Data sheet

1.42.0

Contents

1. System Overview

1.1 "VLucid+" Platform

- ES-S300 brings a confident diagnostic experience with the extraordinary processing power of our breakthrough VLucid+ platform, to deliver superior image quality, thanks to its exceptional intelligent architecture
- The new generation VLucid+ platform is capable of processing multiple data streams simultaneously
- The new 12 bit, low noise, digital circuitry, with up to 280db dynamic range has improved 2D performance and increased Doppler sensitivity
- Directional-enhanced information compiling for more tissue detail and reduction of angle-generated artifacts
- New generation adaptive image processing for noise and artifact reduction that improves tissue presentation and edge definition
- Multi-processors allow simultaneous mode changes and support for advanced system functionality

1.2 Applications

- Abdomen
- Obstetric
- Gynecology
- Cardiology
- Urology
- Vascular
- TCD
- Small Parts
- Pediatrics
- Musculoskeletal

1.3 Imaging Features

- Harmonic
- VFusion
- VSpeckle
- VTissue
- Auto imaging optimization
- Needle enhancement(optional)
- PView for panoramic imaging(optional)
- TView for trapezoidal imaging
- Full screen imaging
- RF based Zoom
- M mode
- Color M mode(optional)
- Multi Angle M-mode(optional)
- Curved M mode(optional)
- CFI function
- CF Velocity Profile
- VFlow(optional)
- VLuminous Flow
- Power Doppler imaging
- Pulse wave Doppler imaging
- Continuous wave Doppler(optional)
- Tissue Doppler (TD)(optional)
- Tissue Velocity Imaging (TVI)(optional)
- Free 3D(optional)
- 3D/4D
- 3D Smart Face(optional)
- HQ Rendering(optional)
- HQ Silhouette(optional)
- Tomographic display (MCUT)(optional)
- Inversion mode(optional)
- Magic Cut(optional)
- Free View(optional)

- Niche view
- Color 3D (optional)
- B/Color steer
- Duplex 2D/CF
- Triplex 2D/CF/PW Doppler
- Sync B/C width
- PWV (optional)
- Stress Echo (optional)
- Auto EF (optional)
- Auto/Live IMT (optional)
- Auto Flow Volume (optional)
- Strain Imaging (optional)
- Elastography imaging(optional)
- VAid Breast (optional)
- VAid Thyroid (optional)
- Auto NT(optional)
- Auto IT(optional)
- VAim(optional)

for OB、Follicle、Hip、Pelvic、LEVA

- VCQ(optional)
- Easy Comparative Function
- Tutorial

1.4 Standard Features

- Up to 1500 seconds standard cine storage
- 250G-SSD
- 500G/1T/2T-SSD(optional)
- Integrated black/white thermal video printer slot
- Patient information database
- Image archive on hard drive
- Quick store to USB memory stick
- Quick store to hard drive
- Wireless networking for easy data sharing, storage and printing
- Bluetooth for image data transfer
- Image data transfer directly by E-Mail with network access
- Up-to-date connectivity and data management solutions, wireless , LAN, Bluetooth, E-Mail, integrated database
- DICOM compatibility(optional)
- Vreport(optional)
- VWork
- 3 or 4 probe ports
- 5 usb+1 typeC ports
- 1 ECG port
- 10 TGC slides
- 1 HD Video
- 1 VGA, 1 S-video
- 1 Speaker interface
- 1 LAN interface

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, Ukraine, Uyghur
- Keyboard input: Chinese, English, German, Greek, Malay, Portuguese, Romanian, Spanish, Swedish, Polish,
Norwegian, Danish, Finnish, French, Russian, Italian, Czech, Cambodia, Polski, Ukraine, Uyghur

2. Ergonomics

- Unique human oriented design for comfort and convenience
- Easy access DVD media drive(optional)
- 6 transducer holders (include one endocavity holder(optional))
- Automatic warming gel bottle holders(optional)
- Alphabetic keyboard(optional)
- Simple, easy and effective cable management structure

2.1 Keyboard

- Highly sensitive 13.3 inch technology touch panel
- Resolution: 1920*1080 pixels
- Intuitive, configurable and touchable interactive operation interface
- Ergonomic hard keys for general ultrasound operations
- 10 TGC slides, functionality at any depth
- Backlight keys
- Independent rotation and up/down adjustment
- Swivel range:±70 degrees
- Down/up range: 120 mm

2.2 Image Display Screen

- 21.5 inch high resolution LED technology, pixel resolution: 1920x1080
- Brightness, contrast and color temperature adjustment
- View angle: -178° ~ 178°
- Number of color: 16.7M
- Multifunctional support arm design
- Independent tilt and swivel adjustment
- Swivel range(triple joint):±350degrees
- Tilt range: 0-100 degrees
- Up/down : 70mm

2.3 Wheels

- Diameter: 125mm
- Front castor (2 ea): Total lock
- Rear castor (2 ea): Total lock

2.4 System Boot-up

- Boot-up from shut-down: about 62sec
- Shut-down: about 6sec

2.5 Comments

- Supports text input and arrow
- Support finger-draw comments
- Adjustable text size and arrow size
- Covers various application
- User customized

2.6 Bodymark

- More than 215 bodymarks for versatile application
- User customizable

2.7 Peripherals

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

2.8 Dimensions and Weight

- Height: 1440mm
- Width: 680mm
- Depth: 900mm
- Net Weight: 64kg

2.9 Electrical Power

- Voltage: 100-240V AC
- Frequency: 50/60Hz
- Power: Max. 500VA
- Support built in battery (optional)

2 pieces is a group, use in groups, can choose 1/2/3/4 groups

- Scan time in B Mode:
  about 1h20min(1 groups)
  about 2h50min(2 groups)

about 4h35min(3 groups)
about 6h10min(4 groups)
- Charging time in B Mode:
about 3h30min(1/2 groups)
about 7h35min(3/4 groups)

2.10 Operating Environment

- Ambient temperature: 10-40° C
- Relative humidity: 30-75%
- Atmospheric pressure: 540hPa-1060hPa

2.11 Storage & Transportation Environment

- Ambient temperature: -5-50℃
- Relative humidity: 10%-80% (no condensation)
- Atmospheric pressure:700hPa-1060hPa

3. Transducers

3.1 Transducer Technology

- Xcen technology for wideband frequency
- Pure wave technology for high resolution imaging

3.2 Transducer Types

- Convex array
- Linear array
- Phased array
- 4D probe
- Endocavity probe
- Micro-convex array
- Curved array volume probe

3.3 Application

- Selectable multiple applications
- Edit exist application preset
- Edit user defined preset
- Rename preset
- Return to factory preset

3.4 Transducer Selection

3.4.1 F2-5C Broadband Curved Array Probe

- Application: Abdomen, OB/Gyn, Urology, Pediatric
- Transducer Elements:128
- Physical Footprint: 72mm×27mm
- Footprint: 17mm×64mm
- Convex Radius: 60mm
- Field Of View: 59degree
- B Frequency range: 2-5.5MHz
- Har Frequency range: 1-8MHz
- CF Frequency range: 2-4MHz
- PW Frequency range: 2-4MHz
- Pulsed Wave Doppler, Color Doppler, Power Doppler, Harmonic, B-Mode
- Multi-Imaging Frequency Setting in 2D, Harmonic, Color Doppler and Wave Doppler Modes
- Reusable Biopsy Guide available

3.4.2 D2-6C Broadband Curved Array Volume Probe

- Application: Abdomen, OB/Gyn, Urology
- Transducer Elements:128
- Physical Footprint: 75.5mm×49.2mm
- Convex Radius: 40mm
- Field Of View: 75degree
- B Frequency range: 3-5.5MHz

- Har Frequency range: 3-6MHz
- CF Frequency range: 2.5-4MHz
- PW Frequency range: 2.5-4MHz
- Pulsed Wave Doppler, Color Doppler, Power Doppler, Harmonic, B-Mode, 3D/4D Grayscale and 3D Color Modes
- Multi-Imaging Frequency Setting in 2D, 3D/4D, Harmonic, Color Doppler and Wave Doppler Modes

3.4.3 G3-9M Broadband Micro Convex Array Probe

- Application: Pediatric, Abdomen, Cardiac
- Transducer Elements:128
- Physical Footprint: 34.2mm×28.7mm
- Footprint: 11.2mm×25mm
- Convex Radius: 15mm
- Field Of View: 103degree
- B Frequency range: 5-10MHz
- Har Frequency range: 4-12MHz
- CF Frequency range: 4-5MHz
- PW Frequency range: 4-5MHz
- Pulsed Wave Doppler, Color Doppler, Power Doppler, Harmonic, B-Mode
- Multi-Imaging Frequency Setting in 2D, Harmonic, Color Doppler and Wave Doppler Modes

3.4.4 F4-9E Broadband Micro Convex Endocavity Array Probe

- Application: OB/Gyn, Urology
- Transducer Elements:128
- Physical Footprint: 32.5mm x 44.2mm
- Footprint: 10.7mm×21mm
- Convex Radius: 10mm
- Field Of View: 150degree
- B Frequency range: 5-10MHz
- Har Frequency range: 4-9MHz
- CF Frequency range: 4-5MHz
- PW Frequency range: 4-5MHz
- Pulsed Wave Doppler, Color Doppler, Power Doppler, Harmonic, B-Mode
- Multi-Imaging Frequency Setting in 2D, Harmonic, Color Doppler and Wave Doppler Modes
- Reusable Biopsy Guide available

3.4.5 F4-12L Broadband Linear Array Probe

- Applications: Vascular, Small Parts
- Transducer Elements:128
- Physical Footprint: 52.5mm×25mm
- Footprint: 9mm×44mm
- Aperture Size: 38.4mm
- B Frequency range: 6-12MHz
- Har Frequency range: 6-18MHz
- CF Frequency range: 3.1-6.3MHz
- PW Frequency range: 3.1-6.3MHz
- Pulsed Wave Doppler, Color Doppler, Power Doppler, Harmonic, B-Mode
- Multi-Imaging Frequency Setting in 2D, Harmonic, Color Doppler and Wave Doppler Modes
- Reusable Biopsy Guide available

3.4.6 S1-6PS Phased Array Probe

- Single Crystal Technology
- Applications: Cardiac, Abdomen, TCD
- Transducer Elements: 96
- Physical Footprint: 36mm x 29mm
- Footprint: 16mm×23mm
- Aperture Size: 16mm
- Field Of View: 90egree
- B Frequency range: 2-5MHz
- Har Frequency range: 1-6MHz
- CF Frequency range: 1.7-3.3MHz
- PW Frequency range: 1.7-3.3MHz
- Pulsed Wave Doppler, Continuous Wave Doppler, Color Doppler, Power Doppler, Harmonic, B-Mode
- Multi-Imaging Frequency Setting in 2D, Harmonic, Color Doppler and Wave Doppler Modes
- Reusable Biopsy Guide available

3.4.7 G1-4P Phased Array Probe

- Applications: Cardiac, Abdomen, TCD
- Transducer Elements: 64
- Physical Footprint: 34.2mm×28.7mm
- Footprint: 15mm×22mm
- Aperture Size: 18mm
- Field Of View: 90degree
- B Frequency range: 2-3.5MHz
- Har Frequency range: 1-4.5MHz
- CF Frequency range: 1.7-3.3MHz
- PW Frequency range: 1.7-3.3MHz
- Frequency range: 1-6Hz
- Pulsed Wave Doppler, Continuous Wave Doppler, Color Doppler, Power Doppler, Harmonic, B-Mode
- Multi-Imaging Frequency Setting in 2D, Harmonic, Color Doppler and Wave Doppler Modes
- Reusable Biopsy Guide available

3.4.8 G3-10P Phased Array Probe

- Application: Pediatric Cardiology, Abdomen
- Transducer Elements: 64
- Physical Footprint: 33mm x 33mm
- Footprint: 12mm×18.6mm
- Aperture Size: 10.2mm
- Field Of View: 90egree
- B Frequency range: 3-8MHz
- Har Frequency range: 3-10MHz
- CF Frequency range: 3.3-5.7MHz
- PW Frequency range: 3.3-5.7MHz
- Pulsed Wave Doppler, Continuous Wave Doppler, Color Doppler, Power Doppler, Harmonic, B-Mode
- Multi-Imaging Frequency Setting in 2D, Harmonic, Color Doppler and Wave Doppler Modes

4. Imaging modes

4.1 2D mode

4.1.1 B Image

- Pre-defined ATGC (adaptive temporal gain compensation) curves optimized for onsistently excellent imaging
- Multi frequency: ≥ 5 levels, probe dependent
- Select between 1 to 4 transmit focal zones
- VSpeckle ： ≥ 6 steps
- B acoustic output: 10-100%
- TGC：10 slides on control pannel
- SGC：8 ponds on touch pannel
- Dynamic range: 30-280 dB ， 2dB/step
- Gain: 0-100%
- Persistence: ≥ 8steps
- Rotation: 0°,90°,180°,270°
- Gray Map：≥ 23types
- Tint Map：≥ 25types
- Gray filter: ≥ 7 steps
- EdgeEnhance (improve detail information and contrast): ≥ 6steps
- Smooth ≥ 11steps
- VSharpen ≥ 8steps
- 2D optimization: on/off
- Centerline: on/off
- L/R flip and U/D flip: on/off
- Display format：Single, Dual, Quad
- TI heat index: TIB, TIS, TIC
- Zoom(up to 10×) 24 steps
- Harmonic imaging both tissue and phase inversion
- Duplex and Triplex mode（including 2D/CF/PW）
- Post-processing in frozen mode includes gain, map, Dynamic range, VSpeckle

4.1.2 Needle enhancement (optional)

• Beam deflection technology is used to make the needle perpendicular to the sound beam, improving the display of the needle

4.1.3 TView

• Expand view of scanning

4.1.4 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

4.2 M mode

4.2.1 M Image

• Selectable display format prospective or retrospective (V2/3, V1/3, V1/2, H1/2, H3/4, full screen)
• M acoustic output: 10-90%
• Dynamic range：108db-128db
• Gain: 0-100%
• Gray Map: ≥ 23types
• Tint Map: ≥ 25types
• Gray filter：≥ 6steps
• Vsharpen: ≥ 6steps
• Color M mode：available
• Selectable sweeping rates ≥ 10steps
• Post-processing in frozen mode includes gain, map, baseline

4.2.2 Multi-angle M Image (optional)

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

4.2.3 Multi-line Angular M-Image (optional)

• Up to 4 lines
• Color MAM is available

4.2.4 Curved M Image (optional)

• Draw the route of the sample line freely and obtain the corresponding anatomical M-mode . This might be helpful to obtain myocardial wall motion
• Color curved M mode is available

4.3 Color Doppler mode

4.3.1 Color Image

• Frequency：≥ 5steps, depend on probes
• Acoustic power：5%-100%
• Color gain：0-100%
• ROI size or position：adjustable
• Baseline： 33 steps
• Smooth ：≥ 7steps
• Color Map：≥ 33types
• Flash reduction：≥ 6 steps
• Persistence：≥ 7steps
• Sensitivity：≥ 5 steps
• Transparency：≥ 6steps
• Invert function: on/off
• FULL screen imaging to larger image size
• L/R flip and U/D flip: on/off
• Color flow M mode display for tissue motion and flow velocity
• Zoom
• Duplex and Triplex mode（including 2D/CF/PW）
• Post-processing in frozen mode includes map, baseline, invert
• VFlow available
• Sync B/C width

4.3.2 Power Doppler Image

- Frequency：≥ 5steps, depend on probes
- Acoustic power：5%-100%
- Color gain：0-100%
- ROI size or position：adjustable
- Smooth ：≥ 7steps
- Color Map：≥ 24types
- Flash reduction：≥ 6 steps
- Persistence：≥ 7 steps
- Transparency：≥ 6steps
- Color level：≥ 11 steps
- Invert function: on/off
- FULL screen imaging to larger image size
- L/R flip and U/D flip: on/off
- Color flow M mode display for tissue motion and flow velocity
- Zoom
- Duplex and Triplex mode（including 2D/CF/PW）
- Post-processing in frozen mode includes map, baseline, invert

4.3.3 VLuminous Flow Image

- Visualize 2D blood flow in 3D to improve spatial resolution, dynamic information display, and continuity of fine flow display

4.4 Spectrum Doppler

4.4.1 Pulse Doppler Image（PW）

- Selectable display format prospective or retrospective (V2/3, V1/3, V1/2, H1/2, H3/4, full screen)
- Baseline: 5%-95%
- PW acoustic output: 5%-100%
- PW gain：0-100%
- Selectable sweep speeds: ≥ 10 steps
- Gray filter: ≥ 6steps
- Sensitivity: ≥ 21steps
- Audio Volume: 0-20
- Angle correction with automatic velocity scale adjustment
- Normal, invert display around horizontal zero line
- Auto optimization: on/off
- Invert: on/off
- Angle correct：±80°, 1° / step
- Spectrum Optimize: ≥ 28steps
- Gray map: ≥ 14types
- Tint map: ≥ 12types
- Cardiac cycle: 1-5
- Trace direction: above, below, all
- Trace type: max, mean, max and mean
- Post-processing in frozen mode includes map, baseline, invert
- High PRF capability in all modes including duplex and triplex

4.5 3D/4D

4.5.1 3D/4D image

- 3D/4D rotation
- Grayscale imaging controls
- Selectable rendering Approaches：HQ Surface, HQ Grad,HQ Silhouette, Surf Texture, Surf Smooth, Grad Light, Surf HDR, Trans Max, X-ray,Transp Min,Light
- Unique high quality rendering algorithm
- Review volume
- Volume Angle:15%-85%
- Quality:low,mid,good,high,best
- Threshold:256
- Transparency:0.1-2, 0.1/step
- Display format:single,Dual,triplex,Quad
- Image Reference:A,B,C,D
- Flip: 0°,90°,180°,270°
- View：Front/Back, Back/Front; Left/Right,Right/Left;Up/Down,Down/Up
- Rotation Direction：X, Y, Z
- 3D Map：≥ 10types
- Tint maps: ≥ 25Types
- Gray maps: ≥ 23Types
- 2D VSpeckle：≥ 4types
- 3D VSpeckle：≥ 4types
- Render Type：Gray，Graylnv

4.5.2 Free 3D (optional)

• Reconstruction of the 3D plane was performed with a 2D ultrasound probe scan

4.5.3 3D/4D HQ Grad (optional)

• Amazing high image quality
• Extreme realistic rendering images
• Similar operation as normal rendering

4.5.4 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
• Direction: X, Y, Z
• Route: curve, straight line
• Reference image: A,B,C
• Slice thickness: 0mm-20mm
• Active line: 1,2,3
• Mix: 10-90
• Threshold: 256 steps
• Transparency: 0.1-2.0, 0.1/step

4.5.5 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

4.5.6 Niche view

• Display 3 orthogonal planes centered on ROI
• Use Depth to translate the selected plane
• Each imaging plane or Niche image can be selected using image reference
• Model type: upper, lower
• Display format: single, quad
• Rotation direction: X, Y, Z
• Image reference: A, B, C, N

4.5.7 Magic Cut (optional)

• Ability to edit images, make possible to cut away structure obstructing the view in the ROI
• Erase mode: inside lasso, outside lasso,big circle, small circle
• Erase type: trace, rectangle, ellipse

4.5.8 MCUT (optional)

• Slice Number：2×2,3×3,4×4,5×5
• Max Slice Number：25
• Gray Map：≥ 33types
• Tint Map：≥ 25types
• Cut plane：A,B,C
• Rotation Direction：X, Y, Z
• Volume Angle: 15°-85°
• Interval: 1mm-20mm, 0.5mm/step
• Quality：low,mid,good,high,best

5. System Feature

5.1 Display modes

• Simultaneous capability
  • 2D/PW/CW
  • 2D/CF or PDI
  • 2D/M
  • Dual, 2D/2D
  • Dual, 2D/2D+CF or PDI
  • Dual, duplex triplex
  • Duplex and Triplex mode
  • Quad display in 3D/4D application
  • 25 slice images display in 3D/4D application
  • Time line display
  • Independent dual 2D/PW or CW
  • Timed based sweep update mode

5.2 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
- First Name,Middle Name,Family Name
- Patient identification: 30 characters
- Gestational age from LMP/EDC/GA/BBT/IVF
- ESSE3 image symbol: Ginkgo leaf
- 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:Depth, 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, sample volume
- Scanline Gain Compensation(SGC) with 8 slides adjustment
- 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

5.3 Simple User Operation Interface

- Simple user interface and easy workflow
- Allows one step on probe & application switch, and intuitive user parameter control

5.4 Cineloop

- Acquisition, storage in memory and display of up to 30000 frames, 1500 seconds long of 2D, color and PW/CW images for review
- Avaliable to decide StartFrame and EndFrame
- Frame by frame manual cine loop review or auto playback with variable speed:400%, 200% , 100%, 80%, 60%, 50%,40%, 20%
- Frame compare: displays one cine in dual format and allows frame by frame compare side by side
- Acquisition, storage and replay of Doppler audio

5.5 Quick save feature

- The system provides quick save function through USB stick, internal/external HDD, DVD during or after exam
- Configurable saving file format, VRD (ESSE3 Raw Data), DICOM, PNG,BMP,JPG MP4and AVI

5.6 Physio

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

5.7 Archive

- Patient data input which include patient ID, name, Date of Birth， Gerder， Perf.Physician,Ref.Physician, 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, DVD
- Export patient data into outside Medias
- Support backend export without interrupting users scan

5.8 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

5.9 VReport(optional)

- VReport is a customer-centric tool to design report templates that allows users to:
- design the layout (arrangement of the measured items)
- add new measurement items/calculations
- auto generates comment list based on the measurement items in the template
- add descriptions : touch to choose, fully utilizing touch screen
- greatly improves the workflow

5.10 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 (DVD, external HDD, USB stick)
    - Ethernet Network Connection
    - Cable connection
    - Wireless connection: need wireless routing adaptor
    - Network linkage
    - Image export to network storage servers
    - DICOM export and retrieve
    - Support multiple DICOM server configuration
    - Mobile data transfer solution by
    - Blue tooth
    - email
    - Hot point connection
    - VCloud
    - External DVDRW
    - Export 3D data for 3D printer(optional)
    - Data storage formats include VRD, DICOM, JPEG,BMP,PNG, AVI
    - JPEG,BMP,PNG,VRD and DICOM images stored in disc can be recalled on the ESSE3 system
    - 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

5.11 Safety Conformance

- Regulatory Notice:

This device is tested to meet all applicable

requirements in relevant. According to Regulation (EU) 2017/745 concerning medical devices.

- Conformity to Standards:
- IEC 60601-1:2005/A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014/A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010/A1:2013+A2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-37:2007/A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance o f ultrasonic medical diagnostic and monitoring equipment
- IEC 61157:2007/A1:2013 Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 62304:2006/A1:2015 Medical device software - Software life-cycle processes
- IEC 62366-1:2015/A1:2020 Medical devices - Application of usability engineering to medical devices
- WEEE according to 2012/19/EU
- RoHS according to 2011/65/EU

6. Measurement and Analysis

6.1 Measurement in different modes

6.1.1 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
  -Trace&H
  -Single line method
  -Dual line method
  -Triple line method
  -Single ellipse method
  -Single ellipse and single line method
- Angle
  -PolyLine
  -TwoLine
- Stenosis
  -Diameter method
  -Square meter method
- A and B ratio
  -Diameter ratio
  -Square meter ratio

6.1.2 Generic Measurement in M mode

- Depth
- Distance
- Time
- Slope(Velocity)

- Heart rate
- Stenosis
- A and B ratio
  -Diameter ratio
  -Time ratio
  -Speed ratioGeneric

6.1.3 Measurement in PW mode

- Velocity (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)
- Mean Vel(Max Mode)
  Mean Vel(Mean Mode)
- 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
- 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)

6.2 Advanced Measurement

6.2.1 VAim Follicle（2D） measurement (optional)

- An automatic tool for follicle calculation, one touch to get the follicle status, dedicated for women's reproductive health.
- Choose left or right follicle
- Automatically identity all the follicles with different colors and calculate follicle volume and diameter

6.2.2 2D/3D Auto Follicle(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

6.2.3 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

6.2.4 Auto NT measurement (optional)

- Automatically detect Nuchal Translucency in interest box
- Automatically report thickness result of NT

6.2.5 Auto IT measurement (optional)

- Support Auto IT(Intracranial translucency) measurement
- Draw the ROI and the system analyses and displays the result

6.2.6 VAim OB measurement (optional)

• VAim OB is an automatic 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 measurement results will be add into the worksheet and report automatically

6.2.7 VAim Pelvic (optional)

• Support automatic acquisition of pelvic measurement function
• Support automatic acquisition of pelvic levator ani hiatus space measurement and pelvic measurement display
• Available in Pelvic application

6.2.8 VAim Hip measurement (optional)

• VAim Hip is an automatic solution in the assessment of DDH(Developmental Dysplasia of Hip) with one simple touch.
• Based on 'Ped HIP' application

6.2.9 Auto IMT measurement (optional)

• Automatically detect intima media thickness in interest box
• Automatically report the result of IMT
• Available in linear probe

6.2.10 Live IMT measurement (optional)

• Real-time automatically display IMT items with the different ROI positions
• The IMT items include: max, min, average, SD, points (how many points are used for the result), size of ROI .
• Available in Carotid application

6.2.11 Auto Flow Volume (optional)

- The flow velocity is multiplied by the cross-sectional area of the vessel
- Mean blood flow velocity
- Vessel diameter

7. Advanced features

7.1 Obstetric applications

7.1.1 3D Smart Face (optional)

- An intelligent tool for fetal face optimization. This tool detects the fluid/tissue interface and smartly removes noise in front of the baby inside the ROI, to obtain an optimal baby face
- Only works on 3D Render
- Can not use this feature together with MagicCut

7.2 General application

7.2.1 Elastic imaging (optional)

- Shows the spatial distribution of tissue elasticity properties in a region of interest to estimate the strain before and after tissue distortion caused by external force
- The strain estimation is scaled by color to have smooth distribution display
- Have quality index to indicate if there is proper external force
- Precision: 0,1,2,3,4
- Resolution: 0,1,2,3,4
- Sensitivity: 0-10
- Transparency: ≥ 13steps
- Smooth: ≥ 7steps
- Persistence: ≥ 7steps
- Map: EI0
- Display format：Single, Dual，Quad

7.2.2 VAid Thyroid (optional)

- VAid Thyroid is a tool for Thyroid lesion detection in real-time or on stored images (static & cine)
- For static image: Depicts boundaries of the Breast lesions and displays the size
- For cine(real time scan or stored cine):The number and position of the Thyroid lesion can be indicated in real time.

7.2.3 VAid Breast (optional)

- VAid Breast is an automatic tool for breast lesion detection in real-time or on stored images (static & cine)
- For static image: Depicts boundaries of the Breast lesions and displays the size
- For cine(real time scan or stored cine):The number and position of the Breast lesion can be indicated in real time

7.3 Cardiovascular applications

7.3.1 PWV (optional)

- A real-time, multi-point, RF tracking at single imaging site of the carotid artery intima media complex with high precision and generates arterial distension/tracking waveform
- Calculates PWV to assess the arterial stiffness and risk stratification of rteriosclerosis

7.3.2 Auto EF (optional)

- Auto EF is a tool for calculating the ejection farction.
- Tracing the endocardium in apical four-chamber view and apical two-chamber view.
- The volume is calculated using Simpson's Method
- The biplane ejection fraction can be calculated

7.3.3 Stress Echo (optional)

- Stress echo is a non-invasive, dynamic evaluation of myocardial structure and its function under an external stress(exercise or pharmocology)
- 12 Ready to use templates(max 8 stages * 6 views) Editable
- User definable template
- Re-arrange & Select default template
- 10 View names available
- 14 Stage names are available (can add user defined stage name)
- One Touch Shuffle (Stage / View)
- Touch & Compare any view of stage
- Systole only review

7.3.4 Strain Imaging(optional)

- The movement of myocardial spots (i.e., spots formed by the interaction of the ultrasound beam with myocardial fibers) on a 2D ultrasound image rapidly measures the strain and strain rate equivalencies to assess myocardial function
- Auto-ROI
- Adjust Segment-wise(Longitudinal strain)
- Adjust Segment-wise and Rotate whole ROI
- ECG to select heart cycle
- View based Bulls Eye view
- Result type (Peak Strain or Peak Time)Parameter type (L Strain C Strain)