

# **SPECIFICATIONS**

for

# **Diagnostic Ultrasound System**

# **ARIETTA 750SE**



## **Scanning Method**

- Electronic Convex
- Electronic Linear
- Electronic Phased Array Sector
- Electronic Radial

### **Operating Modes**

- B-mode
- · BiPlane-mode
- M-mode
- D: Spectral Doppler mode (PW, CW, HPRF-PW)
- Dual Gate Doppler mode
- Color Flow mode
- Power Doppler mode (Directional Power Doppler)
- eFLOW mode (Directional eFLOW)

## Image Display Modes \*1

- B: gray-scale imaging
- Dual B
- Quad B
- M
- B and M
- D
- B and D
- B(Color Flow)
- B(Power Doppler)
- B(eFLOW)
- Dual B(Color Flow)
- Quad B(Color Flow)
- Dual B(Power Doppler)
- Quad B(Power Doppler)
- Dual B(eFLOW)
- Quad B(eFLOW)
- M(Color Flow)
- M(Power Doppler)
- M(eFLOW)
- B(Color Flow) and M (Color Flow)
- B(Power Doppler) and M(Power Doppler)
- B(eFLOW) and M (eFLOW)
- · B(Color Flow) and D
- B(Color Flow) and Dual
- B(Power Doppler) and D
- B(Power Doppler) and Dual
- B(eFLOW) and D
- B(eFLOW) and Dual
- B(Color Flow) and D simultaneous real-time display (Triplex mode)
- B(Power Doppler) and D simultaneous real-time display (Triplex mode)

- B(eFLOW) and D simultaneous real-time display (Triplex mode)
- B and B(Color Flow) simultaneous real-time display (Dual Flow)
- B and B(Power Doppler) simultaneous real-time display (Dual CF)
- B and B(eFLOW) simultaneous real-time display (Dual
- Dynamic Slow-motion Display (Real-time image/Slowmotion image, side by side display)
- Real-time Biplane (Display real time image in 2 crosssections in biplane probe.)
- Panoramic View
- TDI (Tissue Doppler Imaging)
- Intermittent trigger mode \*2
- Monitor mode \*2(Monitor image/CHI mode image, side by side)
- RT-3D (4D) mode \*3
- DFI\*4 (Detective Flow Imaging)
- Request function: In multi-mode display, it is possible to select one mode for full screen display.
- Real-time Tissue Elastography \*5
- \*1 Probe dependent.
- \*2 Option: SOP-ARIETTA750-44 is required.
- \*3 Option: EU-9184 and SOP-ARIETTA750-4 are required.
- \*4 Option: SOP-ARIETTA750-105 is required.
- \*5 Option: SOP-ARIETTA750-43 is required.

### **Beam former**

Transmission

CPWG (Compound Pulse Wave Generator)

Programmable waveform transmission

Reception

Multi processing high-speed digital beam former 12-bit A/D converter (4096 gray levels)

A/D Sampling Frequency: 40[MHz]

Parallel processing:

Up to 20 directions Transmission/Reception method of Harmonics

THI mode image without reducing the frame rate.

· FmT: Filter-method Tissue Harmonic Imaging

· WbT: Wide-band Tissue Harmonic Imaging

THI mode image with higher resolution than FmT.

· HdTHI: High Definition Tissue Harmonic Imaging

THI mode image with higher resolution than WbT.

Reception frequency: 3.2-18.0 MHz

Maximum reception frequency(18MHz) can be achieved under below conditions.

· Probe: L64

- · Frequency: High
- · Frequency Information: Receive
- Tissue Adaptive Technology

Sound speed adjustment: 26 steps Automated sound speed adjustment

- Focusing
  - Transmission:

Multi-stage transmission focus of up to 4 stages out of 16 stages (probe dependent)

· Reception:

**PixelFocus** 

eFocusing

### **System Dynamic Range**

314 dB

## **System Processing Channels**

4,608,000 Channels

#### Frame rate

Max. More than 882 frames/s \*

\* Depends on probes and various settings

#### **B-mode**

- Display Gray Scale: 256 levels
- Scanning area:

Continuously variable

- · Line Density: 8 steps
- HI Frame Rate (Multi Parallel Processing)
- Zoom: 2kinds
  - · HI zoom (real-time image):

Max. Up to 0.5 cm display image (probedependent)

PAN zoom (real-time and frozen image):

Max. Up to 0.5 cm display image (probe

- dependent)
- Frequency selection:
  - · Fundamental:

Max. 5 frequencies (probe dependent)

· Tissue harmonic:

Max. 5 frequencies (probe dependent)

Depth range selections:

0.75/1.0/1.5/2.0/2.5/3.0/3.5/4.0/4.5/5.0, 1 cm intervals from 5.0 to 24 cm, and 2cm intervals from 24cm to 40cm (probe dependent)

- Longitudinal and lateral inversion
- Rotation by 90 degrees (probe dependent)
- Gain: 80 dB range, adjustable in real-time and frozen.
- Echo enhancement: 8 steps

- Texture: 2 steps (Smooth / Sharp), not available in Mmode
- Enhance / Smoothing: 8 steps for each other
- Persistence: 8 steps, including Off (Available to change type for adaptive frame rate)
- TGC (time gain control):
  - · Gain versus depth curve control: 8 slide controls
  - · TGC curve memory function
- LGC (lateral gain control):
  - Gain versus angle curve control: 8 sectors (Sector probes only)
- Dynamic range: 40-90 dB, adjustable in real-time and frozen.
- Gray map: 10 types, adjustable in real-time and frozen.
- AGC: 8 steps
- Gamma curve: 4 types (Linear, Window, Parabolic, Scurve), control points (Rejection, Center, Saturation), adjustable in real-time and frozen.
- Spatial Compound Imaging (possible by selected linear and convex sector probes)
- Trapezoidal scan (possible by selected linear probes)
- B steer function: The oblique function can be used in B mode in addition to Color Flow / Power Doppler mode.
- Adaptive Imaging: HI REZ function 8 steps /HI REZ Plus Adaptive imaging is the technique to generate optimum image by changing filter characteristic depending on input signal.

This technique installed on this ultrasound diagnostic scanner reduces speckle noise in B-mode images and provides uniformly and high contrast images.

• Border Clear Filter

This technique extends grayscale, reduces noise and enhances borders.

· Acoustic Noise Reduction: 4 steps.

This technique reduces acoustic noise (Based on signal level)

 Near-field Noise Reduction: 4 steps, 4 types.
 This technique reduces artifacts and noises in the heart chamber or blood vessel.

Low Echo Reduction

This technique suppresses the hypoechoic area.

Grayscale Enhance

This technique enhances image which is displayed as grayscale.

- · Auto-optimizer: Gain, TGC, LGC, and sound velocity
- Needle Emphasis
- · Wide Scanning
- Panoramic View

It is possible to display an image of an extensive

range of the body by moving the probe. An area wider than the scanning width of the probe can be displayed.

#### M-mode

· Sweep method: Moving bar

• Sweep speed: 300.0, 200.0, 133.3, 100.0, 66.7, 50, 40.0 mm/s

• Gain: B-gain ±30 dB

• Dynamic Range: 40 dB-90 dB

AGC: 8 steps

Acoustic Noise Reduction

Low Echo Reduction

Grayscale Enhancement

FAM (Free Angular M-mode)

## **Spectral Doppler**

Display: Power spectrum

Real-time Doppler Auto Trace

Doppler methods:

· PW (Pulsed Wave) Doppler

· HPRF (High Pulse Repetition Frequency) PW Doppler

Dual Gate Doppler

· CW (Continuous Wave) Doppler \*

• Reference frequencies (probe dependent):

Maximum 3 frequencies

· PW: 1.5, 1.9, 2.1, 2.5, 3.2, 3.5, 3.8, 4.0, 4.4, 5.2, 6.0, 6.3, 7.5, 10.0 MHz

· CW: 1.8, 2.0, 2.1, 3.0, 3.3, 3.8, 5.0 MHz

• Pulse repetition frequency:

· PW: 0.05 to 40 kHz

Analysis rate:

· CW: 1.1 to 40 kHz

Max. velocity range:

 $\cdot$  PW/HPRF:  $\pm 1.26$  cm/s to  $\pm 802.08$  cm/s

 $\cdot$  CW: ±25.07 cm/s to ±1600 cm/s

Base line shift: Adjustable in real-time and frozen

• Steerable CW Doppler: probe dependent

 Steered linear scanning: Max. ±30 degrees changeable at 5 degrees interval (probe dependent)

Auto angle Correction

Spectrum inversion

Angle correction: Available up to 80 degrees

Pre-settable, adjustable in real-time and frozen, auto angle correction and warning function available.

Sample volume size for PW Doppler:

0.5 – 20 mm, changeable in 0.5mm, 1.0 mm step

• Wall filter: 12steps, 1/16 of PRF is Max.

Doppler gain: 60dB variable, adjustable in real-time and

frozen.

• Echo Enhancement (CW): 3 steps

Low Echo Reduction (PW)

Grayscale Enhancement

• Doppler Gamma:

8 steps, adjustable in real-time and frozen

Auto-Optimizer:

Optimization of Doppler gain, PRF, baseline, angle correction, and PW sample gate position

Audio output: 2 channels

\* Option: EU-9184 is required.

## **Color Doppler Mode**

· Color area size: Continuously variable

Steered linear scanning:

Max.  $\pm 30$  degrees (probe dependent), changeable at 5 degrees interval

• Line density:

Up to 8 steps, changeable setting independently with B mode

• Gain: 128 range, adjustable in real-time and frozen

Texture: 2 steps (Smooth/Sharp)

Glossy Level: Off + 4 steps

• HI Frame Rate (Color): Multi Parallel Processing

Auto-Optimizer: Optimization of gain and ROI position

## Color Flow Mode

Display patterns:

Velocity (derived from mean Doppler frequency shift), Velocity + variance, Variance, Velocity + intensity, Velocity + variance + intensity)

Max. velocity range: ±0.63cm/s to ±458.33cm/s

Reference frequency: (Probe dependent)
1.9, 2.1, 2.5, 3.2, 3.3, 3.5, 4.0, 4.4, 5.2, 6.0, 6.3,
7.5, 10.0 MHz

• Pulse repetition frequency:

0.03 to 19.8 kHz

Gradation:

±127 levels for velocity (red and blue) 64 levels for variance (green)

· Color Inversion: Normal, Invert

Smoothing: 5 steps, adjustable in real-time and frozen

Wall filter: 6 steps

• Persistence (Color): 8 steps

Wall Motion Reduction: Off + 3 steps

• Packet Size: 3 levels

• Base line shift (Color):

Up to double velocity (±127 steps)

· Color coding: 15 kinds

- TGC Enhancement: 2 kinds
- Superimposed color image: possible in real-time and frozen.

## Power Doppler Mode

Display patterns:

Power Doppler, Directional Power Doppler

Gradation: 256 levels Color coding: 15 kinds

Non-display of B/W image: Possible in ROI

Smoothing: 5 steps

## High Resolution Power Doppler(eFLOW) Mode

Display patterns:

eFLOW, Directional eFLOW

• Pulse repetition frequency:

0.03 to 19.8 kHz

Gradation: 256 levels (±127 levels for directional)

· Color coding: 15 kinds

Non-display of B/W image: Possible in ROI

· Advanced wall motion reduction

· Smoothing: 5 steps

## **TDI (Tissue Doppler Imaging)**

 Switching Color Doppler and Tissue Doppler during exam: Possible

## **DFI (Detective Flow Imaging)** \*

DFI is a function to detect bloodstream information at high sensitivity and high frame rate with eigen space method.

\* Option: SOP-ARIETTA750-105 is required.

### **Protocol Assistant**

This function provides the capability to guide study by displaying protocol list (view name, mode, measure). It is useful to improve everyday study.

- Available to registered protocol: 128 kinds
- Suspend protocol function
- Available to create and edit protocol on the system
- Available to register and edit reference image
- Available to import or export like preset

## **Manual**

It is applicable to browse instruction manual on this system.

· On-board operation manual

## **Cine Memory**

- Cine search and loop display (in B mode):
   ECG time phase display is possible
- Capacity
  - · B mode: Max. 63,500 frames.
  - · M and D modes: Max. Approx. 900 seconds.

## **Data Management**

#### Image data

- Format
  - · Multiple-frame (moving) image
    - · DICOM (Raw, MJPEG)
    - · PC Format (WMV, AVI, MP4)
    - · Single-frame (still) image
    - DICOM (Non-compressed, RLE, RGB (Plane/Pixel), JPEG)
    - · PC Format (Tiff, Bmp, JPEG)
- Image acquisition mode
  - Real-time multi-frame image acquisition
     Raw, Image, Aquiring both RAW and Image at the same time

Post ECG: Max. 10 cardiac cycles (R-R)
Pre ECG: Max. 10 cardiac cycles (R-R)

Post Time: Max. 90 secondsPre Time: Max. 16 seconds

· Manual:

· Raw data: Max. 150 seconds

· Image data: Max. 180 seconds

- Cine loop high-speed data transfer (Raw, Image)
   It is possible to selectively store data of arbitrary
   section in the Cine Memory.
- Simultaneous output to multiple media
   It is possible to output still image data to multiple of storage media include network and printers at the touch of a button.
- Image data management tool
  - · Image viewer
    - · Compatible with DICOM and PC-format images
    - Simultaneous display of stored and real-time images is possible (Compare mode)
    - Thumbnail display of stored images (1-36 images)
    - · Check mark is put on a transferred image
    - · Image zoom, rotation, inversion
    - Protect stored images
    - · 1:1 replay (main unit HDD or DICOM storage data)
    - · DVD-RAM
    - · CD-R

- · USB memory
- · USB HDD
- · Re-storing to media, transfer
- Adjustment is possible on the reconstructed Rawdata image (gain, dynamic range, gamma curve type, and color coding in Color flow mapping mode)

#### Measurement data

It is possible to store measurement data in the main unit hard disk

## Patient data

- Displayed information \*
  - · Patient information

ID (up to 64 characters), Name (up to 64 characters, including middle name), Birth date, Sex, Age, Height, Weight, Occupation

Study information
 Procedure ID, Accession, Study ID, Study
 Description, Referring Physician, Reporting Phys,
 Sonographer

\*: Conforms to DICOM 3.0 standard

### Data storage

- Main unit hard disk
  - · Capacity: Approx. 1TB
- USB memory
- USB HDD
- · CD-R
- DVD-RAM
- Network interface (DICOM format):
   10 BASE/T or 100 BASE/TX (automatically switched)

## **DICOM network communication**

Conformity to DICOM service class:

#### Ultrasound image storage SCU

Ultrasound multi-image storage SCU

Storage media FSC/FSR

## Print management SCU

Modality worklist management SCU

Modality performed procedure step (MPPS) SCU

(For details, please refer to the DICOM Conformance

Statement issued by Hitachi, Ltd.)

Storage:

Possible to store patient information directly to DICOM file server

• Print:

Possible to printout images with DICOM compatible

#### printer directly

Work list management:

Retrieval of patient and reservation information from hospital information system (HIS)

NOTE: The HIS needs to be compatible with DICOM standard supplement 10. The HIS network and the DICOM network need to be linked.

- Router setting: possible
- Compatible with SR (Structured Report) for OB, cardiology, vascular and abdominal measurements\*1
- Query/Retrieve\*2
- Compatible with ED (Evidence Documents)
- Profile
- IHE (Integrated Healthcare Enterprise)

SWF (Scheduled Workflow)

PDI (Portable Data for Imaging)

ED (Evidence Documents in Radiology/Cardiology domain)

Echocardiography Workflow

CT (Consistent Time)

- \*1 Option: SOP-ARIETTA750-21 is required.
- \*2 Option: SOP-ARIETTA750-59 is required.

## Security measures

- User authentication function is available.
  - · 3 Types of user authority can be set.
  - It is possible to set whether password is required or not at the start of operation.
- Audit logs

Accesses related to user management and patient data are recorded as audit log data.

Handling of these logs is limited to users with Level 1 access.

## Teaching file

Can be created.

## **Measurements and Analysis:**

#### **Basic measurements**

#### B mode

- Distance measurement: Distance, Dist-trace
- Area and Circumference measurement: Area/Circum
- Volume measurement: Volume1, Volume2
- Angle measurement: Angle
- · Histogram measurement: Histogram
- Measurement of Congenital Dislocation of the Hip Joint:
   Hip J Angle
- · General purpose index measurement: B.Index

#### M mode

- · Distance measurement: M.Length
- Time measurement: Time
- · Heart rate measurement: Heart Rate
- · Velocity measurement: M.VEL.
- General purpose index measurement: M.Index

#### D mode

- Blood flow velocity measurement: D.VEL1, D.VEL2
- Time measurement: Time
- Heart rate measurement: Heart Rate
- · Acceleration (deceleration) measurement: ACCEL
- Resistance index measurement: RI
- Pressure half-time measurement: P1/2T
- Dop.Caliper measurement: D.Caliper1, D.Caliper2
- Measurement of mean velocity and mean pressure gradient \*1:

Mean VEL.

- Pulsatility index measurement \*1: PI
- Stenosis flow measurement \*1: Steno Flow
- Regurgitant flow measurement \*1: Regurg Flow
- Dop.Trace measurement \*1: D.Trace1, D.Trace2
- General purpose index measurement \*1: D.Index

#### B/D mode

Blood flow velocity measurement: F.Volume, SV/CO

## CF mode

- Blood flow volume measurement: Flow Profile \*2
- \*1: Auto trace is possible.
- \*2 Option: SOP-ARIETTA750-7 is required.

## Application measurements

#### **Abdominal measurements**

#### B mode

- · Gallbladder measurement: Gallbladder
- · Gallbladder wall thickness measurement: GB Wall-T
- · Common bile duct measurement: CBD
- · Liver measurement: Liver
- Pancreas measurement: Pancreas
- Pancreatic duct measurement: P-Duct
- Renal measurement: Renal Volume
- Spleen measurement: Spleen
- Space-occupying lesion measurement: SOL
- Blood vessel diameter measurement:

Aorta Diam, PV Diam

• Stenosis percentage measurement:

%STENO-Diam, %STENO-Area

#### D mode

- Artery measurement:
  - A-Ao, CA, CHA, SA, SMA, IMA, CIA, HA, Prandial SMA
- Renal artery measurement \*:
  - Renal-A, RA hilum, Seg.A Upp, Seg.A Mid, Seg.A Low
- Portal vein measurement: Main PV, Rt.PV, Lt.PV
- Shunt blood vessel measurement:
  - Pre Shunt PV, Prox Shunt, Mid Shunt, Distal Shunt

## B/D mode

- Blood flow volume measurement:
  - FV(Artery) Abdom, FV(Vein) Abdom
- \*: Auto trace is possible.

## **Cardiology measurements**

## B mode

- Left ventricular function measurement:
  - M.Simpson \*1, Area-Length \*1, Pombo \*2,

Teichholz \*2, Gibson \*2, Bullet, Simpson, BP-Ellipse,

- EyeballEF \*3
- Valve area measurement: AVA, MVA
- Right ventricular diameter measurement:
   RV Dimension
- Left atrial diameter/aortic diameter measurement : LA/AO
- Myocardial wall thickness ratio measurement: Ratio
- Left ventricular myocardial mass measurement:
   LV Mass
- Inferior vena cava diameter measurement: IVC
- Left atrial/right ventricle volume measurement \*4: LA Vol., RA Vol.
- Right ventricular function measurement \*2: FAC

#### M mode

- Left ventricular function measurement \*5:
   Pombo, Teichholz, Gibson
- Mitral valve measurement: Mitral Valve
- Tricuspid valve measurement: Tricuspid Valve
- Pulmonary valve measurement: Pulmonary Valve
- Left atrial diameter/aortic diameter measurement \*6:
   LA/AO
- Inferior vena cava diameter measurement: IVC
- Asynchrony measurement: IntralV.Async.
- Measurement of tricuspid annular plane systolic excursion(TAPSE):

**TAPSE** 

#### D mode

- Left ventricular ejection flow measurement \*7:
   LVOT Flow
- Aortic stenosis flow measurement \*7: AS Flow
- Aortic valve regurgitation flow measurement \*7:
   AR Flow
- Right ventricular ejection flow measurement \*7:
   RVOT Flow
- Pulmonary stenosis flow measurement \*7: PS Flow
- Pulmonary valve regurgitant flow measurement \*7:
   PR Flow
- Left ventricular inflow measurement \*8: Trans M Flow
- Mitral stenosis flow measurement \*7: MS Flow
- Mitral regurgitant flow measurement \*7: MR Flow
- Tricuspid stenosis flow measurement \*7: TS Flow
- Tricuspid valve regurgitant flow measurement \*7:
   TR Flow
- Pulmonary vein flow measurement: PV Flow
- PISA measurement:
   MR Vol. PISA, AR Vol. PISA, TR Vol. PISA, PR Vol.
   PISA
- TDI PW measurement \*8: TDI PW MW, TDI PW1, TDI PW2
- Coronary measurement \*<sup>7</sup>: prox LAD, distal LAD, RCA, LCX, Graft, Coronary1, Coronary2, Coronary3, Coronary Stenosis
- Asynchrony measurement:
   AV Async., InterV.Async., Time to Onset, Time to Peak

#### CF mode

- M TDI measurement:
   M TDI mFS, M TDI WT(LVPW), M TDI WT(IVS)
- \*1: Auto or Full Auto measurement is possible. (Option: SOP-ARIETTA750-74 is required when Full Auto measurement.)
- \*2: Auto measurement is possible.(Option: SOP-ARIETTA750-74

- is required when Auto measurement.)
- \*3 Option: SOP-ARIETTA750-58 and PEU-LISENDO880 is required.
- \*4: Auto or Full Auto measurement is possible. (Option: SOP-ARIETTA750-74 is required when Auto or Full Auto measurement.)
- \*5: Caliper Mark Auto Shift is possible.
- \*6: Auto measurement is possible. (Option: SOP-ARIETTA750-74 and PEU-LISENDO880 is required when Auto measurement.)
- \*7: Auto trace is possible.
- \*8: Auto trace is possible. (Option: PEU-LISENDO880 is required when Doppler Trace method.)

## **Vascular measurements**

#### B mode

- Carotid Artery:
  - Stenosis measurement:
     Carotid %STENO-D, Carotid %STENO-A
  - Mean-IMT measurement: mean-IMT, CmeanIMT(Auto)
  - · Max-IMT measurement: max-IMT
  - · IMT Automatic measurement: CCA\_IMT, ICA\_IMT, ECA\_IMT, BIF\_IMT
- Upper Ext Artery:
  - Stenosis measurement:
     Upper %STENO-D, Upper %STENO-A
- Lower Ext Artery:
  - Stenosis measurement:
     Lower %STENO-D, Lower %STENO-A

#### D mode

- Carotid artery blood flow measurement:
   CCA proximal, CCA mid, CCA distal, ICA, ECA, BIFUR,
   VERT
- Upper extremity artery blood flow measurement:
   ScA, AA, BA, DBA, BasA, RA, UA, SPA
- Lower extremity artery blood flow measurement:
   CIA, EIA, IIA, CFA, DFA, SFA, PopA, PerA, ATA, PTA,
   DPA
- Transit time of vessel flow(TVF) measurement \*: TVF
- Upper extremity venous blood flow measurement:
   IJV, ScV, CV, AV, BV, DBV, BasV, RV, UV
- Lower extremity venous blood flow measurement:
   CIV, EIV, IIV, CFV, DFV, SFV, GSV, PopV, PerV, LSV, ATV,
   PTV
- Transcranial artery blood flow measurement:
   ACA, MCA, PCA, BA, VA, TICA, ACOA, PCOA
- \* Option: SOP-ARIETTA750-47 and PEU-LISENDO880 is

required.

## **Small parts measurements**

#### B mode

Lesion measurement(for breast use): Lesion(Breast)

· Aspect ratio measurement: D/W ratio

· Papilla-tumor distance measurement: NT dist

• Thyroid gland volume measurement: Thyroid Volume

Thyroid isthmus thickness measurement:
 Isthmus Thickness

### D mode

Artery measurement(for mammary blood flow)

Artery measurement(for thyroid blood flow)

#### **Obstetric measurements**

#### B mode

Gestational age measurement \*1: GA

• Fetal wight measurement: FW

· Ratio measurement: Fetus Ratio

• Amniotic fluid index measurement  $\ast^2$ :

AFI, AF Pocket, AFV, MVP

· Cardiothoracic ratio measurement: CTAR, CTR

• Cervical length measurement: Cervix

Nuchal translucency measurement: NT, Auto NT\*1 \*3

Automatic measurement of fetal heart rate \*1 \*4:
 Auto FHR, Auto FHR+ \*5

 Automatic measurement of fetal fractional shortening \*1 \*6:

Auto FS

#### M mode

· Left ventricular function measurement: LF Function

• Fetal heart rate measurement: FHR, PreHR, PstHR

## D mode

• Blood flow measurement:

Umbilical Artery, MCA, Uterine Artery, Descending Aorta, Renal Artery

Left(right) ventricular ejection flow measurement:
 LVOT Flow, RVOT Flow

• Preload index measurement: PLI

• Ductus venosus measurement: Ductus Venosus

• Fetal heart rate measurement: FHR, PreHR, PstHR

### Other

Supports multiple pregnancy examination

\*1 Auto measurement is possible.

\*2 Caliper Mark Auto Shift is possible.

\*3 Option: SOP-ARIETTA750-42 is required.

\*4 Option: SOP-ARIETTA750-72 is required.

\*5: in real time

\*6 Option: SOP-ARIETTA750-71 is required.

## **Gynecology measurements**

#### B mode

· Uterus measurement: Uterus

• Endometrial thickness measurement: Endom-T

Cervix measurement: CervixOvarian measurement: Ovary

• Follicular measurement: Follicles

• Follicle volume measurement: Follicles Volume

• Bladder measurement: Bladder Volume

#### D mode

Uterine artery measurement: Uterine ArteryOvarian artery measurement: Ovarian Artery

## **Urological measurements**

#### B mode

• Prostate measurement: PSA Volume, PRS Slice Vol.

• Seminal vesicle measurement: Seminal Vesicles

• Bladder measurement: Bladder Volume

Testicular measurement: Testis Volume

• Renal measurement: Renal Volume

Cortical measurement: Cortex Thickness

· Adrenal measurement: Adrenal

#### D mode

Arterial blood flow measurement: Renal Artery

## **Report functions**

Measurement report

· Abdominal measurement report

· Cardiac function measurement report

· Vascular measurement report

· Small parts measurement report

Obstetric measurement report

· Gynecology measurement report

· Urological measurement report

• It is possible to recall past measurement reports.

• Examination data history can be plotted on the report.

 Direct printout of each report is possible with an optional PC printer.

• Batch printing is possible with a digital B/W printer.

• Output of measurement values in CSV file is possible.

• Hot Key function:

It is possible to assign measuring functions to the

alphabet keys on the keyboard

- Measurements on VCR playback image:
   Possible (manual calibration)
- User's calculation:

30 equations can be set for each application

- User-assignable terms: 60 words possible
- Font size of measurement result: Possible to change in 3 kinds

## **Physiological Signal Display**

- Displayed information:
   ECG, PCG \*1, Pulse \*2, Breathing waveform
- ECG synchronized display: Available for one phase
- Detect regular pulse from arrhythmia(RRp/RRpp)
- Automated jumping to most optimized R-R Phase
- Reducing Filter for Tachy or Bradycardia
- Display value for each R-R interval time
- Display position:
   Continuously variable (both in B and M modes)
- · Bar graph display for breathing waveform
- 3 type electrocardiogram (I, II, III)
- Automated detection end diastole and end systole phase.
- Automated split as end diastole(left) and end systole(right)
- \*1 Option: MA-300 (Not available in EU) is required.
- \*2 Option: TY-307A (Not available in EU) is required.

## **Dual Gate Doppler**

This is a function which displays Doppler Spectrums of two different sample points simultaneously. Supported combinations are PW/PW, TDI/TDI, and PW/TDI \*. Automated sample gate setting for each gate.

\*: It is possible to measure E/e' immediately(approx. 5 seconds) by recognition of imaging view and placement of sample volumes automatically in addition to detect stable heart beats with R-R Navigation.

## **Automated IMT Measurement**

It is possible to automatically extract max IMT, min IMT and mean IMT by simply setting ROI (region of interest) on a long-axis view of the vessel. In addition, the thicknesses at 3 points, i.e., the point at max IMT, and the points at 1cm on the right and left of the max IMT, can be automatically detected and averaged.

## **Optional Functions**

## **PC** printer

It is possible to printout Abdomen, cardiology, vascular, small parts, OB/GYN, and urology report screens including ultrasound images directly with an external PC printer.

## RT-3D(4D) \*1

- It is possible to display 3 arbitrary sections simultaneously
- MPR(Multi-planar Reconstruction)
- 360 degrees omni-directional rotation
- 4 kinds of rendering selectable
- Combination of 2 kinds of rendering type(Rendering Mode Mix)
- Detail scan of the ROI (Region of interest) is possible
- Inversion Mode (black-and-white)
- B-mode measurements on an arbitrary plane possible
- Auto Clipper: Automated placenta rejection function
- Spatio-temporal Image Correlation (STIC)\*2
- Flow 3D
- Multi Slice Imaging (MSI)
- HI REZ
- Lower Threshold
- Free Axis of MPR(FMPR)
- 4Dshading:

Realistic 3D imaging like endoscopic picture is possible.

Curved MPR:

Displays cross sections on an arbitrary curve or straight line from the volume data. It is possible to display up to 3 cross sections.

- \*1 Option: EU-9184 and SOP-ARIETTA750-4 are required.
- \*2 Option: SOP-ARIETTA750-41 is required.

## Real-time Tissue Elastography \*1

This function is used to visualize the stiffness of a tissue in real time. The strain generated in a tissue on applying pressure is represented by colors.

(it is available to change Elastography Color Map)

· Elasto mode:

Overlapping display of Elastography on B-mode image.

Dual Elasto mode:

Dual image display of Elasto mode, possible to select different color map on each side.

Real-time biplane:

Elasto mode overlapping display of Elastography on B-mode image of either cross-section, in the function to

display B-mode image with the one of different crosssection simultaneously.

Strain Ratio measurement:

Calculation of ratio of strain between arbitrary 2 regions

Assist Strain Ratio:

Clicking center of the tumor automatically sets the measurement ROI to the tumor and the fatty layer (the mammary gland region and lesion are targeted).

Strain Graph:

The time variation of distorted average value is displayed on a graph in real time.

· Auto Select Frame:

The frame under stable pressure is chosen automatically.

- Strain Histogram \*2
- Compatible to RAW data
- Guide of displacement direction:
   Display the direction of displacement of the liver caused by the heart beat in real time.
- \*1 Option: SOP-ARIETTA750-43 is required.
- \*2 Option: SOP-ARIETTA750-60 is required.

## Shear Wave Measurement \*1

It is a function for measuring the propagation velocity of shear waves and elasticity. The propagation velocity of shear waves varies with tissue hardness.

Shear Wave Measurement mode:
 Measures the propagation velocity of shear waves in
 the target region.

ROI setting function:

A trackball can be used to change the position of the ROI you select to measure.

Automatic recording of still images:

The instrument can be set up to automatically send results after measurements.

- Integration with measurement functions:
   Measurement data is saved for each selected
   measurement. You can modify a measurement during
   an examination.
- Data saved to CSV files:
   Measurement data is saved in a CSV file.
- Attenuation measurement \*2:

Simultaneously with the measurement of Vs, the ultrasound attenuation (ATT) is measured near the center of the ROI. It is also possible with Combi-Elasto.

- \*1 Option: SOP-ARIETTA750-73 is required.
- \*2: It is only available with C252 and C253 probe.

#### Combi-Elasto \*

The Shear Wave Measurement screen and the Real-time Tissue Elastography screen are displayed at the same time in the dual-screen view. While viewing an elasticity image, you can perform shear wave measurement to measure the velocity of shear waves, elasticity, and ultrasound attenuation.

\* Option: SOP-ARIETTA750-43, SOP-ARIETTA750-60, and SOP-ARIETTA750-73 are required.

### **Automated NT Measurement \***

It is possible to automatically extract the nuchal translucency(NT) thickness by simply setting ROI(region of interest). In addition, thicknesses at max NT, Mean NT can be automatically calculated.

\* Option: SOP-ARIETTA750-42 is required.

#### **Automated FHR Measurement \***

Set measurement ROI on fetal heart plane in B mode image and measures heart rate automatically.

\* Option: SOP-ARIETTA750-72 is required.

#### **Automated FS Measurement \***

In B mode, specifies a measurement ROI on the tomographic image of the fetal heart and performs tracking processing to automatically calculate the fractional shortening(FS) of the left ventricular internal diameter.

\* Option: SOP-ARIETTA750-71 is required.

#### Real-time Virtual Sonography \*1

It allows volume data previously acquired by CT, MRI, PET or US to be synchronized with real time US images. The magnetic position sensor is installed on the probe to determine the position and angle of the probe.

As a result, the display of cross sections that match ultrasound images is enabled, allowing you to use the

ultrasound images is enabled, allowing you to use the cross sections as a reference for your ultrasound diagnosis.

The same section of ultrasound image and CT/MR/PET image or US volume data is displayed as real time by acquiring the position information on the probe from a magnetic sensor and reconstructing MPR (Multi Planer Reconstruction) image from CT/MR/PET image and US volume data.

In various diagnosis areas (liver, breast and prostate) examination is possible as it supports convex type, linear type, intracavital probe.

Moreover, it can use together with Real-time Tissue Elastography.

Monitor Display

· Dual: Virtual / US

· Quad : Virtual / US / Virtual / Virtual

· Overlay: Virtual + US

Magnetic field quality display: Possible

• 3D body mark display: ON/OFF

3D body mark size: 3 kinds

Marking function: Possible

Multi-volume function:

Max. 4 CT/MR/PET/US images for retrieving, saving and the display switching

• US-US RVS function:

US volume data generated beforehand can be displayed as Virtual image in the same to US real-time image section.

· Last registration:

It is possible to return just before the condition of registration.

Reset function:

It is possible to return initial condition of registration.

Needle Tracking \*2:

Tracks and displays the needle tip location in real time during RFA procedures.

Body Motion Tracking \*3:

The omniTRAX Active Patient Tracker (manufactured by CIVCO) provides automatic image registration of fused images using real time ultrasound with previously acquired CT; with the synchronized status adjusted when small patient movements occur.

\*1 Option: EU-9185B, EZU-RVF1B, PM-AR850-H004, and SOP-ARIETTA750-62 are required.

\*2 Option: SOP-ARIETTA750-84, and EU-9197 are required.

\*3 Option: SOP-ARIETTA750-85, and EU-9197 are required.

#### 2D Tissue Tracking(2DTT) \*1

2DTT enables the evaluations of regional wall motion abnormalities within your region of interest, such as the myocardium and valves automatically by speckle tracking method on a B-mode image. With only minimal angle dependency, analysis form various cross sections have become possible. Multiple analyses, including wall thickness, various strains and rotation angle can be performed.

- Analysis
  - · Free use:

Analyzes the changes in distance between any two points and angular variation from the initial time

phase.

· SAX:

Analyzes differences in thickness between various regions of the myocardium, as well as angular variation with the center of gravity point, based on left ventricular short axis images.

· Apex-S (Strain) \*2:

Calculates the Longitudinal Strain and Transverse Strain of each region of the left ventricle based on the apex image. The global strain of the endocardium trace is also calculated.

· Apex-V (Volume) \*2:

Calculates the volume, ejection fraction, center of gravity and velocity of volume change of the right and left ventricles and atrium based on the apex image.

- View
  - · SAX:

SAX, Basal SAX, Mid SAX, Apical SAX

· APEX-S, -V:

2ch, 3ch, 4ch (Inversion view included)

- Graph Type
  - · Line Graph
  - · Color Graph
  - · Line & Color Graph
  - · Bull's eye (with Overlay function)
- Measurements
  - · Point to Point
  - · Time to Peak
  - · 3 point: One-third point of diastole duration
  - Distance
- \*1 Option: SOP-ARIETTA750-49 is required.
- \*2: It is possible to perform fully automatic measurements using 2D tracking method such as Global Longitudinal Strain or SAX radial strain and ejection fraction measurements by a single click operation in combination with multiple settings.

## Stress Echo analysis \*

- Image display modes in which image acquisition is possible: B, Each Flow modes
- Image acquisition methods: ECG synchronized acquisition
- Compatible frame rate: Up to 75 Hz
- · Recalled screen

Playback speed: SelectableImage allocation: Possible

· Scoring: Possible

· Auto View Recognizing: On/Off

Protocol: Skip Stage/Skip View function is available.

- · Exercise stress protocols:
  - · Exercise Stress Echo
  - · Treadmill Exercise
  - · Bicycle Exercise
- · Pharmacological stress protocols:
  - · DSE
  - · High-Dose DSE
  - · Low-Dose DSE
  - · Arbutamine
  - · Dipyridamole
- · User's protocol:
  - The user can make a protocol within 8 views X
     12 stages in 1 exam.
  - Full disclosure: Max. 2,481 seconds(Depends on probes and various settings)

2,481 seconds can be achieved under below conditions.

· Probe: S121(Adult Heart)

· Protocol: Conti. only(1Stage/1View)

Frequency: 30HzScan Area: MinimumLine Density: Minimum

Automatic labeling: possible

Scoring screen

· Playback speed: Selectable

- Comparison between different stages in the same view is possible
- · Image playback mode is selectable
- · Bull's eye display (16 or 17 segmentation selectable)
- Report screen
  - Display format
     Chart/Schema (Shuffle View)/Schema (Shuffle Stage)
- \* Option: SOP-ARIETTA750-15 and PEU-LISENDO880 are required.

#### TDI analysis \*

Tissue Doppler Imaging (TDI) analysis is an echocardiographic technique employing the Doppler principle to measure the velocity of myocardial segments and other cardiac structures. Strain information analysis is also available.

## <u>B-mode</u>

Temporal Velocity Profile:
 Velocity, time, acceleration, ratio

• Regional Velocity Profile: Velocity, distance

• Strain rate: Time, strain rate

· Strain: Time, strain

Myocardial Thickness (Wall thickness):

Distance, time, velocity

CSV output of analyzed data is possible. CSV is a file format that can be converted into Excel file directly.

\* Option: SOP-ARIETTA750-13 is required.

## CHI (Contrast Harmonic Imaging) \*

Contrast agent generates abundant second harmonics when disrupted, which eases detection by Harmonic Echo. Setting for low-pressure type contrast agent is also incorporated.

- Wide-band Contrast Harmonic Imaging (WbC)
   The wideband pulse inversion method enables
   retrieval of echoes from the ultrasound contrast agent across a broad spectrum and display them in CHI mode at a high level of sensitivity.
- Tissue Reduction Contrast Harmonic Imaging (TrC)
   The Amplitude Modulation method makes it possible to reduce signals from tissue to get clearer CHI mode images.
- CHI-eFLOW

Signals from ultrasound contrast agent are imaged in Power Doppler of CHI mode.

By destroying the contrast agent with high acoustic pressure, the contrasted area can be displayed clearer with CHI-eFLOW.

- Monitor mode
  - In the Monitor mode, images are available with a low sound pressure during the intermission of high sound pressure transmission.
- Motion-compensated Accumulation Imaging
   It is possible to display running of fine blood vessels
   by accumulating contrast echo information.
- Flash

This mode sends high acoustic pressure transmissions at set intervals to destroy the ultrasound contrast agent.

Frame Rate Limit

Function of limiting Frame Rate not to break bubbles.

\* Option: SOP-ARIETTA750-44 is required.

#### Contrast Echo analysis \*

- Analysis
  - Time-Intensity Curve
     Temporal changes in brightness (average) within
     the specified area (ROI) can be displayed
     graphically.
  - Subtraction

A subtraction image can be displayed between frames.

- · Fixed Reference
- · Any 2 Frames
- · By Uni
- · By Group
- · Same Reference
- Measurement
  - · Point to Point
  - · SD
  - · Wash-in
  - · Wash-out
  - Fitting
  - · FWHM (Full Width at Half Maximum)
  - · Distance
  - Inflow Time Mapping Measurement
     This function focuses on the ultrasound contrast agent inflow time difference and assigns colors based on changes in brightness across the entire moving image range.
  - · Area Under the Curve Measurement
- CSV output of analyzed data is possible.
- \* Option: SOP-ARIETTA750-44 is required.

#### **EyeballEF** \*

The EyeballEF function provides the capability to examine the cardiac volume and ejection fraction, GLS (Global Longitudinal Strain) in a short period of time. By using the EyeballEF function, you can check the reference values such as an EF value in real time and check the measurement results immediately after Freeze.

\* Option: SOP-ARIETTA750-58 (Probe dependent) is required.

## eTRACKING (Echo Tracking) \*

It is possible to precisely measure displacement of blood vessel to obtain indices of stiffness of the vessels such as pressure-strain elastic modulus (Ep), stiffness parameter ( $\beta$ ), arterial compliance (AC), one-point pulse wave velocity (PWV $\beta$ ), and augmentation index (AI). Blood-pressure gauge is necessary for this examination.

\* Option: SOP-ARIETTA750-11 and PEU-LISENDO880 are required.

## FMD (Flow Mediated Dilatation) analysis \*

It is possible to continually record and plot the vessel diameter of the whole processes from baseline through occlusion and vasodilatation to recovery.

Blood-pressure gauge is necessary for this examination.

\* Option: SOP-ARIETTA750-16 (includes *e*TRACKING software) and PEU-LISENDO880 are required.

## WI (Wave Intensity) \*

It allows observation of the pulse wave of the vessel, with analysis of the relationship between the systolic function of the heart in the early systolic phase to the diastolic function at the end of the systolic phase. This will reflect the stiffness and stenosis of peripheral vessels.

Blood-pressure gauge is necessary for this examination.

\* Option: SOP-ARIETTA750-34 (includes eTRACKING software) and PEU-LISENDO880 are required.

## **General Specifications**

#### **Acoustic Power**

· 0 to 100%

#### **Preset Function**

- · 100 kinds (Max. 10 kinds per each probe)
- · Preset contents storable in USB memory
- · Q.S.S.(Quick Scanning Selector)

Image modifying parameters (e.g. Gain, frequency, depth) of your choice can be registered. (Up to 4 sets per preset)

These parameters can immediately be registered and selected by touch panel during examinations.

 Preset is booted up in conjunction with ID information (BodyParts or etc,)

### Characters and graphic displays

· Character input area:

ID, name, age, sex, retained text (Can be corrected after exam.)

- Input is possible with virtual keyboard on LCD panel
- Automatic Annotation Labeling:

800 words (User registration is possible. 10 classes.)

- Body mark:
  - · 38 kinds are available per each region.
  - $\cdot$  6 regions+1 user is able to register.
  - Body mark editor to create user's body mark:
     Available
  - · Probe mark: 4 kinds
  - · Display position: changeable
  - · Fetus mark:

rotatable (Only single horizontal fetus marks)

Assist line display

#### Menu control

10.4-inch color TFT LCD touch panel

#### **Active Probe Ports**

- For electronic scanning probes: 6 (4 active, 2 parking)
- For independent probes\*: 1
- \* Option: EU-9184 and EU-9187B are required.

#### **Input/Output Signals**

- Data Input/Output
  - USB2.0: 5 channels(Main unit 2+ Operation Panel 3)
  - USB3.0: 1 channel (Main unit 1) \*
    - \*: 2 channel when Security box is installed.

- Digital Video Input/Output
  - DVI-D digital: 2 channels (Output1, Input1)
  - · Resolution: WXGA++(1600x900)
- Analog Video Input/Output

#### **Output**

- · Color composite (BNC): 1 channel
- · Y/C: 1 channel

#### **Input**

- · Y/C: 1 channel
- Network
  - · LAN (Wired, Wireless)
- Others
  - · Audio (L/R): 2 channels (Output 1, Input 1)

#### **Viewing Monitor**

- 23 inch LCD display
  - Resolution: WXGA++ (1600 x 900)
- Tilt and swivel are possible.
- Height adjustment and swivel together with operation panel.

#### **Safety Regulation**

- IEC 60601-1 Ed.2.0/A2: 1995, IEC 60601-1 Ed.3.1: 2012
- Class I, Type BF

## **Environmental Requirements**

- In Operation
  - · Temperature: +10 to +40 degrees C
  - · Relative Humidity: 30 to 75% (non condensing)
  - · Atmospheric pressure: 700 to 1060 hPa
  - · Altitude: Up to 3000m
- In Storage/Transportation
  - Temperature: -10 to +50 degrees C
     (0 to +50 degrees C for mechanical probes)
  - · Relative Humidity: 10 to 90% (non condensing)
  - · Atmospheric pressure: 700 to 1060 hPa

### **Power Requirement**

- 100 to 120/ 200 to 240V ±10%, 50 or 60 Hz, Max. 900 VA
- · Shut down tool

### Hibernation \*

\* The status is saved even if the power is unplugged.

## **Dimensions**

• 55 cm (W) × 90 cm (D) ×122- 169.5cm (H)

#### Weight

136 kg ±10 % (main unit only)

## **System Configuration**

ARIETTA 750SE main unit (includes a viewing monitor and Alphanumeric Keyboard unit) Physiological Signal Display unit Monochrome Printer DICOM SR software PEU-LISENDO880 UP-X898MD (Sony) P95DW (Mitsubishi) SOP-ARIETTA750-21 B/W Printer connection kit PM-LI880-H001 TVF software DICOM QR software SOP-ARIETTA750-47 SOP-ARIETTA750-59 Color Printer Detective Flow Imaging software Stress Echo software UP-D25MD (Sony) CP30DW (Mitsubishi) SOP-ARIETTA750-15 SOP-ARIETTA750-105 Color Printer connection kit PM-LI880-H002 Mounting Rack of Color Printer MP-FX-AVA-30 (for Sony) or EyeballEF software Picture in Picture software MP-FX-AVA-31 (for Mitsubishi) SOP-ARIETTA750-58 SOP-ARIETTA750-63 HD Video Recorder Automated Cardiac Measurement Contrast Harmonic Imaging software HVO-550MD/FHD (With DVD drive) HVO-500MD/FHD (Without DVD drive) SOP-ARIETTA750-44 SOP-ARIETTA750-74 Digital Video Recorder connection kit PM-LI880-H003B RTE software Mounting kit of Digital Video Recorder MP-FX-AVA-32B (Without Color Printer) eTRACKING software SOP-ARIETTA750-43 SOP-ARIETTA750-11 MP-FX-AVA-33B (With Color Printer) RTE Strain Histogram software Foot Switch (eTRACKING is included) SOP-ARIETTA750-60 MP-2345B (1-point) MP-2819 (3-point) SOP-ARIETTA750-34 Shear Wave Measurement software FMD software Jelly Warmer SOP-ARIETTA750-73 (eTRACKING is included) JW-3000U SOP-ARIETTA750-16 Jelly Warmer Mounting kit MP-FX-AVA-2B-R (right side) or Real-time Virtual Sonography software\* MP-FX-AVA-2B-L (left side) SOP-ARIETTA750-62 2DTT Analysis software Magnetic Sensor unit EU-9185B SOP-ARIETTA750-49 Endo-cavity Probe holder Magnetic Sensor unit connection kit PM-AR850-H004 RVS Flexible stand / RVS Onboard arm MP-PH-AVA-11B TDI Analysis software EZU-RVF1 or EZU-RVF1B or MP-FX-AVA-40 SOP-ARIETTA750-13 Flexible hook MP-HA-AVA-2 Needle Tracking software Flow Profile Measurement software SOP-ARIETTA750-84 SOP-ARIETTA750-7 Flexible hanger Magnetic Sensor for Tracking EU-9197 MP-HA-AVA-3 VirtuTRAX Instrument Navigator CW & 3D unit 610-1059, 610-1153(CIVCO) EU-9184 Adapter for Large Probe holder Body Motion Tracking software MP-PH-ADAPTER-5BU IND probe connecting unit SOP-ARIETTA750-85 Magnetic Sensor for Tracking Adapter for Large Probe holder (for Thin and Long Probes) EU-9187B FU-9197 omniTRAX Active Patient Tracker RT-3D software 610-1228(CIVCO) MP-PHAD-AR70-1U omniTRAX MR Active Patient SOP-ARIETTA750-4 Tracker 610-1306(CIVCO) Security box STIC software MP-FX-NMH-2 SOP-ARIETTA750-41 CD-R/DVD Disk Drive unit NT Auto Measurement software SOP-ARIETTA750-42 Automated FS Measurement software SOP-ARIETTA750-71 Automated FHR Measurement software SOP-ARIETTA750-72 McAfee Embedded Control 3 software SOP-ARIETTA750-128

<sup>\*</sup> Most of attachment/adapter is optional. See "Optional Probes" description.

# OPTIONAL PROBES

## **Electronic convex sector probes**

Application		Frequency					
(description)	Model	range (MHz)	Scanning angle (degrees)	Optional accessories			
Abdominal	C35	8.0-2.0	70	Needle Guide - Ultra-Pro			
				644-082 (CIVCO) *1			
				RVS Attachment			
				RV-004 *2			
Abdominal	C252	6.0-1.0	70	Needle Guide - Ultra-Pro			
				644-082 (CIVCO) *1			
				RVS Attachment			
				RV-004 *2			
Abdominal	C253	5.0-1.0	70	Needle Guide - Ultra-Pro			
				644-082 (CIVCO) *1			
				RVS Attachment			
	0000 42	1	_,	RV-004 * <sup>2</sup>			
Abdominal	C22P *3	6.0-1.0	74	Puncture Adapter			
				EZU-PA7C2 *1			
				MP-2824			
				RVS Attachment RV-012 *2			
Abdominal	C25P *4	5.0-1.0	70	Puncture Adapter			
Abdominal	CZSP	3.0-1.0	70	EZU-PA7B1-1			
				EZU-PA7B1-1			
				EZU-PA7B1-3			
				EZU-PA7B1-4			
				EZU-PA7B1-C			
				RVS Attachment			
				RV-005 *2			
Transvaginal	C41V1	10.0-2.0	200	Puncture Adapter			
J				EZU-PA7V			
				RVS Attachment			
				RV-002 *2			
Transvaginal•	C41B	10.0-2.0	200	Puncture adaptor			
Transrectal				MP-2445			
				RVS attachment			
				RV-013 *2			
				Probe cover			
				RB-945BP-NS			
				Waterproof case			
		1		WP-001			
Transrectal	CC41R	8.0-4.0	100/120	Sterile Puncture Adapter			
				EZU-PA5V			
				Puncture			
				EZU-PA3U RVS Attachment			
				RV-010 *2			
				Waterproof case			
				WP-001			
Abdominal	C42	8.0-4.0	80	Puncture Adapter			
	1	3.5 1.5		EZU-PA532			
				Needle Guide - Ultra-Pro			
				644-077 (CIVCO) *1			
				RVS Attachment			
				RV-006(Normal use) *2			
				RV-007(When Puncture Adapter is used) *2			

**Electronic linear probes** 

Application (description)	Model	Frequency range (MHz)	Scanning width (mm)	Optional accessories
Peripheral Vessel	L441	12.0-2.0	38	Needle Guide - Ultra-Pro 644-075 (CIVCO) *1
Peripheral Vessel	L442	12.0-2.0	38	Puncture Adapter EZU-PA7L1
Small Organ	L55	13.0-5.0	50	Puncture Adapter EZU-PA7L2 *1 Elastography Stabilizer EL-001 RVS Attachment RV-008 *2
Small Organ	L64	18.0-5.0	38	Puncture Adapter EZU-PA7L3 *1 Elastography Stabilizer EL-002 RVS Attachment RV-009 *2 Acoustic Coupler EZU-TECPL1(Acoustic Coupler for Elastography) SF-001(Acoustic Coupler for Superficial) EZU-TEATC2(Attachment)
Intraoperative	L53K	15.0-3.0	25	Waterproof case WP-001

**Electronic phased array sector probes** 

Application (description)	Model	Frequency range (MHz)	Scanning angle (degrees)	Optional accessories
Cardiac Adult	S121	5.0-1.0	120*	-
Cardiac Adult	S11	5.0-1.0	90	-
Cardiac Pediatric	S31	9.0-2.0	90	-
Neonatal Cardiology	S42	14.0-3.0	90	-
Cardiac Adult, TEE	S3ESL1	9.0-2.0	90	-

<sup>\*</sup> When Wide Scanning is ON.

## RT-3D (4D) Probes\*

\* SOP-ARIETTA750-4 and EU-9184 are necessary.

Application	Model	Frequency Scanning range range (MHz) (degrees)		Optional accessories			
Fetal	VC35	8.0-2.0	72	-			
Transvaginal	VC41V	8.0-2.0	140	-			

**Bi-plane** probe

Application	Mode	ما	Frequency range	Scanning angle	Optional accessories
(description)	Model		(MHz)	(degrees)	Optional accessories
Transrectal	C41L47RP Convex		8.0-4.0	200	Puncture Adapter
		Linear		64mm	EZU-PA3U
					RVS Attachment
					RV-011* <sup>2</sup>

## **Independent** CW Doppler Probes \*

\* Independent probe connection unit **EU-9184 and EU-9187B** are necessary.

Application	Model	Frequency range (MHz)	Optional accessories
Cardiac Adult	UST-2265-2	2.0	1

## **Electrical Radial Probes**

Application	Model	Frequency range (MHz)	Scanning angle (degrees)	Optional accessories
Transrectal	R41R	10.0-5.0	360	Waterproof case
				WP-001
Transrectal	R41RL	10.0-5.0	360	Waterproof case
				WP-001

<sup>\*1:</sup> Needle Guide Replacement Kit 610-608(CIVCO) is necessary.

<sup>\*2:</sup> Necessary to perform RVS.

<sup>\*3:</sup> One piece of RV-012 is attached.

<sup>\*4:</sup> One of puncture adapter is necessary to use needle.

## **Probes and available functions**

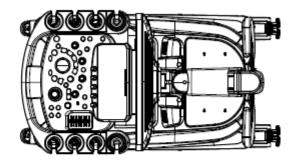
Basic Functions

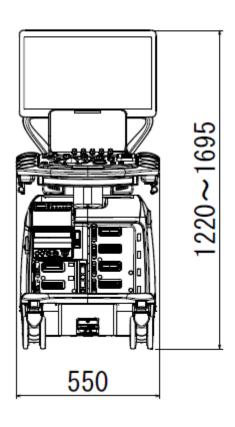
Basic Funct	tion	S	1		_	1		1				1				1	1				1			
	Compound	Trapezoid	B Steer	Wide Scanning	<i>e</i> Focusing	Acoustic Noise Reduction	Near-field Noise Reduction	Real-time Biplane	OMNI Mode	FAM	TGC(B)	TGC(Color)	TDI mode	Hi Frame(B)	Hi Frame(Color)	Puncture Guide Line	Needle Emphasis	Brachy Grid Display	Assist Line	CW mode	THI(FmT)	THI(WbT)	THI(HdT)	Dual Gate Doppler
C252	✓				✓	✓	✓			✓			<b>√</b>	✓	✓	✓	<b>√</b>			✓	✓	✓	✓	<b>✓</b>
C253	✓				✓	✓	✓			✓			✓	✓	<b>✓</b>	✓	✓			✓	✓	<b>✓</b>	<b>✓</b>	✓
C35	✓				✓	✓	✓			✓			<b>✓</b>	✓	✓	✓	<b>√</b>			<b>✓</b>	✓	✓	<b>√</b>	<b>✓</b>
C42	✓				<b>✓</b>	✓	✓			✓						✓	<b>√</b>			<b>✓</b>	✓	✓	<b>√</b>	<b>✓</b>
C22P	✓				✓	✓	✓			✓						✓	✓						<b>✓</b>	✓
C25P	✓				<b>✓</b>	✓	✓			✓						✓	<b>√</b>				✓	✓	<b>√</b>	<b>✓</b>
C41V1	✓				✓	✓	✓			✓						✓	<b>✓</b>					✓	<b>✓</b>	<b>✓</b>
C41B	✓				✓	✓	✓			✓						✓	✓					✓	<b>✓</b>	✓
CC41R							✓	✓		✓						✓	✓					✓		✓
R41R							✓															✓		✓
R41RL							<b>√</b>															✓		✓
L441	✓	✓	✓		✓	✓	✓			✓		✓			<b>✓</b>	✓	✓			✓		<b>✓</b>	<b>✓</b>	✓
L442	✓	✓	✓		✓	✓	✓			✓					<b>✓</b>	✓	✓		✓	✓		<b>✓</b>	<b>✓</b>	✓
L55	✓	✓	✓		✓	✓	✓			✓		✓	✓			✓	✓						✓	✓
L64	✓	✓	✓		✓	✓	✓			✓		✓				✓	✓		<b>✓</b>	✓		✓	✓	✓
L53K	✓	✓	✓		✓	✓	✓			✓												✓	✓	✓
S11				✓	✓	✓	✓			✓			✓	✓	✓					✓	✓			✓
S121				✓	✓	✓	✓			✓			✓	✓	✓					✓	✓			✓
S31						✓	✓			✓			✓		✓					✓	✓			<b>✓</b>
S42						✓	✓			✓			✓		✓					✓	✓			✓
S3ESL1						✓	✓			✓			✓		✓					✓				✓
VC35	✓				✓	✓	✓			✓			✓	✓	<b>✓</b>						✓	✓	<b>✓</b>	<b>✓</b>
VC41V	✓					✓	✓		✓	✓				✓							✓	✓		✓
C41L47RP (Convex)						✓	✓			✓								✓				✓		<b>√</b>
C41L47RP (Linear)		✓	✓			✓	✓			✓						✓						✓		<b>√</b>
UST-2265-2																				✓				

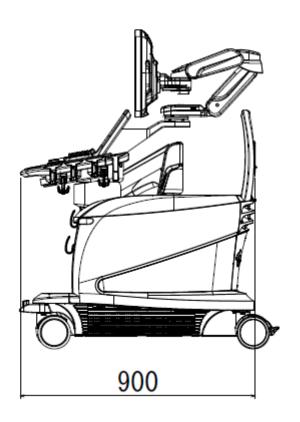
**Optional Functions** 

Орионан	unc	.10115											
	СНІ	Panoramic	RTE	SWM	RVS	Real time 3D	STIC	Stress echo	etracking	FMD	Wave Intensity	CHI- <i>e</i> FLOW	DFI mode
C252	✓	✓	✓	✓	✓							✓	✓
C253	✓	✓	✓	✓	✓							✓	✓
C35	✓	✓	✓		✓								✓
C42		✓	✓		✓								
C22P	✓				✓								
C25P	✓				✓								
C41V1	✓		✓		✓								
C41B	✓		✓		✓								
CC41R	✓		✓		✓								
R41R			✓										
R41RL			✓										
L441	✓	<b>√</b>	✓						✓	✓	✓		✓
L442	✓	✓	✓						✓	✓	✓		✓
L55	✓	✓	✓		✓								✓
L64		✓	✓	<b>√</b> *	✓								✓
L53K			✓										
S11								✓					
S121	✓							✓					
S31								✓					
S42								✓					
S3ESL1													
VC35						✓	✓						
VC41V						✓							
C41L47RP (Convex)			✓		✓								
C41L47RP (Linear)		<b>√</b>	<b>√</b>		<b>√</b>								
UST- 2265-2													

<sup>\*:</sup> Attenuation measurement is not available.







- The specifications are subject to change without notice.
- The standard components and optional items differ depending on the country. Not all products are marketed in all countries.
  - Please contact your local Hitachi distributors for details.
- ARIETTA, HdTHI, HI REZ, Real-time Tissue Elastography, Real-time Virtual Sonography,
   4Dshading, LISENDO are registered trademarks or trademarks of Hitachi, Ltd. in Japan and other countries.
- · McAfee is a registered trademark or trademark of McAfee LLC in the United States and other countries.
- DICOM is a registered trademark of the National Electrical Manufacturers Association in the United States for its standards publications relating to digital communications of medical information.
- Excel is a registered trademark or trademark of Microsoft Corporation in the United States and other countries.
- This document is applicable to ARIETTA 750







## **EC Certificate**

**Full Quality Assurance System** Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 095005 0031 Rev. 01

Manufacturer:

Hitachi, Ltd.

2-16-1, Higashi-Ueno, Taito-ku

Tokyo

110-0015 JAPAN

Product Category(ies): Diagnostic Ultrasound Systems,

related Probes and Their Accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

JAQ235039329

Valid from:

2020-01-10

Valid until:

2024-05-26

Date.

2020-01-10

**Christoph Dicks** 

Head of Certification/Notified Body

Œ ш

008



## **EC** Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 095005 0031 Rev. 01

## Facility(ies):

Hitachi, Ltd.

2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015 JAPAN

Hitachi, Ltd. Healthcare Ultrasound R&D Center 3-1-1, Higashikoigakubo, Kokubunji-shi, Tokyo, 185-0014 JAPAN

Hitachi, Ltd. Healthcare Mitaka Works 6-22-1, Mure, Mitaka-shi, Tokyo, 181-8622 JAPAN

Hitachi Healthcare Manufacturing, Ltd. Tokyo Works 3-7-19, Imai, Ome-shi, Tokyo, 198-8577 JAPAN

Hitachi Healthcare Manufacturing, Ltd. Analytical Systems Kashiwa Factory 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN

Hitachi Healthcare Manufacturing, Ltd. Analytical Systems Kashiwa Factory 3-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN

Hitachi, Ltd. Medical System Operations Group, Kashiwa 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 JAPAN

-/-



# Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Hitachi, Ltd. Medical System Operations Group, Kashiwa 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan

has established and applies a quality management system for medical devices for the following scope:

See attachments for the scope of certification

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2019-12-27

Certificate Registration No.:

SX 60144495 0001

An audit was performed. Report No.: 12031275 009

This Certificate is valid until:

2022-12-26

Certification Body



Date 2019-12-04



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety



Doc.1/2, Rev.0

# TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

SX 60144495 0001

Report No.:

12031275 009

Organization:

Hitachi, Ltd.

Medical System Operations Group,

Kashiwa

2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan

Scope:

Design and Development, Manufacture and Servicing Support of Diagnostic X-ray Equipment, X-ray CT Systems, MRI Systems, Ultrasound Diagnostic Systems, Ultrasound Transducer/Probes, Optical Encephalography Systems, Blood Irradiators, X-ray Tubes, X-ray Tube Assemblies, Diagnostic Image Workstations and Surgical Navigation System

Certification Body



Date: 2019-12-04





Doc.2/2, Rev.0

# TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to

Certificate

Registration No.:

Registration No.: Report No.:

SX 60144495 0001

12031275 009

Organization:

Hitachi, Ltd.

Medical System Operations Group,

Kashiwa

2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804 Japan

Scope:

Sites included:

Hitachi Healthcare Manufacturing, Ltd. Kashiwa Factory 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804, Japan 3-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804, Japan

Scope:

Manufacture of Diagnostic X-ray Equipment, X-ray CT Systems, MRI Systems, Ultrasound Diagnostic Systems, Ultrasound Transducer/Probes, Optical Encephalography Systems, Blood Irradiators, Diagnostic Image Workstations and Surgical Navigation System

Hitachi Healthcare Manufacturing, Ltd. Mobara Branch Factory 1754, Sangaya, Mobara-shi, Chiba, 297-0042, Japan

Scope:

Design, Development and Manufacture of X-ray Tubes and X-ray Tube Assemblies

Certification Body

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2019-12-04



Takashi Matsuda



June, 30th 2021

## **AUTHORIZATION**

We, the undersigned **Image Processing Systems S.A.**, the exclusive distributor of Fujifilm Healthcare Corporation, authorized to sell, service and repair Fujifilm Magnetic Resonance Imaging ("MRI"), Fujifilm Computerized Tomography ("CT") and Fujifilm Ultrasound systems, who are established and reputable manufacturers of **Fujifilm Healthcare Corporation**, a corporation organized under the laws of Japan, having its principal place of business at 2-1, Shintoyofuta, Kashiwa-shi, Chiba, 277-0804, Japan,

do hereby appoint the company

FCPC "DataControl" SRL, 17/6 N. Testimiteanu Street, MD-2025, Chisinau, Republic of Moldova,

to be authorized distributor/representative for registration, renewal and amendments of registration at the responsible authorities of the Republic of Moldova.

This authorization is valid till December, 31<sup>st</sup> 2022 from the date of this letter unless revoked earlier by sending a written notice.

Confirmed by the signature of the legal representative Mr. Leander Scherer, director of the company.

Image Processing Systems S.A.

Leander Scherer Director

R.C. Luxembourg

B 46547

V.A.T. LU 1603 9214

Ton - 1-808

I.P.S. sa, 111 route d'Arlon – L – 8009 Strassen – Tel. : +352 26 20 27 73 – Fax : +352 26 20 27 74 RC Luxembourg B46547 – N° d'identité 19942200601 – T.V.A. : LU 1603 9214



March 30, 2021

Subject: Notification of changes due to company name change

## 1. Background

Based on "Hitachi Announces the Conclusion of Absorption-type Company Split Agreement Relating to Diagnostic Imaging-related Business", issued on February 18, 2021 (hereinafter referred to as "Hitachi News Release Feb 18, 2021), Hitachi, Ltd. will execute an absorption-type split and its Healthcare Business Unit's diagnostic imaging business (CT, MRI, X-ray diagnostic equipment, ultrasound diagnostic imaging equipment, etc.) will be absorbed and split into a newly established company. Based on the absorption-type split, the new company name will change to FUJIFILM Healthcare Corporation.

After the transfer of shares of FUJIFILM Healthcare Corporation, a subsidiary of Hitachi, Ltd., to FUJIFILM Corporation on March 31, 2021, FUJIFILM Corporation will become a shareholder of FUJIFILM Healthcare Corporation, and FUJIFILM Healthcare Corporation will become a subsidiary of FUJIFILM Corporation. Since Hitachi, Ltd. and FUJIFILM Corporation are separate companies that have no capital relationship, Hitachi, Ltd. and FUJIFILM Healthcare Corporation will also be separate companies that have no capital relationship on March 31, 2021.

More information is available on the attached sheet, titled "Hitachi News Release Feb 18, 2021."

## 2. Company name change overview

The table below shows the transition of changes in the shareholders of legal manufacturers, exporters, and sales companies in order to conduct manufacturing registrations and product registrations in each country.

Content	Before March 31,	March 31, 2021~	After July 1, 2021			
	2021	June 30, 2021				
Legal manufacturer	Hitachi, Ltd.	Hitachi, Ltd.	FUJIFILM Healthcare			
Name			Corporation (*1)			
Brand name	HITACHI	HITACHI	FUJIFILM			



Content	Before March 31,	March 31, 2021~	After July 1, 2021
	2021	June 30, 2021	
Exporter	Hitachi, Ltd.	FUJIFILM Healthcare	FUJIFILM Healthcare
		Corporation	Corporation
Sales Company	Hitachi, Ltd.	FUJIFILM Healthcare	FUJIFILM Healthcare
		Corporation	Corporation
Shareholder of Sales	Hitachi, Ltd.	FUJIFILM	FUJIFILM
Company		Corporation	Corporation
ISO13485 holder	Hitachi, Ltd.	Hitachi, Ltd.	FUJIFILM Healthcare
			Corporation
Company name listed in	Hitachi, Ltd.	Hitachi, Ltd.	FUJIFILM Healthcare
FSC (Free Sales			Corporation
Certificate)			

(\*1) However, when shipping products under the new brand, administrative procedures in each country are required because the products can only be shipped after the product registration, which specifies the change in legal manufacturer and address, is completed.

Even after the change of legal manufacturer, the manufacturing process, quality management system (QMS) and product safety of the product will remain unchanged, with no impact on the factory and QMS.

Responsibility for sold HITACHI brand products and HITACHI brand inventory will be transferred to FUJIFILM Healthcare Corporation.

3. Changes regarding global subsidiaries

Following the absorption-type split of the diagnostic imaging business (CT, MRI, X-ray diagnostic equipment, ultrasound diagnostic imaging equipment, etc.) of Hitachi, Ltd. Healthcare Business Unit and the transfer of shares of the new company, the shareholders and company name of the global subsidiaries will also be changed and incorporate FUJIFILM Healthcare Corporation.

Hitachi, Ltd.

Name: Akio Yamamoto

Title: CEO

Healthcare Business Unit

akio Gamameto

@Hitachi, Ltd. Healthcare Business Unit

Ueno East Tower, 2-16-1, Higashi-Ueno, Taito-ku, Tokyo, 110-0015, Japan Tel.:+81-3-6284-3800 http://www.hitachi.com/businesses/healthcare/