Rev. 02

April 2016

MyLabDelta

# GETTING STARTED

***350009500***

# Introduction

This manual refers to all **MyLabDelta** ultrasound models, named in the following chapters as **MyLab**. **MyLab** is available both in **portable** and **mobile** configuration. The term "**MyLab**", used in this manual, refers to both configurations and to all models. When the information refers to only one configuration, it will be specifically indicated.

The manual contains information on **Mylab** indications for use and explains how to install it. All system keys and their functions are described.

The manual is divided into the following chapters:

- Chapter 1: General Information

The chapter provides information on manuals organizations, manufacturer's responsability, product life cycle and software licences. Moreover it contains information on Esaote Traceability and Responsability systems.

- Chapter 2: Additional Information on Safety

The chapter provides information about specific safety features of the **MyLab** system.

- Chapter 3: Clinical Applications

The chapter specifies in which clinical applications the **MyLab** can be used.

- Chapter 4: System Components and Installation

This chapter contains the installation instructions.

- Chapter 5: Control Panel

This chapter describes the **MyLab** control panel.

- Chapter 6: Screen Layout

In this chapter one can learn how information is organized on the screen.

- Chapter 7: Performing an Exam

This chapter describes the operations usually carried out to start and end an exam.

- Chapter 8: eTouch Key

This chapter explains how to use the eTouch key of the control panel.

- Chapter 9: **MyLab** Settings

This chapter explains **MyLab** settings organization and how to use them.

- Chapter 10: **MyLab** Clinical Settings

This chapter explains how to create clinical settings and how to use them.

- Chapter 11: System Maintenance

This chapter lists all necessary maintenance procedures.

- Chapter 12: Technical Specifications

This chapter describes **MyLab** technical specifications.

**WARNING**

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

**CAUTION**

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

Be sure to understand and observe each of the cautions and warnings.

The **MyLab** systems have multiple configuration and feature sets. They are all described in this user manual but not every option may be applied to your system.

System features are dependent on your system configuration, transducer, and exam type. Not all the system features are approved in all countries.

Keep the manual with the system for future reference.

This manual revision refers to release 5.53.00 and 6.03.00 depending on the Country and the respective clearances. Features, probes and applications described in this manual may change depending on your system configuration

Chapter 1



# 1 - General Information

## User's Kit

**MyLab** is equipped with licenses, the USB pen drive and the "Product Documentation" disk.

### Licenses

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

### MyLab Pen Drive

The system is supplied with a customised USB pen drive. The pen drive can be used as a data archive medium. To learn how to use it, please carefully read this manual.

### "Product Documentation" Disk

This disk contains, in digital format, all manuals supplied with the system. The manuals are available in the languages that can be set on the system.

**Note**

The "System Data" document, containing information on Acoustic Output data and transducers surface temperatures, is included in the "Product Documentation" disk.

# MyLab Manuals

**MyLab** systems are equipped with two manuals, called "Operator Manual" and "Advanced Operations". These manuals refer to **MyLab** products, indicated as **MyLab** within the manuals.

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

**MyLab** manuals are written for operators who have been trained on basic ultrasound principles and techniques.

Read and understand all instructions contained in **MyLab** manuals before using the system. Always keep the manuals with the system.

## Operator Manual

The "Operator Manual" consists of following sections:

**Getting Started**

*GS* This section describes how to install the system and provides the main instructions for using it.

**Probes and Consumables**

*PC* This section describes cleaning, disinfecting and maintenance procedures for the probes and related accessories. Information is also supplied on admitted consumables.

**Safety and Standards**

*SS* This section contains information about the patient's and operator's safety. The system's conformity standards are also indicated.

## Advanced Operations Manual

*AO* This symbol is used to indicate the "Advanced Operations" manual. The standard configuration of this manual includes the following sections:

- Image Optimization and Annotations,
- Calculations,

- Archive,
- Clinical and System Settings.

All other sections can be ordered using the specific part numbers.



## System Data

Data on probes temperatures and acoustic output for each probe and mode of operation are included in the "System Data" manual, included in the "Product Documentation" disk.

## Probes - Cleaning, Disinfection, Sterilization

The manual lists the recommended cleaning, disinfection and sterilization agents for **MyLab** probes and needle guides. Information is also supplied on manufacturers of the recommended agents.

## Veterinary Use

Esaote offers dedicated software intended for Veterinary use, providing specific transducers and calculation packages: please refer to the Esaote web site for complete information. However Esaote ultrasound systems dedicated to human applications can be safely used also in veterinary applications by qualified veterinarians. All information concerning the use of the systems, referenced in these manuals, is considered to be applicable also to a veterinary use.

However, the user should be aware of the limitations in calculations and results. Please contact Esaote personnel for information on the correct maintenance procedures to be followed in case of use in veterinary environment.

## 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 system manuals for the use and the maintenance of this system;
- 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 system is used complies with the current safety rules;
- the electrical plant of the environment where the system is used complies with the current applicable rules and is perfectly efficient.

# Product Life Cycle

## Life Time

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

- the system 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 system only by Esaote qualified personnel, using original Esaote spare parts.

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

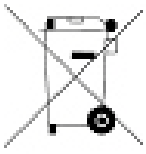
## Maintainability Time

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

## End-of-Life Disposal

**MyLab** ultrasound systems 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 system plate includes therefore the symbol shown below, indicating - in an unequivocal way – that the system 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 system part, the user shall consider the following points:

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

**CAUTION**

**The system 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

**Attention**

**Please read with care the terms and conditions indicated below before using the software on the system**

**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.

## 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.

esaote

**Esaote** S.p.A.

**Sede legale e Direzione**
Via A. Siffredi, 58
16153 Genova
Tel. +39 010 6547.1
Capitale Sociale 30.142.000,00 Euro
interamente versato
C.C.I.A.A. Genova
C.F. / Partita IVA 05131180969

**Sedi operative**

**Genova**
Via A. Siffredi, 58
16153 Genova
Tel. +39 010 6547.1
Fax +39 010 6547275
www.esaote.com
esaote@esaote.com

**Firenze**
Via di Caciolle, 15
50127 Firenze
Tel. +39 055 4229.1
Fax +39 055 434011
www.esaote.com
esaote@esaote.com



## DICHIARAZIONE DI CONFORMITÀ CE
## *EC DECLARATION OF CONFORMITY*

Noi costruttori
*We manufacturer*

**ESAOTE S.p.A.**

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

**Serie 7430 Modello MyLabDelta**
***Series 7430 Model MyLabDelta***

è stato costruito applicando il sistema di garanzia della qualità approvato per la progettazione, fabbricazione e controllo finale del prodotto e risponde ai Requisiti Essenziali presenti in Allegato I della Direttiva 93/42/CEE emendata con la Direttiva 2007/47/CEE.
*has been manufactured by applying the quality system approved for the design, manufacture and final inspection and meets the Essential Requirements listed in Annex I of the 93/42/EEC Directive as amended by the 2007/47/EEC Directive.*

| | |
|---|---|
| Classificazione:<br>*Classification:* | Classe IIa secondo l'allegato IX della Direttiva 93/42/CEE<br>*Class IIa according to Annex IX of 93/42/EEC Directive* |
| Numero identificativo dell'Organismo Notificato:<br>*Notified Body identification number:* | **0123** |
| Nome e indirizzo dell'Organismo Notificato:<br>*Notified Body name and address:* | TÜV Süd Product Service GmbH , Ridlerstr.65,<br>D-80339 Munich – Germany |
| Procedura di conformità:<br>*Conformity procedure:* | Allegato II della Direttiva 93/42/CEE, emendata con la Direttiva 2007/47/CEE, escluso punto 4.<br>*Annex II without point 4 of the 93/42/EEC Directive as amended by the 2007/47/EEC Directive.* |

Firenze, 1 Marzo 2016
*Florence, March 1st, 2016*

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

1/1

**Esaote** S.p.A.

**Sede legale e Direzione**
Via A. Siffredi, 58
16153 Genova
Tel. +39 010 6547.1
Capitale Sociale 30.142.000,00 Euro
interamente versato
C.C.I.A.A. Genova
C.F. / Partita IVA 05131180969

**Sedi operative**

**Genova**
Via A. Siffredi, 58
16153 Genova
Tel. +39 010 6547.1
Fax +39 010 6547275
www.esaote.com
esaote@esaote.com

**Firenze**
Via di Caciolle, 15
50127 Firenze
Tel. +39 055 4229.1
Fax +39 055 434011
www.esaote.com
esaote@esaote.com

## DICHIARAZIONE DI CONFORMITÀ 1999/05/CE
## *DECLARATION OF CONFORMITY 1999/05/EC*

Noi costruttori
*We manufacturer*

**ESAOTE S.p.A.**

dichiariamo, sotto la nostra responsabilità, che il sistema diagnostico ad ultrasuoni
*declare, under our sole responsibility, that the ultrasonic diagnostic system*

**Mod. MyLabDelta**
***Type ref. MyLabDelta***

risponde ai Requisiti Essenziali della direttiva 1999/05/CE - R&TTE
*meets the Essential Requirements of* the *1999/05/EC directive - R&TTE*

e che sono state applicate tutte le norme e specifiche tecniche indicate in allegato.
*and that all the standards and technical specifications indicated in the attachment have been applied.*

Numero Identificativo dell'Organismo Notificato: **0051**
*Notified Body Identification Number:*

Firenze, 1 Marzo 2016
*Florence, March 1st, 2016*

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

**Esaote** S.p.A.

**Sede legale e Direzione**
Via A. Siffredi, 58
16153 Genova
Tel. +39 010 6547.1
Capitale Sociale 30.142.000,00 Euro
interamente versato
C.C.I.A.A. Genova
C.F. / Partita IVA 05131180969

**Sedi operative**

**Genova**
Via A. Siffredi, 58
16153 Genova
Tel. +39 010 6547.1
Fax +39 010 6547275
www.esaote.com
esaote@esaote.com

**Firenze**
Via di Caciolle, 15
50127 Firenze
Tel. +39 055 4229.1
Fax +39 055 434011
www.esaote.com
esaote@esaote.com

## DICHIARAZIONE DI CONFORMITÀ 1999/05/CE
## *DECLARATION OF CONFORMITY 1999/05/EC*

- Norme armonizzate applicate/*Harmonized applied standards*

| **Nr. ed Edizione/*Nr. and Edition*** | **Titolo/*Title*** |
|---|---|
| EN 60601-1:2006 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| EN 60601-1-2:2007 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: ElectroMagnetic Compatibility - Requirements and tests |
| EN 60601-1-6:2010 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| EN 60601-2-37:2008 | Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment |
| EN 60950-1:2006 + A1:2008+A2:2010 | Information technology equipment - Safety - Part 1: General requirements |
| EN 62311:2008 | Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz) |
| EN 301 489-01 v1.9.2 | ElectroMagnetic Compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements |
| EN 301 489-17 v2.2.1 | ElectroMagnetic Compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems |
| EN 300 328 v1.8.1 | ElectroMagnetic Compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive |
| EN 301 893 v1.7.1 | Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive |

Firenze, 1 Marzo 2016
*Florence, March 1st, 2016*

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

# Usage License Agreement for the Software Included in the Apparatus

**Attention**

**Please read with care the terms and conditions indicated below before using the software on the system**

**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.

## License Rights and Limitations

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

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

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

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

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

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

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



## Third Part Software

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

# Product Traceability

To guarantee the product traceability according to what stated by the quality standard ISO13485 and by the European Directive on Medical Devices 93/42/ EEC, Esaote kindly requests the original owner of the equipment to give communication to our central plants, or to one of our subsidiaries, or to one of our official distributors of any eventual conveyance of the product property. Please use a duly filled copy of the form reported below or send us a communication reporting the same data indicated in this form. All data relating to the system can be found on its identification label.

**PRODUCT TRACEABILITY FORM**

To: ESAOTE S.p.A.
Quality Assurance Department
Via di Caciolle, 15
I-50127 Firenze

Esaote system/device name:

.....

REF:

.....

Serial Number (SN):

.....

Name and address of the new owner:

.....

.....

Date:

Signature

# Vigilance System

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

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 labelling 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 system 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.

**POST-MARKETING VIGILANCE FORM**

To: ESAOTE S.p.A.
Quality Assurance Department
Via di Caciolle, 15
I-50127 Firenze
Email: qa@esaote.com

ESAOTE system/device name:

.....

REF:

.....

SN:

.....

Description of the potential/real hazard:

.....

.....

Notes and suggestions:

.....

.....

Contact Person/Department:

.....

Address:

.....

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

Date:

Signature

# Important Information

**MyLab** complies with the Medical Device Directive 93/42/EEC and subsequent amendments and is CE marked.

CE
0123

**MyLab** is a device in Class IIa according to the Medical Device Directive.

**MyLab** complies with the Radio equipment and Telecommunications Terminal Equipment Directive 1999/5/EC and is CE marked.

**MyLab** is a device in Class 2 according to R&TTE Directive and the following symbol is applied on the system.

For US Customers: US Federal Law restricts this device to sale, distribution and use by or on the order of a physician.

The list of countries (code ISO 3166 has been used) in which the system is intended to be sold is contained in the following table.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| AT | DK | DE | IT | MT | SK | GB | CH |
| BE | EE | GR | LV | NL | SI | IS | BG |
| CY | FI | HU | LT | PL | ES | LI | RO |
| CZ | FR | IE | LU | PT | SE | NO | TR |

Chapter 2



# 2 - Additional Information on Safety

SS

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

## Environmental Safety

*Special waste*

The system contains a lithium battery. The auxiliary battery pack contains lithium-ion batteries. The batteries, the LCD screens and the AC/DC adapter 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.

## Transport Safety

In the mobile configuration all the system wheels are equipped with brakes, which can be activated individually.

**WARNING**

**Do not park the system on a slope.**

**Do not use the brakes to park the machine on a slope.**


**If your system 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.**

## Electromagnetic Compatibility

This system was designed for use in the electromagnetic environments declared in the tables below, in compliance with standard IEC 60601-1-2:2007. The operator must make sure that s/he uses it in keeping with this standard.

## Electromagnetic Emissions

| The **MyLab** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **MyLab** system should assure that it is used in such an environment. | | |
|---|---|---|
| **Emission Test** | **Compliance** | **Electromagnetic Environment** |
| RF emissions<br>CISPR 11 | Group 1 | MyLab uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class A | The MyLab is suitable for use in all establishments other than domestic, however may be used in domestic establishments and those directly connected to the public network that supplies buildings used for domestic purposes, provided the following caution is needed:<br><br>**Caution**: This equipment/system is intended to be used by healthcare professionals only. This is a CISPR 11 Class A medical equipment/systems. In a domestic environment this equipment/ systems may cause radio interference, in which case it may be necessary to take adequate mitigation measures, such as reorienting,<br>relocating or shielding the MyLab<br>or filtering the connection to the public mains network |
| Harmonic emissions<br>IEC 61000-3-2 | Passed[a] | |
| Voltage fluctuations and flicker emissions<br>IEC 61000-3-3 | Passed[a] | |

a. (**) this test is not applicable to EQUIPMENTS that are not intended to be connected to the PUBLIC MAINS NETWORK (Class A), but is performed according to Esaote request .

## 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

| The **MyLab** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **MyLab** system should assure that it is used in such an environment. | | | |
|---|---|---|---|
| **Immunity Test** | **IEC60601 Test Level** | **Compliance Level** | **Electromagnetic Environment and Measures to Be Taken** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV on contact<br>±8 kV in air | ±6 kV on contact<br>±8 kV in air | The floor should be in wood, concrete or ceramic tile. 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<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±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<br>±2 kV common mode | ±1 kV differential mode<br>±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5% of rated voltage ($U_T$) (voltage gap >95%) for 0,5 cycle<br>40% $U_T$ (voltage dip 60%) for 5 cycles<br>70% $U_T$ (voltage dip 30%) for 25 cycles<br><5% $U_T$ (voltage dip >95%) for 5 sec | <5% of rated voltage ($U_T$) (voltage gap >95%) for 0,5 cycle<br>40% $U_T$ (voltage dip 60%) for 5 cycles<br>70% $U_T$ (voltage dip 30%) for 25 cycles<br><5% $U_T$ (voltage dip >95%) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the **MyLab** system requires continued operation during power mains interruptions, it is recommended that the **Mylab** system be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE: $U_T$ is the a.c. mains voltage prior to application of the test level | | | |

## Electromagnetic Immunity for Medical Equipment not Life Supporting

The **MyLab** system is intended for use in the electromagnetic environment specified below. The customer or the user of the **MyLab** system should assure that it is used in such an environment.

| Immunity Test | IEC60601 Test Level | Compliance Level | Electromagnetic Environment and Measures to Be Taken |
|---|---|---|---|
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms<br>150 kHz to 80 MHz | Mobile or portable radio frequency (RF) communication equipment should be used no closer to any part of the **MyLab** system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = \left[\frac{3,5}{3}\right]\sqrt{P} = 1,2\sqrt{P}$<br>$d = \left[\frac{3,5}{3}\right]\sqrt{P} = 1,2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = \left[\frac{7}{3}\right]\sqrt{P} = 2,4\sqrt{P}$ 800 MHz to 2,5 GHz<br>where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m<br>80 MHz to 2.5 GHz | |

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.

a. 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 the **MyLab** system is used exceeds the applicable RF compliance level above, the **MyLab** system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re–orienting or relocating the **MyLab** system.

b. 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



📖 ***SS***

As stated in the "Safety and Standards" manual, it is recommended not to use radiofrequency (RF) transmission systems near the ultrasound system. 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 echographic system and the RF communication systems being used (for example cell telephones, mobile telephones). The table shows the minimum distance in meters, according to the maximum power at the RF system output.

**Recommended separation distances between portable and mobile RF communications equipment and the MyLab System**

The **MyLab** system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **MyLab** system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **MyLab** system as recommended below, according to the maximum output power of the communications equipment.

| Rated Maximum Power of the Transmitter [W] | Separation Distance According to Frequency of Transmitter [m] | | |
|---|---|---|---|
| | From 150 kHz to 80 MHz $d = \frac{3,5}{3} \cdot \sqrt{P} = 1,2\sqrt{P}$ | From 150 kHz to 80 MHz $d = \frac{3,5}{3} \cdot \sqrt{P} = 1,2\sqrt{P}$ | From 800 MHz to 2,5 GHz $d = \frac{7}{3} \cdot \sqrt{P} = 2,4\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.33 |
| 10 | 3.69 | 3.69 | 7.38 |
| 100 | 11.67 | 11.67 | 23.33 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

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** system. If the intensity of the electromagnetic fields exceeds that specified in the immunity levels shown in the previous tables, and the echographic system performs incorrectly, additional measures may be necessary, for example by positioning the system in a different way.

## Wireless Requirements

**MyLab** is equipped with built-in wireless capability. The led placed on the right side of the control panel indicates the wireless status: either blue when wireless connection has been activated or completely off.

When wireless is active, the operator should make sure to stay at a minimum distance of 20 cm from the rear of the equipment. If it is necessary to work at a shorter distance, temporarily switch the wireless device off.

**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.

*SS* Refer to the "Safety and Standards" manual for further information on restrictions for the use of wireless connections.

## Device Labels

SS

The following table lists specific labels that are used on the equipment and its options. Refer to the "Safety and Standards" manual for the list of all the other labels.



| Symbol | Explanation |
|---|---|
|   | Device part number |
|   | Device serial number |
|  | Manufacturing address and date. |
|  | General prohibition |
|  | No pushing from the side |
|  | Refer to the instruction manual |
|  | Audio Input on Multiconnector |

Chapter 3



# 3 - Clinical Applications

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

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

## Intended Use

**MyLab** ultrasound system is portable ultrasound system used to perform diagnostic general ultrasound studies. In its complete configuration, MyLab system offers several intended uses.

*SS*

*Carefully read "Safety and Standards" manual.*

**Note**

The operator must always follow the principle known as ALARA (As Low As Reasonably Achievable) and must use minimum acoustic power for the minimum time compatible with obtaining diagnostic information.

**WARNING**

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

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

**Note**

System applications are dependent on your system configuration, transducer and exam type. Not all applications are approved in all Countries, please refer to your Esaote local representative for further information.

**MyLab** models can be configured with one or more of the following applications:

| Licence | Notes |
|---|---|
| **Cardiac Vet** | Cardiac exams for **Canine**, **Feline**, **Equine**, **Bovine** and **Other** species. |
| **General Imaging Vet** | Includes **Abdominal** for **Canine**, **Feline**, **Equine**, **Bovine** and **Other** species. |
| **Reproductive Vet** | Reproductive studies for **Canine**, **Feline**, **Equine**, **Bovine, Porcine**, **Ovine**, **Caprine** and **Other** species. |
| **Musculo Skeletal Vet** | Musculo Skeletal exams, including **Equine Tendon**. |

## Convex Array Probes

| Probe | Application |
|---|---|
| **AC2541** | Abdominal<br>Reproductive<br>Musculo-skeletal |
| **SC3123** | Abdominal<br>Cardiac |
| **SC3421** | Abdominal<br>Reproductive<br>Cardiac |

## Linear Array Probes

| Probe | Application |
|---|---|
| **AL2442** | Abdominal<br>Cardiac<br>Reproductive<br>Musculo-skeletal |
| **SL2325** | Musculo-skeletal |
| **SL1543** | Abdomen<br>Cardiac<br>Musculo-skeletal |

| Probe | Application |
|---|---|
| **SL3323** | Abdomen<br>Musculo-skeletal |
| **SL3235** | Musculo-skeletal |
| **SL3332** | Abdomen<br>Musculo-skeletal |

## Phased Array Probes

| Probe | Application |
|---|---|
| **SP2730** | Abdominal<br>Cardiac<br>Reproductive |
| **P 3-11** | Abdominal<br>Cardiac |
| **P2 3-11** | Abdominal<br>Cardiac |

## Specialty Probes

### Endorectal Probes

| Probe | Application |
|---|---|
| **SV3513** | Reproductive<br>Musculo-skeletal |
| **TL5-10** | Reproductive<br>Musculo-skeletal |

### Transesophageal Probes

| Probe | Application |
|---|---|
| **ST2612** | Cardiac<br>Transesophageal |

**WARNING**

Do not use MyLab for ophthalmic or transorbital applications.

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

> **Note**
>
> Probe availability is dependent on your system configuration and application. Not all probes and application are approved in all Countries, please refer to your Esaote local representative for further information.

## Abdominal and Related Applications

The probe applies ultrasound energy through the patient abdomen to obtain an image of the abdominal organs to detect abnormalities (Imaging) and assess blood velocity, flow and patency of abdominal vessels through the Doppler modalities.

## Cardiac Applications

The probe applies ultrasound energy through the thoracic cavity to obtain an image of the heart sufficient for evaluating any cardiac abnormalities. In Doppler modes, the probe applies energy through the thoracic cavity to determine the velocity and direction of blood in the heart and vessels.

The heart can also be studied through the esophagus and/or transgastrically with a transesophageal probe.

## Musculo-Skeletal

The probe applies ultrasound energy through the skin to obtain an image of tendons, ligaments and muscles and to determine blood flow patterns and velocities.

## Obstetrical Application (for Reproductive studies)

The probe applies ultrasound energy through a pregnant woman's abdomen to obtain an image of the fetus(es) to detect structural abnormalities or to visualize and measure anatomic and physiologic parameters of the fetus(es) for the purpose of assessing fetal growth. In Doppler modes, the probe applies energy through the patient abdomen to detect placental or fetal flow abnormalities. An endocavity probe can also be used for the same purposes (**endorectal** studies in large animals).

*Carefully read "Safety and Standards" manual.*

**Note**

The operator must always follow the principle known as ALARA (As Low As Reasonably Achievable) and, in particular with this application, must use minimum acoustic power for the minimum time compatible with obtaining diagnostic information.

Chapter 4



# 4 - System Components and Installation

The system will be installed by Esaote personnel. Esaote personnel will be responsible for opening the packaging and ensuring that the system is correctly programmed and operational. This chapter provides an overview of the system components and the major operations that may be necessary.

## System Overview

**MyLab** has a built-in LCD screen: in this way, the system can be used as portable configuration. **MyLab** can be supplied with a trolley in its mobile configuration.

### Portable Configuration

The console contains: the electronics, the control panel with speakers, the probe connectors (on the back), the input/output connectors for the ECG, the network and the peripherals and the security lock connector.

The ON/OFF button is located on the upper left part of the control panel; the batteries status led is located on the lower left side of the control panel.

The console is equipped with an handle that can be used to move the system.

The system is equipped with an external AC/DC adapter and internal batteries. Optional the unit can be equipped with mains filter.

## Mobile Configuration

A height-adjustable trolley is available to set **MyLab** in a mobile configuration.

TThe trolley provides a handle and independent brakes on four wheels to be easily moved.

The trolley is equipped with an internal compartment to house and connect the AC/DC adapter and an optional mains filter.

It has a compartment for additional accessories.

The trolley can house an external peripheral to be placed on the dedicated tray.

*Peripheral*

**Note**

When selecting the peripheral, consider its dimension so that it can be safely installed on the console. The shelf measures 33x17 cm.

**CAUTION**

**The peripheral weight may not exceed 3 kg. The shelf could be damaged if the peripheral weight exceeds this limit.**

**CAUTION**

**The weight in the compartment for additional accessories may not exceed 3 kg. The compartment could be damaged if the weight exceeds this limit.**

**CAUTION**

**The max. weight of the trolley is 63.5 kg. (including all options)**

The base of the trolley offers the possibility to mount an optional UPS (uninterruptible power supply) or an optional insulation transformer.

**CAUTION**

**Do not use the optional UPS in combination with the optional insulation transformer or vice versa.**

**SS** The "Safety and Standards" manual provides the safety requirements and standards to be observed for using peripherals devices with **MyLab**.

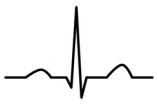
# Installation

## Portable Configuration

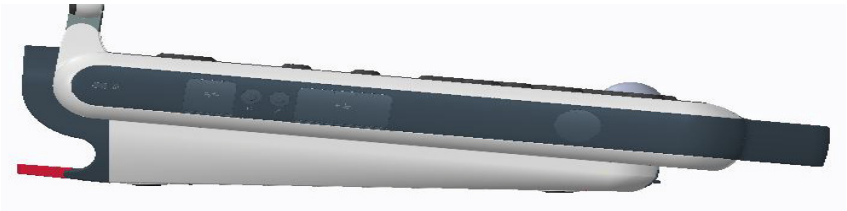
### Identifying the Connectors

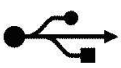
**Probe Connectors** Two probes connectors (EA1÷EA2) are located on the back side of the system.

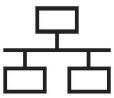
**ECG Connector** The ECG cable connector is placed on the right side. The ECG cable connector is protected with a cover which has to be opened before inserting the ECG lead.

| Connector Symbol | |
|---|---|
|  | ECG Connector |

*System left side* The connectors on the left side are protected with a cover which has to be opened before inserting the device.



| Connector Symbol | |
|---|---|
|  | USB Port |
|  | Headphones |

| Connector Symbol | |
|---|---|
|  | Microphone (*not currently used*) |
|  | RJ45 |
|  | Security Lock |

**USB Ports**

Four USB ports are located on the left side of the system. These ports can be used to connect a USB device for digital storage, a USB footswitch or a USB printer.

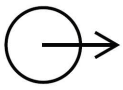
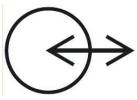
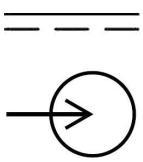
**LAN Connector**

The LAN connector is placed on the left side.

**Security Lock Connector**

This connector is placed on the left side and provides protection for the portable configuration.

*System rear side*

| Connector Symbol | |
|---|---|
|  | HDMI type |
|  | 28 Pins Connector (*not currently used*) |
|  | Mains Socket |

**Mains Socket**

The mains socket is located on the rear side of the system. Connect the AC/DC adapter to the mains socket.

**WARNING**

**Use only the AC/DC adapter provided by Esaote with the MyLab.**

**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.**

**HDMI Type Output**

**MyLab** can be connected to an auxiliary monitor. Any auxiliary monitor connected to this port has not to be used for diagnostic purposes.

> **Note**
>
> The resolution of the auxiliary monitor can not be lower of the main display. The system automatically shuts down whenever a lower resolution is detected.

Connect the monitor's cable to the connector of the rear panel.

**Installing the Portable Configuration**

*Refer further in this chapter for information on probe connection.*

Place the **MyLab** on the work surface. Position the equipment so that the power outlet is easily accessible. Connect the power cable to the system socket. Plug the cable to the reliable grounding power outlet to assure adequate grounding.

> **Note**
>
> Whenever the system has to be insulated from the mains, disconnect the cable from the power outlet.

Open the screen and connect the probes and all accessories.

## Mobile Configuration

**Installing the Console**

*Refer further in this chapter for information on probe connection.*

Place the console on the top surface of the trolley, allowing it to slide to the bottom, so that the profiles of the base match the housings. Secure the console to the trolley, pulling the secure handle.

**WARNING**

**Make sure that the secure handle is completely inserted. If it is not inserted completely, MyLab could come out of the housings and drop down.**

**Probes, Gel and Cable Holders**

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

Follow the instruction provided with the trolley to install the AC/DC adapter and optional mainsfilter. For the optional UPS and insulation transformer follow the instructions provided with them.

**WARNING**

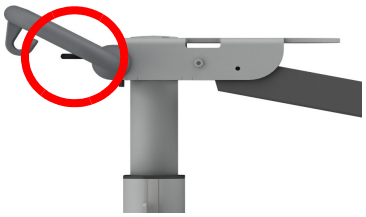
**Do not use the lateral stirrups to push the system.**

### Installation at Working Site

At the examination site, position the equipment so that the power outlet is easily accessible.

Adjust the system into its final position and then lock them to fix the position.

This assembly can be pushed up/down to maximize operator comfort.



A lever is placed in central position of the trolley top.

Activate the lever to adjust the height of the control panel. This lever allows a vertical displacement of ±30 cm.

Put the LCD into its working position. Connect the probes and all accessories.

Plug the power cable into the reliable grounding power outlet to assure adequate grounding.

**Note**

Whenever the system has to be insulated from the mains, disconnect the cable from the power outlet.

**WARNING**

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

**WARNING**

**If the trolley is equiped with an optional insulation transformer or UPS, be sure that in any configuration, the overall load of peripherals (i.e. printers etc), excluding the system, does not exceed 380 VA**

## Turning the System On

Once the installation has been completed, **MyLab** is ready to be powered up. Press the ON/OFF key to turn the system on.

**CAUTION**

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

## Probes Connections

Both imaging and Doppler probes can be connected to the two (2) connectors, on the back of the system, indicated by symbols EA1 and EA2.

Connector-securing devices are placed beneath the probe connectors, on the bottom side.Make sure that the securing device is positioned in the lower position (open position) and carefully attach the probe connector by placing the cable feedthrough frontwards. To secure the probe, move the securing device up.

**WARNING**

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

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

**CAUTION**

**Make sure to correctly align the probe connector before inserting it. Close the securing device only after the complete insertion of the connector.**

# Battery

*Refer to the next chapters for further information on battery using and functioning.*

**MyLab** can be equipped with an internal battery pack, composed of two batteries, that allows the system both to work when no mains power is available and to partially shut down the system, leaving it in stand-by.

A fully charged batterypack ensures 90 minutes of scanning.

**CAUTION**

**When MyLab is equipped with its internal battery, do not leave the system 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.**

**Avoid contact with a leaking batteries, the contents are harm ritation, including caustic burns and injury may occur following exposureto a leaking battery.**

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

**WARNING**

**Do not replace the batteries with other batteries then Esaote p/n 140019400.**
*The batteries installed in the MylabDelta model are manufactured by INSPIRED ENERGY L L C (http://inspired-energy.com/), P/N nh2034hd31.*

When the system 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 the system 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 the system to the mains power or switch the system off. **MyLab** automatically switches itself off when the residual operating time is expired.

***AO***

The battery mode of operation has to be set: refer to section "Clinical and System Settings" of the "Advanced Operations" manual for further information.

## Battery Status Led

The battery led is located on the left corner of 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 the system to the power mains while keeping it switched off. In these conditions the charging cycle lasts around two hours and fifty minutes (2h50min).

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

A system 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 30°C.**

**Whenever the battery pack has been removed from the system, perform one full charging procedure before switching on the unit.**

The battery pack is not charged when overheating.

When the battery reaches the maximum temperature threshold for its working condition, a red cross is displayed over the battery icon.

When this occurs, disconnect the power cable and wait for about two (2) hours before connecting the power cable again, so that the battery cools down.

*Blinking of the battery led*

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

## 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. The batterypack is maintance free. When storing the batteries outside the system be sure that the batteries are not fully discharged.

## Acclimation Time

If the system 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:

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

## Peripheral and Network Connections

📖 ***SS*** The "Safety and Standards" manual provides the safety requirements and standards to be observed for using peripherals devices with **MyLab**.

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

Special care has to be taken, if the device is connected to a computer network (e.g., Ethernet).

When connecting **MyLab** to a local area network (LAN) via the Ethernet connection, the LAN components have to be IEC 60950 compliant.

Because other devices could be connected without any control, an isolated signal link has to be used to operate the system safely, in compliance with IEC60601 incl. national deviations.

For computer networks there are media converters available which convert the electrical signals to optical signals. Please consider that this converter has to comply with IEC XXX[1] standards and is battery operated or connected to the isolated mains output of the **MyLab**.

**MyLab** can be connected to USB printers via a USB Port. To correctly power the peripherals, follow the manufacturer's instructions.

When the peripheral is installed on the trolley, always secure the peripheral by closing the belt.



**WARNING**

**The maximum current supplied by the MyLab USB ports is 500 mA. Peripherals exceeding this limit can be connected only if powered by their external power supply.**

## How to safely connect 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.

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**

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

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

## Safety Concept

**MyLab** in its mobile configuration has the option to be equipped with an insulation transformer to provide required separation from AC mains for both the system and the auxiliary devices.

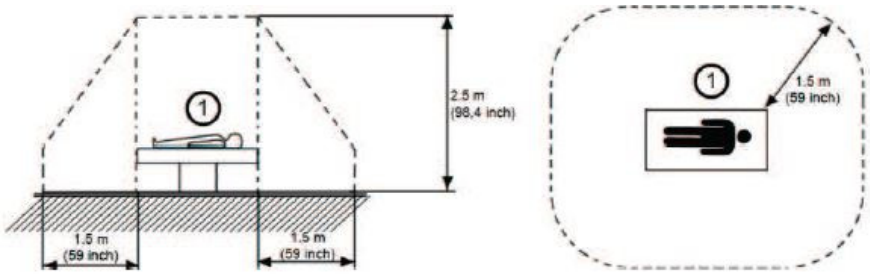
Additional equipment connected to **MyLab** must comply with respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3rd Edition of IEC 60601-1, 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

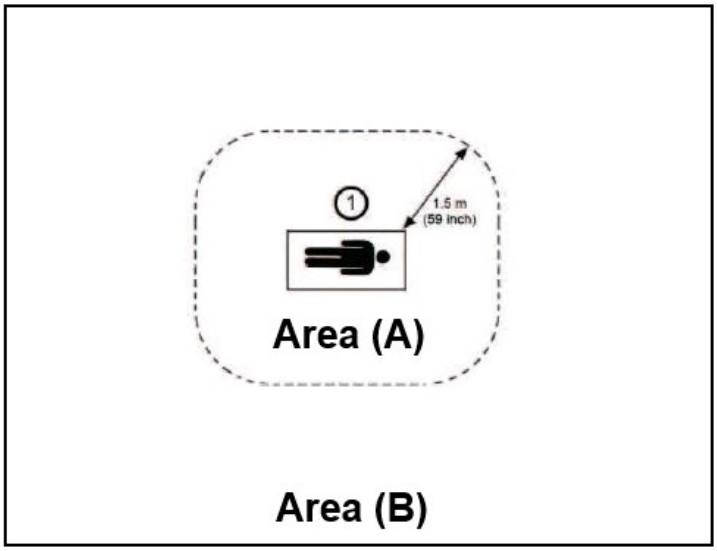
**Medical environments**

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

A) Patient area

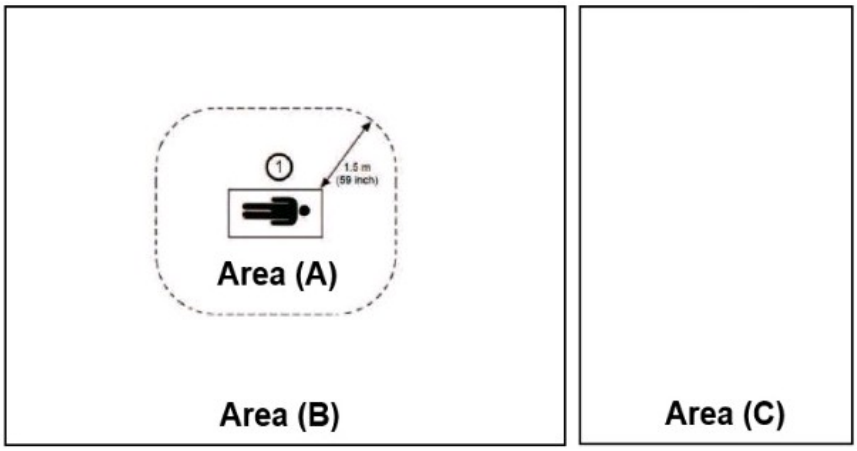


B) Medical Use Room




Intended as area B, area A excluded.

C) Non-medical use room




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

Possible configurations:

- **MyLab** + auxiliary device complying to IEC 60601 in area A - No additional safety requirements.
- **MyLab** + auxiliary device not complying to IEC 60601 (complying to IEC XXX[1]) in area A

- Auxiliary device must be powered through a safety insulation transformer complying to IEC 60601.

- **MyLab** + auxiliary device not complying to IEC 60601 (complying to IEC XXX[1]) in area B or area C connected by WiFi or Ethernet cable
  - No additional safety requirements.

- **MyLab** + auxiliary device not complying to IEC 60601 in area B or area C connected by cable (USB, HDMI,...)
  - Auxiliary device must be powered through a safety insulation transformer complying to IEC 60601.

**Note**

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

Additional safety measures are:

- Additional protective earth connection between the two devices, or a safety insulation mains transformer for the auxiliary device

- Do not connect a multiple-socket outlet or extension cord to **MyLab**.

- Avoid touching the patient and the auxiliary device simultaneously.

Additionally the IEC 60601 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.

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

**WARNING**

**The system must be powered so to satisfy the electrical safety requirements, as specified in the "Safety and Standards" manual. 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.**

### Auxiliary Monitor

Any auxiliary monitor connected to HDMI type port has not to be used for diagnostic purposes.

**Note**

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

*Monitor Connection*

Connect the monitor cable to the connector of the rear panel.

## Moving and Transporting the System

**Portable Configuration**

Disconnect all probes, peripherals and the AC/DC adapter. Close the LCD screen .

Always use the handle to move the system.

**Mobile Configuration**

**MyLab** is provided with wheels and handle to allow the user to easily move the system. The following precautions must be observed:

*Moving the system*

- Switch the system off and unplug the power supply, wrapping its cable on the handle to ensure it.
- Close the LCD display.
- If probes are connected, be sure that they are properly secured and that their cables do not reach the floor, securing them on the hooks.
- Peripheral can be placed on the **MyLab** peripheral platform, provided that it is secured with the locking strips.
- If peripherals are placed on an external additional platform, be sure they are disconnected from **MyLab** before moving the ultrasound system.

- Be sure that the brakes are unlocked before moving the system.
- Avoid any unnecessary mechanical shock to the system while moving it.

**WARNING**

**Use the handles on the trolley only to move the system.**

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

**The handles on the trolley cannot be used to lift the system.**

**To steadily lock the system, all the wheels must be locked.**

**Do not park the system on a slope.**

**Do not use the brakes to park the machine on a slope.**


*Transportation*

When transporting the system in a vehicle, remember to:

- Disconnect and remove all probes and peripheral devices.
- Close the LCD display.
- Use the brakes to lock the system.
- Fasten securely the system inside the vehicle.

Chapter 5



# 5 - Control Panel

This chapter provides a brief description of the system controls.

## The Control Panel

The Control panel consists of touchscreen, general controls (for example ON/OFF switch), and controls section.

Loudspeakers are placed on the left and right upper corners of the panel.

## Touchscreen Section

This section includes the TGC controls, the ON/OFF switch and the **MENU** key.

### Touchscreen

The touchscreen displays exam controls related to the active modality. Press the displayed key to activate/deactivate the corresponding control.

The touchscreen works in different modalities:

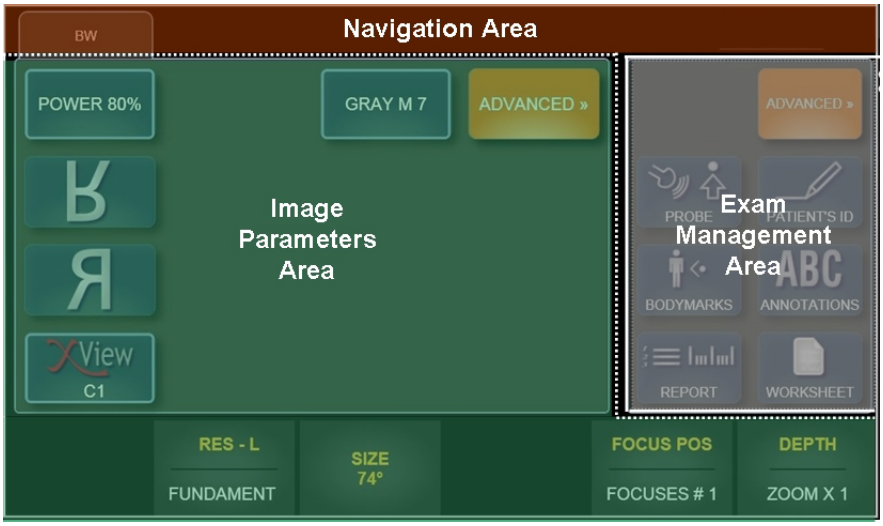
- as Exam panel, providing control keys to perform the exam,

- As Multipurpose panel, providing software buttons to use advanced exam controls,
- As Alphanumeric keyboard to enter data.

The touchscreen lay-out depends on the working modality.

**Exam Panel Layout**

The touchscreen is organized in three main areas, as shown in the figure below:




**Navigation Area**

The upper bar of the touchscreen contains the Navigation tabs. These allow to select the desired features for the relevant controls, e.g. which controls will be available for each active mode (B-Mode, CFM.). To select the desired mode, press the corresponding tab on the touchscreen.

The **Navigation tabs** are indicated in the operator manuals with this FONT SIZE.

**Exam Management Area**

This area of the touchscreen displays the buttons for the exam management, that is the buttons allowing to start the exam, to change the probe or the preset etc. To activate the desired function, press the corresponding button on the touchscreen.

Exam Management buttons are indicated in the operator manuals with this FONT.

If the displayed menu has several levels, press the button ADV>>/BASIC<< to scroll through all functions.

**Image Parameters Area**

This area contains the exam functions and controls, varying according to the active mode, applications and settings.

*Buttons*

The buttons have different colors depending on the active status:

| Disabled Button | Active Button | Selected/Pressed Button |
|---|---|---|
|   |   |   |
| Dark gray | Dark blue | Light blue |

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

*Button with sub-menus*


Touchscreen buttons showing a frame have a dedicated sub-menu: press the button to display the sub-menu allowing to optimize the function.

*Toggles*

On the bottom of the touchscreen there are six levers (or toggles) which act on the functions displayed just above.


Each lever can control two functions, displayed on the area above. The functions depend on the active modality.

The lever acts on the active control, displayed in the upper position. Press up or down the lever to change the control value.

To switch to the other displayed function, press the corresponding button on the touchscreen: the lever will act now on the other control.

Both image parameter buttons and toggles are indicated in the operator manuals with this **FONT**.

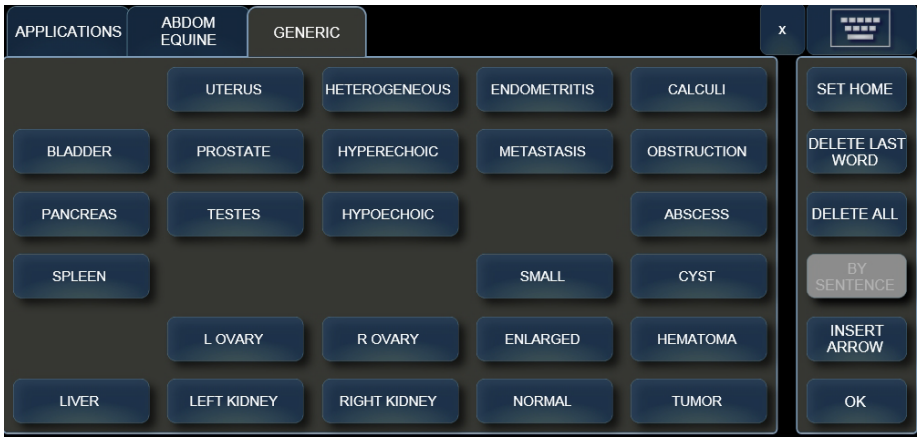
If the displayed menu has several levels, press key **ADV>>/BASIC<<** to scroll through all functions.

### Multipurpose Panel Layout

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

The touchscreen is organized in three main areas.

*Annotation touchscreen*



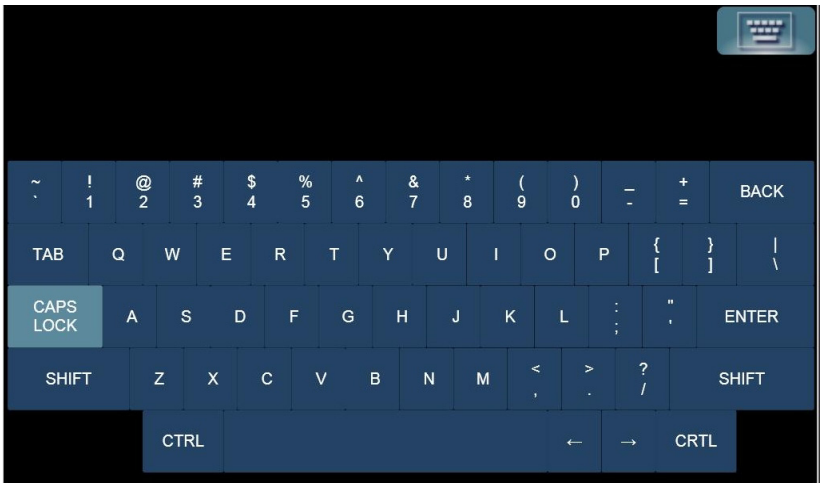

The upper bar of the touchscreen contains the Navigation tabs of the selected functions (for example the glossary library tabs in the Annotation modality). Like the Exam layout, **Navigation tabs** are indicated in the operator manuals with this FONT SIZE.

The right column contains general controls of the active modality (for example "DELETE ALL" in the Annotation modality) These buttons are indicated in the operator manuals with this FONT SIZE.

The remaining area contains more specific controls (like the list of available words/ sentences in the active application glossary in the Annotation modality). These buttons and knobs are indicated in the operator manuals by this **FONT SIZE**.

### Alphanumeric Keyboard Layout

A dedicated button displayed on the upper right side activates the emulation of the Qwerty alphanumeric keyboard.




Press the Qwerty icon to display the keyboard. Press the Qwerty icon again to close the keyboard.

## Touch Screen TGC Sliders

The **TGC** sliders on the touch screen, control signal amplification in individual areas of the image. Touch Screen Sliders are used to adjust the signal zone by zone.

## ON/OFF Button

When **MyLab** is connected to the main, the led located on the left corner of the control panel is lighted and the ON/OFF key switches the system on or off, activating the closing session.

*Batteries*

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

**Note**

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

📖 *AO*

Refer to the "Clinical and System Settings" section for information on how to set the mode of operation.

The table below explains the status of the ON/OFF button:

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

**CAUTION**

**This is a PC based system; data loss or driver damage may occur if the system 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 system off.**

# Controls Section

## Trackball

The trackball operates in two different modes.

**Standard Mode**

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

Each mode automatically activates the trackball on its cursor:

| Mode | Trackball |
|---|---|
| M-Mode, Doppler | LINE cursor |
| Color Flow Mapping (CFM) | CFM Region of Interest (ROI) cursor |

The cursor function is indicated on the left bottom side of the screen. When several cursors are present on the screen, the **ACTION** key switches between the active cursors.

**Mouse Mode**

The trackball can then 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 keys placed on the left and right side of the trackball can be set as mouse keys (as confirmation and context menu keys).

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

The **POINTER** key makes it possible to change the trackball operation from standard to mouse mode.

## Exam Controls

### Exam Flow

The START EXAM button can be pressed only once the desired probe, application and preset have been selected. This button opens every exam activating real time. During the exam, the PROBE button allows to select a different probe, application and preset.

*Closing session*

When the exam is finished, press the **END EXAM** key. It is then possible to archive the patient's data and produce a report on the exam. The system clears the stored data and shows the Exam Start menu again.

During the exam, the PATIENT ID button allows to enter or to modify patient data.

### The Mode Keys

The **B** key 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.


To activate/deactivate Color Doppler (CFM), press the **CFM** key in B- or M-Mode.

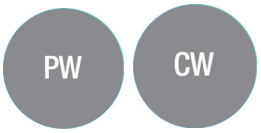

In B-Mode, a cursor delimits the Region of Interest (ROI) where color analysis is performed and displayed. The ROI dimensions and position can be varied with the trackball, after activating the ROI cursor with the **ACTION** key.

The touchscreen menu allows the operator to vary the displayed mode and to switch to Power Color.

**TVM Mode**

The touchscreen menu allows the operator to switch to Tissue Velocity Mapping (TVM). This mode uses Doppler to display heart walls motions, rather than flows. TVM is available with specific probes.

This key activates the M-Mode, and if necessary, its selection cursor (B-Line). There are five possible viewing formats: the format with full screen M-Mode; the dual format, with the screen split vertically with 2D on the left and trace on the right; the split formats, with the screen split horizontally, with the reference 2D above (out of three possible dimensions) and the M-Mode trace below. The viewing format can be preset and varied in real time through the displayed menu.




The **PW** key is used for activating the Pulsed Wave Doppler (PW), **CW** for activating the Continuous Wave Doppler (CW); both keys activate the positioning cursor if necessary. As in M-Mode, there are five viewing formats: the three split formats, the dual format and the full screen format.

**TV Mode**

In PW, the buttons on the touchscreen allows the operator to switch to Tissue Velocity (TV) mode. TV sets Doppler filters to display the strong signals with low motion such as the heart walls motion, rather than flow. TV mode is available with specific probes.

During the exam, the format can be preset or varied interactively through the menu.

In 2D or CFM, the cursor can be interactively activated or disabled to select the M-Mode or Doppler line (taste **LINE UPDATE**). When a trace is active, the same key freezes the trace acquisition and reactivates the 2D reference.

The **AUTO** keys, available both in B-Mode and Doppler, automatically adjusts some controls of the active mode to make the echo acquisition easier.

*Imaging and Color Gain Knobs*

The touchwheel around the Auto button, on the left side of the panel acts on B-, M-Mode CFM, Power Doppler and Doppler signals, adjusting amplification over the entire depth of the image.

To increase gain, scroll clockwise, to reduce it, scroll counter-clockwise.

In Doppler modes, gain acts on the video component of the signal. The level of the audio signal can be independently adjusted with the **AUDIO** rotating knob.


The **NEARFIELD & FARFIELD GAIN** buttons adjust the gain in the near or far field of the image. Left side will reduce the gain while the right side will increase the gain.

This key stops the current analysis or scan and puts the system in Freeze mode. To re-activate real time, press **FREEZE** a second time or directly press the key of the required mode.

**Multiformat Controls**

Depending on system presets or on the active selections on the displayed menu, these keys activate multiple views of two (dual) images both in real time and in freeze.

Press any key to activate multiple presentations. The active 2D/2D-CFM is displayed on the left. If the  key or the  key is pressed, the system freezes the acquisition of the 2D/2D-CFM and activates the following 2D/2D-CFM.

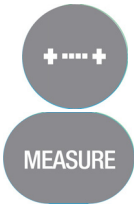
Press the same key again to restore a normal format.

**Exam Revision**

During the exam, the operator can save both individual images (**IMAGE** key) and 2D or CFM sequences (**CLIP** key). The stored images and sequences are displayed as thumbnails on the right of the screen. The EXAM REVIEW tab is used to access the data stored during current exam. Alternatively, images and clips can be accessed by placing the cursor (trackball working as pointer) on the thumbnail and by pressing **ENTER**.

The **ARCHIVE** key is used to access, at any time, the archived data.

**Exam Report**




These functions can always be performed: general measurements (+...+ key) and access to the calculations package (**MEASURE** key). When the required key is pressed, the list of available measurements is shown on the right of the image.

**Printers**


*Printer Keys*

**MyLab** can control two peripheral devices with the **PRINTER KEYS 1 AND 2,** according to the system presets.

**Settings**

This key displays the system menu for all configurations/settings (both clinical and system settings). This key is indicated as **MENU** key within **MyLab** manuals.

## eTouch Key

The **ETOUCH** key allows to configure macro-operations to launch sequences of commands both through touchscreen buttons and control panel keys.

Refer to the dedicated chapter on this manual for further information on its use.

## Acquire Key

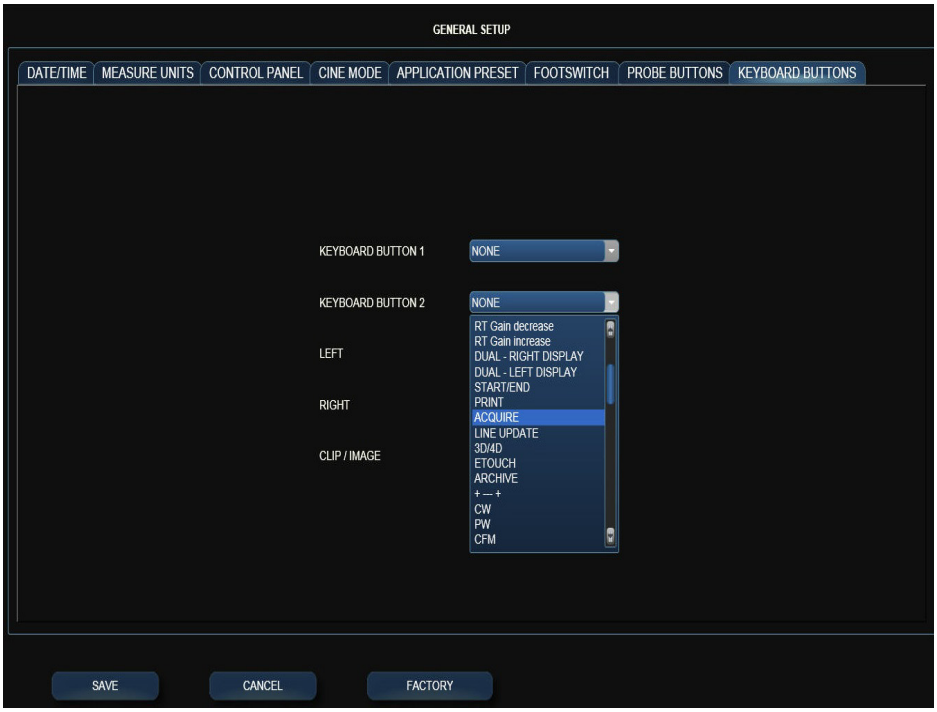
AO

The ACQUIRE key activates advanced operations: further details on how to use them are described in this manual and in the "Advanced Operations" manual.

The MyLab does not has a physical ACQUIRE key, the acquire key can however be assigned to several other keys on the keyboard.

**Assigning the acquire function to a keyboard button**

- Press the MENU key.
- In the MENU select the "**GENERAL SETUP**" menu.
- In the "**GENERAL SETUP**" menu select the "**KEYBOARD BUTTONS**".



- On the "**KEYBOARD BUTTONS**" assign the "**Acquire**" function to one of the available buttons and end with selecting the **SAVE** key.

**Note**

Please be aware that assigning a different function to an existing keyboard button results in loosing its original fuction.

Recommended is to assign the "**Acquire**" function to the **PRINTER KEY 2** (keyboard button 2).

Chapter 6

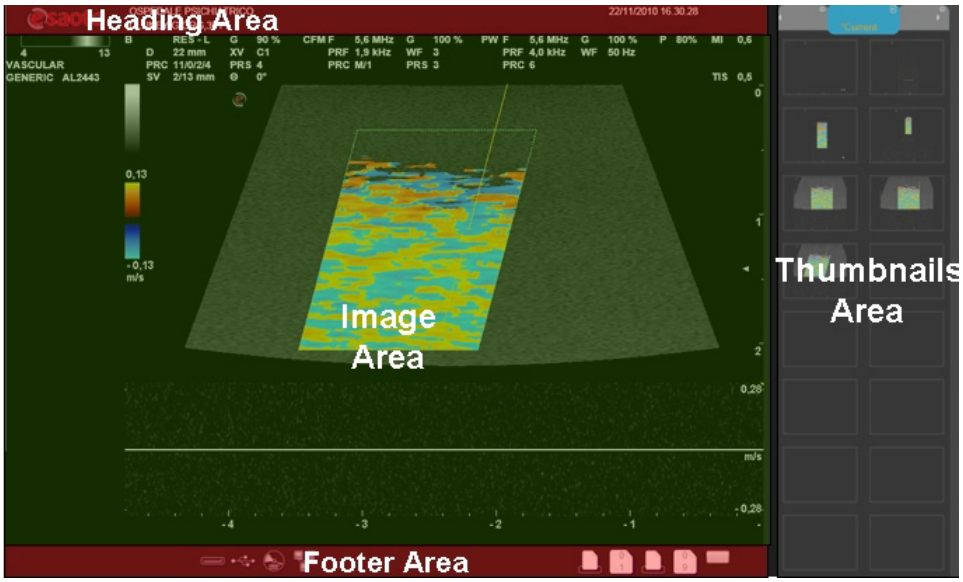


# 6 - Screen Layout

This chapter provides a brief description of the information provided on the **MyLab** screen.

## Information about the Screen

The screen is split into four main areas:




### Heading Area

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

📖 *AO*

To set data of your center, please refer to the "Advanced Operations" manual.

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 the PATIENT ID button.

## Footer Area

This area is used to display the following information:

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

**Trackball**
The trackball function is indicated on the bottom left side of the footer area.

When there are several cursors on the screen, two functions are displayed simultaneously. The function shown on the upper line indicates the active cursor; the one on the lower line indicates the next cursor that can be activated. The ACTION key switches between cursors.

**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.

📖 ***AO*** 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.

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

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

### Battery

When the battery pack is not installed, **MyLab** displays the following icon:

| Battery not installed | Main power cable |
|---|---|
|  |  |

When the battery is installed, the battery icon changes depending on its charging status:

| Fully charged battery | Partially charged battery | Discharged 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.

#### 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. The system 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 the ON/OFF key 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. The system 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 the ON/OFF key pressed, and contact Esaote Service.

**Error #3**

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

> Error #3: problem with battery charging.

If this situation occurs, close the exam as soon as possible by pressing the **END EXAM** key and switch the system off by pressing the ON/OFF key 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. The system displays the following message and shuts down automatically:

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

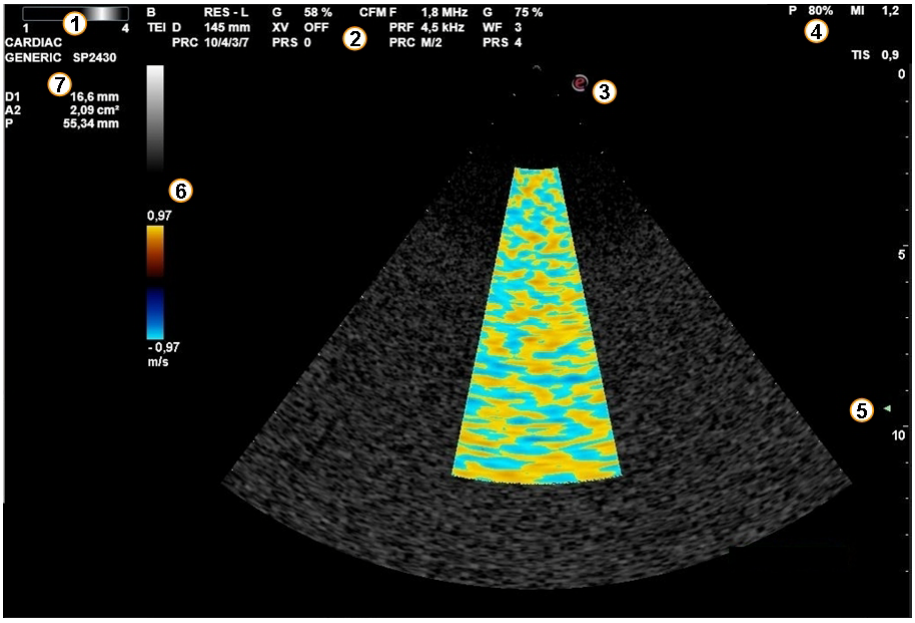
Should this situation occurs, contact Esaote Service.

#### Peripheral Devices

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

## Image Area

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




Legenda:

| Number | |
|---|---|
| 1 | Frequency Bar |
| 2 | System Parameter |
| 3 | Sector orientation |
| 4 | Acoustic output data |
| 5 | Focal zone |
| 6 | Image and color scales |
| 7 | Active application, probe and preset |

**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

### Imaging

| 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% | AutoAdjust |
| D | nn cm | Depth |
| X/M | C/n | XView Algorithm/MView algorithm |
| PRC | n/n/n/n | Dynamic range / Dynamic compression / Density / Gray map |
| PRS | n | Persistence |
| SV | nn/nnn mm | Sample volume size and depth |
| Θ | nn° | Doppler correction-angle |

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

### Color Flow Mapping (CFM)

| 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 |
| PRS | n | Persistence |

**Doppler**

| 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 |
| PRC | n/n | Dynamic range / Gray map |

## 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.

## 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.

Chapter 7



# 7 - Performing an Exam

This chapter describes the operations usually carried out to start and end an exam.

*SS*

Read the "Safety and Standards" manual carefully: all the safety characteristics, cautions and warnings listed there apply to all exams.

Remember that it is necessary to be familiar with the mechanical and thermal indices display and the ALARA principle (As Low As Reasonably Achievable) before using any probe. The patient must be exposed to ultrasound for as short a time as possible and only for as long as it takes to achieve the diagnostic information.

## Exam Start and End

At power-up, at end of the initial autotest and at the start of every new exam the system displays both the Patient ID screen and the touchscreen that allows the operator to enter patient data and application and to select the probe, the application and the preset (PROBE button).

*AO*

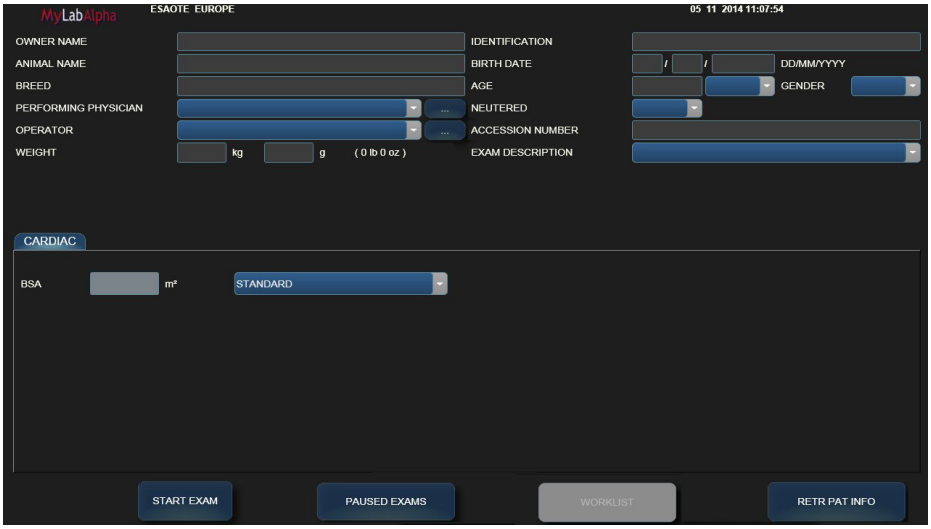
**Note**

At start up **MyLab** displays the window allowing to select the configuration, when more system configurations are set. See further in this manual and in the "Advanced Operations" manual for detailed information.

**CAUTION**

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

*Patient ID screen*




*Probe, Application, Preset touchscreen*


**Starting exam procedure**

The steps to be followed to start an exam are:

1. Probe selection,
2. Spplication selection,
3. Preset selection,
4. Patient data and application data entry.

**Probe selection**

The touchscreen displays all connected probes: the pressed button indicates the active probe. Press the button of the desired probe to activate it.

**Application selection**

Depending on the selected probe, the touchscreen displays the available applications: the pressed button indicates the active one. Press the button of the desired application to set it.

**Preset application**

The preset (or Clinical Settings) can be selected only when both the probe and the application have been set. Press the desired preset button to select it.

> **Note**
>
> The user may program and add presets to better suit individual clinical needs or preferences, while applications depend on the installed optional licenses.

📖 ***GS** and **AO***

See further in this manual and in the "Advanced Operations" manual for detailed information on clinical settings.

**Patient data and application data entry**

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, use either the trackball and the **ENTER** key or the ⇆ tab key of the alphanumeric keyboard. To enter patient data, use the alphanumeric keyboard.

The CURRENT button retrieves the patient data of the last exam.

The RETR PAT INFO button retrieves from the archive the patient data of a previously performed examination.

If the "ENABLE PAUSED EXAM" option is checked in Saving Option Menu, pressing the **PAUSED EXAMS** button 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 characters setting! |
|---|

At any time during the exam, the operator can view and modify the patient's data by pressing the button PATIENT ID. The operator can also select a different probe, application, preset, set a new preset or modify the actual preset by using the PROBE button.

**WARNING**

**Do not use the PATIENT ID key 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 the END EXAM key 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 this data but always check the current patient data.**

Once all patient and application data have been entered, press the START EXAM button to start the exam.

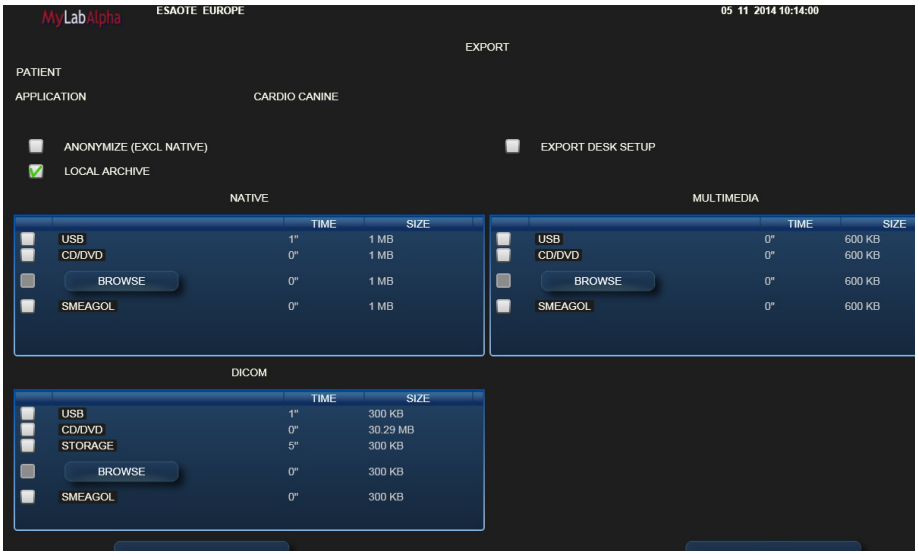
The system activates real time in 2D. The selected application and presets automatically define the type of format, CFM maps and power values...

**WARNING**

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

**End Exam**

To end the exam, press the END EXAM key. 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.




Before archival, patient data can be made anonymous by checking the corresponding box.

**Note**

The native format of the exam cannot be made anonymous.

The exam can be simultaneously exported to the local archive and to external media (in native, DICOM and multimedia formats). Press **OK** to confirm and close the exam.

The system automatically shows the window allowing to start the exam.

**Note**

At power-up, the system prompts the operator to archive the last exam performed if the system 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 "ENABLE PAUSED EXAM" option is checked in Saving Option Menu, pressing the **END EXAM** key you will be asked to end or pause the exam.

**Note**

At switch off, the system will inform if there are any paused exam.

*System reboot*

At the end of each exam **MyLab** executes an auto-test that, in same cases, might requests the system reboot. The following message is displayed:

> Please restart the unit to improve system performance.

Switch the unit off as soon as possible.

## Exam Exported on CD/DVD Medium

CD/DVD are not managed in multi-session: only one burning operation at a time can be activated.

When the exam is exported to a CD/DVD medium, the system will be inoperative during the burning procedure. The system displays the following message:

> Warning:
> one of the selected destinations is CD/DVD;
> during CD/DVD operations, the user interaction will be stopped.
> Do you want to continue?

The duration of the burning procedure corresponds to the estimated time for the selected CD/DVD operation.

Press **NO** to end the procedure.

The burning procedure starts as soon as the **YES** button is pressed. The system displays a waiting icon and the following message:

> A burning procedure is in progress.
> Pressing CANCEL the operation stops.
> Warning: the CD/DVD may be unusable.

The procedure can be stopped at any time by pressing the **CANCEL** button. In this case the CD/DVD is unusable.



**Note**

When burning data, do not use any Double Layer DVD disk nor disks with applied stickers.

## Performing the Exam

By pressing the different mode keys, the specific mode is activated in real time. If the same key is pressed again, the system automatically returns to the previous presentation.

*Line Cursor*

Press **LINE UPDATE** to display the scanning line. During the scan this key freezes the trace and re-activates the 2D reference; the **PLEX** button activates or freezes the 2D reference, maintaining the trace in real time.

The control panel keys and the commands displayed on the touchscreen make it possible to optimize presentation quality. Different menus correspond to each format.

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, press the button **ADV>>/BASIC<<** to scroll through all functions.

**2D and CFM**

To save images and sequences, press **IMAGE** and **CLIP**. These keys respectively save still frames and clips in real time. Images are also saved in Freeze. Clips are acquired in Prospective Mode: the **CLIP** key starts the acquisition. The number of captured loops depends on the set value (**CLIPS DUR** toggle).

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

**Traces**

In the case of traces (M-Mode, Q-Mode, Compass M-Mode and Doppler) the key **IMAGE** saves the image displayed on the screen. When the trace is displayed in cine mode (**PLAY** key), the **ACQUIRE** key allows to save the corresponding clip.

*AO*

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

The thumbnails of the saved data are shown downwards in chronological order on the right side of the screen.

**AO**

The "Advanced Operations" manual provides a detailed description of all active controls in the different modes.

## 2D and CFM Clips with High Frame Rate

**MyLab** allows the acquisition of 2D and CFM Clips with high frame rate.

Clips with high frame rate are acquired in Retrospective Mode. In this modality the system continuously captures consecutive loops, the **ACQUIRE** key stops the acquisition and the last captured loops are shown on the screen.

### Acquisition Procedure

Follow the procedure below to acquire clips with high frame rate:

**Procedure**

- Enter the patient's data,
- Select the probe, the desired application and preset and press **OK** to confirm,
- Start scanning and press the **ACQUIRE** key: the system freezes and displays the last acquired cycles in cine mode.
- Press **ACQUIRE** to save the sequence.

The number of acquired loops depends on the set value (**CLIPS DUR** toggle).

2D and CFM Clips acquired with the ECG signal (**PHYSIO** button) synchronization and using this modality are identified by a specific symbol, shown here on the left. These clips are indicated as Clip ART clips within the manual.

**WARNING**

**Do not use the physiological trace displayed on the screen for diagnosis or monitoring.**

## Freeze and Scrolling Memories

The **FREEZE** key freezes the image. The system displays the scroll bar of the memories, where the images acquired just before the system was frozen are temporarily saved.

On frozen images the ANNOT and BODYMARKS buttons allows the user to add text and icons on images.

### How to Scroll through the Memories

Move the trackball horizontally to scroll through the images one by one. The scrolling bar shows the trackball position.

For multiple formats, several scrolling bars are displayed; the multiformat controls (  and  keys) change over from one bar to the other, whereas the trackball scrolls through the images of the selected bar.

**PLAY** shows the sequence of stored images in cine mode: **MyLab** displays single cardiac cycles (when the ECG is active) or second intervals (when the ECG is off). Use the trackball to scroll along the bar and display another cycle/interval whose duration can be changed using the **CLIPS DUR** toggle.

**SPEED** shows the sequence at different speeds.

ACQUIRE key saves the displayed clip in Retrospective Mode.

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

## Exam Review

During the exam, the EXAM REVIEW tab enables reviewing of the saved images and sequences. When the tab has been pressed, the trackball automatically changes to pointer mode, allowing the operator to scroll through the thumbnails and select the item to be reviewed. Alternatively press the POINTER key, select the thumbnail and press ENTER to confirm: the system 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.

## System Shut Down

**CAUTION**

**This is a PC based system; data loss or driver damage may occur if the system is turned off while working (for example saving data).**

The shut down procedure is always recommended; it is MANDATORY that the operator interrupts any pending PC operation prior to turning the system off. Make sure that no background operations are in progress (archiving media icons are filled with color); this would indicate that there is a pending PC operation, which must be completed, before shutting down the system.

Press the ON/OFF panel key to start the shut down procedure. The system displays a message with a count-down timer: when the time is expired, the system automatically shuts down.

**SHUT DOWN** button confirms the procedure.

**CANCEL** button interrupts the shut down procedure and reactivate the session.

Press the ON/OFF panel key to start the shut down procedure. Press the mains switch placed on the rear panel to turn the system off.

**Note**

If the system isn't correctly shut down, a message will be shown at next switching on.

## Error Messages

Whenever an internal fault occurs, the system automatically freezes and an error message is displayed on the screen. Switch the system 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.

### Power Supply Error Messages

Whenever an error in the management of the power supply occurs, the system 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. The system displays the following message:

| Error #5: overheating!<br>Please, contact the Service department. |
|---|

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

Should the problem persists, contact the Esaote Service department.

**Error #6**

This error indicates that a fan is not working. The system displays the following message:

| Error #6: problem with fan.<br>Please, contact the Service department. |
|---|

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

Should the problem persists, contact the Esaote Service department.

**Error #7**

This error indicates that a fault of the internal voltages occurs. The system displays the following message:

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

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

**Error #8**

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

| Error #8: wrong impulse voltage.<br>Please, contact the Service department. |
|---|

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

Chapter 8



# 8 - eTouch Key

This chapter explains how to use the **ETOUCH** key of the control panel.

## Keys Sequence

**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.

> **Note**
>
> Keys sequences that require interaction with the user (like measurements or pointer positioning) can not be recorded as macro.
>
> The user can not access to system controls and menu whenever a macro is running.

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

Each system configuration is linked only to one customized touchscreen.

## Configuration Menu

The eTouch configuration menu is an option of the **MENU** key. 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.

To access to the configuration menu press:

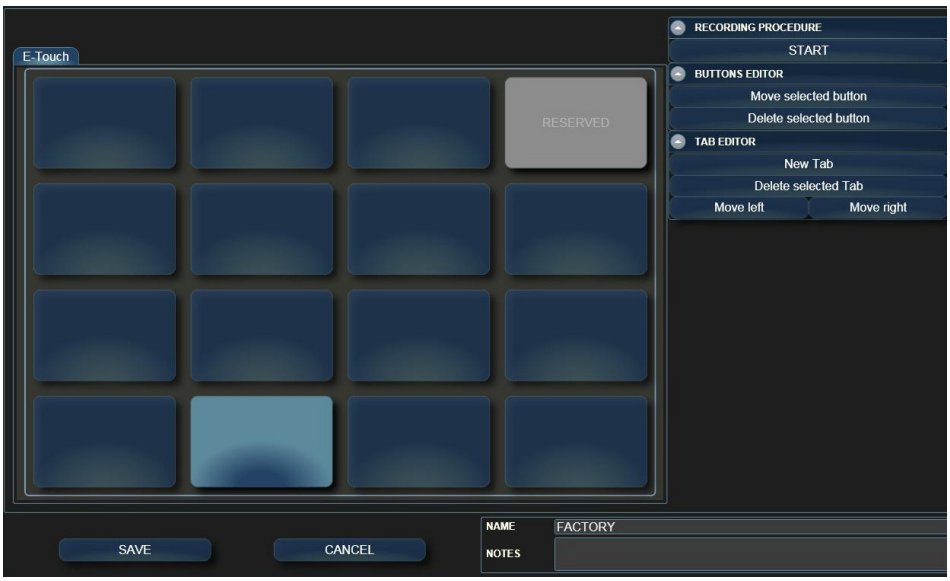
- **EDIT** to modify the customized touchscreen selected with the trackball. Alternatively position the cursor on the desired option and press **ENTER** to select it.
- **CLONE** to duplicate and modify a saved customized touchscreen, always selected with the trackball.

**REMOVE** deletes the selected customized touchscreen.

## How to Create a Customized Touchscreen

The configuration menu shows:

- 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.




**SAVE** saves and activates the settings.

**CANCEL** exits the menu without saving the settings.

To create a customized touchscreen follow this procedure:

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

**Procedure**

- Select the touchscreen to be copied and press the **CLONE** button to add a new customized touchscreen, starting from the selected one.
- Place the cursor on the **NAME** field and using the alphanumeric keyboard enter the desired name and description (**NOTES** field).
- Place the cursor on the **RECORDING** field and press **START** to begin the recording: **MyLab** switches to the frozen status.
- The system 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 the **ETOUCH** key to start.
- Press the desired keys in sequence and press again the **ETOUCH** key 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 Touchscreen Organization

**Customized Buttons Organizations**

The customized button can be freely positioned within the touchscreen.

**Move selected button** changes the button position: select the button with the trackball, place the cursor on the desired position and click **ENTER** to confirm.

**Delete selected button** cancels the button selected with the trackball.

**Tabs 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.

Chapter 9



# 9 - MyLab Settings

This chapter describes the organization of **MyLab** settings and explains how to use them.

## Settings Organization

**MyLab** has two groups of settings:

- System Settings,
- Clinical Settings (or Presets).

**System Settings**

**MyLab** system configuration defines the equipment general parameters. One system configuration (or system profile) is identified by the settings of the following items:

- General configuration, like measure units, control panel setting,
- Center ID to set the name of the center,
- Licence settings,
- Report style configuration,
- Observations configuration,
- Printers configuration,
- Network configuration,
- DICOM configuration,
- End exam saving configuration,
- Exam export configuration,
- Security configuration.

**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.

📖 ***AO***

Refer to the "Advanced Operations" manual for detailed information on which user profile can access to preset modification and how to create and set system configurations.

**Clinical Settings**

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. **MyLab** allows the user to save several clinical settings for each probe in each application.

📖 ***GS***

See next chapter for further information on clinical settings.

## How to Use MyLab Settings

**Use of System Settings**

When more system configurations are set, **MyLab** displays at every start up the window allowing to select a configuration.

> **Note**
>
> To activate the set system configuration, the user needs to restart **MyLab**.
>
> The system profile in use is displayed in the main menu (**MENU** key).

Once the desired configuration has been loaded, the system automatically uses the settings defined for hospital, printers, network and so on.

**Use of Clinical Settings**

All saved clinical settings are displayed in the Probe/Application/Preset touchscreen, under the "PRESET" area. The active probe defines which presets are available. Clinical settings can be changed within the same exam at any time by using the PROBE button.

*Preset area*

.


Once the desired configuration has been loaded, the system automatically uses the selected settings.

Chapter 10



# 10 - MyLab Clinical Settings

This chapter describes how to create clinical settings, usually named "Preset".

## Definition of Clinical Settings

One clinical setting is identified by the settings of the following parameters:

- real time exam controls,
- measurement configuration,
- bodymark configuration,
- annotation configuration,
- eTouch configuration.

This means that the preset, selected at the beginning of the exam or during the exam by using the PROBE button, 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.

**Note**

When licenced, advanced tool configurations (such as 3D/4D settings, Stress Echo protocols) are part of the clinical settings. Refer to the dedicated sections of this manual for further information on these tools.

## How to Create Clinical Settings

To create a new preset or modify an existing preset, follow the procedure below that is organized in two phases, an on-line phase followed by an off-line phase.

In the on-line phase the operator sets the parameters that optimize the real time image in all modes and creates the customized preset; in the off-line phase the

operator adds the desired measurement configuration, annotation and bodymark libraries and eTouch configuration to the customized preset.

**On-Line Phase Procedure**

- Adjust the real time image as desired in all modes (2D, CFM and Doppler).
- Press the PROBE button and then select 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.

**Note**

The parameter set for the **POWER** control in B-Mode is not saved in the user preset, which keeps for this control the factory value.

**Off-Line Phase Procedure**

- Press the MENU key.
- Select the "RT PRESETS" option.
- The system shows the menu displaying on the left the list of all clinical settings, grouped by probes. Within each probe clinical settings are grouped by applications.
- Using the trackball select the desired clinical setting and press **EDIT**.
- Associate to each parameter (measurement, bodymark...) of the preset the desired configuration.
- Press **SAVE** to confirm.

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 using the PROBE key.

**Note**

The above procedure allows also to assign the default application for each probe independently. Each time the probe is selected its default application is selected as well.



*AO*

Refer the "Advanced Operations" manual for detailed information on how to create and set measurement, bodymark and annotation configurations.

## How to Rename or Delete Clinical Settings

Clinical settings can be renamed and deleted from the dedicated option of the system menu (**MENU** key).

**Procedure**

- Press the **MENU** key and select the option "RT PRESETS".
- The system shows the menu displaying on the left the list of all clinical settings, grouped by probes. Within each probe clinical settings are grouped by applications.
- Using the trackball select the desired preset.
- Press **REMOVE** to delete it.
- To change its name, place the cursor on the "NAME" field and using the alphanumeric keyboard enter the desired name and description ("NOTES" field). Press **RENAME** to confirm.

## Factory Clinical Settings

Factory clinical settings can be retrieved at any time.

**Procedure**

- Press the **MENU** key and select the option "RT PRESETS".
- The system shows the menu displaying on the left the list of all clinical settings, grouped by probes. Within each probe clinical settings are grouped by applications.
- Using the trackball select the desired probe and application.

- Press **FACTORY** to restore the default preset.

**Note**

This operation retrieves all factory clinical settings and **deletes all user clinical settings** saved for that probe/application.

Chapter 11



# 11 -System Maintenance

This chapter describes the main maintenance operations that can be directly done by the system user.

**Note**

Periodic maintenance operations that require the access to the system can be performed only by trained personnel: contact the local Esaote Service for further information on required periodic inspections.

## Inspecting the System

On periodic schedule (or whenever there is a reason to do it) disconnect the system from the power outlet and check:

- all system cables for any cut or damage,
- system housings for any damage,
- connector status,
- LCD and touchscreen status,
- movements of all parts composing the system,
- trackball movement.

Contact Esaote personnel for any problem found during inspection.

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

## Cleaning of System and Peripheral Devices

Periodic cleaning of the system and any connected peripheral devices is important. Peripherals may contain dust on sensitive parts, the reliability of which could be compromised in the event of poor maintenance.

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

## Veterinary Applications

**WARNING**

Due to the specificity of the veterinary working place, Esaote recommends the ultrasound machines used in veterinary applications should be thoroughly cleaned at least once every 6 months. Please contact your Esaote distributor/ dealer for further help in this matter.

**WARNING**

**Turn the system off and unplug it before any cleaning operation.**

### Cleaning the system

To clean the system, use a soft cloth slightly dampened with water. If necessary, apply a small amount of ammonia-free and not abrasive detergent on a clean, soft cloth and then wipe the surface. Switch the system off and rub the outside with the cloth.

**WARNING**

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

**CAUTION**

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

### Trackball

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

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

The X-series trackballs contain two 855 nm semiconductor lasers. The device is designed such that it fulfills laser safety class 1M regulations according to IEC60825-1 edition 1.2, 2001-08'.

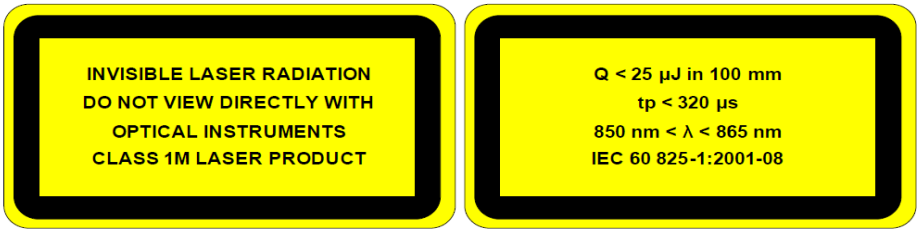
The laser radiation emitted is invisible to the human eye.

Although not considered harmful, staring into the beams is not advised. Staring into the beams by means of optical aids such as eye loupes, magnifiers, microscopes, lenses or other optical means within a distance of 100 mm might cause permanent damage to the human eye.

**WARNING**

**Invisible laser radiation. Do not view directly with optical instruments. Class 1M laser product.**

**Do not remove the ball from the socket.**




**CAUTION**

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

**Cleaning Probe and Gel Holders**

Probe and gel holders are easily removed 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".

**Touchscreen**

To clean the touchscreen, 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.

**WARNING**

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

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

**LCD**

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.**

**To clean 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.**

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

Chapter 12



# 12 - Technical Specifications

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

**Note**

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

## MyLab Characteristics

**MyLab** models differ for default installed licences 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.

### Applications

**MyLab** systems can be equipped with the following application licenses:

| License | Application | Features |
|---|---|---|
| Cardiac Vet | Cardiac for Canine, Feline, Equine, Bovine and Other species. | Presets, Calculations, ECG |
| General Imaging Vet | Abdominal for Canine, Feline, Equine, Bovine and Other species. | Presets, Calculations |
| Reproduction Vet | Reproductive for Canine, Feline, Equine, Bovine, Porcine, Ovine, Caprine and Other species. | Presets, Calculations |
| Musculo Skeletal Vet | Equine Tendon | Presets |

### Modes

**MyLab** models can be licensed for the following modes:

| License | Description | Features |
|---|---|---|
| Doppler | Doppler | Includes Duplex |

1. The specifications can be modified without prior notice.

| License | Description | Features |
|---|---|---|
| CFM | Color (Color Flow Mapping) | With Doppler includes Triplex |
| TVM<br>Cardiac license required | Tissue Velocity Mapping | In Cardiac application; Probe dependent |
| CMM | Compass M-Mode | - |
| MView | MView | Probe dependent |

The CFM license requires prior installation of the Doppler license.

## Additional Features

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

| Licence | Feature | Note |
|---|---|---|
| DICOM | DICOM Classes[a] | - |
| Stress Echo | Stress Echo analysis | Cardiac license |
| VPan | Panoramic View (probe dependent) | Probe dependent |
| Wireless | Wi-Fi connection | - |
| Needle Enhanced Imaging | Increases the needle brightness | Probe dependent |
| Libraries | Tool providing information and suggestions | - |
| Library viewer | Tool providing information and suggestions | - |
| Live preview | Real-time image inside library environment | Library viewer licence required |
| Probe's button License | Management of probe buttons. | For SL3323, SL3235) |

a. Refer to www.esaote.com for further details on supported DICOM classes.

**Note**

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



# MyLab Technical Characteristics

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

## Display

- Built-in color LCD, WXGA resolution
- 8.9" LCD (touchscreen)

## Probe connectors

- 2 electronic probes

## Video Output

- HDMI type [1]

## Connectivity

- I/Os connectors
  - LAN RJ45
  - 4 USB
  - Wi-Fi
- Dedicated connectors
  - ECG input
- Other
  - Laser/Ink jet printers
- Complies with IHE integration profiles[2]

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

## 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 Embedded Standard
- Multi-lingual

## Biometry

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

## Keyboard

- Control panel:
  - Touchscreen TGC
  - Touchwheel for general gains
  - Keys for modes, peripherals management and controls
- Reconfigurable touchscreen LCD

## Power Cables

| | Device Socket | Plug | Cond. # | Sect. | Length |
|---|---|---|---|---|---|
| **CEE Plug (EU)** | IEC 60320/C13 type; 10A-250V | CEE (7/7) type; 16A-250V | 3 | 1.5 $mm^2$ | 4,6 m |
| **CEI Plug (IT)** | EN 60320/C13 type; 10A-250V | CEI 23-16 type; 10A-250V | 3 | 1.5 $mm^2$ | 5 m |
| **NEMA Plug (USA)** | IEC 60320/C13 type; 15A-125V | NEMA 5-15P (Hospital grade); 15A-125V | 3 | AWG 14 | 3,05 m |
| **IRAM Plug (AR)** | EN 60320/C13 type; 10A-250V | IRAM 2073:1982 10A-250V | 3 | 1.5 $mm^2$ | 5 m |
| **SEV Plug (BR)** | EN 60320/C13 type; 10A-250V | SEV 1011 10A-250V | 3 | 1.5 $mm^2$ | 5 m |
| **AS/NZS Plug (AU)** | EN 60320/C15 type; 10A-250V | AS/NZS 4417 10A-250V | 3 | 1 $mm^2$ | 2.5 m |
| **NEMA Plug (JP)** | IEC 60320/C13 type; 15A-125V | NEMA 5-15P 15A-125V | 3 | 2 $mm^2$ | 2.5 m |
| **GB Pug (CN)** | EN 60320/C15 type; 10A-250V | GB 15934-2008 16A-250V | 3 | 1.5 $mm^2$ | 2.5 m |
| **BS Plug (UK)** | EN 60320/C15 type; 10A-250V | BS 1363 UK13 13A-250V | 3 | 1.5 $mm^2$ | 4.6 m |

## Dimensions

- Closed: 34.6 (L) x 12.2 (H) x 44.6 (D) cm
- In working position: 34.6 (L) x 36.6 (H) x 44.6(D) cm

## Weight

- approx. 9 kg (basic configuration with batteries)

## AC/DC Adapter(151004300)

- Input:
  - Voltage: 100 ÷ 240 Vac
  - Current: 2.2 A
  - Frequency: 50/60 Hz
- Output:
  - Voltage: 19 Vdc
  - Current: 9.47 A
  - Power: 180 W

## Batteries(140019400)

- 2 Batteries for standard working condition and standby
- Batteries charger inside
- Battery life: 3 years
- Esaote p/n 140019400, *manufactured by INSPIRED ENERGY L L C (http://inspired-energy.com/), P/N nh2034hd31.*
- Nominal operating voltage is 14.4V
- Approx. 90 min of operating time
- Charging time system off: approx. 2h50min.
- Charging time system on: approx. 3h20min
- Storage Temperature Limits: -20°C to 60°C, ≤80%RH
- Weight per battery Approx. 0.97lbs. (0.435Kg).

## Operating Requirements

- Temperature: 15 ÷ 35°C
- Humidity: 20 ÷ 90% (not condensing)
- Pressure: 700 ÷ 1060 hPa

## Storage requirements

- Temperature: -20 ÷ 60°C
- Humidity: 5 ÷ 85% (not condensing, -20 ÷ 40°C); in the range 40 ÷ 60°C the max allowed humidity decreases from 85% at 40°C to 27% at 60°C
- Pressure: 700 ÷ 1060 hPa

### Optional Footswitch(140001000)

- 3 programable pedal switches
- Cable: 2.8m long, USB connector (type A)
- Electrical Characteristics: 5V DC 50mA
- Waterproof IPX8

## Standards

| Standard | Title |
|---|---|
| IEC 60601-1:2005 and its amendments AMD1:2012 /COR1:2014<br>EN 60601-1:2006 and its amendments A1:2013/ C1:2014 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2007<br>EN 60601-1-2:2007 | Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard: Electromagnetic compatibility - Requirements and tests |
| IEC 60601-1-6<br>EN 60601-1-6 | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability |
| IEC 60601-2-37<br>EN 60601-2-37 | Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment |
| IEC 61157<br>EN 61157 | Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment |
| IEC 62366<br>EN 62366 | Application of Usability Engineering to Medical Devices |
| IEC 62304<br>EN 62304 | Medical device software - Software life cycle processes |
| ISO 14971 | Medical equipment - Application of risk management to medical devices. |
| ISO 15223-1 | Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements |
| ISO 10993-1 | Biological evaluation of medical devices - Evaluation and testing |

| Standard | Title |
|---|---|
| AIUM/NEMA UD2 | Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. |
| AIUM/NEMA UD3 | Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment. |

# Directive

**MyLab** complies with the Radio equipment and Telecommunications Terminal Equipment (R&TTE) Directive.

# Probe

## Storage Requirements

- Probe storage requirements are indicated in the probe case.

# Trolley (150000024) Technical Characteristics

## Dimensions

- Height: approx.: Min. 830 - Max. 1130 mm
- Base dimensions: approx. 580 (D) x 550 mm (W), 4 swiveling wheels
- Printer tray: approx. 220 (L) x 330(W)
- Compartment for additional accessories: 250 (L) x 350 (W)

## Weight

- Max. weight of the trolley: 63.5 kg (incl. all options)
- Trolley stand-alone approx. 23.5 kg

## Scanner Console (150000021)

- 2 large probeholders
- 2 small probeholders

- 2 rails for dedicated holders.

## Optional Insulation transformer (150000018)

- Please refer to the guide and usermanual included with the insulation transformer.

## Optional UPS 230V (150000017)

- Please refer to the guide and usermanual included with the UPS

## Optional UPS 120V (150000019)

- Please refer to the guide and usermanual included with the UPS

## Optional mains filter (140021300)

- Mains in:100-240V~
- Frequency:50-60Hz
- Max Current:10A
- Fuses:2x T 10AH, 250V 5x 20mm
- Mains out:100-240V~
- Frequency:50-60Hz
- Max Current:10A
- Dimensions: 152.4x82.4x47.75 mm (LxWxH)