1. System Overview

1.1. Application
- Abdomen
- Gynecology
- Obstetrics
- Cardiology
- Small parts
- Urology
- Vascular
- Pediatric

1.2. Transducer Types
- Convex array
- Linear array
- Phased array
- Endocavity curved array

1.3. Imaging Modes
- B-mode B
- M-mode M
- Color Doppler
- Power Doppler Imaging/Directional PDI /
- Pulsed Wave Doppler
- Continuous Wave Doppler
- HPRF(High Pulse Repetition Frequency)

1.4. Imaging Technique & Function&
- Frequency Compounding Imaging
- Spatial Compounding Imaging
- Harmonic Imaging
- Speckle Reduction Imaging (eSRI)
- Digital Multi-Beam Beamforming
- Pan Zoom
- Needle Guide

1.5. Display Modes
- B
- B+B
- 4B
- M
- B+M
- B/C
- B/PDI
- B/DPDI
- B+B/C
- B+B/PDI
- B+B/DPDI
- B+PW
- B/C+PW
- B/PDI+PW
- B/DPDI+PW
- B+CW
- B/C+CW
- B/PDI+CW
- B/DPDI+CW

1.6. System Language Support

- Software: English, Chinese, French, German, Italian, Spanish, Russian, Polish, Portuguese
- Keyboard input: English, Chinese, Russian
- Control panel overlay: English, Chinese
- User Manual: English, Chinese

1.7. Standard Features

- C352UB (only for domestic marketing)
- L742UB (only for domestic marketing)
- Battery (only for domestic marketing)
- Hard disk

1.8. Optional Features

- Transducers
- Printers
- USB Disk U
- Battery (only for international marketing)
- Needle Guide Bracket Kit
- Mobile trolley
- Footswitch
- Travelling Case
- Dustproof cloth
- DICOM 3.0
- External DVD DVD
- Feet

2. Physical Specification

2.1. System Architecture

- Physical Channels: 64
- System dynamic range: 0-166dB
- Beam forming: Dual beam 2
- Memory: 504MB
- Hard drive: 500GB
- Operation System: Linux

2.2. Dimension and weight
- Height: 35cm
- Width: 37cm
- Depth: 22cm
- Weight: < 8.5kg (without probe and battery)

2.3. Monitor
- 15 TFT-LCD monitor 15 TFT-LCD
- Resolution: 1024 x 768
- Imaging field size: 640*512
- Video out size: 800 * 600
- Capture size: BMP, JPG, AVI, DCM 1024 * 768; FRM, CIN 640 * 512
- View angle: Up 85, Down 85, Left 85, Right 85
- Brightness and Color Temp adjustable
- Angle adjustable: 0, 15, 3001530
- Built-in stereo speaker

2.4. Transducer port and holder
- 2 active ports 2
- 2 holders 2

2.5. Electrical Power
- Voltage: 110V-240VAC
- Frequency: 50/60 Hz
- Power: 97.4w

2.6. Battery
- Rechargeable lithium ion battery
- Capacity: 5000mAh
- Removable
- Approximately 80 minutes of typical ultrasound exam use
- Max charging time: 8 hours

2.7. Environmental operating requirements
- Ambient temperature: 0 to 40C
- Relative Humidity: 15%~95% (no condensation)
- Atmospheric pressure: 86kPa-106kPa

2.8. Environmental storage requirements
- Ambient temperature: -20 to 55C
- Relative Humidity: 15%~95% (no condensation)
- Atmospheric pressure: 70kPa-106kPa

3. User Interface

3.1. Control Panel
- Interactive back-lighting
- Hard Keys provides tactile feedback
- Physical trackball
- 8 segment TGC sliders 8TGC
- Physical keyboard

3.2. System boot-up
- Boot up from complete shut-down in about 60 sec
- Shut-down in about 3 sec
- Recovery from screen saver in about 3 sec

3.3. Comments
- Arrow
- Block move and delete for separate blocks of text
- Support physical keyboard for text input
- 260 user-defined comments in pre-defined presets
- 6 User customizable comments per a preset

3.4. Body Mark
- Up to 130 Body Mark graphics in library

3.5. Screen Information
- EDAN logo
- Hospital name
- Date
- Time
- Patient ID
- Patient Name
- Patient Gender
- Patient Age
- Transducer model
- Preset name
- Mechanical index (MI)
- Thermal Index (TI)
- Imaging parameters
- Gray Scale bar
- Depth Scale

*Not all the items are listed in here, please refer to the User Manual.*
4. Imaging Parameters

4.1. B-Mode B

- Image Type: Detail/Soft/Contrast/Penetration
- Zoom: 7 levels, x1.44, x1.96, x2.56, x4.0, x5.76, x9.0, x16.0 (available on live state); 7 levels: x1.31, x1.78, x2.56, x4.0, x7.11, x10.24, x16.0 (available on freeze state)
- Depth: 1.9-32.4 cm
- Frequency: 2.0-15.0 MHz (3 fundamental & 2 harmonic frequencies 3&2)
- eSRI: 0-8
- Rejection: 0-7
- Scan Angle: 0-3
- Gain: 0-130 dB, 2 dB/step
- TGC: 8 segments
- Dynamic range: 30-150 dB, 4 dB/step
- Scan Mode: Hidden/HiFR
- Max Frame rate: 244 fps
- Map: 0-14
- Frame Persist: 0-7
- Focus position: 0-15
- Focus Number: 1-4
- Pseudo color: 6 types
- H Reverse: On/Off
- V Reverse: On/Off
- Rotation 90°: 0/90/180/270
- B/W Invert: On/Off
- Spatial compounding: on/off (max 3 angles)
- Display format: single(B), dual(B+B), Quad(4B)
- Center Line: On, Off

4.2. M-Mode M

- Sweep speed: 0-3
- Line Average: 0-7
- Gray Map: 0-14
- Pseudo Color: 6 types
- Gain: 0-130 dB, 2 dB/step
- Frequency: 2.0-15.0 MHz (3 fundamental & 2 harmonic frequencies 3&2)
- Dynamic range: 30-150 dB, step 4 dB/step
- B/M Display: U/D, L/R

4.3. Color Doppler

- Flow Type: H Flow/M Flow/L Flow
- Dual liveB/B+C
- ROI size/position: adjustable ROI
- ROI Color: Green, Yellow ROI
- Frequency: 2.5-8.0 MHz
- Gain: 1-80dB, 1dB/step
- Max Frame rate: 38 f/s
- Persist: 0-7
- Smooth filter: 0-7
- Wall filter: 0-7
- Map: 0-7
- Angle Steer:
  0, 10 (available for linear transducers)
- PRF: 16 levels 0.5-11 kHz
- Scale: 9-175 cm/s
- Baseline: 0-6
- Threshold: 0-15
- Invert: on/off
- Packet Size: 4 levels

4.4. Power Doppler Imaging

- Flow Type: H Flow/M Flow/L Flow/
- Dual liveB/B+PDI
- Directional Power Doppler Imaging(DPDI)
- ROI size/position: adjustable ROI
- ROI Color: Green, Yellow ROI
- Frequency: 2.5-8.0 MHz
- Gain: 1-80dB, 1dB/step
- Max Frame rate: 38 f/s
- Persist: 0-7
- Smooth filter: 0-7
- Wall filter: 0-7
- Map: 0-7
- Angle Steer:
  0, 10 (available for linear transducers)
- Baseline: 0-6 (only available on DPDI)
- Threshold: 0-15
- Invert: on/off (available on DPDI)
- Packet Size: 4 levels

4.5. Pulsed Wave Doppler

- Flow Type: H Flow/M Flow/L Flow/
- HPRF: On/Off (available for C5-2b, L15-7b and P5-1b)
- Duplex and Triplex displays/
- Frequency: 2.5-8.0 MHz
- PRF: 16 levels 1-15kHz
- Gain: 1-80dB, 1dB/step
- Dynamic range: 30-90 dB, 2dB/step
- Wall filter: 0-3
- Sweep speed: 0(10.3 s), 1(7.95 s), 2(5.19 s), 3(3.97 s), 4(2.75 s), 5(1.53 s)
- Baseline: 0-6
- Correct Angle: -79 -79, 1 /step
- Quick Angle: -79 /-60/-30/0/30 /60/79
- Steer: 0,1,0(available on linear transducers)
- Invert: On/Off/
- Volume: 0-7
- Pseudo color: 6 types
- Sample Volume: 16 levels, 0.5-20 mm

4.6. Continuous Wave Doppler
- Flow Type: H Flow/M Flow/L Flow/
- Frequency: 2.0 MHz
- PRF: 0-32, 0.8-80KHz
- Gain: 1-80dB, 1dB/step
- Dynamic range: 30-96 dB, 2dB/step
- Wall filter: 0-3
- Sweep speed: 0(10.3 s), 1(7.67 s), 2(5.14 s), 3(3.88 s), 4(2.62 s), 5(1.35 s)
- Baseline: 0-6
- Correct Angle: -79 -79, 1 /step
- Quick Angle: -79 /-60/-30/0/30 /60/79
- Invert
- Volume: 0-7
- Pseudo color: 6 types

5. Cine Review and Post-Processing

5.1. Cine Review
- Frame by frame manual review
- Auto playback
- Start frame and end frame are selectable for cine loop review
- Maximum cine memory is up to :
  - 1227 frames for B mode B
  - 409 frames for Color mode
  - 90s for M mode M
  - 15s for PW/CW Doppler mode PW/CW

5.2. Post-Processing
- B Mode: zoom, pseudo color, Gray map B
- M Mode: pseudo color, Gray map M
- Color Mode: zoom Color
- PW/CW: pseudo color, Gray map, correct angle PW/CW

*Not available the stored images and clips in Review
- FRM and CINE file support measurement, comments, bodymark FRMCIN
6. **Imaging Storage and Exam Database**

6.1. **Imaging Storage**
- 500GB hard drive
- Storage up to approximately 227,555 static images as BMP format (hard drive) 227,555 BMP (2.25 MB)
- Maximum clip is up to:
  - 1,227 frames for B mode B
  - 409 frames for Color mode Color
  - 90 s for M mode M
  - 15 s for PW/CW Doppler mode PW/CW

6.2. **File Management**
- Support exam storage temporarily without patient information
- Support image files query
- Support delete, rename image files
- Support review image files of current exam or prior exam
- Support store images as BMP, JPG, FRM, AVI, CIN or DCM format BMP/JPG/FRM/AVI/CIN/DCM
- Support export images to a USB disk U
- Support export images and report to DVD/DVD

7. **Connectivity**
- DICOM Storage DICOM:
  - Verify SCP
  - Static image store SCU/DCM
  - Removable media
  - Manual transfer on demand
- 2 USB Ports 2 USB
- Video out:
  - VGA
  - Video: PAL/NTSC
  - S-video: PAL/NTSC
- Footswitch port
- Remote port
- Ethernet

8. **Preset**
- Application
  - Abdomen
  - Obstetric
  - Gynecology
Small Parts
Urology
Vascular
Cardiac
Pediatric
  - Transducer specific presets:
    Abdomen
    Abd Difficult
    Aorta
    Obstetric 1/3
    Obstetric 2/3
    Fetal Cardiac
    Gynecology
    Endovaginal
    Breast
    Thyroid
    Superficial
    MSK
    Testicle
    Endorectal
  - Urology
    Carotid
    PV Artery
    PV Vein
    Adult Cardiac
    Pedia Cardiac
    Peida Abd
  - User customizable presets: Add, Copy, Delete, Rename

9. Peripheral & Accession

9.1. Printer
  - Black/white Digital/Analog Video printer/
    SONY UP-D897MD
    SONY UP-X898MD
    MITSUBISH P93W_Z
    Color Digital video printer
    SONY UP-D25MD
    Color Analog video printer
    SONY UP-25MD
  - Graph/text printer
    HP Laserjet Pro 400 M401d
    HP Laserjet M403D
9.2. Needle Guide Bracket

- **BGK-C5-2**
  - Focus Depth: 45mm
  - Angle: 40
- **BGK-R50UB**
  - Focus Depth: 45mm
  - Angle: 35
- **BGK-L40UB**
  - Focus Depth: 30mm
  - Angle: 43
- **BGK-CR10UA**
  - Focus Depth: 250mm
  - Angle: 3
- **BGK-R10UB**
  - Focus Depth: 20mm
  - Angle: 35
- **BGK-R15UB**
  - Focus Depth: 20mm
  - Angle: 35
- **BGK-R20UB**
  - Focus Depth: 40mm
  - Angle: 35
- **BGK-L50UB**
  - Focus Depth: 45mm
  - Angle: 44

10. Measurement and Report

10.1. General Measurement

- **B Mode B**
  - Distance
  - Cir/Area/
  - Volume: 2-Axis, 3-Axis, 3-Axis(LWH)(LWH)
  - Ratio
  - Angle
  - % Stenosis: Distance, Area
  - Histogram
- **M Mode M**
  - Distance
- Time
- Slope
- Heart Rate

**Doppler**
- Velocity
- Heart Rate
- Time
- Acceleration
- RI
- PI
- Auto: PS, ED, RI, PI, S/D/
- Trace Direction: Above, below, Dual
- Trace Sensitivity++
- Trace Sensitivity--

**Available for Cardiac application:**
- Velocity
- PG
- Time
- Heart Rate
- Slope
- PHT
- Trace(Mual)

10.2. **Application Measurement**

**Abdomen**
- Liver: Length, Width, Height
- Portal V. Diameter
- CBD
- Gallbladder: Length, Width, Height
- GB wall
- Pancreatic: Duct, Head, Body, Tail
- Spleen: Length, Width, Height

**Gynecology**

**B mode**
- UT: Length, Width, Height, UT, UT-V
- Endo
- OV-Vol(L/R): Length, Width, Height, OV-Vol/
- FO(L/R, Number:4): D1, D2, D3, Vol/4123
- CX-L
- UT-L/CX-L/

**PW mode**
- Velocity, L UT A, R UT A, L OV A, R OV A, Trace Direction, Trace Sensitivity+, Trace Sensitivity- +

**Obstetric**

**B mode**
- GS , CRL, NT, BPD, HC, AC, FL, AFI, EFW, TAD, APAD, HUM, CER, FTA, OFD, THD, FBP
- FBP
- Growth Curve
- EDC

**PW mode**
- Velocity, FHR, Umb A, MCA, Fetal AO, Desc.AO, Placenta V, Trace Direction, Trace Sensitivity+, Trace Sensitivity-

**M mode**
- FHR, Time, Slope

● **Cardiac**

**M mode**
- LV: TEICHOLZ(LVIDd, LVIDs, ET, HR, EDV, EDS, SV, CO, EF, FS, SI, CI, MVCF, BSA), CUBE(LVIDd, LVIDs, ET, HR, EDV, EDS, SV, CO, EF, FS, SI, CI, MVCF, BSA)CUBECOTEICHOLZCO
- Mitral Valve: EF Slope, ACV, A/E, Valve VolumeAACE
- Aorta: LAD/AOD, Valve Volume
- Heart Rate
- LVET: LVET, AVSA
- LVMW: LVPWd, IVSTd, LVIDd, LVMW

**B mode**
- RV
- LV: S-P Ellipse (LVLd, LVALd, LVLs, LVALs, EDV, ESV, CO, EF, SI, CI, BSA), B-P Ellipse (LVALd, LVAMd, LVIDd, LVALs, LVAMs, LVIDs, EDV, ESV, CO, EF, SI, CI, BSA), Bullet (LVAMd, LVLd, LVAMs, LVLs, EDV, ESV, CO, EF, SI, CI, BSA), Mod. Simpson(LVAMd, LVLd, LVAPd, LVAMs, LVLs, LVAPs, EDV, ESV, CO, EF, SI, CI, BSA)SIMPSON
- PA
- MVA
- AVA

● **Small Part**
- L.THY-V: Length, Width, Height, Volume
- R.THY-V: Length, Width, Height, Volume
- Isthmus

● **Urology**
- BLV: Length, Width, Height, Volume
- RUV: Length, Width, Height, Volume
- Prostate Vol: Length, Width, Height, Volume, PPSA, PSAD
- ADR(L/R): Length, Width, Height /
- KID(L/D): Length, Width, Height, Volume/
- COR

● **Vascular**
- Velocity, CCA, ICA, ECA, Vert A, Upper, Lower, Trace Direction, Trace Sensitivity+, Trace Sensitivity-, Flow Volume +-

● **Pediatric**
- HIP

*For more measurement information, please refer to the User Manual.*
10.3. Report
- Worksheet
- Diagnostic
- Configure whether print image in report
- Export as PDF format

11. Transducers

- **C5-2b**
  - Imaging Format: convex array
  - Number of Elements: 128
  - Convex Radius: 60 mm
  - FOV58
  - Bandwidth: 2.0-6.0MHz
  - Fundamental Frequency: 2.5 MHz, 3.5MHz, 4.0MHz
  - Harmonic Frequency: H5.0MHz, H6.0MHz
  - Doppler Frequency: 2.5MHz, 3.0MHz
  - Depth: 19-324mm
  - Frame Rate (18cm, Full of FOV): 18cm: max 55 f/s
  - PW velocity PW: max 4.46m/s(60)
  - Applications: Abdomen, OB, Gynecology, Urology

- **C352UB**
  - Imaging Format: convex array
  - Number of Elements: 128
  - Convex Radius: 50 mm
  - FOV73
  - Bandwidth: 2.0-6.0MHz
  - Fundamental Frequency: 2.5 MHz, 3.5MHz, 4.5MHz
  - Harmonic Frequency: H5.0MHz, H5.4MHz
  - Doppler Frequency: 2.5MHz, 3.0MHz
  - Depth: 19-324mm
  - Frame Rate (18cm, Full of FOV): 18cm: max 58 f/s
  - PW velocity PW: max 3.01m/s(60)
  - Applications: Abdomen, OB, Gynecology, Urology

- **L742UB**
  - Imaging Format: general linear array
  - Number of Elements: 128
  - Footprint: 38.4 mm
  - Bandwidth: 5.0-10.0MHz
  - Fundamental Frequency: 6.5 MHz, 7.5MHz, 8.5MHz
  - Harmonic Frequency: 9.0 MHz, 9.4MHz
- Doppler Frequency: 5.5MHz, 6.5MHz
- Depth: 29-127mm
- PW velocity PW: max 1.36m/s(60)
- Applications: SMP, MSK, Vascular

L1042UB
- Imaging Format: general linear array
- Number of Elements: 128
- Footprint: 38.4mm
- Bandwidth: 5.0-13.4MHz
- Fundamental Frequency: 5.0 MHz, 9.5MHz, 11.0MHz
- Harmonic Frequency: 13.0 MHz, 13.4MHz
- Doppler Frequency: 5.5MHz, 6.5MHz
- Depth: 19-108mm
- PW velocity PW: max 1.99m/s(60)
- Applications: SMP, MSK, Vascular

L15-7b
- Imaging Format: high frequency linear array
- Number of Elements: 128
- Footprint: 38.4 mm
- Bandwidth: 7.0-16.0MHz
- Fundamental Frequency: 10.0MHz, 12.0MHz, 14.0MHz
- Harmonic Frequency: 14.4 MHz, 14.8MHz
- Doppler Frequency: 7.2MHz, 8.0MHz
- Depth: 19-108mm
- PW velocity PW: max 1.69m/s(60)
- Applications: SMP, MSK, Vascular

L552UB
- Imaging Format: general linear array
- Number of Elements: 128
- Footprint: 50 mm
- Bandwidth: 3.2-7.0MHz
- Fundamental Frequency: 4.5 MHz, 5.5MHz, 6.5MHz
- Harmonic Frequency: 5.6 MHz, 6.0MHz
- Doppler Frequency: 4.0MHz, 5.0MHz
- Depth: 19-157mm
- PW velocity PW: max 1.39m/s(60)
- Applications: MSK, Vascular

E612UB
- Imaging Format: endocavity micro convex array
- Number of elements: 128
- Convex Radius: 10 mm
- FOV: 150
- Bandwidth: 4.0-9.4 MHz
- Fundamental Frequency: 4.0 MHz, 6.5 MHz, 7.5 MHz
- Harmonic Frequency: 9.0 MHz, 9.4 MHz
- Doppler Frequency: 5.0 MHz, 6.0 MHz
- Depth: 19-127 mm
- Frame Rate (10 cm, Full of FOV): 10 cm: max 31 f/s
- PW velocity PW: max 1.56 m/s (60)
- Applications: OB, Gynecology, Urology
- Needle Guide Bracket: BGK-CR10UA (16G)

- **C612UB**
  - Imaging Format: micro convex array
  - Number of elements: 128
  - Convex Radius: 10 mm
  - FOV: 150
  - Bandwidth: 4.6-9.3 MHz
  - Fundamental Frequency: 5.5 MHz, 6.5 MHz, 7.5 MHz
  - Harmonic Frequency: 9.0 MHz, 9.4 MHz
  - Doppler Frequency: 5.0 MHz, 6.0 MHz
  - Depth: 19-127 mm
  - Frame Rate (10 cm, Full of FOV): 10 cm: max 94 f/s
  - PW velocity PW: max 2.23 m/s (60)
  - Applications: Pediatric, Pediatric Cardiac

- **C6152UB**
  - Imaging Format: micro convex array
  - Number of elements: 128
  - Convex Radius: 15 mm
  - FOV: 100
  - Bandwidth: 4.2-8 MHz
  - Fundamental Frequency: 5.5 MHz, 6.5 MHz, 7.5 MHz
  - Harmonic Frequency: 9.0 MHz, 9.4 MHz
  - Doppler Frequency: 4.0 MHz, 5.0 MHz
  - Depth: 19-127 mm
  - Frame Rate (10 cm, Full of FOV): 10 cm: max 94 f/s
  - PW velocity PW: max 2.53 m/s (60)
  - Applications: Pediatric, Pediatric Cardiac

- **C422UB**
  - Imaging Format: micro convex array
  - Number of elements: 128
  - Convex Radius: 20 mm
  - FOV: 100
- Bandwidth: 2.8-5.5MHz
- Fundamental Frequency: 3.0MHz, 4.0MHz, 5.0MHz
- Harmonic Frequency: 5.0 MHz, 5.4MHz
- Doppler Frequency: 2.5MHz, 3.0MHz
- Depth: 19-196mm
- Frame Rate(18cm, Full of FOV) 18cm: max 58 f/s
- PW velocity PW: max 2.79m/s(60)
- Applications: Abdomen, Cardiac, Pediatric

● **P5-1b**
- Imaging Format: phased array
- Number of Elements: 64
- Footprint: 16.26 mm
- FOV90
- Bandwidth: 1.8-3.9MHz
- Fundamental Frequency: 2.0MHz, 2.5MHz, 3.0MHz
- Harmonic Frequency: 4.0 MHz, 5.0MHz
- Doppler Frequency: 2.0MHz, 2.5MHz
- CW Frequency CW: 2.0MHz
- Depth: 19-314mm
- Frame Rate(18cm, Full of FOV) 18cm: max 55 f/s
- PW velocity PW: max 5.16m/s(60)
- CW velocity CW: max 30.44m/s(60)
- Applications: Adult Cardiac
- Needle Guide: unavailable

12. **Regulatory approvals**

FDA Class II Device
CD/MDD Class IIa

13. **Compiled standards**
- IEC 60601-1: Medical Equipment Safety
- IEC 60601-1-2: Medical Device Electromagnetic Safety
- IEC 60601-2-37: Ultrasonic Medical Equipment Safety
- IEC 62133: Battery Safety
- IEC 62304: Medical Device Software Life-cycle Process
- IEC 62366: Medical Device Usability Engineering
- EN ISO 14971: Medical Device Risk Management
- ISO 10993: Medical Device Biocompatibility
- NEMA UD 2: Output Measurement for Diagnostic Ultrasound Equipment
- NEMA UD 3: Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound
Equipment