

SPECIFICATIONS
for
Diagnostic Ultrasound System

ARIETTA 65



MODEL: ARIETTA 65

ARIETTA 65

A better "Reproducibility", "Versatility", "Accuracy" are required for the ultrasound diagnostic equipment. ARIETTA 65 is available to perform efficiency in use cases by answering your needs. Because it is implemented comfortable workflow, high definition image quality and useful application from premium platform.

1. Smooth workflow

It is implemented design and features to improve efficiency for everyday practice. For example, it is ergonomics design to suppress stress of user and to support comfortable everyday practice. The other side is optimized operation panel switch location.

Also, it is implemented any automated process features (e.x.: "Protocol Assistant" and "Auto Optimizer"). It can be performed everyday practice more smoothly.

2. Superb Imaging

It is implemented any kinds of image processing technology from premium platform. it can be performed "HI REZ", "Compound Imaging" (improved contrast resolution by suppressing speckle noise) and "HdTHI" (improved spatial resolution and penetration).

Also, it can be performed the additional unique image processing technology (ANR/NNR).

3. Simple to use Applications

It is available to provide reliable practice by any kinds of applications.

Real-time Tissue Elastography is displayed stiffness color by calculating distortion of tissue. it is useful when it is examined for breast or it is confirmed hepatitis progress. And 2D Tissue Tracking is available to visualized and to quantified by measuring wall motion of heart.

Scanning Method

- Electronic Convex
- Electronic Linear
- Electronic Phased Array Sector

Operating Modes

- **B-mode**
- BiPlane-mode
- **M-mode**
- D: **Spectral Doppler mode** (PW, CW^{*1}, HPRF-PW)
- **Dual Gate Doppler mode**
- **Color Flow mode**
- **Power Doppler mode** (Directional Power Doppler)
- **eFLOW mode** (Directional eFLOW)
- **RT-3D(4D) mode**^{*2}

^{*1} Option: EU-9198

^{*2} Option: EU-9198 and SOP-ARIETTA65-4

Image Display Modes

- **B: gray-scale imaging**
- **Dual B**
- Quad B
- M
- **B and M**
- D: Spectral Doppler (PW, HPRF PW, and CW)
- 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 Flow)
- Dynamic Slow-motion Display^{*1}
(Real-time image/Slow-motion image, side by side display)
- **Panoramic View**^{*2}
- **TDI (Tissue Doppler Imaging)**
- Intermittent trigger mode^{*3}
- Monitor Mode^{*3} (Fundamental/CHI)
- Real-time Tissue Elastography ^{*4}
- Real Time Biplane (Using biplane probe, display a real time 2 section image. Probe dependent.)
- Request function: In multi-mode display, it is possible to select one mode for full screen display.
- RT-3D(4D) mode^{*5}

^{*1} Option: SOP-ARIETTA65-57

^{*2} Option: SOP-ARIETTA65-1

^{*3} Option: SOP-ARIETTA65-44

^{*4} Option: SOP-ARIETTA65-43

^{*5} Option: EU-9198 and SOP-ARIETTA65-4

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: Multiple directions

Transmission/Reception method of Harmonics

Reception frequency: 3.2-**18.0* MHz**

* Maximum reception frequency can be achieved under below conditions.

• Probe: L64, Freq: High, Freq. Info.: Receive

Tissue Adaptive Technology

Sound speed adjustment: 26 steps

Focusing

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

Reception: PixelFocus

System Dynamic Range

272dB

System Processing Channels

574,976 Channels

Frame rate

Max. More than 661 frames/sec*

* Depends on probes and various settings

B-mode

- Display Gray Scale: 256 levels
- Scanning area: 1 degree step
- Line Density: 8 steps
- HI Frame Rate (Multi Parallel Processing)
- Zoom
 - HI zoom (real-time image):
 - Max. Up to 0.5 cm display image (probe dependent)
 - PAN zoom (real time and frozen image):
 - Max. Up to 0.5 cm display image (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
- Echo enhancement: 8 steps
- Texture: 2 steps (Smooth/Sharp), not available in M-mode
- Smooth/Enhance: 8 steps for each other
- Persistence: 8 steps, including Off
(Available to change type for adaptive frame rate)
- TGC (time gain compensation):
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
- Gray map: 10 types, changeable after frozen
- AGC: 8 steps
- View gamma: 4 types
- Spatial Compound Imaging
(by selected linear and convex sector probes)
- Trapezoidal scan (possible by selected linear probes)
Available to combine with compound scan

- B steer function: This function enables you to use oblique function not only Color Flow/ Power Doppler mode but B mode.
- Adaptive Imaging: HI REZ function 8 steps, 2 types
Adaptive imaging is the technique to generate optimum image with changing filter characteristic depending on input signal.
This technique which installed this ultrasound diagnostic scanner reduces speckle noise on B-mode images and provides uniformly and high contrast images.
* Gain and Dynamic range can be changed after freezing
- Acoustic Noise Reduction: 8 steps
This technique is reduced acoustic noise (Based on signal level)
- Near field Noise Reduction
reduces artifacts and noises in the heart chamber or blood vessel
- Low Echo Reduction
This technique is compressed low gradient echo level.
- Grayscale Enhancement
This technique is enhanced image which is displayed as grayscale.
- Auto-optimizer (Optimization of gain)
- Needle Emphasis (probe dependent)

M-mode:

- Sweep method: Moving bar
Sweep speed:
300.0, 200.0, 133.3, 100.0, 66.7, 50.0, 40.0 mm/sec
 - Gain: B-gain ± 30 dB
 - Dynamic Range: 40 dB-90 dB
 - AGC: 8 steps
 - Acoustic Noise Reduction
 - Low Echo Reduction
 - FAM (Free Angular M-mode) *
- * Option: SOP-ARIETTA65-5

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: 1.9, 2.0, 2.1, 2.5, 3.0, 3.2, 3.3, 3.5, 3.8, 4.0, 4.3, 5.0, 6.0, 7.5, 8.6 MHz

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

- Analysis rate:
 - PW: 0.05 to 40 kHz
 - CW: 1.1 to 40 kHz
 - Max. velocity range:
 - PW/HPRF: -8.02 to 0 or 0 to +8.02 m/s
 - CW: -16.0 to 0 or 0 to +16.0 m/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
 - Auto angle Correction
 - Spectrum inversion
 - Angle correction: Available up to 80 degrees (Pre-settable, changeable after freezing)
Auto angle correction, Warning function available
 - Sample volume size for PW Doppler:
0.5 – 20 mm, changeable in 0.5mm, 1.0 mm step
 - Wall motion 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
 - Dynamic Range: 40-90dB, 1dB steps
(Not changeable after freezing)
 - Auto-Optimizer
(Optimization of gain, velocity range, baseline shift, sample gate position and angle Coreration)
 - Audio output: 2 channels*
- *Option: EU-9198

Color Doppler Mode

- Color area size: Continuously variable
- Steered linear scanning:
Max. ± 30 degrees *, changeable at 5 degrees interval
* Probe dependent
- Line density: Up to 8 steps
(Changeable setting independently with B mode)
- Auto-Optimizer (Optimization of gain)

Color Flow Mode

- Display patterns:
Velocity (derived from mean Doppler frequency shift), Velocity + variance, Variance, Velocity + intensity, Velocity + variance + intensity

- Max. velocity range: $\pm 0.63\text{cm/sec}$ to $\pm 458.33\text{cm/sec}$
- Reference frequency: (Probe dependent)
1.9, 2.0, 2.1, 2.5, 3.0, 3.2, 3.3, 3.5, 3.8, 4.0, 4.3, 5.0, 6.0, 7.5, 8.6 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
- Wall filter: 6 steps
- Persistence (Color): 8 steps
- Wall Motion Reduction: Off + 3 steps, 2 types
- Packet Size: 3 levels
- Base line shift(Color):
Up to double velocity (± 127 steps)
- Color coding: 15 kinds
- TGC Enhancement: 2 kinds

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 levels

High Resolution Power Doppler(eFLOW) Mode

One of the Color Flow imaging functions that can display blood flow information in a high spatial and temporal resolution.

- 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 levels

TDI(Tissue Doppler Imaging)

- Function Available

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

1. Image data

1-1. Format

Multiple-frame (moving) image

DICOM (Raw, MJPEG)

PC Format (AVI, WMV, MP4)

Single-frame (still) image

DICOM (Non-compressed, RLE, RGB (Plane/Pixel), JPEG)

PC Format (TIFF, BMP, JPEG)

1-2. 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 seconds
Pre 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.

1-3 Image data management tool

Image viewer

- Thumbnail display of stored images (1-36 images)
- Check mark is put on a transferred image
- Image zoom, rotation, inversion
- 1:1 replay (main unit HDD or DICOM storage data)
- DVD-RAM
- DVD-R
- CD-R
- USB memory
- USB HDD
- Re-storing to media, transfer
- Adjustment is possible on the reconstructed Raw-data image (gain, dynamic range, gamma curve type, and color coding in Color flow mapping mode)

2. Measurement data

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

3. Patient data

Displayed information*

Patient information

ID (up to 64 characters), Name (up to 64 characters, including middle name), Birthday, 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**

4. Data storage

- Main unit hard disk
Capacity: **Approx. 500GB**
(It is available to change to 1TB HDD)
- USB memory
- USB HDD
- **CD-R**
- **DVD-RAM**
- **DVD-R**
- Network interface(DICOM format): 1000baseT, 100baseTX or 10baseT (automatically switched)
- Network folder(BMP, JPEG, TIFF, AVI, MWV, MP4)

5. DICOM network communication*¹

- Conformity to DICOM service class:
Ultrasound image storage SCU
Ultrasound multi-image storage SCU
Comprehensive SR SCU
Storage media FSC/FSU/FSR
Print management SCU
Modality worklist management SCU
Modality performed procedure step (MPPS) SCU
Storage Commitment Push Model SCU
Query/Retrieve 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-GYN, cardiology, vascular and abdominal measurements*²
 - Query/Retrieve*³
 - 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-ARIETTA65-10
- *² Option: SOP-ARIETTA65-21
- *³ Option: SOP-ARIETTA65-59
6. 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.
7. Teaching file can be made.

Measurements and Analysis:

Basic measurements

B mode

Distance, Dist-trace, Area/Circum, Volume, Hip J Angle, Histogram, Angle, B.Index

M mode

M.Length, Time, Heart Rate, M.VEL, M.Index

D mode

D.VEL, ACCEL, RI, Time, P1/2T, Heart Rate, D.Caliper, D.Index (Caliper), D.Index (Trace), Mean.VEL., PI, D.Trace, Steno Flow, Regurg Flow, Real-time Doppler auto trace

B/D mode

Blood Flow

B(Flow) mode

Flow Profile*

* Option: SOP-ARIETTA65-7

Application measurements

Obstetrical measurements

- Supports multiple gestations
- Growth analysis function (display of past measurement data)

B mode

Gestational age, Fetal weight

Auto GA*¹ is possible.

Ratio

Amniotic Fluid Index(AFI), AF Pocket/AFV, MVP

CTAR/CTR

Cervical length

Auto NT*²

M mode

Fetal Heart Rate

LV Function

D mode

Blood flow

*¹ Option: SOP-ARIETTA65-76

*² Option: SOP-ARIETTA65-42

Gynecological measurements

B mode

Uterus measurements

Endometrial thickness measurements

Cervical measurements

Ovary measurements

Follicular measurements (Volume measurements by 3-axis measurements are possible.)

Urinary bladder measurements

D mode

Uterine artery

Ovarian artery

Urological measurements

B mode

PSA Volume

PRS slice volume

Bladder

D mode

Renal artery

Cardiology measurement

B mode

LV Volume measurements

M.Simpson*, Area-length*, Pombo**, Teichholz**,

Gibson**, Bullet, BP-ellipse, Simpson

*Automatic heart cavity trace is possible. (3-point or full automated method*¹)

** Auto measurement method*¹ is possible.

Valve area measurements (AVA, MVA)

LA/AO

Ratio

Right ventricle measurements

LV myocardial mass

LA/RA Volume measurements

Automatic heart cavity trace*¹ is possible. (3-point or full automated method)

FAC measurements

Automatic heart cavity trace*¹ is possible. (3-point)

IVC (inferior vena cava) measurements

M mode

Pombo (wall), Teichholz (wall), Gibson (wall)

Caliper Mark Auto Shift is possible.

Mitral valve measurements

LA/AO measurements

Auto measurement method*¹ is possible.

Tricuspid valve measurements

Pulmonary valve measurements

IVC (inferior vena cava) measurements

TAPSE measurements

D mode

LVOT (left ventricle outflow tract) flow

RVOT (right ventricle outflow tract) flow

Trans-mitral flow

(Full Automated or Automated setting period method)

Regurgitant flow (AR, PR, MR, TR)

Volumetric flow(MR)

Stenotic flow (AS, PS, MS, TS)

PISA

Pulmonary vein flow
 TDI PW
 (Full Automated or Automated setting period method)
 Coronary flow
 Asynchrony
TDI-CF/M mode
 Shorteningt
 Percent Systolic Wall Thickening
 *1 Option: SOP-ARIETTA65-74 and PEU-ARIETTA65

Vascular measurement

Carotid artery

Blood flow measurement :

CCA (common carotid artery)
 ICA (internal carotid artery)
 ECA (external carotid artery)
 BIFUR (Bifurcation of carotid artery)
 VERT (Vertebral artery)

Stenotic rate:

% Stenosis area
 % Stenosis diameter

IMT (Intima-media thickness) Measurements:

Automated IMT measurements*1
 IMT-C10 measurements*1

Measurements of arteries in extremities

Lower extremity artery flow
 Upper extremity artery flow
 Transit time of Vessel Flow(TVF)*2

Stenotic rate:

% Stenosis area
 % Stenosis diameter

Measurements of veins in extremities

Lower extremity venous flow
 Upper extremity venous flow

Trans-cranial Doppler

Trans-cranial blood flow measurements

*1 Option: SOP-ARIETTA 65-38

*2 Option: SOP-ARIETTA 65-47 and PEU-ARIETTA65

Abdominal measurement

B mode

Gallbladder measurements
 Common buile duct measurements
 Liver measurements
 Pancreas measurements
 Pancreatic duct measurements
 Renal measurement
 Spleen measurements

Space-occupying lesion measurements
 Blood vessel diameter measurements
 Srenosis percentage measurements

D mode

Artery measurements
 Renal artery measurements
 Portal vein measurements
 Shunt blood vessel measurement

B/D mode

Flow quantity(Artery)
 Flow quantity(Vein)

Small parts measurement

B mode

Lesion measurement
 Aspect ration measurements
 Nipple-tumor distance measurement
 Thyroid gland volume measurement
 Thyroid isthmus tickness measurement

D mode

Artery measurements

Report Functions

Measurement reports

Obstetrical report

Gynecological report

Cardiac function report

Vascular report

IMT (Intima-Media Thickness) report

Urological report

Abdominal measurement report

Small parts 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.

Output of measurement values in CSV file is possible.

Others

Hot Key function:

It is possible to assign measuring functions to the alphabet keys on the keyboard. (It is needed 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 wave*², breathing waveform
- ECG synchronized display: Available for one phase
- Detect regular pulse from arrhythmia(RRp/RRpp)
- Display position: Continuously variable (both in B and M modes)
- Bar graph display for breathing waveform
- 3 type electrocardiograms (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)

*² Option: TY-307A (Not available in EU)

Dual Gate Doppler (Probe dependent)

This is a function which displays Doppler Spectrums of two different sample points simultaneously.

Supported combinations are PW/PW, TDI/TDI, and PW/TDI.

This function is beneficial for functional evaluations of heart failures and phase analysis. For example, E/e' measurements can be performed in a single scan.

Automated sample gate setting for each gate is possible.

Optional Functions

PC printer

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

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 cross-section 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

*¹ Option: **SOP-ARIETTA65-43** (Probe dependent)

*² Option: **SOP-ARIETTA65-60**

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.

*¹ Option: **SOP-ARIETTA65-73** (Probe dependent)

*² It is only available with C251 and C253.

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-ARIETTA65-42

Auto GA*

Automatic fetus measurement function that measurement caliper are appeared automatically after selecting measurement items

Measurement items compatible with Auto GA

- Head: BPD, BPD_o, OFD, OFD_o, HC, HC2, HC3
- Abdomen: APTD, APD, TTD, TAD, AC, AC2, FTA
- Femur: FL

* Option: SOP-ARIETTA65-76

2D Tissue Tracking (2DTT) *

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 from various cross sections have become possible. Multiple analyses, including wall thickness, various strains and rotation angle can be performed.

Analysis

- Free use
Distance and angular change between 2 points of your choice can be analyzed.
- SAX: Parasternal short-axis view
 - Circumferential Strain and Strain Rate
 - Radial Strain and Strain Rate Global Circumferential Strain, Strain Rate
 - Angle and Angle Rate
 - Twist (With Overlay function)

- APEX: Apical long-axis view
- Apex-S (Strain)
 - Longitudinal Strain and Strain Rate
 - Transverse Strain and Strain Rate
 - Global Longitudinal Strain and Strain Rate
 - Volume
- Apex-V (Volume)
 - Volume for cavity
 - Single and Biplane EF(With Overlay Function)
 - dv/dt(volume variation velocity)
 - Center of gravity coordinate, display tracking

View

- 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

*Option :SOP-ARIETTA65-49 and PEU-ARIETTA65

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: Selectable
 - Image allocation: Possible
 - Scoring: Possible
 - Automatic registration: On/Off
- Protocol: 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 (Multi acquisition): 270 seconds

- Scoring screen
 - Playback speed: Selectable
 - Comparison between different stages in the same view is possible
 - Image playback range is selectable
 - Systolic image acquisition
 - Bull's eye display (16 or 17 segmentation selectable)
- Report screen
 - Display format
 - Chart/Stage overview/View overview

*Option: SOP-ARIETTA65-15 and PEU-ARIETTA65

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.

B-mode

Temporal Velocity Profile

Velocity, time, acceleration, ratio

Regional Velocity Profile

Velocity, distance

TDI-Myocardial Thickness (Wall thickness)

Distance, time, velocity

Strain rate

Time, strain rate

Strain

Time, strain

M-mode

Velocity trace

Velocity, time, acceleration, ratio, velocity difference

TDI-Myocardial Thickness (wall thickness)

Distance, time, velocity

Velocity Profile

Velocity, distance

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

*Option: SOP-ARIETTA65-13 and PEU-ARIETTA65

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.
 - 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-ARIETTA65-44** (Probe dependent)

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.

* Option: **SOP-ARIETTA65-38**

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.

* Option: **SOP-ARIETTA65-1**

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 edit protocol on the system
- Available to register and edit reference image
- Available to import or export like preset

* Option: **SOP-ARIETTA65-79**

RT-3D (4D)*

- 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
- Multi Slice Imaging (MSI)
- **HI REZ**
- Lower Threshold
- 4Dshading
- Snapshot : 3D image (1 View) is magnified and printed in color

* Option: **EU-9198 and SOP-ARIETTA65-4** (Probe dependent)

General Specifications

Acoustic Power

- 0 to 100%, 5% step

Preset Function

- 100 kinds (Max. 25 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 Class)
- Body mark:
38 kinds are available per each region.
6 regions+1 user are able to register.
Body mark editor to create user's body mark: Available
Probe mark: 4 kinds
Display position: changeable
Fetal body mark: rotatable
- Assist line display (Probe dependent)

Menu control

- 10.1-inch color TFT LCD touch panel

Active Probe Ports

- For electronic scanning probes: 4
- For independent probes*: 1

*Option: EU-9187B, EU-9198

Input/Output Signals

- Data Input/Output
 - USB2.0 : 5 channel
(Main unit 3+ Operation Panel 2)
- Digital Video Input/Output
 - DVI-D digital : 2 channel(Output 1, Input1)
Resolution: WXGA++(1600x900)
- Analog Video Input/Output

Output

- Y/C: 1 channels

Input

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

Viewing Monitor

- 21.5 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: 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
- 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. 750 VA (with options connected)
- Battery drive time *
70 minutes (first time use, 25 degrees C environment,
B mode scanning)
Battery driving time (battery capacity) may reduce
depending on the charge-discharge repetition and
environment.
*Option:EU-9199

Dimensions

- 53.3 cm (W) × 74.2 cm (D) ×126.5 – 163.5 cm (H)

Weight

- 85 kg (main unit only)

System Configuration

Unite			Remarks
Category	Name	Model name	
System	Diagnostic ultrasound system	ARIETTA 65	includes a viewing monitor
Peripheral Interface / Connection Kit / Mounting Rack	Digital color printer (SONY)	UP-D25MD	EU-6060B, PM-AR65-H002, MP-FX-ALB-30 and MP-FX-ALB-31 are necessary.
	Digital color printer (MITSUBISHI)	CP30DW	EU-6060B, PM-AR65-H002, MP-FX-ALB-30 and MP-FX-ALB-32 are necessary.
	Digital monochrome printer (SONY)	UP-X898MD	PM-AR65-H001 is necessary
	Digital monochrome printer (MITSUBISHI)	P95DW	PM-AR65-H001 is necessary
	Medical video recorder	HVO-500MD/FHD	EU-6060B, PM-AR65-H003, MP-FX-ALB-33 and MP-FX-ALB-35 are necessary. PM-AR65-H003 is available for the model with SN:114857~.
	Medical video recorder	HVO-550MD/FHD	EU-6060B, PM-AR65-H003, MP-FX-ALB-33 and MP-FX-ALB-35 are necessary. PM-AR65-H003 is available for the model with SN:11071~.
	CD-R/DVD Disk Drive unit		
	Outlet expansion unit	EU-6060B	Unavailable during the operation on battery power.
	connection kit	PM-AR65-H001	
	connection kit	PM-AR65-H002	
	connection kit	PM-AR65-H003	
Hardware Option	Physiological signal display unit	PEU-ARIETTA65	
	Independent probe connection unit	EU-9187B	EU-9198 is necessary.
	CW & 3D unit	EU-9198	
	Battery unit	EU-9199	
	SWM unit	EU-9206	
	Jelly warmer	JW-3000U	EU-6063 and MP-FX-AVA-2B-R or MP-FX-AVA-2B-L are necessary. Unavailable during the operation on battery power.
	AC adopter for Jelly warmer	EU-6063	JW-3000U and MP-FX-AVA-2B-R or MP-FX-AVA-2B-L are necessary.
	Foot switch	MP-2819	3-point
	Foot switch	MP-2345B	1-point
	Small tray	MP-FX-ALB-21	
	Side tray	MP-FX-ALB-22	
	Mounting bracket	MP-FX-ALB-30	This is required when mounting color printer, medical video recorder, and when mounting monochrome printer in combination with aforementioned devices.
	Color printer mounting bracket (SONY)	MP-FX-ALB-31	
	Color printer mounting bracket (MITSUBISHI)	MP-FX-ALB-32	
	Medical video recorder mounting bracket	MP-FX-ALB-33	
	Peripheral expansion rack	MP-FX-ALB-34	This is required when mounting UP-D25MD and medical video recorder together on the system.
	Peripheral expansion rack	MP-FX-ALB-35	This is required when mounting CP30DW and medical video recorder together on the system.
	Flexible hook	MP-HA-ALB-2	It is impossible to simultaneously mount this and MP-HA-ALB-3.
	Flexible hanger	MP-HA-ALB-3	It is impossible to simultaneously mount this and MP-HA-ALB-2.
	Keyboard tray	MP-FX-ALB-6B	Optional keyboard is necessary.
	Jelly warmer right mount kit	MP-FX-AVA-2B-R	JW-3000U and EU-6063 are necessary.
	Jelly warmer left mount kit	MP-FX-AVA-2B-L	JW-3000U and EU-6063 are necessary.
	Small probe holder (RS)	MP-PH-AR70-2U	
	Small probe holder (LS)	MP-PH-AR70-4U	

	Large probe holder (LS,RF)	MP-PH-AR70-5U	
	Large probe holder (RS,LF)	MP-PH-AR70-6U	
	Adapter for large probe holder (for thin and long probes)	MP-PHAD-AR70-1U	
	Adapter for large probe holder	MP-PH-ADAPTER-5BU	
	Endo-cavity probe holder kit	MP-PH-AVA-11B	
	HDD expansion unit	AR65 Built-in 1T HDD	Fuctory built-in option
Software Option	Panoramic View software	SOP-ARIETTA65-1	
	Real-time 3D software	SOP-ARIETTA65-4	EU-9198 is necessary.
	FAM software	SOP-ARIETTA65-5	
	Flow Profile Measurement software	SOP-ARIETTA65-7	
	DICOM network software	SOP-ARIETTA65-10	
	TDI Analysis software	SOP-ARIETTA65-13	
	Stress Echo software	SOP-ARIETTA65-15	PEU-ARIETTA65 is necessary.
	DICOM Structured Report software	SOP-ARIETTA65-21	SOP-ARIETTA65-10 is necessary.
	Automated IMT Measurement software	SOP-ARIETTA65-38	
	Automated NT Measurement software	SOP-ARIETTA65-42	
	Real-time Tissue Elastography software	SOP-ARIETTA65-43	Most of attachment / adapter is optional. See "Optional Probes" description.
	Contrast Harmonic Imaging software	SOP-ARIETTA65-44	
	Transit Time of Vessel Flow measurement software	SOP-ARIETTA65-47	PEU-ARIETTA65 is necessary.
	2D Tissue Tracking Analysis software	SOP-ARIETTA65-49	
	Dynamic Slow-motion Display software	SOP-ARIETTA65-57	
	DICOM Query/Retrieve software	SOP-ARIETTA65-59	SOP-ARIETTA65-10 is necessary.
	RTE Strain Histogram software	SOP-ARIETTA65-60	SOP-ARIETTA65-43 is necessary.
	Shear Wave Measurement Software	SOP-ARIETTA65-73	EU-9206 is necessary
	Automated Cardiac Measurement software	SOP-ARIETTA65-74	PEU-ARIETTA65 is necessary.
	Automated OB Measurement software	SOP-ARIETTA65-76	
	Protocol Assistant software	SOP-ARIETTA65-79	
	McAfee Embedded control 3 software	SOP-ARIETTA65-128	

Optional Probes

Electronic convex sector probes

Application (description)	Model	Frequency range (MHz)	Scanning angle (degrees)	Optional accessories
Abdominal	C251	5.0~1.0	70	Needle Guide - Ultra-Pro II 644-082 (CIVCO)* ¹
Abdominal	C253	5.0~1.0	70	Needle Guide - Ultra-Pro II 644-082 (CIVCO)* ¹
Abdominal	C35	8.0~2.0	70	Needle Guide - Ultra-Pro II 644-082 (CIVCO)* ¹
Abdominal	C41	13.0~4.0	100	-
Abdominal	C42	8.0~4.0	80	Puncture Adapter EZU-PA532 Needle Guide - Ultra-Pro 644-077 (CIVCO)* ¹
Abdominal	C22K	6.0~1.0	82	Puncture Adapter MP-2781 MP-2781-5 MP-2781-25 Needle Guide - Ultra-Pro 614-109 (CIVCO)* ¹
Abdominal	C22P	6.0~1.0	74	Puncture Adapter EZU-PA7C2* ¹ MP-2824
Abdominal	C25P* ²	5.0~1.0	70	Puncture Adapter EZU-PA7B1-1 EZU-PA7B1-2 EZU-PA7B1-3 EZU-PA7B1-4 EZU-PA7B1-C
Intraoperative	C42K	10.0~4.0	65	Puncture Adapter MP-2783 MP-2458 Needle Guide - Ultra-Pro 614-100 (CIVCO)* ¹
Intraoperative	C42T	10.0~3.0	65	Waterproof case WP-001
Transvaginal Transrectal	C41B	10.0~2.0	200	Puncture Adaptor MP-2445 Probe Cover RB-945BP-NS Waterproof case WP-001
Transvaginal Transrectal	C41V	8.0~4.0	200	Puncture Adapter EZU-PA5V
Transvaginal Transrectal	C41V1	10.0~2.0	200	Puncture Adapter EZU-PA7V
Transrectal	C41RP	9.0~2.0	180	Puncture Adapter MP-2452 Probe Cover RB-665P-NS Waterproof case WP-001

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 II 644-075 (CIVCO)* ¹ Elastography Stabilizer MP-2804
Peripheral Vessel	L442	12.0~2.0	38	Puncture Adapter EZU-PA7L1

Small Organ	L34	7.0~3.0	38	Puncture Adapter EZU-PA3C1H Needle Guide - Ultra-Pro II™ 644-079 (CIVCO)* ¹
Small Organ	L55	13.0~5.0	50	Puncture Adapter EZU-PA7L2* ¹ Elastography Stabilizer EL-001
Small Organ	L64	18.0~5.0	38	Puncture Adapter EZU-PA7L3* ¹ Acoustic Coupler SF-001(Acoustic Coupler) EZU-TEATC2(Attachment) Acoustic Coupler for Elastography EZU-TECPL1(Acoustic Coupler) EZU-TEATC2(Attachment) Elastography Stabilizer EL-002
Intraoperative	L43K	12.0~2.0	26	Waterproof case WP-001
Intraoperative	L44K	14.0~2.0	42	Waterproof case WP-001
Intraoperative	L44LA	13.0~2.0	36	-
Intraoperative	L46K1	14.0~2.0	63	Waterproof case WP-001
Intraoperative	L51K	15.0~3.0	13	Waterproof case WP-001
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	S11	5.0~1.0	90	-
Cardiac Adult	S211	5.0~1.0	90	-
Cardiac Pediatric	S31	9.0~2.0	90	-
Cardiac, TEE	S3ESEL* ³	8.0~2.0	90	-
Intraoperative	S31KP* ⁴	8.0~3.0	90	Puncture Adapter MP-2450 Waterproof case WP-001

RT-3D(4D) probes*

* **EU-9198** and **SOP-ARIETTA65-4** are necessary

Application (description)	Model	Frequency range (MHz)	Scanning angle (degrees)	Optional accessories
Fetal	VC35	8.0~2.0	72	-
Transvaginal	VC41V	8.0~2.0	145	-

Electronic radial probes

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

Bi-plane probe

Application (description)	Model	Frequency range (MHz)	Scanning angle(degrees) / width(mm)	Optional accessories
Transrectal	CC41R	8.0~4.0	100/120	Puncture Adapter EZU-PA5V EZU-PA3U Waterproof case WP-001
Transrectal	CC41R1	10.0~2.0	180/180	Puncture Adapter EZU-PA5V Probe Cover RB-945BP-NS Waterproof case WP-001
Transrectal	CL4416R Convex Linear	10.0~2.0	180	Puncture Adapter BA-001 Probe Cover RB-945BP-NS Waterproof case WP-001
		14.0~2.0	63	
Transrectal	C41L47RP Convex Linear	8.0~4.0	200	Puncture Adapter EZU-PA3U
		10.0~5.0	64	

Independent CW Doppler probes*

* Independent probe connection unit **EU-9198** and **EU-9187B** are necessary

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

*¹ Needle Guide Replacement Kit 610-608(CIVCO) is necessary.

*² One of puncture adapter is necessary to use needle.

*³ Probe cover (CIVCO transducer cover 610-933) is necessary to use S3ESEL

*⁴ One piece of MP-2450 is attached.

Probes and available functions

Convex sector

Function Probe	FmT	WbT	HdTHI	CHI (Low)	CHI (Mid)	CHI (High)	TDI	Panoramic View	Needle Emphasis	Elastography	eFLOW	CW	Compound
C251	✓	✓	✓	-	-	-	✓	✓	-	✓	✓	✓	✓
C253	✓	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓
C35	✓	✓	✓	-	-	-	✓	✓	-	✓	✓	✓	✓
C41	-	-	✓	-	-	-	-	-	-	-	✓	-	✓
C42	✓	✓	✓	-	-	-	-	✓	-	✓	✓	✓	✓
C22K	-	-	✓	-	-	-	-	-	-	-	✓	-	✓
C22P	✓	✓	✓	-	-	-	-	-	-	-	✓	-	✓
C25P	✓	✓	✓	-	-	-	-	-	-	-	✓	-	✓
C42K	-	-	✓	-	-	-	-	-	-	✓	✓	-	✓
C42T	-	-	✓	✓	✓	-	-	-	-	✓	✓	-	✓
C41B	-	-	✓	-	-	-	-	-	-	✓	✓	-	✓
C41V	-	-	✓	-	-	-	-	-	-	✓	✓	-	✓
C41V1	-	-	✓	-	-	-	-	-	-	✓	✓	-	✓
C41RP	-	-	✓	-	-	-	-	-	-	-	✓	-	✓

Linear

Function Probe	FmT	WbT	HdTHI	CHI (Low)	CHI (Mid)	CHI (High)	TDI	Panoramic View	Needle Emphasis	Elastography	eFLOW	CW	Compound	Trapezoid
L441	-	✓	✓	-	-	-	-	✓	✓	✓	✓	✓	✓	✓
L442	-	✓	✓	-	-	-	-	✓	✓	✓	✓	✓	✓	✓
L34	-	✓	✓	-	-	-	-	✓	✓	✓	✓	✓	✓	✓
L55	-	✓	✓	-	-	-	✓	✓	✓	✓	✓	-	✓	✓
L64	-	✓	✓	-	-	-	-	✓	✓	✓	✓	✓	✓	✓
L43K	-	-	✓	✓	✓	-	-	-	-	✓	✓	-	✓	✓
L44K	-	-	✓	✓	✓	-	-	-	-	✓	✓	-	✓	✓
L44LA	-	-	✓	✓	✓	-	-	-	-	✓	✓	-	✓	✓
L46K1	-	-	✓	-	-	-	-	-	-	✓	✓	-	✓	✓
L51K	-	-	✓	-	-	-	-	-	-	✓	✓	-	✓	✓
L53K	-	-	✓	-	-	-	-	-	-	✓	✓	-	✓	✓

Phased array sector

Function Probe	FmT	WbT	HdTHI	CHI (Low)	CHI (Mid)	CHI (High)	TDI	Panoramic View	Elastography	eFLOW	CW	Compound
S11	✓	-	-	-	-	-	✓	-	-	✓	✓	-
S211	✓	-	-	-	-	-	✓	-	-	✓	✓	-
S31	✓	-	-	-	-	-	✓	-	-	✓	✓	-
S3ESEL	-	-	-	-	-	-	✓	-	-	✓	✓	-
S31KP	-	-	-	-	-	-	-	-	-	✓	-	-

RT-3D (4D)

Function Probe	Real-time 3D	Compound	CW	eFLOW	Elastography	Panoramic View	TDI	CHI (High)	CHI (Mid)	CHI (Low)	HdTHI	WbT	FmT
VC35	✓	✓	·	✓	·	·	✓	·	·	·	✓	✓	✓
VC41V	✓	✓	·	✓	✓	·	·	·	·	·	·	✓	✓

Radial

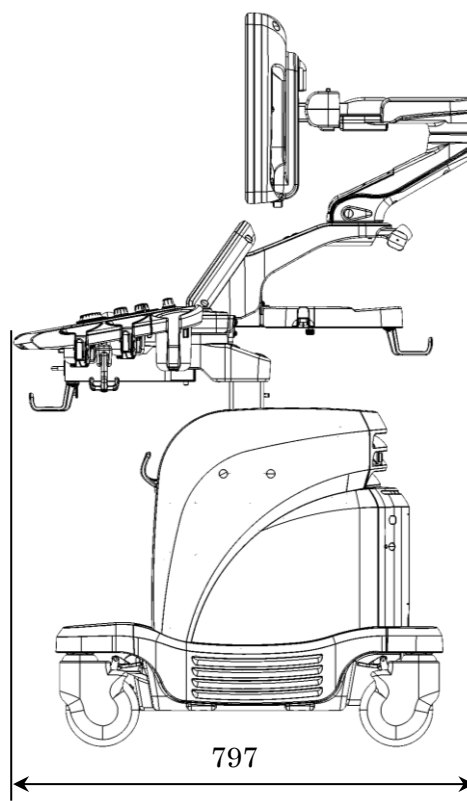
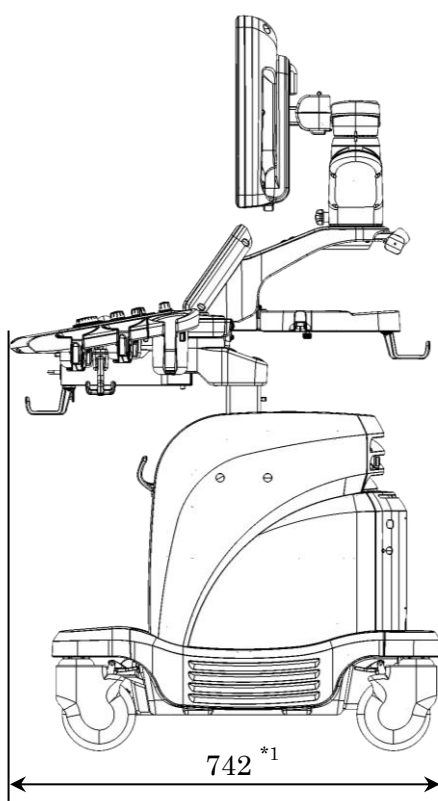
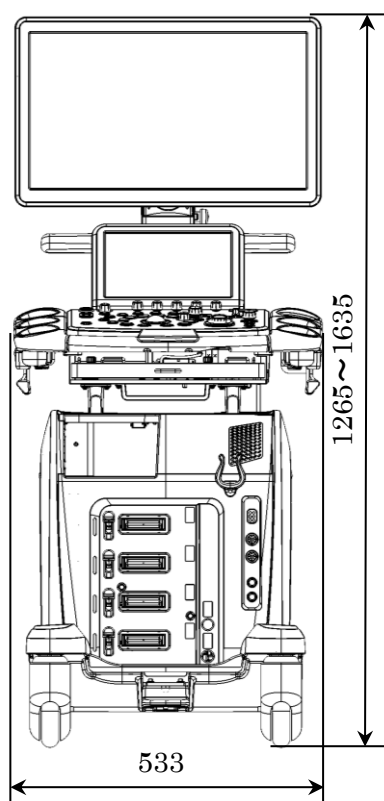
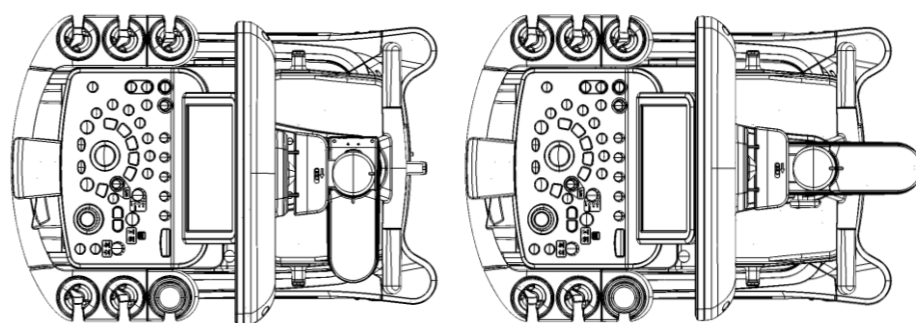
Function Probe	Compound	eFLOW	Elastography	Panoramic View	TDI	CHI (High)	CHI (Mid)	CHI (Low)	HdTHI	WbT	FmT
R41R	·	✓	✓	·	·	·	·	·	·	✓	·

Bi-plane

Function Probe	Realtime BiPlane	Trapezoid	Compound	eFLOW	Elastography	Panoramic View	TDI	CHI (High)	CHI (Mid)	CHI (Low)	HdTHI	WbT	FmT
CC41R	✓	·	·	✓	✓	·	·	·	·	·	·	·	·
CC41R1	✓	·	·	✓	✓	·	·	·	·	·	·	·	·
CL4416R (Convex)		·	✓	✓	✓	·	·	·	·	·	·	·	·
CL4416R (Linear)		✓	✓	✓	✓	✓	·	·	·	·	·	·	·
C41L47RP (Convex)		·	·	✓	✓	·	·	·	·	·	·	·	·
C41L47RP (Linear)		✓	·	✓	✓	✓	·	·	·	·	·	·	·

Independent

Function Probe	Trapezoid	Compound	CW	eFLOW	Elastography	Panoramic View	TDI	CHI (High)	CHI (Mid)	CHI (Low)	HdTHI	WbT	FmT
UST-2265-2	·	·	✓	·	·	·	·	·	·	·	·	·	·



Unit: mm

*1 when the monitor arm is folded

-
- 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.
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Product Service

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



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Product Service

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



T. Matsuda
Takashi Matsuda

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>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc.1/2, Rev.0

**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


Takashi Matsuda

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc.2/2, Rev.0

**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: 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



Date: 2019-12-04


Takashi Matsuda

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

©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/>

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

(*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.

Akio Yamamoto

Name: Akio Yamamoto

Title: CEO

Healthcare Business Unit



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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/>