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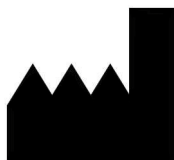
June 2021

MyLabX75 Family

**GETTING STARTED**

*350079900*





## Manufacturer's Address

ESAOTE S.p.A.  
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## Important Information

**MyLabX75, MyLabX75 eHD, MyLabX75 eXP and MyLab XPro75** comply with the Medical Device Directive 93/42/EEC and subsequent amendments and are CE marked.

**MyLabX75, MyLabX75 eHD, MyLabX75 eXP and MyLab XPro75** are devices in Class IIa according to the Medical Device Directive.

**MyLabX75, MyLabX75 eHD, MyLabX75 eXP and MyLab XPro75** comply with the Radio Equipment Directive 2014/53/EU and are CE marked.

**MyLabX75, MyLabX75 eHD, MyLabX75 eXP and MyLab XPro75** 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: **MyLabX75, MyLabX75 eHD, MyLabX75 eXP and MyLab XPro75**.

In this manual, all the above mentioned devices can be also referred as **MyLabX75 Family** or **MyLab**.

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

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## **Guarantee**

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

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# RED Declaration of Conformity



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

Noi costruttori  
*We manufacturer*

### **Esaote S.p.A.**

Via Enrico Meloni 77, 16152 Genova - Italy

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

### **Modello MyLabX75**

### **Model MyLabX75**

risponde ai Requisiti Essenziali dell'Allegato II della direttiva 2014/53/UE - RED  
*meets the Essential Requirements of Annex II 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.*

Genova, 23 aprile 2021  
*Genoa, April 23<sup>rd</sup>, 2021*

Ing. Massimo Polignano  
Responsabile Assicurazione Qualità  
*Chief Quality Officer*




**DICHIARAZIONE DI CONFORMITÀ 2014/53/UE**  
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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
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ETSI EN 300 328 v2.2.2	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band. 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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# 1. Introduction

**MyLabX75 Family** devices are supplied with a set of manuals to provide all necessary and sufficient information to operate the device safely and effectively.

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**WARNING**

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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:

- **MyLabX75 Family** 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 describes the most extensive configuration of your **MyLabX75 Family** 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.

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**WARNING**

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**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](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.

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**WARNING**

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

---

**CAUTION**

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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](http://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.

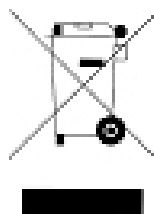


## Maintainability Time

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**

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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](http://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:.....

GETTING STARTED



## 2. Additional Information on Safety



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.

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**WARNING**

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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.

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**CAUTION**

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

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**WARNING**

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

---

**WARNING**

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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 (4<sup>th</sup> 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**

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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**

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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		
<p><b>MyLab</b> is suitable for use in the specified electromagnetic environment. The purchaser or user of <b>MyLab</b> should assure that it is used in an electromagnetic environment as described below:</p>		
Emission Test	Compliance	Electromagnetic Environment
RF emissions CISPR 11	Group 1	This <b>MyLab</b> 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	<p><b>MyLab</b> 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.</p>
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

<p><b>MyLab</b> is intended for use in the electromagnetic environment specified below. The customer or the user of <b>MyLab</b> should assure that it is used in such an environment.</p>			
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 at 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 <b>MyLab</b> requires continued operation during power mains interruptions, it is recommended that <b>MyLab</b> 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 <b>MyLab</b> requires continued operation during power mains interruptions, it is recommended that <b>MyLab</b> 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.

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

**Electromagnetic Immunity for Medical Equipment not Life Supporting**

<p><b>MyLab</b> is intended for use in the electromagnetic environment specified below. The customer or the user of <b>MyLab</b> should assure that it is used in such an environment.</p>			
Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment and Measures to Be Taken
Conducted RF IEC 61000-4-6	<p>3 V 0.15-80 MHz</p> <p>6 V in ISM band between 0.15 MHz and 80 MHz</p> <p>80% AM at 1 kHz</p>	<p>3 V 0.15-80 MHz</p> <p>6 V in ISM band between 0.15 MHz and 80 MHz</p> <p>80% AM at 1 kHz</p>	<p>Mobile or portable radio frequency (RF) communication equipment should be used no closer to any part of <b>MyLab</b>, including cables.</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>1</sup>, should be less than the compliance level in each frequency range<sup>2</sup>.</p>
Radiated RF IEC 61000-4-3	<p>3 V/m 80 MHz - 2.7 GHz</p> <p>80% AM at 1 kHz</p>	<p>3 V/m 80 MHz - 2.7 GHz</p> <p>80% AM at 1 kHz</p>	<p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>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.</p>			

- 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**.
- 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.

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**WARNING**

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**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<sup>1</sup> 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<sup>2</sup>. 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  $\leq 0.2\%$  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*

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**WARNING**

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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**

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**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**

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**WARNING**

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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**

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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.



**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 MyLabX75 Family and MyLab XPro75*



## 3. MyLab Overview

**MyLabX75 Family** is a professional, innovative and versatile real-time high-resolution ultrasound scanner. The wide range of probes makes it suitable for many clinical applications.

**MyLabX75 Family** is based on a mainframe easily movable platform. **MyLabX75 Family** has four swiveling wheels and a range of height adjustments for one-time installation, the main screen can be easily moved due to an optional articulated arm. Due to its small footprint it 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 Purpose

The multifunctional ultrasound scanner **MyLabX75 Family** is used to collect, display, and analyze ultrasound images during ultrasound imaging procedures in combination with supported echographic probes.

*Table 3-1: Intended purpose*

Main application	Districts	Invasive access
Cardiac	Cardiac Adult, Cardiac Pediatric	Not applicable
Vascular	Neonatal, Adult Cephalic, Vascular	Not applicable
General Imaging	Abdominal, Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organs (Testicles), Thyroid, Urological	Intraoperative (Abdominal), Laparoscopic, Transrectal
Women Health	OB/Fetal, Gynecology	Transrectal, Transvaginal

## Clinical Applications and Supporting Probes

A variety of ultrasound probes can be connected to **MyLabX75 Family**.

*Table 3-2: Available probes and applications*

Probe	Applications / Districts	Biopsy
AC2541	Abdominal, Gynecology, Musculo-skeletal, Obstetric and Fetal, Pediatric, Urology, Vascular	YES
E 3-12	Gynecology, Obstetric and Fetal, Urology	YES
IH 6-18	Abdominal, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Vascular	YES
IL 4-13	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, Neonatal, Obstetric and Fetal, Pediatric, Small Organ, Thyroid, Vascular	YES
L 4-15	Abdominal, Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	YES
LP 4-13	Abdominal	YES
mC 3-11	Abdominal, Cardiac, Neonatal, Obstetric and Fetal, Pediatric, Pediatric Cardiac, Small Organ, Thyroid, Vascular	YES
P 1-5	Abdominal, Adult Cephalic, Cardiac, Pediatric Cardiac, Vascular	NO
P 2-9	Cardiac, Neonatal, Pediatric Cardiac	NO
P2 5-13	Cardiac, Neonatal, Pediatric, Pediatric Cardiac, Small Organ, Vascular	NO
S2MCW	Cardiac, Pediatric Cardiac	NO
S5MCW	Vascular	NO
SB2C41	Abdominal, Gynecology, Musculo-skeletal, Obstetric and Fetal, Pediatric, Urology	YES
SB3123	Gynecology, Obstetric and Fetal, Urology	NO
SI2C41	Abdominal, Gynecology, Musculo-skeletal, Obstetric and Fetal, Pediatric, Urology	YES
SL3116	Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	YES
TLC 3-13	Gynecology, Urology	YES

Table 3-3: Available applications and related probes

Application / District <sup>1</sup>	Probes
Abdominal	AC2541, L 3-11, L 4-15, mC 3-11, P 1-5, SB2C41, SI2C41 Intraoperative: IH 6-18, IL 4-13, IOT342 Laparoscopic: LP 4-13
Adult Cephalic	P 1-5
Breast	IL 4-13, L 3-11, L 4-15, SL3116
Cardiac	mC 3-11, P 1-5, P 2-9, P2 5-13, S2MCW
Gynecology	AC2541, SB2C41, SI2C41, Transrectal/Transvaginal: E 3-12, SB3123, TLC 3-13
Musculo-skeletal <sup>2</sup>	AC2541, IH 6-18, IL 4-13, IOT342, L 3-11, L 4-15, SB2C41, SI2C41, SL3116
Neonatal <sup>3</sup>	IH 6-18, L 3-11, L 4-15, mC 3-11, P 2-9, P2 5-13, SL3116
Obstetric and Fetal	AC2541, L 3-11, mC 3-11, SB2C41, SI2C41 Transrectal/Transvaginal: E 3-12, SB3123
Pediatric	AC2541, IH 6-18, IL 4-13, IOT342, L 3-11, L 4-15, mC 3-11, P2 5-13, SB2C41, SI2C41, SL3116
Pediatric Cardiac	mC 3-11, P 1-5, P 2-9, P2 5-13, S2MCW
Small Organ	IH 6-18, IL 4-13, IOT342, L 3-11, L 4-15, mC 3-11, P2 5-13, SL3116
Thyroid	IL 4-13, L 3-11, L 4-15, mC 3-11, SL3116
Urology	AC2541, SB2C41, SI2C41, Transrectal/Transvaginal: E 3-12, SB3123, TLC 3-13
Vascular	AC2541, IH 6-18, IL 4-13, IOT342, L 3-11, L 4-15, mC 3-11, P 1-5, P2 5-13, S5MCW, SL3116

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

- Patient population: Fetal, Neonatal, Pediatrics and Adult
- Location: worldwide
- Sex: male and female
- Weight: all weight categories (in terms of Body Mass Index)
- Adult: no limitations

## Intended users

**MyLabX75 Family** is designed for Ultrasound practitioners.

The operator must have read and understood the user manuals.

Ultrasound practitioner is a healthcare professional who holds recognized qualifications in medical ultrasound and is able to competently perform ultrasound examinations falling within his/her personal scope of practice. The professional background of ultrasound practitioners can be very varied and will include radiologists, radiographers, sonographers, midwives, physiotherapists, obstetricians and clinical scientists.

## Contraindications

**MyLabX75 Family** is not intended for:

- ophthalmic use or any use causing the acoustic beam to pass through the eye;
- monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient;
- for diagnosis in clinical situations where the patient is in immediate danger.

---

**WARNING**

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**Do not use MyLab for ophthalmic or transorbital applications.**

**The ultrasound beam must not be directed to the eyes.**

The review of the State of the art of ultrasound demonstrates the residual risk for diagnostic ultrasound scans is sufficiently low and the related clinical benefit sufficiently great that there's no concern as its safety and performance when used in clinical settings by qualified and trained ultrasound practitioners following the appropriate professional guideline for the scope of the practice.

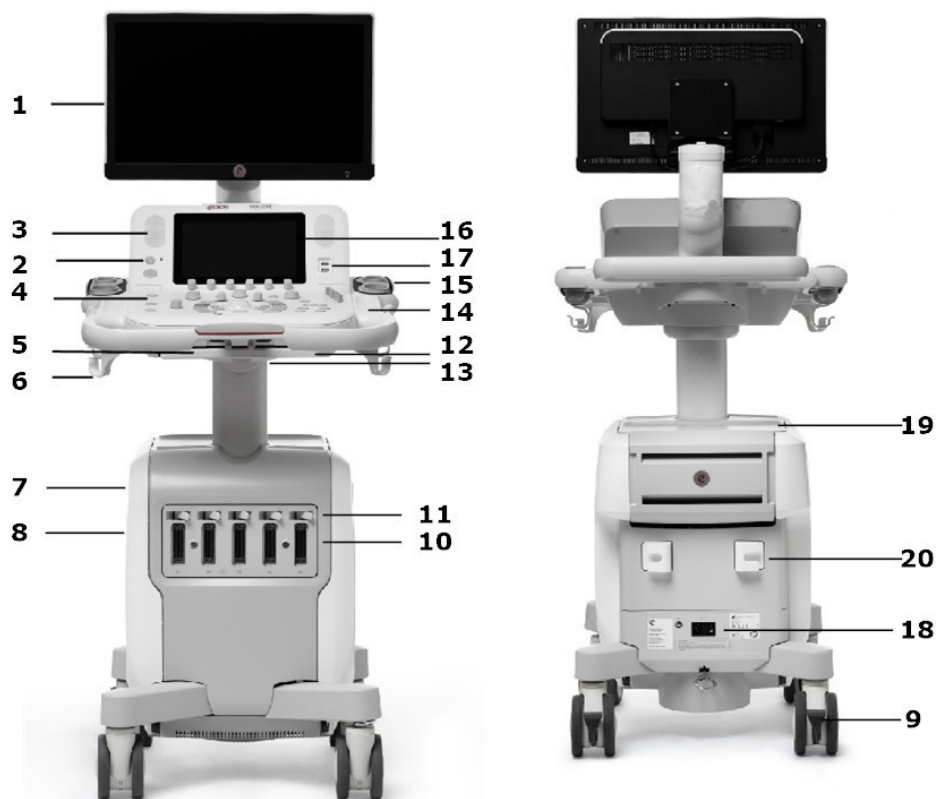
## MyLab Components

**MyLab** consists of a control panel assembly with LCD monitor and a console with the device electronics and connectors, housed in an ergonomic cart designed to be both highly mobile and adjustable for a range of users and operating conditions.

The cart 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 for front and rear wheels for movement and transportation.

Removable components can be locked in place so the cart can be safely moved.

*Fig. 3-1: MyLab components*



*Table 3-4: Components description*

Number	Component
1	Monitor
2	On/Off button
3	Loudspeakers (on both sides)
4	Control Panel Assembly
5	Orientation lever
6	Cable hangers
7	Printer slot
8	Connections panels
9	Wheel brake pedal (on each wheel)
10	Probe connectors
11	Probe connector locks
12	Pull-out QWERTY keyboard
13	Lifting lever
14	Gel holder (on both sides)
15	Probe holder (on both sides)
16	Touch screen
17	USB ports
18	Main switch
19	Peripheral plate
20	Power cord hook

### **Monitor (1)**

**MyLab** is equipped with an LCD LED flat-plan display on an articulated mounting arm. The monitor is adjustable to accommodate different operating positions.

The monitor is suitable for reading medical images, in particular each production unit is calibrated according to the Greyscale Standard Display Function (GSDF) defined in Part 14 of the DICOM medical standard.



In addition, the entire apparatus, of which the monitor is an integral part, complies with the mandatory standards of biomedical equipment (safety according to IEC 60601-1 Ed. 3.1 and EMC according to IEC 60601-1-2 Ed. 4).

### On/Off Button (2)



The ON/OFF button is located beside the touchscreen, on the left side of the control panel assembly, while the Main Switch and the power cable socket (18) are 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 3-5: On/Off button light

Led Colour	Meaning
GREEN	<b>MyLab</b> is on
AMBER	<b>MyLab</b> can be turned on
OFF	<b>MyLab</b> can not be turned on, unless an optional battery pack is mounted.

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 can be configured in order to place the device 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 malfunctioning: when this occurs, MyLab displays an information message. The following start up will require running the whole initialization phase.*

### Control Panel Assembly (4)

The Control Panel Assembly includes the main controls: physical buttons, knobs, and trackball, TGC, touchscreen and a pull-out QWERTY keyboard placed in the drawer below the panel.

The control module also allows to select transducers, enter patient data, review and annotate images, perform measurements and calculations, and change setups.

The Control Panel Assembly includes the handle, the probe and ECG cables holders.

Two loudspeakers (3) are placed on both side of the touchscreen.

*Fig. 3-2: Control Panel Assembly*



*Table 3-6: Control Panel Assembly description*

Number	Control Panel Assemble
17	USB Port
3	Loudspeakers
16	Touch screen

Number	Control Panel Assemble
22	Knob controls
23	TCG slide controls
24	Trackball



Two USB ports (17) are located on the right side of the control panel next to the touchscreen. These ports can be used to connect a USB device for digital storage. The lateral port can be used instead to connect USB foot-switch or a USB printer.

### Control Panel Assembly Orientation

The Control Panel Assembly is adjustable to accommodate a wide range of operator heights and operating positions.



These adjustments can be controlled by two levers located below the Control Panel Assembly (as shown in the image beside).

The orientation lever (5), located on the left, allows to rotate by up to 50° clockwise (with intermediate steps) and by up to 180° counterclockwise (closed position for optimal handling). Push the lever to rotate the control panel into the new position; release it when the control panel is correctly positioned.

### 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.**

The lifting lever (13), located on the right, allows to adjust the position of the control panel vertically, lifting or lowering it.

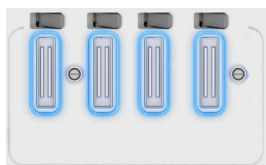
Push the lever and act on the handle to adjust the height of the control panel. This lever allows a vertical displacement of  $\pm 25$  cm.

### Pull-out Qwerty Keyboard (12)



Beneath the Control Panel there is a pull-out alphanumeric keyboard. The keyboard is mounted on a sliding drawer: just pull it to extract the keyboard.

The keyboard is used to enter patient data, comments and text annotation on images.



## Probe Connectors and Cable Management

Four probe connectors (10) are located on the front of the console. All connectors can be occupied simultaneously, but only one probe at time can be active.

Probe Connector Locks (11) are placed above the probe connectors.

Make sure that the Probe Connector Lock is positioned on the right (open position) and carefully attach the probe connector by placing the cable feed-through downwards. To secure the probe, move the securing device towards left (locked position).

---

**WARNING**

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

**Never disconnect the probe while it is active. Press `FREEZE` 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.**

When a transducer is not in use, store it in one of the probe holders (15) on the sides of Control Panel Assembly. Always loop transducer cables over the cable hangers (6) to prevent cables from being stepped on or run over by the cart wheels.

## Peripherals Housing

The console top is equipped with a peripheral plate (19) to house peripheral devices. Those devices can be any combination of the following devices: a black-and-white printer, a color printer, and a DVD recorder. The peripheral can be easily connected and disconnected and secured to the device console with belts.

A dedicated storage area (7) for B/W thermal USB printer is located on the left side of the console.

## Connections panels (8)

On the left side of the console you can find additional connections:

- ECG and Physio cable connector,
- auxiliary USB 3.0 ports that can be used to connect a USB printer, a USB footswitch or a USB digital archive medium,
- LAN port,
- Display port for video output.



## Wheel Brakes

**MyLab** is equipped with four rotational wheels and independent brakes on each of them.

When the pedal is fully pressed down, the brake is engaged to avoid rotation of wheels keeping the device stationary during use. To release the brake, move the pedal to the upper position.

## 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.




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

*Blinking of the battery LED*

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

**Battery Status Icons**

Table 3-7: 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.

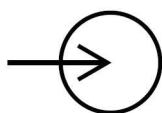
### Acclimation Time

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

<b>T(C°)</b>	60	55	50	45	40	35÷15	10	5	0	-5	-10	-15	-20
<b>Hours</b>	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*

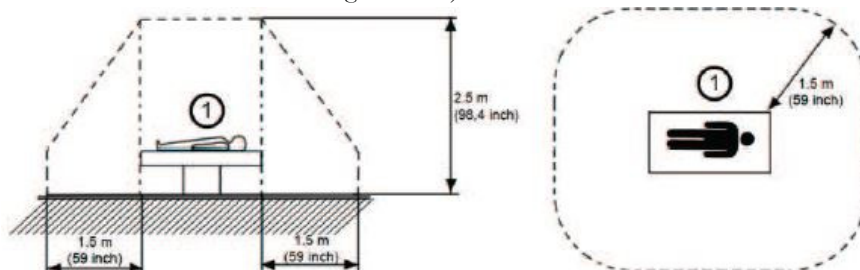
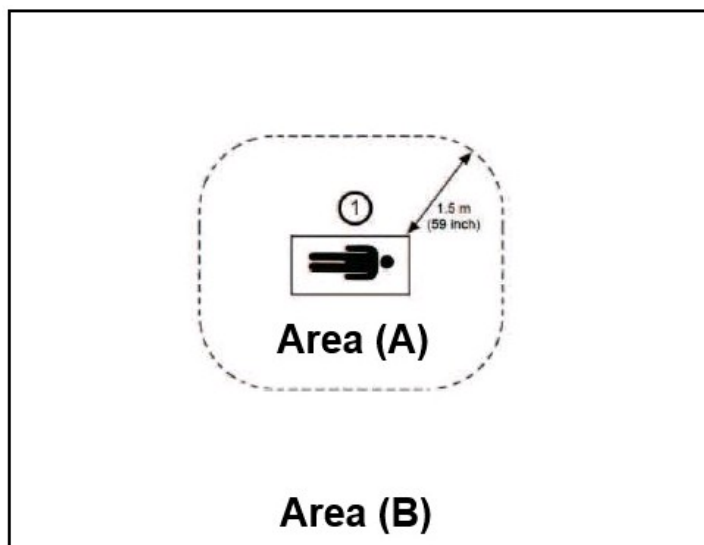
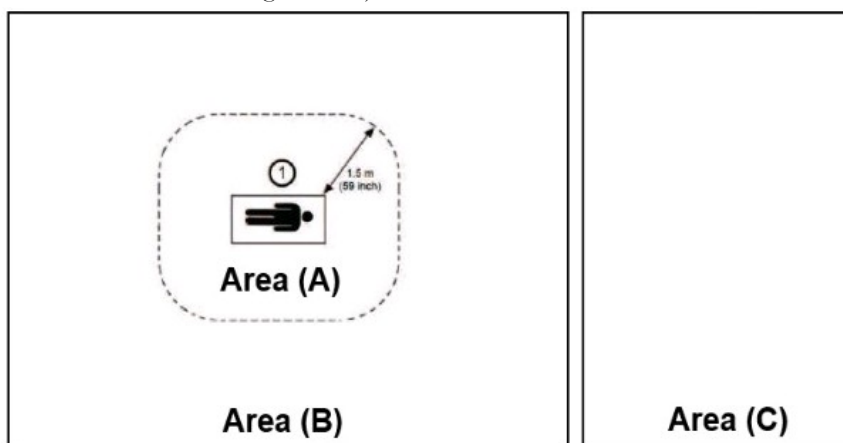


Fig. 4-2: B) *Medical Use Room*



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<sup>1</sup>) 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<sup>1</sup>) 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.

### Thermasonic gel warmer

Thermasonic gel warmer supplied by Esaote presents an operation button to select the desired temperature and LEDs that provide working information and alarms, if any.

*Fig. 4-4: Thermasonic gel warmer*



### Heat indicator lamp

The Heat Indicator Lamp (in the lower front) will blink while the unit is approaching the set temperature. Once that temperature has been reached, the lamp will remain illuminated. Should the unit restart the heating process, the Heat Indicator Lamp will again begin to blink.

### Operating the gel warmer

The Gel Warmer will warm a full bottle of gel to 104° F (40° C).

---

**CAUTION**

---

Temperature can vary. Always test a small quantity of gel before applying.

Allow approximately two hours for a full bottle of gel to reach proper temperature.

**Error codes**

The Thermasonic Gel Warmer contains a temperature sensor to consistently monitor functions and to protect against overheating.

If the temperature sensor is not operating at all, the Heat Indicator Lamp will blink once every five seconds. If a short circuit occurs, the Heat Indicator Lamp will blink twice every five seconds. In either circumstance, the heater will not operate.

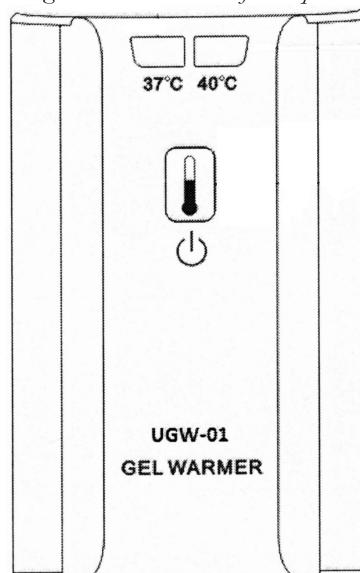
**Cleaning**

The Gel Warmer may be cleaned by using a soft, damp cloth and a mild detergent or hospital grade disinfectant, such as ProteX™ ULTRA Wipes. Do not allow the electronic controls to get wet. Do not use an abrasive cleaner or isopropyl alcohol to clean the Gel Warmer. Do not submerge or immerse the Gel Warmer in water.

**Lifeguard UGW-01 gel warmer**

Lifeguard UGW-01 gel warmer supplied by Esaote presents an operation button to select the desired temperature and LEDs that provide working information and alarms, if any.

*Fig. 4-5: UGW-01 front panel*

**Operation Button**

Press the operation button on the front panel:

- shortly (less than 1 second) to change the temperature setting value between 37°C and 40°C
- long (longer than 1 second) to change the gel warmer between on and off status.

**LED Indicators**

The two green LED indicators on the front panel give the following information:

- Both LEDs are not lighted means the gel warmer is off
- Left LED is lighted means the gel warmer is on and the temperature is set to 37°C
- Right LED is lighted means the gel warmer is on and the temperature is set to 40°C.
- Both LEDs are flashing at 2Hz indicates the alarm if the gel warmer is over temperature (higher than 42.5°C).
- Both LEDs are flashing at 0.5Hz indicates the alarm if the gel warmer faces the following conditions: temperature sensor error, input power supply is lower than 7V, input power supply is higher than 26V.

## 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 hung 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.

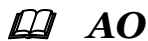
**NOTE**

*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.*

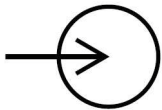
## 5. Using MyLab



This chapter provides a brief description of the device controls.

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 all 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 the pedals 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 **MyLab** on.

---

**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.

**NOTE**

*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 touchscreen and the alphanumeric keyboard.

### Control Panel Section

The control panel includes the main imaging controls: the TGC slide controls, a trackball, two encoders and the exam control buttons and knobs. 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
ETOUCH	Toggles between factory and customized touchscreen that can be created by the user. Refer to the chapter “Customizing MyLab” further in this manual.
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.
CW	Activates the Continuous Wave Doppler (CW). At its pressure the positioning cursor is activated as well.
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.
PD/TVM	Activates the Power Color Doppler or Tissue Velocity Mapping.
C	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.
M	Activates the M-Mode and, if necessary, its selection cursor (B-Line).
B	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 and 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.
MARK	Activates bodymarks; further details on how to use them are described in the “Advanced Operations” manual.
CLEAR ALL	Deletes all measurements or annotations from the screen.
ABC	Activates annotations; further details on how to use them are described in the “Advanced Operations” manual.
MEASURE	Activates Advanced Measurements showing the list of available measurements on the right of the image.



Button	Description
+ ... +	Activates Generic Measurements showing the list of available measurements on the right of the image.
ACTON	Changes the function linked to the trackball. Refer to the “Trackball” paragraph further in this chapter.
AUTO	Automatically adjusts both the overall gain and TGC distribution improving the contrast resolution of the image. The activation is indicated on the screen by the corresponding icon and it is labeled as “AG”. Refer to “Advanced Operations” Manual, “Imaging Optimization” Section for further information.
POINTER	Toggles the trackball operation from standard to mouse mode. Refer to the “Trackball” paragraph further in this chapter.
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
FREEZE	Stops the current analysis or scan and puts <b>MyLab</b> in Freeze mode. To re-activate real time, press it again or directly press the button of the required mode.
3D/4D	Activates three dimension features; further details on how to use them are described in the “Advanced Operations” manual
DUAL	Activates dual and quad view both in real time and freeze. Press <b>LEFT</b> or <b>RIGHT</b> to activate dual presentations: the active image is displayed on the left/right. Press <b>CENTER</b> to restore a single format. Press <b>CENTER</b> to activate quad presentations: the active image is displayed on the top-left. Press <b>LEFT</b> or <b>RIGHT</b> to add other images. Press <b>CENTER</b> to restore a single format.
1, 2, 3, 4	These buttons can be customized to save clips, save and print images. Refer to chapter 6 “Customizing MyLab” for further information.



### TGC Sliding

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

## 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 on the left bottom side of the screen. When several cursors are present on the screen, `ACTDN` switches between the active cursors. Blue 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.

## Encoders

The `ENCODER` is a special control, located close to the trackball, providing multiple functions to make easy your workflow. The functions linked to both the encoders depend on the current status (they are contextual the operative mode).

A proper layout on the screen indicates the current function.

Refer to “Advanced Operations” Manual, “Imaging Optimization” Section for further information.

## Touchscreen Section

This section includes the `MENU` and the `ON/OFF` buttons, a touchscreen and two USB ports.

### Menu Button

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

### 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 tapped while by **NORMAL BLUE CAPITAL LETTERS** for software text strings.

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

Many modes provide two or more pages of controls.

Swipe left/right to move to the next/previous page.

A page indicator shows you the page in which you are.



The touchscreen layout changes depending on the different working modality:

- as Exam panel, providing control keys to perform the exam,
- as Multipurpose panel, providing software buttons to use advanced exam controls,
- as Alphanumeric keyboard to enter data,
- as an image viewer.

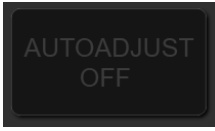

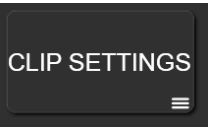
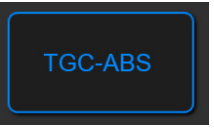
### Multipurpose Panel Layout

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

#### *Keys*

The keys have a color coding depending on their status.

Table 5-3: Touchscreen key status

Disabled Key	Active Key	Active Key with Sub-menu	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.

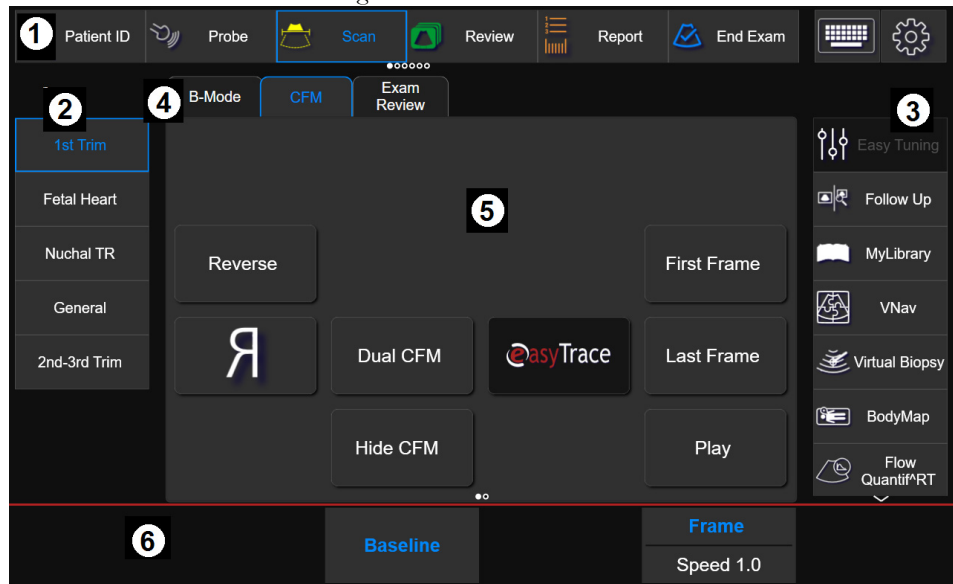


**Multipurpose Panel Layout**

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

The touchscreen is organized in six main areas.

*Fig. 5-1: CFM touchscreen*



1. Work flow Area, it contains keys related to the exam flow.
2. Smart Preset, it displays the available smart presets.
3. Tools, it lists the available tools.
4. Navigation tab bar, each tab contains additional keys.
5. Main Area, it contains main controls for the active modality.
6. Knobs Area, it contains functions whose value can be changed by rotating the knob beneath.

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 to adapt the contrast and brightness of your display to the lighting conditions of your room.

**Image Review Layout**



This layout is used to display both real-time and saved images on the touchscreen. Swipe down on the blue arrow on top center of the touchscreen to access this layout, two keys allow you to choose to view the image in real time or review the saved ones. Swipe left/right to scroll the images. Tap the

bottom right button to switch between real-time and review. Swipe up to close.

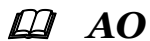
**WARNING**

The only monitor allowed for diagnosis is MyLab’s main monitor, images displayed on any other display or monitor are intended only for reference and should not be used for diagnostic purposes.

**Alphanumeric Keyboard Section**

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 +, \*).

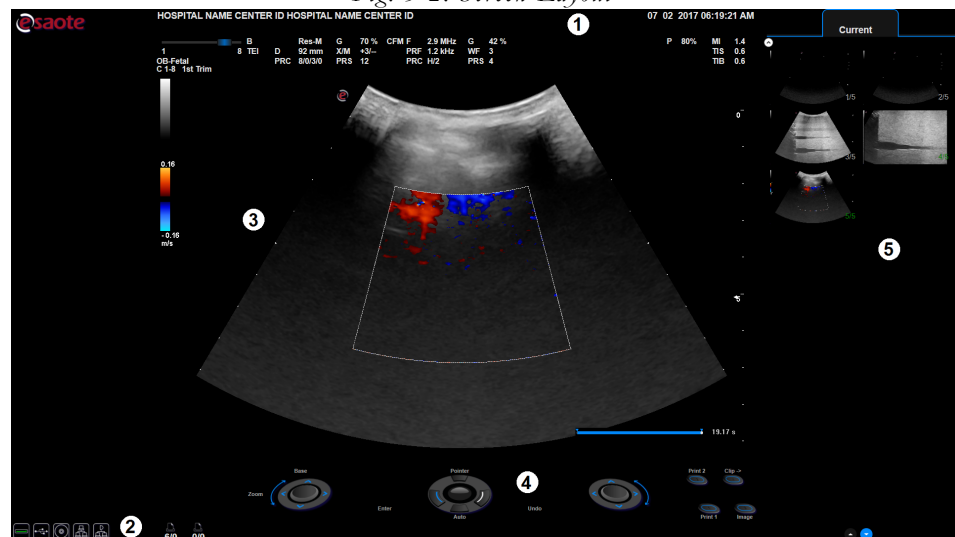


Refer to the “Advanced Operations” manual for the use of the keyboard in annotation modality.

**Information about the Screen Layout**

The screen is split into five main areas.

Fig. 5-2: Screen Layout



1. Heading Area

2. Footer Area
3. Image Area
4. Encoder Area
5. 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:

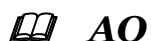
- Wi-Fi icon (when enabled),
- archival media icons,
- advanced features icons,
- peripherals icons.

#### 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.



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, beside the trackball function. The icon is shown crossed out whenever there are management problems involving the specific archival system.

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.

**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 depends and the probe. The following figure shows the elements in the image area that are independent of these factors.

Fig. 5-3: Image Area

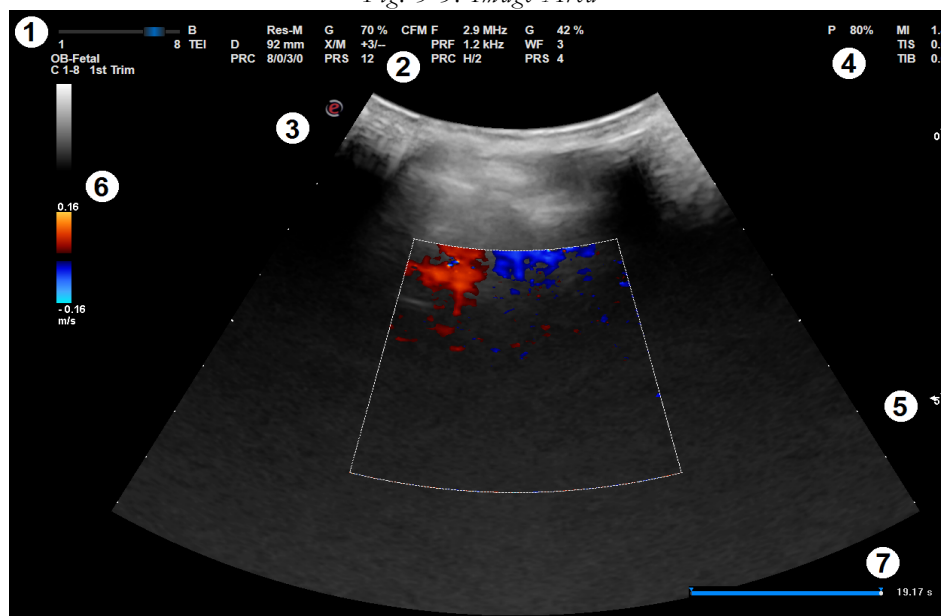


Table 5-4: Image Area description

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 2D, M-Mode, Doppler and color information image by image.

**Machine Parameters**

*Table 5-5: 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 CrystalLine 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
⊖	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 ⊖ are displayed only if the relevant cursor is active.

*Table 5-6: 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 5-7: 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

## Encoder Area

Control Panel Commands are displayed in this area providing information about the function related to encoders, trackball and 1, 2, 3, 4 buttons.

### Trackball

When there are several cursors on the screen, the trackball can move just one of them; to swap to the next of them press **ACTDN**: the active cursor is represented in yellow on the image while the next cursor is indicated above the image of the trackball as gray text.

## 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.

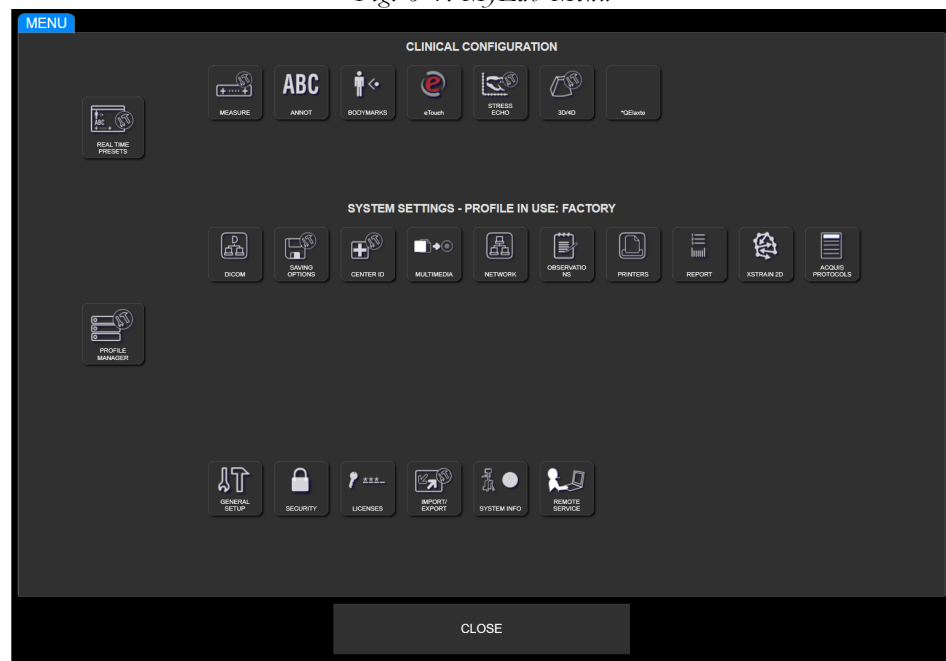
## 6. Customizing MyLab

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

 **AO**

## Clinical Configurations

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**.

**Procedure****Creating a new preset from Real-Time**

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



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

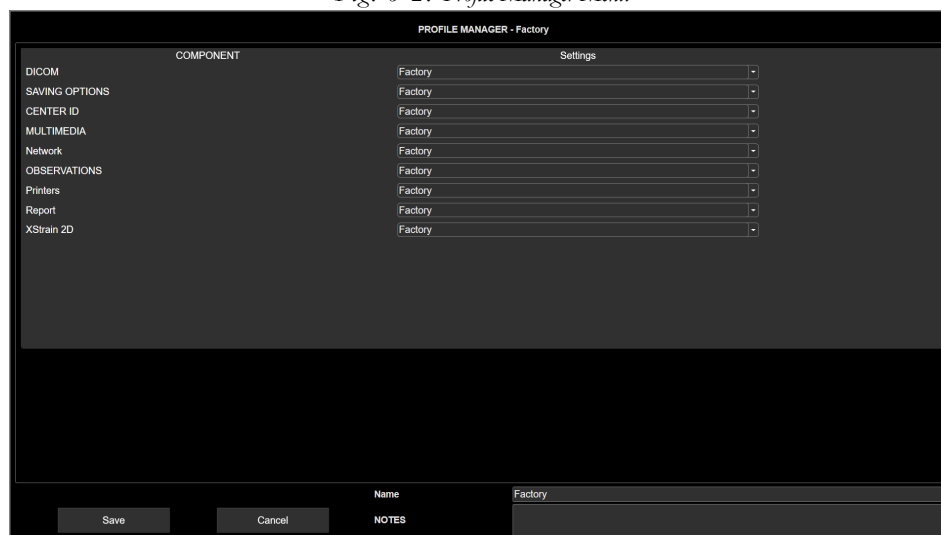
### Profile Manager

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**

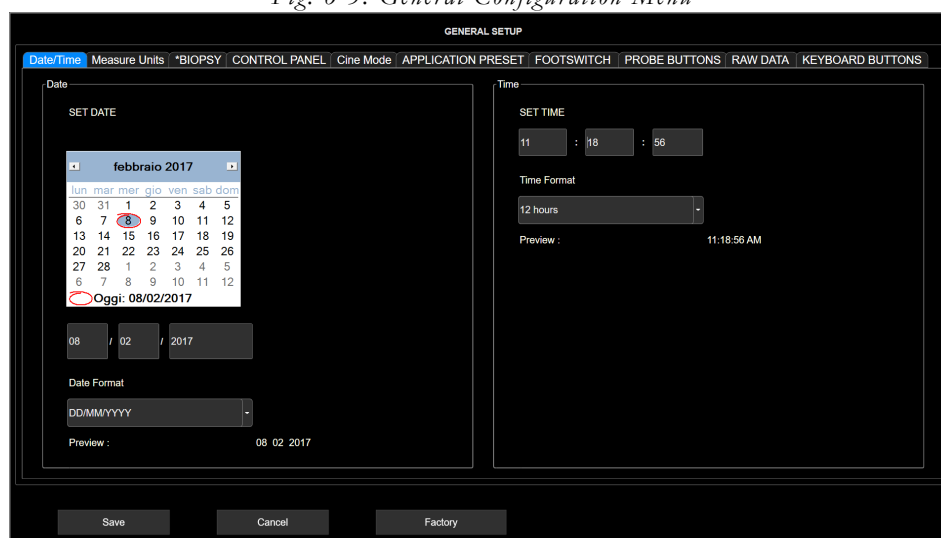
*Some settings described below may be unavailable on your product's configuration.*



## 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

Format	Displayed date
MM/DD/YYYY	04/01/2011
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 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.
SHOW CONTROL PANEL COMMANDS ON MONITOR	When checked, functions related to joysticks (or encoders) and 1, 2, 3, 4 buttons are displayed on monitor.
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, <b>MyLab</b> goes in hibernation state saving all configurations allowing a following quick boot-up. In these conditions <b>MyLab</b> can be unplugged from the main. When <b>OPTIMIZE MEMORY USAGE</b> 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, <b>MyLab</b> performs a complete shut-down.
SHUT DOWN WITH VIRUS SCAN	When the OFF button is pressed, <b>MyLab</b> 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, <b>MyLab</b> 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.*

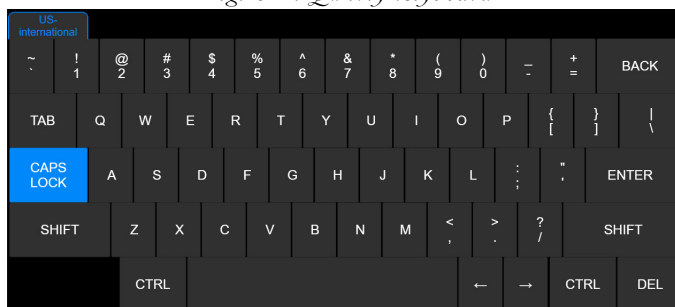
*The antivirus scan could take a long time. Before starting the scan, a confirmation is requested.*

*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 <b>FREEZE</b> pressure.
AUTO BUTTON SETUP	Sets the action after <b>AUTO</b> pressure: <b>AUTOADJUST</b> (to automatically adjust the B-Mode image), <b>ECFM</b> (to automatically optimize CFM image) or <b>BOTH</b> of them.
EASYTRACE ENABLED	When checked, this option allows to enable easyTrace.
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 CHANGE OVER ENABLED FOR PW, CW, M-MODES	When checked, pressing PW from B-Mode, <b>MyLab</b> switches to B-Mode frozen + Doppler live at once. When not checked, pressing PW from B-Mode, <b>MyLab</b> 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 <b>FREEZE</b> is pressed, <b>MyLab</b> goes in freeze without any other action associated.
GENERIC MEASUREMENTS	When <b>FREEZE</b> is pressed, <b>MyLab</b> goes in freeze with the trackball linked to the generic measurements menu.
GENERIC MEASUREMENT CINE	When <b>FREEZE</b> is pressed, <b>MyLab</b> goes in freeze with the trackball linked to cineloop.
APPLICATION MEASUREMENTS	When <b>FREEZE</b> is pressed, <b>MyLab</b> goes in freeze with the trackball linked to application measurements menu.
APPLICATION MEASUREMENT CINE	When <b>FREEZE</b> is pressed, <b>MyLab</b> goes in freeze with the trackball linked to cineloop.
BODYMARK	When <b>FREEZE</b> is pressed, <b>MyLab</b> goes in freeze with bodymarks active.
ANNOTATIONS	When <b>FREEZE</b> is pressed, <b>MyLab</b> 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 for 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. Download the antivirus upgrade from the following web page <https://go.microsoft.com/fwlink/?LinkID=121721&arch=x64>

**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.

To know if your **MyLab** has a working internet access press **MENU - REMOTE SERVICE - CHECK CONNECTION**.



The update can take long time; at the end a message window will let you know if the operation is successfully ended.

**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.

Encryption can be enabled by Esaote Service personnel only.

## 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

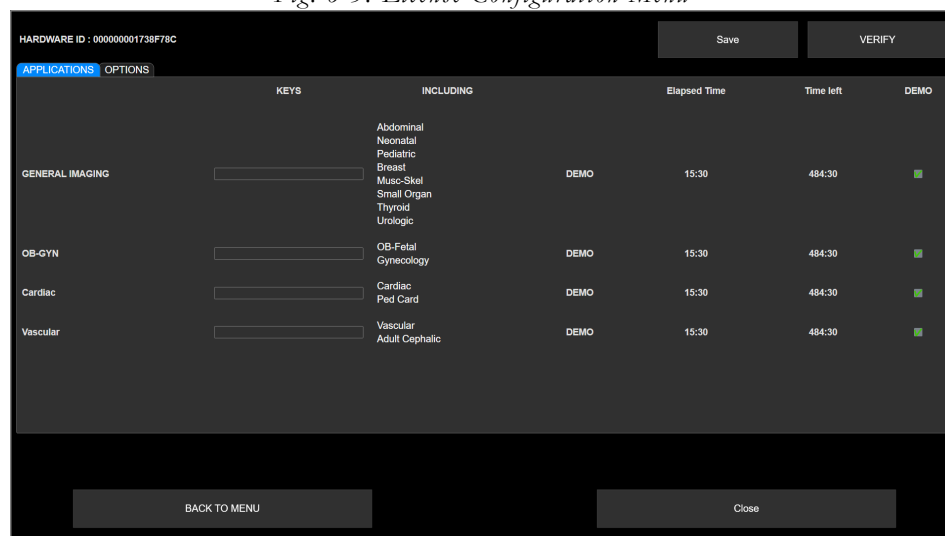
Licenses Manager allows to install optional licenses and to check the status of a demo license.

### 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



GETTING STARTED

**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*

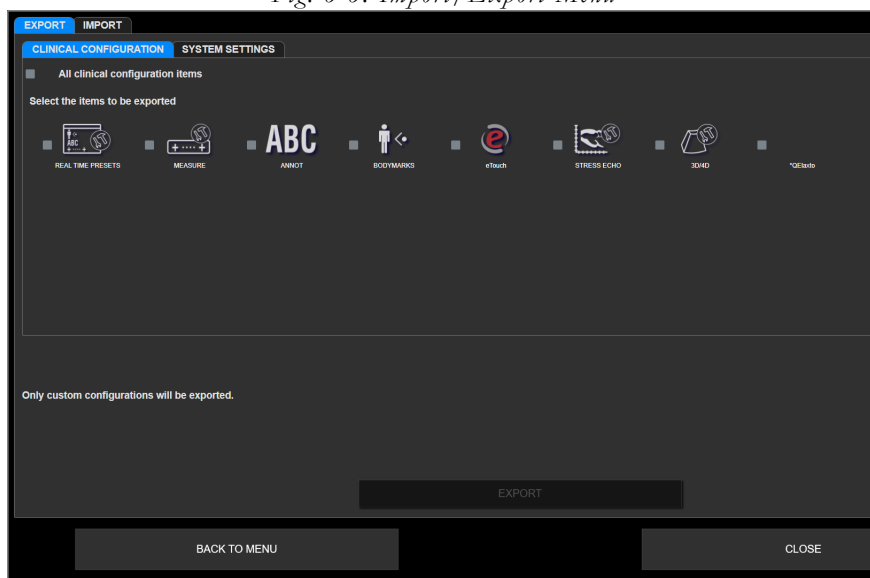
If a demo license has been activated (DEMO box checked), EXPIRATION DATE shows the expiration date of each demo licence.

**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;
- **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.

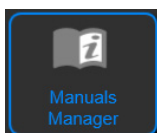
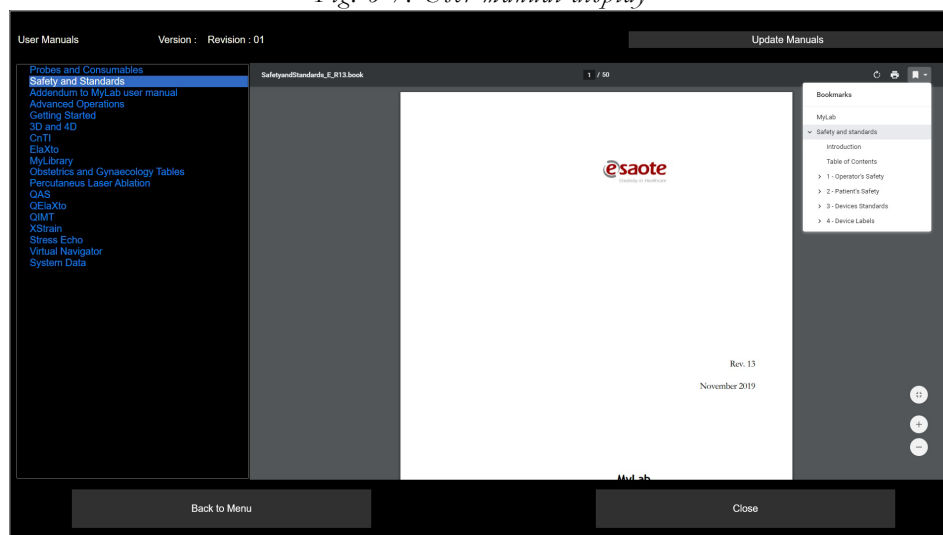


Fig. 6-7: User manual display



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.

## 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

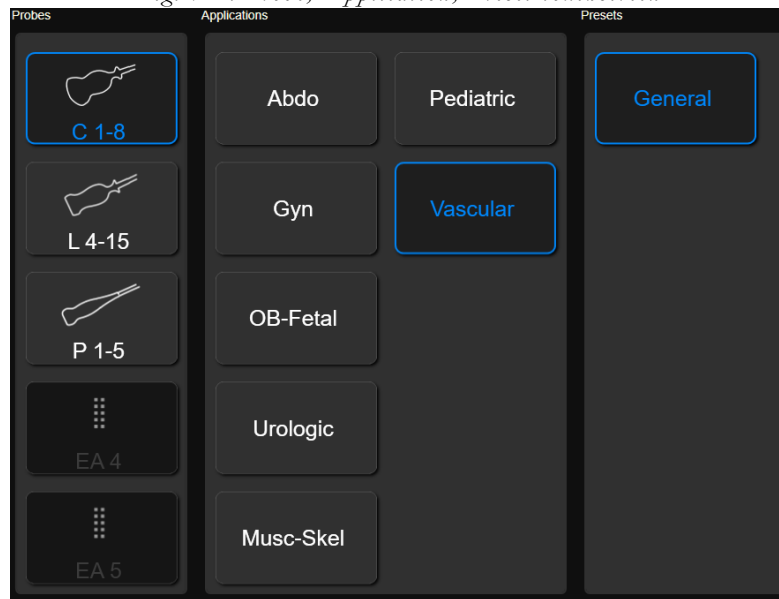
Do not turn **MyLab** off during the initialization phase: the hard disk could be damaged by this operation.

*Fig. 7-1: Patient ID screen*

The screenshot shows the Patient ID screen with the following fields and options:

- saote** logo and hospital name: HOSPITAL NAME CENTER ID HOSPITAL NAME CENTER ID
- Date and time: 02.02.2017 10:27:29 AM
- Last Name**: [Input field]
- First Name**: [Input field]
- Middle Name**: [Input field]
- Identification**: [Input field]
- Birth Date**: [Input field] / [Input field] / [Input field] DDMM/YYYY
- Age**: [Input field] - [Input field] Gender: [Input field] - [Input field]
- Height**: [Input field] cm (ft in)
- Weight**: [Input field] kg [Input field] g (lb oz)
- Adm Diagnosis**: [Input field]
- Accession Number**: [Input field]
- Exam Description**: [Input field]
- Referring Physician**: [Input field]
- Performing Physician**: [Input field]
- Operator**: [Input field]
- Navigation tabs: Cardiac | Urologic | **Vascular** | Gynecology | OB-Fetal | Ped Card
- QIMT Table**: [Dropdown menu] Howard 1993
- QIMT Ethnicity**: [Dropdown menu] White
- Systolic Pressure**: [Input field] mmHg
- Diastolic Pressure**: [Input field] mmHg
- Start Exam**: [Button]
- Worklist**: [Button]
- Retr Pat Info**: [Button]

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 **IMAGE** 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.

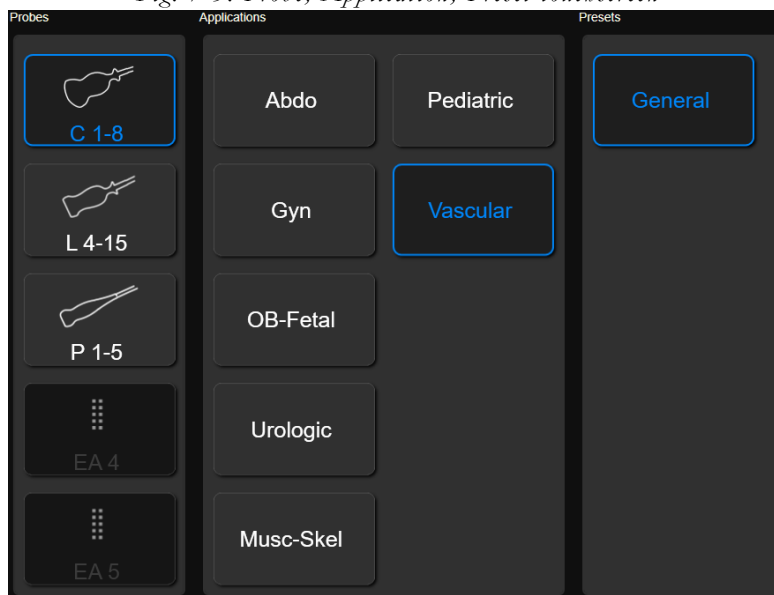
### Selecting Probe

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.*

### Smart Preset

After exam starts, at the right side of the touchscreen, presets for the active probe and application are shown.

When the preset is changed during the exam tapping one of them on the touchscreen, all acquisition parameters are reset while the geometrical characteristics (such as depth, size) are maintained.

## Performing the Exam

**MyLab** offers a set of imaging modes to cover a variety of imaging needs. By pressing the different mode buttons (B, M, C, PD/TVM, PW, CW) 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, swipe left/right 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 cine loop 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, tapping **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.

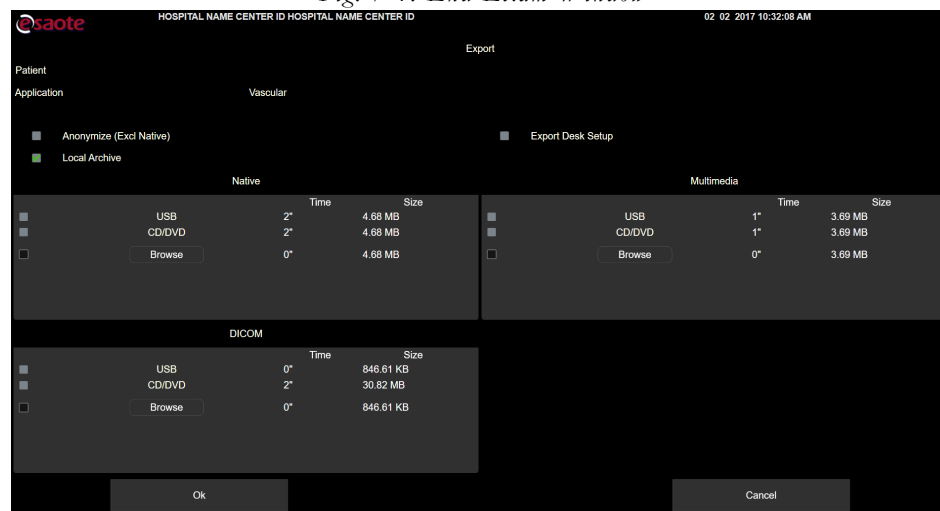
### AO

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** or tap **START 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 Options Menu, pressing **END EXAM** also **PAUSE** will be prompted.

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

## Monitor adjustments



Tapping the gear icon in the advanced level of the touchscreen, you can access a menu where quickly and intuitively adjust the brightness and contrast of the monitor depending on your work environment. Three preset levels are available: **DARK ROOM**, **MEDIUM DARK ROOM**, and **BRIGHT ROOM**.

You can also customize the **CONTRAST**, **BRIGHTNESS** and **GAMMA** values by tapping **USER-DEFINED** and rotating the related knobs. Tap **FACTORY DEFAULT** to go back to the default values.

**PHYSICAL CLONE** and **SMART CLONE** act on the resolution when a second monitor is present; refer to Advanced Operations manual for further information.

Tap the gear icon again to exit the monitor adjustments menu.



## 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 **MyLab**.

*Table 8-2: MyLab compatible cleaning agents*

Product	Supplier
Cavicide Caviwipes Metrizyme	<b>Metrex Research Corporation</b> ( <a href="http://www.metrex.com/company/contact/index.cfm">www.metrex.com/company/contact/index.cfm</a> )
Mid Soap	-
Mikrozyd Universal wipes premium Mikrozyd AF wipes Mikrozyd PAA wipes Mikrozyd sensitive wipes	<b>Schülke&amp;Mayr GmbH,</b> ( <a href="http://www.schuelkemayr.com/int/en/contact/smi044_adresses.htm">www.schuelkemayr.com/int/en/contact/smi044_adresses.htm</a> )
Sani-Cloth HB	<b>Professional Disposable International</b> ( <a href="http://www.pdipdi.com">www.pdipdi.com</a> )
Trionic D	<b>Ebiox</b> ( <a href="http://www.ebiox.co.uk">www.ebiox.co.uk</a> )

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.

---

**CAUTION**

---

**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.**

**NOTE**

*The QWERTY keyboard can be protected with a latex-free plastic cover. The life of the cover depends on how the QWERTY is used and how it is cleaned. If the cover is broken or damaged contact Esaote Service or Sales Representative to purchase a new one, then replace it according to the instructions enclosed with the cover itself.*

### **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”.

**NOTE**

*Sonogel and Scan MV gels, listed in Probes and Consumables manual as compatible with Esaote probes, have not been tested on MyLab plastic covers.*

### 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.

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.**

## 9. Technical Specifications

This chapter describes the technical specifications<sup>1</sup> 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.

**MyLab** can be equipped with the following application licenses.

*Table 9-1: Applications licenses*

Licence	Main applications
Cardiology	Cardiac
Radiology Gen. Imaging	General Imaging
Women’s Health Ob/Gyn	Women Health
Vascular	Vascular

#### Applications

#### Features

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

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

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 <sup>a</sup> Ultrasound DICOM Query/Retrieve
Multi-modality & Dicom Q/R	Multi-modality management Multi-modality DICOM Query/Retrieve
eDoppler	Automatic correction of the Doppler angle, box position and steering, for a fast and optimized calculation
ElaXto	ElaXto allows you to perform elastosonographic analysis of the tissues.
ElaXto Measures	It enables measurements in elastosonography
eStreaming	Possibility to visualize the <b>MyLab</b> images on different devices on the same network
Fiber Guidance	It enables on <b>MyLab</b> a dedicated guidance to be used with Echolaser X4 laser units produced by Elesta <sup>b</sup>
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 <sup>c</sup>
QAS	Quality Arterial Stiffness
QElaXto - (pSWE)	It allows to perform a Quantitative Elastasonographic analysis of tissues.
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 cine loop 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](http://www.esaote.com) for further details on supported DICOM classes.
- b. [www.elesta-echolaser.com](http://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

- Main: Full HD LCD 21.5” monitor (16:9 aspect ratio)
- Auxiliary: LCD with touchscreen

### Probe connectors

- 4 electronic probes

### Connectivity

- I/O connectors
  - LAN RJ45
  - 2 USB 2.0 on keyboard control panel
  - 2 USB 3.0 on lateral panel
  - Wi-Fi (802.11.A,B,G,N)
- Video Output
  - DVI (main display)
  - Display port <sup>1</sup>

- Dedicated connectors
  - ECG input
- Other
  - Laser/Ink jet printers
- Complies with IHE integration profiles<sup>1</sup>

### **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

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1. Auxiliary monitors connected to this input have not to be used for diagnostic purposes.  
1. Refer to [www.esaote.com](http://www.esaote.com) for further details.

## Keyboard

- Height adjustable control panel
- Control panel:
  - 8 sliders for TGC
  - Encoders for general gains and other functions
  - Keys for modes, peripherals management and controls
- Reconfigurable touchscreen LCD
- Pull out alphanumeric QWERTY keyboard

## Dimensions

- Closed (approximately): 605 (W) x 1135 (H) x 730 (D) mm
- In working position: 605 (W) x 773÷1035 (H) x 730 (D) mm (height of trackball)
- In working position: 605 (W) x 1315÷1577 (H) x 730 (D) mm (at top of the monitor)

## Weight

- < 85 kg (basic configuration without peripheral units)

## IP Grade

According to the degree of protection against harmful ingress of water:

- **MyLab** is IPX0, this means **MyLab** models are not watertight.
- The probes are IPX7, this means Esaote probes are protected against the effects on temporary immersion in liquids up to the maximum immersion level indicated in the Probes and Consumables manual.
- The footswitch is IPX8, this means it is watertight.

## Power supply

- Voltage operative range:
  - 100 ÷ 120 V
  - 200 ÷ 240 V
- Voltage limit range:
  - 90 ÷ 132 V
  - 180 ÷ 264 V

- Working frequency range: 47 ÷ 63 Hz
- Total maximum power available on peripheral outlets:
  - up to 320 VA in the 100 ÷ 120 V operative range
  - up to 450 VA in the 200 ÷ 240 V operative range
- Power consumption:
  - ≤ 260 VA (**MyLab** only excluding peripherals)

### Fuses

Table 9-3: Fuses used on MyLabX75

AC Mains Fuse (F1, F2)	Technical data	Standards	Marks
For 100-120V mains supply	10A 250V T: Time lag H: High breaking capacity (1500A) 5x20mm	UL 248-1 CSA C22.2 No. 248-14 IEC 60127	UR (E10480) CSA (29862) VDE (40013521)
For 200-240V mains supply	5A 250V T: Time lag H: High breaking capacity (1500A) 5x20mm	UL 248-1 CSA C22.2 No. 248-14 IEC 60127	UR (E10480) CSA (29862) VDE (40013521)

## Batteries

- Batteries for:
  - stand-by suspension
  - standard working condition
- Battery operating time:
  - up to 60 minutes with system on
  - more than 120 hours in stand-by
- Battery charger inside
- Battery life: 3 years

## Power Cables

Table 9-4: Power Cables

	Connector (MyLab side)	Plug Type (Mains side)	Cord Type	Length
<b>Italy</b>	EN60320/C13	I/3G CEI 23-50	H05VVF3G Section 1 mm <sup>2</sup> 3 conductors 10A-250V	4,5 m
<b>Europe</b> <b>France</b> <b>Germany</b> <b>Spain</b>	EN60320/C13	Type VII G CEE (7) VII	H05VVF3G Section 1 mm <sup>2</sup> 3 conductors 10A-250V	4,5 m
<b>USA</b> <b>North America</b>	C13M EN60320/C13	HG (Hospital grade) NEMA 5-15	SJT3x14AWG 3 conductors 15A-125V	4,5 m
<b>UK</b>	EN60320/C13	BS13/13 BS 1363/A	H05VVF3G Section 1 mm <sup>2</sup> 3 conductors 10A-250V	4,5 m
<b>Brazil</b>	EN60320/C13	BR/3 NBR14136	H05VVF3G Section 1 mm <sup>2</sup> 3 conductors 10A-250V	4,5 m

## Opti-light

The monitor top edge hosts the Opti-light function that provides a subtle room lighting for optimal scanning conditions.

The position of the lighting source eliminates any kind of reflection on the monitor resulting in improved image contrast resolution.

Opti-light can be activated by a finger-touch on the bottom-right corner of the monitor frame. The illumination level can be adjusted sliding the finger on the corner to increase/decrease the level.

## Operating Requirements

- Temperature: 15 ÷ 35°C
- Humidity:
  - 20 ÷ 85% (not condensing) without batteries
  - 20 ÷ 80% (not condensing) with batteries
- Pressure:
  - 700 ÷ 1060 hPa

## Storage requirements

- Temperature: -20 ÷ +60°C
- Humidity:
  - 10 ÷ 85% (not condensing) without batteries
  - 10 ÷ 80% (not condensing) with batteries
- Pressure: 700 ÷ 1060 hPa

## Heat output

- 950 BTU/h

## Probe Storage Requirements

- Probe storage requirements are indicated in the probe case.

## European and international standards

- IEC 60601-1:2012 (Ed 3.1)
- IEC 60601-1-2:2014 (Ed. 4)
- IEC 60601-1-6:2010 + A1:2013 (Ed. 3.1)
- IEC 60601-2-37:2007 (Ed. 2) + A1:2015
- IEC 61157:2007 (Ed. 2.1) + A1
- NEMA UD-2 / UD-3
- EN ISO 10993-1: 2009
- EN ISO 14971: 2012
- RoHS Compliance
- IEC 60601-1-9
- Radio Equipment Directive RED 2014/53/UE