EFFICIENCY
STRAIGHTAWAY

MyLab™ SIGMA

esaote

EFFICIENCY
STRAIGHTAWAY

MyLab™Sigma is the latest generation portable ultrasound.
It is a smart, portable, multidisciplinary ultrasound unit that allows you to bring ultrasound to where it is needed for a quick and complete diagnosis.
It offers extreme agility thanks to its onboard dual connector (4 with additional trolley multi-connector), and extensive workflow with zero-click automation tool for faster diagnostics.
It includes a unique built-in touchscreen in addition to its rotating and tilting monitor. Its ergonomic and innovative design along with its great transportability further increase daily productivity and diagnostic efficiency.

FAST AND EASY

SWIVELLING
15,6" MONITOR

ZERO-CLICK
AUTOMATION

TWO SOCKET
CONNECTORS

TOUCHSCREEN

EXTENSIVE
CONNECTIVITY

MyLab™ SIGMA

MOBILITY
STRAIGHTAWAY

MyLab™Sigma offers a large variety of mobile solutions to meet any possible need, application, and location.

BATTERY OPERATED

BOOTING TIME LESS THAN 15 SEC*

DEDICATED MOBILE SOLUTIONS

(*) from stand-by mode

MyLab™ SIGMA

CONNECTIVITY
STRAIGHTAWAY

Based on Windows® 10, **MyLab™Sigma** enhances the possibility of sharing the value of information in order to meet today's medical needs.

DICOM CONNECTIVITY
(INCLUDING QUERY/RETRIEVE)

MULTI-MODALITY ARCHIVE

WIRELESS CONNECTIVITY

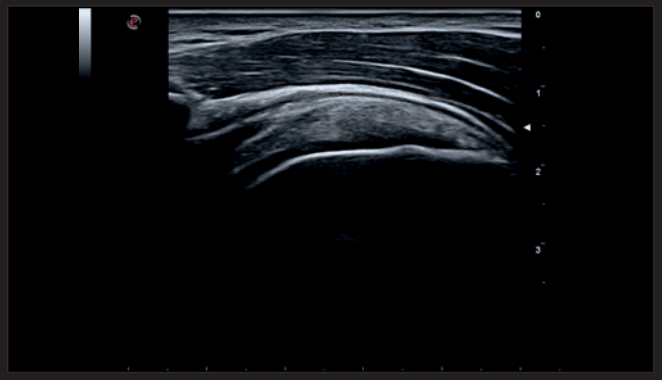
MYLAB™ TABLET

STREAMING

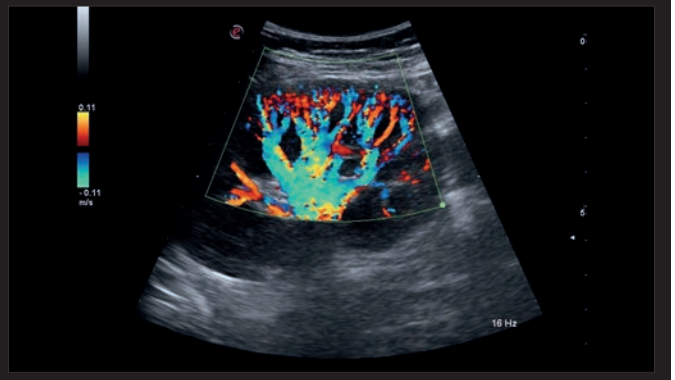
GI

STRAIGHTAWAY

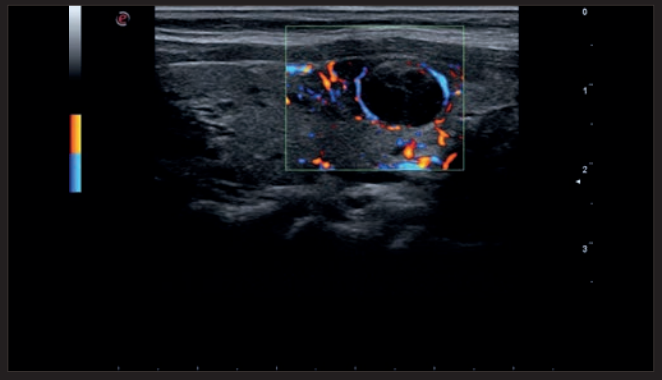
MyLab™Sigma covers all clinical needs, from abdominal to point-of-care applications including special features and technologies such as Full screen, VPan, Needle Visibility and MyLibrary.



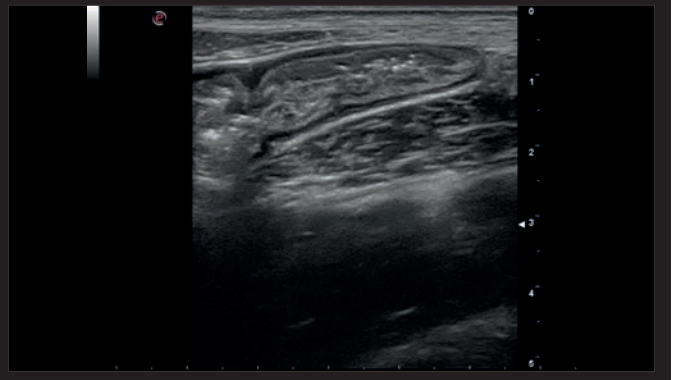
MSK imaging of the shoulder.



Kidney perfusion with high sensitivity Color Doppler mode.



Thyroid lesion, imaging 2D with Color Doppler.



High Frequency Imaging B-mode of Intestine.

WH

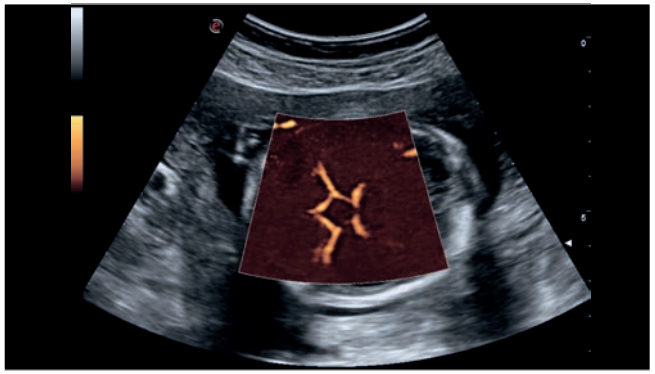
STRAIGHTAWAY

From Obstetric to Gynecology application, **MyLab™Sigma** delivers extraordinary imaging including 3D-4D imaging (convex and endovaginal), AutoNT and full report / graphics.

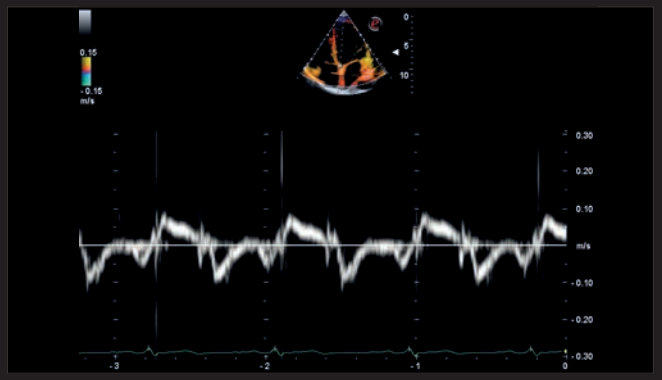
CV

STRAIGHTAWAY

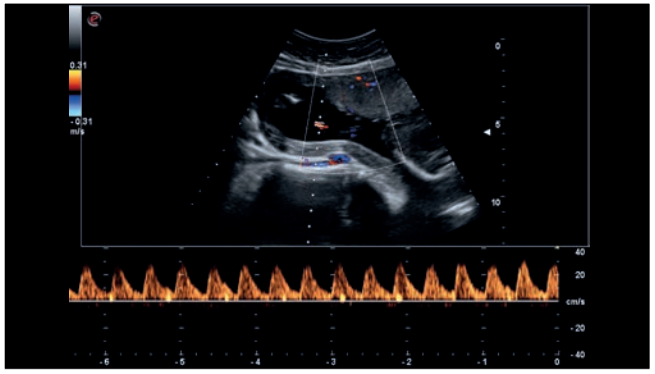
MyLab™Sigma offers cardiac and vascular configurations with extreme added value including Zero-click AutoEF, Anatomical M-mode, Stress Echo analysis, QIMT technologies and dedicated reporting.



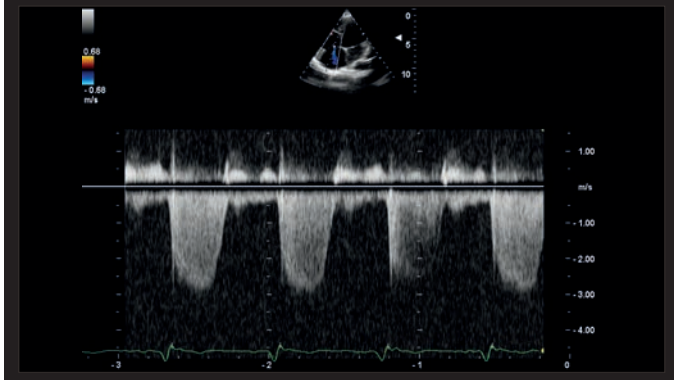
Fetal Willis circle with Power Doppler.



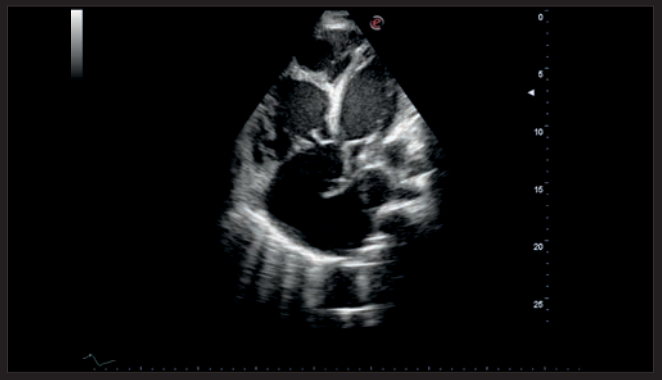
Mitral valve posterior leaflet analysis with Tissue Velocity Mapping.



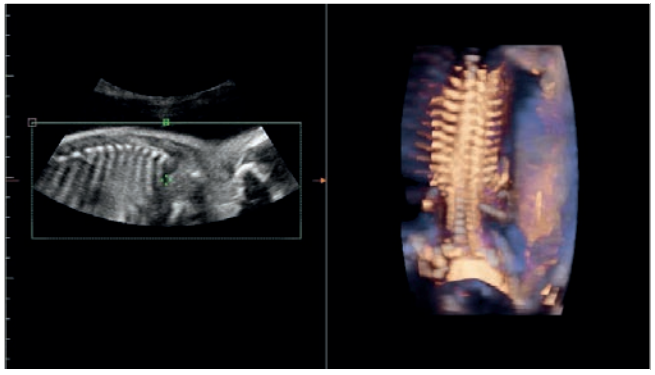
Umbelical cord PW Doppler mode.



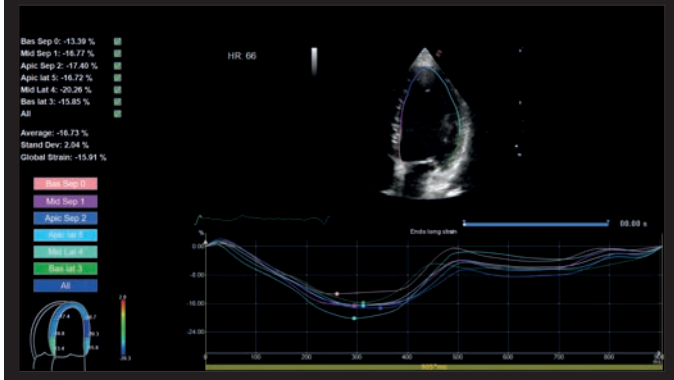
CW Doppler of Tricuspid regurgitation.



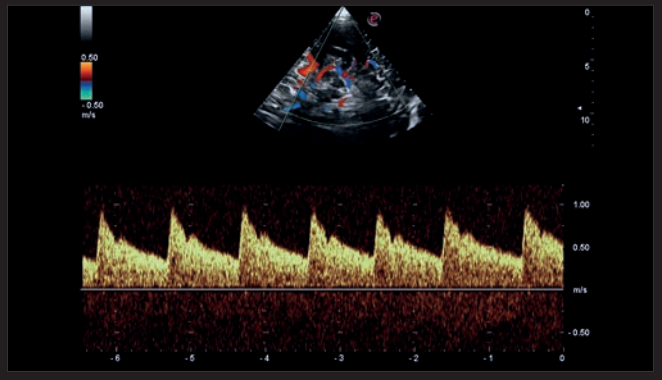
High definition B-mode cardiac imaging.



Semi transparent rendering of fetal spine.



Left Ventricle XStrain 2D analysis.



Mid cerebral artery investigation with PW Doppler mode.

Italian design

160000165MA Ver. 03

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www.esaote.com

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Please visit us online
for more information

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Date 03/2021

performance data sheet

MyLabSigma™

Evo 4.0
Build F100001

Approved by: Giovanni Altobelli

esaote
Creativity in Healthcare

Date 03/2021

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Content

1. Introduction

MyLab™Sigma is the latest generation portable ultrasound. It is a smart, portable, multidisciplinary ultrasound unit that allows you to bring ultrasound to where it is needed for a quick and complete diagnosis.
It offers extreme agility thanks to its onboard dual connector (4 with additional trolley multi-connector), and extensive workflow with zero-click automation tool for faster diagnostics.
It includes a unique built-in touchscreen in addition to its rotating and tilting monitor. Its ergonomic and innovative design along with its great portability further increase daily productivity and diagnostic efficiency.

1.1 Applications

The MyLabSigma ultrasound imaging system has been designed for the following applications:

- Abdominal
- Cephalic (Adult, Neonatal)
- Breast
- Cardiac (Adult)(Pediatric) (Neonatal)
- Gynecology
- Musculoskeletal
- Obstetric
- Pediatric
- Small Parts
- Thyroid
- Intraoperative/Interventional
- Vascular
- General Imaging (Neonatal, Pediatric, Adult)
- Urology

2. System Overview

- Ergonomic and compact cart designed for easy maneuverability
- LCD Main Screen with ±90° rotation
- Multilanguage touch screen keyboard
- 2 active probe connectors
- Integrated cooling system with very silent fans
- Cart with:
  - Four multidirectional wheels with breaking mechanism
  - Easy regulation of the height of the console-keyboard
  - Vertical displacement: ±92 cm
  - On Board location for peripherals storage
  - 3 ports Multiconnector (optional)
  - Movable transducer holders
  - Movable Gel & ECG cable holders
  - Movable Transducer cables supports
  - cart dimensions 47 x 50 x up to 105,5 cm

2.1 Software

- Operating system: Microsoft® Windows 10
- Multilanguage Operation Menus (English, French, German, Italian, Spanish, Portuguese, Russian, Hungarian)
- Reports, calculations and measurements (application dependent)
- Start-up: less than 20s (with batteries)
- Shut-down: around 30s

2.2 Security

- Two account profiles: administrator and users
- Multiple users
- Login by user

2.3 Keyboard

- LEDs Brightness Digital adjustment
- Ergonomic Key Layout
- Ergonomic and adjustable back lighting control panel
- Primary controls easily accessible and logically grouped
- Programmable keys
- eTouch: Macro Recorder
- Trackball with two keys - PC mouse logic
- Dedicated buttons to activate primary modalities:
  - B-Mode
  - M-Mode
  - 3D/4D
  - CFM
  - PW
  - CW
- Direct multifunction knob to activate and control primary modalities:
  - Imaging Gain
  - Doppler Gain
- Dedicated key for
  - System ON/OFF
  - End exam
  - General Setup Menu
  - Archive
  - eTouch
  - Application Measure
  - Generic Measurement
  - Line/Update (in Split modes)
  - Dual Imaging
  - Image/Clip Storage
  - Acquire (for advanced operations)
  - Peripherals remote control
  - AutoAdjust
  - 8 TGC slide controls

Integrated Loudspeakers

2.4 Touch screen

- Capacitive Touch screen
- Resolution: 1024x600px 32bit
- Brightness Digital Adjustment
- Dimension: 19.5x11.8cm (7.7x4.6inch) – Wide Screen 15/9 – 8.9”
- Tools activation
- Physio (ECG signal)
- Exam Review
- Reverse
- Orientation
- Duplex/Triplex (in Split modes)
- XView
- MView
- Gray Map
- High Definition Zoom
- TPView
- Power
- TVM
- Color Map
- CMM
- ADM: Automatic Doppler Measurements
- B-Ref (for Split modes)
- B-Ref/Trace representation format
- Special functions buttons
- 6 direct encoders for Software Keys (up to 2 layers)
- Multilanguage Alphanumeric keyboard (US International, Italian, Danish, Norwegian, French, Swedish, German, Russian)
- Block of Keyboard and Touch Screen for cleanability

2.5 Monitor

- 15,6” 16/9 Wide Screen full HD monitor
- Resolution: 1920x1080 32bit
- Colors: 16.7M
- image area fullscreenmode: 12,9"
- image area standardmode: 9,7"
- Image Resolution
  - Ultrasound Image Matrix: 1120*800
  - Brightness digital adjustment
- Information on Monitor:
  - Application
  - Selected Preset
  - Date and Hour
  - Transducer in Use
  - Transducer Orientation
  - Operating Frequency Range
  - Selected Central Frequency Range
  - Acoustic Power Output
  - Gray Map
  - Dynamic Range
  - Compression
  - Persistence
  - Enhancement
  - XView
  - MView
  - Depth
  - Focus (position/number)
  - Doppler Angle
  - CFM and Spectral Doppler Filter
  - Sample Volume Size and depth
  - Frame Rate
  - PRF
  - Gain 2D, CFM, PW/CW
  - Patient Data
  - Hospital Data
  - Body mark
  - Remote Digital Printing and Storage Status
  - Remote DICOM Storage Status
  - Heart Rate
  - Timer
  - Icons for XView, AutoAdjust, MView, Battery, Peripherals, Media Storage options and Networks
  - sweep time indication on trace

2.6 Image Modes

- B-Mode (2D)
- Colorize 2D, M-Mode and PW/CW
- PW/CW Doppler
- HPRF
- Non Imaging CW
- CFM (Color Doppler)
- Power Doppler
- Directional Power Doppler (VeloPower)
- XFlow
- TEI (Tissue Enhancement Imaging)
- ECG
- Breathing Curve
- CMM (Compass M – Mode)
- TVM (Tissue Velocity Mapping)
- TPView
- MView on linear and convex and microconvex transducers
- VPan (Panoramic View)
- 3D/4D Imaging

<u>2D</u>

- Field of view:
  - 19° ÷ 190° on Convex Array
  - 14° ÷ 89° on Phased Array
  - 16 ÷ 47 mm on Linear Array
  - 3° ÷ 60° on Linear Array with TP-View

(The values above are dependent on the transducer)

- Probe depending formats:
  - Phased Array
  - Linear Array (with steering and TPView)
  - Convex Array
- Depth: 22÷410 mm depending on probe
- Digital scan converter with bilinear interpolation process (860x600x8bits)
- Dynamic Range >250dB
- Digital Processing channel >3.000.000
- Frame rate: up to 1449 Hz

- Maps:
  - up to 10 (customizable) post processing gray maps
  - up to 20 Color Doppler color maps
  - up to 9 Power Doppler color maps
- Zoom:
  - High definition zoom (Real time)
  - Variable magnification from 1.3 up to 20X / 12X (Real time / Frozen image)
  - Navigation window for Zoom Mode
- XView processing:
  - 3 custom algorithms (4 parameters each)
  - Steering (linear probes): up to ±30° with up to 15 step
- Gain and TGC AutoAdjust
- Biopsy kits and display line
- Capability to change gain on freezed images

M-Mode

- Sweep time: 1.7 ÷ 12 sec
- Lines with CMM: up to 3
- Capability to change gain on freezed images. RAW DATA management CMM on archive.

COLOR DOPPLER

- Frequencies: 1.5 ÷ 16.7 MHz
- Sampling PRF: 125 Hz ÷ 23,2KHz
- Wall filters: 5 levels
- Data dynamic: 11 bit (+5 for intensity)
- Frame rate: up to 180 Hz
- Maps: up to 18
- Frame interpolation
- Interleave: up to 32 lines
- Samples: up to 512 lines
- Velocity range CFM 5.35 m/s (SP2730, 1.7MHz)
- Packet size: 4 ÷ 16
- Format: ROI w/wo wider b/w
- Steering (linear probes): up to ±30° with up to 15 step
- HD CFM (up to 4 values of color spatial resolution)
- AutoAdjust

DOPPLER PW

- Frequencies: 1.7 ÷ 16,7MHz
- PRF: 500 Hz ÷ 41.7 KHz
- Multigate HPRF
- Wall filters: 50 ÷ 1200 Hz (10 step)
- Stereophonic audio
- Sweep Time: 1.7 ÷ 12 sec
- Spectrum: FFT with 64, 128 or 256 frequencies, interpolated up to 512 points (analysis time: ≤1 ms)
- Sample Size: 0,5 ÷ 24 mm
- Angle correction : 0° to 90°
- Velocity range PW 19,2 m/s (SP2730, 1.7 MHz)
- Steering (linear probes): up to ±30° with up to 15 step
- Doppler gain, baseline and scale AutoAdjust
- Capability to change Baseline and gain on frozen images
- Smart Doppler with Linear Probes

DOPPLER CW

- Frequencies: 2.0 ÷ 8 MHz
- Wall filters: 40 ÷ 1800 Hz (8 step)
- Stereophonic audio
- Sweep Time 1.7 ÷ 12 sec
- Spectrum: FFT with 64, 128 or 256 frequencies
- Velocity range: up to +/- 6.42 m/s (@ 2.1 MHz)
- Capability to change Baseline and gain on frozen images
- Doppler gain, baseline and scale AutoAdjust

2.7 Image on Display

- 256 gray levels or B-color levels
- Orientation: Left / Right, Up / Down
- Real Time Triplex mode (2D+CFM+PW)
- 2D+2D (w or w/o CFM or PWR_D)
- 2D+M-Mode (update or Real time Duplex)
- 2D+CFM+M-Mode (update)
- 2D+Doppler (update or Real time Duplex)
- 2D+CFM+Doppler (update or Real time Triplex)
- 2D+PWRD/VeloPower
- 2D+PWRD/VeloPower+Doppler (update or Real time Triplex)
- 2D+TVM
- 2D+TV
- 2D+TVM+(M-Mode or PW)
- 2D+TVM+TV
- Colorize on all combinations

2.8 Formats

- Imaging
  - Full / Split / Multiple
  - Full Screen
  - Left-Right / Up-Down
- Tracings
  - Split / Dual (scroll by line)
- CFM – Color On/Off in Freeze
- Quad view format (1 live+3 freezed)

2.9 Beam Former

- Ultrasound beam generation with:
  - Programmable number of cycles
  - Frequencies: up to 22 MHz
- Up to 8 focal zones dynamically controlled
- Up to 15 steering angle dynamically switchable (on frame basis for Linear/Convex Probe)
- CW generation capability
- Programmable ultrasound beam aperture
- TEI

2.10 Calculation and Reports

- Standard Calculation Packages for:
  - Abdomen
  - Breast
  - Cardiology
  - Gynecology
  - Obstetric with programmable tables
  - Pediatric
  - Small Parts
  - Thyroid
  - Transcranial
  - Vascular
- Standard biometry reports & user programmable reports
- AutoNT
- All the reports are automatically stored in the patient file
- Automatic Doppler Measurements (ADM) and profiles (Real Time profiles extraction with Aliasing managing capability; Measurement on automatically detected hearth cycle or on selectable time slot for venous flow; Averaged values on selectable number of measurement; Selection of Full, Negative or Positive range; Add to report capability, Automatic point to point Doppler measurement)
- Refer to Operation Manual

3. Archiving Capabilities

3.1 SAVE feature

- Still image (Full resolution)
- > 3 million of images
- Video clips (Full resolution)
- Doppler Video clips (Full resolution)
- Patient data, Annotations, Bodymarks and Measurement from the graphic overlay
- Reports
- Offline capability

- Pause a study
- Visual comparison (saved images and clips can be compared both with each other and with archived images and clips).
- Compressed images and clips
- Cine Memory: > 4.000 frames
- PC: ≥ 4 GByte
- Local drivers
  - Hard disk: 500 GB
- Internal Patient Database
- Visual comparison with real time images and clips
- User selectable filter for the database search
- Still images and loops storage in DICOM formats
- Real Time Archive capability for still frames and video clips
- Stored data thumbnails always displayed on two columns on the right side of the screen
- IHE Compliant
- Annotation/Bodymark/Measurements capability on previously stored images
- Possibility to share and review system archive from an external device (MylabTablet license is needed)

3.2 Data export

- Image formats:
  - Standard output file formats (BMP, PNG, JPEG)
  - Native format
  - DICOM format, compressed (lossy, lossless) and uncompressed
- Clips formats:
  - AVI Codec: Microsoft® MPEG4-V2 and Microsoft® -Video1
  - Native format
  - DICOM format, compressed (lossy) and uncompressed
- Patient data, Annotations, Bodymarks and Measurements from the graphic overlays
- Reports in PDF and XLM

3.3 Connectivity

- Compatibility with External 5T USB Hard disk
- I/Os connectors
  - LAN RJ45
  - 4 USB:
- Dedicated connectors
  - Audio input/output (stereo): dedicated port for headset with microphone
  - ECG input
- Wi-Fi (optional)

3.4 DICOM Connectivity

MyLabSigma system supports the following DICOM service classes:

- Verification service class as the SCU and SCP
- Modality Worklist management service class in the role of SCU
- Modality Performed Procedure Step (MPPS) class in the role of SCU
- Storage service class as a SCU
- Storage Commitment service class as SCU
- DICOM Print SCU
- DICOM Query retrieve SCU (multimodality)

Verification Service Class
As the SCU for the Verification SOP class, the system allows the user to test the availability of remote DICOM nodes from the DICOM configuration pages
As the SCP for the Verification SOP class, the system answers to verification requests coming in from remote DICOM nodes (when Storage Commitment is active)

Modality Worklist Management Service Class
As the SCU for the Modality Worklist management SOP class, the system allows for querying the Information System obtaining

information about scheduled exams and patient demographics

Modality Performed Procedure Step (MPPS)
As the SCU for the Modality Performed Procedure Step SOP class, the system automatically updates systems involved in the echocardiography workflow (CIS, PACS) about the status of the study

Storage Service Class
As the SCU for the Storage service class, the system supports transferring objects of the following SOP classes to remote DICOM nodes (PACSs):

- DICOM Ultrasound Image storage SOP class for transfer of 2D single frame images either uncompressed or using lossless or lossy image compression
- DICOM Ultrasound Multi-Frame Image Storage SOP class for the transfer of 2D clips using lossy image compression
- DICOM Secondary Capture Image Storage SOP class for the for measurement information in a human readable format
- DICOM Comprehensive Structured Report Storage SOP class using the Adult Echocardiography Procedure Report template (TID 5200), the Vascular Ultrasound Procedure Report template (TID 5100) and the OB-GYN Ultrasound Procedure Report template (TID 5000) for the transfer of measurement information about Cardiac, Vascular, Abdominal (as an extension of the TID 5100) and Ob-Gyn exams
- The system allows for the following storage modes:
  - “End of exam”, the system automatically stores all image and measurement data in the background once the study has been closed
  - “on the fly”, the system immediately stores all the acquired images
  - “Manual Image by image”, the user can store a single image while viewing it
  - “Manual”, the system stores multiple exams as selected by the user in the background

Storage Commitment Service Class
As the SCU of the Storage Commitment service class, the system automatically requests the archive to take responsibility for the safekeeping of data that were stored using the above mentioned storage classes
Query/Retrieve Service Class
As the SCU of the Query/Retrieve service class, the system can query an archive and retrieve studies for reviewing them
For more details on all the provided DICOM services, please refer to the updated version of the DICOM Conformance Statement present in the Esaote website (www.esaote.com).

3.5 IHE Compliance

Integrating the Healthcare Enterprise (IHE) is an initiative by the healthcare industry and professionals to improve the way computer systems in healthcare share information.

IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care. System developed in accordance with IHE communicate with one another better, are easier to implement and enable care providers to use information more effectively.

MyLabSigma complies with the following IHE profiles:

- Scheduled Workflow,

- Echocardiography Workflow integrates ordering, scheduling, imaging acquisition, storage and viewing for digital echocardiography

- Cardiology Evidence Documents adds cardiology specific options to the Radiology ED profiles (specifies how data objects such as digital measurements are created, exchanged, and used)

- Portable Data for Imaging

- Patient Information Reconciliation

For more details, please refer to the updated version of the IHE Integration Statement available on the Esaote website (www.esaote.com).

3.6 Printing Capability

- Ink jet color and Laser-Color printers, 1, 2, 4, 6 and 9 images printed out on A4 format
- Thermal Digital B/W and Color Printers

3.7 MyLab Desk evo

Dedicated software (not for diagnostic use) for review, post-process and printing of exams performed with a MyLab™ ultrasound system on a PC Workstation working with Windows 10 Operative Systems.

- User interface extremely similar to the MyLabSigma user interface for convenience
- To import native Esaote file format
- To perform generic measurements
- For reviewing, modifying and printing the examinations (images)
- To export the data by using the standard features of the PC (burn on a CD/DVD, archiving on the local HDD or store on an USB key in standard PC formats, transfer to e-mail, etc.)

3.8 MyLab Tablet

Mobile application which allows to remotely review images for non-diagnostic purpose on Tablet or mobile.

3.9 MyLab Remote*

Real-time image visualization and possibility to remotely control the system from mobile device. An adaptive layout has been implemented to reach the maximum confort at any resolution and screen size.

*(licence code 340065100)

4. Generic Measurements

The tables below list the measurements available in each/application mode (configurable and depending on the application.)

4.1 B-Mode

Parameter	Measurement	Displayed results
Distance	Distance	Distance
Distance ratio	Distance1, Distance2	Distance1, Distance2, Distance1/Distance2
% Distance reduction	Distance1, Distance2	Distance 1, Distance 2, (Distance1 - Distance2)/Distance1
Length (Vertex)	More distances	Global distance
Length (Trace)	Profile	Global distance
Area (Ellipse axes)	Area, Distance	Area, Perimeter

Parameter	Measurement	Displayed results
Area (Vertex)	More distances	Area, Perimeter
Area (Trace)	Profile	Area, Perimeter
Area ratio	Area1, Area2	Area1, Area2, Area1/ Area2
% Area reduction	Area1, Area2	Area1, Area 2, (Area 1 - Area 2)/Area1
Volume (Ellipse)	Distance, Area	Area, Volume
Volume (Trace)	Profile, Distance	Area, Distance, Volume
Biplane volume	Distance1, Distance2, Distance3	Distance1, Distance2, Distance3, Volume
Ellipse ratio	Two areas (ellipse based)	Two areas, Area1/Area2
Hip angle	Distance1, Distance2, Distance3	α and β angles

4.2 M-Mode

Parameter	Measurement	Displayed results
Distance	Distance	Distance
Distance ratio	Distance1, Distance2	Distance1, Distance2, Distance1/Distance2
Time	Time	Time
Time ratio	Time1, Time2	Time1, Time 2, Time 1/Time 2
Heart Rate	Time	R-R interval, Heart rate
Velocity	Velocity	Distance, Time, Velocity
Velocity ratio	Velocity1, Velocity2	Velocity1, Velocity2, Velocity1/Velocity2

4.3 Doppler

Parameter	Measurement	Displayed results
Time	Time	Time
Time ratio	Time1, Time2	Time1, Time2, Time1/Time2
Velocity	Velocity	Instantaneous velocity
Cardiac Velocity	Velocity	Instantaneous velocity, Instantaneous gradient
Velocity ratio	Velocity1, Velocity2	Velocity1, Velocity2, Velocity1/Velocity2
Heart Rate	Time	R-R interval, Heart rate

Parameter	Measurement	Displayed results
Systolic velocity /Diastolic velocity	Systolic velocity, Diastolic velocity	Systolic velocity, Diastolic velocity, Systolic velocity/Diastolic velocity
Cardiac FVI	Spectral envelope	FVI, Peak velocity, Reverse velocity, Peak and mean gradient
Vascular FVI	Spectral envelope	FVI, Pulsatility index, Resistive index, Reverse velocity, Diastolic velocity, Peak and mean velocity, Peak and mean gradient, Acceleration, Acceleration time, Systolic velocity/Diastolic velocity
Pulsatility index	Spectral envelope	FVI, Pulsatility index, Resistive index, Reverse velocity, Peak and mean velocity, Diastolic velocity
Resistive index	Systolic velocity, Diastolic velocity	Peak systolic velocity, Diastolic velocity, Resistive index
Flow (Trace)	Envelope, Contour	Time average velocity, Area, Volume,
Flow (Ellipse)	Envelope, Ellipse	Time average velocity, Area, Volume,
Flow (Diameter)	Envelope, Distance	Time average velocity, Diameter, Area, Volume
Slope	Velocity	Acceleration, PHT

4.4 Advanced Measurements

Refer to the Advanced Operations Manual for further information.

4.5 Custom Measurements

Refer to the Advanced Operations Manual for further information.

5. System Feature

5.1 TEI

TEI is using Harmonic Imaging technology that includes pulse inversion capability.
TEI (Tissue Enhancement Imaging) increases the signal-to-noise ratio and further enhances contrast resolution allowing the visualization of a high level of detail, even in difficult-to-scan patients.
The superb contrast and detailed resolution of TEI technology is based on the information always present in returning echoes.

- Touch Screen access and quick response time
- Available in combination with CFM, M-Mode, Power/VeloPower Doppler, TVM

5.2 MView

MView consists in an ultrasound technique which applies beam-line steering and acquire several coplanar scans of an object from different view angles.

- Improved images quality by reducing the presence of artefacts, shadowing and speckle
- Available with all linear and convex/microconvex transducers.
- Up to 15 lines

5.3 XView

XView elaborates the pattern of every single frame at the pixel level, eliminating speckle and noise artifacts, dynamically enhancing tissue margins, improving tissue conspicuity and increasing diagnostic confidence through real-time adaptive algorithm.

- Adaptive - During acquisition, XView uses different techniques in order to produce as little speckle as possible.
- Optimized - XView removes speckle, while the information necessary for the diagnostic image is preserved and enhanced

5.4 AutoAdjust

AutoAdjust enables the automatic adjustment of Imaging, CFM and Doppler parameters at the press of a button.

5.5 TPView

TPView enlarges the field-of-view without losing resolution and extending structures in breast, vascular and musculoskeletal applications.

- Max FOV 60°
- Specially studied for breast, thyroid and vascular applications
- Available on all linear transducers

5.6 VPan

VPan (Panoramic Imaging) merges multiple B-Mode images in one complete panoramic image extending the field-of-view to entire organs.

- Auto fit of composite image
- Image Zoom
- Merging Level – realigning
- Frame marker
- Colorize
- Distance measurement
- VPAN measurement capability > 60 cm
- Images can be saved to the patient's file
- CFM capability
- Rotation/Pan/Zoom

5.7 Directional Power Doppler (VeloPower)

- VeloPower - Directional Power Doppler
- Automatic algorithm for noise rejection
- Five VeloPower maps
- Analysis: Autocorrelation with use 8/16 selectable samples
- Frequency: User selectable from 2MHz up to 16.7MHz
- PRF: 125Hz up to 25KHz
- Motion Discrimination Filter: 3 levels (Min – Med – Max)
- Processing Parameters:
  - Persistence: 10 Levels
  - Smoothing: Low, Med & Max
  - Moving Artifact Suppression: 5 levels
  - Gain: 0 to 255
- Post Processing Parameters:
  - Correlation
  - Rejection
  - Saturation
  - Grey Maps
- Electronic Steering (LA Transducers ±30°)
  - Read and scrolling Pan Zoom with user adjustable ROI (max. magnification factor 8x)
- Information on monitor:
  - Selected Frequency
  - PRF and HPRF
  - Color Map
  - Filter
  - Gain

5.8 XFlow

XFlow technology provides extraordinary flow sensitivity and spatial resolution. XFlow gives direct visualization of blood echoes, extending the wideband resolution, high frame rate and wide dynamic range of blood flow. High sensitivity in detecting slow flow.

5.9 Bi-rads, Ti-rads

- Breast and Thyroid lesion scoring following American College of Radiology indications
- Ti-Rads: scoring is determined from five categories, higher the cumulative score is, higher the TR level and likelihood of malignancy
- Bi-Rads: The Breast Imaging Reporting and Data System (BI-RADS®) is a standardized system of reporting breast pathology as seen on mammogram, ultrasound, and magnetic resonance imaging. It encourages consistency between reports and facilitates clear communication between the radiologist and other physicians by providing a lexicon of descriptors, a reporting structure that relates assessment categories to management recommendations, and a framework for data collection and auditing. The reporting can be performed directly on the touch screen (with the aid of the displayed nodule on the screen) or from the worksheet.

6. System Options

6.1 Needle Enhancement

Esaote's Needle Enhancement Technology makes the needle especially visible during angled needle insertions for different clinical procedures.

Esaote's advanced detection and visualization technology makes the needle clearly distinguishable from the surrounding tissues while maintaining top image quality of the target.

6.2 QIMT

The QIMT (Quality Intima Media Thickness) calculation automatically measures the Carotid Intima-media thickness in real-time, using radio frequency signal. The calculated value is displayed on a graph including patient's expected values:

- Direct analysis of the radiofrequency signal
- Standard deviation real time visualization
- Add to report capability
- Dedicated report with graph

6.3 Auto NT

Automatic detection of nuchal translucency

6.4 Auto IT (Intracranial Translucency)

The fourth ventricle presents as an intracranial translucency (IT)
between the brain stem and the choroid plexus. In the same mid-sagittal
view of the fetal face as used for measurement of NT and assessment of
the nasal bone is also used for early detection of open spina bifida.

6.5 Auto OB

Automatic biometric softwar provides a precise automatic placement of the measure calipers involved in the particular measurement leaving the end user the last step to minor fine tuning and confirmation.
Automatic Biometry is available for the following measures:

- Head Circumference
- Biparietal Diameter (outer-inner / outer-outer)
- Abdominal Circumference
- Femur Length

Each measure can be configured as manual / automatic in the measure Editor.

6.6 3D/4D

- Volumetric transducers management
- Bi-Scan probes management
- Volume data acquisition
- Volume rendering reconstruction
- Real time modality (4D)
- Volume Rate: 40 volumes/second
- Depth Color Algorithm to improve 3D depth effect
- Multiplan sections with rotating planes
- Multiple tomographic slices
- Grey map on volume and slices for contrast improvement
- Measurement on bi-dimensional slices
- VRA
- 3D color
- 3D Freehand
- XGlass : trasparency/gradient algorithm able to highlight the areas where there is a change in the ultrasound impedence.
  This technique is aimed to make the internal fetal structures, and the different organs surfaces visible inside the volume
  New Opacity curves are available to determine the best Transparency effect, even in combination of the Bmode Settings used for the acquisition.

6.7 TVM

TVM (Tissue Velocity Mapping) provides a complete Wall Motion Analysis for both systolic and diastolic myocardial function evaluation.

- TVM displays color coded information on moving tissue in velocity mode. The Velocity mode displays velocity distribution of moving myocardial tissue
- TVM can operate in
  - 2D imaging/TVM
  - M–Mode/MTVM
  - PW/Doppler/TV
  - Factory and user programmable presets for TVM
  - Requires the cardio module
  - Available on the SP2730, P2 3-11 and Transesophageal transducer ST2612

6.8 CMM

CMM (Compass M-Mode) allows to improve the M-Mode visibility during cardiac exams and acquire all information even in hard-to-scan situations with particular or difficult heart positioning.

- Up to three independent lines in real time

6.9 XStrain

XStrain allows physician to estimate and quantify endocardial velocities of contraction and relaxation, and estimate and quantify local deformation of the heart.

- Extensive potential applications.
- Innovation and non-invasiveness
- Angle-independent technology
- User-friendly interface
- Intuitive workflow
- Comprehensive measurement possibilities

6.10 Stress-Echo

Stress-Echo provides a dedicated report template for a complete wall motion score and ejection fraction reporting, which allow the evaluation of any cardiac segment.

- Real Time 2D loops digitally synchronized with the ECG trace
- User-programmable protocols
- Multi-format reviewing capabilities for accurate monitoring of cardiovascular pathologies.
- Loop comparison

- Continuous capture

6.11 AutoEF

AutoEF, “zero click” function performs the Automatic Ejection Fraction computation. This simplified tool provides border tracking estimation, and plots LV Volume over Time: Vd (Diastolic Volume), Vs (Systolic Volume), and EF (Ejection Fraction)

6.12 MyLibrary

- Dedicated Library for Rheuma, Vascular, Regional Anaestesia, MSK and emergency market.
- Live Preview feature allows to scan in real-time while using anatomical references and scanning guidance

6.13 Lung Ultrasound Protocol

Based on 14 points of degmentation, this tool provide the help needs during lung investigation. The software is driving the operator during the acqusition, helping to have a complete and clear study. The sw is also providing the possibility to score (from 0 to 3) each single point and it provide a complete report of the lung sitution.

7. Transducers

7.1 Transducer Types

- Multifrequency Electronic Convex Array
- Multifrequency Electronic Volumetric Convex Array
- Multifrequency Electronic Linear Array
- Multifrequency Electronic Phased Array
- Multifrequency Electronic End-Fire Endocavity
- Multifrequency Electronic bi-plane for transrectal exams
- Multifrequency Electronic Volumetric End-Fire Array
- Pencil CW/PW

7.2 Transducers Technical Specifications

AC2541

- Type: Convex
- Technology: Wideband Electronic Array
- Operating Bandwidth: 1-8 MHz
- Max Field of view: 17° - 63°
- Radius of Curvature: 50 mm
- Footprint: 65x19mm
- Depth: 50- 414 mm
- B-M Frequencies: PEN-H, PEN-L, RES-H, GEN-M,
- TEI-MTEI Frequencies: PEN-H,PEN-L, GEN-M, RES-H
- CFM–PW Frequencies: 1.8, 2.0, 2.5, 3.3 MHz
- CW: Not Available
- Steered Angle: Not Available
- Biopsy: 15°, 25°, 35°
- Weight: 95 g transducer head excluding cable and connector; 520 g complete transducer
- Dimensions: 101,4x66,7x34,7 mm

SC3421

- Operating Bandwidth: 2 – 8MHz
- R 40
- Max Depth: 47 - 357mm

- Field of view: 20° - 86°
- B-M Modes Frequencies: RES – H; GEN – M; GEN – L; PEN - H
- TEI Frequencies: RES – H; GEN – M; GEN – L; PEN – H for CrystaLine model: CPI –P, CPI- G, CPI - R
- CFM–PW Frequencies: 1.8 -2.0 – 2.5 – 3.3 MHz

SI2C41

- Type: convex with 0° biopsy groove
- Technology: Wideband Electronic Convex Array
- Operating Bandwidth: 1-8MHz
- Max Field of view: 20° - 63°
- Radius of Curvature: 50mm
- Footprint: 68x23mm
- Depth: 50-357mm
- B-M Mode Frequencies: PEN-H, PEN-L, GEN-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-M, PEN-L, GEN-L, RES-L
- CFM–PW Frequencies: 1.8, 2.0, 2.5, 3.3 MHz
- CW: Not Available
- Steered Angle: Not Available
- Biopsy: 0°, 5°, 15°
- Weight: 95g transducer head excluding cable and connector; 520g complete transducer
- Dimensions: 67x50x110 mm

SB2C41

- Type: Volumetric Convex
- Technology: Volumetric Wideband Electronic Convex
- Operative Bandwidth: 1–8MHz
- Max Field of view: 8° - 82°
- Radius of curvature: 40mm
- Footprint: 68x23mm
- Depth: 46-343mm
- B-Mode Frequencies: PEN–H, PEN-L, GEN-M, RES-L, RES-H
- TEI-MTEI Frequencies: PEN–H, PEN-L, GEN-M, RES-L,RES-H
- CFM-PW Frequencies: 2.4 – 2.8 – 3.3 – 3.8 MHz
- CW: Not Available
- Steered Angle: Not Available
- Biopsy: not Available
- Weight: 190 g transducer head excluding cable and system connector, 640 g transducer complete
- Dimensions: 67x50x110mm

SC3123

- Type: Microconvex
- Technology: Wideband Electronic Microconvex
- Operating Bandwidth: 4–9 MHz
- Max Field of view:42° - 91°
- Radius of Curvature: 14°
- Footprint: 11 x 25 mm
- Depth: 186 mm
- B-Mode Frequencies: PEN-H, GEN-L, GEN-M, RIS-L, RES-H
- TEI Frequencies: PEN-H, PEN-L, GEN-M, RIS-H
- CFM Frequencies: 4.2 – 4.5 – 5.0 – 6.3 MHz
- PW Frequencies: 4.2 – 4.5 – 5.0 – 6.3 MHz
- Weight: 45 g transducer head excluding cable and system connector, 245 g transducer complete
- Dimensions: 88 x 31 x 27mm

mC 3-11

- Type: Microconvex
- Technology: Wideband Electronic Microconvex
- Operating Bandwidth: 3–11 MHz
- Field of view: 20° - 94°
- Radius of Curvature: 10°

- Footprint: 11 x 25 mm
- Max Depth: 186 mm
- B-M Modes Frequencies: PEN-H, PEN-M, PEN-L, GEN-L, GEN-M, RES-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-M, PEN-L, GEN-L, RES-L, RES-M
- CFM–PW Frequencies: 4.2, 5, 5.6, 6.3, 7.1 MHz
- Weight: 45 g transducer head excluding cable and system connector, 390 g transducer complete
- CW: Not Available
- 2D-CnTi Frequencies: PEN-H, PEN-M, GEN-M, RES-M
- Steered Angle: not available
- Tilt: from -37° to 37°
- Biopsy: 20°, 35°
- Dimensions: 31x27x88 mm

L 4-15

- Type: Linear
- Technology: Wideband Electronic Linear Array
- Operative Bandwidth: 4-15MHz
- Max field of view: 16-46 mm (3°-36° Tp-View)
- Footprint: 52x10mm
- Max Depth:22-103 mm
- B-M Modes Frequencies: PEN-H, PEN-M, PEN-L, GEN-L, GEN-M, RES-L, RES-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-L, GEN-L, RES-L, RES-H
- CFM–PW Frequencies: 4.2, 4.5, 5.0, 5.6, 6.3, 7.1, 8.3 MHz
- CW: Not Available
- Steered Angle: Maximum 21° (in Color mode)
- Biopsy: 40°, 60°
- Weight: 120 g transducer head excluding cable and connector, 475 g complete transducer
- Dimension: 88,5x58,1x27,2 mm

L 3-11

- Type: Linear
- Technology: Wideband Electronic Linear Array
- Operating Bandwidth: 3-11 MHz
- Max Field of view: 9-39 mm (6°-60° Tp-View)
- Footprint: 49x12 mm
- Depth: 22-177 mm
- B-M Modes Frequencies: PEN-H, PEN-L, GEN-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-L, GEN-L, RES-L, RES-M, RES-H
- CFM–PW Frequencies: 2.5, 3.3, 4,2, 5.0 MHz
- CW: Not Available
- Steered Angle: Maximum 28° (in Color mode)
- Biopsy: 25°, 30°, 50°
- Weight: 120 g transducer head excluding cable and system connector; 470 g complete transducer
- Dimension: 93x51x28 mm

SL2325

- Bandwidth: 6 – 19 MHz
- Depth: 15-103 mm
- Field of view: TP view 4°-36°
- B-Mode Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- TEI Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- CFM Frequencies: 6.3 – 8.3 – 10.0 – 12.5 MHz
- PW Frequencies: 6.3 – 8.3 – 10.0 – 12.5 MHz
- Steering angles: 7 steps
- Ωειγητ: 100 γ τρανσδυχερ ηεαδ εξχλυδινγ χαβλε ανδ χοννεχτορ, 470 γ χομπλετε προ βε
- Dimensions: 105 x 56.4 x 25.8 mm
- Biopsy angles: 45°/50°/60°/70°

SL3235

- Bandwidth: 6 – 18 MHz
- Depth: 15-103 mm
- Field of view: 28 mm (TP view 5°-36°)
- B-Mode Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- TEI Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- CFM Frequencies: 6.3 – 8.3 – 10.0 – 12.5 MHz
- PW Frequencies: 6.3 – 8.3 – 10.0 – 12.5 MHz
- Steering angles: 7 steps
- Weight: 100 g
- Footprint: 28 x 6.5 mm

SL3323

- Bandwidth: 3 – 13 MHz
- Depth: 22- 103 mm
- Field of view: 33 mm (TP view 9°-54°)
- B-Mode Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- TEI Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- CFM Frequencies: 4.2 - 5.0 - 6.3 - 7.1 MHz
- PW Frequencies: 4.2 - 5.0 - 6.3 - 7.1 MHz
- Steering angles: 7 steps
- Weight: 100 g

SL3332

- Operating Bandwidth: 3 – 11MHz
- Depth: 22- 177mm
- Field of view: 33 mm (TP view 11°-80°)
- B-M Modes Frequencies: RES – H, GEN – M, PEN – L, PEN - H
- TEI Frequencies: RES – H, GEN – M, PEN – L, PEN - H
- CFM–PW Frequencies: 2.5 – 3.3. – 4.2 – 5.0 MHz
- Steered angles: 7 angles

SL3116 22MHz

- Operating Bandwidth: 10 – 22 MHz
- Depth: Linear 15 mm- 44 mm
- Field of view: Linear 13 mm(TP view 8°-80°)
- Steering angles (Linear array): 7 steps
- B-M Modes Frequencies: PEN-H, PEN-L, GEN-M, RES-H
- TEI Frequencies: PEN-H, PEN-L, GEN-M, RIS-H
- CFM Frequencies: 10 -12,5 -16,7 MHz
- PW Frequencies: 10 -12,5 -16,7 MHz
- Footprint: 28 x 6,5 mm
- Weight: 435 gr complete probe

IH 6-18

- Type: linear – hockey stick
- Technology: Wideband Electronic Linear Array
- Operating Bandwidth: 6-18 MHz
- Footprint: 32x5 mm
- Depth: 15-103 mm
- Field of view: 18-28 mm (4°- 36° Tp-View)
- B-M Modes Frequencies: PEN-H, PEN-L, GEN-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-L, GEN-M, RES-H
- CFM Frequencies: 8.3, 10, 12.5, 16.7 MHz, PW Frequencies: 8.3, 10, 12.5, 16,7 MHz
- CW: Not Available
- Steered Angle: Maximum 21° (in Color mode)
- Biopsy: Not available
- Weight: 90 g transducer head excluding cable and system connector; 410 g complete transducer
- Dimension: 5 x 32 x118 mm

LP 4-13

- Application: Laparoscopic
- Technology: Wideband Electronic Linear Array

- Depth: 22– 103 mm
- Operating Bandwidth: 4-13 MHz
- B-M Modes Frequencies: Pen H, Pen L, Gen M, Res H
- TEI Frequencies: Pen H, Pen L, Gen M, Res H
- CFM–PW Frequencies: 5.0, 5,6, 6.3, 7,1 MHz
- Field of view: 17-35 (6°-40° TP-View)
- Articulation ± up/down 90°
- Articulation ± right/left 90°
- Biopsy: Not Available
- Weight: 620 gr complete probe

IL 4-13

- Application: Intraoperative
- Technology: Wideband Electronic Linear Array
- Depth: 22– 103 mm
- Footprint: 30mm
- Operating Bandwidth: 4-13 MHz
- Field of view: 17-35 (6°-40° TP-View)
- B-M Modes Frequencies: Pen H, Pen L, Gen M, Res H
- TEI Frequencies: Pen H, Pen L, Gen M, Res H
- CFM–PW Frequencies: 5.0,5.6,6.3,7.1 MHz
- Biopsy: Multi angle reusable autoclave sterilised adaptor
- Weight 320 gr complete probe

SP2730

- Operating Bandwidth: 1 – 4MHz
- Depth: 44-349mm
- Field of view: 16° - 87°
- Footprint: 19x25 mm
- Max Depth: 356 mm
- B-M Modes Frequencies: PEN–H, PEN– L, GEN–M, RES-H
- TEI Frequencies: PEN–H, PEN– L, GEN– M, RES-H
- CFM–PW Frequencies:1.7, 2.0 ,2.5 MHz
- CW Frequencies: 2.1 - 2.5 MHz
- Steered Angle: Not Available
- Biopsy: Not Available
- Weight: 85g transducer head excluding cable and system connector; 825g complete transducer
- Dimensions: 80.5 x 34.2 x 27.7 mm

P2 3-11

- Bandwidth: 2,6 – 11 MHz
- Depth: 44-296 mm
- Field of view: 18° - 90°
- B-Mode Frequencies: PEN–H,PEN–L, GEN-M, RES L, RES-H
- TEI Frequencies: PEN–H,PEN–L, GEN-M, RES L, RES-H
- CFM Frequencies: 2.8 – 3.6 – 4.2 MHz
- PW Frequencies: 2.8 – 3.6 – 4.2 MHz
- CW Frequencies: 3.6 – 5.0 MHz
- Weight: 96 g

ST2612

- Application: Transesophageal Adult
- Bandwidth: 3 – 7 MHz
- Depth:22-177 mm
- Field of view: 18° - 90°
- B-Mode Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- TEI Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- CFM Frequencies: 3.3 – 3.6 – 3.8 MHz
- PW Frequencies: 3.3 – 3.6 – 3.8 MHz
- CW Frequencies: 3.6 – 5.0 MHz
- Weight: 1500 g
- Dimensions:1100x14x12 mm Endoscope length 110 cm, endoscope diameter 10.5 mm

SB3123

- Type: Volumetric - Microconvex

- Technology: Wideband Electronic endfire microConvex
- Operating Bandwidth: 3 – 9 MHz
- Field of view: 50° - 151°
- Footprint: 25x25 mm
- Depth: 27-159 mm
- B-Mode Frequencies: PEN–H, GEN-L, GEN-M, RES-L
- TEI Frequencies: PEN–H, PEN-L, GEN-M, RES-H
- CFM-pw Frequencies: 4.2 – 5.0 – 6.3 -7.1 MHz
- Steered Angle: not available
- Tilt: from -84° to 84°
- Biopsy: Not Available
- Weight: 300 g transducer head excluding cable and system connector; 660 g complete transducer
- Dimension: 306 x 36 x 50 mm

SE3133

- Technology: Wideband Electronic end fire Microconvex
- Operating Bandwidth: 3 – 10 MHz
- Depth:23-156 mm
- Field of view: 50° - 200°
- B-M Modes Frequencies: PEN–H, PEN–L, GEN–M; RES-L
- TEI Frequencies: RES – M, GEN – M, PEN – L, PEN - M
- CFM–PW Frequencies: 3.8 – 4.2 – 5.0 – 5.6 MHz
- Radius of curvature: 10 mm
- Weight: 195 g transducer head excluding cable and connector, 565 g complete transducer
- Dimensions: 48 x 304.8 x 31.8 mm
- Biopsy angles: 0°/3.8

TLC 3-13

- Type: Linear/Convex Transrectal
- Operating Bandwidth: Convex 3-9 MHz; Linear 4-13 MHz
- Technology: Biplane Wideband Electronic Linear-Convex Array
- Field of view: Convex 48°-199°; Linear 15-58mm (4°-36° Tp-View)
- Tip size: 20.2 mm
- Depth: Convex 17-162 mm; Linear 15-118 mm
- B-M Frequencies: PEN-H, PEN-L, GEN-M, RES-H
- TEI-MTEI Frequencies: Convex PEN-H, PEN-M, PEN-L, GEN-L, GEN-M, RES-L, RES-M, RES-H
- Linear PEN-H, PEN-L, GEN-L, GEN-M, RES-H
- CFM–PW Frequencies: Convex 3.8, 5,0, 6.3, 7.1 MHz
- Linear 4.2, 5.6, 6.3, 7.1 MHz
- CW: Not Available
- Steered Angle: Convex: Not Available; Linear: Maximum 21° (in Color mode) B
- Biopsy: 90°
- Weight: 540g transducer head excluding cable and system connector; 950g complete transducer
- Dimension: 353,4 x 12,4 x 47,8mm

7.3 Non – Imaging Pencil Transducers

S2MCW - Doppler

- Number of elements: 2
- CW Frequencies: 1.9, 2.08 MHz
- Footprint: 18 mm diameter
- Weight: 250 g complete transducer
- Dimensions: 126 x 78 x 18 mm

S5MCW - Doppler

- Number of elements: 2
- CW Frequencies: 5 MHz
- Footprint: 10 mm diameter
- Weight: 250 g complete transducer
- Dimensions: 90 x 10 mm

SHFCW - Doppler

- Number of elements: 2
- CW Frequencies: 6.25, 7.8 MHz
- Footprint: 8 mm diameter
- Weight: 240 g complete transducer
- Dimensions: 90 x 8 mm

8. Physical specifications

8.1 Dimensions

- Approximately 38 (w) x 9.8-34(h) x 38-40(d) cm (on site)

8.2 Weight

- Approximately 5.9 Kg without batteries and AC/DC power supply
- Approximately 7.6 Kg with batteries
- Approximately 6.4 Kg with AC/DC power supply

8.3 Noise value

Position	Level [dBA]
Operator seated	41.0
Operator standing	41.4
Patient	39.9

Operator seated: measurement point centered on the front surface of the ultrasound at a horizontal distance of 0.30m from the trackball and a height, with respect to the support plane of the ultrasound system, equal to 0.94m.

Operator standing: measurement point centered on the front surface of the ultrasound at a horizontal distance of 0.30m and a height of 1.37m, with respect to the support plane of the ultrasound system.

Patient: point of measurement is centered on the front surface of the scanner at a horizontal distance of 0.60 m from it and at a height of 0.94 m from the floor

8.4 Video I/O

- HDMI output (auxiliary monitor)

8.5 Power supply

- Optional batteries for 120 minutes of operating time
- Full charging 0-100%: 178 minutes
- Battery charger inside
- Voltage operative range: 100÷120V / 200÷240V
- Voltage limit range: 90÷132V /180÷264V
- Working frequency range: 47÷63 Hz
- Power consumption: ≤200 VA
- Heating: ≤750,67 BTU/h
- extra battery option working time: > 240 minutes (PN 150000050 - available for CE Mark Countries - need to be used with trolley only - can be installed only if the system is already equipped with internal battery kit)

8.6 Power Cables

- Power cable with CEE socket
  - Socket: 510 IEC 320/C13 type: 10A-250V
  - Plug: VII (7) VII type; 10A-250V
  - Conductors: 3
  - Section: 1 mm2
  - Length: 2,5 m
- Power cable with CEI socket
  - Socket: 510 IEC 320/C13 type: 10A-250V
  - Plug: I/3 CEI 23-16 type; 10A-250V
  - Conductors: 3
  - Section: 1 mm2
  - Length: 2,5 m
- Power cable with NEMA socket

  - Socket type and amperage: 510 IEC 320/C13 type; 13A-125V
  - Plug type: NEMA 5-15; 13A-125V
  - Conductors: 3
  - Section: AWG 16
  - Length: 3 m
- Power cable with China socket
  - Cord: PRC 250V 10A
  - Chinese plug: PRC/3
  - H05VVF3G1(cable 1mm²)
  - C13/2 (plug IEC)
  - Length 2,5m
  - Color: black
- Power cable with Brazil socket
  - Cord: 250V 10A BR/3 (Brazil plug – follows NBR14136)
  - H05VVF3G1(cable 1mm²)
  - C13/2 (plug IEC)
  - Length 2,5m
  - Color: black

8.7 Operating requirements

- Temperature: 15÷35°C
- Humidity:
  - 15÷85 % (not condensing) without standby batteries
  - 15÷80 % (not condensing) with standby batteries
- Pressure: 700÷1060 hPa

8.8 Storage Requirements

- Temperature: -20 ÷ +60°C
- Humidity: 5÷85 % (not condensing) without standby batteries
- Humidity: 5÷80 % (not condensing) with standby batteries
- Pressure: 700÷1060 hPa

8.9 Standard Compliance

The MyLabSigma system meets the requirements of the Medical Device Directive and carries the CE mark.

- EN 60601-1
- EN 60601-1-2
- EN 60601-2-37
- ENISO 10993-1
- EN 61157
- AIUM / NEMA UD-2 / UD-3 – FDA 510(k) Track 3
- MyLabSigma complies with the Medical Device Directive 93/42/EEC and subsequent amendments and is CE marked.
- MyLabSigma is a device in Class IIa according to the Medical Device Directive.
- MyLabSigma complies with the Radio Equipment Directive 2014/53/EU and is CE marked.
- MyLabSigma is a device in Class 2 according to RED Directive.
- For US Customers: US Federal Law restricts this device to sale, distribution and use by or on the order of a physician

8.10 Management and Privacy of patient data

Esaote develops its products, including MyLab, with the aim of providing its customers with enhanced security capabilities and is committed to cooperate with customers in their efforts to comply with security and privacy laws and regulations (such as HIPAA in the U.S.A., GDPR in Europe and PRC Cybersecurity Law in China).

Manufacturer's Address
ESAOTE S.p.A.
Via Enrico Melen 77
16152 Genova
ITALY

Italia

Scegli la certezza.
Aggiungi valore.

TÜV Italia srl - Ufficio di Bologna - I - 40033 Casalecchio di Reno (BO) via Isonzo 61

Spett.le ESAOTE Spa
Via Enrico Melen, 77
16152 Genova
Italy

Alla c.a. Ing. Massimo Polignano, Ing. Alessio Di Domenico

Vostro rif. del	Nostro rif.	Telefono / E-Mail	Fax	Data	Pag.
	20190000086			25/11/2019	1 / 1

Oggetto: List of CE0123 products

Dear Mr. Polignano and Mr. Di Domenico

We confirm that:

- the products included in the List of EC marked products rev11 2019-11-21 are covered by the EC certificate Annex II excluding (4) nr. G1 095545 0023 rev00 exp. date 2024-05-26, issued by TUV SUD Product Service (notified body 0123).

At disposal for any doubt.

Local MHS manager
Ing. Loris Chiusoli

Attachment:
List of EC marked products rev11 2019-11-21 (2 pages)
EC certificate G1 095545 0023 rev00 (1 page)

ESAOTE S.p.A.– List of CE marked products

Category	*Articles - models numbers*	*Articles/models name*	*MD group*	*Class*	*Rule*	*GMDN code*	*UMDNS code*	*CE Cert. TUV SUD*	*Exp. date*
Ultrasonic medical diagnostic systems	2760	MyLab40	MD 1202_1	IIa	10, 5, 6	40761	14278	G1 095545 0023 rev.00	2024 May 26
	6100	MyLab70 XVG; MyLab70 XVG-L							
	6150	MyLab70; MyLab70 XVision; HIFU 6150; MyLab60; MyLab65; MyLab70 XV-L; MyLab75							
	6200	MyLabTwice eHD; MyLabEight eXP; MyLabTwice; MyLabClass C Advanced; MyLab 8 eHD; MyLab 8 eXP							
	6250	MyLabClass C; MyLabClass C eHD; MyLabEight; MyLabClass eHD; MyLabClass eXP							
	6400	MyLabSeven; MyLabSeven eHD; MyLab 7 eHD; MyLab 7 eXP; MyLabX6; MyLabX7; MyLabX7 eHD; MyLabX7 eXP							
	6420	MyLabSix; MyLabX5							
	6425	MyLabSix CrystaLine; MyLab 6 eHD; MyLab 6 eXP							
	6440	MyLab 9 eXP; MyLab 9; MyLab 9 eHD;							
	6450	MyLabX8; MyLabX8 eHD; MyLabX8 eXP; MyLab XPro80							
	7340	MyLab25 Gold; MyLab30 Gold Cardiovascular; MyLabVinco							
	7343	MyLab40 Advanced							
	7348	7348							
	7350	MyLab50; MyLab50 CV; MyLab50 XVision Cardiovascular; MyLab50 Gold; MyLab50 Gold Cardiovascular; MyLab50 Gold V; MyLab50 XVision							
	7400	MyLabAlpha; MyLabAlpha eHD; MyLabOmega; MyLab XPro30							
	7410	MyLabGamma; MyLabSigma; MyLabSigma elite							
	7430	MyLabDelta							
	8100	MyLabOne; MyLabTouch; MyLabSat							
Probes for ultrasonic medical diagnostic systems	Convex, Micro convex	AC2541; C 1-8; C5-2 R13; CA123; CA133; CA421; CA430E; CA431; CA541; CA621; CA631; CA1123; CA1421; mC 3-11; SC3121; SC3123; SC3421; C 2-9	MD 1202_1	IIa	10, 5, 6	40768	16272	G1 095545 0023 rev.00	2020 Nov 28
	Linear	AL2442; AL2443; AL2445; L 3-11; L 4-15; L 8-24; LA332E; LA424; LA435; LA522E; LA523; LA523E; LA532E; LA533; LA923; SL1543; SL2325; SL3116; SL3235; SL3323; SL3332; IHX 6-18							
	Phased Array	P 1-5; P2 3-11; P2 5-13; P 3-11; P 5-13; PA023E; PA121E; PA122E; PA230E; PA240; PA250; SP2430; SP2442; SP2730; SP3630; P 2-9; PX 1-5; PX 1-5B							
	Volumetric	BC431; BC441; BE1123; BL433; SB2C41; SB3123							
	Doppler	2 MHz CW; 5 MHz CW; HF CW; S2MCW; S2MPW; S5MCW; SHFCW							
	Endocavity	E8-5 R10P; EC123; EC1123; SE3123; SE3133; E 3-12	MD 1202_1	IIa	10, 5, 6	40771	16272		
	Trans-esophageal	ST2612; ST2613; TEE022; TEE122; TEE132							
	Intraoperative & Special	CAB411A; IH 6-18; IL 4-13; IOE323; IOT332; IOT342; LP 4-13; LP323; SI2C41; TLC 3-13; TRT33				40770	16272		
Magnetic resonance imaging units for medical diagnosis		G-scan Brio; G-scan Pelvi; O-scan; O-scan eXP; S-scan; S-scan eXP; S-scan X; S-scan C	MD 1202_2	IIa	10, 5, 6	37651	18109	G1 095545 0023 rev.00	2020 Nov 28
		G-scan Brio Premium; S-scan Premium				37652	18108		
Software for diagnostic imaging		E-MRI Brio Viewer eXP	MD 1111	IIa	10	40943	17960	G1 095545 0023 rev.00	2020 Nov 28

All the products are not sterile and not OEM.

ESAOTE S.p.A.– List of CE marked products

Revisions history

Rev.1	Mar 11th, 2015	products list for rollover activity.
Rev.2	Jul 13th, 2015	first issue of CE marked products list.
Rev.3	Sep 9th, 2015	added ultrasonic systems “MyLabClass C eHD” and “MyLabSeven eHD”.
Rev.4	Oct 7th, 2015	added probes “IH 6-18” and “PA250”.
Rev.5	Nov 29th, 2015	revised the EC certificate number.
Rev.6	Dec 1st, 2015	added the probe “L 3-11”.
Rev.7	Feb 26th, 2016	added the ultrasonic system “MyLabSix CrystaLine”; added the probe “SE3133”; introduced the column “GMDN codes” and the section “Revisions history”; added model number “6150” to model “HIFU 6150” and added model number “7410” to model “MyLabGamma”.
Rev.8	Mar 24th, 2016	added ultrasonic systems “MyLabDelta”.
Rev.9	Apr 22nd, 2016	added the probe “L 4-15”.
Rev.10	Jun 9th, 2016	added ultrasonic systems “MyLabEight” and “MyLabEight eXP”.
Rev.11	Jun 23rd, 2016	the software “SUITESTENSA” was deleted.
Rev.12	Jun 27th, 2016	added four ultrasonic systems: “MyLab 8 eHD”, “MyLab 8 eXP”, “MyLabClass eHD”, “MyLabClass eXP”.
Rev.13	Jul 18th, 2016	added probes “P2 3-11” and “P2 5-13”.
Rev.14	Jul 26th, 2016	added two full-body MRI systems: “S-scan Premium” and “G-scan Brio Premium”.
Rev.15	Nov 4th, 2016	revised the EC certificate number.
Rev.16	Dec 7th, 2016	added four ultrasonic systems: “MyLab 6 eHD”, “MyLab 6 eXP”, “MyLab 7 eHD”, “MyLab 7 eXP”.
Rev.17	Dec 23rd, 2016	added the ultrasonic system “MyLab 9 eXP” and added the two probes “mC 3-11” and “L 8-20”.
Rev.18	Feb 2nd, 2017	revised the EC certificate number.
Rev.19	May 29th, 2017	change of commercial name for a probe – old name L 8-20, new name L 8-24.
Rev.20	Jun 5th, 2017	added new DM: -four ultrasonic systems = MyLabOne, MyLabTouch, MyLabSat, MyLabSix; -nine probes = SC3421, SC3123, SC3121, SL3116, SL3323, SL3235, SL3332, SP3630, SB3123.
Rev.21	Jun 28th, 2017	revised the EC certificate number.
Rev.22	Sep 5st, 2017	MyLab 6 eHD ultrasonic system changes its model number and p/n; Magnetic Resonance Imaging device "G-scan Pelvi" is added; this list in Rev.22 is reorganized.
From here the revisions restart from rev.1 and the revisions are managed using the Product Lifecycle Management software “Windchill”		
Rev.1	Oct 3rd, 2017	added the software for diagnostic imaging “E-MRI Brio Viewer eXP” as draft list.
Rev.2	Dec 13th, 2017	added the ultrasonic system “MyLab 9”; added the software for diagnostic imaging “E-MRI Brio Viewer eXP”; revised the EC certif. number to introduce the new category “Software for diagnostic imaging”.
Rev.3	Mar 29th, 2018	added two probes “E 3-12” and “P 2-9”; removed the probe “LV513”.
Rev.4	May 3rd, 2018	added the ultrasonic system “MyLab40”.
Rev.5	Jun 27th, 2018	added the ultrasonic systems “MyLabX5”, “MyLabX6” and “MyLabX7”.
Rev.6	Jul 25th, 2018	added the ultrasonic system “MyLabX8”.
Rev.7	Oct 2nd, 2018	added two ultrasonic systems “MyLabOmega”, “MyLabSigma”.
Rev.8	Feb 1st, 2019	added four ultrasonic systems “MyLabX7 eHD”, “MyLabX7 eXP”, “MyLabX8 eHD”, “MyLabX8 eXP”.
Rev.9	Feb 5th, 2019	added two ultrasonic systems “MyLab XPro30”, “MyLab XPro80”; added the probe “C 2-9”.
Rev.10	Nov 7th, 2019	added new certificate CE number and new expiration date
Rev.11	Nov 21st, 2019	added the ultrasonic systems “MyLab 9 eHD”, “MyLab Sigma lite” and probes “PX 1-5”, “PX 1-5B” and “IHX 6-18”

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 095545 0023 Rev. 00

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Product Category(ies):

Ultrasonic medical diagnostic systems, Probes for ultrasonic medical diagnostic systems, Magnetic resonance imaging units for medical diagnosis, Software for diagnostic imaging

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.: ITA1290265

Valid from: 2019-06-14
Valid until: 2024-05-26

Date, 2019-06-14

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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A4 / 07.17