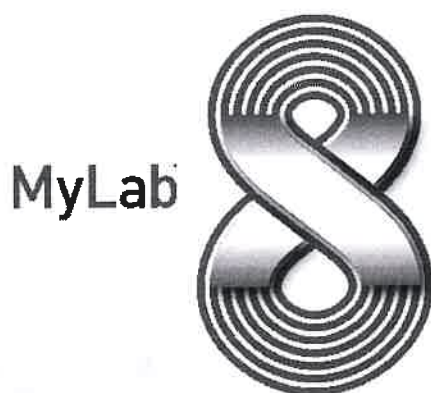


Date 05/2024

Performance Data Sheet



Prepared by: Guillaume Gauthier
Approved by: Luca Bombino

MY2024 EVO 1
Build F120101
Rev. 1

Only for Esaote Personnel. Confidential

esaote
HEALTH WITH CARE

1.

1. Introduction

1.1 Applications

The MyLab™X8 ultrasound imaging system has been designed for the following applications:

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

2. System Overview

- 1.1. • Ergonomic and compact cart designed for easy maneuverability
- 1.2. • Adjustable control panel:
 - 1.3. • Lateral orientation: 50° left, 50° right; Transport and storage 180° right; number of right detents: 6, number of left detents: 6, 1 detent for transport
 - 6. • Vertical displacement: +/-260 mm
 - 4.4. • Monitor displacement:
 - Rotation: left 80° - right 80° - front 20° - back 90°
 - Arm lateral orientation: right 236 mm - left 236 mm
- Back-illuminated control panel including alphanumeric keyboard
- Color LCD touchscreen with additional controls and mode-depending keys

- EasyMode allows user to adjust image display to match office preference
- EasyTrace automation tool guides clinician to ensure all information has been captured
- Four multidirectional wheels with breaking mechanism for easy mobility 1.1.
- Lever for easy height adjustment of the console-keyboard
- Dedicated space for peripherals or printers
- Four transducer holders for more application flexibility
- Gel and ECG cable holders
- Integrated Gel Warmer (Optional)
- Transducer cables supports
- ECG cables supports
- Five active transducers connectors 5.
- Integrated cooling system with ultra quiet fans
- Fully digital modular platform
- Factory presets (unlimited programmable) for every transducer and application

2.1 Software

- Operating system: Microsoft® Windows 10
- Multi-language Operation Menus (English, French, German, Italian, Spanish, Portuguese, Ukrainian, Russian, Chinese)
- Reports, calculations and measurements (application dependent)
- Boot up and shut down time
 - Start-up: < 1 min
 - < 15 sec from the stand-by
 - Shut-down: 15 seconds

2.2 Security

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

- 2D+TV
- 2D+TVM+(M-Mode or PW)
- 2D+TVM+TV
- 2D+ElaXto
- Colorize on all combinations

2.8 Formats

- Imaging
 - Full / Split / Multiple
 - Left-Right / Up-Down
- Tracings
 - Split / Dual (scroll by line)
- CFM – Color On/Off in Freeze
- Dual 2D+CFM live
- Quad-view

2.9 Beam Former

- Ultrasound beam generation with:
 - CPI and arbitrary wave generation
 - Frequencies: up to 25MHz
- Full digital beam former with 12 bit A/D converter
- System digital processing channels >17.000.000
- Up to 16 Tx focal zones dynamically controlled
- Up to 64 Rx focal zones dynamically controlled
- Up to 15 steering angle dynamically switchable (on frame basis for Linear/Convex Transducer)
- CW generation capability
- Programmable ultrasound beam aperture
- Interpolated data RF lines generation capability
- TEI

2.10 Calculation and Reports

- Standard Calculation Packages for:
 - Abdomen
 - Breast
 - Cardiology
 - Gynecology
 - Obstetric with programmable tables
 - Urology
 - Pediatric
 - Small Parts
 - Thyroid
 - Transcranial
 - Vascular
- Standard biometry reports and user programmable reports
- Auto NT
- All 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)
- Video clips (Full resolution)
- Patient data, Annotations, Bodymarks and Measurement from the graphic overlay
- Reports
- Offline capability
- Capability to edit image/clip from Archive

2.3 Keyboard



- Full sliding alphanumeric keyboard → 3.2.
- LED brightness digital adjustment → 3.2.
- Ergonomic key layout
- Ergonomic and adjustable back lighting control panel
- Primary controls easily accessible and logically grouped
- Programmable keys 3.3.
- eTouch: Multiple function Macro recorder 3.4.
- Trackball with three keys - PC mouse logic
- Dedicated buttons to activate primary modalities:
 - B-Mode
 - M-Mode
 - CFM
 - PWR D
 - PW
 - CW
- Direct multifunction knob to activate and control primary modalities:
 - B-Mode/M-Mode
 - Depth/Zoom
 - Freq/TEI
 - Color Gain
 - Steer
 - Doppler Gain
 - Body Mark
- Dedicated keys for

- System ON/OFF
- End exam
- General Setup Menu
- Archive
- eTouch: Macro Recorder
- Application Measurements
- Generic Measurements
- Line/Update (in Split modes)
- Dual Imaging
- Acquire (for advanced operations)
- User Configurable buttons (1 – 2 – 3 – 4 + ACQUIRE)
- AutoAdjust
- 8 TGC (slide gain controls)

2.4 Touch screen

The MyLab™X8 's large tablet-style touch screen with different interactive zones, allows user to quickly browse and select the desired function, while the rest of the display remains unchanged.

- Resolution: 1280x800
- Brightness Digital Adjustment
- Dimension: 10.1"
- Innolux LCD – TFT Liquid Crystal Display module with LED Backlight units
- Active area: 216,96 mm (H) x 135,6 mm (V) – Diagonal 257 mm
- Realtime and Archived ultrasound image visualization capability
- Tools activation
- Physio (ECG signal)
- Exam Review
- Image and clips Review from archive
- Image Reverse Up and Down
- Image Orientation left/right
- Duplex/Triplex (in Split modes)
- XView
- MView
- Gray Map
- microV
- XFlow
- Needle Enhancement
- High-Definition Zoom

- TPView
- PowerTVM
- Color Map
- EasyMode
- EasyTrace
- MyLibrary
- ElaXto
- QPack
- Fast Settings
- LVO
- ADM: Automatic Doppler Measurements
- B-Ref (for Split modes)
- B-Ref/Trace representation format
- Special functions buttons
- Six direct encoders for Software Keys (up to two layers)
- Multilanguage Alphanumeric keyboard (US International, Italian, Spanish, Danish, Norwegian, French, Swedish, German, Russian, Latin America, Hungarian)
- Block-off keyboard and touch screen for easy cleaning
- Real-time gestures workflow and image parameters modification/ optimization on touchscreen interface when live image is present.

2.5 Monitor



4.2

- BARCO 21,5" Wide Screen full HD LED monitor (Resolution: 1920x1080)

4.3

4.1

- Colors: 16.7M
- IPS Technology
- Image Resolution:
 - Image Matrix: 1200x760
 - Brightness digital adjustment
 - Articulated monitor arm

4.4

- Information displayed 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
- ElaXto
- Sample Volume Size and depth
- Frame Rate
- PRF
- Gain 2D, CFM, PW/CW
- AutoGain
- Patient Data
- Hospital Data
- Body mark
- Remote Digital Printing and Storage Status
- Remote DICOM Storage Status

- Heart Rate
- Timer
- Sweep time indication on trace
- Trackball action function
- Icons for Peripherals, Media Storage options, DICOM and Networks

2.6 Image Modes

- B-Mode (2D) *10.1.*
- Colorize 2D, M-Mode and PW/CW
- PW/CW Doppler *10.2.*
- Non Imaging CW
- CFM (Color Doppler) *10.3.*
- Power Doppler *10.1.*
- Directional Power Doppler (VeloPower)
- XFlow
- microV *13.3.*
- TEI (Tissue Enhancement Imaging)
- ECG *25.1.*
- EDR – (ECG Derived Breathing curve) *25.3.*
- CMM (Compass M¹– Mode)
- TVM (Tissue Velocity Mapping)
- TPView *11.3.*
- MView on linear, convex and microconvex transducers *11.2.*
- VPan (Panoramic View)
- CPI (Combined Pulse Imaging)
- 3D/4D Imaging
- ElaXto

2D

- Field-of-view:
 - 7°-241° on Convex Array
 - 16° - 87° on Phased Array
 - 9 - 58 mm on Linear Array
 - 3° - 54° on Linear Array with TPView
- Depth: *11.1.*

- 47 - 500 mm on Convex Array *11.1.*
- 46 - 356 mm on Phased Array
- 5 - 200 mm on Linear Array

(The values above are dependent on the transducer.)

- Transducer formats:
 - Phased Array
 - Linear Array (with steering and TPView)
 - Convex Array
- Digital scan converter 1200x760x32bits
- Frame rate: up to 6667Hz
- Maps:
 - up to 10 (customizable) post processing gray maps
 - up to 30 Color Doppler color maps
 - up to 9 Power Doppler color maps
 - up to 11 microV color maps
 - up to 6 XFlow color maps

- Zoom:
 - High-definition zoom (real-time)
 - Variable magnification (real time and frozen image)
 - Zoom level up to 50x on real-time image
 - Zoom level up to 10x on frozen image

Zoom navigation window can be enabled both in PAN and HD zoom to represent the zoomed region dimension within the complete region.

- XView processing:
 - 3 custom algorithms (4 parameters each)
 - 3 algorithms for XView+
- Steering (linear transducers) up to ± 21° with up to 14 steps

- Gain and TGC AutoAdjust 5.
- Needle Guidance kits and display line
- Capability to change gain when image is frozen

M-Mode

- Sweep time: 1 - 16 sec
- Sweep speed: 17,7 - 247,9 mm/sec
- Lines with CMM: up to 3

Capability to change gain when image is frozen.
Raw data management CMM on archive.

COLOR DOPPLER

- Frequencies: 1,7 - 16,7MHz
- Sampling PRF: 125Hz - 23,2 KHz
- Wall filters: 5 levels, depending on PRF
- Data dynamic: 11 bit (+5 for intensity)
- CFM Max Frame Rate: 612 Hz
- TVM Max Frame Rate: 750 Hz
- Maps: up to 16
- Frame interpolation
- Interleave: up to 32 lines
- Samples: up to 512 lines
- Velocity range: from 0,01m/sec to 8,75 m/s
- Packet size: 4 - 16
- Format: ROI w/wo wider b/w
- Size: 5 - 95 % of max b/w size
- Steering (linear transducers) up to 15 steps, depending on transducer
- HD CFM (up to 4 values of color spatial resolution)

DOPPLER PW

- Frequencies: 1.7 - 16,7MHz
- PRF: 0.5 - 52,1kHz
- Multigate HPRF 14.1.
- Wall filters: 65 - 1200 Hz (10 step)
- Stereophonic audio
- Sweep Time: 1 - 16 sec

- Spectrum: FFT with 64, 128 or 256 frequencies, interpolated up to 512 points (analysis time: £1 ms)
- Sample Size: 0,5 - 24 mm 143.
- Velocity range: from 0,01m/s to 19,21 m/s (35,8 m/s with P1-5@ 1.7 MHz 60° correction) 14.2.
- Angle correction : 0° to 90°
- Steering (linear transducers): up to 15 steps, depending on transducer
- Doppler gain and scale auto-adjustment

DOPPLER CW

- Frequencies: 1.9 - 8 MHz
- Sample frequency: up to 138,8kHz
- Wall filters: 40 - 900 Hz (8 steps)
- Stereophonic audio
- Sweep Time: 1 - 16 sec
- Spectrum: FFT with 64, 128 or 256 frequencies, interpolated up to 512 points (analysis time: £1 ms)
- Velocity range: up to 25,5 m/s (@ 2.1 MHz)
- Angle correction : 0° to 90°

2.7 Image on Display

- 8 bits (256) gray levels
- 24 bits (TRUE color) Color levels
- Dynamic range >350 dB 9.
- 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+M-Mode+TVM (Update)
- 2D+CFM+M-Mode (update)
- 2D+PW (update or Real-time Duplex)
- 2D+ CFM+PW (update or Real-time Triplex)
- 2D+PWR_D/VeloPower
- 2D+PWR_D/VeloPower+ PW (update or Real time Triplex)
- 2D+IVM

5.4 AutoAdjust

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

5.5 eScan: AutoAdjust Real-time

Automatically calibrate the US Image Gray level continuously without the need to repetitively push the <AUTO> button on control panel.

Different algorithm calibrations are available for Cardiac and GI/OBGYN applications.

The offset level is adjustable with the gain knob (from -10 to 10 dB). Available in BMode (Fund/TEI).

5.6 eSpeed: speed of sound regulation

Possibility to modify the speed of sound value, in order to have better better focalization on the lateral direction. eSpeed index range from -14 (1400 m/s) to 16 (1800 m/s).

5.7 EasyMode

The MyLab™X8's context-sensitive user interface is designed to make imaging tasks simpler and quicker. While automated settings manage routine clinical needs, clinicians always retain control over all imaging parameters. The EasyMode on-screen boosts workflow and efficiency By helping clinicians through the exam, it allows you to adapt and operate the system within a few seconds.

EasyMode is an unique feature which allows clinicians to optimize the image more quickly by operating with three simple slide keys :

- From Resolution to Penetration, manage the frequencies and enhancement automatically.

- From Contrast to Soft, manage the image dynamic's parameters.
- From Smooth to Sharp manage the xView algorithm

5.8 EasyColor

The EasyMode philosophy becomes available also for color mode CFM, allowing user to adjust the color signal by operating on three sliders:

- From Superficial to Deep, to manage color frequency
- From Fast to Slow, to manage PRF, wall filter, persistence
- From Large to Small, to manage HD-CFM, color smoothing and density

5.9 EasyTrace

Vascular automatic optimization that corrects the position and angle of color box and position and sample volume following the course of the vessel. Available in B+CFM, B+CFM+PW.

5.10 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

5.11 VPan

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

IQ – Shared Services

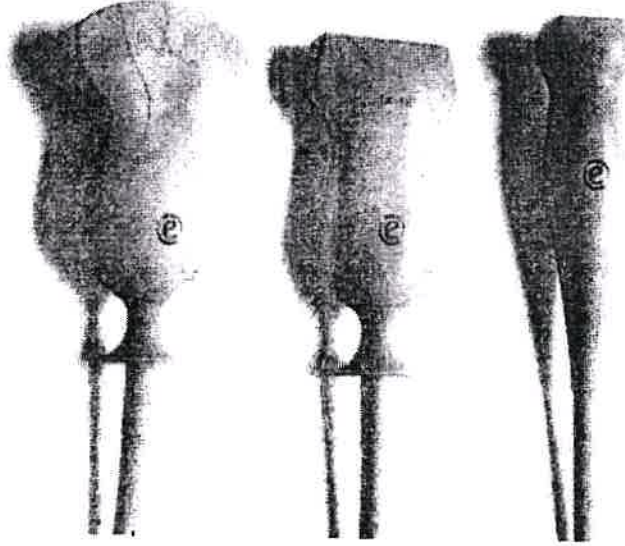
- **iQ Probes**

- **Performance in all applications**

- Radiology / Gen. Imaging
- Interventional Radiology
- Cardiovascular
- Obstetrics / Gynaecology

Transducers operating bandwidth: 1-24 MHz

8



Advanced Measurements

Refer to the Advanced Operations Manual for further information

Custom Measurements

Refer to the Advanced Operations Manual for further information

System Features

TEI

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 and CnTI

XView and 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

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

AutoAdjust

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

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 SP2430, SP2442 and Transesophageal transducer ST2612

TPView

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

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

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

contouring, area and perimeter of the detected contour is displayed waiting for user approval.

In addition, several morphologic parameters (following Bi-Rads : shape, orientation and circumscribed & Ti-Rads: shape) are automatically proposed to the customer and upon validation is inserted in the final report. The tool is available in Breast and Thyroid application.

Breast eDetect Automatic Cross Diameter is automatically tracing axial and longitudinal distance caliper on potential lesion. User can modify and/or approve the proposed measurements to include it inside the report.

6.18 TVM

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

- TVM is a Doppler-based technique that provides color-coded information of Myocardial tissue velocities
- TVM is available in the following modes:
 - 2D /TVM
 - M-Mode/MTVM
 - PW Doppler/TV
- Factory and user programmable presets for TVM (Requires the cardio module) Available on transducers PX 1-5 and P 1-5

6.19 CMM

- CMM (Compass M-Mode) allows clinicians to correct M-Mode line position to optimize tracing acquisition, even when the position of the heart is not perpendicular to the ultrasound beam. Up to three independent lines in real-time

6.20 XStrain

XStrain allows clinicians to quantify endocardial velocities of contraction and relaxation and local deformation of the heart (Strain/Strain rate)

- Based on 2D speckle tracking technology
- Innovative and non-invasive
- Angle-independent technology
- User-friendly customizable interface
- Intuitive A.I. Powered for auto border detection of left ventricle (LV), Zero-click technology workflow
- Manual segmentation for right ventricle (RV) and Left Atrium (LA) technology
- Comprehensive measurement package, including Global Strain LV, Free Wall Longitudinal Strain RV, and Strain LA

6.21 Stress-Echo

Stress-Echo allows clinicians to acquire multiple views of the Left Ventricle under stress, using customizable protocols

- Real-time 2D loops digitally synchronized with the ECG trace
- User-programmable protocols
- Multi-format reviewing capabilities for accurate monitoring of cardiovascular function
- Loop comparison by view, by stage or free mode
- Continuous capture, prospective and retrospective modes. Dedicated report with bull's eye and Wall motion score

6.22 AutoEF

AutoEF, based on Artificial Intelligence, detects and track, automatically, the LV endocardial border to calculate LV Volumes (Diastolic

Zero-click automation

AutoNT



Automatic measurement of Nuchal Translucency (NT).

AutoEF



Automatic measurement of the Ejection Fraction (fully automated).

QIMT



Automated real-time detection of Intima Media Thickness, including standard deviation and reliability index, based on RF signal analysis.

GAS



RF data technology makes it possible to measure carotid wall stiffness automatically and accurately, and automatically calculate the PWV, CC, AI, c, β indexes.

XStrain™

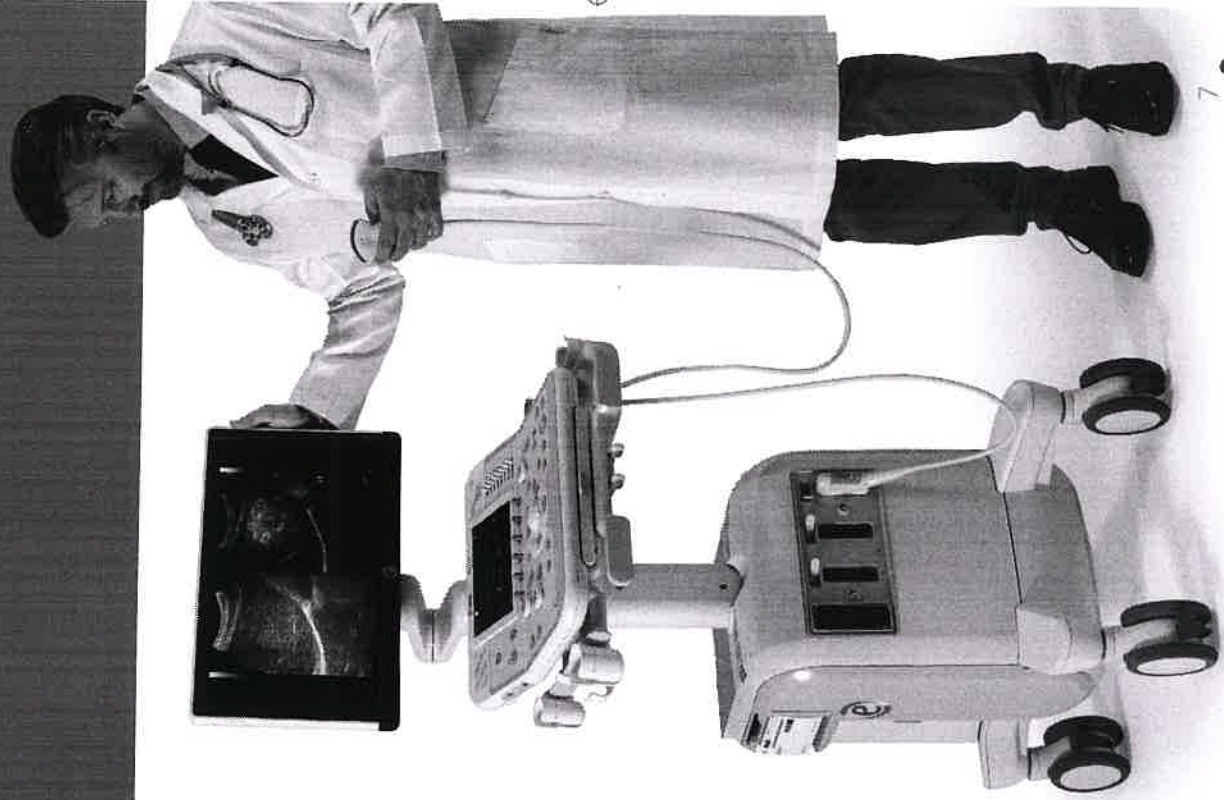


Global strain bullseye (17 segments) as a result of the 3 apical GLS outcomes. Same strain palette as XStrain4D.

XStrain4D



XStrain4D is speckle tracking technology which provides a volumetric model of the heart's function and a bullseye report.



4 - QAS Worksheet

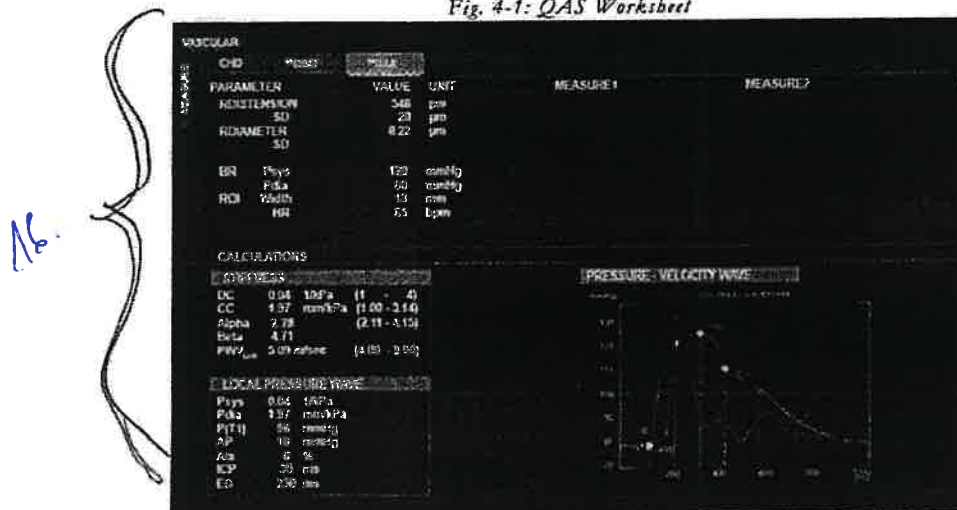
This chapter explains the structure of the QAS worksheet.

Worksheet Organization

Once QAS measurements have been performed, the Vascular Worksheet includes a dedicated folder containing the relevant QAS measurements and graphics.

Two separate pages are available for left and right Common Carotid Artery.

Fig. 4-1: QAS Worksheet



QAS Worksheet folder consists of 3 sections:

- Measure,
- Calculation,
- Pressure - Velocity Waveforms.

1 - QAS Option and its activation

16 } This chapter explains how to activate and use the QAS (Quality Arterial Stiffness) calculation.

The QAS option requires a specific licence ¹ to be installed on the MyLab.

NOTE *The QAS licence requires the Vascular licence.*

General Information

QAS is the real-time measurement of the change in diameter (or Distension) of the blood vessel walls caused by a traveling Blood Pressure Wave originated by heart pumping.

Distension in combination with Brachial Pressure (P_{sys}/P_{dia}) can be used to assess the Arterial Stiffness parameters and characteristics time point on the Local Pressure Waveform.

In the clinical literature, Arterial Stiffness is emerging as the most important parameter to evaluate Cardio-Vascular complications and events.

WARNING

The QAS algorithm works correctly on normal patients thanks to the automatic detection in real time. However, there might be cases where the algorithm could be unable to track the vessel wall. In all these situations, it is recommended to check the results of the automatic tracking and to discard them, if they are not satisfactory.

Probes

The following probes can be used in QAS:

- L 3-11
- L 4-15
- SL1543
- SL2325

1. Not available in the U.S.A. market.

- Technology: Wideband Electronic Single Crystal Array
- Operating Bandwidth: 1-5 MHz
- Field of view: 16°- 91°
- Footprint: 12x25 mm
- Max Depth: 356 mm
- B-M Modes Frequencies: PEN-H, GEN-L, GEN-M, RES-H
- TEI-MTEI Frequencies: PEN-H, GEN-L, GEN-M, RES-H
- CFM-PW Frequencies: 1.7, 2.2, 2.5, 3.1 MHz
- CW Frequencies: 1.9, 2.1, 2.5 MHz
- 2D-CnTi Frequencies: GEN-L, GEN-M, RES-L - In Cardio LVO RES-M
- Steered Angle: Not Available
- Tilt: from -34° to 34°
- Needle Guide: Not Available
- Weight: 85g transducer head excluding cable and system connector; 825g complete transducer

P 1-5

- Type: Phased Array
- Technology: Wideband Electronic Single Crystal Array
- Operating Bandwidth: 1-5 MHz
- Field of view: 16°- 93°
- Footprint: 12x25 mm
- Max Depth: 356 mm
- B-M Modes Frequencies: PEN-H, PEN-L, GEN-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-M, GEN-M, RES-L
- CFM-PW Frequencies: 1.7, 2, 2.5, 3.1 MHz
- CW Frequencies: 1.9, 2.1, 2.5 MHz
- 2D-CnTi Frequencies: PEN-H, PEN-L, PEN-M, GEN-L, GEN-M, RES-M, RES-L
- Steered Angle: Not Available
- Tilt: from -35° to 35°
- Needle Guide: Not Available

- Weight: 90g transducer head excluding cable and system connector; 390g complete transducer
- Dimension: 80,3 x 34,2 x 27,7mm

P 2-9

- Type: Phased Array
- Technology: Wideband Electronic Phased Array
- Operating Bandwidth: 2-9 MHz
- Field of view: 16°- 87°
- Footprint: 17x10.1 mm
- Max Depth: 360 mm
- B-M Modes Frequencies: PEN-M, GEN-L, GEN-M, RES-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-M, GEN-M, RES-L, RES-M, RES-H
- PW Frequencies: 2.5, 3.3 MHz
- CW Frequencies: 2.5, 3.6 MHz
- CFM-PWR-XFLOW Frequencies: 2.9, 3.3, MHz
- Steered Angle: not available
- Tilt: from -35° to 35°
- Needle Guide: Not Available
- Weight: 90g transducer head excluding cable and system connector; 370g complete transducer
- Dimension: 79.5x29.2x24.9 mm

P2 5-13

- Type: Phased Array
- Technology: Wideband Electronic Phased Array
- Operating Bandwidth: 5-13 MHz
- Field of view: 14°- 83°
- Footprint: 17.2x14.1 mm
- Max Depth: 128 mm
- B-M Modes Frequencies: PEN-H, PEN-L, RES-L, RES-H
- TEI-MTEI Frequencies: PEN-L, GEN-M, RES-H
- CFM-PW Frequencies: 4.2 – 7.1 MHz

- Multi View format (up to 16 images/clip)
- Visual comparison (saved images and clips can be compared both with each other and with archived images and clips)
- Follow-up (saved images and clips can be compared with real-time acquisition)
- Compressed images and clips

RAW Data images and clips with postprocessing capabilities

- Cine Memory: 1 GB (>41000 frames)
- Clip Real-time unlimited *22.*
- PC RAM: 8 GB
- Local drives

- 19.
 - SSD 512 GB for OS and archives (up to 100.000 images)
 - Expansion to 5 TB HDD – optional

- Internal Patient Database
- User selectable filter for the database search
- Automatic cleaning capability

- Still images and loops storage in DICOM 3.0 formats
- Real-time Archive capability for still frames and video clips *24.3.*
- Stored data thumbnails always displayed on the right side of the screen *24.4.*
- Measuring capability on stored images
- IHE Compliant
- More than 400 user presets
- Annotation/measurements capability on previously stored images
- Raw data management

3.2 Data export

- Image formats: *20.*
 - Standard output file formats (BMP, PNG, JPEG, TIFF)

- Native format
- DICOM format, compressed (lossy, lossless) and uncompressed

• Clips formats:

- AVI Codec: Microsoft® WMV9, Microsoft® MPEG4-V1, MPEG4-V2 and MS-Video1
- Native format
- DICOM format, compressed (lossy) and uncompressed

- Patient data, Annotations, Bodymarks and Measurements from the graphic overlays
- Reports (xml, html, PDF)
- Ability to send DICOM images and clips while the exam is ongoing
- RF DATA export capability for external post-processing, compatible with B-Mode functionality using all probes and length clip customizable (Optional)

3.3 Connectivity

- I/Os connectors
 - LAN RJ45 *24.1./26.3.*
 - 2 USB 2.0 on keyboard control panel
 - 2 USB 3.0 on lateral panel
- Dedicated connectors
 - ECG input
- Wi-Fi (802.11.A,B,G,N) *21.*

3.4 DICOM Connectivity

The MyLab™X8 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

As the SCU of the Query/Retrieve service class, the system can query an archive and retrieve studies for reviewing them

available on the Esaote website (www.esaote.com).

For more details on provided DICOM services, please refer to the updated version of the DICOM Conformance Statement available on 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. Systems developed in accordance with IHE, communicate with one another better, are easier to implement and enable care providers to use information more effectively.

The MyLab™X8 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

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
- Wireless

3.7 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.

3.8 eStreaming

Possibility to visualize the US image displayed on the system, in real-time on up to 5 clients simultaneously, by inserting the IP address and the password on the client platform. Available in every context: BMode, CFM, Doppler, Archive, Follow-up).

Different display visualizations admitted:

- Full Layout
- Echo Image
- Anonymize (patient archive automatically hidden to the client devices)

Together with the ultrasound image there is the possibility to see a picture-in-picture camera on the second device, embedding environmental video together with the clinical one on the same display.

3.9 Raw Data Post-processing

Technical Characteristics

This section describes the product when fully loaded with all options; refer to the previous paragraph for basic configurations.

Display

- Built-in color LCD, WVGA resolution
- Full HD LED 21.5" monitor (16:9 aspect ratio)
- 8.9" LCD (touchscreen)

Probe connectors

- 3 electronic probes (small)
- 1 electronic probes (big)

Video Output

- HDMI type ² 24.2.

Connectivity

- I/O connectors
 - LAN RJ45 24.1.
 - 2 USB 2.0 on keyboard control panel
 - 2 USB 3.0 on console left side } 24.3.
 - 2 USB 2.0 on rear panel
 - Wi-Fi (802.11 a, b, g, n) 24.4.
- Dedicated connectors
 - ECG input
- Other
 - Laser/Ink jet printers
- Complies with IHE integration profiles³

Keyboard

- Height adjustable control panel

2. Auxiliary monitors connected to this input has not to be used for diagnostic purposes. Refer to previous chapters for further information.

3. Refer to www.esaote.com for further details.

Use the controls available to optimize the image within the ROI.

NOTE

Adjust the controls so that the structure under examination is well defined.

Adjust the image in order to increase the density of the lines: high density means high quality in measuring the intima-media thickness. When the lines are stable and optimal, it is recommended to minimize the standard deviation.

Controls in QAS

In QAS the B-MODE tab displays the touchscreen with available system keys and controls for the image optimization.

The QAS tab of the touchscreen displays the following controls:

FREQUENCY	affects the imaging frequency (PEN for optimal penetration, RES for optimal resolution, GEN for the best balance between resolution and penetration).
REF LINE	sets the distance between the vertical line and the ROI.
DEPTH	increases or decreases the scanning depth.
AVERAGES ONLY	When it is activated, only the average values (AVG and SD) are shown in the measure area.
TRACK SEL	allows to select the visualization of Distension or Velocity Waveform.
ZOOM	enlarges the 2D area; the enlargement factor can be modified.
To Enlarge the 2D Area	<ul style="list-style-type: none">• If necessary, press the button to activate the ZOOM control: the image will be contoured by a yellow frame.• Act on the toggle to change the zoom factor.• Use the trackball to pan the image.

Press the ZOOM button to activate the full 2D format.

PHYSIO	activates the menu to change the trace position, when available, and to adjust its gain and amplitude.
--------	--

Procedure

1. Tap PHYSIO to display the menu.
2. ECG enables or disables the ECG trace display on the screen.

25.1. The ECG signal is displayed on the ultrasound image if visualization is set to ON, together with the Distension Waveform. If ECG is connected and active it is used as input for cardiac cycle detection. If ECG is not connected or inactive the cardiac cycle will be automatically detected by the software.

25. 2. When the ECG is connected and active also ECG Track and Heart Rate (HR) value are displayed.

The values related to the last computed cardiac cycles are highlighted in yellow.

NOTE

In Live mode the output values are related to the last complete cardiac cycle.

It is possible to select the visualization of the averages only by AVERAGES ONLY.

The vessel distension and diameter are measured several times on each cardiac cycle. The average is calculated for each cardiac cycle.

Fig. 3-2: QAS Measurements Area

	Dist	Diam	
1>>	587	8.24	
2>>	532	8.27	
3>>	498	8.28	
4>>	507	8.18	
5>>>	509	8.20	(1)
6>>	555	8.20	(2)
AVG	509 μ m	8.27 mm	(3)
SD	33 μ m	0.05 mm	(4)
HR	60 bpm		

Standard Deviation (SD) of the Distension should be below 20 micrometers

Standard Deviation (SD) of the Diameter should be below 0.2 millimeters

GRAY MAP

Offers different gray scales for the B-Mode image presentation, ranging from minimum to maximum contrast. Rotate the knob to change gray map. Define the gray map before changing other parameters.

Also available in Freeze.

Taping this key the system displays the following controls:

- GRAY M** This knob selects the desired post-processing curve: the number corresponds to the active curve.
- CENTER** This knob moves the center of the curve to the left or to the right.
- REJECT** This knob reduces the noise in the image modifying the rejection factor that is the level below which echoes will not be amplified.
- SATURATION** This knob modifies saturation.
- SLOPE** This knob changes the curve slope.
- PEAK** This knob increases or decreases the curve peak.
- BACK** goes back to main menu keeping the modifications.



PHYSIO

When the ECG is available, this key allows to display the ECG trace and/or the EDR trace.

ECG trace has no diagnostic purposes but it is used to identify certain points, such as diastole and systole, where to take measurements. In addition, the R wave of the ECG QRS complex is used as reference for the 2D and/or 2D+CFM trigger clip acquisition of entire cardiac cycles. On the ECG trace displayed on the screen, the point where the system identifies the R wave is pointed with a marker. MyLab can be set to acquire in a perspective or retrospective way. ECG synchronism is necessary for stress-echo clip acquisition and XStrain processing.

25.2.

25.2

EDR is a special algorithm retrieving information about patient breathing detected by the ECG electrodes on minor movements during the inspiration/expiration phases.

NOTE

*EDR trace requires a specific license.
The EDR trace is not displayed on archived clips.*

NOTE

MyLab displays on the screen one of the peripheral leads (I, II, III). The ECG trace is not intended for diagnostic purposes but it is provided as

- Storage service class as a SCU (and SCP for query retrieve)
- 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

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

- The system allows for the following worklist workflow query:
 - Upon request on Touchscreen interface
 - "End of exam", the system automatically opens the worklist interface
 - Automatic Query/Retrieve (Q/R) same patient previous exams available in PACS and local archive. Performed from Worklist when a patient has been selected using button "Select Exam and retrieve"

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 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) or 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

- CD-RW, DVD-RW, DVD+RW can be read and written;
- USB memory devices can be read and written.

All the formats supported by Windows® 10 are admitted.

26.1.2) 4.5.1.4. Storage format

Exam Data are available for export to USB or CD/DVD in the following formats:

- DICOM (Digital Imaging and Communications in Medicine): international standard for medical images and related information (ISO 12052)
- Esaote proprietary format UAF

The exam data can be exported in the following formats:

- Report:
 - PDF format
- Images:
 - Bitmap (.bmp)
 - Portable Network Graphics (.png)
 - Joint Photographic Expert (.jpg)
- Clips:
 - Audio Video Interleave (.avi)

Selection can be made either by checking the desired destinations in the End Exam screen using the trackball or by pressing the buttons in the touchscreen.

MyLab allows to manage many USB media devices; you can select the destination you prefer in the combo box. Different USB devices can be selected for saving in Native, Multimedia or DICOM format.

26.2.1. When the exam is archived on CD or DVD in DICOM format, the DVLite¹ viewer is automatically stored in the medium, allowing the user to review the exams on any PC.

Before archiving, you can also select ANONYMIZE, to made anonymous the patient's data.

NOTE *The native format of the exam can not be made anonymous.*

Selecting EXPORT DESK SETUP MyLabDesk will be exported on the external media with data.

Once all the options have been selected, press **OK** to start the saving procedure. Instruction messages will open if there are any user or system errors. Archiving is always carried out in background, therefore real time can be reactivated almost immediately. While data are being transferred, the icon is filled with color; when color disappears the archiving procedure is over.

NOTE *If no option is selected in the End Exam screen, all stored data are deleted.*

NOTE *When wireless connection is active, the exams ought to be archived in a network directory only when the Signal Strength level is higher than 80%; the operation could fail when the signal level is below this threshold. Refer to "Network Configuration" chapter on this manual for further information on wireless connection.*

When the free disk space is lower than 10GB, the system displays a warning message to alert the user. In this case, back the archive up and then delete exams from the internal data base.

Exported exams are organized in folders: each exam is included in a specific folder with its images, clips and report.

1. DVLite is a DICOM viewer developed by Esaote.

Beside each destination the TIME field shows the estimated time for the operation while the SIZE field shows the estimated size of data.

The exam can be:

- archived in native format in the local archive and on an external medium (NATIVE area),
- exported in multimedia formats on an external medium (MULTIMEDIA area),
- exported in DICOM format on an external medium (DICOM area).

26.2.2.

Still images can be exported on external media with full (BMP format) or compressed resolution (PNG and JPEG formats); clips are compressed. The system menu allows to set the clip duration.

Data can be archived both in native format, in DICOM format (for systems equipped with a DICOM license) and exported as single frames and AVI files (refer to the "Getting Started" manual for information on supported images and clip formats). Exported data cannot be reviewed by the system.

The corresponding report can be simultaneously saved on an external medium in pdf format.

The following media can be selected for archiving and exporting operations:

Table 1-1: Archiving Media

Medium	Native Format	Other Formats	Notes
Internal Hard Disk	Yes	No	
CD (R and RW)	Yes	Yes	Empty disks must be used. If the disk contain data, the system will not allow it to be written. Rewritable CDs can be used to archive data as far as they are empty
DVD (+R, -R, single layer)	Yes	Yes	Empty disks must be used. If the disk contain data, the system will not allow it to be written. Double Layers DVDs are NOT supported by MyLab systems.
USB Media	Yes	Yes	USB archiving media devices are managed as multi-session: data can be added to the ones already available.
Network directory	Yes	Yes	
DICOM Storage Server	No	Yes	Data are saved in DICOM format only

- 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: 6.3, 7.8 MHz
- Footprint: 8 mm diameter
- Weight: 240 g complete transducer
- Dimensions: 90 x 8 mm

8. Physical specifications

8.1 Dimensions

- Closed (approximately): 605 (W) x 1135 (H) x 730 (D) mm
- In working position: 605 (W) x 765-1025 (H) x 730 (D) mm (height of trackball)
- In working position: 605 (W) x 940-1202 (H) x 730 (D) mm (at top of Control Panel)
- In working position: 605 (W) x 1315-1577 (H) x 730 (D) mm (at top of the Monitor)

8.2 Weight

- 89,1 kg (basic configuration without peripheral units)

8.3 Noise value

Around 28dBA* (Operator standing)

*System noise value depend on system configuration and condition of use (including ambient temperature).

Operator standing: measurement point centered on the front surface of the ultrasound

at a horizontal distance of 0.40m and a height of 1.60m, with respect to the support plane of the ultrasound system.

8.4 Video I/O

- Full HD
- DVI (main monitor)
- Display Port (auxiliary monitor)

8.5 Power supply

- Voltage operative range: 100-120V / 200-240V
- Voltage limit range: 90-132V / 180-264V
- Working frequency range: 50-60 Hz
- Standby suspension/hybernate functions
- Power consumption < 260 VA
- Available power on peripherals:
 - up to 320VA 100-120V operative range
 - up to 450VA 200-240V operative range
- BTU/h < 950

8.6 Power Cables

- Power Cable with CEE Plug
 - Connector: EN60320 / C13 10A-250V
 - Plug: Type VII G CEE(7) VII
 - Cord Type: H05VVF3G 3x1,00mm²
 - Length: 4.5m
- Power Cable with CEI Plug
 - Connector: EN60320 / C13 10A-250V
 - Plug: I/3G CEI 23-50
 - Cord Type: H05VVF3G 3x1,00mm²
 - Length: 4.5m
- Power Cable with NEMA Plug

- Connector: EN60320 / C13M 10A-250V
- Plug: HG NEMA 5-15
- Cord Type: SJT 3 x 14AWG
- Length: 4.5m
- Power Cable with Brazil Plug
 - Connector: EN60320 / C13 10A-250V
 - Plug: BR/3 according to NBR14136
 - Cord Type: H05VVF3G 3x1,00mm²
 - Length: 4.5m
- Power Cable with UK Plug
 - Connector: EN60320 / C13 10A-250V
 - Plug: BS13/13 BS1363/A
 - Cord Type: H05VVF3G 3x1,00mm²
 - Length: 4.5m

8.7 Optional battery

Availability of 14V battery, which guarantees around 80 mins of system autonomy and more than 120h in stand by mode.

Time to reach complete charge: approximately 2h.

8.8 Operating requirements

- Temperature: 15-35°C
- Humidity: 20-80 % (not condensing)
- Pressure: 700-1060 hPa

8.9 Storage Requirements

- Temperature: -20 - +60°C
- Humidity: 10-80 % (not condensing)
- Pressure: 700-1060 hPa

8.10 Standard Compliance

The MyLab™X8 system complies with the requirements of the 2017/745 EU Medical Device Regulation and carries the CE mark.

- EN 60601-1
- EN 60601-1-2

8.11 Patient data privacy Management

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

Features

Depending on the model, **MyLab** can be configured with one or more of the following features.

Table 9-2 Features

Feature	Description
3D/4D	3D and 4D Volumetric acquisition
3D/4D Advanced	TPI, TMI and TSI modalities VRA analysis XLight (Advanced illumination rendering technique)
AutoAdjust	It enables the automatic adjustment of imaging parameters.
Auto EF	It automatically detects and tracks the left ventricle (LV) endocardial borders to calculate LV Volumes (Diastolic Volume, Systolic Volume) and EF (Ejection Fraction).
AutoNT	Automatic Nuchal Translucency allows to automatically capture Nuchal Translucency measurement.
Breast Suite	It enables features for Breast Navigation, breast MRI navigation and Breast Biopsy.
CMM	Compass M-Mode allows to correct M-Mode line position to optimize tracing acquisition, even when the position of the heart is not perpendicular to the ultrasound beam.
CnTI	Contrast Tuned Imaging used in combination with ultrasound contrast agents enhances the B-Mode imaging.
Dicom (including US Q/R)	DICOM Classes ^[1] Ultrasound DICOM Query/Retrieve
Multi-modality & Dicom Q/R	Multi-modality management Multi-modality DICOM Query/Retrieve
eDoppler	Automatic correction of the Doppler angle, box position and steering, for a fast and optimized calculation
ElaXto	ElaXto allows you to perform elastosonographic analysis of the tissues.
ElaXto Measures	It enables measurements in elastosonography
eStreaming	Possibility to visualize the MyLab images on different devices on the same network
Fiber Guidance	It enables on MyLab a dedicated guidance to be used with Echolaser X4 laser units produced by Elesta ^[2]
Fusion Imaging 2D - BodyMap	Real-time synchronization of ultrasound and second diagnostic modality 2D (e.g. Mammography or RX) and Body Map
Fusion Imaging 3D	Real-time synchronization of ultrasound and volumetric modality (e.g. CT, MR, PET) images
HyperDoppler	Tool for the investigation of the intra-cardiac flows.
LVO	Left Ventricular Opacification uses low mechanical index ultrasound to interact with 2nd generation contrast agents to enhance left ventricle (LV) visualization in difficult-to-scan patients.
microE	It emphasizes small hyperechoic structures in the image.

15.

4. Color Doppler Controls and Optimization

4.2.3. Controls in Freeze

HIDE CFM

enables or disables the Color presentation displaying only B-Mode reference image.

4.2.4. EasyMode

EasyMode provides an easy way to optimize image settings by quickly operating with three simple sliders.

Tapping **EASYMODE** opens a menu with three sliders, each of them manages automatically many image parameters:

- Superficial Vs Deep. Move the slider to optimize visualization for superficial or deep vessels.
- Fast Vs Slow. Move the slider to optimize visualization for fast or slow flows.
- Large Vs Small. Move the slider to optimize visualization for large or small vessels.

Slide directly the cursor on the touchscreen or rotate the corresponding knob to change value.

4.3. Color Doppler Scanning Optimization

To obtain a good CFM signal, the B-Mode reference image must first be optimized and B-Mode gain properly adjusted. ROI position and dimension have to be correctly set.

NOTE

Excessive B-Mode gain may “mask” the flow.

NOTE

Only one transmitting focal point is active in CFM, regardless of the B-Mode settings, and it is automatically positioned at the center of the ROI CFM.

Adjust the color gain rotating **CFM GAIN** (the knob around **C** key) to obtain the most useful signal level.

Optimize then other parameters so that an appropriate color flow image is achieved.

AUTO

Depending on the selection in AUTO BUTTON SETUP option (in **MENU - GENERAL SETUP - APPLICATION PRESET** folder), at **AUTO** pressure you can obtain the following actions:

- when **AUTOADJUST** has been selected, it automatically adjusts the color to the system default value,

- 5.
- when EDOPPLER has been selected, it exploits the Color Doppler Signal to estimate the vessel position and orientation to automatically set:
 - Color Doppler best centering;
 - Sample gate vertical position;
 - Color Doppler beamline steering angle;
 - Doppler correction angle.
 - when BOTH has been selected, it adjusts both the above parameters.

4.4. Q-Mode - M CFM Mode

4.4.1. Activation of Q-Mode Format

1. If needed, in CFM or in Power Doppler press **LINE UPDATE** to view the M-Mode cursor.
2. Place the cursor with the trackball on the desired position.
3. Press **M** to activate Q-Mode analysis.
4. Press **B** to return to B-Mode.

During the exam pressing **LINE UPDATE** freezes the trace acquisition and the reference 2D image is temporarily re-activated.

NOTE

When more modes are active, the navigation tab **M-MODE** allows you to access the M-Mode controls menu.



WARNING

The Doppler analysis of some pathologies could require low **FFT RESOLUTION** values. Set the **FFT RESOLUTION** on the highest value compatible with the diagnostic level of the image.

FILTER	increases/decreases the wall filter values thus reducing/increasing the noise level. Use low filter to display low flow velocity.
SWEEP	changes the scanning speed: the time scale of the trace changes accordingly.

3.3. Doppler Scanning Optimization

The gain must first be optimized using the relative knob until a clear envelope of the spectral analysis is obtained; the wall filters must be set in order to eliminate wrong low-speed signals caused by moving structures. Interaction with other commands or the acoustic parameters further improves the spectrum quality.

DOPPLER GAIN knob, placed around the **PW** key, affects the Doppler video component.

AUTO automatically optimizes the Doppler by adjusting general gain, baseline and velocity range.

When in freeze, the scrolling memories for B-Mode image and PW or CW trace can be moved independently to select the best image to be saved. Rotate the trackball horizontally to scroll through the images one by one. Press the **ACTION** key to switch between the B-Mode and PW or CW memories.

8.5. Automatic Ejection Fraction

Automatic Ejection Fraction (Auto EF) is an automatic tool to calculate the Ejection Fraction on:

- frozen clips acquired with the ECG trace,
- archived clips acquired with the ECG trace and saved in raw data format.

Values of ejection fraction obtained by automatic measurements are intended as a suggestion and should not be considered sufficient to make a diagnosis.



WARNING

Automatic measurement results are intended as a suggestion and should not be considered sufficient to make a diagnosis.

NOTE

The Automatic Ejection Fraction calculation is available in Adult Cardiac application and it requires a specific licence (Auto EF licence).

NOTE

The Automatic Ejection Fraction calculation strongly depends on the quality of the 2D images and on their temporal resolution (frame rate).

NOTE

Improper or suboptimal acquisition of apical four chamber (A4C) and apical two chamber (A2C) views might lead to significant underestimation of the Left Ventricular End Diastolic and End Systolic Volumes.

NOTE

During imaging acquisition make sure to avoid plane positioning errors, which can lead to chamber foreshortening.

NOTE

Please refer to Tab.1 Recommendation for the echocardiographic assessment of LV size and function "Recommendations for Cardiac Chamber Quantification by Echocardiography in Adults: An Update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging" Roberto M. Lang et al, J Am Soc Echocardiogr 2015; 28:1-39.

Procedure to perform Auto EF calculation on frozen clips

1. Acquire a Cardiac image with ECG trace.
2. Press **FREEZE**.
3. Select the desired cardiac cycle.
4. Press **MEASURE**;
5. Select the tab **VOLUME (LVEF)** on the touchscreen.
6. Select **AUTO EF - BIPLANE** as measurement;
7. Tap **A4C** or **A2C** to select the correct projection.
8. After a short processing time the Automatic Ejection Fraction calculation is done. Refer to the paragraph "After Calculation" for information on how to correctly manage the results.

Procedure to perform Auto EF calculation on archived clips

1. Select from the archive a clip acquired with the ECG trace and saved in raw data format (those clips are identified as thumbnails with green counter and heart superimposed).
2. Select the desired cardiac cycle.
3. Press **EDIT**;
4. Press **MEASURE**.
5. Select the tab **VOLUME (LVEF)** on the touchscreen.
6. Select **AUTO EF - BIPLANE** as measurement.
7. Tap **A4C** or **A2C** to select the correct projection.
8. After a short processing time the Automatic Ejection Fraction calculation is done. Refer to the paragraph "After Calculation" for information on how to correctly manage the results.

8.5.3. After Calculation

15.

When the Ejection Fraction has been automatically calculated, the results are displayed on the left side of the screen, the End Diastolic frame automatically contoured is also displayed and the touchscreen provides the following controls.

Fig. 8-2 Automatic Ejection Fraction calculation



NOTE

The End Diastolic frame has to be selected carefully before activating Auto EF. An inadequate selection of the End Diastolic frame can lead to underestimation of End Diastolic volumes and EF.

NOTE

Carefully verify the endocardial border tracking and make sure that papillary muscles are excluded from the cavity in the tracing. In case of incorrect or suboptimal endocardial border tracking, adjust the tracking point and process the data again.

A4C	Tap the key to update the calculation for apical four chamber (A4C) or two chamber (A2C) views.
A2C	
ED	moves the clip to the End Diastolic frame.
ES	moves the clip to the End Systolic frame.
ED FRAME	Rotate the knob to move the End Diastolic frame. Press it to repeat the reprocessing with new position.
ES FRAME	Rotate the knob to move the End Systolic frame. Press it to repeat the reprocessing with new position.
MANUAL CONTOUR	allows to trace the contour manually.

- 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°
- Disposable Needle Guide: 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 (4°-36° Tp-View)
- Footprint: 55x7mm
- Max Depth: 166 mm
- B-M Modes Frequencies: PEN-H, PEN-L, GEN-L, RES-L, RES-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-L, GEN-M, RES-L, RES-H
- CFM-PW Frequencies: 4.2, 4.5, 5, 5.6, 6.3, 7.1, 8.3, 10 MHz
- CW: Not Available
- 2D-CnTi Frequencies: PEN-H, PEN-M, PEN-L, GEN-L, GEN-M, RES-L, RES-H
- Steered Angle: max 21°
- Reusable Needle Guide
- Disposable Needle Guide: 40°, 60° or free angle 42-75°

- Weight: 120 g transducer head excluding cable and connector, 470 g complete transducer
- Dimension: 58x89x 26 mm

LX 3-15

- Type: Linear
- Technology: Wideband Electronic Linear Array
- Operative Bandwidth: 3-15 MHz
- Max field of view: 16-46 mm (4°-36° Tp-View) *18.1.1*
- Footprint: 50.5x7.5 mm
- Max Depth: 166 mm
- B-M Modes Frequencies: PEN-H, PEN-L, GEN-L, RES-L, RES-M, RES-H
- TEI-MTEI Frequencies: PEN-H, PEN-L, GEN-L, GEN-M, RES-L, RES-M, RES-H
- CFM-PW Frequencies: 4.2, 4.5, 5, 5.6, 6.3, 7.1, 8.3, 10 MHz
- CW: Not Available
- 2D-CnTi Frequencies: PEN-H, PEN-M, PEN-L, GEN-L, GEN-M, RES-L, RES-M, RES-H
- Steered Angle: max 21°
- Reusable Needle Guide
- Disposable Needle Guide: 40°, 60° or free angle 42-75°
- Weight: 100 g transducer head excluding cable and connector, 470 g complete transducer
- Dimension: 140 x 58 x 27 mm

L 3-11

- Type: Linear
- Technology: Wideband Electronic Linear Array
- Operating Bandwidth: 3-11 MHz
- Max Field of view: 9-39 mm (5°-54° Tp-View)
- Footprint: 49x12 mm



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 Endocavity
- Intraoperative
- Laparoscopic
- Pencil CW

7.2 Contrast Transducers

The following transducers can be used with CnTi in the applications indicated below:

C 1-8: Abdominal, Gynecology
 C 2-9: Abdominal, Gynecology
 E 3-12: Gynecology, Ob-fetal, Urology
 IOT342: Abdominal, Small Parts, Vascular, Musculoskeletal
 TLC 3-13: Urology, Gynecology
 L 3-11: Abdominal, Musculoskeletal, Vascular
 L 4-15: Breast, Musculoskeletal, Small Parts, Thyroid, Vascular
 LX 3-15: Breast, Musculoskeletal, Small Parts, Thyroid, Vascular
 BL433: Breast, Musculoskeletal, Small Parts, Thyroid, Vascular
 PX 1-5: Cardiac (LVO), Adult Cephalic, Vascular, Abdominal

P 1-5: Cardiac (LVO), Adult Cephalic, Vascular, Abdominal
 SB2C41: Abdominal, Gynecology
 SI2C41: Abdominal, Gynecology
 mC 3-11: Abdominal, Vascular, Small Parts
 SB3123: Gynecology, Ob-fetal, Urology

7.3 Transducers Technical Specifications

C 1-8

- Type: Convex
- Technology: Wideband Electronic Single Crystal Array
- Operating Bandwidth: 1-8 MHz
- Max Field of view: 7° - 105° *18.2-1.*
- Radius of Curvature: 50 mm *18.2-2.*
- Footprint: 65x19 mm
- Max Depth: 500 mm
- B-M Frequencies: PEN-H, PEN-M, PEN-L, GEN-L, RES-L, RES-M, RES-H
- TEI-MTEI Frequencies: CPI-H, CPI-L, GEN-L, GEN-M, RES-M, RES-H
- CFM-PW Frequencies: 1.9, 2.3, 2.5, 2.8, 2.9, 3.1 MHz
- CW: Not Available
- 2D-CnTi Frequencies: PEN-H, GEN-M, RES-L, RES-M
- Steered Angle: not available
- Tilt: from -49° to 49°
- Reusable Needle Guide
- Disposable Needle Guide: 15°, 25°, 35°
- Weight: 95 g transducer head excluding cable and connector; 520 g complete transducer
- Dimensions: 101,4x66,7x34,7 mm

C 2-9

- Type: Convex
- Technology: High-sensitivity transducer array
- Operating Bandwidth: 2-9 MHz
- Max Field of view: 7° - 105°