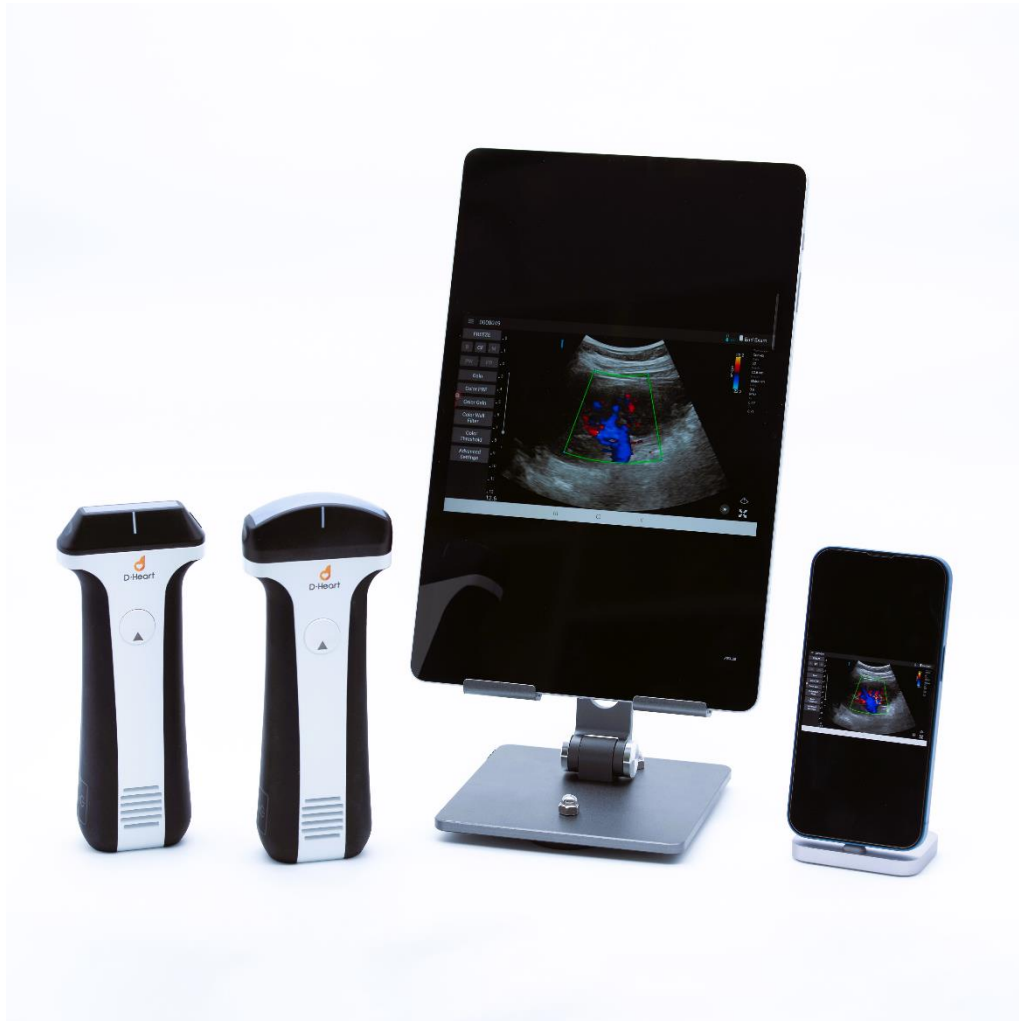




# D·Heart



## LU700 Series Datasheet



## Wireless and Handheld Mobile Ultrasound

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## About LU700

The D-Heart Ultrasound Imaging System (Model: LU700 ) 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.

## Model types

	Frequency Bandwidth	Max. Depth	No. of Element	Field of View	Pitch	Elevation Focus	Clinical Applications
<b>LU700L</b>	5.0 – 12.5 MHz	6.0 cm	128	-	300µm	2 cm	Peripheral Vessels Thyroid Breast Superficial MSK Carotid Superficial Mirror
<b>LU700C</b>	2.0 – 5.0 MHz	18.0 cm	128	60°	326µm	8 cm	Abdomen Abdomen Difficult Renal GYN OB Mid Late OB Early Spleen Bladder Meas. FAST

## System architecture

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- 12-bit ADC with sample rate 50 MHz
- 32 channel ADC system
- Adjustable FPS design
- Battery operating time up to 4 hours, charge time 3~4 hours
- Wireless (Wi-Fi) transmission
- Wired (USB3.0) support<sup>1</sup>

## Image Modes

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- (Dual) B mode
- M mode
- Color Doppler<sup>2</sup>
- Power Doppler<sup>2</sup>
- Pulsed Wave<sup>2</sup>

## Mobile Platform

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Works with Android / iOS tablets or phones.

## Functions

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- **Parameter tuning**
  - ◆ Frequency
  - ◆ THI
  - ◆ Gain
  - ◆ Image Enhancement
  - ◆ FPS
  - ◆ Dynamic Range
  - ◆ Gray Map
  - ◆ Freeze Timer
  - ◆ Mirror
  - ◆ Line Density
  - ◆ Persistence
  - ◆ M PRF
  - ◆ Color PRF
  - ◆ Color Gain
  - ◆ Steering Angle

- ◆ 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<sup>2</sup>
- Data Storage
  - ◆ Local export
  - ◆ DICOM Worklist and Store
- Measurement Tool
  - ◆ Distance
  - ◆ Area
  - ◆ Angle
  - ◆ Arrow
  - ◆ Mark

## Safety Conformance

- IEC 60601-1:2005+AMD1:2012 / EN 60601-1 :2006+ A1 2013 CSV Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 / EN 60601-1-1 :2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Capability - Requirements and tests
- EN IEC 60601-2-37 2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- ISO 10993-1 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- AIUM/NEMA UD 2- 2004 2009 NEMA Standards Publication UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3. (Radiology)
- AIUM/NEMA UD 3- 2004 2009 NEMA Standards Publication UD 3-2004 (R2009) Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- EN IEC 62304 2006 Medical device software - Software life cycle processes
- IEC 62366-1: 2015/EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
- IEC 60601-1-6 / EN 60601-1-6 Usability
- ISO 15223-1 2016 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
- ISO 13485 2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
- EN ISO 14971:2012-Medical devices. Application of risk management to medical devices
- EN ISO 10993-1:2009 -Biological evaluation of medical devices - Evaluation and testing within a risk management process
- EN ISO 10993-5:2009 -Biological evaluation of medical devices - Tests for in vitro cytotoxicity
- ISO 10993-10:2010-Biological evaluation of medical devices. Tests for irritation and skin sensitization

## About Us

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Strena Medical is a company specializing in the development and production of innovative medical devices and services. Our mission is to promote the prevention of human diseases, by making accessible to as many people as possible, low-cost and high impact screening services. Every element, from the device to the application, reflects the principle of the D-Heart brand: Reliability Meets Simplicity.

Ultrasound miniature technology is expected to provide an opportunity for the ultrasound to enter small clinics, ambulances, home care, and emergency medical services to provide customers with great potential value. We take the mission of improving the quality of human life, innovate the technology to provide more user-friendly medical products and services. Strena Medical aims to be the best high performance and reliable ultrasound system provider.

Strena Medical S.r.l. SB

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