LX Series Datasheet

Wireless • Handheld • Dual-Probe Ultrasound Imaging System

V.25.09.01.01

Datasheet

Handheld Ultrasound Imaging System

About LX Series

The Ultrasound Imaging System is a software-based imaging system and accessories intended for use by qualified physicians and healthcare professionals who has the ability to conduct ultrasound scan process for evaluation by ultrasound imaging system or fluid flow analysis of the human body. The device is intended for use where healthcare is provided by trained healthcare professionals.

System and Transducer types

Linear, Convex + Cardiac 3 in 1

	Type	Operating Frequencies (MHz)	Max. Operating Depth (cm)	Supported Array Element	Field of View	Pitch (mm)	Elevation Focus (cm)	Weight (grams)	Dimension (mm)
LX 192LC	**Convex (C5-2)**	2.0 – 5.0	30.0	192	60°	0.326	8.0	278	146 x74 x34
	Convex as Cardiac	(H)2.6 – 4.8			80°				
	Linear (L12-5)	4.2 – 12.5	12.6		-	0.2	2.0		
LX 128 LC	**Convex (C5-2)**	2.0 – 5.0	30.0	128	60°	0.49	8.0	275	146 x74 x34
	Convex as Cardiac	(H)2.6 – 4.8			80°				
	Linear (L12-5)	4.2 – 12.5	12.6		-	0.3	2.0		

Clinical Application

Indications for use

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

LX128LC & LX192LC

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

Convex Transducer: Abdominal, Renal, Adult Cardiac, Pediatric Cardiac, Neonatal, Fetal, Gynecology, Musculoskeletal, Nerve, Obstetric, Pediatric, Peripheral Vessel, Small Parts, (Breast, Testicles, Thyroid), Prenatal, Pulmonary, Blockage.

Application Preset can be customized in app				
	LX192LC		**LX128LC**	
	L12-5	C5-2	L12-5	C5-2
Abdomen	-	✓	-	✓
Abdomen Difficult	-	✓	-	✓
Renal	-	✓	-	✓
GYN	-	✓	-	✓
OB Mid Late	-	✓	-	✓
OB Early	-	✓	-	✓
Spleen	-	✓	-	✓
Bladder Meas.	-	✓	-	✓
FAST	-	✓	-	✓
TCD	-	✓	-	✓
Lung	✓	-	✓	-
Peripheral Vessels	✓	-	✓	-
Thyroid	✓	-	✓	-
Breast	✓	-	✓	-
Superficial	✓	-	✓	-
MSK	✓	-	✓	-
Carotid	✓	-	✓	-
Ocular	✓	-	✓	-
Nerves	✓	-	✓	-
Cardiac	-	✓	-	✓

System architecture

- 12-bit ADC with sample rate 40 or 25 MHz
- Dual headed probe design
- Support up to 192 physical elements, 128 Tx channels, and 64 Rx channels system
- Power off mode: 2.04mA max
- Scan mode: 4.7W avg (Default B mode 15fps)
- IP67 waterproof tested
- Adjustable FPS design; the frame rate can reach 30fps.
- Battery working/ standby time: 4.5/72 hours
- HW user interface: Power key, Freeze key, and Indicators
- 2.4G & 5G Wireless (Wi-Fi) transmission
- Wireless charging, charge time 2.5 hour (15 W Qi)
- Play back frames: up to 1000 (optional)

Image Modes

- (Dual) B mode
- M mode
- Color Doppler
- Power Doppler
- Pulsed Wave Doppler(optional)
- Elastography
- TVI (Cardiac application)
- TDI (Cardiac application)

Mobile Platform

Works with Smartphone, Tablet, Laptops (Android / iOS / Windows)

Functions

- Parameter tuning
  - Frequency
  - THI
  - Gain
  - TGC
  - Image Enhancement

- Needle enhances
  - Needle Angle
  - Needle Gain
- Multi Focus
  - Multi focus depth
- View Extension
- FPS
- Dynamic Range
- Gray Map
- Freeze Timer
- Mirror (L/R, U/D)
- Persistence
- Voltage
- M PRF
- Color PRF
- Color Gain
- Steering Angle
- Invert
- Color Wall Filter
- Color Threshold
- PW Angle
- PW Gate
- PW Baseline
- PW Reverse
- PW PRF
- PW Gain
- PW Wall Filter

- **Annotation**
- **Body Mark**
- **Image Export**
  - JPG, PNG, BMP, MP4
  - DICOM(optional)
- **Data Storage**
  - Local export
  - DICOM Worklist and Store
- **Measurement Tool**
  - Distance
  - Area
  - Angle
  - Arrow
  - Mark
  - Volume
  - Hip Joint
  - Obstetrics formulas and report LMP/EDD
  - Cardiac measurements in B/M/PWD modes

Safety Conformance

- EN ISO 13485 2016 Medical devices. Quality management systems. Requirements for regulatory purposes;
- EN ISO 14971 2019 Medical devices. Application of risk management to medical devices;
- EN ISO 24971 2020 Medical devices – Guidance on the application of ISO 14971 - Compliance Navigator
- ISO 10993-1 2018 Biological evaluation of medical devices
- ISO 10993-5 2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 2010 Biological evaluation of medical devices. Tests for irritation and skin sensitization;
- ISO 10993-23 2021 Biological evaluation of medical devices — Part 23: Tests for irritation
- EN 60601-1 2012 Medical electrical equipment - Part 1
- EN 60601-1 2020 Medical electrical equipment - Part 1
- EN 60601-1-2 2015 General requirements for safety - Collateral standard
- EN 60601-2-37 2015 Particular requirements for the basic safety and essential performance of ultrasonic

- IEC 62359 2017 Amendment 1 - Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields
- EN 62304 2015 Medical device Software-Software life-cycle processes;
- EN 60601-1-6 2020 Medical electrical equipment - Part 1-6
- EN 62366-1 2015 Medical devices - Application of usability engineering to medical devices;
- EN ISO 15223-1 2021 Medical devices Symbols to be used with medical General requirements; device labels, labelling and information to be supplied
- 2002/96/EC(WEEE) 2002 Waste Electrical and Electronic Equipment Directive
- EN 300 328 V2.1.1 2016 Wireless Radio Frequency Wideband Transmission);
- EN 301 489-1 v2.2.3 2019 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
- EN 301 489-17 v2.3.4 2020 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
- EN 301 893: v2.1.1 2017 Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
- E_ST_SG_AC.10_11_Rev6 2015 UNITED NATIONS “Recommendations in the TRANSPORT OF DANGEROUS GOODS” Manual of Tests and Criteria ST/SG/AC.10/11/Rev.6/Amend 1, 38.3
- EN 62133 2013 Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.
- 2011/65/EU Annex II 2021 RoHS 2.0
- IEC 60529 2013 Degrees of protection provided by enclosures (IP Code)
- EN 62479 2010 Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
- ISTA 2A 2011 Partial Simulation Performance Test for Individual Packaged Products
- EN 1041 2008 Information supplied by the manufacturer medical devices