

Data sheet V1.11

Ultrasound System Specifications

The premium performance of the full functional Portable ESE-A6 provides a fast and easy diagnosis by:

- Ultra-premium contrast and resolution imaging benefited from the first RF platform of the world
- All ranges offeatures, functions and probes
- Ease of use and ergonomic design

1. System Overview

1.1 Architecture

• The revolutionary RF platform, The First In The World, allows for more accurate information. This platform transfers all RF data for computing without any information loss. It has a much better advantage in detail imaging than current advanced platforms.

• Thanks to the RF platform, it allows the development of many RF-based processing algorithms, which have ultra-premium contrast and resolution imaging



 This unique platform is capable of processing multiple data streams simultaneously

- Directional-enhanced information compiling for more tissue detail and reduction of angle-generated artifacts
- Next generation adaptive image processing for noise and artifact reduction thatimproves tissue presentation and edge definition
 Fully independent, triplex multiple mode operation for easy in Doppler procedures
- Multi-processors allow simultaneous mode changes and supportfor advanced system functionality
- World-class design to be thinner and lighter
- VLuminous Flow provides the color



Doppler flow innovatively in a 3D view with excellent sensitivity, which can help understand the structure of blood flow and small vessels intuitively

• Sync ROI enables the width of 2D scan area is synchronized with the CF ROI, which effectively improves the frame rate

 Diverse customized tools make ESE-A6 a truly elite unit, which enhances efficiency dramatically

- Zscore analysis, provide a new way for fetal heart evaluation
- Support multiple DICOM server configuration
- Background transfer, supports
 background export without
 interrupting the actual scan

• VReport, a customer-centric tool for report templates design, makes the whole report procedure more smooth and individual

• VWork, an intelligent feature, which enables users to configure workflows for every application scenario. This leads to easy and effective adherence to a department protocol and saves operation time to a great extent

 Less 80 sec boot up time for easy mobile ability

1.2 Applications

- Abdomen
- Obstetric

- Gynecology
- Cardiology
- Urology
- Vascular
- Small Parts
- Pediatrics

1.3 Imaging features

• 2D grayscale imaging

 Harmonic imaging both in tissue harmonic and pulse inversion harmonic technologies

• VFusion, directional-enhanced information compounding

• VSpeckle, specialized and adaptive imaging processing to remove speckle noise artifacts and enhance tissue edge for clarity and accuracy

• VTissue, the advanced adaptive image processing to compensate for sound and speed variation in different tissue

- Auto imaging optimization
- Easy Comparative Function to compare previous exam
- M Mode imaging
- Color Doppler imaging
- Power Doppler imaging
- Pulse wave Doppler imaging
- Duplex 2D/PW Doppler
- Triplex 2D/Color/PW Doppler
- High PRF pulsed wave Doppler
- Continuous wave Doppler
- Zoom
- FULL screen imaging to enlarge



imaging size

- Dual real time imaging without compromising imaging size
- PView for panoramic imaging (optional)*
- TView for trapezoidal imaging
- 3D/4D imaging
- Inversion mode(optional)*
- Magic cut(optional)*
- Multiline-Free view (optional)*
- Tomographic display (MCUT) (optional)*
- Volume Contrast Imaging(VCI)
- Niche view(optional)*
- Three leads ECG function(optional) *
- Tissue Doppler (TD) mode(optional)*
- Auto NT(Nuchal

translucency)(optional)*

- VLuminous flow, a feature which shows the blood flow in a 3-D view with excellent sensitivity
- Curved M mode, user can draw any curved sample line freely and get corresponding results(optional)*
- Sync B/C width, the width of B mode interest area is always be the same with the CF mode
- Multi-line Angular M-Mode, Up to 4 sample lines(optional)*
- Live IMT, display intima-media thickness in real time(Optional)
- VAim(Visual Artificial Intelligent Measurement) for OB、Follicle、Hip、 pelvic(optional)*
- Auto IT, automatic measurement of

Intracranial translucency(optional)*

1.4 Standard features

- Up to 25Mhz high frequency in system platform.
- RF platform and RF data processing
- Up to 1500 seconds cine storage
- 120GB SSD
- Patient information database
- Image archive on hard drive
- Quick store to USB memory stick
- Quick store to hard drive
- Report package
- Quick print to B/W and color thermal video printer
- Network storage and printing
- Full measurement and analysis package
- Real time auto wave Doppler track and calculations
- Vascular calculations
- Cardiac calculations
- OB calculations and tables
- Gynecological calculations
- Urological calculations
- Renal calculations
- Volume calculations
- Wireless networking for easy data sharing, storage and printing*(optional)
- Up-to-date connectivity and data management solutions, wireless,
 LAN, integrated database*(optional)
- Capability to send data to mobile by mail and blue tooth*(optional)



• Total mobile medical solution for remote data transfer and diagnostic

- DICOM compatibility*(optional)
- 2USB ports
- 8 TGC slides
- Average 4 multiple adjustable frequency in every probe and mode
- Up to 512 line density

1.5 Language support

 Software: Chinese, English, German, Greek, Malay, Portuguese, Romanian, Spanish, Swedish, Norwegian, Danish, Finnish, French, Polish, Russian, Uighur, Italian, Czech, Hungarian, Cambodia

- Keyboard input: Chinese, English,
 German, Greek, Malay,Portuguese,
 Romanian, Spanish, Swedish, Polish,
 Norwegian, Danish, Finnish, French,
 Russian, Italian, Czech, Cambodia,
 Polski
- Control panel overlay: English
- User manual: Chinese, English,
 German, Russian, Portuguese, Spanish,
 Italian, French

2. Ergonomics

- Unique human oriented design for comfort and convenience
- 15.6-inch high resolution flat panel display with nearly infinite positioning adjustments
- Easy to carry by integrated handle
- Three probe ports

- Easy detachable probe holder
- USB DVDRW *(optional)

2.1 Keyboard

- Ergonomic hard keys for general ultrasound operations
- 8 TGC slides, functionality at any depth
- Backlight keys

2.2 Image display screen

- 15.6 inch high resolution IPS, LED technology, pixel resolution
- Big angel tilting capability(up to 130 $^\circ\,$)
- Backlight adjustment
- Resolution: 1920*1080 pixels

2.3 Comments

- Supports text input and arrow
- Adjustable text size and arrow size
- Supports home position
- Covers various application
- User customizable

2.4 Bodymark

- More than 215 bodymarks for versatile application
- User customizable



2.5 Peripherals

- B&W thermal video printer: Sony UP-D898MD(optional)
- Color thermal video printer: Sony UP-D25MD (optional)
- Memory stick(optional)

2.6 Dimensions and Weight

- Length: 412mm
- Width: 390mm
- Depth: 85mm
- Weight: without accessories approx.
- 6.4kg

2.7 Electrical Power

- Voltage: 100-240V AC
- Frequency: 50/60Hz
- Power: Max.170VA

2.8 Operating Environment

- Ambient temperature: 10-40° C
- Relative humidity: 30-75%
- Atmospheric pressure: 700hPa-1060hPa

2.9 Storage & Transportation

Environment

• Ambient temperature: -5-50° C

- Relative humidity: 10%-80% (no condensation)
- Atmospheric
 pressure:700hPa-1060hPa

3. Transducers

3.1 Transducer types

- Convex array
- Linear array
- Phase array
- 4D probe
- Endocavity probe

3.2 Transducer selection

- Electronic switching of transducers
- User customizable imaging presets for each transducer and application
- Automatic dynamic receiving focus in all transducers
- Multiple adjustable transmit focal zone, up to 8 focal zoom

A3-6D broadband curved array volume probe

- Field of view: 75 degree
- Convex radius: 40mm
- Application: abdomen, OB/Gyn, urology
- B-mode Frequency range:
 3.0 6.0MHz
- Physical Footprint: 82mm×53mm



- Center frequency: 4.0 MHz
- Transducer elements: 128
- Pulsed wave Doppler, color Doppler, power Doppler, harmonic, 3D/4D grayscale and 3D color modes

Multi-imaging frequency setting in
 2D, Harmonic, color Doppler and Wave
 Doppler modes

A2-5C Broadband Curved Array

- Field of view: 59 degree
- Convex radius: 60mm
- Application: abdomen, OB/Gyn, urology, pediatric
- B-mode Frequency range:
 2.0 -6.5MHz
- Center frequency: 3.2 MHz
- Physical footprint:
 72mm x 27mm
- Transducer elements: 128
- Pulsed wave Doppler, color Doppler, power Doppler, harmonic
- Multi-imaging frequency setting in
 2D, Harmonic, color Doppler and Wave
 Doppler modes
- Reusable biopsy guide available
- Measurement accuracy to be better than 2% over 10cm distance.

A4-9E broadband micro convex endocavity array

- Field of view: 156degree
- Convex radius: 10mm
- Application: Ob/Gyn, urology
- B-mode Frequency range:

5.0 - 11.0MHz

- Center frequency: 3.2MHz
- Physical footprint:
 21.0mm (lens) x 19.0mm(lens)
- Transducer elements: 128
- Pulsed wave Doppler, color Doppler, power Doppler, harmonic
- Multi-imaging frequency setting in
 2D, Harmonic, color Doppler and Wave
 Doppler modes
- Reusable biopsy guide available
- Measurement accuracy to be better than 2% over 10cm distance.

A4-12L broadband linear array

- Fine pitch, high resolution
- Applications: vascular, small parts
- Aperture size: 38.4mm
- B-mode Frequency range:
 6.0 -16.0MHz
- Center frequency: 7.5MHz
- Physical footprint: 50mm×18.5mm
- Transducer elements: 128
- Pulsed wave Doppler, color Doppler, power Doppler, harmonic
- Multi-imaging frequency setting in
 2D, Harmonic, color Doppler and Wave
 Doppler modes
- Reusable biopsy guide available
- Measurement accuracy to be better than 2% over 10cm distance.

A1-4P phased array

• Applications: cardiac, abdomen



- Field of view 90 degree
- Aperture size: 17.92mm
- B-mode Frequency range: 2.0-5.0Mhz
- Physical Footprint: 34.5mm×28.5mm
- Center frequency: 2.5MHz
- Transducer elements: 64
- Pulsed wave Doppler,
- continuous wave Doppler, color Doppler, power Doppler, harmonic
- Multi-imaging frequency setting in
 2D, Harmonic, color Doppler and Wave
 Doppler modes
- Reusable biopsy guide available
- Measurement accuracy to be better than 2% over 10cm distance.

A4-9M broadband micro convex array

- Field of view: 138 degree
- Convex radius: 12mm
- Application: pediatric, abdomen, cardiac
- B-mode Frequency range: 5.0 -11.0 MHz
- Center frequency: 7.0 MHz
- Physical footprint: 34mm imes 29mm
- Transducer elements: 128
- Pulsed wave Doppler, color Doppler, power Doppler, harmonic
- Multi-imaging frequency setting in 2D, Harmonic, color Doppler and Wave
 Doppler modes

4. Advanced Imaging controls

4.1 VFusion

- Available on all transducers and for 2D, 3D/4D
- Operate in conjunction with
 VSpeckle, harmonic imaging

4.2 VSpeckle

- Available on all transducers and for 2D, 3D/4D
- Virtually eliminate speckle noise artifact and dynamically enhances tissue margins
- Selectable multiple levels of speckle noise reduction and smoothing
- Operates in conjunction with
 VFusion and harmonic imaging

4.3 VTissue

- Speical imaging processing to adapt
- to the speed of the ultrasound
- variation in different tissue
- Improved conspicuity of lesions, such as stone and tendon

4.4 3D/4D

- 3D/4D rotation
- Grayscale imaging controls
- Selectable rendering



approaches

 Unique high quality rendering algorithm

- Selectable gray maps
- Multi slide cutting
- Cineloop 3D
- Review volume

4.5 Smart Operation

4.5.1 Free View(optional)

• Provide any plane view to visualize the internal tissue information

• Improve the contrast resolution to facilitate the detection of diffuse lesions in organs

4.5.2 Inversion mode*(optional)

• This render mode is used to display anechoic structures such as vessels

• It invert the gray values of the rendered image, such as black image information become white and vice versa

4.5.3 Magic Cut(optional)

 Ability to edit images, make possible to cut away structure obstructing the view in the ROI
 Several cutting methods available

4.6 Smart 3D

4.6.1 Volume Measurement(optional)

Trace the margin of the irregular circle in different slices of volume data in irregular shape Automatically report the volume of the irregular object

4.6.2 Auto Follicle(2D)(optional)

- Just click on the area of follicle in B mode, the area of this follicle
- will be reported automatically Report the area of different follicle in the volume data automatically

4.7 Multi-angle M mode *(optional)

- •Sample on moving tissue from multi-angle
- Present wall motion spectrum based on tissue moving

4.8 Tissue Doppler Imaging (TD)

*(optional)

- Present wall motion spectrum by using Doppler principle
- Provide wall motion direction and velocity information
- Available on all sector transducer for cardiac imaging
- Gain



4.9 Next generation RF-based image

processing

- Available on all imaging transducers in 2D grayscale modes
- Virtually eliminates speckle noise artifact and dynamically enhance tissue edge
- Operates with other real-time processing algorithms

5. Imaging modes

5.1 2D Imaging

• Pre-defined ATGC (adaptive temporal gain compensation) curves optimized for consistently excellent imaging

- B/M acoustic output: 10%-100%
- Select between 1 to 8 transmit focal zones
- Reverse function: on/off
- 2D optimization: on/off
- Centerline: on/off
- L/R flip and U/D flip: on/off
- Display format: Single, Dual, Quad
- TGC: 8 slides on control pannel
- VFusion : \geq 7steps
- VSpeckle: ≥ 7steps
- Harmonic imaging both tissue harmonic and phase inversion
- Cineloop image review
- Selectable 2D line density

- Dual imaging with independent cineloop
- 256(8 bit) gray level
- Up to 8 focus zone adjustable
- Multiple color maps with chroma imaging
- FULL screen imaging to larger image size
- Multi frequency:

probe dependent

- Gray filter: ≧ 7 steps
- Persistence: ≥ 8steps
- Selectable image angles, probe dependent
- Gain: 0-100%
- Dynamic range: 30-280 db
- VSharpen to enhance edge contrast:

8steps

Smooth to improve spatial resolution:

11steps

- Gray Map: ≧ 23types
- Tint Map: ≧ 24types
- TI heat index: TIB, TIS, TIC
- Rotation:
- 0° ,90 $^\circ$,180 $^\circ$,270 $^\circ$
- Zoom(up to 10imes)
- Max frame rate(with phased array
-): ≥3125 fps

5.2 Harmonic Imaging

• Supports both tissue harmonic and phase inversion imaging (transducer and frequency dependence)



 Second harmonic processing to reduce artifacts and improve image clarity

 Maximize detail resolution and enhance contrast

Available on all imaging transducers

• Extends high performance imaging capabilities to all patient body types

5.3 M mode

- Selectable sweeping rates,
 ≥ 10steps
- Time marks: 0.025 0.5s
- Selectable display format prospective or retrospective (V2/3, V1/3, V1/2, H1/2, H3/4, full screen)
- Chroma colorization with multiple color maps
- Cineloop review for retrospective analysis of M-mode data
- 256 gray levels
- Acoustic output: 10%-100%
- Gray filter: ≧ 7steps
- Dynamic range: 108db-128db
- Vsharpen: ≧ 6steps
- Gray Map: ≥ 23types
- Tint Map: ≧ 24types
- Gain: 0-100%
- MultiAngle: available

5.4 Color Doppler mode

Available on all imaging transducers

Automatically adapts transmit and receive bandwidth processing based on

the color box position

- Cineloop review with full playback control
- Steering on linear array transducers
- Selectable in baseline, line density, flash reduction, persistence, maps, frequency, PRF, wall filter, packet size, color level, sensitivity, focus position, acoustic power, and smooth
- FULL screen imaging to larger image size
- L/R flip and U/D flip: on/off
- Frequency: ≥4steps, depend on probes
- Baseline: 0-100%
- Acoustic power: 5%-100%
- Line density: \geq 6 steps
- Flash reduction: \geq 6 steps
- Persistence: \geq 20 steps
- Color Map: ≧ 33types
- Smooth : \geq 7steps
- Sensitivity: \geq 5 steps
- Transparency: \geq 6 steps
- Color level: \geq 14 steps
- Packet size: ≧ 10 steps
- Reverse function: on/off
- Color gain: 0-100%
- Region of interest
- Baseline invert
- Simultaneous mode during PW mode
- Zoom

5.5 Power Doppler mode



- High sensitive mode for small vessel visualization
- Available on all transducers
- Cineloop review
- Display format: Single, Dual, Quad
- Individual controls for gain
- Selectable baseline, line density, flash reduction, persistence, maps, frequency, PRF, wall filter, packet size, color level, sensitivity, focus position, acoustic power, and smooth
- Color maps: \geq 24 types
- Color levels: \geq 11 steps
- Sensitivity: ≧ 5steps
- Smooth: \geq 7steps
- Persistence: \geq 20steps
- Adjustable region of interest

5.6 Pulsed Wave (PW) Doppler

- Ultra high resolution spectral FFT rate
- Angle correction with automatic velocity scale adjustment
- Normal, invert display around horizontal zero line
- Selectable gray filter, dynamic range, frequency, PRF, wall filter, baseline, angle correct, sample volume
- Selectable sweep speeds: 10 steps
- PW acoustic output: 5%-100%
- Gray filter: ≧ 6steps
- Dynamic range: 108db-128db

- Baseline: 5%-95%
- Sample volume: 0.5mm-10mm
- Angle correct: -80 $^{\circ}$ +80 $^{\circ}$
- Audio Volume: 0-20
- Spectrum Optimize: ≥ 28steps
- Gray map: ≧ 13types
- Tint map: \geq 11types
- Trace direction: above, below, both
- Trace type: max, mean, both
- Cardiac cycle: 1-5
- Selectable low frequency signal filtering with adjustable wall filter settings
- Selectable grayscale curve for optimal display
- Selectable chroma colorization maps
- •Selectable display format prospective or retrospective (V2/3, V1/3, V1/2, H1/2, H3/4, full screen)
- •Auto function to optimize spectral Doppler displ
- Digitally enhanced stereo output
- 256 gray levels
- Post-processing in frozen mode includes map, baseline, invert and chroma
- Simultaneous or duplex mode of operation
- Simultaneous 2D, color Doppler, pulsed Doppler
- High PRF capability in all modes including duplex and triplex



5.7 Continuous Wave Doppler

(CWD)*(optional)

- Cardiac sector array transducer only
- Maximum velocity range: 19m/sec

5.8 Pview*(optional)

- Real time extended field of view composite imaging
- Ability to back up and realign the image during acquisition
- Full zoom, cineloop review and image rotation capabilities
- User can measure distance and area
- Measurement can be made on individual frames during cineloop review
- Available on linear transducers

5.9 Tview

- Expand view of scanning
- Available on all transducers

5.10 3D/4D

- 3D/4D rotation
- Grayscale imaging controls
- Selectable rendering

approaches: Surf Texture, Surf Smooth, Grad Light, Surf HDR

- Review volume
- Volume Angle:15%-70%
- Quality:low,mid,good,high
- Threshold: 256
- Transparency:0.1-2, 0.1/step
- •Category:Face,Spine,Brain,Heart, Hi speed,Lip&plate,Limbs,Custom
- Display format: single,dual,MRP,Quad
- Image Reference:A,B,C,3D
- Flip:0°,90°,180°,270°
- View: Front/Back, Back/Front;
 Left/Right, Right/Left; Up/Down,
 Down/Up
- Perspective mode: Transp Max, X-ray,
 Transp Min, Light
- Rotation Direction: X, Y, Z
- 3D Map: ≧ 10types
- Tint maps: ≥24Types
- Gray maps: ≥ 23Types
- 2D VSpeckle: ≧ 3types
- 3D VSpeckle: ≧ 3types
- Render Type: Gray, GrayInv
- MCUT(optional)
- Slice Number: 2×2 , 3×3 , 4×4 , 5

imes5

- Max Slice Number: 25
- Gray Map: ≧ 23types
- Tint Map: ≧ 24types
- Cut plane: A,B,C
- Rotation Direction: X, Y, Z
- Volume Angle: 5 $^{\circ}$ -70 $^{\circ}$
- Interval: 1mm-20mm, 0.5mm/step
- Quality: low,mid,good,high



- Free view(optional)
- Rotation Direction: X, Y, Z
- Route: curve, line
- Reference image: A,B,C
- Slice thickness: 0mm-20mm
- Active line: 1,2,3
- Display format: single, dual, MPR
- Mix: 10-90
- Threshold: 256steps
- Transparency: 0.1-2.0, 0.1/step
- Magic cut(optional)
- Erase mode: inside Lasso, outside Lasso, big circle, small circle
- Erase type: trace, rectangle, ellipse
- Rotation direction: X, Y, Z
- Niche view(optional)
- Model type: upper, lower
- Rotation direction: X,Y,Z
- Display format: single, quad
- Gray map: ≥ 23 types
- Tint map: ≥ 24 types
- Image reference: A, B, C, N
- 3D cut(optional)
- Gray map: ≥ 23 types
- Tint map: ≥24 types
- Max slice number: 25
- Rotation direction: X, Y,Z
- Slice number: 2 \times 2, 3 \times 3, 4 \times 4, 5 \times
- 5
- Interval: 1-20mm
- Cut plane: A, B, C

6. System Feature

6.1 Display modes

- Simultaneous capability
 - 2D/PW/CW
 - 2D/CF or PDI
 - 2D/M
 - Dual, 2D/2D
 - Dual, 2D/2D+CF or PDI
 - Dual, duplex and triplex
 - Duplex and Triplex mode
 - Quad display in 3D/4D

application

- 9 slice images display in
- 3D/4D application
- Time line display
 - Independent dual 2D/PW or
- CW
- Timed based sweep update

mode

6.2 Display annotation

- Institution/hospital name
- Date: 3 types selectable:
- Year-Month-Day, Day-Month-Year, Month-Day-Year
- Time: 2 types selectable, 24hours and 12 hours
- Operator identification
- Patient name, first, last
- Patient identification: 30 characters



 Gestational age from LMP/BBT/DOC/IVF/GA/Avg.US

- Esse 3 image symbol:
- Power output index
 - MI: mechanical index
 - TIS: thermal index soft

tissue

• TIC: thermal index cranial (Bone)

- TIB: thermal index bone
- Probe orientation marker: coincide with a probe orientation marking on the probe
- Gray/color bar
- Measurement result window
- Probe type
- Application name
- Image depth
- Imaging parameters by mode

 2D/M mode: acoustic power output, gain, frequency, frame rate, dynamic range

• Color mode: color acoustic power output, color gain, color flow frequency, PRF, wall filter

• PW/CW mode: Doppler acoustic power output, Doppler gain, Doppler frequency, PRF, wall filter, sample depth

- Focus zone marker
- Body pattern
- PW and CW scale markers:

time/speed

- M scale markers: time/depth, time
- System measurement display

- System message display
- Biopsy guide line
- Heart rate

6.3 Cineloop

 Acquisition, storage in memory and display of up to 1500 seconds long of 2D, color and PW/CW images for review

6.4 Compare

• Compare live imaging with stored imaging

6.5 Quick save feature

• The system provides quick save function through USB stick, internal/external HDD during or after

exam

 Configurable saving file format, VRD (Visual Raw Data),

DICOM, JPEG, BMP, PNG, MP4 and AVI

6.6 Physio

- One 3-lead ECG input*(optional)
- Gain, sweep rate and display position controls
- Automatic heart rate calculation and display
- Fault condition display



6.7 Archive

 Patient data input which include patient ID, name, birth date, sex, exam physician, quality check, exam operator

- Physical data such as weight, height
- Patient exam management
- Patient exam images storage and management
- Import VRD format data into the system from outside media, such as USB stick, external HDD
- Export patient data into outside medias

6.8 Report

• Automatically pull patient data into the report

•Automatically load measurement worksheet into the report

- Pull related exams' images into the report
- Write comments in the report
- Print report through network or local printer

6.9 Connectivity

• Standard connectivity features

 Local print to on-board or off-board video printers through USB port

- Page report print
- Image export to removable media (external HDD, USB stick)

• Network linkage

 Image export to network storage servers

- DICOM export and retrieve
 *(optional)
- Mobile data transfer solution by
 - Blue tooth*(optional)
 - Email*(optional)
 - Hot point connection

• DICOM workstation for remote diagnostic solution *(optional)

• DICOM, JPEG, BMP, PNG, AVI

• VRD and DICOM images stored in disc can be recalLCD on the system

- JPEG,BMP,PNG and AVI images can be played on normal computers
- On-board patient exam storage

• Direct digital storage of static image or cineloop images to internal hard disk drives

• Fully integrated user interface

6.10 Probes/application

- Selectable multiple applications
- Edit exist application preset
- Edit user defined preset
- Rename preset
- Return to factory preset
- Quick save user defined parameters in related application



6.11 Safety Conformance

 Regulatory Notice: This device is tested to meet all applicable requirements in relevant. According to 93/42 EEC, it is class IIa medical device. Conformity to Standards: IEC 60601-1 : 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2007 Electromagnetic compatibility - Requirements and tests IEC 60601-1-6:2010 Usability IEC 60601-2-37:2007 Medical electrical equipment - Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment IEC 61157:2007 Declaration of acoustic output parameters ISO 10993-1:2009 Biological evaluation of medical devices IEC 62304:2006 Medical device software – Software life cycle processes IEC 62366:2007 Medical devices -Application of usability engineering to medical devices Council Directive 93/42/EEC on Medical

Device

WEEE according to 2012/19/EU RoHS according to 2011/65/EU

7. Measurement and Analysis

7.1 Measurement in different

modes

7.1.1 Generic Measurement in 2D

mode

- Depth
- Distance
- Perimeter
 - Length and width method
 - Ellipse method
 - Polygon method
 - Spline method
 - Tracing method
- Area
 - Length and width method
 - Ellipse method
 - Polygon method
 - Spline method
 - Tracing method
- Volume
 - Single line method
 - Dual line method
- Triple line method
 - Single ellipse method
- Single ellipse and single line method
- Angle
- Stenosis
 - Diameter method
 - Square meter method
- A and B ratio
 - Diameter ratio

Generic Measurement in CFM



mode

- CFV
 - point
 - profile

7.1.2 Generic Measurement in M

mode

- Depth
- Distance
- Time
- Slope
- Heart rate
- Stenosis
- A and B ratio
 - Diameter ratio
 - Time ratio
 - Velocity ratio

7.1.3 Generic Measurement in PW

mode

• Speed (include PV

(Peak Velocity))

- •Time (include AT (Accelerate Time))
- Acceleration
- PS (Peak Speed in systole period)
- ED (The speed in the end of diastole period)
- MD (Minimum speed in diastole period)
- TAMAX (maximum speed in time average)
- TAMEAN (mean speed in time

average)

- TAMIN (minmum speed in time average)
- PI (Pulsatility Index)
- RI (Resistance Index)
- PS and ED ratio
- ED and PS ratio
- A and B ratio (A/B ratio)
 - Speed ratio
 - Time ratio
 - Acceleration ratio
- Square meter ratio
- FLOWVOL (Flow Volume)
- MaxPG (maximum pressure gradient)
- MeanPG (Mean pressure gradient)
- SV (Stroke Volume)
- Each volume diameter cardiac
- Time mean speed in each stroke volume
- Cardiac output
- Heart rate
- SV(LVOT)/SV(RVOT)

7.2 Measurement in different

applications

7.2.1 Abdominal Measurement

- General abdomen
- Difficult abdomen
- Kidney
- Renal vessel
- Abdominal trauma



7.2.2 Small Part Measurement

- Thyroid
- Breast
- Testis
- Musculoskeletal
- Upper and lower extremity joint
- Nerve block

7.2.3 Vessel Measurement

- Carotid artery
- Upper artery
- Upper vein
- Lower artery
- Lower vein
- Vessel puncture
- Transcranial Doppler

7.2.4 Gynecology Measurement

- Uterus and Pelvis
- Follicle

7.2.5 Urology Measurement

- Bladder
- Prostate
- Renal
- Kidney and ureter
- Pelvic Floor dysfunction

7.2.6 Pediatric Measurement

- Neonatal Head
- Neonatal Abdomen
- Pediatric Abdomen

• Pediatric Hip

7.2.7 Obstetrics Measurement

- OB Early
- OB Mid
- OB Late
- Fetal Heart

7.2.8 Cardiac Measurement

- General
- LV
- MV
- Ao
- AV
- LA
- RV
- TV
- PV
- RA
- System

7.2.9 Auto NT (Nuchal Translucency

measurement)(Optional)*

Automatically detect Nuchal

Translucency in interest box

• Automatically report thickness result of NT

Auto IMT (Intima-Media Thickness) measurement

- Automatically detect intima media thickness in interest box
- Automatically report the result of IMT



• Available in linear probe

7.2.10 Auto IMT (Intima-Media Thickness) measurement*(Optional) *

• Automatically detect intima media thickness in interest box

 Automatically report the result of IMT

• Available in linear probe

7.2.11 Auto IT (Intracranial

translucency) measurement(Optional)

*

• Support Auto IT(Intracranial translucency) measurement

• Draw the ROI and the system analyses and displays the result

7.2.12 Auto Follicle(2D/3D)(Optional)

*

 Just click on the area of follicle in B mode, the area of this follicle will be reported automatically

•Report the area of different follicle in the volume data automatically

7.2.13 Smart 3D Volume

Measurement(Optional) *

• Trace the margin of the irregular circle in different slices of volume data in irregular shape

• Automatically report the volume of

the irregular object

7.2.14 VAim OB measurement (Optional) *

 VAim OB is an intelligent tool for fetal growth calculation, just one touch to activate the measurement items

(BPD, OFD, HC, AC, FL, HL) and get the results, helps to make clinical decisions quickly and confidently, improving the speed and ease of exams

 The intelligent results will be add into the worksheet and report automatically

7.2.15 VAim Hip measurement

(Optional) *

VAim Hip is an intelligent solution in the assessment of DDH(Developmental Dysplasia of Hip) with one simple touch.

• Based on 'Ped HIP' application

7.2.16 VAim Follicle (2D)

measurement (Optional) *

An intelligent tool for follicle calculation, one touch to get the follicle status,

dedicated for women's reproductive health.

Choose left or right follicle



- Automatically report the result of IMT
- Available in linear probe



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