possible setting is used to acquire an image. If a suitable image can be obtained with increasing gain, then a decrease in output should be made. Only after making these adjustments do you increase production to the next level. Having acquired the 2D display of the liver, Color can be used to locate blood flow. As with displaying 2D images, the gain and image processing controls must be optimized before increasing the output. In summary: Select the correct transducer frequency and application for the job; start with a low output level; and optimize the image by receiver gain and other image controls.
eDisturbances in heart rhythm during perfusion studies using gaseous ultrasound contrast agents were observed in the diagnostic range of Mechanical Index (MI) values. For details, refer to the specific package insert of the contrast agent used.

11. Output Display

aThere are two types of indexes that can be displayed: one is the mechanical index (MI) and the other is the thermal index (TI). The mechanical index (MI) provides an indication of the risk due to mechanical or non-thermal mechanisms. The thermal index (TI) provides an indication of the risk of damage due to thermal mechanisms. The mechanical index (MI) is displayed continuously in the range of 0.0 to 1.9, in increments of 0.1.
bThe thermal index also consists of the following indices: soft tissue (TIS), bone (TIB) and cranial bone (TIC). Only one of them is displayed at any given time. Each transducer application has a standard selection appropriate for this combination. The TIB, TIS, or TIC is displayed continuously in the range of 0.0 up to the maximum output, based on the transducer and application. The application-specific nature of the default configuration is also an important factor of index behavior. A default setting is a system control state predefined by the manufacturer or operator. The system has default index settings for the transducer application. The default settings are automatically invoked by the ultrasound system when the power is turned on, when new patient data is entered into the system database, or when a change occurs in the application. The decision on which of the three thermal indices to display should be based on the following criteria:
cApplication-appropriate index: TIS is used for soft tissue imaging, TIB for a focus on or near bone, and TIC for imaging through bone near the surface, such as in a cranial examination.
dMitigating factors that can create artificially high or low thermal index readings: fluid or bone location or blood flow. For example, is there a highly attenuating tissue path for the actual warming potential of the local zone to be less than the thermal index displays?
eScanned operating modes versus non-scanned operating modes affect the thermal index. For digitized modes, the heating tends to be close to the surface; For non-digitized modes, the heating potential tends to be deeper in the focal zone.
fAlways limit the time of exposure to ultrasound. Do not rush the exam. Ensure that indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

12. Display Accuracy

aMI and TI have an accuracy of 0.01 units in the system.
bEstimates of the MI and IT display accuracies are shown in the Acoustic Output Tables. Many factors are considered when estimating the accuracy of the displayed values:
cHardware variations, such as piezoelectric crystal efficiencies, process-related impedance differences, and variations in sensitive lens focus parameters.
dAccuracy of the estimation algorithm, including variations in pulsator voltage control, operating conditions, and efficiencies.
eMeasurement variability, such as inaccuracies in laboratory measurements caused by hydrophone calibration and performance, positioning, alignment and scanning tolerances, and variability of test operations.
fControls that affect indexes
1. B-mode controls
2. Transducer Frequency
3. Color Controls
gColor Sector Width: The narrower width of the color sector will increase the color frame rate and IT will increase. The system can automatically decrease the pulse voltage to be below the system maximum. A decrease in pulse voltage will decrease the IM.
hColor sector depth: Deeper color sector depth may decrease

automatically the color frame rate or select a new color focal zone or color pulse length. The TI will change due to the combination of these effects. Generally, IT will decrease with increasing depth of the color sector. The IM will correspond to the IM of the dominant pulse type, which is a colored pulse.

iMeasurement accuracy and uncertainty of the acoustic output values: The measurement accuracy of the quantities is listed in the table below. They are measured as part of determining the IM or TI values. Quantities are listed as a standard deviation, in percentage.

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

III. Technical Characteristics A.PCBA

● There are some of the technical aspects of the system as listed:

a. Receiving frequency and/or receiving section bandwidth and bandwidth.
b. Frequency and/or transmission band, modulation and ERP
c. Functions: Image data transmission and control data communications
d. FPGA High-Performance Computing Technology
e. unique "Ultra Image Block Algorithm" (UIBA) technology solution for B-mode, color mode, M-mode, Power Doppler and PW Doppler block image
f. High frame rate
g. High contrast
h. High resolution
i. Harmonic Tissue Imaging
j. Support Imaging Mode
k. B-mode
l. Color Doppler
m. M Mode
n. PW Doppler
o. Power Doppler
p. Tissue Doppler

● Built-in battery continuous time use

a. Approximately 2 hours of continuous scanning at standard settings.
b. Battery life may vary depending on mode and settings.

● Example compatible adapter in compliance with IEC 60601-1 for two MOPP insulation systems:

● SHENZHEN SUNSHINE TECHNOLOGICS CO., LTD.

● Model Name: XSD-0503000DEXUs

the INPUT: 100-240V-50/60Hz 0.5A max.
b OUTPUT: 5.0V --- 3.0A 15.0W

● Description of Radio Frequency Wireless Technology

aThe technical aspects of 2.4 GHz and 5 GHz wireless communication of the system as listed below

Parameter	Specification	Comment
IEEE 802.11 Level	IEEE 802.11a/b/g/n	802.11bChapter 1-11 802.11 goldsChapter 1-11 802.11n20 million 802.11a5150-5250 (UNII-1) 802.11a5725-5850 (UNII-3)
Wireless Signal Rate	1 - 11 Mbps (IEEE 802.11b) 6 - 54 Mbps (IEEE 802.11g) 6 - 54 Mbps (IEEE 802.11a)	The actual data transfer rate is lower and is affected by device distance and packet error rates, network condition, environmental factors, etc.
Security type	WPA2. 128 works as AP mode connection with SSID and password selection required; Only one authenticated connection at a time.	Encryption for added security and authentication for secure connection.
Redundancy mechanism	CRC	Checking metadata for integrity
Distance between 128 and mobile device	<3 meters; <1 meter if in crowded environment	In most tests See Wi-Fi Coexistence Test.
Error rate	<5%	See Wi-Fi Coexistence Test.
Data frame rate (relative to latency and data throughput)	8 fps	See Wi-Fi Coexistence Test. By default, the frame time of normal condition is about 0.128s, a sigma is about 0.009s.

B. Clinical measurement range and accuracies

				Limitations or Conditions

Measurement	Units	Useful Range	Reported accuracy	Probe	Mode
					of operations
Distance:					
Vertical	millimeter	Full screen	Maximum error. 2.17 % Maximum error. 2.5% Maximum error. 2.8% Successful Maximum error. 1.81 % Maximum error. 2.5% Maximum error. 3.6% Maximum error. 1.9% Maximum error. 2.8%	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■B
Horizontal	millimeter	Full screen	Maximum error. 1.67 % Maximum error. 0.7% Maximum error. 3.0% Successful Maximum error. 1.67 % Maximum error. 2.9% Maximum error. 2.8% Maximum error. 3.5% Maximum error. 2.8%	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■B
Area:					
Circle	mm2	Full screen	Maximum error 2.15% Maximum error 3.45% Maximum error 3.47% Maximum error 1.81% Maximum error 2.3% Maximum error. 3.9% Maximum error. 3.5% Maximum error. 2.5%	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■B
Dead zone					
Dead zone	mm2	-	0 mm 0mm 1mm 0 mm 0 mm 0 mm 2 mm 0 mm	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■B
Doppler					
Speed and	mm/s	Full screen	Max Error 3.81% Max Error 4.48% Max Error 6.31% Max Error 3.00% Maximum error 4.1% Maximum error. 2.8% Maximum error. 3.6% Maximum error. 2.7%	128L LK128L LK128LH 128C LK128C LK128M LK128PA LK128E	■PWD

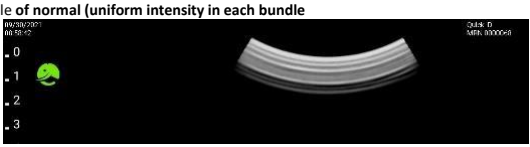
● * Run translation element check

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

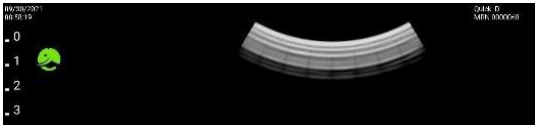
Press the in the menu to the left of the main view. the user can use Verification of the to determine if the element is working according to the

expected. The system transmits and receives through a projected sequence and forms the image. Abnormal variations in intensity (e.g., dark lines) near the surface should be considered as a possible element failure. Contact the service for guidance on other necessary actions.

● Example **of normal (uniform intensity in each bundle**



● Example of a probmatic element or channel failure.



● Declaration of Conformity

The products comply with international and national standards and laws. Users are responsible for ensuring that the smart device and scanner they choose complies with the law of the jurisdiction where the product is used. Leltek meets all regulatory standards listed in this chapter.

● Product Classification

The device with transducers: Class IIa/ME equipment internally powered. Transducers: Applied parts type BF, IPX68

Ordinary Equipment/Non-AP/APG

Continuous Operation

● Electromechanical safety standards met

The transducers and software comply with the requirements of IEC 60601-1 Medical Electrical Equipment, General Safety Requirements, including all applicable warranties and specific standards, as well as all applicable deviations. Users of the system are responsible for ensuring that the device they choose complies with the law of the jurisdiction in which the product is used.

● System Specs Grayscale:

256 in B-mode

Pressure, Humidity, and Temperature Limits: These limits apply only to the transducer, not to the Android or iOS device on which the user runs the Imaging System application. It is the user's responsibility to select a compatible device that meets the needs of the user's clinical environment.

For information about the environmental specifications of the user's device, refer to the documentation that came with the user's device.

[128C] Acoustic Output Reporting Table

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128C
Operating Mode: B Mode

Index label			MI	TIS			TIB			TIC	
				Sweeping	Do Not Scan		Sweeping	Do Not Scan		Sweeps hard	Don't Miss near
				Surface	Surface	Below the surface le	Surface	Surface	Below the surface le	On the surface	In Superificie
Maximum index value			1.69	0.72			0.72			IN	
Component Value index			1.69	0.72	IN	IN	0.72	IN	IN	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		2.33								
	P (mW)			323.20	IN		323.20	IN		IN	IN
	P1x1 (mW)			79.18	IN		79.18	IN			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	e.g., (cm)								IN		
	ZPI (cm)		6.22			IN			IN		
	zMI (cm)		4.16								
	D to ZB (cm)								IN		
	fawf (MHz)		1.91	1.91	IN		1.91	IN		IN	IN
	Dimof Aaprt	X (cm)		3.14	IN		3.14	IN		IN	IN
		Y (cm)		1.30	IN		1.30	IN		IN	IN
Other information	Components of the mode		B	B	IN		B	IN		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		2368.50								
	srr (Hz)		14.13								
	pr at zpii (MPa)		3.06								
	Deq in zpii (cm)								IN		
	Ipa,α on ZPII,α (W/cm2)		405.00								
	Focal Comprimen t to	FLX (cm)	6.40			IN			IN		
		MOSCA (cm)	4.20			IN			IN		
Operational control conditions	Focus (cm)		6.4	6.4	IN	IN	6.4	IN	IN	IN	IN
	Depth and (cm)		12.6	12.6	IN	IN	12.6	IN	IN	IN	IN
	THI		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MHz)		3.6	3.6	IN	IN	3.6	IN	IN	IN	IN

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128C
Operation Mode: B+M Mode

Index label			MI	TIS			TIB			TIC	
				Sweeping	Do Not Scan		Sweeping	Do Not Scan		Sweeps hard	No Escanear
				Surface	Surface	Below the surface le	Surface	Surface	Below the surface le	On the surface	In Superificie
Maximum index value			1.69	0.79			1.09			IN	
Component Value index			1.69	0.70	0.03	0.09	0.70	0.16	0.39	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		2.33								
	P (mW)			312.20	14.87		312.20	14.87		IN	IN
	P1x1 (mW)			76.48	3.64		76.48	3.64			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					9.30					
	zS (cm)					3.42					
	ZBP (cm)					3.41			3.41		
	ZB (cm)								4.16		
	ZPI (cm)		6.22			6.22			6.22		
	zMI (cm)		4.16								
	D to ZB (cm)								0.49		
	fawf (MHz)		1.91	1.91	1.91		1.91	1.91		IN	IN
	Dimof Aaprt	X (cm)		3.14	3.14		3.14	3.14		IN	IN
		Y (cm)		1.30	1.30		1.30	1.30		IN	IN
Other information	Components of the mode		B+M	B	M		B	M		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		B: 2288.16 M: 108.99								
	srr (Hz)		13.62								
	pr at zpii (MPa)		3.06								
	Deq in zpii (cm)								0.48		
	Ipa,α on ZPII,α (W/cm2)		405.00								
	Focal Comprimen t to	FLX (cm)	6.40			6.40			6.40		
		MOSCA (cm)	4.20			4.20			4.20		
Operational control conditions	Focus (cm)		6.4	6.4	6.4	6.4	6.4	6.4	6.4	IN	IN
	Depth and (cm)		12.6	12.6	12.6	12.6	12.6	12.6	12.6	IN	IN
	THI		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MHz)		3.6	3.6	3.6	3.6	3.6	3.6	3.6	IN	IN
	M PRF (Hz)		114.0	--	114.0	114.0	--	114.0	114.0	IN	IN
NA indicates that there is no corresponding intended use or no data reported.											

Acoustic Output Reporting Table for Band 3 Transducer

Model: 128C

Operation Mode: B+CF/B+PD Mode

Index label			MI	TIS			TIB			TIC	
				Sweeping	Do Not Scan		Sweeping	Do Not Scan		Sweeping	No Ear Scan
				Surface	Surface	Below the surface le	Surface	Surface	Below the surface le	On the surface	On the surface
Maximum index value			1.69	0.75			0.75			IN	
Index Component Value			1.69	B: 0.40 CF: 0,35	IN	IN	B: 0.40 CF:0.35	IN	IN	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		2.33								
	P (mW)			B: 178.60 CF: 94,30	IN		B: 178.60 CF: 94,30	IN		IN	IN
	P1x1 (mW)			B: 43.75 CF: 23,10	IN		B: 43.75 CF: 23,10	IN			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	ZB (cm)								IN		
	ZPI (cm)		6.22			IN			IN		
	zMI (cm)		4.16								
	D to ZB (cm)								IN		
	fawf (MHz)		B: 1.91	B: 1.91 CF: 3,17	IN		B: 1.91 CF: 3.17	IN		IN	IN
	Dimof Aaprt	X (cm)		3.14	IN		3.14	IN		IN	IN
		Y (cm)		1.30	IN		1.30	IN		IN	IN
Other information	Mode components		B+CF	B+CF	IN		B+CF	IN		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		B: 1308.72 CF: 3600.0								
	srr (Hz)		7.79								
	PR at ZPII (MPa)		3.06								
	Deq in zpii (cm)								IN		
	Ipa,α on ZPII,α (W/cm2)		405.00								
	Focal Compriment to	FLX (cm)	6.40			IN			IN		
		MOSCA (cm)	4.20			IN			IN		

Conditions	Focus (cm)	6.4	6.4	IN	IN	6.4	IN	IN	IN	IN

de controle operación al	Depth and (cm)	12.6	12.6	IN	IN	12.6	IN	IN	IN	IN
	POETRY	IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MHz)	B: 3.6 CF: 3.1	B: 3.6 CF: 3.1	IN	IN	B: 3.6 CF: 3.1	IN	IN	IN	IN
	PRF Color (kHz)	3.6	3.6	IN	IN	3.6	IN	IN	IN	IN
NA indicates that there is no corresponding intended use or no data reported.										

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128C
Operation Mode: PW Mode

Index label			MI	TIS			TIB			TIC	
				Sweeping	Do Not Scan		Sweeping	Do Not Scan		Sweeping	No Escanear
				Surface	Surface	Below the surface le	Surface	Surface	Below the surface le	On the surface and	On the surfac e
Maximum index value			1.04	0.69			1.60			IN	
Component Value index			1.04	IN	0.30	0.69	IN	1.16	1.60	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		1.62								
	P (mW)			IN	105.53		IN	105.53		IN	IN
	P1x1 (mW)			IN	25.85		IN	25.85			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					59.30					
	zS (cm)					3.42					
	ZBP (cm)					3.41			3.41		
	ZB (cm)								4.16		
	ZPI (cm)		5.52			5.52			5.52		
	zMI (cm)		5.52								
	D to ZB (cm)								0.65		
	fawf (MHz)		2.45	IN	IN		IN	2.45		IN	IN
	Dimof Aaprt	X (cm)		IN	3.14		IN	3.14		IN	IN
		Y (cm)		IN	1.30		IN	1.30		IN	IN
Other information	Mode component s		Prison of war	IN	Prisoner of war		IN	Prisoner of war		IN	IN
	TD (USEC)		1.58								
	PRR (Hz)		4170.00								
	srr (Hz)		IN								
	pr at zpii (MPa)		1.78								
	Deq in zpii (cm)								0.65		
	Ipa,α in zpii,α (W/cm2)		75.33								
	Focal	FLX (cm)	6.40			6.40			6.40		

	Comprimen t to	MOSCA (cm)	4.20			4.20			4.20		
Control conditions Operation	Focus (cm)		6.4	IN	6.4	6.4	IN	6.4	6.4	IN	IN
	Depth and (cm)		12.6	IN	12.6	12.6	IN	12.6	12.6	IN	IN
	Frequency		2.6	IN	2.6	2.6	IN	2.6	2.6	IN	IN

AI	(MHz)									
	PRF (kHz)	4.17	IN	4.17	4.17	IN	4.17	4.17	IN	IN
	Gate (mm)	0.5	IN	0.5	0.5	IN	0.5	0.5	IN	IN
NA indicates that there is no corresponding intended use or no data reported.										

[128L] Acoustic Output Reporting Table

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128L
Operating Mode: B Mode

Index label			MI	TIS			TIB			TIC	
				Sweeping	Do Not Scan		Sweeping	Do Not Scan		Sweeps hard	Do Not Scan
				Surface	Surface	Below the surface le	Surface	Surface	Below the surface le	On the surface	On the surface and
Maximum index value			1.59	0.44			0.44			0.93	
Component Value index			1.59	0.44	IN	IN	0.44	IN	IN	0.93	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		3.46								
	P (mW)			37.42	IN		37.42	IN		37.42	IN
	P1x1 (mW)			19.49	IN		19.49	IN			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	ZB (cm)								IN		
	ZPI (cm)		1.20			IN			IN		
	zMI (cm)		1.00								
	D to ZB (cm)								IN		
	fawf (MHz)		4.74	4.74	IN		4.74	IN		4.74	IN
	Dimof Aaprt	X (cm)		1.92	IN		1.92	IN		1.92	IN
		Y (cm)		0.42	IN		0.42	IN		0.42	IN
Other information	Components of the mode		B	B	IN		B	IN		B	IN
	TD (USEC)		0.52								
	PRR (Hz)		3203.00								
	srr (Hz)		11.30								
	pr at zpii (MPa)		4.08								
	Deq in zpii (cm)								IN		
	Ipa,α on ZPII,α (W/cm2)		391.30								
	Focal Compriment to	FLX (cm)	1.20			IN			IN		
		MOSCA (cm)	1.00			IN			IN		
Operational control conditions	Focus (cm)		1.2	1.2	IN	IN	1.2	IN	IN	1.2	IN
	Depth and (cm)		3.0	3.0	IN	IN	3.0	IN	IN	3.0	IN
	THI		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MHz)		10	10	IN	IN	10	IN	IN	10	IN

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

Acoustic output reporting table for band 3
Transducer Model: 128L
Operation mode: B eye mode

Index label	MI	TIS	TIB	TIC

				On the surface	Lower the surface icie	On the surface	Lower the surface icie	
Overall maximum value of the index			0.166	0.022		0.051		0.051
Value of index component1				0.022	0.022	0.051	0.022	
Associated acoustic parameters	pr,α at zMI	(MPa)	0.51					
	P or W0	(mW)		1.56				
	P1x1	(mW)		0.49				
	Zs	(cm)						
	Zb	(cm)						
	zMI	(cm)	1.36					
	zpii,α	(cm)	1.4					
	FAWF or FC	(MHz)	9.51					
Other information	PRR	(Hz)	4080					
	SRR	(Hz)	15					
	NPPs		272					
	Ipa,α @zpii, α	(W/cm2)	9.31					
	ISPTA, α@zpii, α or zsii,α	(mW/cm2)	0.76					
	Ispta @zpii or ZSII	(mW/cm2)	2.08					
	pr@zpII	(MPa)	0.81					
Operational control conditions	Screen focus (cm)		IN	IN	IN	IN	IN	IN
	Depth Display (cm)		2.4	2.4	2.4	2.4	2.4	2.4
	Frequency of Working (MHz)		10.0	10.0	10.0	10.0	10.0	10.0

	Show number	1	1	1	1	1	1

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128L
Operation Mode: B+M Mode

Index label			MI	TIS			TIB			TIC	
				Sweeping	Do Not Scan		Sweeping	Do Not Scan		Sweeps hard	Does not scanr
				Surface	Surface	Below the surface le	Surface	Surface	Below the surface le	On the surface	On the surface
Maximum value of the index			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
Acoustic Associate Parameters	pr,a in zMI (MPa)		3.46								
	P (mW)			36.93	1.02		36.93	1.02		36.93	1.02
	P1x1 (mW)			19.23	0.53		19.23	0.53			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					1.52			1.52		
	ZB (cm)								1.52		
	ZPI (cm)		1.20			1.20			1.20		
	zMI (cm)		1.00								
	D to ZB (cm)								0.26		
	fawf (MHz)		4.74	4.74	4.74		4.74	4.74		4.74	4.74
	Dimof Aaprt	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
	TD (USEC)		0.52								
	PRR (Hz)		B: 3161.00 M: 87,19								
	srr (Hz)		10.90								
	pr at zpii (MPa)		4.08								
	Deq in zpii (cm)								0.23		
	Ipa,α in zpii,α (W/cm2)		391.30								
	Focal Compriment to	FLX (cm)	1.20			1.20			1.20		
		MOSCA (cm)	1.00			1.00			1.00		
Operation	Focus (cm)		1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
	Depth and (cm)		3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0

al control conditions	THI	IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MHz)	10	10	10	10	10	10	10	10	10
	M PRF (Hz)	89.38	--	89.38	89.38	--	89.38	89.38	--	89.38

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128L
Operation Mode: B+CF/B+PD Mode

Index label			MI	TIS			TIB			TIC	
				Sweeping	Do Not Scan		Sweeping	Do Not Scan		Sweeps hard	No Escanear
				Surface	Surface	Below the surface le	Surface	Surface	Below the surface le	On the surface	On the surface
Maximum index value			1.59	0.38			0.38			0.79	
Index Component Value			1.59	B: 0.25 CF: 0.13	IN	IN	B: 0.25 CF: 0.13	IN	IN	B: 0.52 CF: 0,27	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		3.46								
	P (mW)			B: 21.11 CF: 11.06	IN		B: 21.11 CF: 11.06	IN		B: 21.11 CF: 11.06	IN
	P1x1 (mW)			B: 10.99 CF: 5,76	IN		B: 10.99 CF: 5.76	IN			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	ZB (cm)								IN		
	ZPI (cm)		1.20			IN			IN		
	zMI (cm)		1.00								
	D in ZB (cm)								IN		
	fawf (MHz)		B: 4.74	B: 4.74 CF: 4.83	IN		B: 4.74 CF: 4.83	IN		B: 4.74 CF: 4,83	IN
	Dimof Aaprt	X (cm)		1.92	IN		1.92	IN		1.92	IN
		Y (cm)		0.42	IN		0.42	IN		0.42	IN
Other information	Mode components		B+CF	B+CF	IN		B+CF	IN		B+CF	IN
	TD (USEC)		0.52								
	PRR (Hz)		B: 1806.70 CF: 4940.0								
	srr (Hz)		6.23								
	PR at ZPII (MPa)		4.08								
	Deq in zpii (cm)								IN		
	Ipa,α on ZPII,α (W/cm2)		391.30								
	Focal	FLX (cm)	1.20			IN			IN		

	Comp rimen t to	MOS CA (cm)	1.00			IN			IN		
Conditions	Focus (cm)		1.2	1.2	IN	IN	1.2	IN	IN	1.2	IN

de controle operación al	Depth and (cm)	3.0	3.0	IN	IN	3.0	IN	IN	3.0	IN
	THI	IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MHz)	B: 10 CF: 5	B: 10 CF: 5	IN	IN	B: 10 CF: 5	IN	IN	B: 10 CF: 5	IN
	PRF Color (kHz)	4.94	4.94	IN	IN	4.94	IN	IN	4.94	IN
NA indicates that there is no corresponding intended use or no data reported.										

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128L
Operation Mode: PW Mode

Index label			MI	TIS			TIB			TIC	
				Sweeping	Do Not Scan		Sweeping	Do Not Scan		Sweeping	No Escanear
				Surface	Surface	Below the surface le	Surface	Surface	Below the surface le	On the surface and	On the surfac e
Maximum index value			1.07	0.43			1.71			0.82	
Component Value index			1.07	IN	0.36	0.43	IN	0.82	1.71	IN	0.82
Acoustic Associate Parameters	pr,a in zMI (MPa)		2.22								
	P (mW)			IN	33.14		IN	33.14		IN	33.14
	P1x1 (mW)			IN	17.26		IN	17.26			
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					1.52			1.52		
	ZB (cm)								1.52		
	ZPI (cm)		0.88			0.88			0.88		
	zMI (cm)		0.86								
	D to ZB (cm)								0.28		
	fawf (MHz)		4.31	IN	4.31		IN	4.31		IN	4.31
	Dimof Aaprt	X (cm)		IN	1.92		1.92	1.92		IN	1.92
		Y (cm)		IN	0.42		0.42	0.42		IN	0.42
Other information	Mode components		Prisoner of war	IN	Prisoner of war		IN	Prisoner of war		IN	Prisoner of war the
	TD (USEC)		0.89								
	PRR (Hz)		3920.00								
	srr (Hz)		IN								
	pr at zpii (MPa)		2.52								
	Deq in zpii (cm)								0.23		
	Ipa,α on ZPII,α (W/cm2)		161.50								

	Focal Compriment to	FLX (cm)	1.20			1.20			1.20		
		MOSCA (cm)	1.00			1.00			1.00		
Conditions	Focus (cm)		1.2	IN	1.2	1.2	IN	1.2	6.4	IN	1.2
of	Depth		3.0	IN	3.0	3.0	IN	3.0	12.6	IN	3.0

Operational Control	and (cm)									
	Frequency (MHz)	4.2	IN	4.2	4.2	IN	4.2	2.6	IN	4.2
	PRF (kHz)	3.92	IN	3.92	3.92	IN	3.92	4.17	IN	3.92
	Gate (mm)	0.3	IN	0.3	0.3	IN	0.3	0.5	IN	0.3
NA indicates that there is no corresponding intended use or no data reported.										

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128LH
Operation Mode: PW Mode

Index label			MI	TIS		TIB		TIC
				On the surface and	Below the surface and	On the surface and	Below the surface and	
Overall maximum value of the index			0.50	0.05		0.24		0.11
Value of index component1				0.05	0.03	0.11	0.24	
Acoustic Associate Parameters	pr,α at zMI	(MPa)	1.02					
	P or W0	(mW)		2.02				
	P1x1	(mW)		2.53				
	Zs	(cm)			0.74			
	Zb	(cm)					0.76	
	zMI	(cm)	0.92					
	zpii,α	(cm)	0.62					
	FAWF or FC	(MHz)	4.21					
Other information	PRR	(Hz)	4170					
	SRR	(Hz)						
	NPS		IN					
	Ipa,α@zpii,α	(W/cm2)	23.65					
	Ispta,α@zpii,α or zsii,α	(mW /cm2)	89.19					
	Ispta @zpii or zsii	(mW /cm2)	110.40					
	pr@zpii	(MPa)	1.12					
Multinacional Control conditions	Screen focus (cm)		1.5	1.5	1.5	1.5	1.5	1.5
	Depth of Display (cm)	fr	3.9	3.9	3.9	3.9	3.9	3.9
	Working Frequency (MHz)		4.2	4.2	4.2	4.2	4.2	4.2
	Display focus number		1	1	1	1	1	1
NA indicates that there is no corresponding intended use or no data reported.								

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128LH
Operation Mode: B+M Mode

Index label			MI	TIS		TIB		TIC
				On the surface and	Below the surface and	On the surface and	Below the surface and	
Overall maximum value of the index			0.77	0.039		0.073		0.073
Value of index component1				0.05	0.03	0.11	0.24	
Acoustic Associate Parameters	pr,α at zMI	(MPa)	2.52					
	P or W0	(mW)		B: 1.41 M: 0.03				
	P1x1	(mW)		B: 0.73 M: 0.06				
	Zs	(cm)			0.74			
	Zb	(cm)					1.1	
	zMI	(cm)	1.12					
	zpii,α	(cm)	1.12					
	FAWF or FC	(MHz)	B: 10.42 M: 10.64					
	PRR	(Hz)	2373					
	SRR	(Hz)	8.4					
	NPS		272					

Other information	Ipa,α@zpii,α	(W/cm2)	271.74					
	Ispta,α@zpii,α or zsii,α	(mW/cm2)	5.14					

	Ispta @zpii or ZSII	(mW/cm2)	11.86					
	pr@zpii	(MPa)	3.69					
Multinacional Control conditions	Screen focus (cm)		IN	IN	IN	IN	IN	IN
	Depth Display (cm)		3.9	3.9	3.9	3.9	3.9	3.9
	Working Frequency (MHz)		10.0	10.0	10.0	10.0	10.0	10.0
	Display focus number		1	1	1	1	1	1
NA indicates that there is no corresponding intended use or no data reported.								

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128LH
Operating Mode: B Mode

Index label			MI	TIS		TIB		TIC
				On the surface and	Below the surface and	On the surface and	Below the surface and	
Overall maximum value of the index			0.51	0.06		0.12		0.12
Value of index component1				0.06	0.06	0.12	0.06	
Acoustic Associate Parameters	pr,α at zMI	(MPa)	1.64					
	P or W0	(mW)		2.45				
	P1x1	(mW)		1.27				
	Zs	(cm)						
	Zb	(cm)						
	zMI	(cm)	0.9					
	zpii,α	(cm)	1.02					
	FAWF or FC	(MHz)	10.42					
Other information	PRR	(Hz)	4080					
	SRR	(Hz)	15					
	NPS		272					
	Ipa,α@zpii,α	(W/cm2)	105.29					
	Ispta,α@zpii,α or zsii,α	(mW /cm2)	3.63					
	Ispta @zpii or ZSII	(mW /cm2)	7.77					
	pr@zpii	(MPa)	2.27					
Multinacional Control conditions	Screen focus (cm)		IN	IN	IN	IN	IN	IN
	Depth Display (cm)		3.9	3.9	3.9	3.9	3.9	3.9
	Working frequency (MHz)		10.0	10.0	10.0	10.0	10.0	10.0
	Display focus number		1	1	1	1	1	1
NA indicates that there is no corresponding intended use or no data reported.								

Acoustic output reporting table for band 3 Transducer
model: 128LH ;
Operation Mode: B THI Mode

Index label			MI	TIS		TIB		TIC
				On the surface and	Below the surface and	On the surface and	Below the surface and	
Overall maximum value of the index			1.14	0.03		0.13		0.13
Value of index component1				0.03	0.03	0.13	0.03	
Acoustic Associate Parameters	pr,α at zMI	(MPa)	2.67					
	P or W0	(mW)		2.36				
	P1x1	(mW)		1.19				
	Zs	(cm)						
	Zb	(cm)						
	zMI	(cm)	0.96					
	zpii,α	(cm)	0.96					
	FAWF or FC	(MHz)	5.49					
Other information	PRR	(Hz)	3840					
	SRR	(Hz)	15					
	NPS		256					
	Ipa,α@zpii,α	(W/cm2)	164.33					
	Ispta,α@zpii,α or zsii,α	(mW /cm2)	6.98					
	Ispta @zpii or zsii	(mW /cm2)	10.36					
	pr@zpii	(MPa)	3.20					

Multinational	Screen focus (cm)	1.6	1.6	1.6	1.6	1.6	1.6
	Depth fr om	3.9	3.9	3.9	3.9	3.9	3.9

Control conditions	Display (cm)						
	Working Frequency (MHz)	H 10	H 10	H 10	H 10	H 10	H 10
	Display focus number	1	1	1	1	1	1
NA indicates that there is no corresponding intended use or no data reported.							

Acoustic output reporting table for band 3 Transducer
model: 128LH ;
Operating mode: B+C mode

Index label			MI	TIS		TIB		TIC
				On the surface and	Below the surface and	On the surface and	Below the surface and	
Overall maximum value of the index			0.46	0.03		0.05		0.05
Value of index component1				B: 0.01 C: 0.02	B: 0.01 C: 0.02	B: 0.01 C: 0.04	B: 0.01 C: 0.02	
Acoustic Associate Parameters	pr,α at zMI	(MPa)	1.05					
	P or W0	(mW)		B: 0.26 C: 0.85				
	P1x1	(mW)		B: 0.15 C: 0.75				
	Zs	(cm)						
	Zb	(cm)						
	zMI	(cm)	1.08					
	zpii,α	(cm)	0.96					
	FAWF or FC	(MHz)	B: 10.39 C: 5.20					
Other information	PRR	(Hz)	1344					
	SRR	(Hz)	8					
	NPS		168					
	Ipa,α@zpii,α	(W/cm2)	54.11					
	Ispta,α@zpii,α or zsii,α	(mW/cm2)	6.76					
	Ispta @zpii or zsii	(mW/cm2)	10.07					
	pr@zpii	(MPa)	1.85					
Multinacional Control conditions	Screen focus (cm)		(4.0)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0)
	Depth from Display (cm)		3.9	3.9	3.9	3.9	3.9	3.9
	Working Frequency (MHz)		10.0	10.0	10.0	10.0	10.0	10.0
	Display focus number		1	1	1	1	1	1
NA indicates that there is no corresponding intended use or no data reported.								

Acoustic output reporting table for band 3 Transducer
model: 128LH ;
Operation mode: B eye mode

Index label			MI	TIS		TIB		TIC
				On the surface and	Below the surface and	On the surface and	Below the surface and	
Overall maximum value of the index			0.16	0.01		0.02		0.02
Value of index component1				0.01	0.01	0.02	0.01	
Acoustic Associate Parameters	pr,α at zMI	(MPa)	0.54					
	P or W0	(mW)		0.54				
	P1x1	(mW)		0.27				
	Zs	(cm)						
	Zb	(cm)						
	zMI	(cm)	1.00					
	zpii,α	(cm)	1.00					
	FAWF or FC	(MHz)	11.15					
Other information	PRR	(Hz)	4080					
	SRR	(Hz)	15					
	NPS		272					
	Ipa,α@zpii,α	(W/cm2)	5.70					

n	Ispta,α@zpii,α or zsii,α	(mW /cm2)	0.57					
	Ispta @zpii or	(mW	1.27					

	zsii	/cm2)						
	pr@zpii	(MPa)	0.80					
Multinacional Control conditions	Screen focus (cm)		IN	IN	IN	IN	IN	IN
	Depth Display (cm)		2.4	2.4	2.4	2.4	2.4	2.4
	Working Frequency (MHz)		10.0	10.0	10.0	10.0	10.0	10.0
	Display focus number		1	1	1	1	1	1
NA indicates that there is no corresponding intended use or no data reported.								

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128M
Operating Mode: B Mode

Index label			MI	TIS			TIB			TIC	
				Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
				Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	In Surface and
Maximum index value			1.45	1.21			1.21			1.84	
Index Component Value			1.45	1.21	IN	IN	1.21	IN	IN	1.84	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		3.21								
	P (mW)			68.45	IN		68.45	IN		68.45	IN
	P1x1 (mW)			52.25	IN		52.25	IN			
	Min of [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	ZB (cm)								IN		
	ZPI (cm)		1.66			IN			IN		
	zMI (cm)		1.52								
	D to ZB (cm)								IN		
	fawf (MHz)		4.88	4.88	IN		4.88	IN		4.88	IN
	Dimof	X (cm)		1.31	IN		1.31	IN		1.31	IN
	Aaprt	Y (cm)		0.52	IN		0.52	IN		0.52	IN
Other information	Mode Components		B	B	IN		B	IN		B	IN
	TD (USEC)		0.39								
	PRR (Hz)		6403.40								
	srr (Hz)		11.30								
	pr at zpii (MPa)		4.15								
	Deq in zpii (cm)								IN		
	Ipa,α to zpii,α (W/cm2)		272.10								
	Focal length	FLX(cm)	2.10			IN			IN		
		FLY (cm)	1.50			IN			IN		
Operational control conditions	Focus (cm)		2.1	2.1	IN	IN	2.1	IN	IN	2.1	IN
	Depth (cm)		4.0	4.0	IN	IN	4.0	IN	IN	4.0	IN
	THI		OFF	OFF	IN	IN	OFF	IN	IN	OFF	IN
	Frequency (MHz)		5.0	5.0	IN	IN	5.0	IN	IN	5.0	IN

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128M
Operation Mode: B+M Mode

Index label		MI	TIS			TIB			TIC	
			Scan	Do Not Scan		Scan	Do Not Scan		Scan	No Scan
			Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	In Surface and
Maximum index value		1.45	1.19			1.22			1.80	
Index Component Value		1.45	1.17	0.02	0.01	1.17	0.03	0.05	1.77	0.03
Acoustic Associate Parameters	pr,a in zMI (MPa)	3.21								
	P (mW)		65.95	0.93		65.95	0.93		65.95	0.93
	P1x1 (mW)		50.34	0.71		50.34	0.71			
	[Pa(zs),Ita,α(zs) x1cm2] min(mW)				IN					
	zS (cm)				IN					

	ZBP (cm)					1.40			1.40		
	ZB (cm)								1.52		
	ZPI (cm)		1.66			1.66			1.66		
	zMI (cm)		1.52								
	D to ZB (cm)								0.27		
	fawf (MHz)		4.88	4.88	4.88		4.88	4.88		4.88	4.88
	Dimof	X (cm)		1.31	1.31		1.31	1.31		1.31	1.31
	Aaprt	Y (cm)		0.52	0.52		0.52	0.52		0.52	0.52
Other information	Mode Components		B+M	B	M		B	M		B	M
	TD (USEC)		0.39								
	PRR (Hz)		B: 6169.40 M: 87.19								
	srr (Hz)		10.90								
	pr at zpii (MPa)		4.15								
	Deq in zpii (cm)								0.27		
	Ipa,α to zpii,α (W/cm2)		272.10								
	Focal length	FLX(cm)	2.10			2.10			2.10		
		FLY (cm)	1.50			1.50			1.50		
Operational control conditions	Focus (cm)		2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1	2.1
	Depth (cm)		4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
	THI		OFF	OFF	OFF	OFF	OFF	OFF	OFF	OFF	DISCONNECT FROM
	Frequency (MHz)		5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0	5.0
	M PRF (Hz)		89.38	--	89.38	89.38	--	89.38	89.38	--	89.38

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128M
Operation Mode: B+CF/B+PD Mode

Index label			MI	TIS			TIB			TIC	
				Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
				Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	In Surface and
Maximum index value			1.45	0.82			0.82			1.28	
Index Component Value			1.45	B: 0.67 CF: 0.15	IN	IN	B: 0.67 CF:0.15	IN	IN	B: 1.01 CF: 0.27	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		3.21								
	P (mW)			B: 37.70 CF: 9.93	IN		B: 37.70 CF: 9.93	IN		B: 37.70 CF: 9.93	IN
	P1x1 (mW)			B: 28.78 CF: 7.58	IN		B: 28.78 CF: 7.58	IN			
	Min of [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	ZB (cm)								IN		
	ZPI (cm)		1.66			IN			IN		
	zMI (cm)		1.52								
	D to ZB (cm)								IN		
	fawf (MHz)		B: 4.88	B: 4.88 CF: 4.26	IN		B: 4.88 CF: 4.26	IN		B: 4.88 CF: 4.26	IN
	Dimof	X (cm)		1.31	IN		1.31	IN		1.31	IN
	Aaprt	Y (cm)		0.52	IN		0.52	IN		0.52	IN
Other information	Mode Components		B+CF	B+CF	IN		B+CF	IN		B+CF	IN
	TD (USEC)		0.39								
	PRR (Hz)		B: 3526.18 CF: 2740.0								
	srr (Hz)		6.23								
	pr at zpii (MPa)		4.15								
	Deq in zpii (cm)								IN		
	Ipa,α to zpii,α (W/cm2)		272.10								
	Focal length	FLX(cm)	2.10			IN			IN		
		FLY (cm)	1.50			IN			IN		
Operational control conditions	Focus (cm)		2.1	2.1	IN	IN	2.1	IN	IN	2.1	IN
	Depth (cm)		4.0	4.0	IN	IN	4.0	IN	IN	4.0	IN
	THI		OFF	OFF	IN	IN	OFF	IN	IN	OFF	IN
	Frequency (MHz)		B: 5.0 CF: 4.2	B: 5.0 CF: 4.2	IN	IN	B: 5.0 CF: 4.2	IN	IN	B: 5.0 CF: 4.2	IN
	PRF Color (kHz)		2.74	2.74	IN	IN	2.74	IN	IN	2.74	IN

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128M
Operation Mode: PW Mode

Index label			MI	TIS			TIB			TIC	
				Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
				Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	In Surface and
Maximum index value			0.79	0.39			1.21			0.68	
Index Component Value			0.79	IN	0.39	0.34	IN	0.68	1.21	IN	0.68
Acoustic Associate	pr,a in zMI (MPa)		1.62								
	P (mW)			IN	25.28		IN	25.28		IN	25.28

Parameters	P1x1 (mW)			IN	19.30		IN	19.30				
	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN						
	zS (cm)					IN						
	ZBP (cm)					1.40			1.40			
	ZB (cm)								1.40			
	ZPI (cm)		1.64			1.64			1.64			
	zMI (cm)		1.24									
	D to ZB (cm)								0.31			
	fawf (MHz)		4.24	IN	4.24		IN	4.24			IN	4.24
	Dimof	X (cm)		IN	1.31		IN	1.31			IN	1.31
	Aaprt	Y (cm)		IN	0.52		IN	0.52			IN	0.52
Other information	Mode Components		Prisoner of war	IN	Prisoner of war		IN	Prisoner of war			IN	I arreste d the war
	TD (USEC)		0.88									
	PRR (Hz)		3270.00									
	srr (Hz)		IN									
	pr at zpii (MPa)		1.94									
	Deq in zpii (cm)								0.31			
	Ipa,α to zpii,α (W/cm2)		104.10									
	Focal length	FLX(cm)	2.10			2.10			2.10			
		FLY (cm)	1.50			1.50			1.50			
Operational control conditions	Focus (cm)		2.1	IN	2.1	2.1	IN	2.1	2.1	IN	2.1	
	Depth (cm)		4.0	IN	4.0	4.0	IN	4.0	4.0	IN	4.0	
	Frequency (MHz)		4.2	IN	4.2	4.2	IN	4.2	4.2	IN	4.2	
	PRF (kHz)		3.27	IN	3.27	3.27	IN	3.27	3.27	IN	3.27	
	Gate (mm)		0.3	IN	0.3	0.3	IN	0.3	0.3	IN	0.3	
NA indicates that there is no corresponding intended use or no data reported.												

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128PA
Operating Mode: B Mode

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

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128PA
Operation Mode: B+M Mode

Index label		MI	TIS			TIB			TIC	
			Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
			Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	On the surface and
Maximum index value		1.61	0.79			0.93			IN	
Index Component Value		1.61	0.73	0.04	0.06	0.73	0.14	0.20	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)	2.12								
	P (mW)		207.20	9.87		207.20	9.87		IN	IN
	P1x1 (mW)		87.89	4.18		87.89	4.18			
	Min of [Pa(zs), Ita,α(zs)x1cm2] (mW)				7.18					
	zS (cm)				2.60					
	ZBP (cm)				2.60			2.60		

	ZB (cm)								2.96		
	ZPI (cm)		3.92			3.92			3.92		
	zMI (cm)		2.96								
	D to ZB (cm)								0.79		
	fawf (MHz)		1.74	1.74	1.74		1.74	1.74		IN	IN
	Dimof	X (cm)		2.05	2.05		2.05	2.05		IN	IN
	Aaprt	Y (cm)		1.15	1.15		1.15	1.15		IN	IN
Other information	Mode Components		B+M	B	M		B	M		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		B: 2288.16 M: 108.99								
	srr (Hz)		13.62								
	pr at zpii (MPa)		2.54								
	Deq in zpii (cm)								0.78		
	Ipa,α to zpii,α (W/cm2)		233.80								
	Focal length	FLX(cm)	3.20			3.20			3.20		
		FLY (cm)	3.00			3.00			3.00		
Operational control conditions	Focus (cm)		3.2	3.2	3.2	3.2	3.2	3.2	3.2	IN	IN
	Depth (cm)		6.3	6.3	6.3	6.3	6.3	6.3	6.3	IN	IN
	THI		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MHz)		3.6	3.6	3.6	3.6	3.6	3.6	3.6	IN	IN
	M PRF (Hz)		114.0	--	114.0	114.0	--	114.0	114.0	IN	IN

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128PA
Operating Mode: B+CF (TVI)/B+PD(TEI) Mode

Index label			MI	TIS			TIB			TIC	
				Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
				Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	In Surface and
Maximum index value			1.61	1.66			1.66			IN	
Index Component Value			1.61	B: 0.76 CF: 0.90	IN	IN	B: 0.76 CF: 0.90	IN	IN	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		2.12								
	P (mW)			B: 214.90 CF: 173.90	IN		B: 214.90 CF: 173.90	IN		IN	IN
	P1x1 (mW)			B: 91.16 CF: 73.76	IN		B: 91.16 CF: 73.76	IN			
	Min of [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	ZB (cm)								IN		
	ZPI (cm)		3.92			IN			IN		
	zMI (cm)		2.96								
	D to ZB (cm)								IN		
	fawf (MHz)		B: 1.74	B: 1.74 CF: 2.56	IN		B: 1.74 CF: 2.56	IN		IN	IN
	Dimof	X (cm)		2.04	IN		2.04	IN		IN	IN
	Aaprt	Y (cm)		1.15	IN		1.15	IN		IN	IN
Other information	Mode Components		B+CF	B+CF	IN		B+CF	IN		IN	IN
	TD (USEC)		1.05								
	PRR (Hz)		B: 2373.5 CF: 3600.0								
	srr (Hz)		14.13								
	pr at zpii (MPa)		2.54								
	Deq in zpii (cm)								IN		
	Ipa,α to zpii,α (W/cm2)		238.80								
	Focal length	FLX(cm)	3.20			IN			IN		
		FLY (cm)	3.00			IN			IN		
Operational control conditions	Focus (cm)		3.2	3.2	IN	IN	3.2	IN	IN	IN	IN
	Depth (cm)		6.3	6.3	IN	IN	6.3	IN	IN	IN	IN
	POETRY		IN	IN	IN	IN	IN	IN	IN	IN	IN
	Frequency (MHz)		B: 3.6 CF: 2.6	B: 3.6 CF: 2.6	IN	IN	B: 3.6 CF: 2.6	IN	IN	IN	IN
	PRF Color (kHz)		3.6	3.6	IN	IN	3.6	IN	IN	IN	IN

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128PA
Operation Mode: PW Mode (TDI)

Index label		MI	TIS			TIB			TIC	
			Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
			Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	On the surface and
Maximum index value		0.76	1.28			3.87			IN	
Index Component Value		0.76	IN	0.79	1.28	IN	2.70	3.87	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)	1.10								
	P (mW)		IN	186.53		IN	186.53		IN	IN
	P1x1 (mW)		IN	79.12		IN	79.12			

	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					127.80					
	zS (cm)					2.60					
	ZBP (cm)					2.60			2.60		
	ZB (cm)								2.62		
	ZPI (cm)		3.08			3.08			3.08		
	zMI (cm)		2.62								
	D to ZB (cm)								0.74		
	fawf (MHz)		2.09	IN	2.09		IN	2.09		IN	IN
	Dimof Aaprt	X (cm)		IN	2.05		IN	2.05		IN	IN
		Y (cm)		IN	1.15		IN	1.15		IN	IN
Other information	Mode Components		Prisoner of war	IN	Prisoner of war		IN	Prisoner of war		IN	IN
	TD (USEC)		1.83								
	PRR (Hz)		4170.00								
	srr (Hz)		IN								
	pr at zpii (MPa)		1.33								
	Deq in zpii (cm)								0.73		
	Ipa,α to zpii,α (W/cm2)		33.17								
	Focal length	FLX(cm)	3.20			3.20			3.20		
		FLY (cm)	3.00			3.00			3.00		
Operational control conditions	Focus (cm)		3.2	IN	3.2	3.2	IN	3.2	3.2	IN	IN
	Depth (cm)		6.3	IN	6.3	6.3	IN	6.3	6.3	IN	IN
	Frequency (MHz)		2.1	IN	2.1	2.1	IN	2.1	2.1	IN	IN
	PRF (kHz)		4.17	IN	4.17	4.17	IN	4.17	4.17	IN	IN
	Gate (mm)		0.5	IN	0.5	0.5	IN	0.5	0.5	IN	IN
NA indicates that there is no corresponding intended use or no data reported.											

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128E
Operating Mode: B Mode

Index label			MI	TIS			TIB			TIC	
				Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
				Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	In Surface and
Maximum index value			1.06	0.84			0.84			IN	
Index Component Value			1.06	0.84	IN	IN	0.84	IN	IN	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		2.33								
	P (mW)			48.76	IN		48.76	IN		IN	IN
	P1x1 (mW)			36.94	IN		36.94	IN			
	Min of [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	e.g., (cm)								IN		
	ZPI (cm)		1.74			IN			IN		
	zMI (cm)		1.54								
	D to ZB (cm)								IN		
	fawf (MHz)		4.79	4.79	IN		4.79	IN		IN	IN
	Dimof	X (cm)		1.32	IN		1.32	IN		IN	IN
	Aaprt	Y (cm)		0.52	IN		0.52	IN		IN	IN
Other information	Mode Components		B	B	IN		B	IN		IN	IN
	TD (USEC)		0.43								
	PRR (Hz)		6400.70								
	srr (Hz)		11.30								
	pr at zpii (MPa)		3.00								
	Deq in zpii (cm)								IN		
	Ipa,α to zpii,α (W/cm2)		142.90								
	Focal length	FLX(cm)	2.10			IN			IN		
		FLY (cm)	1.50			IN			IN		
Operational control conditions	Focus (cm)		2.1	2.1	IN	IN	2.1	IN	IN	IN	IN
	Depth (cm)		4.0	4.0	IN	IN	4.0	IN	IN	IN	IN
	THI		OFF	OFF	IN	IN	OFF	IN	IN	IN	IN
	Frequency (MHz)		5.0	5.0	IN	IN	5.0	IN	IN	IN	IN

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128E
Operation Mode: B+M Mode

Index label		MI	TIS			TIB			TIC	
			Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
			Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	On the surface and
Maximum index value		1.06	0.82			0.84			IN	
Index Component Value		1.06	0.81	0.01	0.01	0.81	0.02	0.03	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)	2.33								
	P (mW)		47.00	0.66		47.00	0.66		IN	IN
	P1x1 (mW)		35.61	0.50		35.61	0.50			
	Min of [Pa(zs), Ita,α(zs)x1cm2] (mW)				IN					
	zS (cm)				IN					
	ZBP (cm)				1.40			1.40		

	ZB (cm)								1.54		
	ZPI (cm)		1.74			1.74			1.74		
	zMI (cm)		1.54								
	D to ZB (cm)								0.79		
	fawf (MHz)		4.79	4.79	4.79		4.79	4.79		IN	IN
	Dimof	X (cm)		1.32	1.32		1.32	1.32		IN	IN
	Aaprt	Y (cm)		0.52	0.52		0.52	0.52		IN	IN
Other information	Mode Components		B+M	B	M		B	M		IN	IN
	TD (USEC)		0.43								
	PRR (Hz)		B: 6169.40 M: 87.19								
	srr (Hz)		10.90								
	pr at zpii (MPa)		3.00								
	Deq in zpii (cm)								0.32		
	Ipa,α to zpii,α (W/cm2)		142.90								
	Focal length	FLX(cm)	2.10			2.10			2.10		
		FLY (cm)	1.50			1.50			1.50		
Operational control conditions	Focus (cm)		2.1	2.1	2.1	2.1	2.1	2.1	2.1	IN	IN
	Depth (cm)		4.0	4.0	4.0	4.0	4.0	4.0	4.0	IN	IN
	THI		OFF Or	OFF	OFF	OFF	OFF	OFF	OFF	IN	IN
	Frequency (MHz)		5.0	5.0	5.0	5.0	5.0	5.0	5.0	IN	IN
	M PRF (Hz)		89.38	--	89.38	89.38	--	89.38	89.38	IN	IN

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

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128E
Operation Mode: B+CF/B+PD Mode

Index label			MI	TIS			TIB			TIC	
				Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
				Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	In Surface and
Maximum index value			1.06	0.53			0.53			IN	
Index Component Value			1.06	B: 0.46 CF: 0.07	IN	IN	B: 0.46 CF: 0.07	IN	IN	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)		2.33								
	P (mW)			B: 26.86 CF: 4.50	IN		B: 26.86 CF: 4.50	IN		IN	IN
	P1x1 (mW)			B: 20.35 CF: 3.41	IN		B: 20.35 CF: 3.41	IN			
	Min of [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					IN			IN		
	ZB (cm)								IN		
	ZPI (cm)		1.74			IN			IN		
	zMI (cm)		1.54								
	D to ZB (cm)								IN		
	fawf (MHz)		B: 4.79	B: 4.79 CF: 4.33	IN		B: 4.79 CF: 4.33	IN		IN	IN
	Dimof	X (cm)		1.32	IN		1.32	IN		IN	IN
	Aaprt	Y (cm)		0.52	IN		0.52	IN		IN	IN
Other information	Mode Components		B+CF	B+CF	IN		B+CF	IN		IN	IN
	TD (USEC)		0.43								
	PRR (Hz)		B: 3526.18 CF: 2740.0								
	srr (Hz)		6.23								
	pr at zpii (MPa)		3.00								
	Deq in zpii (cm)								IN		
	Ipa,α to zpii,α (W/cm2)		142.90								
	Focal length	FLX(cm)	2.10			IN			IN		
		FLY (cm)	1.50			IN			IN		
Operational control conditions	Focus (cm)		2.1	2.1	IN	IN	2.1	IN	IN	IN	IN
	Depth (cm)		4.0	4.0	IN	IN	4.0	IN	IN	IN	IN
	POETRY		OFF	OFF	IN	IN	OFF	IN	IN	IN	IN
	Frequency (MHz)		B: 5.0 CF: 4.2	B: 5.0 CF: 4.2	IN	IN	B: 5.0 CF: 4.2	IN	IN	IN	IN
	PRF Color (kHz)		2.74	2.74	IN	IN	2.74	IN	IN	IN	IN
NA indicates that there is no corresponding intended use or no data reported.											

Acoustic Output Reporting Table for Band 3 Transducer
Model: 128E
Operation Mode: PW Mode

Index label		MI	TIS			TIB			TIC	
			Scan	Do Not Scan		Scan	Do Not Scan		Scan	Do Not Scan
			Surface	Surface	Below the surface	Surface	Surface	Below the surface	Surface	Surface
Maximum index value		0.73	0.36			1.19			IN	
Index Component Value		0.73	IN	0.36	0.31	IN	0.62	1.19	IN	IN
Acoustic Associate Parameters	pr,a in zMI (MPa)	1.52								
	P (mW)		IN	23.12		IN	23.12		IN	IN
	P1x1 (mW)		IN	17.52		IN	17.52			

	Min de [Pa(zs), Ita,α(zs)x1cm2] (mW)					IN					
	zS (cm)					IN					
	ZBP (cm)					1.40			1.40		
	ZB (cm)								1.68		
	ZPI (cm)		1.68			1.68			1.68		
	zMI (cm)		1.68								
	D to ZB (cm)								0.27		
	fawf (MHz)		4.28	IN	4.28		IN	4.28		IN	IN
	Dimof Aaprt	X (cm)		IN	1.32		IN	1.32		IN	IN
		Y (cm)		IN	0.52		IN	0.52		IN	IN
Other information	Mode Components		Prisoner of war	IN	Prisoner of war		IN	Prisoner of war		IN	IN
	TD (USEC)		0.89								
	PRR (Hz)		3270.00								
	srr (Hz)		IN								
	pr at zpii (MPa)		1.95								
	Deq in zpii (cm)								0.27		
	Ipa,α to zpii,α (W/cm2)		89.05								
	Focal length	FLX(cm)	2.10			2.10			2.10		
		FLY (cm)	1.50			1.50			1.50		
Operational control conditions	Focus (cm)		2.1	IN	2.1	2.1	IN	2.1	2.1	IN	IN
	Depth (cm)		4.0	IN	4.0	4.0	IN	4.0	4.0	IN	IN
	Frequency (MHz)		4.2	IN	4.2	4.2	IN	4.2	4.2	IN	IN
	PRF (kHz)		3.27	IN	3.27	3.27	IN	3.27	3.27	IN	IN
	Gate (mm)		0.3	IN	0.3	0.3	IN	0.3	0.3	IN	IN

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

C. Manufacturer's Guidance and Declaration

1.The 128 series requires special precautions with respect to EMC.
2.The 128 series should not be used adjacent to or stacked with other equipment.
3.Use of the wrong cables and accessories can adversely affect EMC's performance

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

D. Electromagnetic emissions

The Series 128 is intended for use in electromagnetic environments as specified below. The customer or user of the 128 Series must ensure that it is used in such an environment.

Manufacturer's declaration - electromagnetic emissions		
O LK128C, LK128L, LK128LH, LK128LH, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA is intended for use in the electromagnetic environment (for home and professional health care) specified below. The customer or user of LK128C, LK128L,LK128LH,LK128LH,LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA should ensure that it is used in such an environment.		
Emissions testing	Compliance	Electromagnetic Ambient Guidance (for home and professional healthcare environment)
RF emissions CISPR 11	Group 1	The LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	O LK128C, LK128L, LK128LH, LK128LH, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply grid that supplies used buildings for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Fluctuations of IEC 61000-3-3 scintillation voltage/emissions	Not applicable	

Manufacturer's Declaration – Electromagnetic Immunity The LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA intended for if for use in the electromagnetic environment (for home and professional health care) specified below. The customer or user of LK128C, LK128L,LK128LH,, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA should ensure that it is used in such an environment.			
Immunity test	IEC 60601 Test Level	Level of compliance	Electromagnetic Orientation of the Environment (for home health environment and professional)

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	The floors must be made of wood, concrete or ceramic. If the floors are covered with synthetic material, the relative humidity should be at least 30%

Magnetic field energy frequency (50, 60 Hz) IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The magnetic fields of energy frequency LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M LV128PA should be at levels characteristic of a typical location in a typical home and healthcare professional setting.
Note: UT is the AC mains voltage before the test level is applied.			

Manufacturer's Declaration – Electromagnetic Immunity

The LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA intended for
if for use in the electromagnetic environment (for home and professional health care) specified below.
The customer or user of LK128C, LK128L,LK128LH,, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA should ensure that it is used in such an environment.

Immunity test	IEC 60601 Test Level	Level of compliance	Electromagnetic Ambient Guidance (for home and professional healthcare environment)
IEC 61000-4-39 Proximity Magnetic Field	8 A/m to 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	8 A/m to 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	

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

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

Recommended separation distance between
portable and mobile RF communication equipments and LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA

The LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA intended for
is for use in an electromagnetic environment (for home and professional health care) in which radiated RF disturbances are controlled. Customer or user of LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA can
help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA as recommended below, according to the maximum output power of the communication equipment.

Maximum rated output power of transmitter W	Separation distance according to the frequency of the 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 transmitter frequency,

where p is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer. NOTE1 At 80 MHz and 800 MHz, the separation distance for the highest frequency range applies.

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

Manufacturer's Declaration – Electromagnetic Immunity
Test Specifications for CABINET DOOR IMMUNITY to RF Wireless Communication Equipment
The LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA intended for
if for use in the electromagnetic environment (for home and professional health care) specified below.
The customer or user of LK128C, LK128L, LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA should ensure that it is used in such an environment.

Test Frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	Modulation (b)	Maximum Power (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**LEVEL OF COMPLIANCE** (V/m) (for home and professional health care)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM (c) Deviation of ±5 kHz 1 kHz sinusoidal	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Wrist 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	Wrist 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	Wrist 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	Wrist modulation (b) 217 Hz	2	0,3	28	28
5 240	5,100 – 5,800	WLAN 802.11	Wrist modulation (b)	0,2	0,3	9	9
5 500							

5 785		Attn:	217 Hz			

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

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

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

%.

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

Manufacturer's Declaration – Electromagnetic Immunity

Test Specifications for CABINET DOOR IMMUNITY to Proximity Magnetic Fields

The LK128C, LK128L, LK128LH,,LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA is intended for use in the electromagnetic environment (for home and professional health care) specified below.

The customer or user of LK128C, LK128L,LK128LH,,LK128LH, LK128M, LK128PA, LV128C, LV128L, LV128M, LV128PA should ensure that it is used in such an environment.

Frequencies	Test Level [A/m]	Modulation	Dwell time[s]	LEVEL OF COMPLIANCE [A/m] (for home and professional health care)
30 kHz (a)	8	CW	3	8
134.2 kHz	65	Pulse modulation (b) 2.1 kHz	3	65 (c)
13.56 MHz	7,5	Pulse modulation (b) 50 kHz	3	7.5 c)

Note:

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

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

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

E. Federal Communications Commission (FCC) Statement

15.21

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

15.105(b)

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

•Reorient or relocate the receiving antenna.

•Increase the separation between the equipment and the receiver.

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

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

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

1) This device may not cause harmful interference and

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

FCC RF Radiation Exposure Statement

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

A、Maintenance

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

B、Troubleshooting

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

Manufacturer's Address

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

IV. References

A、 Acoustic

i. EN IEC 60601-2-37:2008/AMD1:2015 - Medical electrical equipment - Part 2-37: Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
ii. AIUM/NEMA UD 2- 2004 2009 Publication of NEMA UD 2-2004 Standards (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3. (Radiology)
iii. AIUM/NEMA UD 3- 2004 2009 Publication of NEMA UD 3-2004 Standards (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices in Diagnostic Ultrasound Equipment

B、Biocompatibility

i. EN ISO 10993-1:2009 - Biological evaluation of medical devices - Evaluation and testing within a risk management process
ii. EN ISO 10993-5:2009 - Biological evaluation of medical devices - In vitro cytotoxicity tests
iii. ISO 10993-10:2010 - Biological evaluation of medical devices. Skin irritation and sensitization tests

C、Chemical

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

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

D、Battery

i. UN 38.3 - Transportation of lithium battery
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. 2/96/EC(WEEE)- Directive 2002/96/EC; Waste Electrical and Electronic Equipment Directive
ii. EN 300 328 V2.1.1; 2016 - Broadband transmission by wireless radio frequency);
iii. EN301 489-1 & EN301 489-17:2017 03 (Wireless Electromagnetic Compatibility Standard

F、Waterproof

i. IEC 60529 Edition 2.2:2013 - Degrees of Protection Provided by G、Cabinets Safety and Performance
i. IEC 60601-1 Edition 3.2 2020-08 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
ii. IEC 60601-1-2 Edition 4.1 2020-09 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Capability - Requirements and Tests
iii. IEC 60601-1-6 Edition 3.2 2020-07 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
iv. IEC 60601-2-37 Edition 2.1 2015 Medical Electrical Equipment - Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Medical Monitoring Equipment
v. EN IEC 62304:2006 Medical Device Software - Software Lifecycle Processes
vi. IEC 62366-1:2015 / EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
vii. ISO 15223-1 2016 Medical Devices - Symbols to be used with medical device labels, labeling and information to be provided

H、Quality Management

i. ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
ii. ISO 14971:2019 Medical devices – Application of risk management to medical devices

I、Labelling

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

Symbol	Description
	This icon indicates useful information or tips.

	Indicates the need for the user to refer to the instructions for use for important warning information, such as warnings, warnings, and precautions that cannot, for various reasons, be presented on the medical device itself.

	Refer to the Operator's Manual
	Electrical protection. Isolated application with IEC60601-1 (type BF applied part)
	Wi-Fi. This symbol means wireless communication
	Non-ionizing radiation
	This way up. Indicates this correct vertical position of the transport package.
	Manufacturer. Indicates the manufacturer of the medical device as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC
	Batch code. Indicates the manufacturer's lot code so that the lot can be identified
	Serial number. This means that the manufacturer's serial number and medical device can be identified.
	Model name. This means that the manufacturer's model name and medical device can be identified.
	Indicates the authorized representative in the European Community.
	Fragile and handle with care. Indicates a medical device that can be broken or damaged if not handled with care.
	Non-sterile

	Keep dry. It means a medical device that needs to be protected from moisture.

	Indicates medical device that should not be used if the package is damaged or opened.
	Atmospheric pressure limitation
	For indoor use only. Identify electrical equipment designed primarily for indoor use.
	Requires separate collection for electrical and electronic equipment in compliance with Waste Electrical and Electronic Equipment (WEEE). Directive. When accompanied by or, device components may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local state federal laws. The backlight lamps in an LCD system monitor contain mercury.
	Identify electrical and electronic equipment that meets the Restriction of Hazardous Substances Directive (RoHS) 2011/65/EU.
	European Compliance. In accordance with European Council Directive 93/42/EEC.
	Recyclable material. To indicate that the tagged item or its material is part of a recovery or recycling process.
	Federal law restricts this device to sale by or on the order of a licensed (USA) healthcare professional.
	MR Insecure an item that poses unacceptable risks to the patient, medical staff, or others within the MR setting.
	Medical Device Indicates that the item is a medical device
	Unique Device Identifier Indicates a carrier that contains Unique Device Identifier information The use of this symbol is optional, but can be used when multiple media are present in the label. If used, this symbol should be placed next to the unique device identifier holder.

	NOTE: Used to identify what information is associated with the Unique Device Identifier

	Model Number To identify a product's model number or type number This symbol must be accompanied by the model number or catalogue number of the product, adjacent to the symbol.
	importer Indicate the entity importing the medical device to the location This symbol must be accompanied by the name and address of the importing entity, adjacent to the symbol
	Distributor To indicate the entity distributing the medical device on-site This symbol must be accompanied by the name and address of the distributor, adjacent to the symbol

A.ID of the label

No.	Templates	Label Current Version
2	LK128L	
3	LK128LH	
5	LK128C	
6	LK128M	
7	LK128PA	
8	LK128E	

1. Maintenance:

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

	if the image gets stuck, check the battery level 3. Close other apps on mobile devices to Improving the situation	Please refer to the following link (https://www.leltek.com/support/)
Any serious incident that occurs in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established		

V. DEVICE MAINTENANCE

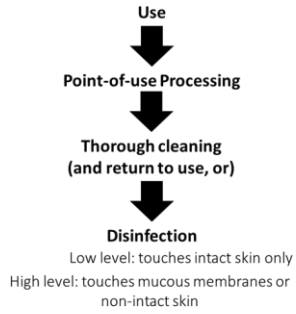
B.WARNING

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

C. Reprocessing Equipment

1. Cleaning & Disinfection

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



3. Point-of-use processing
aItems to use: Disposable paper towel.
bPlease note that the above-mentioned item must not include abrasive parts or abrasive cleaners.
cTurn off the device.
dUse a gentle wiping motion to remove any visible dirt or particulate matter from the surface of the transducer using a clean, disposable paper towel. eVisually inspect and confirm the entire surface of the transducer with no visible residual dirt or particulate matter. If some debris or contaminants dry on the surface of the transducer, follow the cleaning instructions (section below) to remove it.
fConfirm that the compatible smart device does not have cracks or other damage. If it does, contact your local distributor or the manufacturer's service representative immediately.
4. Complete cleaning
The transducers should be cleaned before each use and suggested that the parts that can be cleaned with isopropyl alcohol are the transducer housing and the lens (acoustic window).
Inspect all transducer parts carefully before each use. Check for cracks or other damage that will harm
bintegrity of the transducer. Report any damage to the manufacturer's agent and discontinue use of the transducer.
cUse of disinfectants not recommended, use of incorrect solution dosages, or immersion of a transducer deeper or longer than recommended may damage or discolor the transducer and void the transducer warranty.
5. Disinfection
aSpaulding ratings are a tool to help reduce cross-contamination and infection by specifying the level of cleaning and disinfection required for medical equipment. Based on these criteria, the compatible smart device is classified as a "non-critical" or "semi-critical" device, because the device must scan the surface of the skin or mucous membranes and not penetrate it. Therefore, "low-level cleaning" and "disinfection" for non-critical devices and "high-level cleaning" and "high-level disinfection" for semi-critical devices are required for the next use.

Class	Use	Method	Example
Non-critical	Touches intact skin	Cleaning followed by low-level disinfection.	convex, linear, phase, microconvex
Semi-critical	Membrane Touches mucous membranes or skin not intact	Cleaning followed by high-level disinfection.	Endocavitary

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.

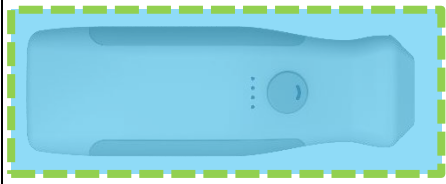
When cleaning and disinfecting:

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

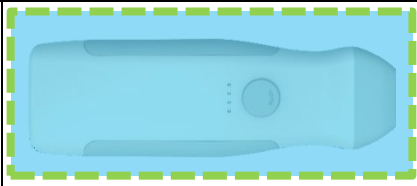
- Recommendations for cleaning the ultrasound probe as per the following step:
- Turn off your devices before wiping them.
- To ensure that all coupling gel and other visible substances from the probe are removed with a clean paper towel. If necessary, to Remove the dry material to the surface, the cloth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

Recommendations for disinfecting the ultrasound probe (after cleaning):

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

Model	Photography
LK128L	
LK128LH	

Model	Photography

LK128C	
LK128M	
LK128PA	
LK128E