Ultrasound Imaging System

Introduction

ASUS Ultrasound Imaging System (Model: LU700) is a software-based ultrasound solution enabling qualified and trained healthcare professionals to visualize anatomical structures and fluid. Easy-to-use interface and handheld availability meet requirements of use in clinical purposes and home/ community healthcare environment.

Applications

- Abdominal
- Obstetrical/Gynecological
- Musculoskeletal
- Vascular
- Soft tissue
- Superficial
- Small organ (Breast/Thyroid)

LU700C

LU700L

System Overview

System Architecture

- 12 bit ADC with sample rate 50MHz
- 32 channel ADC system
- Adjustable FPS design
- Wireless (Wi-Fi)/ wired USB3.0 transmission
- Battery continuously operating time up to 4 hours, Charging 2 hours to 60%. Full charging time 5-6 hours

Imaging Modes

B mode
M mode
Color Flow
Power Doppler
PW Doppler

Imaging Parameters and Functions

Depth
Freq
Gain
Persistence
Enhancement
C mode TGC
Dynamic range
Gray Map
Freeze Timer
Color PRF
Color Sensitive
Color Angle

Workflow

APP Home Page

- Quick access to scan via QR code
- Create patient profile
- Probe connection review

Cineloop Review

- Images for retrospective review and image selection/save
- Acquisition and storage depend on compatible smart device memory

Output Display

- Menu
- Scan modes
- On-screen display of parameters
- Freeze
  - Annotates/Body mark/Save image/ Measure/Make video
- Clinical application presets*
  - LU700L (Linear, L10-5): 6
  - LU700C (Convex, C5-2): 7
  - *allow to create own preset
- Scan Info.
- Mechanical Index (MI)
- Thermal Index (TI)
- Depth
- Adjust TGC
- On-display centerline marker
- Save image and video
- Full screen
- End exam
- Battery status icon

Exam Documentation

- Wi-Fi uses include DICOM networking, exporting exams/images, and network shared drive connection for specific server/cloud
- USB port uses include connecting the transducer, supporting data transfer and charging

Connectivity

- Data storage on device
- Configurable barcode reader APP
- DICOM image store
- Extensive image management capability (ASUS DICOM Viewer)
- Able to export in PC format (MP4/PNG/JPEG images) via direct/indirect connection to PC

Probes

Probes	LU700L	LU700C
Types of array	Linear	Convex
Frequency	5-10MHz	2-5MHz
Depth	6cm	18cm
Abdomen		◎
Abdomen difficult		◎
Renal		◎
GYN		◎
OB Mid Late		◎
Bladder Meas		◎
Peripheral vessels	◎	
Thyroid	◎	
Breast	◎	
Superficial	◎	
Musculoskeletal	◎	
Carotid	◎	
FAST		◎

Physical Specifications

Product Classification

- The device with transducers: Class IIa/ internally powered ME equipment
- Transducers: Type BF applied parts, IPX1

Battery

- UN 38.3, Lithium Battery Transportation
- EN IEC 62133

Acoustic Standards

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

Biocompatibility Standards

- EN ISO 10993-1:2009, Biological evaluation of medical devices
- EN ISO 10993-5:2009, Biological evaluation of medical devices
- ISO 10993-10:2010, Biological evaluation of medical devices

Safety Standards

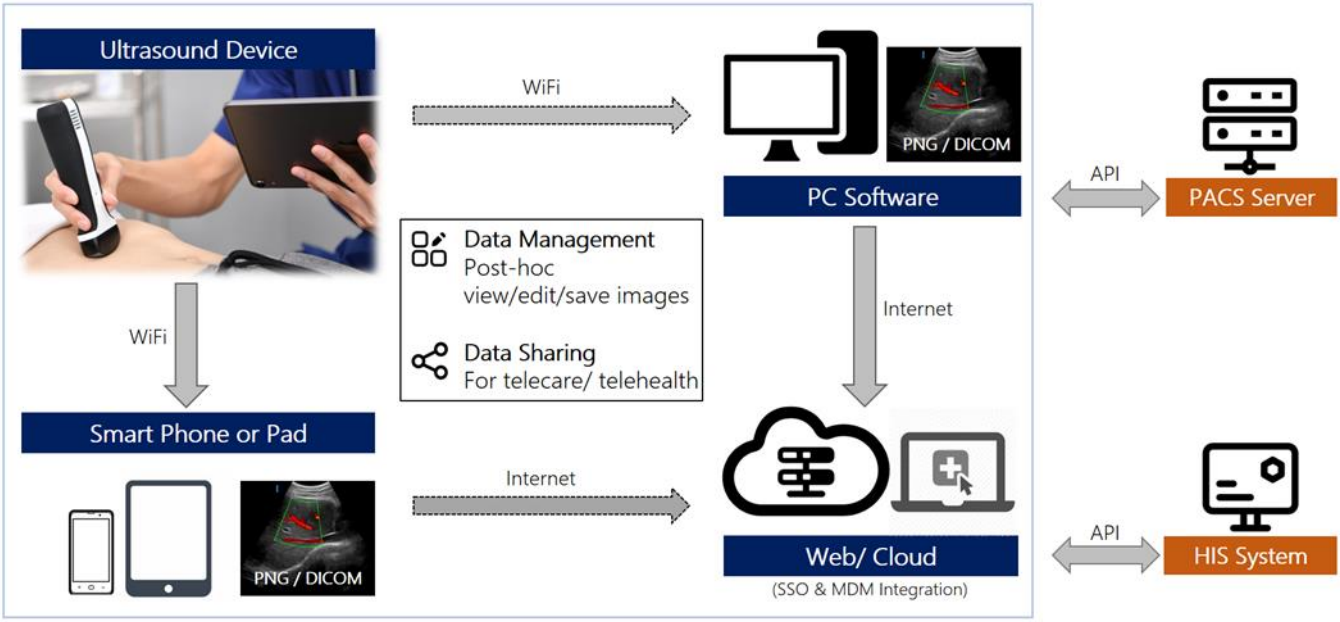
- IEC 60601-1:2005+AMD1:2012 / EN 60601-1 :2006+ A1 2013 CSV Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 / EN 60601-1-1 :2015 Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance, Collateral Standard: Electromagnetic Capability - Requirements and tests
- 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

ASUS PACS Platform

ASUS PACS Platform is a flexible solution, including Android app, iOS app, Window app and web-based app. It's a comprehensive management tool for medical professionals that brings flexibility, simplicity and mobility to POCUS (point-of-care ultrasound).

Overview and Data Flow

- Flexible applications: PC Software (Windows app), web-based app, Android & iOS app
- Collecting the ultrasonic images via ASUS portable ultrasound device, and transferring the data to Android / iOS / Windows through WiFi
- Enabling to save the data in ASUS web-based app which support DICOM or PNG data format. Images can be shared to other medical professionals for telemedicine service or medical education
- ASUS web-based app also meet the standard of HIPPA and ISO 27001 for data security control



ASUS PACS Platform

Window App

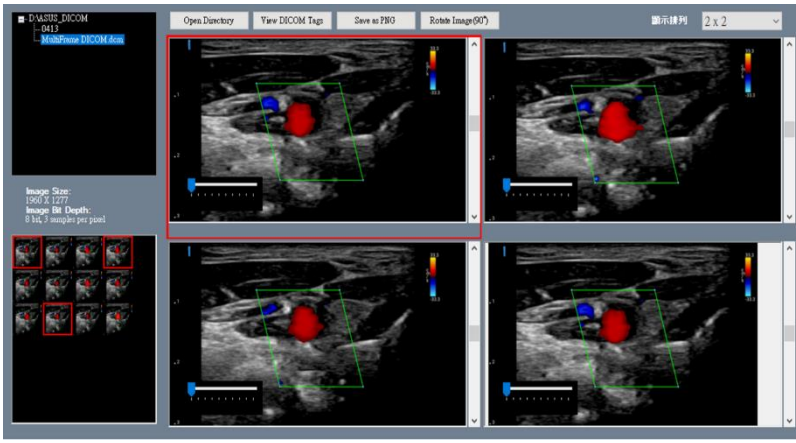
- The application allows viewing DICOM images
  - Real-time scanning ultrasonography transmission via a USB port or Wi-Fi connection
  - Zooming/ Brightness adjustment
  - Support B mode and C mode ultrasound imaging
  - Create patient information
- This allows it to be used on any device that has a Windows OS

Web-based App

- Viewing image features, which includes DICOM tags / labeling, multiple images comparison, image rotation, zooming, contrast / brightness adjustments
- Editing features, including distance measurement and image labeling
- Image output features, including PNG / DICOM saving, PNG / DICOM image export, image report output (link to the printing feature of PC or cloud)
- Data management, including Clinics account management, User account management, Patient information management, Patient profile management

Minimum Spec Requirement

- **CPU:** Intel Core-i5
- **System:** Windows 10 64-bit
- **Memory**: 4GB



ASUS PACS Platform

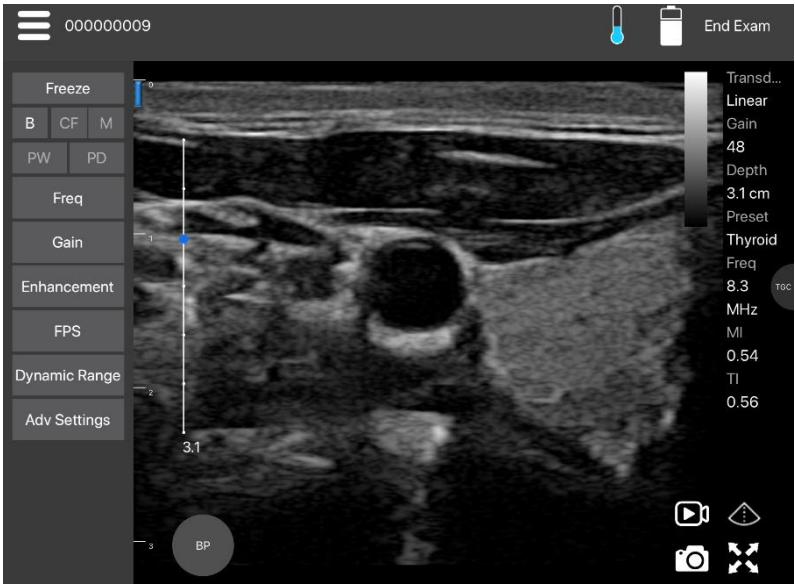
iOS App and Android App

- Annotation and measurement, save , restore and playBack : Freeze/live
- Parameter tuning: Parameter tuning & select the scanned position of a body Image saving
- Parameter tuning, image display and gesture: B, M, CF, PD, PW mode
- Image saving: Save the image file in APP (DICOM, PNG, JPEG data format)
- Make video: Provide real-time video records for medical professionals doing scan exam.
- Data transfer to HIS system: Depend on customers' request, the DICOM/PNG/JPEG file can be transferred from the mobile/windows/web-based platform to HIS system via API
- Data transfer to ASUS Windows app or web-based app: Users can also transfer the image data, including DICOM, PNG or JPEG file to ASUS Windows app or web-based app

Minimum Spec Requirement

- **iOS**
  - iOS 11 or above
  - iPhone 7 or above
  - iPad 3 or above

- **Android**
  - CPU Snapdragon 650 or above
  - RAM 1.5G or above



User Scenario

ASUS Portable Ultrasound Solution is a smart point-of-care ultrasound device that integrates seamlessly via mobile app or web platform. Small in size, it is ideal for **Healthcare facilities**, **Home- and Community-Based Services** or **Ambulance**, even for **Vet clinic** or **Livestock** use.

Solution

- ASUS wireless portable ultrasound device
- 4G/5G smart phone or pad (android, iOS, Windows) or gateway
- ASUS telemedicine platform