

U60

Diagnostic Ultrasound System

Version 1.0

Datasheet



EDAN

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, 30, 45, 60, 75, 90, 105, 120, 135, 150, 165, 180
- 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 sec60
- Shut-down in about 3 sec3
- Recovery from screen saver in about 3 sec3

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 presets260
- 6 User customizable comments per a preset6

3.4. Body Mark

- Up to 130 Body Mark graphics in library130

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/HContrast/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) 7
- Depth: 1.9- 32.4cm
- Frequency: 2.0-15.0MHz (3 fundamental & 2 harmonic frequencies 3&2)
- eSRI: 0-8
- Rejection: 0-7
- Scan Angle: 0-3
- Gain: 0-130dB, 2dB/step 2dB
- TGC: 8 segments 8
- Dynamic range: 30-150 dB, 4dB/step 4dB
- Scan Mode: Hiden/HiFR /
- Max Frame rate: 244 f/s
- 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/
- 90rotation 90: 0/90/180/270
- B/W Invert: On/Off /
- Spatial compounding: on/off (max 3 angles)/3
- Display format: single(B),dual(B+B), Quad(4B)B2B4B
- Center Line: On, Off /

4.2. M-Mode M

- Sweep speed: 0-3
- Line Average: 0-7
- Gray Map : 0-14
- Pseudo Color: 6 types6
- Gain: 0-130dB, 2dB/step
- Frequency: 2.0-15.0MHz(3 fundamental and 2 harmonic frequencies 3&2)
- Dynamic range: 30-150 dB, step 4dB/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/DPDI)
- Threshold: 0-15
- Invert: on/off (available on DPDI) /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)C5-2bL15-7BP5-1b
- 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(10.3s), 1(7.95s), 2(5.19s), 3(3.97s), 4(2.75s), 5(1.53s)
- Baseline: 0-6
- Correct Angle: -79 -79, 1 /step
- Quick Angle: -79 /-60/-30/0/30 /60/79
- Steer: 0,10(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(10.3s), 1(7.67s), 2(5.14s), 3(3.88s), 4(2.62s), 5(1.35s)
- 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 500GB
- storage up to approximately 227555 static images as BMP format (hard drive)227555BMP(BMP2.25MB)
- Maximum clip is up to:
1227 frames for B mode B 1227
409 frames for Color mode Color 409
90s for M mode M 90s
15s for PW/CW Doppler mode PWCW 15s

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 formatBMP/JPG/FRM/AVI/CIN/DCM
- Support export images to a USB diskU
- Support export images and report to DVDDVD

7. Connectivity

- DICOM Storage DICOM:
Verify SCP
Static image store SCU/DCM
Removable media
Manual-transfer on demand
- 2 USB Ports 2USB
- 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
 - MITSUBISHI 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

HP Laserjet M402D
HP Deskjet Ink Advantage Ultra 2029
HP Deskjet 1112

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(Maual)

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, Placent A, Ductus V, Trace Direction, Trace Sensitivity+, Trace Sensitivity- +-

M mode

- FHR, Time, Slope

● **Cardiac**

M mode

- LV: TEICHHOLZ(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)CUBECOTEICHHOLZCO
- Mitral Valve: EF Slope, ACV, A/E, Valve VolumeACAE
- 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, SV, CO, EF, SI, CI, BSA), B-P Ellipse (LVALd, LVAMd, LVIDd, LVALs, LVAMs, LVIDs, EDV, ESV, SV, CO, EF, SI, CI, BSA), Bullet (LVAMd, LVLd, LVAMs, LVLs, EDV, ESV, SV, CO, EF, SI, CI, BSA), Mod. Simpson(LVAMd, LVLd, LVAPd, LVAMs, LVLs, LVAPs, EDV, ESV, SV, 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 formatPDF

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
- Needle Guide Bracket: BGK-C5-2(16G, 18G, 20G, 22G)

● 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
- Needle Guide Bracket: BGK-R50UB(16G, 18G, 20G, 22G)

● 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
- Needle Guide Bracket: BGK-L40UB(16G, 18G, 20G, 22G)

● **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
- Needle Guide Bracket: BGK-L40UB(16G, 18G, 20G, 22G)

● **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
- Needle Guide Bracket: BGK-L40UB(16G, 18G, 20G, 22G)

● **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
- Needle Guide Bracket: BGK-L50UB(16G, 18G, 20G, 22G)

● **E612UB**

- Imaging Format: endocavity micro convex array
- Number of elements: 128

- Convex Radius: 10 mm
- FOV: 150
- Bandwidth: 4.0-9.4MHz
- Fundamental Frequency: 4.0MHz, 6.5MHz, 7.5MHz
- Harmonic Frequency: 9.0 MHz, 9.4MHz
- Doppler Frequency: 5.0MHz, 6.0MHz
- Depth: 19-127mm
- Frame Rate(10cm, Full of FOV)10cm: max 31 f/s
- PW velocity PW: max 1.56m/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: 4.6-9.3MHz
- Fundamental Frequency: 5.5 MHz, 6.5MHz, 7.5MHz
- Harmonic Frequency: 9.0 MHz, 9.4MHz
- Doppler Frequency: 5.0MHz, 6.0MHz
- Depth: 19-127mm
- Frame Rate(10cm, Full of FOV)10cm: max 94 f/s
- PW velocity PW: max 2.23m/s(60)
- Applications: Pediatric, Pediatric Cardiac
- Needle Guide Bracket: BGK-R10UB(16G, 18G, 20G, 22G)

● **C6152UB**

- Imaging Format: micro convex array
- Number of elements: 128
- Convex Radius: 15 mm
- FOV: 100
- Bandwidth: 4.2-8MHz
- Fundamental Frequency: 5.5 MHz, 6.5MHz, 7.5MHz
- Harmonic Frequency: 9.0 MHz, 9.4MHz
- Doppler Frequency: 4.0MHz, 5.0MHz
- Depth: 19-127mm
- Frame Rate(10cm, Full of FOV)10cm: max 94 f/s
- PW velocity PW: max 2.53m/s(60)
- Applications: Pediatric, Pediatric Cardiac
- Needle Guide Bracket: BGK-R15UB(16G, 18G, 20G, 22G)

● **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
- Needle Guide Bracket: BGK-R20UB(16G, 18G, 20G, 22G)

● 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