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Creativity in Healthcare

Rev. 11

June 2021

MyLabX6
MyLabX7

GETTING STARTED

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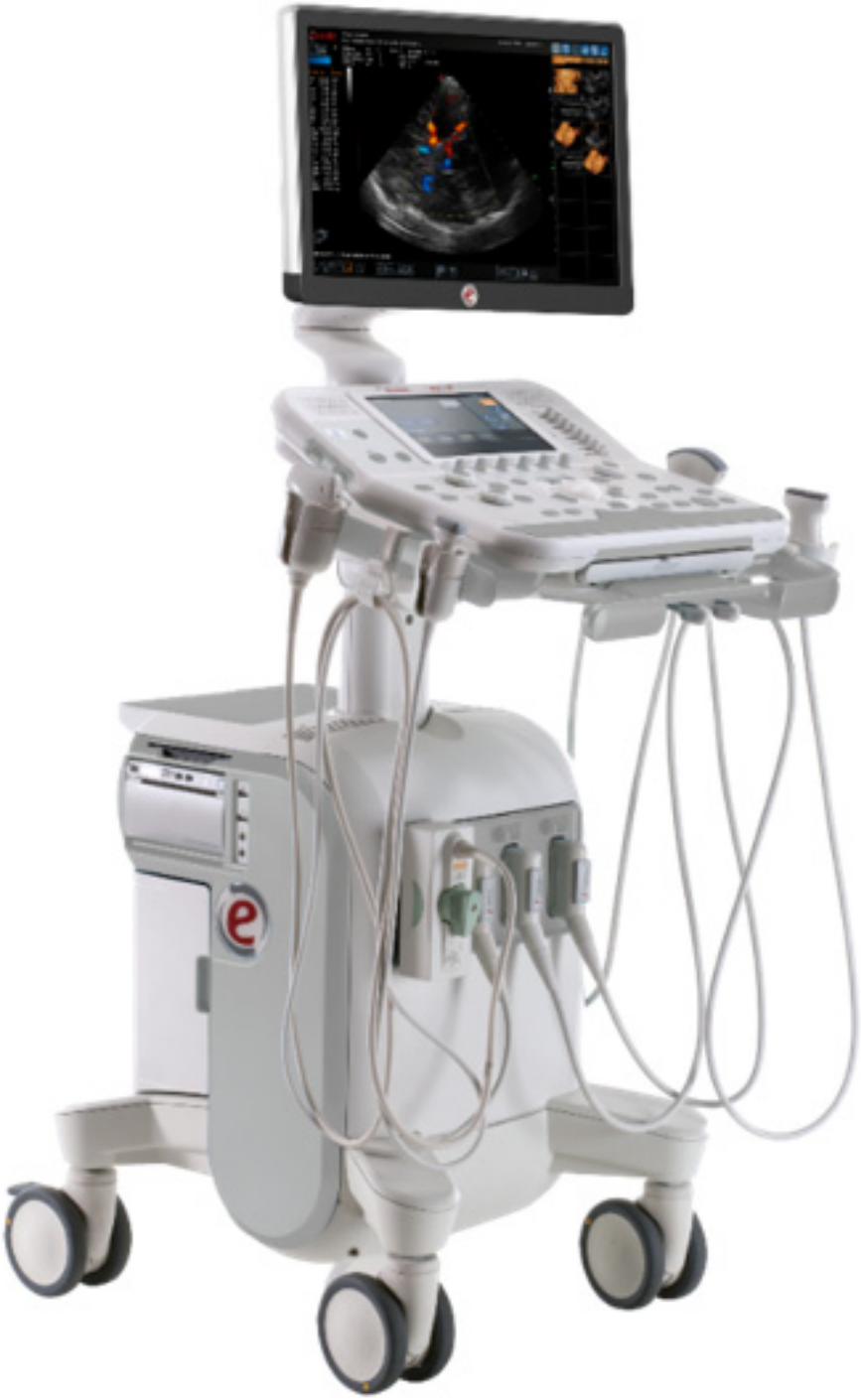

Manufacturer's Address

ESAOTE S.p.A.
Via Enrico Melen 77
16152 Genova
ITALY

Phone +39 010 65471
info@esaote.com
www.esaote.com

Important Information

MyLabX6 and **MyLabX7** comply with the Medical Device Directive 93/42/EEC and subsequent amendments and are CE marked.

MyLabX6 and **MyLabX7** are devices in Class IIa according to the Medical Device Directive.

MyLabX6 and **MyLabX7** comply with the Radio Equipment Directive 2014/53/EU and are CE marked.

MyLabX6 and **MyLabX7** are devices 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.

All information included in this manual is relative to the following Esaote ultrasound equipments: **MyLabX6** and **MyLabX7**.

In this manual, all the above mentioned devices are referred to as **MyLab**.

Unless specifically noted, sections of this manual pertain to all the devices.

Guarantee

All screenshots, pictures and graphics in this manual are used for descriptive purposes only and may be different from what you see on the screen or device.

This manual has been written taking care to ensure the accuracy of all of the information included, however, Esaote assumes no liability for errors or omissions.

No translations of this documentation are allowed without the consent of Esaote S.p.A.

The information contained in this documentation is subject to change without prior notice.

Trade Marks

All names are property of the respective owners and are used exclusively for identification purposes.

RED Declaration of Conformity

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DICHIARAZIONE DI CONFORMITÀ 2014/53/UE
***DECLARATION OF CONFORMITY* 2014/53/EU**

Noi costruttori
We manufacturer

Esaote S.p.A.
Via Enrico Melen 77, 16152 Genova - Italy

dichiariamo, sotto la nostra sola responsabilità, che il sistema per diagnostica ad ultrasuoni
declare, under our sole responsibility, that the ultrasonic medical diagnostic system

Modello MyLabX6
Model MyLabX6

risponde ai Requisiti Essenziali della direttiva 2014/53/UE - RED
meets the Essential Requirements of the 2014/53/EU *directive - RED*

e che sono state applicate tutte le relative norme armonizzate e specifiche tecniche indicate nella pagina seguente.
and that all the relevant harmonized standards and technical specifications indicated in the following page have been applied.

L'ente notificato IMQ S.p.A. (numero di identificazione 0051) ha effettuato l'esame di tipo UE in conformità ai requisiti dell'Allegato III Modulo B della direttiva 2014/53/UE e ha rilasciato il certificato N0. 0051-RED-0082.
The notified body IMQ S.p.A. (identification number 0051) performed the EU-type examination in compliance with the requirements of Annex III Module B of the 2014/53/EU Directive and issued the EU-type examination Certificate No. 0051-RED-0082.

Firenze, 18 ottobre 2018
Florence, October 18th, 2018

Ing. Massimo Polignano
Responsabile Assicurazione Qualità
Chief Quality Officer

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DICHIARAZIONE DI CONFORMITÀ 2014/53/UE
DECLARATION OF CONFORMITY 2014/53/EU

- Norme armonizzate applicate/*Harmonized applied standards*

Nr. ed Edizione/*Nr. and Edition*	**Titolo/*Title***
EN 60601-1:2006+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: ElectroMagnetic Compatibility - Requirements and tests
EN 60601-1-6:2010+A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-2-37:2008	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
ETSI EN 301 489-1 v2.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Harmonised Standard covering the essential requirements of article 3.1(b) of the Directive 2014/53/EU and the essential requirements of article 6 of the Directive 2014/30/EU; Part 1: Common technical requirements
ETSI EN 301 489-17 v3.1.1	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
ETSI EN 300 328 v2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 301 893 V2.1.1	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

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Noi costruttori
We manufacturer

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Via Enrico Melen 77, 16152 Genova - Italy

dichiariamo, sotto la nostra sola responsabilità, che il sistema per diagnostica ad ultrasuoni
declare, under our sole responsibility, that the ultrasonic medical diagnostic system

Modello MyLabX7
Model MyLabX7

risponde ai Requisiti Essenziali della direttiva 2014/53/UE - RED
meets the Essential Requirements of the 2014/53/EU *directive - RED*

e che sono state applicate tutte le relative norme armonizzate e specifiche tecniche indicate nella pagina seguente.
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Table of Contents

Chapter 1

1. Introduction

MyLabX6 and **MyLabX7** devices are supplied with a set of manuals to provide all necessary and sufficient information to operate the device safely and effectively.

WARNING

Before operating the equipment, read carefully the complete set of manuals in order to understand the detailed operating procedures, functions, performance, and maintenance procedures.

The complete set of manuals is composed by:

- **Essential Instructions for Use** - describes the basic information you need to operate with **MyLab** and information on foreseeable medical emergency situations.
- **Safety and Standards** - provides information about the patient's and operator's safety.
- **Getting Started** (this manual) - describes how to install **MyLab** and provides the main instructions for using it.
- **Probes and Consumables** - provides detailed instructions for using and reprocessing **MyLab** probes and their accessories.
- **System Data** - provides data on probe temperatures and acoustic output for each probe and mode of operation.
- **Advanced Operations** - provides advanced instructions to use **MyLab** and includes the following sections:
  - Advanced Features,
  - Image Optimization,
  - Measurements,
  - Archiving.
- **Optional Sections** - additional sections to describe specific features (i.e. 3D/4D, Virtual Navigator, QElaXto,...)

NOTE ***All manuals are provided in electronic format with exception of Essential Instructions for Use that is provided in hard-copy.***

The manuals can refer to:

- **MyLabX6** and **MyLabX7** when the contents are relevant only to this family, or
- **MyLab** when the contents are common to the other ultrasound devices belonging to the Esaote **MyLab** platform.

This manual revision applies to release 24.xx.yy and subsequent maintenance releases, depending on the Country and the respective clearances.

The instructions for use describe the most extensive configuration of your **MyLabX6** or **MyLabX7** device, with the maximum number of options and accessories. Some functions, probes or applications described may be unavailable on your product's configuration.

NOTE ***Technology and features are device/configuration dependent.***

Specifications subject to change without notice. Information might refer to products or modalities not yet approved in all countries. Product images are for illustrative purposes only. For further details, please contact your Esaote sales representative.

Before attempting to use **MyLab**, read and understand all the instructions in the set of manuals. Strictly observe all cautions and warnings. Always keep the manuals with the equipment in an easily accessible place for future reference.

NOTE ***The manuals describe all operations to be performed for a proper and safe use of* MyLab*. Any device malfunction caused by incorrect operations is considered as falling under the user's responsibility.***

Intended audience

MyLab manuals are written for sonographers, physicians, and biomedical engineers who have been trained on basic ultrasound principles and techniques.

Before reading these instructions for use, you need to be familiar with ultrasound techniques. Sonography training and clinical procedures are not included here.

Disclaimer

Ultrasound scanner should only be used by persons who are fully trained in its safe and proper operation. They should have detailed knowledge of ultrasound scanner, they should be aware of its specifications, accuracy and limitations, and should be able to manipulate the ultrasound scanner correctly in order to ensure that patient diagnosis and management are not compromised. For this reason, anyone operating the ultrasound scanner should read and understand the ultrasound scanner operating manual.

Ultrasound scanner, transducers, cables, monitor and image recorders should be regularly inspected and kept on acceptable levels of performance. In case of device failure to operate correctly, the operator should contact the nearest Esaote Service Office.

Special attention should be dedicated to intra-cavitary probes (e.g. vaginal, rectal or oesophageal probes). They should be cleaned according to established protocols (AIUM guidelines for cleaning probes) and should not be used if there is noticeable self-heating of the probe when operating in air. Particular care should be taken if trans-vaginal probes are to be used to investigate a pregnancy during the first 10 weeks after LMP.

The images and calculations provided by ultrasound scanner should never be regarded as the only basis for clinical diagnosis. They are intended to be just a part of a more complex diagnostic process that includes medical history, symptoms and other instrumental examinations.

A proper patient ID and exact examination date and time must be always included and must appear on all recorded data and prints. Identification error could result in mistaken diagnosis.

WARNING

It should be considered that ultrasound scanner is not meant for long-term data storage and that in case of serious device failure and consecutive repair, the stored data can be lost. Thus, a regular backup of data is recommended.

For more detailed information please consult:

Guidelines For Professional Ultrasound Practice. Society and College of Radiographers and British Medical Ultrasound Society. December 2015 https://www.sor.org/sites/default/files/document-versions/ultrasound_guidance.pdf

AIUM guidelines for cleaning probes.

http://www.aium.org/officialStatements/57

Guidelines for the safe use of diagnostic ultrasound equipment. The British Medical Ultrasound Society.

https://www.bmus.org/static/uploads/resources/BMUS-Safety-Guidelines-2009-revision-FINAL-Nov-2009.pdf

Guidelines for Diagnostic Imaging During Pregnancy and Lactation. The American College of Obstetricians and Gynecologist. 2017.

https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Guidelines-for-Diagnostic-Imaging-During-Pregnancy-and-Lactation

MyLab use

This product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions supplied with the product, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for image clinical evaluation and best clinical procedure.

Installation, use, and operation of this product are subject to the law in the jurisdictions in which the product is used. Install, use, and operate the product only in such ways that do not conflict with applicable laws or regulations, which have the force of law.

Use of the product for the purposes other than those intended and expressly stated by Esaote, as well as incorrect use or operation, may relieve Esaote or its agents from all or some responsibility for resultant noncompliance, damage, or injury.

MyLab Manual Conventions

In this manual device controls are indicated using the following graphical conventions:

- Control panel buttons are indicated by GREY CAPITAL LETTERS.
- Touchscreen keys are indicated by **BOLD BLUE CAPITAL LETTERS**.
- Touchscreen software strings are indicated by NORMAL BLUE CAPITAL LETTERS.
- Screen software buttons and options are indicated by **BOLD BLACK CAPITAL LETTERS**.
- Screen software strings are indicated by NORMAL BLACK CAPITAL LETTERS.

Select/Click means positioning the cursor with the trackball over the desired option and pressing ENTER to confirm.

Right click means positioning the cursor with the trackball over the desired option and pressing UNDO to confirm.

Double click means positioning the cursor with the trackball over the desired option and pressing ENTER twice.

Tap means touching with your finger the desired command on the touchscreen.

Swipe means placing your finger on the desired area of the touchscreen and moving it to the left or to the right.

WARNING

In this manual WARNING identifies a risk for the patient and/or the operator.

CAUTION

The word CAUTION describes the precautions necessary for protecting the equipment.

NOTE

In this manual NOTE points out information of special interest but not related to risks for patient, operator or device.

CONTRAINDICATION

This information notifies the user of a condition in which the system must not be used. The reason for this is that the risk involved clearly outweighs the benefits of using the system in such conditions.

Manufacturer's Responsibility

Esaote is responsible for the safety, reliability and functioning of this product only if:

- the user follows all the instructions contained in the device manuals for the use and the maintenance of this device;
- the manuals are kept integral and readable in all parts;
- calibrations, modifications and repairing are performed only by Esaote qualified personnel;
- the environment where the device is used complies with the current safety rules;
- the electrical plant of the environment where the device is used complies with the current applicable rules and is perfectly efficient.

Product Life Cycle

Life Time

The safety and efficiency of **MyLab** ultrasound scanners are guaranteed for at least seven (7) years from the purchase date, provided that:

- the device is used in accordance with the instructions given in the Operator Manual (and its eventual Addenda), which must be always accessible to the whole personnel in an integral and readable status;
- any installation, maintenance, calibration, modification and repairing operation is performed on the device only by Esaote qualified personnel, using original Esaote spare parts.

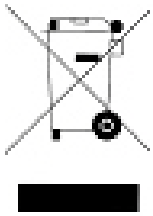
When approaching the seven (7) years limit from the purchase date, it is recommended to contact Esaote Service or to visit Esaote web site (www.esaote.com), to get updated information on the product's end of life and/or to agree on the most suitable solution for its safe disposal.

Maintainability Time

Esaote ensures maintainability of **MyLab** ultrasound scanners for seven (7) years from the purchase date.

End-of-Life Disposal

MyLab ultrasound scanners fall within the application field of the 2002/96/EC Directive on waste electrical and electronic equipment (WEEE), amended by directive 2003/108/EC.



The main device label includes therefore the symbol shown below, indicating - in an unequivocal way – that the device must be disposed of in a separate collection from urban waste and that it was introduced in the market after August 13th, 2005.

When disposing of any device part, the user shall consider the following points:

- any recyclable part of the device and/or of its packaging is labelled with the corresponding symbol;
- all components used for the packaging are recyclable and/or reusable, except the closed-coupled barriers.

CAUTION **The device and its consumable parts must be disposed of, at end of life, according to the applicable state and/or federal and/or local regulations.**

Usage License Agreement for the Software Included in the Apparatus

NOTE ***Please read with care the terms and conditions indicated below before using the software on the device.***

Use of the software implies acceptance of the terms and conditions listed below.

Proprietary Rights

You have acquired a device ("DEVICE") which includes Esaote S.p.A. proprietary software and/or software licensed by Esaote S.p.A. from one or more software licensors ("Software Suppliers"). Such software products ("SOFTWARE"), as well as associated media, printed materials, and "online" or electronic documentation are protected by international intellectual property laws and treaties. The SOFTWARE is licensed, not sold. The SOFTWARE and, similarly, any copyrights and all industrial and intellectual

ownership rights are and shall remain the exclusive propriety of Esaote S.p.A. or its Software Suppliers.

The user will acquire no title or right on the SOFTWARE, except for the usage license granted herein.

For any software updates and/or upgrades installed on the Equipment after installation, the terms herein shall apply in full.

License Rights and Limitations

With this license, Esaote S.p.A. grants the end user the right to use the SOFTWARE on the supplied DEVICE.

The user may not, under any circumstances, make unauthorized copies and/ or reproductions of the SOFTWARE or parts of it, including the enclosed documentation.

On the basis of the above, and if the SOFTWARE is not protected against copying, only one copy of the SOFTWARE may be made for security purposes (back up copy).

The user may not rent or lease the SOFTWARE, but he may transfer, on a permanent basis, the rights granted herein, on condition that he transfers all copies of the SOFTWARE and all written material, and that the transferee accepts all the conditions of this agreement. Any transfer must include the most up-to-date version and all the previous ones.

The user may not convert, decode, reverse-engineer, disassemble or change in any way the SOFTWARE.

The user may not remove, obscure or alter the copyright notice, trademarks or other proprietary rights notices affixed to or contained within the SOFTWARE.

The user may not publish data or information comparing the performances of said SOFTWARE with that of software written by others.

Third Part Software

Esaote software uses parts of the 7-Zip program. The 7-Zip is licensed under the GNU LGPL license; the source code can be found in www.7-zip.org.

Product Traceability

To guarantee the product traceability according to requirements of the standard EN ISO 13485:2016, and the European Directive on Medical Devices 93/42/EEC (1993) and subsequent amendments, original owners, in

the event of equipment transfer to third parties, are requested to notify ESAOTE S.p.A., associate company or authorized distributor of the said transfer by means of the following form, duly compiled, or written notification with the same data as specified in the form. Equipment data are found on the relative identification label.

PRODUCT TRACEABILITY FORM

To: ESAOTE S.p.A.

Quality Assurance Department

Via Enrico Melen, 77

16152, Genova, Italy

[or associate company]

[or authorized distributor]

Esaote system/device name:.....

REF.....

Serial Number (SN):.....

Name and address of original owner:

.....

.....

Name and address of new owner:

.....

.....

Date:..... Signature:.....

Vigilance System

This equipment is subject to Esaote vigilance system (post-market surveillance) in case of potential or real hazards for the patient or for the operator which might occur during the normal device functioning, in order to be able to remove them with the best efficiency and timing.

The equipment is subject to a supervision device (post-sales supervision), which ESAOTE S.p.A., all associates and authorized distributors apply to products issued onto the market, in relation to real or potential hazards that may arise for the patient or operator during normal use of the equipment, to ensure optimal solutions in the most efficient and prompt manner possible.

Therefore if the user records any malfunction or deterioration in the characteristics and/or performances of the device, as well as any inadequacy in the labeling or the instructions for use which might lead to potential or real hazards for a patient or for an operator, we kindly request to immediately inform Esaote central plants, or one of our subsidiaries, or one of our official distributors immediately through the following form, or through a communication reporting the same data contained in this form. All data relating to the device can be found on its identification label. In this way we will be able to take all adequate measures with the best efficiency and timing.

Therefore, in the event of malfunctions, defective performance of the equipment, or inadequate instructions, which may constitute a hazard to the patient or operator, the user must notify ESAOTE S.p.A., associate company or authorized distributor in writing, providing the information as specified in the form below. Equipment data are found on the relative identification label.

On receipt of the notification ESAOTE S.p.A. will immediately activate the process of examination and resolve the non-conformity that has been reported.

POST-MARKET SURVEILLANCE FORM

ACCIDENT REPORT FORM

To: ESAOTE S.p.A.

Quality Assurance Department

Via Enrico Melen, 77

16152, Genova, Italy

[or associate company]

[or authorized distributor]

[and competent authorities]

ESAOTE system/device name:.....

Code (REF):.....

Serial Number (SN):.....

Description of the potential/real hazard: Description of accident or potential accident:.....

.....

Comments or suggestions:.....

.....

Contact Person/Department:

.....

Address:

.....

Phone:..... Fax:.....

Date:..... Signature:.....

Chapter 2

2. Additional Information on Safety

SS

This chapter provides additional information on safety specifically for your **MyLab**. Please read the "Safety and Standards" manual carefully for a complete overview of all safety aspects of **MyLab** products.

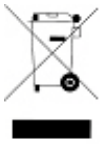
Environmental Safety

Information about Reusing/Recycling

This symbol identifies a recyclable component. Depending on the size of the recyclable component, Esaote prints on it this symbol and the indication of the material it is made of.

In this system, packing materials are reusable and recyclable; the casings of the system and the monitor (plastics) and most of the cart components (plastics) are also recyclable.

Special waste



The device contains lithium-ion batteries. The fluorescent lamp included in the LCD screen contains mercury. The batteries and the LCD screens must be treated as special waste according to the applicable local regulations.

Dispose of the equipment as special waste according to the applicable local regulations. For further information please refer to the local authority for waste disposal.

Exam Waste

Consider any exam waste as potentially infectious and dispose of it accordingly.

Electrical Safety

MyLab uses high frequency signals. Pacemakers could interfere with these signals. The user should be aware of this minimal potential hazard and immediately turn the system off if interference with the pacemaker operation is noted or suspected.

Observe the following warnings for maximum safety.

WARNING

The system must be properly grounded to prevent shock hazards. Protection is provided by grounding the chassis with a three-wire cable and plug; the system must also be powered through a properly grounded receptacle.

MyLab models are not watertight and provide a class IP(X)0 degree of protection to liquids; do not expose the system to rain or moisture. Avoid placing liquid containers on the system.

CAUTION

Do not replace the system fuses with different types from those specified by the MyLab "Getting Started" manual.

WARNING

Electrical shock hazard. Do not remove the system or the monitor cover. Refer servicing and internal adjustments to qualified Esaote personnel only.

WARNING

Turn MyLab off and unplug it before any cleaning operation.

Electromagnetic Compatibility

This device was designed for use in the electromagnetic environments declared in the tables below, in compliance with standard IEC 60601-1-2:2014 (4th edition). The operator must make sure that s/he uses it in keeping with this standard.

Ultrasound scanners require special precautions regarding EMC and must be installed and put into service according to the provided information.

Ultrasound scanners are designed to generate and receive radiofrequency (RF) energy and are, therefore, susceptible to other RF sources. As an example, other medical devices, information technology products or TV/radio transmitters may cause interference with the ultrasound system.

NOTE ***Sensitivity to interference is more noticeable in Doppler modes.***

In the presence of RF interference, the physician must evaluate the image degradation and its diagnostic impact.

CAUTION **Use of accessories, probes and cables other than those authorized by Esaote may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**

CAUTION **Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of MyLab, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

WARNING **Portable and mobile RF communication equipment may cause interference with the ultrasound system. Do not use these devices in proximity of ultrasound equipment.**

If an ultrasound system causes interferences (which can be identified by turning the system off and on) with other devices, the user could try to solve the problem by:

- relocating the system,
- increasing the distance from other devices,

- powering the ultrasound system from an outlet different from the one of the interfering device,

- contacting Esaote Service personnel for help.

Electro-Surgical Devices (ESUs)
Electro-surgical devices or other devices that introduce radiofrequency electromagnetic fields or currents into the patient may interfere with the ultrasound image. An electro-surgical device in use during ultrasound imaging will grossly affect the 2D image and render Doppler modalities useless.

NOTE ***Cables and accessories other than the supplied ones could negatively affect EMC performance of the device.***

Electromagnetic Emissions

Guidance and manufacturer's declaration – Electromagnetic emissions		
MyLab is suitable for use in the specified electromagnetic environment. The purchaser or user of **MyLab** should assure that it is used in an electromagnetic environment as described below:		
Emission Test	**Compliance**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	This **MyLab** uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	**MyLab** is suitable for use in all establishments, other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies Class A	
Voltage fluctuations and flicker emissions IEC 61000-3-3	Complies	

NOTE ***The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.***

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Essential performance

- Free from noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.
- Free from the display of inaccurate numerical values associated with the diagnosis to be performed.
- Free from the display of inaccurate safety-related indications.
- Free from the production of unintended or excessive ultrasound output.
- Free from the production of unintended or excessive transducer assembly surface temperature.
- Free from the production of unintended or uncontrolled motion of transducer assemblies intended for intra-corporeal use.

Electromagnetic Immunity

The electromagnetic tests are aimed at simulating the typical transients of an electromagnetic environment. **MyLab** was tested for immunity to transients and at their typical levels in a domestic, hospital or commercial environment.

Electromagnetic Immunity for All Medical Equipment

MyLab is intended for use in the electromagnetic environment specified below. The customer or the user of **MyLab** should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment and Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV on contact ±15 kV in air	±8 kV on contact ±15 kV in air	The floor should be in wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0% U_T; 0,5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	0% U_T; 0,5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of **MyLab** requires continued operation during power mains interruptions, it is recommended that **MyLab** is powered from an uninterruptible power supply or a battery.
Power interruptions IEC 61000-4-11	0% U_T; 250/300 cycles	0% U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of **MyLab** requires continued operation during power mains interruptions, it is recommended that **MyLab** is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

MyLab is intended for use in the electromagnetic environment specified below. The customer or the user of **MyLab** should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment and Guidance**
NOTE: U_T is the a.c. mains voltage prior to application of the test level			

Electromagnetic Immunity for Medical Equipment not Life Supporting

MyLab is intended for use in the electromagnetic environment specified below. The customer or the user of **MyLab** should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment and Measures to Be Taken**
Conducted RF IEC 61000-4-6	3 V 0.15-80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15-80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Mobile or portable radio frequency (RF) communication equipment should be used no closer to any part of **MyLab**, including cables. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which **MyLab** is used exceeds the applicable RF compliance level above, **MyLab** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re–orienting or relocating **MyLab**.
2. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Distances between Radiofrequency (RF) Communication Systems and MyLab

It is recommended not to use radiofrequency (RF) transmission systems near the ultrasound scanner. RF systems can cause interference, which alters the echographic image and Doppler traces.

The operator can prevent interference caused by electromagnetic fields by maintaining a minimum distance between the ultrasound scanner and the RF communication systems being used (for example cell telephones, mobile telephones).

The following degradation shall not be allowed:

- the disturbance shall not produce noise on a waveform, artefacts, distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis;
- the disturbance shall not produce an error displaying inaccurate numerical values associated with the diagnosis to be performed;
- the disturbance shall not produce an error displaying inaccurate safety-related indications;
- the disturbance shall not produce unintended or excessive ultrasound output;
- the disturbance shall not produce unintended or excessive transducer assembly surface temperature.

MyLab, according to the definition of the IEC 60601-1-2 ed. 4 standard is suitable to be installed in professional healthcare facility environment.

The operator must remember that the intensity of the electromagnetic fields generated by fixed transmitters (for example radio-base stations for cellular or cordless telephony, TV and radio transmissions, amateur radio transmissions) cannot be predicted on a theoretical basis. Consequently, a direct measure may be necessary in the use environment of a **MyLab**. If the intensity of the electromagnetic fields exceeds that one specified in the immunity levels shown in the previous tables, and the ultrasound scanner performs incorrectly, additional measures may be necessary, for example by positioning the ultrasound scanner in a different way.

Work related musculoskeletal disorders

Execution of ultrasound examination can provoke work related musculoskeletal disorders (WRMDs) of ultrasound practitioners due to long-lasting arm abduction, body twisting, extensive wrist flexion and extensive transducer grip and pressure. There are several causative factors including high workload, increasing BMI of the patient, poor equipment and room design, poor posture while scanning.

WARNING

WRMDs can be minimized both by an application of medical device ergonomic and usability requirements and by following the best practice of ultrasound practitioners.

Repetitive Strain Injury

In the category of occupational diseases, musculoskeletal disorders have been reported by the clinical literature[1] as a result of repetitive scanning. These musculoskeletal disorders are also referred to as Repetitive Strain Injury (RSI). To prevent the risk of RSI, it has been recommended:

- to maintain a balanced position while scanning,
- not to grip the probe with excessive force,
- to take work breaks to allow muscles to relax,
- to introduce routine exercises such as gentle passive stretching.

Working with Video Display

Scanning can require long sessions in front of a screen. Consequently visual problems such as eyestrain and irritation can result[2]. Visual discomfort is reduced when the following recommendations are observed:

1. Necas M. "Musculoskeletal symptomatology and Ripetitive Strain Injuries in Diagnostic Medical Sonographers", Journal of Diagnostic Medical Sonography 12, p. 266-273, 1996
   Pike I, Russo A., Berkowitz J et al. "the prevalence of musculoskeletal disorders among Diagnostic Medical Sonographers", Journal of Diagnostic Medical Sonography 13, p. 219-227, 1997
2. See for example OSHA 3092 "Working safely with video terminals display" 1997

- orientate the display so that it can be comfortably observed while scanning,
- take rest breaks after a long scanning session.

Information about ultrasound residual risks

In conformity to the requirement set by the European Regulation 2017/745/EU (Medical Device Regulation) in Annex I General Safety and Performance Requirements, art 23.4 Information in the instruction for use, comma (g), this paragraph draws to the attention of ultrasound practitioners to the following residual risks that, even though not directly related to the technical implementation of this medical device itself, can be encountered during its professional use.

As such, to the best of its current knowledge on the state of the art in ultrasound diagnostic imaging, Esaote has identified the following additional potential residual risks that are hereafter grouped for main applications.

Cardiac

Stress Echocardiography

Absolute and relative contraindications as indicated by American Society of Echocardiography must be applied to avoid serious complications.

The incidence rate of serious complications (e.g., serious arrhythmias, myocardial infarction) has been reported to be 0.04% during stress exercise testing, 0.01% after stress exercise testing, and ≤0.2% for overall complications.

Stress echocardiography should be performed in a sufficiently spacious room with the following equipment readily available: an emergency cart with emergency drugs and airway management devices, exercise stress monitoring system (automated sphygmomanometer, 12-lead ECG monitor), defibrillator, and oxygen tanks.

Contrast Echocardiography

Contrast Agents increase risk of capillary hemorrhaging in soft tissues through mechanical effect of ultrasound.

The ALARA principle should be observed when adjusting controls that affect the acoustic output and transducer dwell times should be considered.

Although anaphylactoid reactions are rare, echocardiographic laboratories that routinely use contrast agent should have policies in place for emergent resuscitation of patients who may experience serious side effects.

Contrast Media are medicinal products for diagnostic use whose intended purpose is to enhance the echogenicity of the blood, or of fluids which results in an improved signal to noise ratio. Those medical products are made available on the market with an appropriate product labeling including specific information related to product's indications, contraindication, posology and precaution for use.

Multifunctional ultrasound scanners are indicated for the use in conjunction with such kind of medicinal products in order to assist them in achieving their own specific intended purpose. Esaote does not support or encourage the off-label use of contrast media

Our Medical devices do not integrate or control the way how these medicinal products are administered to the patients.

Usually, they are administered via an intravenous injection performed directly by a medical doctor or by a qualified healthcare professional.

Esaote invites the ultrasound practitioners to read carefully the contrast media IFU provided by the manufacturer before administering it to the patient and to follow the appropriate professional guidelines

Vascular and Neonatal Cephalic

At the bone-brain interface US can result in temperature rises above recommended safety threshold that can potentially alter neuronal structure and function and affect behavioral and cognitive function.

Scans should be minimized as possible and exposure should be ALARA to answer the diagnostic question.

Color Doppler should not be utilized except for clearly defined clinical reasons which provide additional diagnostic or prognostic information.

General Imaging

Contrast Enhanced US

Contrast Agents increase risk of capillary hemorrhaging in soft tissues through mechanical effect of ultrasound.

The ALARA principle should be observed when adjusting controls that affect the acoustic output and transducer dwell times should be considered.

Although anaphylactoid reactions are rare, echocardiographic laboratories that routinely use contrast agent should have policies in place for emergent resuscitation of patients who may experience serious side effects.

Contrast Media are medicinal products for diagnostic use whose intended purpose is to enhance the echogenicity of the blood, or of fluids which results in an improved signal to noise ratio. Those medical products are made available on the market with an appropriate product labeling including specific information related to product's indications, contraindication, posology and precaution for use.

Multifunctional ultrasound scanners are indicated for the use in conjunction with such kind of medicinal products in order to assist them in achieving their own specific intended purpose. Esaote does not support or encourage the off-label use of contrast media.

Our Medical devices do not integrate or control the way how these medicinal products are administered to the patients.

Usually, they are administered via an intravenous injection performed directly by a medical doctor or by a qualified healthcare professional.

Esaote invites the ultrasound practitioners to read carefully the contrast media IFU provided by the manufacturer before administering it to the patient and to follow the appropriate professional guidelines

Shear Wave Elastography

When acoustic radiation force impulses are used, significant temperature rises may occur, especially, if bones lie in the beam.

Transducer self-heating increases with high number of pulse sequences and scan duration.

It may not be appropriate or valid to apply the current TI models in the SWE, since TI is a steady state estimates while the SWE is generated by the ultra-fast repetitive of short-duration focused acoustic pulses. So far, no specific risk indicator has been developed, thus the duration of the SWE should be kept as less as possible to reduce the thermal stress to the targeted tissue.

Transrectal access

Examinations should be performed with more cautions because heating of the transducer has the potential to produce additional heat to adjacent tissue.

The ALARA principle should be observed when adjusting controls that affect the acoustic output and transducer dwell times should be considered.

Intraoperative and Laparoscopic access

Laparoscopic ultrasound-related morbidity is low and has been reported to range between 0% and 4%.

Equipment cleaning and disinfection should be performed according to institutional/hospital approved infection-control guidelines utilizing vendor-recommended disinfection products.

Ultrasound transducers used in image-guided interventional procedures are generally classified as semi-critical items (objects that come into contact with mucous membranes or skin that is not intact). Direct transducer contact with critical medical products should be avoided during the procedure despite the use of sterile, disposable transducer covers. Critical medical products, which include ultrasound transducers that are used intraoperatively, or through which a needle will be introduced (e. g. for abscess drainage or PTCD) must be sterilized. After every examination, residual US gel should be carefully removed with a disposable towel and the transducer cord wiped with a towel moistened with cleanser, followed by disinfection with a virucidal agent. The sterilization process should always conform to standard operating procedures.

The ALARA principle should be observed when adjusting controls that affect the acoustic output and transducer dwell times should be considered.

Neonatal

During neonatal diagnostic ultrasound examinations capillary hemorrhaging in lung may occur in neonates, especially if they are pre-term.

Ultrasound exposure of the neonatal brain may lead to a significant temperature elevation at the bone-brain, which can potentially alter neuronal structure and function and affect behavioral and cognitive function.

The ALARA principle should be observed when adjusting controls that affect the acoustic output and transducer dwell times should be considered.

Color Doppler should not be utilized except for clearly defined clinical reasons which provide additional diagnostic or prognostic information.

Women Health

Gynecology - Transvaginal

Examination should be performed with more cautions because heating of the transducer has the potential to produce additional heat to adjacent tissue.

The ALARA principle should be observed when adjusting controls that affect the acoustic output and transducer dwell times should be considered.

Gynecology - Shear Wave Elastography

When acoustic radiation force impulses are used, significant temperature rises may occur, especially, if bones lie in the beam.

Transducer self-heating increases with high number of pulse sequences and scan duration.

It may not be appropriate or valid to apply the current TI models in the SWE, since TI is a steady state estimates while the SWE is generated by the ultra-fast repetitive of short-duration focused acoustic pulses. So far, no specific risk indicator has been developed, thus the duration of the SWE should be kept as less as possible to reduce the thermal stress to the targeted tissue.

Fetal

Acoustic output from diagnostic ultrasound devices is sufficient to cause temperature elevations in fetal tissue. In general, temperature elevations become progressively greater from B-mode to color Doppler to spectral Doppler applications.

For identical exposure conditions, the temperature rise near bone increases with ossification development throughout gestation.

Although, in general, an adverse fetal outcome is possible at any time during gestation, most severe and detectable effects of thermal exposure in animals have been observed during the period of organogenesis.

For identical exposure conditions, the potential for thermal bioeffects increases with the dwell time during examination. Ultrasound exposures that elevate fetal temperature by 4°C above normal for 5 minutes or more have the potential to induce severe developmental defects.

In current clinical practice, using commercially available equipment, it is unlikely that such thermal exposure would occur at a specific fetal anatomic site.

Transducer self-heating is a significant component of the temperature rise of tissues close to the transducer. This may be of significance in transvaginal scanning, but no data for the fetal temperature rise are available.

The TI should not be interpreted as an actual degree Celsius temperature rise in the region of interest. Its use should be limited to a relative indication of the maximum temperature rise. Although the TI is not ideal, it should be used to assess the potential thermal risk in conjunction with the dwell time.

Scans should be minimized as possible and exposure should be ALARA to answer the diagnostic question. If it is ever clinically indicated in the first trimester, spectral Doppler examination of the fetus should be used with caution.

The application of SWE in human fetuses was not approved so far due to the potential risk concerns of SWE to the developing fetuses and the lack of literature reporting an ascertaining risk in this field.

Biocompatibility and Infection Control

Probes and electrodes intended to be used on intact skin have very limited probabilities to propagate infections; basic procedures as described in the "Probes and Consumables" manual are sufficient for infection control.

Endocavity and transesophageal probes require specific cleaning and disinfecting procedures. See the "Probes and Consumables" manual for complete details on these procedures.

Before each exam properly clean the probes. Refer to the "Probes and Consumables" manual for further details on cleaning and disinfecting probes, kits and electrodes.

Items in Contact with Patient

Esaote probes and electrodes materials that are in contact with the patient have been proved to comply with EN ISO 10993 "Biocompatibility Tests Requirements", according to their intended use. No negative reactions to these materials have been reported.

The probe and electrode materials that are in contact with patients, comply with the applicable requirements of EN ISO 10993-1, according to their intended use. No negative reactions to these materials have been reported.

Latex Sensitive Patient

The USA Food and Drug Administration (FDA) has issued an alert on products composed of latex, because of reports of severe allergic reactions.

NOTE ***Esaote probes do NOT contain latex***

WARNING

The probe protective covers used during the patient exam are usually made of latex. Carefully read the protective cover package labeling to check the material used. Be certain to identify latex sensitive patients before starting the exam. Serious allergic reactions to latex have been reported and the user should be ready to react accordingly (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices"). For additional information in the U.S.A., refer to FDA Medical Alert MDA91-1.

Device Modifications

Esaote is not responsible for any unauthorized modification of equipment (including cables) and/or probes.

CAUTION

Do not modify any Esaote equipment without authorization. Always refer to Esaote personnel for authorized modifications of the device.

If the equipment has been modified, appropriate inspections and testing must be carried out to ensure the continued safe use of the equipment.

Explosive Hazard

WARNING

MyLab is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide. Do not use MyLab in the presence of flammable anaesthetics. Explosion is a hazard under such conditions.

Wireless safety

MyLab is equipped with built-in wireless capability.

If the equipment is not installed and used in accordance with the instructions, the equipment may cause harmful interference to radio communications.

NOTE ***The wireless capability has to be considered as an intentional RF (Radio Frequency) transmitter as indicated by the symbol:***

When the wireless is active, **MyLab** ***might interfere with other equipment.***

When wireless is active, the following safety precautions should be observed:

- Maintain a minimum distance of 20 cm (8 inches) or more from the antennas of the equipment and the body of patient and operators. If a shorter distance is needed to work, temporarily switch the wireless device off.

- Use in specific environments:

  – the use of wireless devices in hospitals is restricted to the limits set forth by each hospital.

  – the use of wireless devices in hazardous locations is limited by the constraints posed by the safety directive of such environments.

MyLab is equipped with a standard Wireless LAN RF receiver and transmitter module that uses the following frequencies:

Receiver/Transmitter Band [MHz]	Modulation	Maximum Transmitter Power [dBm]
2400 to 2483.5	DSSS and OFDM	20
5150 to 5350	OFDM	23
5470 to 5725	OFDM	23

MyLab may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.

CAUTION **The use of wireless devices might be restricted in certain locations: always verify local regulations before using them.**

Users in the European Union

MyLab complies with the Radio Equipment Directive 2014/53/EU and is CE marked.

MyLab is a device in Class 2 according to RED Directive: it can operate in European countries without restrictions indoor. Refer to local regulations for further information.

NOTE ***Indoor use only is allowed in the frequency range of 5150-5350 MHz.***

Users in the United States of America

MyLab contains radio modules fully compliant with CFR47 Part 15 Sub. C (under FCC Rules). This equipment meets the requirements of CFR47 Part 18 (under FCC rules).

The FCC logo label, placed on the device certifies that the device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation.

N28711

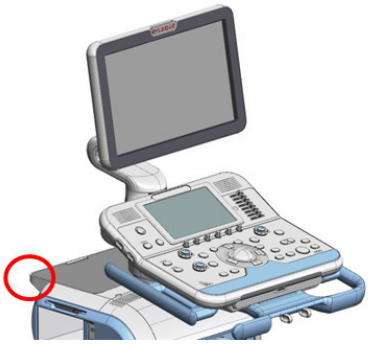
Users in Australia

MyLab meets the requirements of the AS/NZS 4268:2008 standard, which is mandatory for Wi-Fi and Bluetooth equipment in Australia (C-tick registration). Please note that the C-tick logo label is placed on the device.

Wireless antenna position

MyLab generates and radiates radio-frequency energy. A minimum body-to-antenna distance of 20 cm must be maintained when the device is installed and operated. The antennas are located on the **MyLab** where indicated by the red circle in the figure below.

Fig. 2-1: Wireless antenna position on MyLabX6, MyLabX7 Family (both right and left edges)



Chapter 3

3. MyLab Overview

MyLabX6 and **MyLabX7** are professional, innovative and versatile real-time high-resolution ultrasound scanners. The wide range of probes makes them suitable for many clinical applications.

MyLabX6 and **MyLabX7** are based on a mainframe easily movable platform. **MyLabX6** and **MyLabX7** have four swiveling wheels, they have a range of height adjustments for one-time installation, the main screen can be easily moved due to an optional articulated arm. Due to their small footprint they can fit in any real-world clinical environment.

The possibility to adjust both the main screen, control panel and touch screen brightness enables the use of **MyLab** in any environment even with really different lighting conditions: from the really bright scenario of the operative room, to the dark scenario of the examination room, passing through the medium-light environment of the bed-side examination setting.

About MyLab

Intended Use

MyLabX6 and **MyLabX7** are intended to perform diagnostic general ultrasound studies including:

Fetal, Abdominal, Intraoperative (Abdominal), Laparoscopic, Pediatric, Small organ, Neonatal, Neonatal Cephalic, Adult Cephalic, Transrectal, Transvaginal, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Urological, Cardiovascular Adult, Cardiovascular Pediatric, Transoesophageal (cardiac), Peripheral Vessel.

The equipment provides imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

The ultrasonic medical diagnostic equipment is intended to be connected to mechanical and electronic ultrasound probes (convex array, linear array and phased array) and Doppler probes.

Clinical Applications and Supporting Probes

A variety of ultrasound probes can be connected to **MyLabX6** and **MyLabX7**.

Table 3-1: Available probes and applications

Probe	Applications	Biopsy
AC2541	Abdominal, Gynecology, Musculo-skeletal, Obstetric and Fetal, Urology, Vascular	YES
CA430E	Abdominal, Gynecology, Musculo-skeletal, Urology, Vascular	YES
E 3-12	Gynecology, Obstetric and Fetal, Urology	YES
EC1123	Gynecology, Obstetric and Fetal, Urology	YES
IH 6-18	Abdominal, Breast, Gynecology, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	YES
IL 4-13	Abdominal, Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	YES
IOE323	Abdominal, Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	YES
IOT342	Abdominal, Musculo-skeletal, Pediatric, Small Organ, Vascular	YES
L 3-11	Abdominal, Breast, Musculo-skeletal, Obstetric and Fetal, Pediatric, Small Organ, Thyroid, Vascular	YES
L 4-15	Abdominal, Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	YES
LA435	Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	YES
LP323	Abdominal	NO
LP 4-13	Abdominal	NO
mC 3-11	Abdominal, Cardiac, Neonatal, Obstetric and Fetal, Pediatric, Pediatric Cardiac, Small Organ, Thyroid, Vascular	YES
P 1-5	Abdominal, Adult Cephalic, Cardiac, Obstetric and Fetal, Vascular	NO
P 2-9	Cardiac, Pediatric Cardiac	NO
P2 5-13	Adult Cephalic, Cardiac, Neonatal, Pediatric, Pediatric Cardiac, Vascular	NO
S2MCW	Abdominal, Cardiac, Pediatric Cardiac	NO
S2MPW	Adult Cephalic	NO
S5MCW	Vascular	NO
SB2C41	Abdominal, Gynecology, Obstetric and Fetal	YES
SB3123	Gynecology, Obstetric and Fetal, Urology	NO

Probe	Applications	Biopsy
SC3123	Abdominal, Cardiac, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	YES
SE3133	Gynecology, Obstetric and Fetal, Urology	YES
SHFCW	Vascular	NO
SI2C41	Abdominal, Breast, Gynecology, Musculo-skeletal, Obstetric and Fetal, Small Organ, Urology, Vascular	YES
SL1543	Abdominal, Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	YES
SL2325	Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	YES
SL3116	Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	YES
SP2442	Cardiac, Neonatal, Pediatric, Pediatric Cardiac, Vascular	NO
ST2612	Cardiac	NO
ST2613	Cardiac, Pediatric Cardiac	NO
TLC 3-13	Gynecology, Urology	YES

Table 3-2: Available applications and related probes

Application[1]	Probes
Abdominal	AC2541, CA430E, IH 6-18, IL 4-13, IOE323, IOT342, L 3-11, L 4-15, mC 3-11, P 1-5, S2MCW, SB2C41, SC3123, SI2C41, SL1543 Laparoscopic: LP 4-13, LP323
Adult Cephalic	P 1-5, S2MPW
Breast	IH 6-18, IL 4-13, IOE323, L 3-11, L 4-15, LA435, SI2C41, SL1543, SL2325, SL3116
Cardiac	mC 3-11, P 1-5, P 2-9, P2 5-13, S2MCW, SC3123, SP2442 Transoesophageal: ST2612, ST2613
Gynecology	AC2541, CA430E, IH 6-18, L3-11, SB2C41, SI2C41 Transrectal/Transvaginal: E 3-12, EC1123, SB3123, SE3133, TLC 3-13
Musculo-skeletal[2]	AC2541, CA430E, IH 6-18, IL 4-13, IOE323, IOT342, L 3-11, L 4-15, LA435, SI2C41, SL1543, SL2325, SL3116
Neonatal[3]	IH 6-18, mC 3-11, P2 5-13, SC3123, SP2442
Obstetric and Fetal	AC2541, L 3-11, mC 3-11, P 1-5, SB2C41, SI2C41 Transrectal/Transvaginal: E 3-12, EC1123, SB3123, SE3133

Application[1]	Probes
Pediatric	IH 6-18, IL 4-13, IOE323, IOT342, L 3-11, L 4-15, LA435, mC 3-11, P2 5-13, SC3123, SL1543, SL2325, SL3116, SP2442
Pediatric Cardiac	mC 3-11, P 2-9, P2 5-13, S2MCW, SP2442, Transoesophageal: ST2613
Small Organ	IH 6-18, IL 4-13, IOE323, IOT342, L 3-11, L 4-15, LA435, mC 3-11, SC3123, SI2C41, SL1543, SL2325, SL3116
Thyroid	IH 6-18, IL 4-13, IOE323, L 3-11, L 4-15, LA435, mC 3-11, SC3123, SL1543, SL2325, SL3116
Urology	AC2541, CA430E, SI2C41 Transrectal/Transvaginal: E 3-12, EC1123, SB3123, SE3133, TLC 3-13
Vascular	AC2541, CA430E, IH 6-18, IL 4-13, IOE323, IOT342, L 3-11, L 4-15, LA435, mC 3-11, P 1-5, P2 5-13, S5MCW, SC3123, SHFCW, SI2C41, SL1543, SL2325, SL3116, SP2442

1. Applications are listed here as they appear on user interface. Some clinical applications are managed by using proper probe and preset.
2. Both conventional and superficial (including nerve blocks)
3. Includes Neonatal and Neonatal Cephalic

NOTE ***Applications are dependent on your MyLab configuration, transducer and exam type. Not all applications are approved in all Countries. Please refer to your Esaote local representative for further information.***

Patient population

- Age: all ages (including embryos and fetuses)
- Location: worldwide
- Sex: male and female
- Weight: all weight categories (in terms of Body Mass Index)
- Height: no limitations

Operator profile

MyLabX6 and **MyLabX7** are designed for operators who are qualified and trained in using ultrasound scanner:

- Sonographers
- Cardiologist
- Maternal-fetal Medicine Obstetrician / Perinatologist
- Radiologist and Internist
- System Administrator and Customer Service Engineer

The operator must have read and understood the user manuals.

Contraindications

MyLabX6 and **MyLabX7** are not intended for:

- ophthalmic use or any use causing the acoustic beam to pass through the eye.

WARNING

Do not use MyLab for ophthalmic or transorbital applications.

The ultrasound beam must not be directed to the eyes.

MyLab Overview

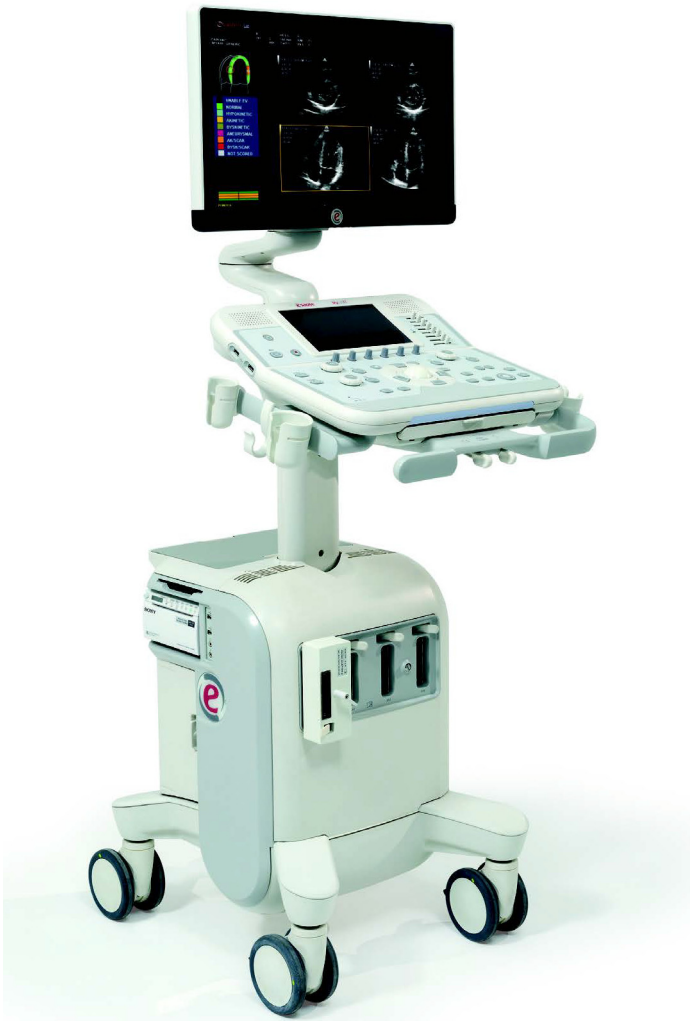
MyLab models differ in the installed licences. Refer to the corresponding Sales Area manager for further information.

MyLab is equipped with a free-orientable LCD. The orientable LCD holder can be easily adjusted to reach the optimal LCD position for the exam.

MyLab consists of a control panel assembly with the LCD and a console with the device electronics and connectors.

The console top is equipped to house peripherals. It has a rear mains switch to power up the console, the screen and the peripheral devices. The device provides handles and independent brakes on four wheels for movement and transportation.

Fig. 3-1: MyLab



Control Panel Assembly

The control panel assembly includes the handle, all device controls, the touchscreen, the loud speakers, the probes, gel and ECG cables holders. The LCD is installed on top of the assembly.

The ON/OFF switch is located beside the touchscreen, on the left side.

USB Port

Two (2) USB ports are located on the left side of the control panel. These ports can be used to connect a USB device for digital storage, a USB footswitch or a USB printer.

Pull out Qwerty Keyboard

A pull out alphanumeric keyboard is placed at the base of the control panel. The keyboard is mounted on a sliding drawer: just push it to extract the keyboard.

The control panel assembly can be rotated for optimal working orientation and for transportation.

Fig. 3-2: Pull out Qwerty keyboard

Probe, Gel and Cable Holders

Insert the holders on the lateral stirrups and place them in the desired position.

Console

Probe Connectors

Four probe connectors (EA1÷EA4) are located on the front of the device.

Auxiliary USB Port and Burner

On the left side and on the rear side of the console there are four (4) auxiliary USB ports and a CD/DVD burner (left side). The USB ports can be used to connect a USB printer, a USB footswitch or a USB digital archive medium.

The burner allows the operator both to burn and to read CDs/DVDs.

Peripherals Housing

The console top is equipped to house peripheral devices (for example a USB printer); the peripheral can be easily connected and disconnected and secured to the device console with belts.

Storage area for B/W thermal USB printer is located on the left side of the console.

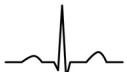
To properly connect the printer, use the connector placed on the rear panel.

Headphone and Microphone

On the left side of the console, just below the USB ports, there are two (2) connectors: one connector for the headphone and one connector for the microphone.

The microphone has not current use.

ECG Connector



The ECG cable connector is placed on the right side (at the bottom) of the console.

Power Plug

The power plugs and the electrical power switch (mains switch) are located on the bottom of the device, at the rear.

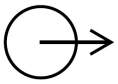
LAN Connector

The LAN connector is placed at the bottom of the rear side.

Wheels

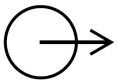
All four wheels are rotational. Each wheel has a brake-pedal above each wheel.

Line Out



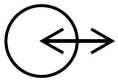
On the left side of the console there is a jack for audio signal output.

Video Out



On the left side of the console there is a video output for a secondary monitor.

Aux Out



On the left side of the console, currently not used.

Electrical Connection

The fuse box, the main switch, the power cable socket and an earth terminal are placed on the rear at the right side.

The main switch is placed just below the main cable socket.

Fig. 3-3: Main switch on the rear of the device

Procedure

1. Open the rear door.
2. Plug in the power cord.
3. Close the rear door by letting the cord go through the lower slot.
4. Connect **MyLab** to the power mains.

WARNING

When installing MyLab, check that the power cable is not tightly bent, that it can't be squashed by a misplaced foot or by heavy objects.

The earth terminal can be connected to an external protective earthing system as additional protection. This connection is not necessary in most cases and is only recommended for situations involving multiple equipment in a high-risk patient environment to provide assurance that all equipment is at the same potential and operates within acceptable leakage current limits.

Probe Connections

Both imaging and Doppler probes can be connected to four (4) connectors, indicated by symbols EA1, EA2, EA3 and EA4. The EA1 connector can host any probe equipped with a big connector while EA2, EA4 connectors can host any probe equipped with a small connector.

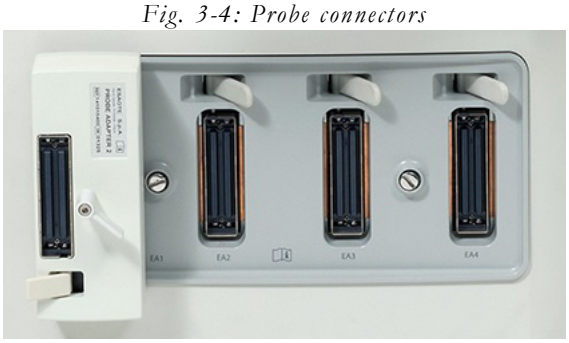
Probe Adapter

MyLab can be equipped with a probe adapter to be placed in EA1 connector. This adapter changes the connector dimension, from big to small size, allowing the use of small connector probes in EA1.

NOTE ***All small connector probes can be used with probe adapter, with the exception of transesophageal probes, phased array probes and SB2C41 Bi-Scan probe.***

Biopsy procedure can not be activated on probes connected to **MyLab** ***through the probe adapter.***

Fig. 3-4: Probe connectors



Probes with big connector Make sure that the connector-securing device is in the "OPEN" position, align the pins of the two connectors and carefully attach the probe. To secure it, move the securing device to its "LOCK" position.

Probes with small connector Connector-securing devices are placed above the probe small connectors.

Make sure that the securing device is positioned on the right (open position) and carefully attach the probe connector by placing the cable feedthrough downwards. To secure the probe, move the securing device towards left (clockwise).

WARNING **Do not touch the probe connector pins or the probes receptacle.**

Never disconnect the probe while it is active. Press the FREEZE **key before disconnecting the probe.**

CAUTION **Check to correctly align the probe connector before inserting it. Close the connector-securing device only after having completely inserted the connector.**

Control Panel Assembly Orientation

This assembly can be pushed up/down and laterally oriented to maximize operator comfort; also, it can be rotated by 180° for optimal handling (closed position).

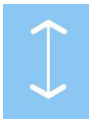
These two rotations are controlled by two levers located below the control panel (as shown in the drawings below).

Fig. 3-5: Orientation and lifting levers

The levers can be used to optimally adjust the control panel and the screen into its working position.

The orientation lever, located on the left, allows lateral rotation of the assembly.

The lifting lever, located on the right, allows to lift or lower the control panel.

Symbol	
	Orientation lever
	Lifting lever

The LCD can be directly rotated and oriented independently from the control panel.

Push the orientation lever to rotate the control panel into the new position. Release the lever when the control panel is correctly positioned. This lever allows to rotate by up to 90° clockwise and by up to 180° counterclockwise.

Push the lifting lever and acting on the handle to adjust the height of the control panel. This lever allows a vertical displacement of ±20 cm.

CAUTION

When rotating the keyboard, pay attention not to damage the peripherals placed on the console. If the peripheral falls down, injury may be caused.

Batteries

MyLab can be equipped with an internal battery pack.

NOTE ***The battery pack is installed by Esaote personnel. This person will be responsible for its installation and for ensuring that the device is working properly.***

CAUTION **When MyLab is equipped with its internal battery, do not leave the device exposed to direct sunlight.**

If some smell is noticed coming from a MyLab equipped with its internal battery, stop using it immediately and contact Esaote personnel.

Remove the batteries from the device if it will not be used for a long time.

WARNING **Avoid contact with leaking batteries, the contents are harmful. Irritation, including caustic burns and injury may occur following exposure to a leaking battery.**

When **MyLab** is connected to the power mains and the main switch is on ON, the battery is continuously charged, even if **MyLab** is switched off. On the other hand, the battery discharges whenever **MyLab** is disconnected from the power mains.

When the charging level of the battery reaches the minimum threshold needed for working, the icon is contoured by a blinking frame and the residual time is displayed beside. Either connect **MyLab** to the mains power or switch it off. **MyLab** automatically switches itself off when the residual operating time is expired.

Battery Status

Battery Status LED The battery LED is located on the control panel.

Its color indicates the status of the battery: when the LED is lighted, at least one battery is being charged.

The best method for charging the battery is to connect **MyLab** to the power mains while keeping it switched off.

During the charging procedure the battery LED is orange: the procedure is completed when the battery LED switches off.

A device which has not been used for a month needs to be charged before using it with the battery.

CAUTION

Charge and discharge the battery only when the environment temperature is between 15°C and 35°C.

The battery pack is not charged when overheating.

Blinking of the battery LED

When the battery can't be charged, the LED starts blinking.

Battery Status Icons

When the battery pack is installed, **MyLab** displays the icons below.

Table 3-3: Battery icons

Fully charged battery	Partially charged battery	Low battery
		

The residual charge (indicated in percentage) is displayed above the battery icon and it is continuously updated.

Once the minimum threshold of the working condition is reached, the residual operating time, indicated in minutes, replaces the main power icon, surrounded by a flashing yellow frame.

When the battery is charging, its icon replaces the Main power cable icon. Once the battery is fully charged, the Main power cable icon is displayed again.

First Use

A new battery pack might be partially discharged: before using it for the first time, perform one full charging procedure.

Battery Lifetime

The battery lifetime is limited and varies according to circumstances. In normal conditions battery pack lasts three years. Esaote recommends to replace the battery pack every three years.

NOTE

The battery pack has to be replaced by Esaote personnel. This person will be responsible for ensuring that the device is working properly.

Error Messages

Whenever an internal fault occurs, the device automatically freezes and an error message is displayed on the screen. Switch **MyLab** off and then turn it on again to see whether the error message persists.

AO

Save anyway the log file (refer to the "Archive" section of the Advanced Operation manual for further information) and contact the Esaote Service department.

Errors in Battery Management

The battery icon is shown crossed out whenever an error in the battery management occurs.

The number in the warning message indicates the type of error.

Error #1

This error indicates a fault on the Power Supply: in this case, information on batteries may not be correct. **MyLab** displays the following message:

> Error #1: wrong communication with power supply. The automatic shut down is disabled.

If this situation occurs, shut down **MyLab**, by keeping ON/OFF pressed, and contact Esaote Service.

Error #2

This error indicates a failed access to the battery pack: in this case, information on batteries may not be correct. **MyLab** displays the following message:

> Error #2: wrong communication with battery logics. The automatic shut down is disabled.

If this situation occurs, shut down **MyLab**, by keeping ON/OFF pressed, and contact Esaote Service.

Error #3

This error indicates that one battery couldn't be charged. **MyLab** displays the following message:

> Error #3: problem with battery charging.

If this situation occurs, close the exam as soon as possible by pressing END EXAM and switch **MyLab** off by pressing ON/OFF and then the main switch

placed on the rear panel. Switch **MyLab** on again and check whether the message is still present. If the problem persists, contact Esaote personnel.

Error #4 This error indicates that at least one of the batteries has reached the maximum temperature allowed for its working conditions. **MyLab** displays the following message and shuts down automatically:

> Error #4: problem with battery status.
> The automatic shut down will start in a few seconds.

Should this situation occur, contact Esaote Service.

Power Supply Error Messages

Whenever an error in the management of the power supply occurs, **MyLab** displays a numbered error message: the number in the warning message indicates the type of error.

Error #5 This error indicates an overheating problem of the power supply. **MyLab** displays the following message:

> Error #5: overheating!
> Please, contact the Service department.

If this situation occurs, shut down **MyLab** and leave it off for a while. Verify that there is adequate ventilation to prevent the overheating of the device.

Should the problem persist, contact the Esaote Service department.

Error #6 This error indicates that a fan is not working. **MyLab** displays the following message:

> Error #6: problem with fan.
> Please, contact the Service department.

If this situation occurs, press **OK** and then shut down **MyLab**. Verify that nothing is blocking the fan functioning, especially on the rear panel.

Should the problem persist, contact the Esaote Service department.

Error #7 This error indicates that a fault of the internal voltages occurs. **MyLab** displays the following message:

> Error #7: problem with internal voltage.
> Please, contact the Service department.

If this situation occurs, press **OK** and then shut down **MyLab**. Contact the Esaote Service department.

Error #8

This error indicates that a fault of the impulse voltages occurs. **MyLab** displays the following message:

> Error #8: wrong impulse voltage.
> Please, contact the Service department.

If this situation occurs, press **OK** and then shut down **MyLab**. Contact the Esaote Service department.

4. Preparing for use

MyLab will be installed by Esaote personnel. Esaote personnel will be responsible for opening the packaging and ensuring that the device is correctly programmed and operational.

The information and procedure provided in this chapter will guide to prepare **MyLab** for use. Preparation includes connecting probes and external devices, locking articulated components for moving, and ensuring that device operating is met.

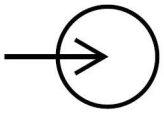
Acclimation Time

If the device has been exposed to temperatures which are outside the range given for its correct working (15÷35°C), it must acclimate, before being switched on. The following table indicates the necessary waiting times.

Table 4-1: Acclimation Time

T(C°)	60	55	50	45	40	35÷15	10	5	0	-5	-10	-15	-20
Hours	8	6	4	2	1	0	1	2	4	6	8	10	12

Connecting MyLab to a Network



To use connectivity features, the device must be connected to a network.

The LAN plug is placed at the bottom of the rear side; it supports Gigabit, 10Base-T, and 100Base-T Ethernet LAN. An Esaote field engineer or your network administrator must configure **MyLab** for network connectivity.

1. Turn off **MyLab** power.
2. Connect one end of the provided network connection cable to the wall plug for your network.
3. Connect the other end of the cable to the network plug on **MyLab**.
4. Turn **MyLab** on.

Connecting Peripherals

Peripherals, that have been ordered simultaneously with the **MyLab**, are usually already mounted and connected. The first mounting and connecting will usually be performed by an Esaote technician.

NOTE ***Esaote suggests to contact its Service representative to install any auxiliary device.***

Before installing the peripheral devices, make sure that **MyLab** is switched off and unplug the power cable from the mains outlet. Brake the wheel to fix **MyLab**.

Powering sockets for peripheral devices are placed at the rear on the left; peripheral connections are placed at the rear, on the right. The network connector is placed at the rear in the bottom central position.

How to connect peripheral devices:

1. Ensure that the **MyLab** is switched off (complete shut down not stand-by or other conditions).
2. Connect the peripheral device to the **MyLab**.
3. Switch the peripheral device on, making sure that the device is not in stand-by condition.
4. Switch the **MyLab** on by pressing the Power ON button.

NOTE ***Always observe the instructions given in the manual of the peripheral/ auxiliary device.***

NOTE ***Contact Esaote personnel for recommended USB printers and for safe and proper installation.***

NOTE ***Not all the external monitors are compatible with* MyLab*. Please contact your Service representative to select an external monitor that can be managed by* MyLab*.***

Safety Concept

MyLab is equipped with an insulation transformer to provide required separation from AC mains for both **MyLab** and the auxiliary devices. Two plugs for connecting auxiliary devices are located in the back of **MyLab** and are accessible opening the rear door.

Additional equipment connected to **MyLab** must comply with respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment).

Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3rd Edition of IEC 60601-1, respectively).

Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

WARNING

Mobile configurations provide insulated plugs and connectors to manage optional hard copy devices (VTR, printers). Follow the instructions below to install such a device.

Incorrect connections or use of peripherals with improper safety characteristics may compromise the electrical safety.

Medical environments

Based on IEC60601 three different conditions can be defined for patient environment:

Fig. 4-1: A) Patient area

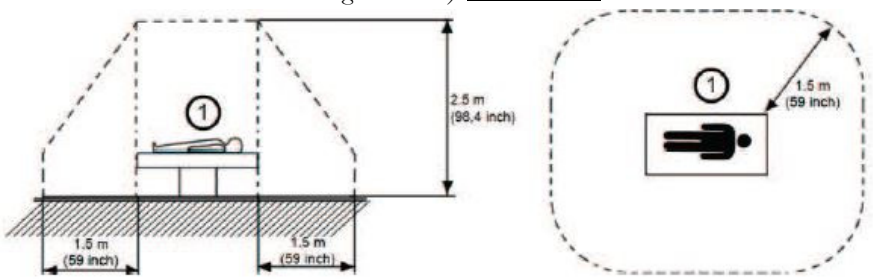
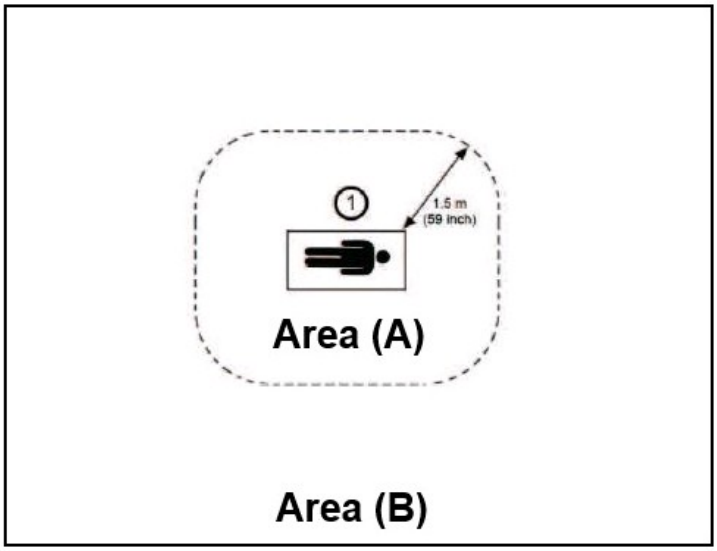
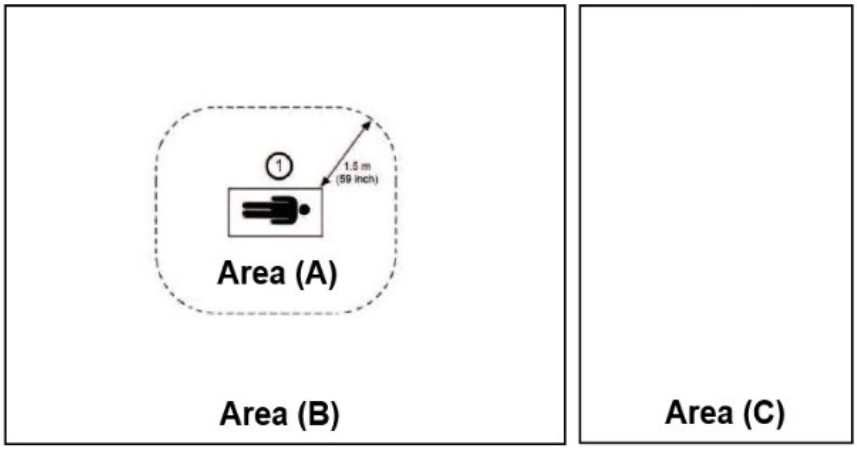


Fig. 4-2: B) Medical Use Room



Intended as area B, area A excluded.

Fig. 4-3: C) Non-medical use room



A room not designed for medical treatment, for example, an office or a storage room.

Possible configurations:

- **MyLab** + auxiliary device complying to IEC 60601 in area A
  - No additional safety requirements.
- **MyLab** + auxiliary device not complying to IEC 60601 (complying to IEC XXX[1]) in area A
  - Auxiliary device must be powered through a safety insulation transformer complying to IEC 60601.

1. IEC XXX stands for standards such as: IEC 60601 for medical devices, IEC 60950 for information technology equipment etc.

- **MyLab** + auxiliary device not complying to IEC 60601 (complying to IEC XXX[1]) in area B or area C connected by WiFi or Ethernet cable
  - No additional safety requirements.
- **MyLab** + auxiliary device not complying to IEC 60601 in area B or area C connected by cable (USB, HDMI,...)
  - Auxiliary device must be powered through a safety insulation transformer complying to IEC 60601.

NOTE ***Auxiliary Devices must be approved by Esaote. Auxiliary Devices must also comply with EN 60601-1-2 safety standard and subsequent amendments or the electromagnetic compatibility.***

Additional safety measures are:

- Additional protective earth connection between the two devices, or a safety insulation mains transformer for the auxiliary device.
- Do not connect a multiple-socket outlet or extension cord to **MyLab**.
- Avoid touching the patient and the auxiliary device simultaneously.

Additionally the IEC60601 requires control measurement of leakage currents.

The system integrator (any person connecting the medical device to other devices) is responsible that the connections are safe.

WARNING

The system must be powered so to satisfy the electrical safety requirements. Esaote recommends running a current leakage (patient and environment) test when installing in order to check whether the applicable limits of standard EN60601-1 are not being surpassed.

B/W Thermal Medical USB Printer housing

Those kinds of printers can be hosted in the lateral storage area.

Procedure

1. Open the rear door.
2. Connect both the power and the USB cables to the printer.
3. Insert the printer into the storage area by first introducing the cables.
4. Let the cables come out from the slot placed just above the peripheral powering sockets.
5. Plug the printer power cable to any of the socket indicated by symbols J1, J2 and J3.
6. Connect the USB printer cable to any of the USB ports placed on the right.
7. Switch the printer on.
8. Close the rear door.

USB Printer housing

MyLab can be connected to USB printers via a USB Port. The printer can be housed on the console top. **MyLab** is equipped with belts to secure the peripheral device.

NOTE ***When selecting the peripheral, consider its dimension so that it can be safely installed on the console. The console top measures 29 x 20 cm.***

CAUTION **The peripheral weight does not have to exceed ten (10) kg. The console could be damaged if the peripheral weight exceeds this limit.**

Procedure

1. Introduce the belt below the stirrup mounted on the console top and stretch it along the console top.
2. Place the printer on the console top.
3. Introduce the belt into the hole placed at the top of the rear side of the console.
4. Secure the peripheral by closing the belt.
5. Connect both the power and the USB cables to the printer.
6. Open the rear door and connect both cables to the console.
7. Close the rear door by letting the cable come out from the upper door slot.

8. Switch the printer on.

WARNING

Always power any USB device (such as USB printers or external USB archiving devices) through the trolley.

Now **MyLab** can be connected to the mains and the entire configuration can be powered through the main switch.

CAUTION

Before connecting the peripheral verify not to exceed the maximum power consumption limits indicated for insulated sockets. There is a risk of blowing the device fuses.

WARNING

The maximum current supplied by the MyLab USB ports is 500mA (for USB 2.0) and 1A (for USB 3.0). Peripherals exceeding this limit can be connected only if powered by their external power supply through a medical insulation transformer.

WARNING

Epson WF-110W printer:
- the printer must be connected to the MyLab insulation transformer,
- do not use the printer auxiliary battery,
- the cover of the auxiliary battery shall never be removed; if the battery cover is open, do not use the printer.

Auxiliary Monitor

Any auxiliary monitor connected to the Display Port has not to be used for diagnostic purposes.

NOTE

The resolution of the auxiliary monitor cannot be lower than the main display. The device automatically shuts down whenever a lower resolution is detected.

Monitor Connection

Connect the monitor cable to the suitable connector on **MyLab**.

Gel warmer

Gel Warmers can be mounted on **MyLab**.

WARNING

To provide required separation from AC mains for both the MyLab and the auxiliary devices, any gel warmer must be powered through the MyLab insulation transformer.

External CD/DVD and HDD drives

Any external USB CD/DVD drive and/or USB hard disk drive have to be connected to **MyLab** USB ports both for data transfer and power. For safety reasons, the drive must be fixed to **MyLab** console. Mechanical damage may occur if the drive falls down.

The External Slim DVD Writer kit supplied by Esaote includes a Velcro tape to easily and securely fix it to **MyLab** console. Stick the tape both on the **MyLab** console and on the DVD case, then attach them to fix the External Slim DVD Writer to **MyLab** console. Power the External Slim DVD Writer through two USB ports using the split cable present on the kit.

WARNING

The maximum current supplied by the MyLab USB ports is 500mA (for USB 2.0) and 1A (for USB 3.0). Peripherals exceeding this limit can be connected only if powered by their external power supply through a medical insulation transformer.

Moving and Transporting MyLab

MyLab is designed to be easily moved by the operator, however you have to observe the following warnings and cautions.

WARNING

The handles on the control panel cannot be used to lift MyLab.

To steadily lock MyLab, all the wheels must be locked.

Do not park MyLab on a slope.

Do not use the brakes to park MyLab on a slope.

Avoid any unnecessary mechanical shock to MyLab while moving it.

WARNING

Make sure that the probes are locked and the probe cables are properly hanged in the cable hooks while moving MyLab.

WARNING

Use the handles on the keyboard only to move MyLab and rotate the control panel.

WARNING

Protect the LCD screen (for example with bubble wrap) and place it horizontally, taking care to place something thick (such as foam or bubble

wrap) between the control panel and the LCD itself, to avoid any contact between the parts and to avoid screen swing during transportation.

WARNING

If your MyLab is equipped with peripherals, make sure that they are safely attached using locking belts; for transportation in a vehicle, it is strongly recommended to remove the peripheral(s) and follow the device manufacturer guidelines.

CAUTION

The keyboard could be damaged during transportation in a vehicle, if it is locked.

Moving MyLab

1. Switch the **MyLab** off.
2. Engage the wheel brakes by pressing the pedals fully down.
3. Push in the QWERTY keyboard completely beneath the Control Panel.
4. Use the handle lever to center the control panel and move it to a comfortable height for moving.
5. Turn the mains switch off and unplug the power cord, wrapping it on the rear hook or on the handle to ensure it.
6. Disconnect all external cables, including network and external devices.
7. Secure all cables, probes and accessories so that they do not interfere with the wheels. When transporting **MyLab** with the probes attached, make sure the cables are not dragging on the floor and that the probes are properly positioned in the cart's probe holder.
8. Peripheral device can be placed on the **MyLab** peripheral platform, provided that it is secured with the locking belt.
9. If peripheral devices are placed on an external additional platform, be sure they are disconnected from **MyLab** before moving the ultrasound device.
10. Lock the monitor arm by rotating the lever on the monitor arm on lock position.
11. Release the wheel brakes and set the steering locks for comfortable moving.
12. Move the **MyLab** using the front or rear handle.

13. Avoid any unnecessary mechanical shock to the device while moving it paying attention to the door jambs and when get in and out of elevators.

Transporting MyLab

When transporting **MyLab** in a vehicle, in addition to the points above, remember to:

- Disconnect and remove all probes and peripheral devices.
- Disconnect any cable or item (for example probes, ECG cable) attached to the device and place the probes in their cases.
- Rotate the control panel in its closing position.
- Bring the control panel to its lowest position.
- Protect the LCD screen (for example with bubble wrap) and placed it horizontally, taking care to place something thick (such as foam or bubble wrap) between the control panel and the LCD itself, to avoid any contact between the parts and to avoid screen swing during transportation.
- If present, protect the monitor orientable arm so that no lateral movements are possible (for example with film).
- Use the brakes to lock the device when loaded on the vehicle.
- Fasten securely the device inside the vehicle.

Quick Displacement

When **MyLab** is equipped with batteries, it can be quickly moved from one working position to another without partially switching it off.

Wait for the pending operations to be completed and then disconnect the mains cable: **MyLab** is automatically frozen keeping the LCD display off and the control panel with the touchscreen on.

The touchscreen displays a message indicating the residual time after which **MyLab** will automatically start the shut down procedure.

Move **MyLab** to the working position and connect it to the mains: the LCD display is automatically turned on and **MyLab** is ready for its use.

NOTE ***Before disconnecting MyLab, verify the battery charging status by clicking on the icon.***

NOTE ***Fully charged batteries ensure more than half an hour of self-powering.***

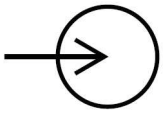
Chapter 5

5. Using MyLab

This chapter provides a brief description of the device controls.

AO Refer to the "Advanced Operations" Manual for further detailed information.

Connecting MyLab to the mains



The power plug and the electrical main switch are located on the rear-bottom of **MyLab**. The power plug symbol is screen-printed on the console plastic.

Procedure

1. Plug in the power cord.
2. Connect **MyLab** to the power mains.

WARNING

When installing MyLab, check that the power cable is not tightly bent, that it can't be squashed by a misplaced foot or by heavy objects.

The earth terminal can be connected to an external protective earthing system as additional protection. This connection is not necessary in most cases and is only recommended for situations involving multiple equipment in a high-risk patient environment to provide assurance that the whole equipment is at the same potential and operates within acceptable leakage current limits.

Turning MyLab On and Off

At the examination site:

1. Place **MyLab** into its final position.
2. Rotate the control panel assembly into its working position.
3. Set the control panel height into a comfortable position.
4. Engage the wheel brakes by pressing each pedal fully down.
5. Position the monitor where you want it.

6. Connect the network and other cables from **MyLab** to the appropriate wall plugs.
7. Plug the cable to a reliable grounding power outlet to assure adequate grounding.
8. Turn the main switch of the rear panel on.
9. Press ON/OFF to turn on **MyLab**.

WARNING **When installing MyLab, check that the power cable is not tightly bent, that it can't be squashed by a misplaced foot or by heavy objects.**

WARNING **Place MyLab in a location allowing an easy unplug of MyLab from the mains in case of need.**

NOTE ***It is recommended to turn the rear panel switch off before unplugging the power cable, whenever MyLab is expected not to be used for long periods.***

NOTE ***Whenever MyLab has to be insulated from the mains, disconnect the cable from the power outlet.***

CAUTION **Do not turn MyLab off while working (for example saving data) or during the initialization phase: the hard disk could be damaged by this operation.**

CAUTION **MyLab is a PC based device; data loss or driver damage may occur if the device is turned off while working (for example saving data) or during the initialization phase. Refer to the appropriate chapters of this manual for detailed information on when and how to safely power the device off.**

MyLab Controls

MyLab controls are located on the Control Panel Assembly that includes the control panel, the touch screen and the alphanumeric keyboard (when present).

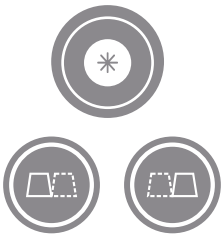
Control Panel Section

The control panel includes the main imaging controls: the exam control buttons and knobs, and the trackball. The control module also allows to select imaging modes, review and annotate images, perform measurements and calculations.

Table 5-1: Exam Control Buttons

Button	Description
ARCHIVE	Gives access, at any time, to the archived data.
END EXAM	Closes the current exam archiving the patient's data and producing a report on the exam. The device clears the stored data and shows the Exam Start menu again.
CFM	Activates/deactivates Color Doppler (CFM). The knob around this button amplifies both CFM and Power Color gains. To increase gain, turn the knob clockwise, to reduce it, turn the knob counter-clockwise. In B-Mode, a cursor delimits the Region of Interest (ROI) where color analysis is performed and displayed.
PW	Activates the Pulsed Wave Doppler (PW). At its pressure the positioning cursor is activated as well. The knob around this button amplifies both CW and PW gains. To increase gain, turn the knob clockwise, to reduce it, turn the knob counter-clockwise.
PWRD	Activates the Power Color Doppler or Tissue Velocity Mapping.
CW	Activates the Continuous Wave Doppler (CW). At its pressure the positioning cursor is activated as well.
MEASURE	Activates Advanced Measurements showing the list of available measurements on the right of the image.
+...+	Activates Generic Measurements showing the list of available measurements on the right of the image.
POINTER	Toggles the trackball operation from standard to mouse mode. Refer to the "Trackball" paragraph further in this chapter.
ACTION	Changes the function linked to the trackball. Refer to the "Trackball" paragraph further in this chapter.
AUTOADJUST	The AUTOADJUST key, available both in B-Mode and Doppler, automatically adjusts some controls of the active mode to make the echo acquisition easier.
M	Activates the M-Mode and, if necessary, its selection cursor (B-Line)
B/M	This button re-activates a B-Mode image in real time when any other mode is active. If pressed in M-Mode, Doppler or Freeze, it restores a full screen bi-dimensional image. The knob around this button amplifies both B-Mode add M-Mode gains over the entire depth of the image. To increase gain, turn the knob clockwise, to reduce it, turn the knob counter-clockwise.

Button	Description
3D/4D	Activates three dimension features; further details on how to use them are described in the "Advanced Operations" manual
LINE UPDATE	In B-Mode or CFM, this button allows to interactively activate the cursor or disable it to select the M-Mode or Doppler line. During the exam, when a trace is active, the same button freezes the trace acquisition and temporarily reactivates the reference B-Mode image.
ACQUIRE	Activates advanced features; further details on how to use them are described in the "Advanced Operations" manual.
IMAGE	During the exam it saves single images. The stored images are displayed as thumbnails on the right of the screen.
CLIP	During the exam it saves a sequence of images. The stored clips are displayed as thumbnails on the right of the screen.
FREEZE	Stops the current analysis or scan and puts **MyLab** in Freeze mode. To re-activate real time, press it again or directly press the button of the required mode.
DUAL	Activates dual and quad view both in real time and freeze. Press LEFT or RIGHT to activate dual presentations: the active image is displayed on the left/right. Press **CENTER** to restore a single format. Press **CENTER** to activate quad presentations: the active image is displayed on the top-left. Press LEFT or RIGHT to add other images. Press **CENTER** to restore a single format.
1, 2	These buttons can be customized to print images. Refer to chapter 6 "Customizing MyLab" for further information.



Trackball

The trackball operates in two different modes.

Standard Mode

In its standard mode, the trackball makes it possible to quickly position the cursors on the screen.

Each mode automatically activates the trackball on its cursor.

Table 5-2: Trackball cursors

Mode	Trackball
M-Mode, Doppler	LINE cursor
Color Flow Mapping (CFM)	CFM ROI cursor

The cursor function is indicated below the image. When several cursors are present on the screen, ACTION switches between the active cursors. Yellow indicates active cursor function while white next cursor function.

Mouse Mode

In its mouse mode, the trackball can be used to move a pointer on the screen, to access to the thumbnails of the images, displayed on the right side of the screen or to access to the archiving media and peripheral menus. The buttons placed on the left and right side of the trackball can be set as mouse keys (as confirmation and context menu buttons).

Regardless of the trackball configuration, the confirmation and context menu buttons are respectively indicated as ENTER and UNDO in this manual.

Press POINTER to change the trackball operation from standard to mouse mode.

Touchscreen Section

This section includes the ON/OFF, the MENU and ETOUCH buttons, a touchscreen and the TCG Sliders.

On/Off Button

The ON/OFF button is located beside the touchscreen, on the left side of the control panel assembly, while the Main Switch is located on the rear-bottom of the device.

Beside the Main Switch is also located an earth terminal to be connected to an external protective earthing system as additional protection.

When **MyLab** is connected to the mains and the Main Switch is on, the lighting of the ON/OFF button changes to indicate its status. The different indicators are described in the table below.

Table 5-3: On/Off button light

Led Colour	Meaning
GREEN	**MyLab** is on
AMBER	**MyLab** can be turned on
OFF	**MyLab** can not be turned on. In this case check both the rear main switch and the mains connection.

Pressing the ON/OFF button turns **MyLab** on or off, activating or closing the examination session.

Optional Batteries

When **MyLab** is equipped with optional batteries, the same button places the system in stand-by, partially shutting it down: in this case the initialization phase at start up is significantly reduced.

NOTE

A complete shut down procedure is periodically and automatically run to prevent misfunctioning: when this occurs, MyLab displays an information message. The following start up will require running the whole initialization phase.

Menu Button

MENU displays the menu for all configurations/settings (both clinical and system settings).

ETOUCH Button

ETOUCH	Toggles between factory and customized touchscreen that can be created by the user. Refer to the chapter "Customizing MyLab" further in this manual.

Touchscreen

The touchscreen displays controls used to select probes, enter patient data, select applications and change setups; it also displays exam controls related to the active modality.

Touchscreen controls are indicated in the operator manuals by **BOLD BLUE CAPITAL LETTERS** for keys that can be taped while by NORMAL BLUE CAPITAL LETTERS for software text strings.

Tap the displayed key to activate/deactivate the corresponding control.

Many modes provide two pages of controls: tap **ADV>>**/**BASIC<<** to switch from the first page to the second page.

The touchscreen layout changes depending on the different working modality:

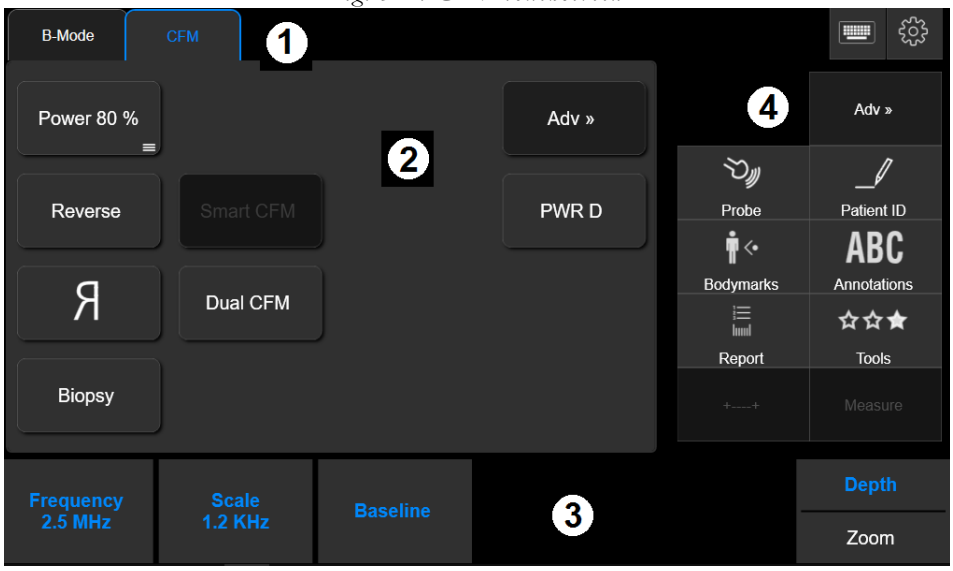
- as exam panel, providing control keys to perform the exam,
- as multipurpose panel, providing keys for advanced functions,
- as alphanumeric keyboard to enter data.

Exam Panel Layout

This layout is used for standard exam functions necessary to perform the exam.

The touchscreen is organized in four main areas.

Fig. 5-1: CFM touchscreen



1. Navigation area, it contains the navigation tabs allowing to select the desired features for the relevant controls. For example B-Mode, CFM.
2. Main area, it contains main controls, varying according to the active mode, application and settings.
3. Knobs area, it contains functions whose value can be changed by rotating the knob beneath.
4. Exam management area, it contains the keys for the exam management, that are the keys allowing to change the probe or the preset, to access the tools and other additional functions.

On top-right, a dedicated key activates the emulation of the Qwerty alphanumeric keyboard. Tap the keyboard icon to display the keyboard. Tap again to hide the keyboard.

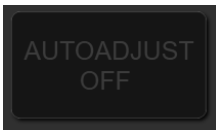
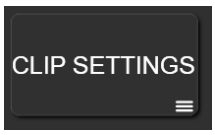
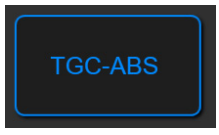
Tap the cogwheel icon to access a menu for easy configuration of display settings.

If the displayed area has several levels, press **ADV>>/BASIC>>** to scroll through all levels.

Keys

The keys have a color coding depending on their status.

Table 5-4: Touchscreen key status

Disabled Key	Active Key	Active Key with Submenu	Selected Key
			
Gray text on dark gray background	White text on light gray background	As Active Key with three lines at bottom right	Blue text on dark gray background

If the key is active, the displayed function will be enabled when tapping the corresponding key on the touchscreen.

Knobs

Six rotating knobs are located along the bottom side of the touchscreen.

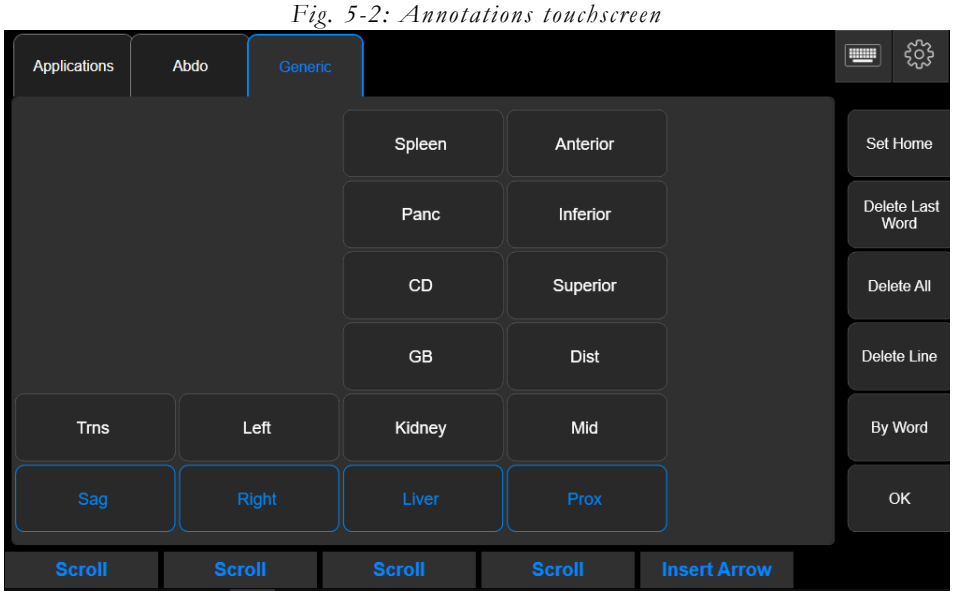
Each knob acts on the control key just above it. Rotate the knob to change the control value.

Sometimes, two controls are available for a knob. Only one of the controls can be active at a time. Pressing the corresponding knob or tapping the label toggles the active control.

Multipurpose Panel Layout

This layout is used for advanced exam functions, for example body marks or annotations.

Fig. 5-2: Annotations touchscreen



AO Refer to the "Advanced Operations" manual for further details.

Alphanumeric Keyboard Layout

The alphanumeric keyboard is based on the QWERTY standard. The alphanumeric keys are used to enter text data in the enabled windows. The **Caps Lock** key sets the keyboard to upper case characters.

The **↑Shift** key is used to type in lower case or upper case characters (according to how the keyboard is set); the **Fn** key is used to type numeric functions (for example +, *).

AO

Refer to the "Advanced Operations" manual for the use of the keyboard in annotation modality.

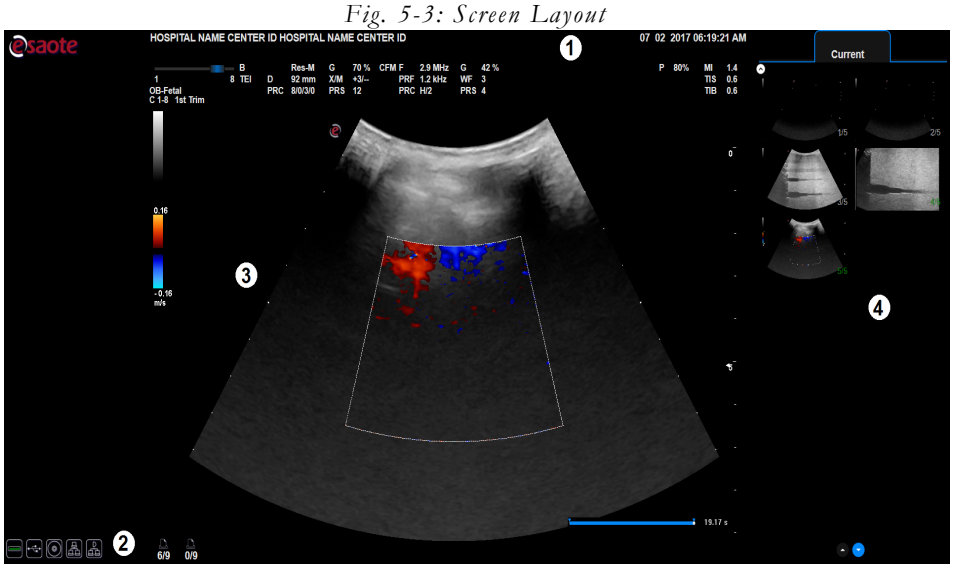
TGC Sliding

The TGC sliding control signal amplification in individual areas of the image. Potentiometers are used to adjust the signal zone by zone.

Information about the Screen Layout

The screen is split into four main areas.

Fig. 5-3: Screen Layout



1. Heading Area
2. Footer Area
3. Image Area
4. Thumbnails Area

Controls on the Screen Layout are indicated in the operator manuals with **BOLD BLACK CAPITAL LETTERS**, while strings and fields are indicated with NORMAL BLACK CAPITAL LETTERS.

Symbol on Screen

When this symbol is displayed on the screen, it indicates to carefully read the manual. Refer to the appropriate section of the manual for a detailed explanation.

Heading Area

This area is used to display the following information: center and patient data, accession number and date.

Patient data are displayed only if entered at the beginning of the exam.

Data can be entered or modified at any time during the exam by pressing PATIENT ID.

Footer Area

This area is used to display the following information:

- trackball functionality,
- Wi-Fi icon (when enabled),
- archival media icons,
- advanced features icons,
- battery icons,
- peripherals icons.

Trackball

When the trackball can perform multiple functions, the next function is indicated below the image as yellow text. Press ACTDN to switch the function.

Wi-Fi

When Wi-Fi is enabled, its icon is shown beside the archival media icons. The icon is shown crossed out whenever Wi-Fi is not connected.

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For more details on Wi-Fi connectivity, consult the relevant section on the "Advanced Operations" manual.

Archival Media

Archival media are shown on the left. The icon is shown crossed out whenever there are management problems involving the specific archival system.

📖 ***AO*** For more details on data archival, consult the relevant section on the "Advanced Operations" manual.

Advanced Features

When advanced features such as XView or MView are activated, the corresponding icons are displayed on the center of the footer area.

Battery

When the battery pack is installed, battery status icons are displayed.

Peripheral Devices

MyLab is able to simultaneously manage two peripheral devices (b/w or RGB printers). The icons of the peripheral devices are shown at right of the footer area. The icon is shown crossed out whenever there are management problems involving the specific peripheral device.

Image Area

The visualization of the image depends on various factors such as the active mode, the selected application and the probe. The following figure shows the elements in the image area that are independent of these factors.

Fig. 5-4: Image Area

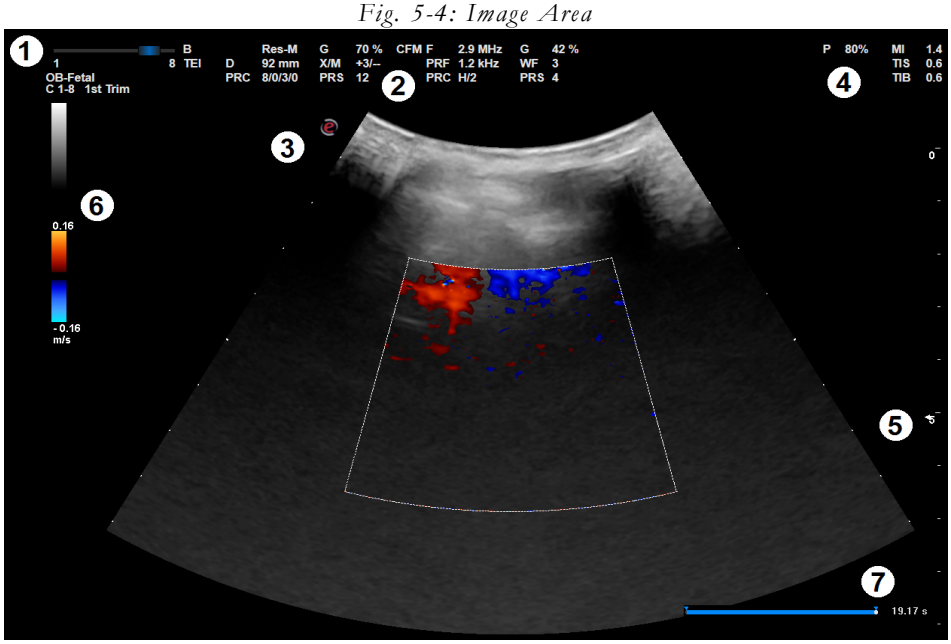


Table 5-5: Image Area description

Number	Description
1	Frequency Bar, active application, probe and preset
2	System Parameter
3	Sector orientation
4	Acoustic output data
5	Focal Zone(s)
6	Image and color scales
7	Memory bar

Freeze Status

Whenever an image is frozen, a memory bar is displayed (at bottom right) concerning the scrolling memories. The images acquired immediately before are frozen and archived in these memories. The trackball can be used to examine the B-Mode, M-Mode, Doppler and color information image by image.

Machine Parameters

Table 5-6: Imaging Parameters

Parameter	Displayed format	Description
F	l	Imaging or TEI (Tissue Enhancement Imaging) mode: General, Resolution or Penetration (L: Low, H: High)
G	nn%	Imaging gain (Min,%, Max)
AG	nn%	Auto Adjust
D	nn mm	Depth
X/M	C or +n/n	XView Algorithm or CrystaLine Imaging / MView algorithm
PRC	n/n/n/n	Dynamic range / Dynamic compression / Density / Gray map
PRS	n	Persistence
SV	nn/nnn mm	Sample volume size and depth
Θ	nn°	Doppler angle correction
	nn°	CFM/PW steering angle when the beamline is present (0° when beamline has no steering, positive value when steered to the right, negative value when steered to the left)

SV and Θ are displayed only if the relevant cursor is active.

Table 5-7: Color Flow Mapping (CFM) Parameters

Parameter	Displayed format	Description
F	nnn MHz	Color frequency or TVM (Tissue Velocity Mapping) frequency when enabled
G	nn%	Color gain (Min,%, Max)
PRF	nnn kHz	Pulse Repetition Frequency
WF	n	Wall filter
PRC	l/n	Smooth (L: Low, M: Medium, H: High) / Density

Parameter	Displayed format	Description
PRS	n	Persistence

Table 5-8: Doppler Parameters

Parameter	Displayed format	Description
F	nnn MHz	Doppler frequency or TV (Tissue Velocity) frequency when enabled
G	nn%	Doppler gain (Min,%, Max)
PRF	nnn kHz	Pulse Repetition Frequency
PRC	n/n	Dynamic range / Rejection
WF	nnn Hz	Wall filter
PRS	n	Persistence

Thumbnails Area

Clips and images both saved during the exam and previously archived are displayed on the right side of the screen as thumbnails. The thumbnails are displayed in chronological order, from left to right.

The tabs displayed at the top of the thumbnails columns allow to scroll among the images saved during current exam and images retrieved from other exams.

Chapter 6

6. Customizing MyLab

MyLab can be customized to increase efficiency and streamline your workflow. You can do the following:

- Create preset designed specifically for the exams you perform.
- Change device settings to reflect your needs.
- Add options to enhance your imaging abilities.
- Create custom procedures for specific patients, transducers, and presets.

The MENU button is used to access the device menu. **MyLab** displays all the available options.

Fig. 6-1: MyLab Menu

The menu is organized in three areas:

- Clinical Configuration, the upper area shows all options relating to Clinical Settings or Presets,
- System Settings, the central area shows all options relating to System Settings,
- General Settings, the lower area shows all options relating to General Settings.

Clinical Configuration

A clinical setting is a group of configurations optimizing **MyLab** for a specific type of exam (for example for a cardiac exam or an obstetrical exam). This clinical setting is associated to the specific probe in the selected application.

You can save several clinical settings for each probe in each application. This means that the preset, selected at the beginning of the exam or during the exam pressing PROBE, establishes the initial settings of the exam controls (like gray map, depth...) together with the initial available measures (measurement configuration), the initial available library both for annotations and for bodymarks (Annotation and Bodymark configurations) and the customized touchscreen.

Clinical Configuration allows to set different parameters listed below:

- Real Time Preset for Presets configuration,
- Measure for measurement configuration,
- Annotations for annotation configuration,
- Bodymarks for bodymark configuration,
- eTouch for eTouch configuration,
- When licensed, advanced tool configurations (such as 3D/ 4D, Stress Echo) are part of the clinical settings.

NOTE ***Refer to the dedicated sections of this manual for further information on the above Clinical Configurations.***

System Settings

System Settings define the **MyLab**'s parameters related to a specific device profile:

- Profile Manager,
- DICOM configuration,
- Saving Options for end exam saving configuration,
- Center ID for hospital configuration to set the name of the hospital,
- Multimedia,
- Network for network configuration,
- Observations for observation configuration,
- Printers for printer configuration,
- Report for report style configuration,
- XStrain2D,
- Acquisition Protocols.

You can save several device profiles. If, for example, **MyLab** is used in two structures differing in Network and DICOM connectivity, two specific System Configuration profiles can be created: each time the user will load the configuration required by the structure.

MyLab allows the user to save several system configurations. If, for example, **MyLab** is used in two structures differing in Network and DICOM connectivity, two specific System Configuration profiles can be created: each time the user will load the configuration required by the structure.

General Settings

General Settings define the **MyLab**'s general parameters:

- General Setup for general configuration, like measure units, control panel setting,
- Security for general configuration,
- Licenses for license settings,
- Import/Export for exam export configuration,
- System Info,
- Remote Service,
- ePortal,
- Manuals Manager.

Generic Configuration Procedure

Once accessed the configuration screen for the parameter you want to set, a common set of commands is available and a common setting procedure can be used.

In a few limited cases the procedure may differ to the one described below, in these cases it will be described in the specific paragraph.

Procedure

- Press MENU, and select the parameter you want configure. The configuration screen for the selected parameter is displayed.
- On the left of the screen is displayed the list of possible items.
- Select the desired item, then choose one of the following options.

Table 6-1: Configuration Menu Options

Option	Description
EDIT	To modify the settings of the item selected on the top-left list. Alternatively double click on the item you want to modify
CLONE	To create a new customized item starting from a copy of the existing selected one.
NEW	It replaces **CLONE** when no customized items are present.
REMOVE	To delete the selected customized item. A confirmation dialog will be displayed. Only customized items can be deleted.
FACTORY	To retrieve all factory values and to delete all customized items.

- Once in editing mode you can change the name of the selected item (NAME field), enter a description (NOTES field), confirm and save the settings (**SAVE**), or exit the menu without saving the settings (**CANCEL**).

At any time you can go back to the main menu (**BACK TO MENU**) or exit from the menu and go back to Real Time (**CLOSE**).

Clinical Configurations

📖 *AO*

This chapter explains how to set many **MyLab** options. For configurations not described here refer to relevant chapters in the "Advanced Operations" manual.

Real Time Preset

A Preset is a group of settings that optimizes **MyLab** for a specific type of exam. Presets establish many initial settings, such as gain value, color map, filter and items on the touchscreen.

You can choose from several default presets, modify them and create many others. Default presets can not be deleted, however, they provide a starting point from which you can create your own presets.

The available presets are determined by the selected transducer.

The creation/modification of a preset is achievable in two steps:

- from MENU, where you can add the desired measurement configuration, annotation and bodymark libraries,
- from Real Time, where you can set the parameters that optimize the real time image in all modes and create the customized preset.

Creating a new preset from MENU

To create a new preset or modify an existing one press MENU, then select **REAL TIME PRESET** and then follow the generic configuration procedure, taking in account that on the left of the screen is displayed the list of all clinical settings, grouped by probes. Within each probe clinical settings are grouped by applications.

During editing you can select from the curtain menu each parameter (Measure, Annotation, Body Marks...) to be associated of the preset in the desired configuration.

Here you can also assign the default application for each probe independently. Each time the probe is selected its default application is selected as well.

When selecting each probe you can also establish which application to show on the touchscreen. Uncheck the application in order not to show it. The option ALL PROBES allows to select/unselect the application for all probes.

The configured preset is associated to the active probe and application: this preset will be available each time the same probe and application are selected either from the Start Exam page or by tapping **PROBE**.

Creating a new preset from Real-Time

Procedure

To create a new preset or modify an existing one:

- Adjust the real time image as desired in all modes (2D, CFM and Doppler).
- Tap **PROBE** and then **PRESET MANAGER**.
- Press **OVERWRITE** to overwrite the current preset (also factory presets can be overwritten) or using the alphanumeric keyboard type a new preset NAME and NOTE and press **NEW** to confirm.

OVERWRITE saves all settings done in real time in the active preset.

NEW creates a new preset whose configuration is the one defined in every modality in real time.

CLOSE exits without saving any modification.

eTouch Button

MyLab allows the user to record sequences of keys both of the touchscreen and of the control panel. Each recorded sequence (Macro) can be named and saved to be available as customized button in customized touchscreens.

ETOUCH switches between factory and customized touchscreen. Whenever the customized button is pressed, **MyLab** will automatically launch the keys sequence.

Each configuration is linked only to one customized touchscreen.

NOTE ***Keys sequences that require interaction with the user (like measurements or pointer positioning) can not be recorded as macro.***

Configuring eTouch button

To access to the ETOUCH configuration menu:

- Press MENU. The configuration menu is organized in two main areas: the list of all saved customized touchscreens on the left side and the eTouch configuration menu on the right side.
- Select one of the saved customized touchscreens, then follow the generic configuration procedure.

During editing the screen displays:

- in the center the touchscreen layout,

- on the right the menu to record the macro and to edit the customized buttons,
- on the bottom the fields where customized touchscreens are named and described.

From here you can:

- Record the Macro sequence,
- Customize the touchscreen,
- Create additional tabs on the touchscreen.

To create a customized touchscreen, follow one of the following procedures.

NOTE ***Wait for any background operations to be finished before starting the procedure.***

Recording Procedure

- Place the cursor on the **RECORDING** field and press **START** to begin the recording: **MyLab** switches to the frozen status.
- **MyLab** displays on the upper left side of the screen the following flashing message:

  Press eTouch to start recording.

  Prepare **MyLab** to be ready for the recording so that only the keys to be used can be pressed and then press ETOUCH to start.
- Press the desired keys in sequence and press again ETOUCH to end the recording. During the sequence recording, the message turns color.

The eTouch configuration menu displays the customized button. Place the cursor on the button and press ENTER to change its name, using the alphanumeric keyboard to edit it.

Repeat the procedure to add other customized buttons.

Customized Button Organizations

The customized button can be freely positioned within the touchscreen.

MOVE BUTTON changes the button position: select the button with the trackball, place the cursor on the desired position and click ENTER to confirm.

DELETE BUTTON cancels the button selected with the trackball.

Tab Organization

Customized touchscreen can be organized in more tabs. Each tab has one level of buttons.

NEW TAB button adds a new tab that will be automatically displayed. Place the cursor on the tab and press ENTER to change its name, using the alphanumeric keyboard to edit it.

MOVE LEFT and **MOVE RIGHT** buttons respectively shift to left or to right the selected tab: select the tab with the trackball and press the desired button.

DELETE SELECTED TAB button cancels the tab selected with the trackball.

NOTE ***Empty tabs (that is tab not containing customized button) are not displayed in the customized touchscreen.***

System Settings

AO This chapter explains how to set many **MyLab** options. For configurations not described here refer to relevant chapters in the "Advanced Operations" manual.

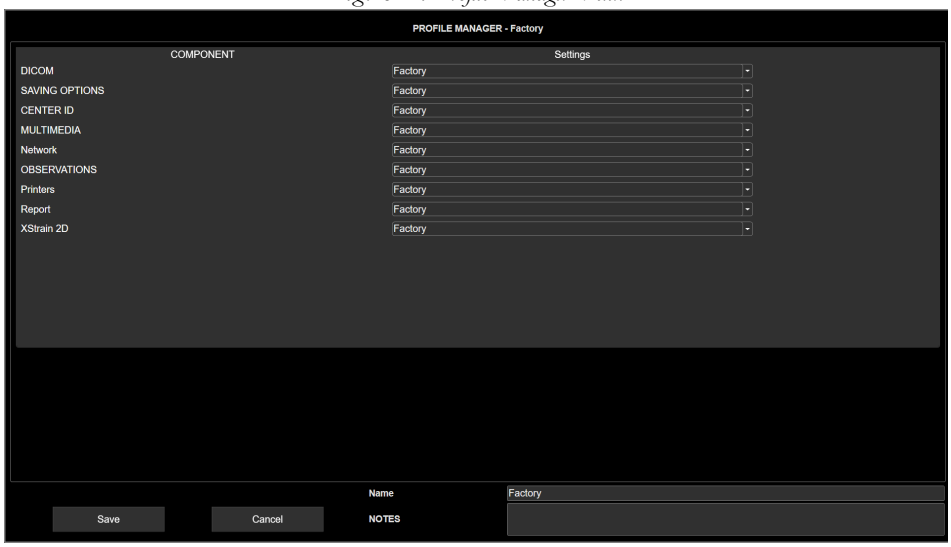
Profile Manager

Profile Manager allows to create a profile for each user with a personalized system configuration.

To configure the Profile press MENU, then select **PROFILE MANAGER** and then follow the generic configuration procedure.

During editing you can configure each displayed component selecting the desired option among the ones available in the relevant SETTINGS combo.

Fig. 6-2: Profile Manager Menu



Corrupted System Profile

Whenever a profile is corrupted, a red exclamation mark is displayed on the Profile Manager option. In this case, enter the profile manager menu and, for each system profile, check that every component has a specific setting (no component has to be without any setting).

Should this not solve the problem, contact Esaote personnel.

Center ID

Center ID allows to set the center name displayed in the Heading Area of the screen and the center information shown in the report.

To configure the Center ID press MENU, then select **CENTER ID** and then follow the generic configuration procedure.

During editing you can configure many fields described below.

Center ID Field

The name entered in this field will be displayed in the heading area of the screen.

Report Information Field

This option allows to add to the report header the following information:

- the hospital name;
- the department name;
- the contact details;
- two fields for other additional information;
- the hospital logo.

DICOM Field

This option allows to enter the station name used in DICOM.

General Settings

📖 ***AO***

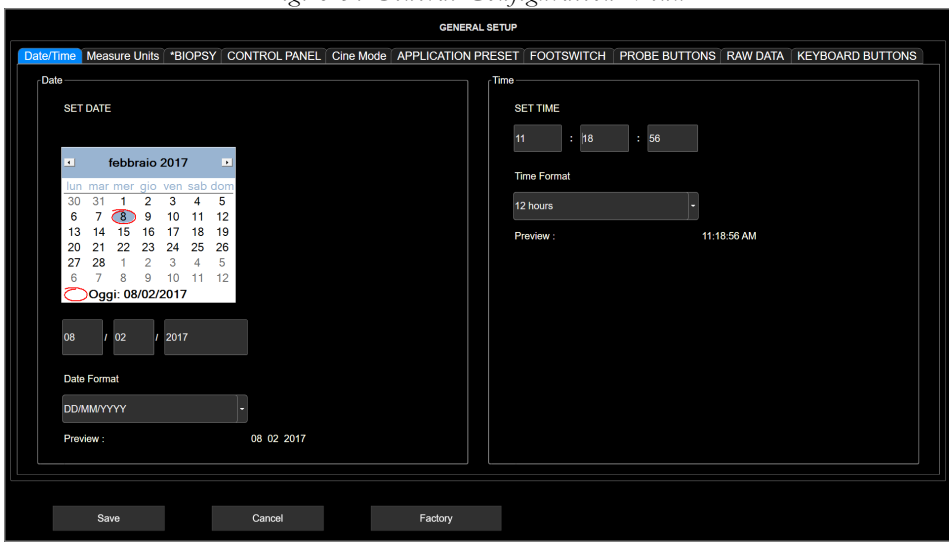
This chapter explains how to set many **MyLab** options. For configurations not described here refer to relevant chapters in the "Advanced Operations" manual.

NOTE ***Some settings described below may be unavailable on your product's configuration.***

General Setup

The menu is organized in internal folders, selectable using the tabs displayed on the top of the menu.

Fig. 6-3: General Configuration Menu



SAVE saves the settings, which will be activated as soon as they are saved.

CANCEL exits the menu without saving the new settings.

FACTORY retrieves all factory values and deletes all customized items.

DATE/TIME Folder

This option is used to set date and time, displayed on the screen: you can set date and time manually or automatically.

Set Date

Using the trackball scroll the month and select the day on the calendar to set date manually.

Date Format

Various formats can be set: the available options are listed in the following table.

Table 6-2: Date Formats

Format	Displayed date
DD/MM/YYYY	01/04/2011
DD/MMM/YYYY	01/Apr/2011
MM/DD/YYYY	04/01/2011

Format	Displayed date
MMM/DD/YYYY	Apr/01/2011

Set Time Using the keyboard set the time manually.

Time Format The time format is available on a 24 or 12 hour basis. In the 12 hour option, the time is shown as AM and PM.

When SET DATE AND TIME AUTOMATICALLY is checked, **MyLab** automatically sets date and time taking information from a NTP (Network Time Protocol) Server.

Select the desired server from the NTP SERVER drop-down menu or press **ADD** to insert a new one. Set your time zone and country related information from SET TIME ZONE drop-down menu.

When AUTOMATICALLY SET DAYLIGHT SAVING TIME is checked, **MyLab** automatically sets the daylight saving time.

MEASURE UNITS Folder

This option is used to set the desired units for height and weight. You can choose between cm/kg and ft/lb.

The Celsius or Fahrenheit scale can be selected for probes equipped with temperature sensor.

BIOPSY Folder

This option is used to set the type of needle guide line to be superimposed on the image during biopsy procedures. For further information about biopsy and needle guides, refer to the related chapter in the Advanced Features section of the Advanced Operations manual.

CONTROL PANEL Folder

The table below lists and explains the available fields and the corresponding actions.

Table 6-3: Control Panel Folder

Fields	Action
TRACKBALL SPEED	Sets the speed of the trackball.
TRACKBALL ACCELERATION	When checked, it adjusts cursor pointer acceleration in order to react exactly on how quickly you move your trackball.
LEFT CLICK	Sets the action of the left key of the trackball. The left key can be set as confirming key (ENTER) or as context menu key (UNDO)
CHARACTER SET	Sets the characters used for all the device information (for example screen information, touchscreen button).
SHUTDOWN TYPE	Sets the preferred shutdown type.
SCREEN RESOLUTION	Sets the screen resolution when secondary monitor is connected.
AVAILABLE QWERTIES	Sets which alphanumeric keyboards are available in the touchscreen and which is the default one. When more alphanumeric keyboards have been set, the touchscreen displays an alphanumeric keyboard with dedicated tabs allowing to select the desired keyboard.
BEEP VOLUME	Sets the volume of the beep.
FOCUS CONTROLLED BY TRACKBALL	Sets the default action of the trackball when starting the exam.
ETOUCH BUTTON	When Acquisition Protocol is licensed, the eTouch button can be configured to work with protocols.
DEPTH INCREASE	Allows to set the depth changing the value clockwise/counterclockwise.
AUTOMATIC START EXAM	When checked, it allows a direct access to B-Mode after booting without passing through Patient ID.
DISPLAY LIBRARIES ON TOUCHSCREEN	When checked, MyLibrary protocols are displayed on the touchscreen instead of the main screen.

Fields	Action
DIRECT PROBE SELECTION	When checked, it allows to show on the touchscreen work flow area icons of connected probes for quick change. If the current application is available on the new probe, the application is maintained, otherwise it will be changed to the default one at probe switching.
TOUCHSCREEN	Sets the brightness of the touchscreen.
CONTROL PANEL	Sets the brightness of the control panel.

Field SHUTDOWN TYPE

Various shutdown types can be set; the available options are listed in the table below.

Table 6-4: Shutdown types

Fields	Action
STANDBY	When the OFF button is pressed, **MyLab** goes in hibernation state saving all configurations allowing a following quick boot-up. In these conditions **MyLab** can be unplugged from the main. When OPTIMIZE MEMORY USAGE is checked, all memory is erased to make repeated use of standby more reliable over time. This results in a slowdown of boot-up time.
SHUT DOWN	When the OFF button is pressed, **MyLab** performs a complete shut-down.
SHUT DOWN WITH VIRUS SCAN	When the OFF button is pressed, **MyLab** performs an antivirus scan and then a complete shut-down. If viruses are found, the shut-down is not executed and an information pop-up is displayed.
SHUT DOWN WITH VIRUS SCAN ONCE	When the OFF button is pressed, **MyLab** performs an antivirus scan and then a complete shut-down. At the next OFF pressure the previous choice is restored.

When **MyLab** is equipped with batteries, the STANDBY AT POWER FAIL field is displayed. When checked, if you disconnect **MyLab** from the power supply without pressing the OFF key, **MyLab** enters autonomously in hibernation mode by saving all the configurations that allow a subsequent rapid restart.

NOTE ***Esaote does not install a real-time antivirus program, because it could affect the regular operations of*** **MyLab.**

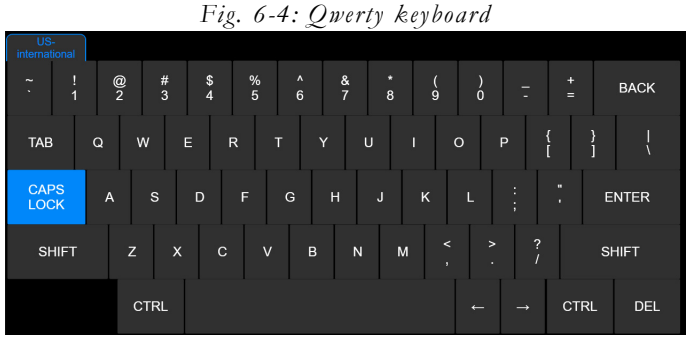
The antivirus scan could take a long time. Before starting the scan, a confirmation is requested.

If a virus is found, it is advisable to switch off the **MyLab,** ***disconnect it from the data network and call the Esaote service, which will check for the presence of a virus and restore*** **MyLab.**

Field AVAILABLE QWERTIES

When more alphanumeric keyboards have been set, the touchscreen displays an alphanumeric keyboard with dedicated tabs allowing to select the desired keyboard.

Fig. 6-4: Qwerty keyboard



CINE MODE Folder

When set, the AUTOMATIC PLAY and TRACE AUTOMATIC PLAY options respectively allow to review the stored images and the trace in cine mode when FREEZE is pressed.

APPLICATION PRESET Folder

This option is used to set specific features for each application.

The menu is organized in two areas: the left side shows the list of the available applications, the right side the list of the features.

Select the application and then check the boxes of the desired features.

The table below lists and explains the available fields and the corresponding actions.

Table 6-5: Application Preset Folder

Fields	Action
ABSOLUTE ANGLE	The angle correction factor of linear probes can be correlated either to the line cursor or to the line perpendicular to the transducer surface (absolute angle). In the first case the angle correction is kept constant when the line is moved; in the latter case an angle correction is calculated whenever the line is moved.
SHOW SWEEP VELOCITY	When checked, this option allows to display the Sweep Velocity (cm/s) below the PW/CW/M scroll area.
SAMPLE VOLUME SWIVELING STEERING	When checked, the Doppler line can be oriented by using the center of the sample gate as rotation axis.
SHOW ZOOM REFERENCE WINDOW	When checked, the zoom navigation window is displayed on the screen just as the zoom has been activated.
USE REFERENCE BOX ON DUAL COLOR DOPPLER	When checked, in dual visualization, the ROI box is overlaid to the B-Mode image as a reference.
IMAGE SIZE	Sets the default dimension for reference image in split format for the selected application.
ACTION ON FREEZE	Sets the action after FREEZE pressure.
AUTO BUTTON SETUP	Sets the action after AUTO pressure: AUTOADJUST (to automatically adjust the B-Mode image), ECFM (to automatically optimize CFM image) or BOTH of them.
IMAGE AUTOFITTING	When checked, for linear probes and superficial depths, it adapts the size to the width of the screen.
ENABLE SMARTOUCH	When checked, it enables the smarTouch for the selected application.
INVERT CFM SCALE WITH STEERING	When checked, this option allows to automatically invert the Doppler scale when inverting the steering with reference to the vertical line.
USE REFERENCE BOX ON DUAL ELAXTO	When checked, in dual visualization, the ROI box is overlaid to the B-Mode image as a reference.
AVF ENABLED	When checked, this option enables AVF that makes the focus positioning automatic, improving the focus management. When enabled, all controls related to focus management are disabled.

Fields	Action
1-CLICK CHANGEOVER ENABLED FOR PW, CW, M-MODES	When checked, pressing PW from B-Mode, **MyLab** switches to B-Mode frozen + Doppler live at once. When not checked, pressing PW from B-Mode, **MyLab** switches to B live + PW frozen. This step allows to position the beamline into the target vessel and it is necessary then to press PW once again. The same behaviour applies to CW and M modes.
INVERT CFM AND DOPPLER SCALE	When checked, it makes the palette/scale inversion completely independent, even when the automatic inversion controlled by the steering is enabled (i.e. invert PW spectrum without inverting the CFM scale).

WARNING

The displayed Sweep Velocity is correct as long as you do not use a secondary monitor and/or an incorrectly calibrated monitor.

Field ACTION ON FREEZE

Various actions can be associated at FREEZE pressure; the available options are listed in the table below.

Table 6-6: Actions on freeze

Fields	Action
NO ACTION	When FREEZE is pressed, **MyLab** goes in freeze without any other action associated.
GENERIC MEASUREMENTS	When FREEZE is pressed, **MyLab** goes in freeze with the trackball linked to the generic measurements menu.
GENERIC MEASUREMENT CINE	When FREEZE is pressed, **MyLab** goes in freeze with the trackball linked to cineloop.
APPLICATION MEASUREMENTS	When FREEZE is pressed, **MyLab** goes in freeze with the trackball linked to application measurements menu.
APPLICATION MEASUREMENT CINE	When FREEZE is pressed, **MyLab** goes in freeze with the trackball linked to cineloop.
BODYMARK	When FREEZE is pressed, **MyLab** goes in freeze with bodymarks active.
ANNOTATIONS	When FREEZE is pressed, **MyLab** goes in freeze with annotations active.

FOOTSWITCH Folder

This option is used to set which function is associated to each pedal (left, middle and right) of the footswitch.

Select from the curtain menu the function then press **SAVE**.

PROBE BUTTONS Folder

This option is used to set which function is associated to each probe button.

Select from the curtain menu the function then press **SAVE**.

RAW DATA Folder

When the associated license is enabled and the option selected, data are saved in raw format for Post Processing elaboration.

Refer to the "Archiving" section of the Advanced Operations manual further information on this feature.

KEYBOARD BUTTONS Folder

This option is used to set which function is associated to ACQUIRE button and to each of the four configurable buttons (1, 2, 3, and 4).

From the curtain menu select the function you desire then press **SAVE**.

NOTE ***When the buttons 1, 2, 3, 4 are associated to save image or save clip, they will be named further in this manual as IMAGE or CLIP respectively.***

SECURITY Folder

Antivirus

Microsoft Windows Defender anti-virus protects your **MyLab** from external threats.

DEFINITION VERSION lets you know the version number installed.

You can update the antivirus on your own through **UPDATE FROM FILE** if you have already downloaded the upgrade on a USB pen drive or **UPDATE FROM THE WEB** to automatically search on the web any available update and install them. The update from the web requires a web access and it can take long time to finish, so a message warns you before starting.

SCAN is not enabled and can be used from Esaote Service personnel only. If you want to perform an antivirus scan, you have to perform a shut-down with virus scan.

Encryption

Disk data encryption and decryption can be performed by Esaote Service personnel only but, for best protection of your data, Esaote Service Personnel is not permitted to know the recovery key that is the file used to decrypt the disk. Only you, as user of **MyLab**, are allowed to access recovery key data.

SHOW offers to you, when logging into **MyLab** as Security Administrator, the capability to produce and save the recovery key.

The recovery key can be printed or saved on a USB memory drive as text or as XML format. When saved, keep the recovery key in a safe place.

The recovery key is necessary to decrypt the disk in the remote case the machine on which it is located is broken. Without recovery key Esaote Service personnel will not be able to recover any encrypted data from the disk.

Disk encryption + security access are the strongest way to protect the personal data of your patients, so at every boot **MyLab** reminds you to enable both features with a message on the screen.

Security

For further information about security options provided by **MyLab**, refer to the related chapter in the Advanced Features section of the Advanced Operations manual.

Licenses Manager

Licenses Manager allows to install optional licenses and to check the status of a demo license.

NOTE ***To activate a new license, the operator needs the appropriate form listing the licenses associated to the device. License codes are generated according to the*** **MyLab** ***Hardware ID, shown on the left upper corner of the license configuration menu.***

Press MENU then **LICENSES** to enter the License Manager Menu. It is organized in internal folders, selectable using the tabs displayed on the top of the menu.

Fig. 6-5: License Configuration Menu

License Activation

Tabs **APPLICATIONS** and **OPTIONS** allow to respectively activate the application licenses and the optional licenses.

The INCLUDING field, shown in the **APPLICATIONS** menu, indicates which applications will be available once the license is activated.

License Activation

To activate a new license, type the license number in the KEYS field and press **VERIFY** to confirm. If the number is correct, the status changes to PERMANENT.

NOTE ***All license fields are not case sensitive with the exception of the CrystaLine license that is case sensitive.***

Demo License

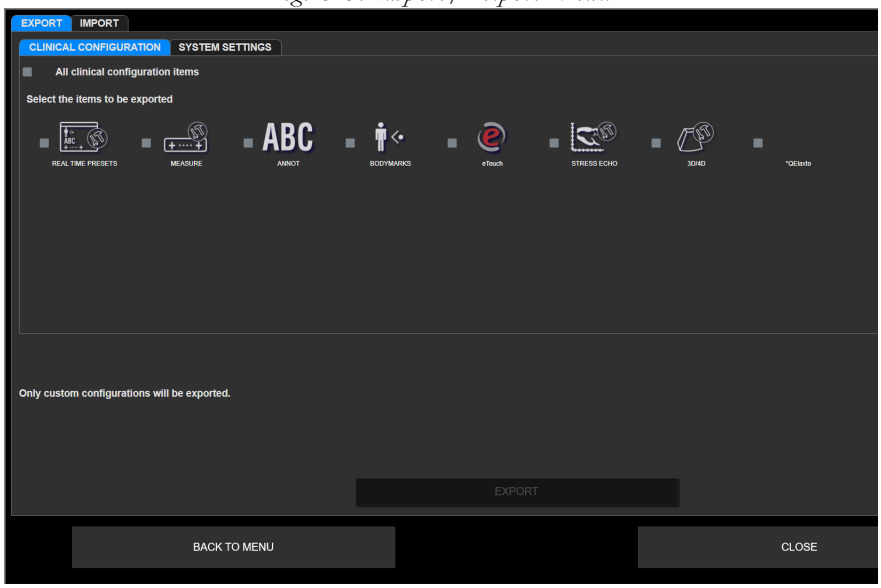
If a demo license has been activated (DEMO box checked), EXPIRATION DATE shows the expiration date of each demo licence.

SAVE saves the configuration, activating the licenses.

Import/Export Menu

The menu is organized with internal folders, selectable using the tabs displayed on the top of the menu.

Fig. 6-6: Import/Export Menu



EXPORT Folder

This option allows the user to save customized clinical and system settings on the USB medium.

The option is organized in internal folders, one folder for the clinical settings and one folder for the system configuration settings.

Clinical Configuration Folder

The clinical settings that can be exported are:

- customized real-time settings (REALTIME PRESETS);
- customized calculation packages (MEASURE);
- customized glossary libraries (ANNOTATIONS);
- customized body-mark libraries (BODYMARKS);
- customized ETOUCH;
- when available, other customized profiles.

System Settings Folder

The system configuration settings that can be exported are:

- customized DICOM configuration;

- customized SAVING OPTIONS;
- customized center configuration (CENTER ID);
- customized MULTIMEDIA export settings;
- customized NETWORK configurations;
- customized OBSERVATIONS;
- customized printer profiles (PRINTERS);
- customized report styles (REPORTS);
- customized XSTRAIN 2D settings;
- customized acquisition protocols (ACQUISITION PROTOCOLS);
- customized general configuration (GENERAL SETUP);
- customized SECURITY profiles;
- customized streaming settings (EPORTAL).

In both folders the menu allows the user to select both individual settings and all settings.

Select the desired options, connect the USB medium to **MyLab** and press **EXPORT** to confirm.

NOTE ***Only custom configurations will be exported.***

IMPORT Folder

This option allows the user to load customized clinical and system configuration settings. **MyLab** allows the user to load specific clinical and system configurations.

Procedure

- Connect the USB medium containing the customized configurations to **MyLab**,
- Select the configuration you want to import,
- Press **IMPORT** to start the loading procedure.

MyLab shows the list of all saved configurations, grouped by components. The menu allows either to select all profiles included in a component (by checking the box beside the component), or to separately load a specific configuration (by checking the box displayed beside the configuration).

NOTE ***In case of homonymy,*** **MyLab** ***asks for confirmation to completely overwrite the existing profiles, saved on the device. If confirmed, the previous configurations are then lost.***

System Info

Press MENU then **SYSTEM INFO**, the following information is displayed:

- the model name and serial number;
- the **MyLab** hardware ID, necessary for license generation;
- the current installed software version and its build;
- the BIOS revision;
- the hardware level of the installed boards.

From this menu you can export the log file on a USB medium and you can also check if the encryption is enabled or not (ENCRYPTION MODE).

Encryption Mode

Encryption allows to preserve health data storage confidentiality.

Encryption can be performed by Esaote Service personnel only. Encryption can be applied to the internal hard disk and to one or more external USB memory devices.

At the end of encryption a recovery key will be given to you. The recovery key is stored on USB pen drive, or on file, or by printing it.

You have the responsibility to store the key in a safe place for future use.

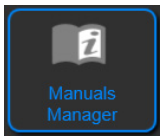
NOTE ***To make effective use of encryption it is strongly advised to use it with security access enabled.***

When data are encrypted, they can only be read on **MyLab** where the encryption was performed.

When an encrypted USB memory device is connected to the **MyLab** where it has been encrypted, data will be automatically unlocked and accessible.

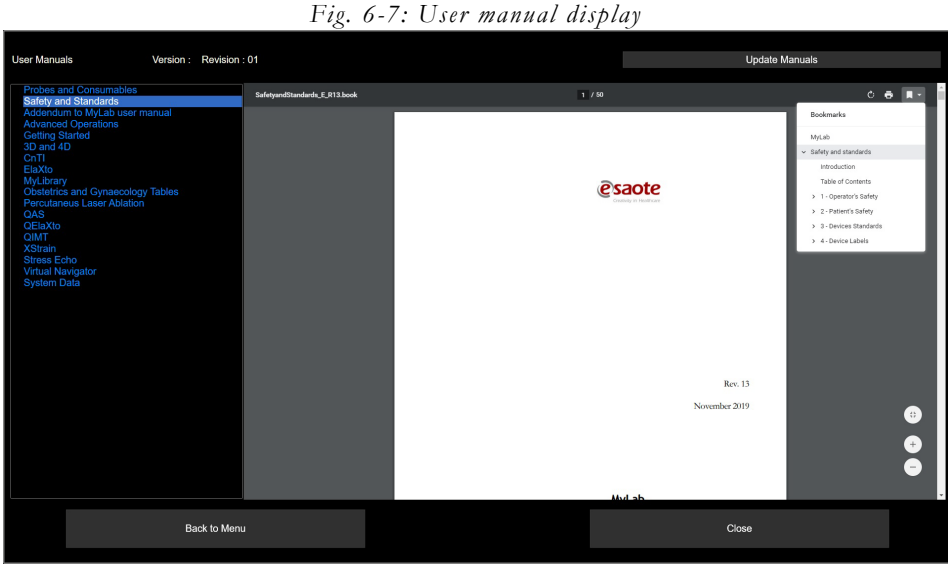
When an encrypted USB memory device is connected to a different system, data will remain locked and then not accessible.

Manuals Manager



MyLab operation manuals are provided in electronic form and are accessible through the user interface clicking on **MANUALS MANAGER**: the window below is displayed showing on the left the list of the available manuals.

Fig. 6-7: User manual display



Click on one of the manual titles in the list to open the related content.

NOTE ***The PDF reader is already integrated in*** **MyLab*****.***

The manuals installation and update is always done by the Esaote service personnel. The UPDATE MANUALS button on top-right is for the unlikely event you have to update manuals on your own. If this particular case happens, the package for the update is provided by the Esaote service. This remote case is communicated by **MyLab** through a warning message at starting-up.

Electronics manuals on Esaote website

MyLab operation manuals are accessible also on Esaote website, to access them you have to:

1. Access the website https://eifu.esaote.com;
2. Click on the dropdown menu CHOOSE THE MEDICAL SYSTEM;
3. Select the **MyLab** for which the manuals are needed;
4. Once the page related to the selected **MyLab** is displayed, select the manuals corresponding to the software version installed on your **MyLab**;

5. Select the language you desire;

6. Click on the manual to open it or click on  to download it.

NOTE ***You can download the entire set of manuals by clicking on*** DOWNLOAD ALL FILES (.ZIP).

Manuals are PDF files, you may need a PDF reader installed on your PC to consult them. You can download for free the program Adobe® Acrobat® Reader from the Adobe web site.

Chapter 7

7. Performing an Exam

This chapter describes the procedures commonly used in performing patient exams with **MyLab**. These procedures include entering patient and application data, acquiring images, making measurements and calculations; annotating and reviewing images.

MyLab is designed for operators who are qualified in using ultrasound scanners.

Only physicians or sonographers who are qualified in using ultrasound scanners should perform ultrasound scanning on human subjects for medical diagnostic purposes.

NOTE ***Improper use of MyLab can result in serious injury.***

Operating MyLab without a proper awareness of safe and effective use could lead to fatal or other serious personal injury.

As user, you must be thoroughly familiar with the instructions and potential hazards of using ultrasound before proceeding to use the device.

It is the user responsibility to operate according to currently approved recommendations provided by the relevant published clinical guidelines and by the best clinical practices.

NOTE ***The operator must be familiar with the mechanical and thermal indexes display as well as know the ALARA (As Low As Reasonably Achievable) principle. The patient must be exposed to ultrasound for as short time as possible and only for as long as it takes to achieve the diagnostic information.***

The potential benefits and risks of each examination should be considered before starting the exam execution.

The ALARA (as low as reasonably achievable) principle should be observed when adjusting controls that affect the acoustic output and by considering transducer dwell times.

WARNING **Different conditions can limit the possibility to obtain adequate US images of target organs, which may reduce diagnostic accuracy of US examination.**

Among these conditions belong obesity, scoliosis, chronic obstructive lung disease, scars, decubitus.

Starting an Exam

At power-up, at end of the initialization phase, or when starting every new exam, **MyLab** displays the Patient ID screen and the touchscreen is configured to allow the operator to enter patient and application data, and to select the probe, the application and the preset.

CAUTION

Do not turn MyLab off during the initialization phase: the hard disk could be damaged by this operation.

Fig. 7-1: Patient ID screen

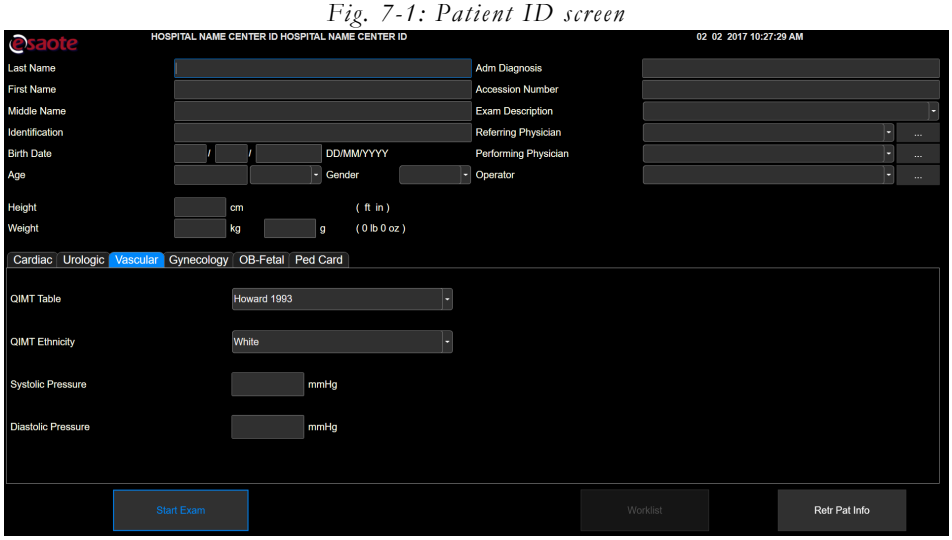
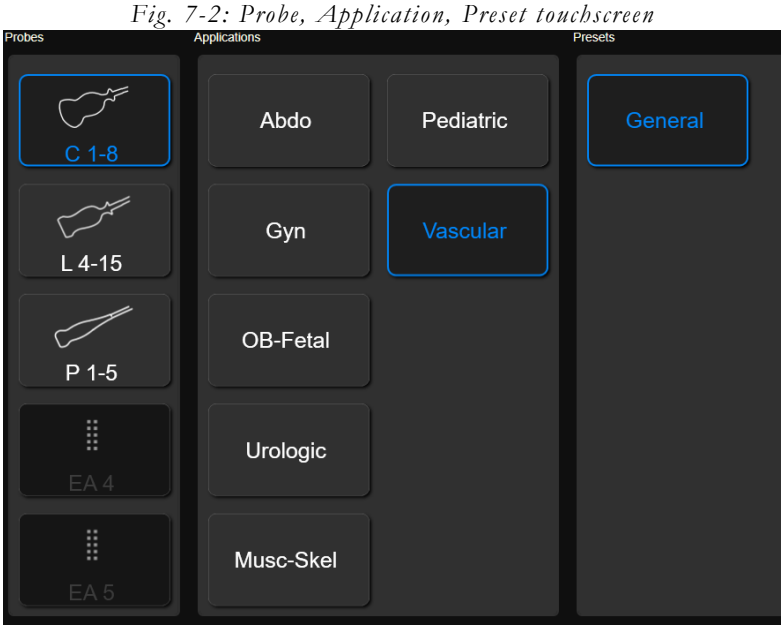


Fig. 7-2: Probe, Application, Preset touchscreen



Starting exam procedure

The steps to be followed to start an exam are:

1. Entering patient and application data;
2. Selecting probe;
3. Selecting Application;
4. Selecting Preset.

Entering Patient and Application data

There are two ways to enter patient data:

- Filling the Patient ID screen,
- Retrieving existing data from archive.

Filling the Patient ID screen

The Patient ID screen is used to enter patient data and application data, when applicable. Age is automatically calculated from the date of birth. Patient data will be saved together with images, measures and reports during archiving operations.

To navigate the Patient ID screen, you can use either the trackball and the ENTER key or the ⇆ tab key of the alphanumeric keyboard. To enter the patient data use the alphanumeric keyboard.

The Application data are additional information required for specific application (Cardiac, Urologic, Vascular, Gynecology, Obstetric and Pediatric Cardio) for calculation purposes.

Retrieving data from archive

CURRENT retrieves the patient data of the last exam.

REOPEN EXAM allows to open an exam already closed to add images and/or measurements.

NOTE ***The key is enabled only for exam closed in the same day of reopening. It is not allowed to reopen exams taken the days before the current one.***

RETR PAT INFO or **RETR PAT INFO** retrieves from the archive the patient data of a previously performed examination. Once pressed the list with archived exams is opened, double click on the exam to retrieve patient data, the Patient ID fields will be automatically filled with the data of the selected exam. Press CANCEL to exit without retrieving any exam.

If the PAUSE EXAM option is checked in Saving Option Menu, pressing **PAUSED EXAMS** a list with paused exams will be displayed, allowing to resume, close or delete them.

If a DICOM archive is available, it is also possible to load data from it using the **WORKLIST** button displayed on the screen. In this case **MyLab** displays the following warning message whenever the characters used to enter patient data are not supported:

Unsupported character setting!

At any time during the exam, Patient Data can be viewed and modified by pressing **PATIENT ID**.

WARNING

Do not use PATIENT ID to start a new exam of a new patient as it will update existing patient's data with new entries. To activate a new exam, close first the current exam by pressing END EXAM and then proceed with the Starting Exam procedure.

Pressing MAGE when the Patient ID Screen is displayed, a screenshot of this window is saved.

WARNING

The screenshot of the Patient ID Screen contains the patient data at the date and time of when the image has been taken. Do not refer to these data but always check the current patient data.

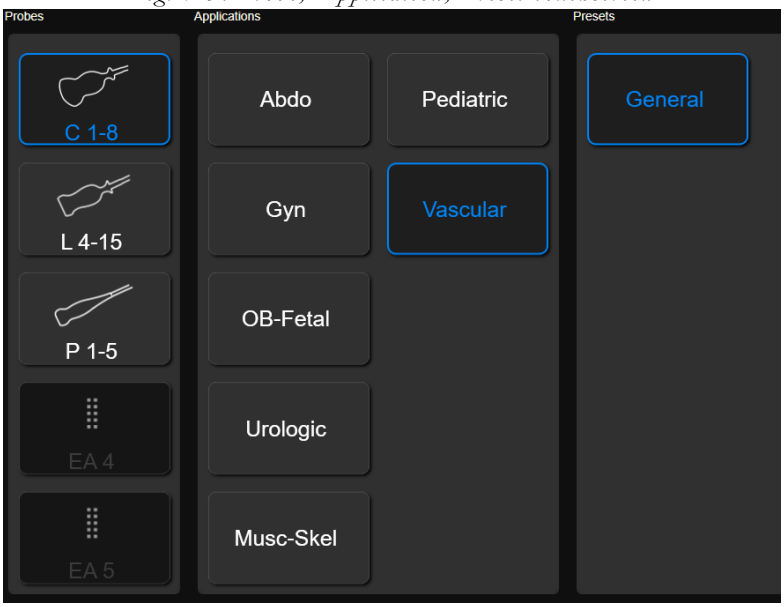
Selecting Probe

On the left side of the touchscreen all connected probes are displayed.

Tap the probe image to select it.

The blue rounded image indicates the active probe.

Fig. 7-3: Probe, Application, Preset touchscreen



At any time during the exam, a different probe can be selected tapping **PROBE** or the new probe key on the touchscreen work flow area (available when DIRECT PROBE SELECTION is enabled).

Selecting Application

When a probe has been selected, on the middle of the touchscreen all the application available with the selected probe are displayed. Tap the name of the desired application to set it.

The blue rounded application indicates the active one.

At any time during the exam, a different application can be selected tapping **PROBE**.

Selecting Preset

The Preset (or Clinical Setting) can be selected only when both the probe and the application have been set. Tap the name of the desired preset to select it.

The blue rounded preset indicates the active one.

At any time during the exam, a different preset can be selected tapping **PROBE**.

At Preset selection the exam starts; **MyLab** enables the selected probe to operate in the application and preset you selected.

WARNING

Before beginning the exam, ensure that the active probe displayed on the screen matches the one selected.

Alternatively, the exam can be started also pressing END EXAM, **END EXAM** or **START EXAM**.

NOTE

You can program and add presets to better suit your individual clinical needs or preferences, while applications depend on the installed optional licenses.

Performing the Exam

MyLab offers a set of imaging modes to cover a variety of imaging needs. By pressing the different mode buttons the specific mode is activated in real time. If the same button is pressed again, **MyLab** automatically returns to the previous presentation.

Special modes are also available for 3D imaging and advanced imaging.

Touchscreen buttons change according to the activated mode.

When more modes are active, the navigation tabs (**B–MODE**, **M–MODE**) allow the operator to scroll among the specific mode menu. If the displayed menu has several levels, tap **ADV>>** / **BASIC<<** to scroll through all functions.

📖 ***AO***

The control panel buttons and the commands displayed on the touchscreen make it possible to optimize presentation quality. Different menus correspond to each format., the "Advanced Operations" manual provides a detailed description of all active controls in the different modes.

Acquiring images

MyLab allows to capture and save a single image or a cineloop sequence pressing IMAGE or CLIP respectively.

These buttons respectively save still frames and clips in real time. Images are also saved in Freeze.

Images and clips are saved in patient study and thumbnails of the saved data are shown downwards in chronological order on the right side of the screen.

Single images are saved with full definition or compressed, whereas sequences are compressed with a minimum loss of information.

📖 ***AO***

Compression of both images and clips to be saved on external media can be set: refer to the "Archiving" section for further information.

Freeze and Scrolling Memories

Use FREEZE to stop and start real-time image acquisition and update.

At FREEZE pressure **MyLab** displays the scroll bar of the memories, assigning the trackball to manual cineloop review (frame-by-frame). Move the trackball horizontally to scroll through the images one by one. The scrolling bar shows the trackball position.

📖 ***AO***

The "Advanced Operations" manual provides a detailed description of all the available controls in Freeze.

Reviewing Images

During the exam, taping **EXAM REVIEW** enables reviewing of the saved images and sequences, and the trackball automatically changes to pointer mode, allowing you to scroll through the thumbnails and select the item to be reviewed. Alternatively press POINTER, select the thumbnail: **MyLab** automatically switches to Exam Review.

The selected image or sequence is shown on the screen.

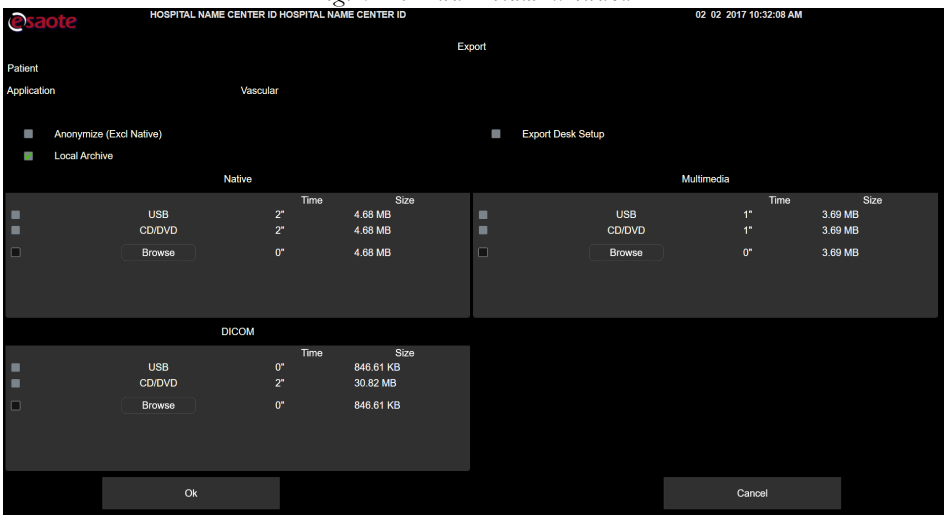
AO

The functionalities available in Exam Review are the same of the Archive Review: refer to this specific session of the "Advanced Operations" manual for further details.

Ending the Exam

To end the exam, press END EXAM. The window displayed at the end of the exam is used to archive the exam. This window shows the patient's name, the applications, the size of the stored images and the estimated time to complete each selected operation.

Fig. 7-4: End Exam Window



Before archival, Patient Data can be made anonymous by checking the ANONYMIZE box.

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

The exam can be simultaneously exported to the local archive and to external media (in native, DICOM and multimedia formats). Check all the destinations you want, then press **OK** to confirm and close the exam archiving it in the selected destination(s). **MyLab** automatically shows the window allowing to start the exam.

NOTE ***At power-up,*** **MyLab** ***prompts the operator to archive the last exam performed if the device was switched off without first closing the exam in progress.***

The exams that have been performed and not archived into the local database can be locally saved at a later time from Archive Review. Refer to the specific section of the "Advanced Operations" manual for further information.

If the PAUSE EXAM option is checked in Saving Option Menu, pressing END EXAM also **PAUSE** will be prompted.

NOTE ***At switch off,*** **MyLab** ***will inform if there are any paused exams.***

8. Maintenance

To ensure that **MyLab** operates over time at its maximum efficiency, Esaote recommends to perform maintenance procedures regularly.

Maintenance procedures should be performed both by the user itself and by Esaote authorized service personnel. The maintenance operations and schedule are provided in the table below.

Table 8-1: Maintenance Operations

Maintenance	Minimum frequency	Performed by
cleaning the probes	after use	user
checking the probes	every week	user
cleaning control panel and device	every week	user
cleaning touch screen	every week	user
cleaning probe and gel holders	every week	user
cleaning LCD case and screen	every week	user
checking device housings for any damage	every month	user
checking control panel and keyboard for defects	every month	user
checking equipment for loose or missing hardware	every month	user
checking movements of all parts composing the device	every month	user
checking LCD and touchscreen status	every month	user
checking trackball movement	every month	user
cleaning trackball	every month	user
checking connectors on cables for any mechanical defects	every month	user

Maintenance	Minimum frequency	Performed by
checking entire length of electrical and power cables for cuts or damages	every month	user
checking the device integrity, functionality and cleaning (including internal components)	every year	Esaote personnel or authorized personnel
Electrical Safety Tests	every two years	Esaote personnel or authorized personnel

NOTE ***Frequency of cleaning can change depending on environment cleanliness.***

NOTE ***Periodic maintenance operations that require the access to the device can be performed only by trained personnel: contact your local Esaote representative for further information on required periodic inspections.***

Only trained persons are allowed to perform the safety inspection mentioned above.

Disconnect **MyLab** from the power outlet before checking it.

Contact Esaote personnel for any problem found during inspection.

PC Refer to "Probes and Consumables" manual for periodic inspections for probes and cleaning instructions.

Cleaning Operations

Periodic cleaning of **MyLab** and any connected devices is important.

In the event of poor maintenance, dust and dirt can compromise the reliability and performance of **MyLab** and connected devices.

The following table indicates the cleaning agents that have tested the compatibility with the **MyLab**.

Table 8-2: MyLab compatible cleaning agents

Product	Supplier
Asepti-Wipes II	**Ecolab Co** (www.ecolab.com)
Cavicide Caviwipes Metrizyme	**Metrex Research Corporation** (www.metrex.com/company/contact/index.cfm)
CidezymeXTRA Enzol	**Advanced Sterilization Products** (www.aspjj.com)
Cleanisept-wipes	**Dr.Schumacher** (www.schumacher-online.com)
Mid Soap	-
Mikrozid AF wipes Mikrozid PAA wipes Mikrozid sensitive wipes	**Schülke&Mayr GmbH**, (www.schuelkemayr.com/int/en/contact/smi044_adresses.htm)
Sani-Cloth HB Sani-Cloth Plus Sani-Cloth Super	**Professional Disposable International** (www.pdipdi.com)
SaniZide plus	**Safetec of America** (www.safetec.com)
Trionic D	**Ebiox** (www.ebiox.co.uk)

To clean the peripheral devices, follow the instructions supplied by the manufacturer.

WARNING **Turn MyLab off and unplug it before any cleaning operation.**

NOTE ***The cleaning operation should be performed accordingly to the equipment environment requirements in terms of temperature, pressure and humidity.***

Check the instructions supplied by the manufacturer of the cleaning agents for possible stricter limitation. Do not use hot cleaning agents for cleaning the equipment.

CAUTION

Apply the cleaning agents only for the time necessary to remove the dirt without exceeding over.

A visual inspection of the parts subjected to the cleaning process in order to evaluate possible damages or deteriorations.

Cleaning control panel and device

To clean the control panel and device, switch the **MyLab** off, unplug it and use a soft cloth slightly dampened with water.

If necessary use the suggested wipes, or a soft cloth slightly dampened with one of the suggested cleaning agents.

Otherwise, apply a small amount of ammonia-free and not abrasive detergent on a clean, soft cloth and then wipe the surface.

WARNING

Make sure that the detergent has completely evaporated before turning the equipment on.

CAUTION

Do not use any type of ammonia- or benzene-based cleaners on the case.

Cleaning the QWERTY keyboard

To clean the QWERTY keyboard switch your **MyLab** off, unplug it and use commercial wet wipes only.

CAUTION

Do not use any kind of spray, foam, gel cleaner on the QWERTY keyboard, either directly or on moistened soft cloths, which could lead to a drop inside. This can cause damage to the QWERTY keyboard, which could lead to system malfunctioning.

Cleaning the trackball

The trackball can be accessed, for cleaning purpose only, by rotating counterclockwise the upper locking disk.

Once the disk has been removed, clean the trackball using a soft dry cloth. Clean the trackball housing using a cotton swab.

CAUTION

When cleaning the trackball housing, make sure not to spray any liquid into the trackball housing.

Clean the ball rotating it in its socket. Do not remove the ball from the socket.

WARNING

Do not remove the ball from the socket.

WARNING

Do not try to disassemble the trackball during the cleaning of the removable sealing ring.

Cleaning Probe and Gel Holders

Probe and gel holders are easily removable from their location for cleaning and can be washed in a mild soap solution. Make sure they are completely dry before replacing them.

PC

To clean the probes, refer to the manual "Probes and Consumables".

Cleaning the Touchscreen

To clean the touchscreen, switch **MyLab** off, unplug it and use a soft dry cloth, lightly rubbing the display surface. To remove stains, lightly dampen the cloth with ethanol and water mixed in a 1:1 ratio and gently wipe the touch panel surface; afterwards, dry the touch panel with a new dry cloth.

If strictly necessary, to clean the touchscreen during an examination, you can temporarily lock the keyboard and the touchscreen pressing FREEZE while keeping ETOUCH pressed. When **MyLab** is on and connected to the mains, for safety reason, you must use only a soft dry cloth to clean the touchscreen.

WARNING

Do not spray or apply the cleaning agents directly on the touchscreen surface as the liquid of the cleaning agents may permeate into the front bezel of the display and cause damage.

Do not press the touchscreen with any sharp objects as this may damage the screen.

When MyLab has not been unplugged, clean the touchscreen exclusively using a dry cloth. Never use wet cloth.

Cleaning the LCD Screen

To clean the LCD use a soft dry cloth, lightly rubbing the display surface to remove dust and other particulate matter. If necessary, apply a small amount of ammonia- free glass cleaner onto a clean, soft cloth and then wipe the surface.

Never spray or pour any liquid directly onto the screen or case.

WARNING

Overspray or liquid may cause electrical shock.

Cleaning the LCD case

Use a soft, dry cloth to wipe the surface of the case. If necessary, apply a small amount of ammonia-free and not abrasive detergent onto a clean, soft cloth and then wipe the surface.

CAUTION

Do not use any type of ammonia- or benzene-based cleaners on the monitor's screen and case.

Chapter 9

9. Technical Specifications

This chapter describes the technical specifications[1] of **MyLab**.

NOTE ***Special packages (such as Strain) are listed and described in the specific sections of the "Advanced Operations" manual.***

MyLab Characteristics

MyLab models differ in licences that are installed per default and licences that can be installed. The tables below list all the available licences regardless the model on which they could be installed. Refer to the corresponding Sales Area manager for further information.

Licenses

Licenses enable specific functions of **MyLab**, they are linked to **MyLab** serial number and are, therefore, unique. They should be carefully stored. The device is delivered by Esaote, with the licenses already installed.

Additional features can be added buying the related license.

Applications

MyLab can be equipped with the following application licenses.

Table 9-1: Application licenses

Licence	Application	Features
Cardiology	Cardiac (adult and pediatric)	Presets, Calculations, ECG, Auto EF
Radiology Gen. Imaging	Abdominal, Neonatal, Musculo-skeletal, Pediatric, Breast, Small Organ, Thyroid, Urology	Presets, Calculations
Women's Health Ob/Gyn	Obstetrics, Fetal, Gynaecology	Presets, Calculations, AutoNT
Vascular	Peripheral Vascular, Adult cephalic	Presets, Calculations

1. Specifications subject to change without notice. Information might refer to products or modalities not yet approved in all countries.

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.
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[a] Ultrasound DICOM Query/Retrieve
Multi-modality & Dicom Q/R	Multi-modality management Multi-modality DICOM Query/Retrieve
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[b]
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.
microV	It automatically recognizes the lowest speeds with ultra sensitivity for small vessels and slow flow detection.

Feature	Description
MView	It is an ultrasound technique which applies beam-line steering and acquires several coplanar scans of an organ from different view angles.
MyLab Tablet	Mobile application which allows to remotely review **MyLab** images on tablet or mobile.
MyLibrary	Dedicated libraries for Rheumatology, MSK, Regional anesthesia, Physiotherapy and Advanced vascular. Live Preview features allow to scan in real-time while using anatomical references and scanning guidance.
Needle Enhancement Imaging	It increases the needle visibility.
Protocols	Clinical protocols[c]
QAS	Quality Arterial Stiffness
QIMT	Quality Intima Media Thickness calculation automatically measures the Carotid Intima-media thickness in real-time.
QPack - Quantification	Time/Intensity analysis
Raw Data Processing	It enables raw data management in post-processing allowing to act on the raw data of captured images and clips by modifying some of the parameters represented.
Stress-Echo	Stress-Echo allows to acquire multiple views of the left ventricle (LV) under stress, using customizable protocols.
TEI	Tissue Enhanced Imaging improves the signal-to-noise ratio and enhances contrast resolution.
TPView	It enlarges the field-of-view.
TVM	Tissue Velocity Mapping provides a complete Wall Motion Analysis for both systolic and diastolic myocardial function evaluation.
VPan	Panoramic Imaging merges multiple B-Mode images in one complete panoramic image.
XSTIC	It is a three-dimensional technique ,which allows the acquisition of a volume of data from fetal heart, displayed as a cineloop of a single cardiac cycle.
XStrain	XStrain allows to quantify endocardial velocities of contraction and relaxation and local deformation of the heart (Strain/Strain Rate analysis).

Feature	Description
XStrain 4D	XStrain 4D creates a volumetric model of the left ventricle (LV) based on the acquisition of standard apical views (Strain/Strain Rate volumetric analysis).
XView XView+	XView and XView+ enhance the pattern of every frame at the pixel level, eliminating speckle and noise artefacts.

a. Refer to www.esaote.com for further details on supported DICOM classes.
b. www.elesta-echolaser.com
c. Refer to the corresponding Sales Area manager for further information.

NOTE ***Features, probes and applications availability is dependent on your device configuration. Not all features, probes and applications are approved in all Countries. Please refer to your Esaote local representative for further information.***

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 18.5" monitor (21.5" optional)
- 8.9" LCD (touchscreen)

Probe connectors

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

Video Output

- HDMI type [1]

Connectivity

- I/O connectors

1. Auxiliary monitors connected to this input have not to be used for diagnostic purposes.

    - LAN RJ45
    - 2 USB 2.0 on keyboard control panel
    - 2 USB 3.0 on console left side
    - 2 USB 2.0 on rear panel
    - Wi-Fi (802.11 a, b, g, n)
- Dedicated connectors
    - ECG input
- Other
    - Laser/Ink jet printers
- Complies with IHE integration profiles[1]

Image Files

- Formats
    - BMP (uncompressed)
    - PNG (lossless)
    - JPEG (lossy)
    - AVI: Codec Microsoft MPEG-4 V2 and MS-Video 1
    - Native formats

Software

- Operating system: Windows 10
- Multi-lingual

Biometry

- Basic and advanced calculation, application dependent
- Annotations, bodymarks

Keyboard

- Height adjustable control panel
- Control panel:
    - Potentiometers for TGC
    - Encoders for general gains
    - Keys for modes, peripherals management and controls
- Reconfigurable touchscreen LCD

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

- Pull out alphanumeric QWERTY keyboard

Dimensions

- Closed: 490 (L) x 1000 (H) x 645 (D) mm
- In working position with gel and probe holders: 580 (L) x 1220÷1430 (H) x 700 (D) mm

Weight

- < 65 kg (basic configuration without peripheral units)

IP Grade

- IP (X)0, this means **MyLab** models are not watertight.

Power supply

- Voltage operative range:
  - 100 ÷ 120 V
  - 200 ÷ 240 V
- Working frequency range: 50 ÷ 60 Hz ±10%
- Power consumption: ≤ 220 VA (**MyLab** only)
- Power consumption: ≤ 600 VA (**MyLab** + peripherals)
- Available power on peripherals: up to 250 VA
- Fuses: T 5Ah, 250 V (220V)/ T 10Ah, 250 V (110V), 5x 20mm

Batteries

- Batteries for:
  - stand-by suspension
  - fast movement without switching off
- Battery charger inside
- Battery charging cycle: around three and a half hours (3 h 30 min)
- Battery life: 3 years

Power Cables

Table 9-3: Power Cables

	Connector	Plug Type	Cord Type	Length
Italy **Chile**	EN60320/C13	I/3G CEI 23-50	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m
EU **Germany**	EN60320/C13	Type VII G CEE (7) VII	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m
USA **North America**	C13M EN60320/C13	HG (Hospital grade) NEMA 5-15	SJT3x14AWG Section AWG 14 3 conductors 15A-125V	4,5 m
China	EN60320/C13	PCR/3 GB2099 / GB1002	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m
Brazil	EN60320/C13	BR/3 according to NBR14136	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m
UK **Singapore**	EN60320/C13	BS13/13 BS 1363/A	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m
Swiss	EN60320/C13	12G SEV 1011-2009 SEV 6534/2	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m
Israel **Middle East**	EN60320/C13	IL/3G SI32	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m
Australia **New Zealand**	EN60320/C13	SAA/3 AS/NZS 3112-2000	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m

	Connector	Plug Type	Cord Type	Length
Denmark	EN60320/C13	DK3/HGA SB 107-2D1 DK2-8a	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m
South Africa **India** **Namibia**	EN60320/C13	ZA/3 SANS 164/1 IS 1292	H05VVF3G Section 1 mm^2 3 conductors 10A-250V	4,5 m

Operating Requirements

- Temperature: 15 ÷ 35°C
- Humidity: 15 ÷ 85% (not condensing)
- Pressure: 700 ÷ 1060 hPa

Storage requirements

- Temperature: -20 ÷ +60°C
- Humidity: 10 ÷ 85% (not condensing)
- Pressure: 700 ÷ 1060 hPa

Probe Storage Requirements

- Probe storage requirements are indicated in the probe case.

Standards

Table 9-4: Standards

Standard	Title
IEC 60601-1:2012 (Ed.3.1) EN 60601-1:2006 + CORR. 1 (2006) + CORR. 2 (2007) + AMD. 1 (2015)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
CAN/CSA C22.2 No. 60601-1:08 CAN/CSA C22.2 No. 60601-1.14	Medical Electrical Equipment - Part 1: General Requirements for Safety
ANSI/AAMI ES60601-1: 2005 + A2:2010	Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-1-2:2014 (Ed.4) EN 60601-1-2:2015 (Ed.4)	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2010 + A1:2013 (Ed. 3.1) EN 60601-1-6:2010 + A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-37:2007 (Ed. 2.1) + A1:2015 EN 60601-2-37:2008	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
IEC 61157:2007 (Ed. 2.1) +A1:2013	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
IEC 62304 EN 62304	Medical device software - Software life cycle processes
IEC 62366:2007 + A1:2014 (Ed. 1.1) EN 62366:2008	Application of Usability Engineering to Medical Devices
EN ISO 10993-1:2009	Biological evaluation of medical devices - Evaluation and testing
EN ISO 14971:2012	Medical equipment - Application of risk management to medical devices.
ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements
AIUM/NEMA UD-2:2004 (R2009)	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.

Standard	Title
AIUM/NEMA UD-3:2004 (R2009)	Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment.
CAN/CSA C22.2 NO. 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment