Creativity in Healthcare

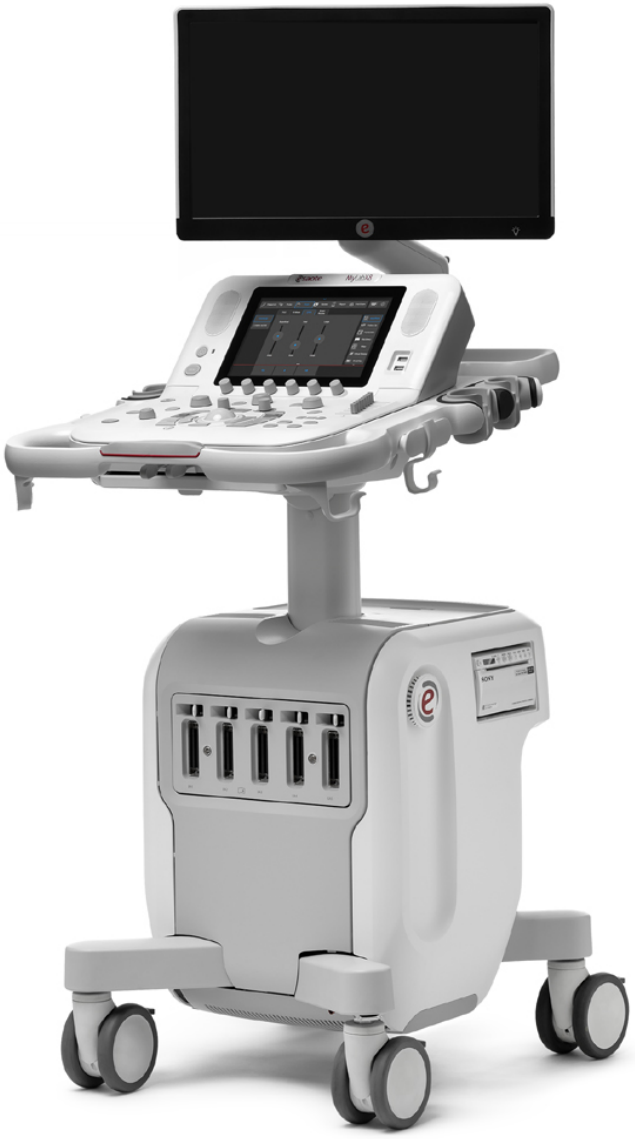
Rev. 13

June 2023

MyLabX8
MyLabX8 eXP

GETTING STARTED

350031600



Manufacturer's Address

Esaote S.p.A.

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info@esaote.com

www.esaote.com

Compliance Information

MyLab ultrasound scanners are CE marked and comply with:

- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 and successive amendments — Medical Device Regulation (MDR). The devices are in Class IIa according to this Regulation.
- Directive 2014/53/EU and successive amendments — Radio Equipment Directive (RED). The devices are in Class 2 according to this Directive.

List of products described in the present manual and CE marked under MDR		
Basic UDI-DI	**Model name**	**First Serial Number MDR**
805630445ESA.US0000004.Y4	**MyLabX8**	9100001
	MyLabX8 eXP	9200001

MyLab devices with Serial Number below the first Serial Number MDR listed in the table above have been placed on the market under the MDD CE certificate.

Unauthorized modification of the product or configuration invalidates the CE Marking.

You can find copy of Declaration of Conformity on Esaote web site.

For other countries, please contact your local distributor.

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

In this manual, all the above mentioned devices can be also referred as **MyLabX8 Family** or **MyLab**.

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

Copyright and Trade Marks

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1. INTRODUCTION

MyLabX8 Family devices are supplied with a set of manuals to provide all necessary and sufficient information to operate the device safely and effectively.

The complete set of manuals is composed by:

- **Essential Instructions for Use** - describes the basic information you need to operate with **MyLab** and information on foreseeable medical emergency situations.
- **Getting Started** (this manual) - describes how to install **MyLab** and provides the main instructions for using it.
- **Probes and Consumables** - provides detailed instructions for using and reprocessing **MyLab** probes and their parts.
- **System Data** - provides data on probe temperatures and acoustic output for each probe and mode of operation.
- **Advanced Operations** - provides advanced instructions to use **MyLab** and includes the following sections:
  - Advanced Features,
  - Image Optimization,
  - Measurements,
  - Archiving.
- **Optional Sections** - additional sections to describe specific features.

NOTE

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

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

The manuals can refer to:

- **MyLabX8 Family** when the contents are relevant only to this family, or
- **MyLab** when the contents are common to the other ultrasound scanners belonging to the **MyLab** platform.

This manual revision applies to release 26. xx. yy and subsequent maintenance releases, depending on the Country and the respective clearances.

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

NOTE

Technology and features are device/configuration dependent.

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

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

NOTE

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

1.1. Intended audience

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

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

1.2. Disclaimer

MyLab is designed for Ultrasound practitioners.

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

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

Special attention should be dedicated to intra-cavitary probes (e. g. vaginal, rectal or oesophageal probes). They should be cleaned according to established protocols (AIUM guidelines for cleaning probes) and should not be used if there is noticeable self-heating of the

probe when operating in air. Particular care should be taken if trans-vaginal probes are to be used to investigate a pregnancy during the first 10 weeks after LMP.

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

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

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

WARNING

The exam backup is the correct procedure in order to preserve the data.

For more detailed information please consult:

- Guidelines For Professional Ultrasound Practice. Society and College of Radiographers and British Medical Ultrasound Society. December 2022

  https://www. sor. org/getmedia/d4920fb9-043c-47a0-b425-d3545aea73b0/SoR-and-BMUS-guidelines-2022-7th-Ed-docx

- AIUM guidelines for cleaning probes.

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

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

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

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

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

1.3. Device use

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

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

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

1.4. Manual Conventions

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

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

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

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

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

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

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

WARNING

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

CAUTION

In this manual CAUTION describes the precautions necessary for protecting the equipment.

NOTE

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

CONTRAINDICATION

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

1.5. Manufacturer's Responsibility

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

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

1.6. Product Life Cycle

1.6.1. Life Time

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

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

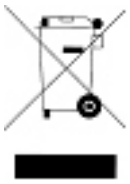
When approaching the seven (7) years limit from the purchase date, it is recommended to contact Esaote Service or to visit Esaote web site (www. esaote. com), to get updated information on the product's end of life and/or to agree on the most suitable solution for its safe disposal.

1.6.2. Maintainability Time

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

1.6.3. End-of-Life Disposal

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



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

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

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

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

1.7. Usage License Agreement for the Software Included in the Apparatus

NOTE

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

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

1.7.1. Proprietary Rights

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

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

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

1.7.2. 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.

1.7.3. 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.

1.8. Product Traceability

To guarantee the product traceability according to requirements of the standard EN ISO 13485:2016, and the European Directive on Medical Devices 93/42/EEC (1993) and subsequent amendments, original owners, in the event of equipment transfer to third parties, are requested to notify Esaote S.p.A., associate company or authorized distributor of the said transfer by means of the following form, duly compiled, or written notification with the same data as specified in the form. Equipment data are found on the relative identification label.

1.8.1. Product Traceability Form

PRODUCT TRACEABILITY FORM

To: Esaote S.p.A.

Quality Assurance Department

Via Enrico Melen, 77

16152, Genova, Italy

[or associate company]

[or authorized distributor]

Device name:.....

REF.....

Serial Number (SN):.....

Name and address of original owner:

.....

.....

Name and address of new owner:

.....

.....

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

1.9. Vigilance System

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

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

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

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

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

1.9.1. Vigilance System Form

POST-MARKET SURVEILLANCE FORM

ACCIDENT REPORT FORM

To: Esaote S.p.A.

Quality Assurance Department

Via Enrico Melen, 77

16152, Genova, Italy

[or associate company]

[or authorized distributor]

[and competent authorities]

Device name:.....

Code (REF):.....

Serial Number (SN):.....

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

.....

Comments or suggestions:.....

.....

Contact Person/Department:

.....

Address:

.....

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

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

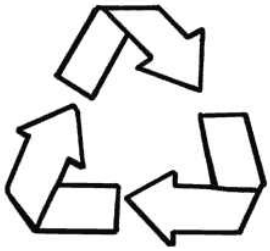
2

2. INFORMATION ON SAFETY

This chapter provides general safety information for your **MyLab**, read this information before using it.

2.1. Environmental Safety

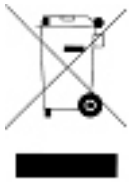
2.1.1. Information about Reusing/Recycling



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

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

2.1.2. Special waste



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

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

2.1.3. Exam Waste

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

2.2. Electrical Safety

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

Observe the following warnings for maximum safety.

WARNING

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

WARNING

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

WARNING

Electrical shock hazard. Do not remove any cover. Refer servicing and internal adjustments to qualified Esaote personnel only.

CAUTION

Do not replace the system fuses with different types from those specified in the manual.

2.3. Electromagnetic Compatibility

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

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

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

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

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

- relocating the ultrasound device,
- increasing the distance from other devices,
- powering the ultrasound device from an outlet different from the one of the interfering device,

- contacting Esaote Service personnel for help.

CAUTION

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

CAUTION

Portable and mobile RF communication equipment may cause interference with the ultrasound device. Do not use these equipments closer than 30 cm (12 inches) to any part of MyLab, including cables.

NOTE

Sensitivity to interference is more noticeable in Doppler modes.

Electro-Surgical Devices (ESUs)

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

WARNING

While using MyLab in combination with HF (high frequency) surgical devices, be aware that a failure in the surgical device or a damage of the transducer lens can cause electro-surgical currents that can burn the patient. Thoroughly check MyLab and the probe before applying HF surgical currents to the patient. Disconnect the probe when not imaging.

WARNING

Electro Surgical Units intentionally emit Radio Frequency ElectroMagnetic fields. Severe noise can impair the image and the Doppler trace.

2.3.1. Electromagnetic Emissions

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

WARNING

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

NOTE

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

2.3.2. Essential performance

- Free from noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis.
- Free from the display of inaccurate numerical values associated with the diagnosis to be performed.
- Free from the display of inaccurate safety-related indications.
- Free from the production of unintended or excessive ultrasound output.

- Free from the production of unintended or excessive transducer assembly surface temperature.
- Free from the production of unintended or uncontrolled motion of transducer assemblies intended for intra-corporeal use.

2.3.3. 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.

2.3.3.1. Electromagnetic Immunity for All Medical Equipment

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

2.3.3.2. Electromagnetic Immunity for Medical Equipment not Life Supporting

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

Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment and Measures to Be Taken
Conducted RF IEC 61000-4-6	3 V0.15-80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V0.15-80 MHz 6 V in ISM band between 0.15 MHz and 80 MHz 80% AM at 1 kHz	Mobile or portable radio frequency (RF) communication equipment should be used no closer to any part of **MyLab**, including cables. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m80 MHz - 2.7 GHz 80% AM at 1 kHz	3 V/m80 MHz - 2.7 GHz 80% AM at 1 kHz	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2.3.3.3. Recommended Distances between Radiofrequency (RF) Communication Systems and Ultrasound Scanner

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

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

The following degradation shall not be allowed:

- the disturbance shall not produce noise on a waveform, artefacts, distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis;

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

- the disturbance shall not produce an error displaying inaccurate numerical values associated with the diagnosis to be performed;
- the disturbance shall not produce an error displaying inaccurate safety-related indications;
- the disturbance shall not produce unintended or excessive ultrasound output;
- the disturbance shall not produce unintended or excessive transducer assembly surface temperature.

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

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

2.4. Patient's Safety

WARNING

Remove probes and electrocardiography leads from patient contact before applying a high voltage defibrillation pulse.

NOTE

Improper use of MyLab can result in serious injury.

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

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

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

NOTE

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

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

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

2.5. Operator's Safety

2.5.1. Work related musculoskeletal disorders

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

WARNING

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

2.5.2. Repetitive Strain Injury

In the category of occupational diseases, musculoskeletal disorders have been reported by the clinical literature[3] as a result of repetitive scanning. These musculoskeletal disorders are also referred to as Repetitive Strain Injury (RSI). To prevent the risk of RSI, it has been recommended:

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

3. Necas M. "Musculoskeletal symptomatology and Ripetitive Strain Injuries in Diagnostic Medical Sonographers", Journal of Diagnostic Medical Sonography 12, p. 266-273, 1996 Pike I, Russo A., Berkowitz J et al. "the prevalence of musculoskeletal disorders among Diagnostic Medical Sonographers", Journal of Diagnostic Medical Sonography 13, p. 219-227, 1997

2.5.3. Working with Video Display

Scanning can require long sessions in front of a screen. Consequently visual problems such as eyestrain and irritation can result [4]. Visual discomfort is reduced when the following recommendations are observed:

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

2.6. Biocompatibility and Infection Control

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

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

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

2.6.1. Items in Contact with Patient

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

2.6.1.1. Latex Sensitive Patient

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

WARNING

The protective probe covers may contain natural rubber latex which may cause allergic reactions: refer to the protective cover labeling to identify whether the product contains latex. Make sure to identify latex sensitive patients before starting the exam. Serious allergic reactions to latex have been reported and the user should be ready to react accordingly (for further information refer to the FDA Medical Alert MDA91-1, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

NOTE

Esaote probes do NOT contain latex.

4. See for example OSHA 3092 "Working safely with video terminals display" 1997

2.6.2. Ultrasound Scanner Drapes

Ultrasound scanner drapes are available on the market in a range of sizes and configurations to be placed over device helping to prevent the transfer of microorganisms, body fluids, and particulate material to the patient and healthcare worker and protect the integrity of the equipment.

Use of drapes with **MyLab** is allowed but you have to pay special attention the drapes do not cover fans: incorrect ventilation may cause overheating and unexpected shut-down.

WARNING

The usage of plastic drapes can be applied only on Ultrasound Mobile devices with the precaution not to cover any fan of the device to avoid overheating and consequent damage. Do not apply on Ultrasound Portable devices, unless they are put on a cart. In any case the device must be switched off and plastic drapes have to be removed and disposed of as soon as the examination is completed, according to the relevant local guidelines.

WARNING

The operator has to pay attention not to obstruct the cooling air access of the device and can contact the Esaote support for further information about their localization.

WARNING

The operator has to pay attention not to cover the screen in a way that reduces the view for the ultrasound image. This may reduce the quality of the study and increase scan duration. Similarly, the keyboard should be fully operative during the investigation.

2.7. Device Modifications

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

CAUTION

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

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

2.8. Explosive Hazard

WARNING

MyLabX8 is not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide. Do not use MyLabX8 in the presence of flammable anaesthetics. Explosion is a hazard under such conditions.

2.9. Wireless safety

MyLab is equipped with built-in wireless capability.

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

NOTE

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

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

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

- Maintain a minimum distance of 20 cm (8 inches) or more from the antennas of the equipment and the body of patient and operators. If a shorter distance is needed to work, temporarily switch the wireless device off.
- Use in specific environments:
  - the use of wireless devices in hospitals is restricted to the limits set forth by each hospital.
  - the use of wireless devices in hazardous locations is limited by the constraints posed by the safety directive of such environments.

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

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

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

CAUTION

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

2.9.1. Users in the European Union

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

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

NOTE

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

2.9.2. Users in the United States of America

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

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

Operation is subject to the following two conditions:

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

2.9.3. Users in Australia

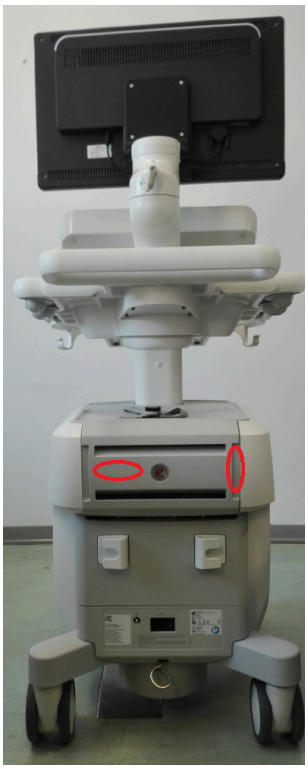
N28711

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

2.9.4. Wireless antenna position

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

Fig. 2–1 Wireless antenna position on MyLabX8 Family



3

3. MYLAB OVERVIEW

MyLabX8 Family devices are professional, innovative and versatile real-time high-resolution ultrasound scanners. The wide range of probes makes them suitable for many clinical applications.

MyLabX8 Family devices are based on a mainframe easily movable platform. **MyLabX8 Family** devices have four swivelling wheels, they have a range of height adjustments for one-time installation, the main screen can be easily moved due to an optional articulated arm. Due to their small footprint they can fit in any real-world clinical environment.

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

3.1. About the device

3.1.1. Intended Purpose

The multifunctional **MyLabX8 Family** ultrasound scanners are used to collect, display, and analyze ultrasound images during ultrasound imaging procedures in combination with supported echographic probes.

Table 3–1 Intended Purpose

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

NOTE

Invasive access is referred to the ultrasonic device in combination with the supported ecographic probes in respect of the MDR Annex VIII, Point 2.1 - 'Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

3.1.2. Patient population

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

3.1.3. Intended users

MyLab is designed for Ultrasound practitioners.

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

The operator must have read and understood the user manuals.

3.1.4. Implementing Rules

The ultrasonic diagnostic equipment is an active device intended for diagnosis and monitoring, through the application of ultrasound energy for imaging purposes. It is not intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient and it is not intended for diagnosis in clinical situations where the patient is in immediate danger. According to Annex VIII, Rule 10, it is in Class IIa.

The device integrates embedded SW that is intended to provide information used to take decision with diagnosis or therapeutic purpose and it is not intended to

- take decisions with diagnosis or therapeutic purposes including the ones may have an impact that may cause death or an irreversible deterioration of a person's state of health or a serious deterioration of a person's state of health or a surgical intervention,
- monitor physiological processes.

According to Annex VIII, Rule 11, it is in Class IIa.

As for the IMDRF/SaMD WG/N12FINAL:2014 the multifunctional ultrasound scanner **MyLabX8 Family**, as above defined in the implementing rules paragraph, results in the following categories.

Significance of information provided by SaMD to healthcare decision

To drive clinical management

The device, as well as its embedded software, is intended to aid the ultrasound practitioner in diagnosis to guide next diagnostics or treatment interventions and to aid to early identify signs of a disease or conditions.

To treat and to diagnose

The device, as well as its embedded software, is NOT intended to diagnose or provide therapy to a human body alone or in combination with medical device, medicinal, actuators or other means.

To inform clinical management

The device, as well as its embedded software, is NOT intended to inform of options for treating, diagnosing, preventing, or mitigating a disease or condition and NOT to provide clinical information by aggregating relevant information.

Healthcare Situation or Condition

Non-Serious situation or condition

The device, as well as its embedded software, is intended to operate in situations or conditions where an accurate diagnosis and treatment is important but not critical for interventions to mitigate long term irreversible consequences on an individual patient's health condition or public health. The device, as well as its embedded software, is intended to operate in NOT urgent situations where time is NOT crucial to improve or stabilize individual patient's health condition or public health by timely diagnosis or treatment.

Critical situation or condition

The device, as well as its embedded software, is NOT intended to operate in situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health and its intended target population is NOT fragile with respect to the disease or condition.

Serious situation or condition

The device, as well as its embedded software, is NOT intended to operate in situations or conditions where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions or timely interventions are important to mitigate long term irreversible consequences on an individual patient's health condition or public health. The device, as well as its embedded software, is NOT intended to be used by lay person.

Appling these criteria to the MDCG 2019-11, Annex III - Usability of the IMDRF risk classification framework in the context of the MDR, we can state that in combination of Medium (drives clinical management) and Non Serious (situation or condition) the device is confirmed in class IIa.

3.1.5. Contraindications

MyLab is not intended for:

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

WARNING

Do not use MyLab for ophthalmic or transorbital applications.

The ultrasound beam must not be directed to the eyes.

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

The above contraindications are related to the **MyLab**.

Contraindications related to imaging ultrasound applications are reported in Appendix C *Ultrasound Residual Risks*.

3.1.6. Intended clinical benefits

Ultrasound is a diagnostic medical procedure that uses high-frequency sound waves to produce dynamic visual images of organs, tissues or blood flow inside the body. Ultrasounds come with several benefits:

- They are typically painless and require no needles, injections or incisions of any kind to be performed.
- Patients are not exposed to any radiation, making the procedure safer than X-rays or CT scans.

  Thanks to its non-ionizing nature, it is a good choice for imaging when radiation-sensitivity is a concern, such as in pediatrics or in women of child-bearing age.

  There are no known harmful effects of ultrasounds when they are performed properly.
- Ultrasounds can capture soft tissue images that do not show up well on X-rays.
- Ultrasounds can be used to examine many parts of the body, such as the abdomen, heart and blood vessels, breasts, muscles, carotid arteries, and female reproductive system including pregnancy and prenatal diagnostics.
- Ultrasounds are widely accessible and generally less expensive than other diagnostic methods.

3.1.7. Medical conditions

Multifunctional ultrasound scanners are medical imaging diagnostic tools that can help a physician evaluate, confirm, and diagnose many different medical conditions. Some of these include:

- Pregnancy: Ultrasounds can help determine a due date or reveal the presence of multiple children, bur they can also detect potential birth defects, placental issues, and other problems before birth.

- Diagnostics: Doctors can use ultrasounds to diagnose conditions, including those in the heart, blood vessels, liver, gallbladder, spleen, pancreas, kidneys, bladder. uterus, ovaries, eyes, thyroid, prostate, and testicles.

However, Ultrasound waves do not transmit well through dense bones or parts of the body that hold air or gas. This intrinsic limitation of the technology and patient-specific body habitus may limit in some circumstance its use.

3.2. Clinical Applications and Supporting Probes

A variety of ultrasound probes can be connected to **MyLabX8 Family**.

Table 3–2 Available probes and applications

Probe	Applications/Districts	Biopsy
2CWS	Cardiac, Pediatric Cardiac	NO
5CWS	Vascular	NO
BL433	Abdominal, Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	NO
C 1-8	Abdominal, Gynecology, Musculo-skeletal, Obstetric and Fetal, Pediatric, Urology, Vascular	YES
C 2-9	Abdominal, Gynecology, Musculo-skeletal, Obstetric and Fetal, Pediatric, Urology, Vascular	NO
E 3-12	Gynecology, Obstetric and Fetal, Urology	YES
EC123	Gynecology, Obstetric and Fetal, Urology	YES
IH 6-18	Abdominal, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Vascular	YES
IL 4-13	Abdominal, Breast, Musculo-skeletal, Pediatric, Small Organ, Thyroid, Vascular	YES
IOT342	Abdominal, Musculo-skeletal, Pediatric, Small Organ, Vascular	YES
L 3-11	Abdominal, Breast, Musculo-skeletal, Neonatal, Obstetric and Fetal, Pediatric, Small Organ, Thyroid, Vascular	YES
L 4-15	Abdominal, Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	YES
L 8-24	Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	YES
LP 4-13	Abdominal	NO
LX 3-15	Abdominal, Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	NO
mC 3-11	Abdominal, Cardiac, Neonatal, Obstetric and Fetal, Pediatric, Pediatric Cardiac, Small Organ, Thyroid, Vascular	YES
P 1-5	Abdominal, Adult Cephalic, Cardiac, Pediatric Cardiac, Vascular	NO
P 2-9	Cardiac, Neonatal, Pediatric Cardiac	NO

Table 3–2 Available probes and applications (cont'd.)

Probe	Applications/Districts	Biopsy
P2 5-13	Cardiac, Neonatal, Pediatric, Pediatric Cardiac, Small Organ, Vascular	NO
PX 1-5	Abdominal, Adult Cephalic, Cardiac, Pediatric Cardiac, Vascular	NO
S2MCW	Cardiac, Pediatric Cardiac	NO
S5MCW	Vascular	NO
SB2C41	Abdominal, Gynecology, Musculo-skeletal, Obstetric and Fetal, Pediatric, Urology	YES
SB3123	Gynecology, Obstetric and Fetal, Urology	NO
SHFCW	Vascular	NO
SI2C41	Abdominal, Gynecology, Musculo-skeletal, Obstetric and Fetal, Pediatric, Urology	YES
SL2325	Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	YES
SL3116	Breast, Musculo-skeletal, Neonatal, Pediatric, Small Organ, Thyroid, Vascular	YES
ST2612	Cardiac	NO
TE 3-8	Cardiac	NO
TLC 3-13	Gynecology, Urology	YES

Table 3–3 Available applications and related probes

Application[1]	Probes
Abdominal	BL433, C 1-8, C 2-9, L 3-11, L 4-15, LX 3-15, mC 3-11, P 1-5, PX 1–5, SB2C41, SI2C41 Intraoperative: IH 6-18, IL 4-13, IOT342 Laparoscopic: LP 4-13
Adult Cephalic	P 1-5, PX 1–5
Breast	BL433, IL 4-13, L 3-11, L 4-15, L 8-24, LX 3-15, SL2325, SL3116
Cardiac	2CWS, mC 3-11, P 1-5, P 2-9, P2 5-13, PX 1–5, S2MCW Transoesophageal: ST2612, TE 3-8
Gynecology	C 1-8, C 2-9, SB2C41, SI2C41, Transrectal/Transvaginal: E 3-12, EC123, SB3123, TLC 3-13
Musculo-skeletal[2]	BL433, C 1-8, C 2-9, IH 6-18, IL 4-13, IOT342, L 3-11, L 4-15, L 8-24, LX 3-15, SB2C41, SI2C41, SL2325, SL3116
Neonatal[3]	IH 6-18, L 3-11, L 4-15, L 8-24, LX 3-15, mC 3-11, P 2-9, P2 5-13, SL2325, SL3116
Obstetric and Fetal	C 1-8, C 2-9, L 3-11, mC 3-11, SB2C41, SI2C41 Transrectal/Transvaginal: E 3-12, EC123, SB3123
Pediatric	BL433, C 1-8, C 2-9, IH 6-18, IL 4-13, IOT342, L 3-11, L 4-15,L 8-24, LX 3-15, mC 3-11, P2 5-13, SB2C41, SI2C41, SL2325, SL3116
Pediatric Cardiac	2CWS, mC 3-11, P 1-5, P 2-9, P2 5-13, PX 1–5, S2MCW

Table 3–3 Available applications and related probes (cont'd.)

Application[1]	Probes
Small Organ	BL433, IH 6-18, IL 4-13, IOT342, L 3-11, L 4-15, L 8-24, LX 3-15, mC 3-11, P2 5-13, SL2325, SL3116
Thyroid	BL433, IL 4-13, L 3-11, L 4-15, L 8-24, LX 3-15, mC 3-11, SL2325, SL3116
Urology	C 1-8, C 2-9, SB2C41, SI2C41, Transrectal/Transvaginal: E 3-12, EC123, SB3123, TLC 3-13
Vascular	5CWS, BL433, C 1-8, C 2-9, IH 6-18, IL 4-13, IOT342, L 3-11, L 4-15, L 8-24, LX 3-15, mC 3-11, P 1-5, P2 5-13, PX 1–5, S5MCW, SHFCW, SL2325, SL3116

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

NOTE

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

In some advanced optional feature (i.e. CnTI, QElaXto,...) not all the probes are enabled, refer to Appendix A *Probes used in Optional Features* to find out which probes are enabled for optional functions with your **MyLab**.

3.3. MyLab Components

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

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

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

Fig. 3–1 MyLab components

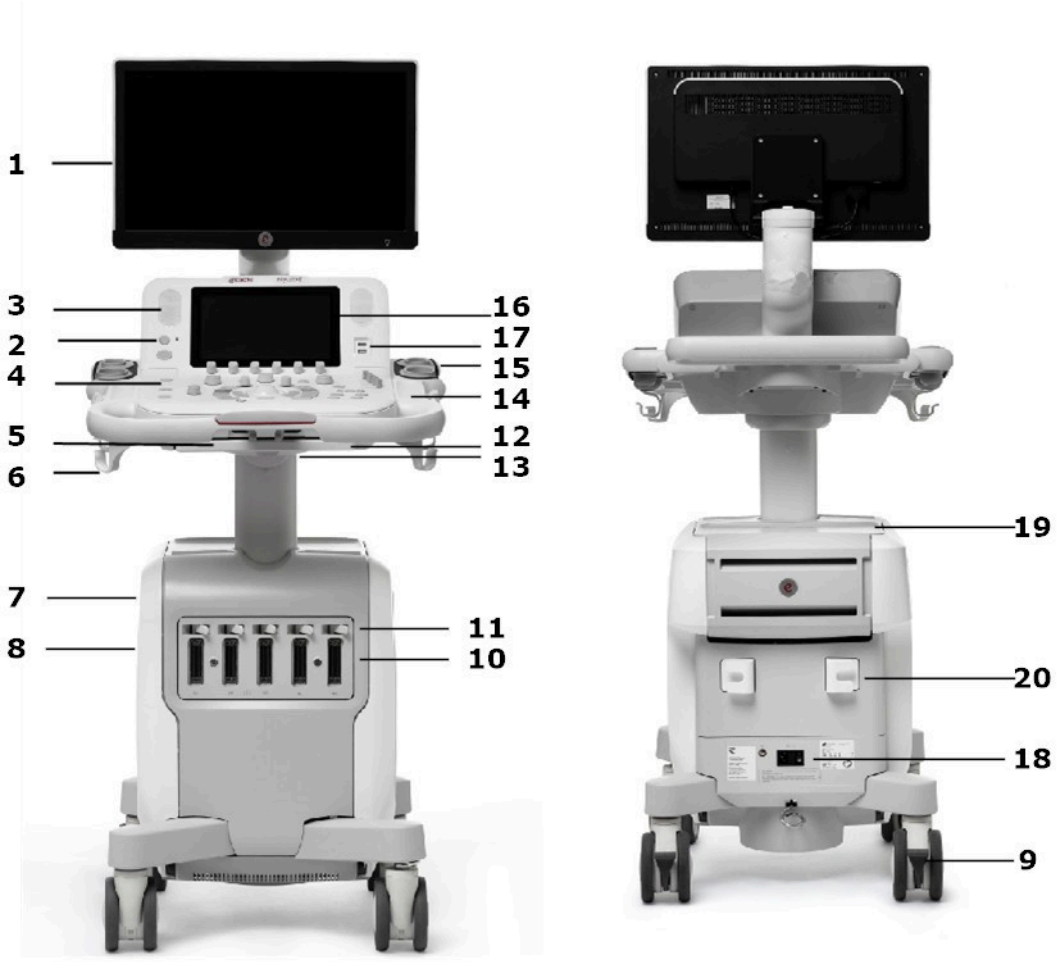


Table 3–4 Components description

Number	Component
1	Monitor
2	On/Off button
3	Loudspeakers (on both sides)
4	Control Panel Assembly
5	Orientation lever
6	Cable hangers
7	Printer slot
8	Connections panels
9	Wheel brake pedal (on each pedal)
10	Probe connectors
11	Probe connector locks
12	Pull-out QWERTY keyboard
13	Lifting lever

Table 3–4 Components description (cont'd.)

Number	Component
14	Gel holder (on both sides)
15	Probe holder (on both sides)
16	Touch screen
17	USB ports
18	Main switch
19	Peripheral plate
20	Power cord hook

3.3.1. Monitor (1)

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

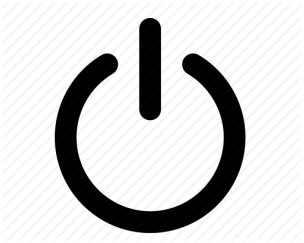
The monitor is suitable for reading medical images, in particular each production unit is calibrated according to the Greyscale Standard Display Function (GSDF) defined in Part 14 of the DICOM medical standard.

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

WARNING

The LCD must be considered an Information Technology (IT) device: it can be safely used inside the patient area only when it is powered through the cart insulation transformer.

3.3.2. On/Off Button (2)



The ON/OFF button is located beside the touchscreen, on the left side of the control panel assembly, while the Main Switch and the power cable socket (18) are located on the rear-bottom of the device.

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

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

Table 3–5 On/Off button light

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

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

Optional Batteries

When **MyLab** is equipped with optional batteries, the same button can be configured in order to place the device in stand-by, partially shutting it down: in this case the initialization phase at start up is significantly reduced.

NOTE

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

3.3.3. Control Panel Assembly (4)

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

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

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

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

Fig. 3–2 Control Panel Assembly

Table 3–6 Control Panel Assembly description

Number	Control Panel Assemble
17	USB Port
3	Loudspeakers
16	Touch screen
22	Knob controls
23	TCG slide controls
24	Trackball

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

3.3.3.1. Control Panel Assembly Orientation

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

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

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

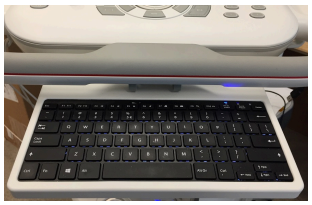
CAUTION

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

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

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

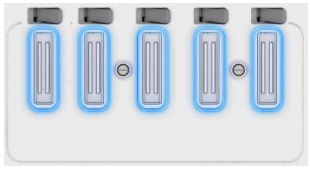
3.3.4. Pull-out Qwerty Keyboard (12)



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

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

3.3.5. Probe Connectors and Cable Management



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

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

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

WARNING

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

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

CAUTION

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

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

3.3.6. Peripherals Housing

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

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

3.3.7. Connections panels (8)

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

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

3.3.8. Wheel Brakes

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

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

3.4. Batteries

MyLab can be equipped with an internal battery pack.

WARNING

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

CAUTION

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

Charge and discharge the battery only when the environment temperature is between 15 ℃ and 30 ℃.

NOTE

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

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

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

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

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

3.4.1. Battery Status

Battery Status LED

The battery LED is located on the control panel.

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

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

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

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

The battery pack is not charged when overheating.

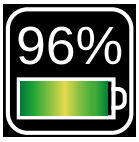
Blinking of the battery LED

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

Battery Status Icons

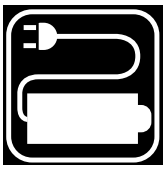
When the battery pack is installed, **MyLab** displays the icons below.

Table 3–7 Battery icons

Fully charged battery	Partially charged battery	Low battery
		

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

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



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

In case of error in the battery management, the icon on the screen is marked with a red "X". Click on the icon to show a dialogue window with details about the error.

3.4.2. First Use

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

3.4.3. Battery Lifetime

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

NOTE

Dispose batteries according to local regulation.

NOTE

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

3.5. Error Messages

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

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

3.5.1. Errors in Battery Management

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

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

Error #1

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

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

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

Error #2

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

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

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

Error #3

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

Error #3: problem with battery charging.

If this situation occurs, close the exam as soon as possible by pressing **END EXAM** and switch **MyLab** off by pressing **ON/OFF** and then the main switch placed on the rear panel. Switch **MyLab** on again and check whether the message is still present. If the problem persists, contact Esaote personnel.

Error #4

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

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

Should this situation occur, contact Esaote Service.

3.5.2. Power Supply Error Messages

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

Error #5

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

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

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

Should the problem persist, contact the Esaote Service department.

Error #6

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

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

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

Should the problem persist, contact the Esaote Service department.

Error #7

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

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

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

Error #8

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

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

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

4. PREPARING FOR USE

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

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

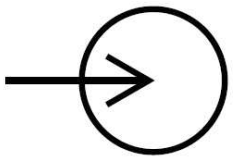
4.1. Acclimation Time

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

Table 4–1 Acclimation Time

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

4.2. Connecting the Device to a Network



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

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

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

4.3. Connecting Peripherals

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

NOTE

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

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

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

How to connect peripheral devices:

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

NOTE

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

NOTE

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

NOTE

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

4.3.1. Safety Concept

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

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

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

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

WARNING

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

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

4.3.1.1. Medical environments

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

Fig. 4–1 A) Patient area

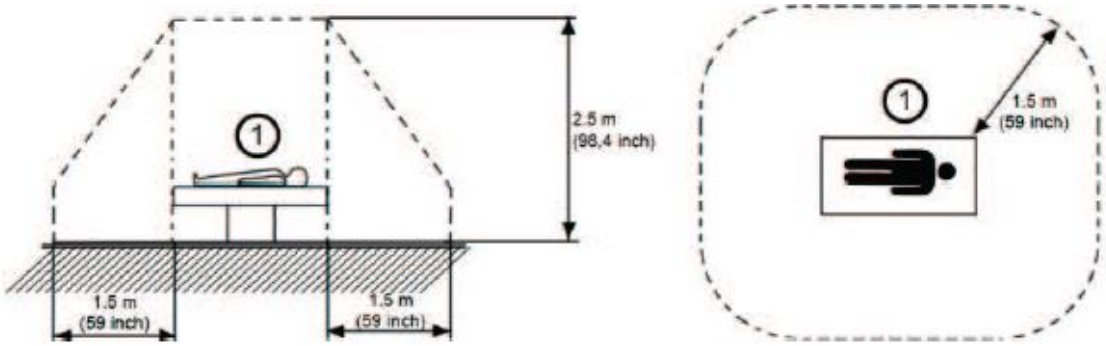
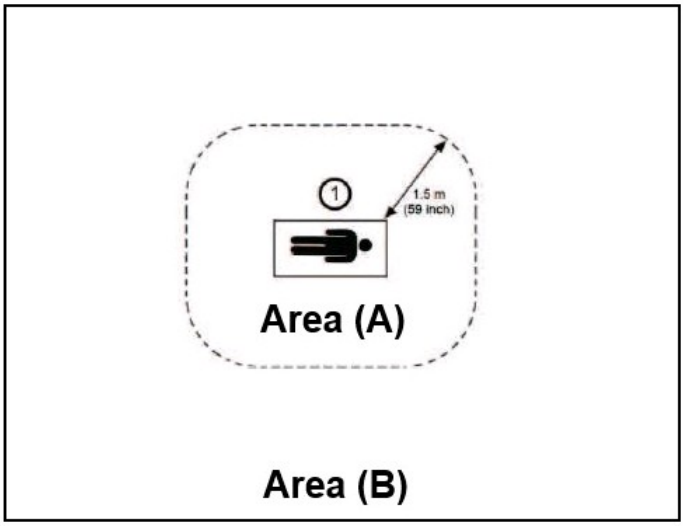
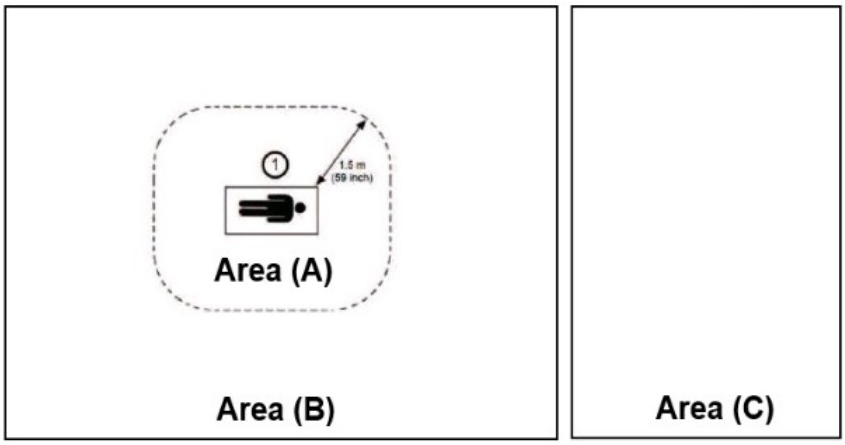


Fig. 4–2 B) Medical Use Room



Intended as area B, area A excluded.

Fig. 4–3 C) Non-medical use room



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

Possible configurations:

- **MyLab** + auxiliary device complying to IEC 60601 in area A

  - No additional safety requirements.

- **MyLab** + auxiliary device not complying to IEC 60601 (complying to IEC XXX[1]) in area A

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

- **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

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

- No additional safety requirements.

- **MyLab** + auxiliary device not complying to IEC 60601 in area B or area C connected by cable (USB, HDMI,...)

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

NOTE

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

Additional safety measures are:

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

Additionally the IEC60601 requires control measurement of leakage currents.

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

WARNING

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

WARNING

Auxiliary device not complying to IEC 60601 connected to MyLab must be powered through a safety insulation transformer complying the IEC 60601 to provide required separation from AC mains for both MyLab and auxiliary device itself.

4.3.2. B/W Thermal Medical USB Printer housing

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

Procedure

1. Open the rear door.
2. Connect both the power and the USB cables to the printer.
3. Insert the printer into the storage area by first introducing the cables.

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

4.3.3. USB Printer housing

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

NOTE

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

CAUTION

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

Procedure

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

WARNING

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

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

CAUTION

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

WARNING

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

WARNING

Epson WF-110W printer:

- **the printer must be connected to the MyLab insulation transformer,**
- **do not use the printer auxiliary battery,**
- **the cover of the auxiliary battery shall never be removed; if the battery cover is open, do not use the printer and contact the Service.**

4.3.4. 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 one of the main display. MyLab automatically shuts down whenever a lower resolution is detected.

Monitor Connection

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

4.3.5. Gel warmer

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

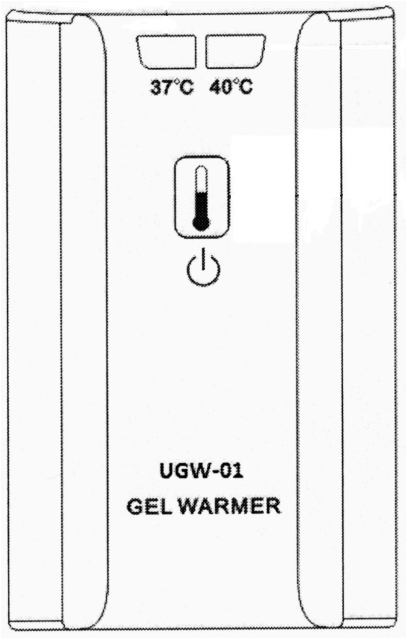
WARNING

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

4.3.5.1. Lifeguard UGW-01 gel warmer

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

Fig. 4–4 UGW-01 front panel



Operation Button

Press the operation button on the front panel:

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

LED Indicators

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

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

4.3.6. External CD/DVD and HDD drives

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

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

WARNING

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

4.4. Moving and Transporting the device

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

WARNING

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

To steadily lock MyLab, all the wheels must be locked when in working position.

Do not park MyLab on a slope.

Avoid any unnecessary mechanical shock to MyLab while moving it.

WARNING

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

WARNING

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

WARNING

Protect the LCD screen (for example with bubble wrap) and place it horizontally, taking care to place something thick (such as foam or bubble wrap) between the control panel and the LCD itself, to avoid any contact between the parts and to avoid screen swing during transportation.

WARNING

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

CAUTION

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

Moving

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

Transporting

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

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

Quick Displacement

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

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

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

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

NOTE

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

NOTE

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

5. USING THE DEVICE

This chapter provides a brief description of the device controls.

Refer to the "Advanced Operations" manual for further detailed information.

5.1. Turning the device On and Off

At the examination site:

1. Place **MyLab** into its final position.
2. Rotate the control panel assembly into its working position.
3. Set the control panel height into a comfortable position.
4. Engage the wheel brakes by pressing the pedals fully down.
5. Position the monitor where you want it.
6. Connect the network and other cables from **MyLab** to the appropriate wall plugs.
7. Plug the cable to a reliable grounding power outlet to assure adequate grounding.
8. Turn the main switch of the rear panel on.
9. Press ON/OFF to turn **MyLab** on.

WARNING

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

NOTE

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

NOTE

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

CAUTION

MyLab is a PC based device; do not turn MyLab off while working (for example saving data) or during the initialization phase: data loss or hard disk damage may occur.

5.2. Device Controls

MyLab controls are located on the Control Panel Assembly that includes the control panel, the touchscreen and the alphanumeric keyboard.

5.2.1. Control Panel Section

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

Table 5–1 Exam Control Buttons

Button	Description
 ETOUCH	Toggles between factory and customized touchscreen that can be created by the user. Refer to the chapter 6 *Customizing the device* further in this manual.
ARCHIVE	Gives access, at any time, to the archived data.
END EXAM	Closes the current exam archiving the patient's data and producing a report on the exam. The device clears the stored data and shows the Exam Start menu again.
CW	Activates the Continuous Wave Doppler (CW). At its pressure the positioning cursor is activated as well.
PW	Activates the Pulsed Wave Doppler (PW). At its pressure the positioning cursor is activated as well. The knob around this button amplifies both CW and PW gains. To increase gain, turn the knob clockwise, to reduce it, turn the knob counter-clockwise.
PD/TVM	Activates the Power Color Doppler or Tissue Velocity Mapping.
C	Activates/deactivates Color Doppler (CFM). The knob around this button amplifies both CFM and Power Color gains. To increase gain, turn the knob clockwise, to reduce it, turn the knob counter-clockwise. In B-Mode, a cursor delimits the Region of Interest (ROI) where color analysis is performed and displayed.
M	Activates the M-Mode and, if necessary, its selection cursor (B-Line).
B	This button re-activates a B-Mode image in real time when any other mode is active. If pressed in M-Mode, Doppler or Freeze, it restores a full screen bi-dimensional image. The knob around this button amplifies both B-Mode add M-Mode gains over the entire depth of the image. To increase gain, turn the knob clockwise, to reduce it, turn the knob counter-clockwise.

Table 5–1 Exam Control Buttons (cont'd.)

Button	Description
MARK	Activates bodymarks; further details on how to use them are described in the "Advanced Operations" manual.
CLEAR ALL	Deletes all measurements or annotations from the screen.
ABC	Activates annotations; further details on how to use them are described in the "Advanced Operations" manual.
MEASURE	Activates Advanced Measurements showing the list of available measurements on the right of the image.
+...+	Activates Generic Measurements showing the list of available measurements on the right of the image.
ACTION	Changes the function linked to the trackball. Refer to the *Trackball* paragraph further in this chapter.
AUTO	Automatically adjusts both the overall gain and TGC distribution improving the contrast resolution of the image. The activation is indicated on the screen by the corresponding icon and it is labeled as "AG". Refer to "Advanced Operations" Manual, "Imaging Optimization" Section for further information.
 POINTER	Toggles the trackball operation from standard to mouse mode. Refer to the *Trackball* paragraph further in this chapter.
LINE UPDATE	In B-Mode or CFM, this button allows to interactively activate the cursor or disable it to select the M-Mode or Doppler line. During the exam, when a trace is active, the same button freezes the trace acquisition and temporarily reactivates the reference B-Mode image.
ACQUIRE	Activates advanced features; further details on how to use them are described in the "Advanced Operations" manual
 FREEZE	Stops the current analysis or scan and puts **MyLab** in Freeze mode. To re-activate real time, press it again or directly press the button of the required mode.
3D/4D	Activates three dimension features; further details on how to use them are described in the "Advanced Operations" manual
 DUAL	Activates dual and quad view both in real time and freeze. Press LEFT or RIGHT to activate dual presentations: the active image is displayed on the left/right. Press CENTER to restore a single format. Press CENTER to activate quad presentations: the active image is displayed on the top-left. Press LEFT or RIGHT to add other images. Press CENTER to restore a single format.
1, 2, 3, 4	These buttons can be customized to save clips, save and print images. Refer to chapter 6 *Customizing the device* for further information.

5.2.1.1. TGC Sliding

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

5.2.1.2. Trackball

The trackball operates in two different modes.

Standard Mode

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

Each mode automatically activates the trackball on its cursor.

Table 5–2 Trackball cursors

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

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

Mouse Mode

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

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

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

5.2.1.3. Encoders

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

A proper layout on the screen indicates the current function.

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

5.2.2. Touchscreen Section

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

5.2.2.1. Menu Button

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

5.2.2.2. Touchscreen

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

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

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

Many modes provide two or more pages of controls.

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

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

The touchscreen layout changes depending on the different working modality:

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

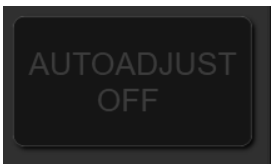
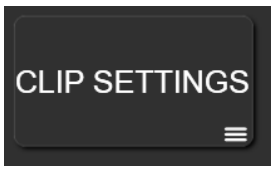
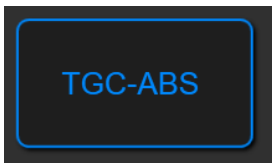
Multipurpose Panel Layout

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

Keys

The keys have a color coding depending on their status.

Table 5–3 Touchscreen key status

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

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

Knobs

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

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

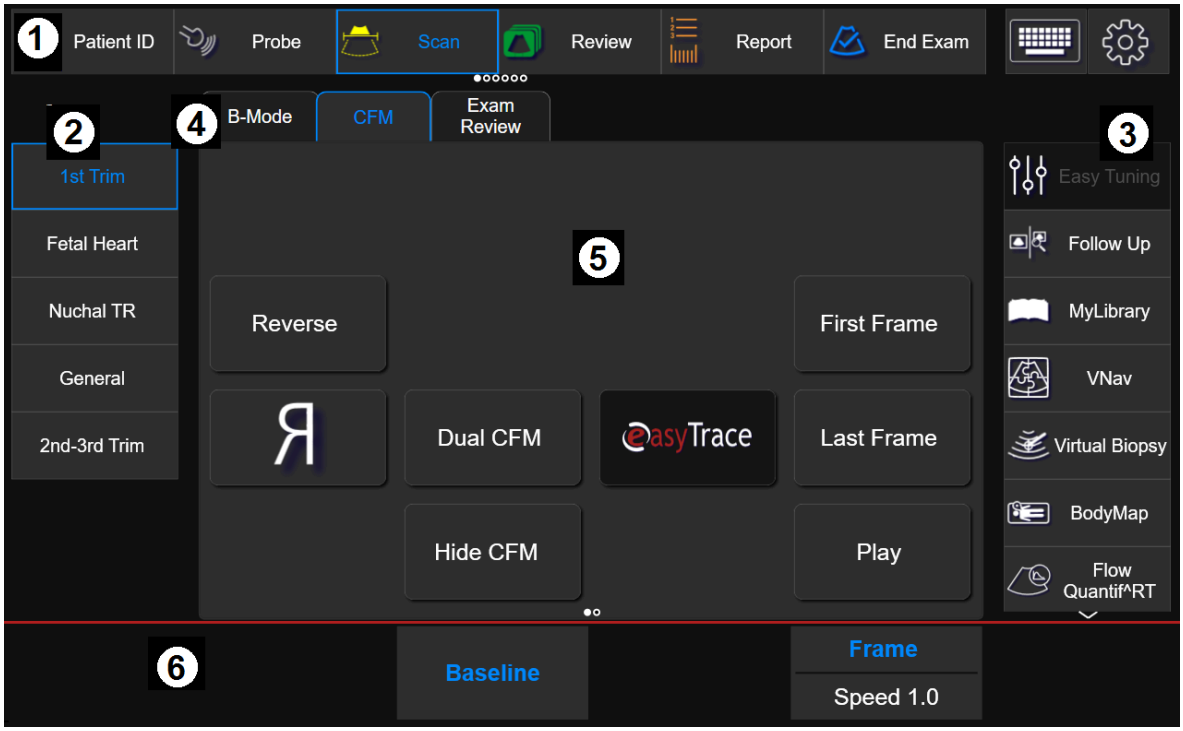
Sometimes, two controls are available for a knob. Only one of the controls can be active at a time. Pressing the corresponding knob or tapping the label toggles the active control.

Multipurpose Panel Layout

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

The touchscreen is organized in six main areas.

Fig. 5–1 CFM touchscreen



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

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

Tap the cogwheel icon to access a menu for easy configuration of display settings to adapt the contrast and brightness of your display to the lighting conditions of your room.

Image Review Layout

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

WARNING

The only monitor allowed for diagnosis is MyLab's main monitor, all the other internal or external displays are not allowed for diagnosis.

5.2.3. Alphanumeric Keyboard Section

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

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

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

5.3. Information about the Screen Layout

The screen is split into five main areas.

Fig. 5–2 Screen Layout

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

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

Symbol on Screen

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

5.3.1. Heading Area

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

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

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

5.3.2. Footer Area

This area is used to display the following information:

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

5.3.2.1. Wi-Fi

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

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

5.3.2.2. Archival Media

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

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

5.3.2.3. Advanced Features

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

5.3.2.4. Peripheral Devices

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

5.3.3. Image Area

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

Fig. 5–3 Image Area

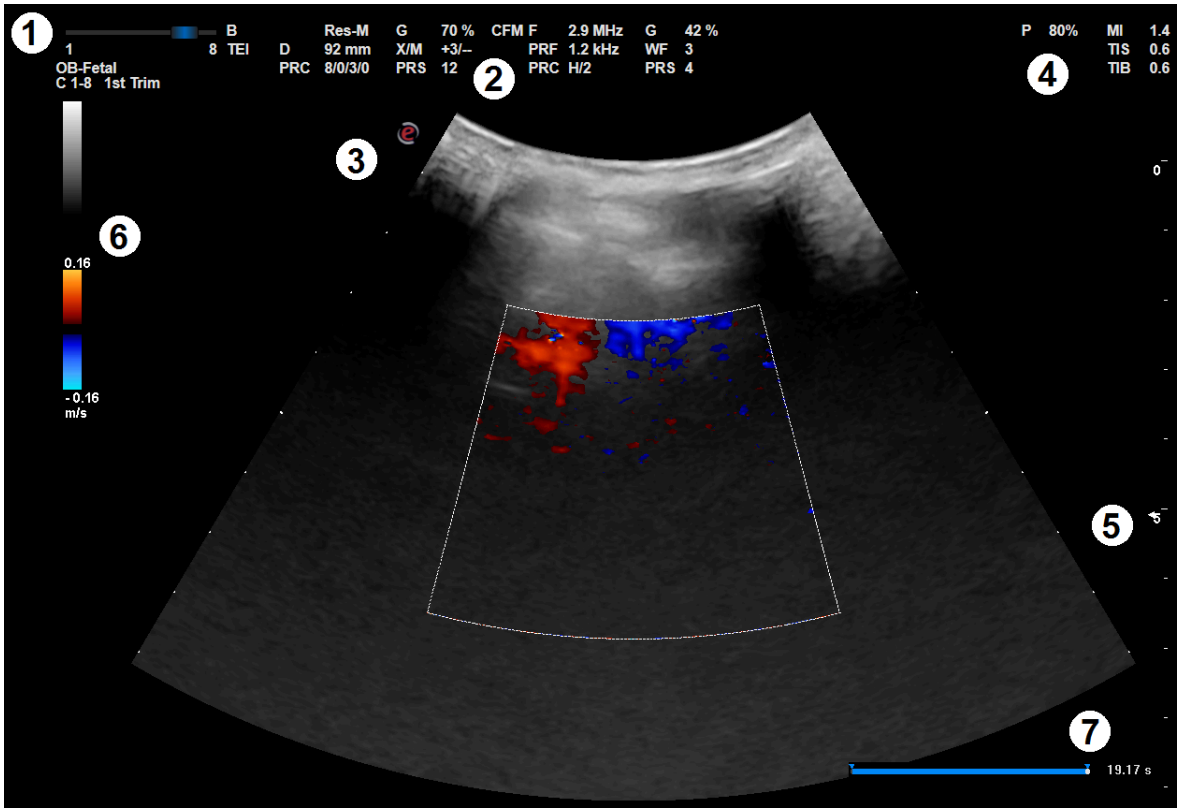


Table 5–4 Image Area description

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

Freeze Status

Whenever an image is frozen, a memory bar is displayed (at bottom right) concerning the scrolling memories. The images acquired immediately before are frozen and archived in these memories. The trackball can be used to examine the 2D, M-Mode, Doppler and color information image by image.

5.3.3.1. Machine Parameters

Table 5–5 Imaging Parameters

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

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

Table 5–6 Color Flow Mapping (CFM) Parameters

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

Table 5–7 Doppler Parameters

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

5.3.3.2. Encoder Area

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

5.3.3.2.1. Trackball

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

5.3.3.3. Thumbnails Area

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

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

6

6. CUSTOMIZING THE DEVICE

6.1. Configuration Menu

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

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

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

Fig. 6–1 MyLab Menu

The menu is organized in three areas:

- Clinical Configuration, in the upper area, shows all options relating to clinical settings, presets or advanced tools.
- System Settings, in the central area, shows all options relating to **MyLab** standard features.
- General Settings, in the lower area, shows all options relating to general settings.

Clinical Configuration

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

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

Clinical Configuration allows you to configure many parameters related to:

- Real Time Preset.
- Measure.
- Annotations.
- Bodymarks.
- eTouch.
- Advanced tools (such as Stress Echo, 3D/4D and so on) when licensed.

NOTE

Refer to the dedicated sections of the user manual for further information on the above Clinical Configurations.

System Settings

System Settings allows you to configure parameters related to a specific device profile:

- Profile Manager.
- DICOM.
- Saving Options for end exam saving configuration.
- Center ID for hospital configuration to set the name of the hospital.
- Multimedia.
- Network.
- Observations.
- Printers.
- Report.
- Advanced tools (such as XStrain 2D, HyperDoppler) when licensed.
- Acquisition Protocols.

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

General Settings

General Settings allows you to configure general parameters:

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

6.1.1. Generic Configuration Procedure

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

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

Procedure

1. Press **MENU**, and select the parameter you want configure. The configuration screen for the selected parameter is displayed.
2. Select the desired item from the list displayed on the left of the screen.
3. Choose one of the following options.

Table 6–1 Configuration Menu Options

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

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

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

6.2. Clinical Configurations

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

6.2.1. Real Time Preset

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

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

The available presets are determined by the selected transducer.

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

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

6.2.1.1. Creating a new preset from MENU

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

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

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

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

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

6.2.1.2. Creating a new preset from Real-Time

Procedure

To create a new preset or modify an existing one:

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

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

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

CLOSE exits without saving any modification.

6.2.2. SmartTouch Manager

A clinical setting (or preset) is associated to a specific probe in a specific application. Different clinical settings can be associated to the same probe in the same application.

When the preset is changed during the exam, all acquisition parameters are reset: this entails that the image optimization has to be done again. However during the exam it could be useful to change the preset maintaining, for instance, the set geometrical characteristics (such as depth, size).

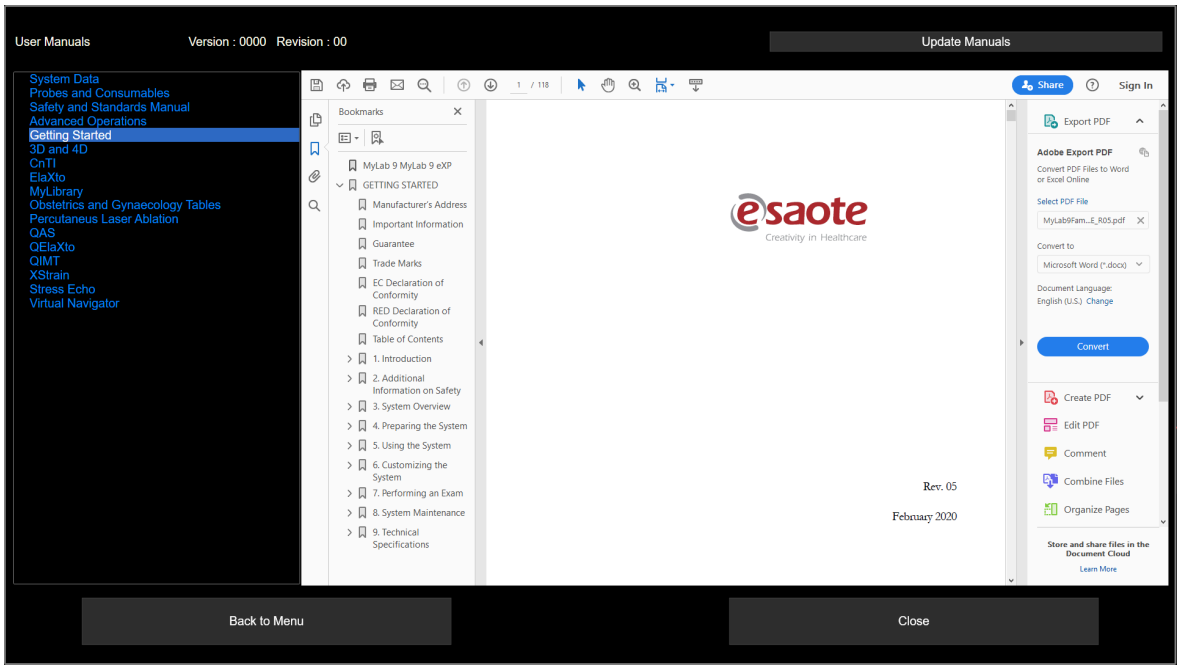
It can be useful to group similar clinical settings so that the acquisition controls remain fixed whenever the preset is changed.

SmarTouch, offered by **MyLab**, allows the operator to group similar presets and to change them during the same exam without resetting some acquisition controls.

These controls are:

- Active mode
- CFM ROI position and size
- Doppler gate position and size
- Depth
- Sector size
- Focus position
- Focus number

Fig. 6–2 Smartouch Configuration



The smart preset configuration menu shows:

- in the center the touchscreen layout;
- on the right the selected probe and application and the lists of all the associated clinical settings;
- on the bottom the fields where customized smartouches are named and described.

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

CANCEL exits the menu without saving the new settings.

Configuration

To create a smart preset, follow this procedure:

- to create a completely new smartouch, select the desired probe and application from the left list and press the **NEW** button to add a new smartouch;
- to create a new smartouch starting from an existing one, select the desired option from the left list and press the **CLONE** button to add a new smartouch;
- place the cursor on the **NAME** field and using the alphanumeric keyboard enter the desired name and description (**NOTES** field);
- select the desired clinical setting from the list on the right. By keeping the **ENTER**key pressed drag and drop it into the desired position of the touchscreen;
- repeat the operation to add other preset;
- in the SET AS DEF field set the preset that will be automatically activated whenever the set of probe and application are selected.

6.2.2.1. Smartouch Organization in the Touchscreen

Preset can be freely positioned within the touchscreen.

Moving a Preset

Select the preset with the trackball and by keeping the **ENTER** key pressed move it in the desired position. Release **ENTER** to confirm.

Deleting a Preset

Place the cursor on the preset to be removed and by keeping the **ENTER** key pressed drop it into the waste bin.

6.2.2.2. Working with Smartouches

Refer to the "General Setup" chapter in this section for further information on how to activate smartouch.

When a smartouch has been activated and created, **MyLab** automatically starts the exam using it whenever the correlated probe and application are selected. The active preset is the one set as default in the configuration menu.

The same happens during the exam if the probe and application are changed and for this combination of probe/application a set of smartouches has been created.

SmarTouch has a dedicated button (SMARTOUCH button) in the Exam Management area of the touchscreen that allows to change preset during the exam. Once this button is pressed, the touchscreen displays the list of all clinical settings grouped in the smartouch. Press the desired button to select the new preset.

ADVANCED button (displayed at the Start Exam page and when the PROBE button is pressed during the exam) allows the user to access to all presets available for this probe/application.

6.2.3. eTouch

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

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

Each configuration is linked only to one customized touchscreen.

NOTE

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

6.2.3.1. Configuring eTouch

To access to the eTouch configuration menu:

1. Press **MENU**, then select **ETOUCH**. 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.
2. Select one of the saved customized touchscreens, then follow the generic configuration procedure.

During editing the screen displays:

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

From here you can:

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

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

NOTE

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

Recording Procedure

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

  Press eTouch to start recording.

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

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

Repeat the procedure to add other customized buttons.

Customized Button Organizations

The customized button can be freely positioned within the touchscreen.

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

DELETE BUTTON cancels the button selected with the trackball.

Tab Organization

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

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

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

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

NOTE

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

6.3. System Settings

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

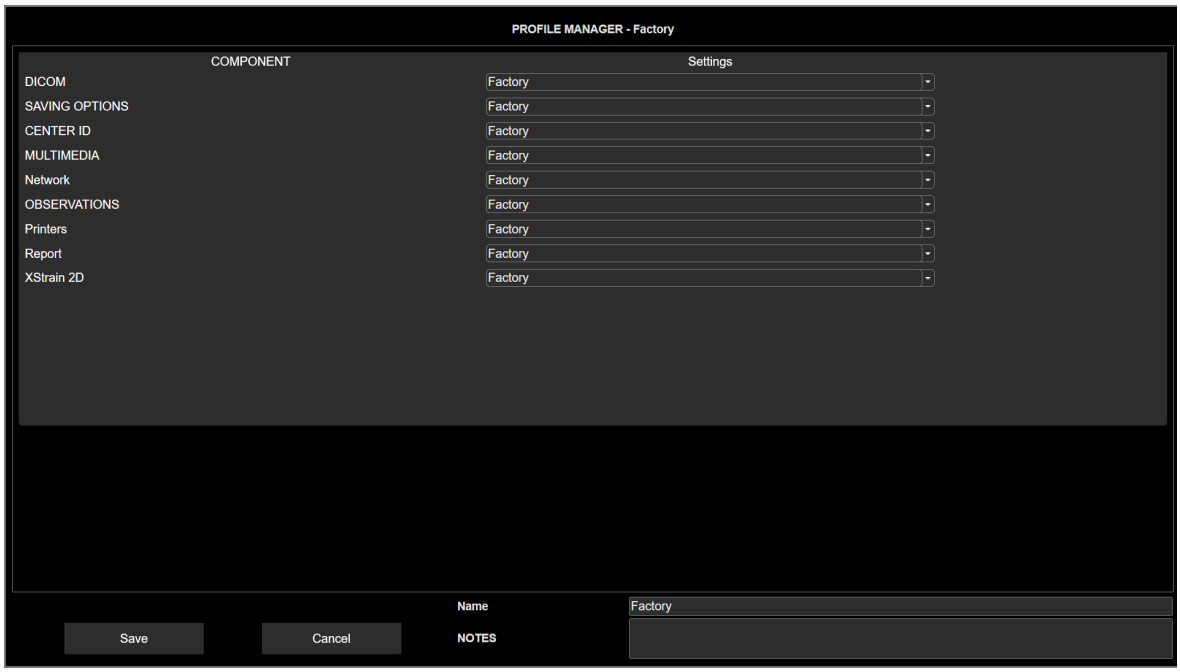
6.3.1. Profile Manager

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

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

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

Fig. 6–3 Profile Manager Menu



6.3.1.1. Corrupted System Profile

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

Should this not solve the problem, contact Esaote personnel.

6.3.2. Center ID

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

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

During editing you can configure many fields described below.

6.3.2.1. Center ID Field

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

6.3.2.2. Report Information Field

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

- the hospital name;
- the department name;
- the contact details;

- two fields for other additional information;
- the hospital logo.

6.3.2.3. DICOM Field

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

6.4. General Settings

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

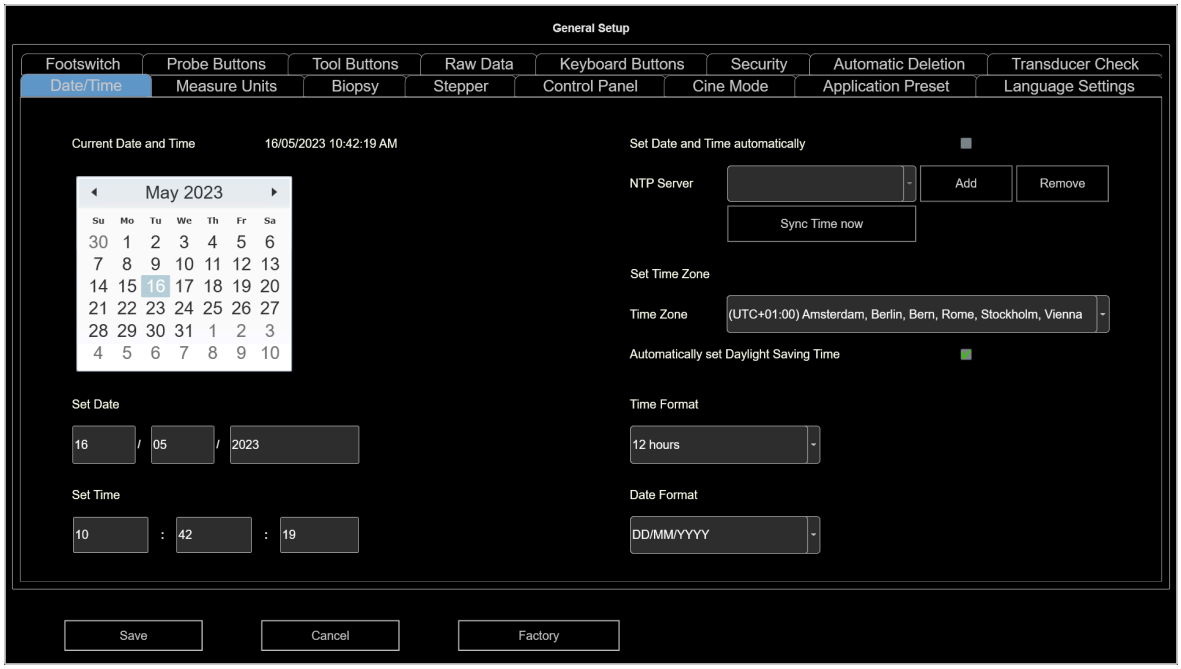
NOTE

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

6.4.1. General Setup

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

Fig. 6–4 General Setup Menu



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

CANCEL exits the menu without saving the new settings.

FACTORY retrieves all factory values and deletes all customized items.

6.4.1.1. DATE/TIME Folder

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

Set Date

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

Set Time

Using the keyboard set the time manually.

Date Format

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

Table 6–2 Date Formats

Format	Displayed date
DD/MM/YYYY	01/04/2023
DD/MMM/YYYY	01/Apr/2023
MM/DD/YYYY	04/01/2023
MMM/DD/YYYY	Apr/01/2023

Time Format

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

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

Select the desired server from the NTP SERVER drop-down menu or press **ADD** to insert a new one.

Set your time zone and country related information from SET TIME ZONE drop-down menu.

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

6.4.1.2. MEASURE UNITS Folder

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

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

6.4.1.3. BIOPSY Folder

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

6.4.1.4. STEPPER Folder

This option is used to set the grid template when biopsy stepper is enabled for prostate biopsy procedures. For further information about stepper, refer to the related chapter in the Probes and Consumables manual.

6.4.1.5. CONTROL PANEL Folder

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

Table 6–3 Control Panel Folder

Fields	Action
TRACKBALL SPEED	Sets the speed of the trackball.
TRACKBALL ACCELERATION	When checked, it adjusts cursor pointer acceleration in order to react exactly on how quickly you move your trackball.
LEFT CLICK	Sets the action of the left key of the trackball. The left key can be set as confirming key (**ENTER**) or as context menu key (**UNDO**).
CHARACTER SET	Sets the characters used for all the device information (for example screen information, touchscreen button).
SHUTDOWN TYPE	Sets the preferred shutdown type. Refer to 6.4.1.5.1 *Field SHUTDOWN TYPE*
SCREEN RESOLUTION	Sets the screen resolution when secondary monitor is connected.
AVAILABLE QWERTIES	Sets which alphanumeric keyboards are available in the touchscreen and which is the default one. When more alphanumeric keyboards have been set, the touchscreen displays an alphanumeric keyboard with dedicated tabs allowing to select the desired keyboard.
BEEP VOLUME	Sets the volume of the beep.
FOCUS CONTROLLED BY TRACKBALL	Sets the default action of the trackball when starting the exam.
ETOUCH BUTTON	When Acquisition Protocol is licensed, the eTouch button can be configured to work with protocols.
DEPTH INCREASE	Allows to set the depth changing the value clockwise/counterclockwise.
AUTOMATIC START EXAM	When checked, it allows a direct access to B-Mode after booting without passing through Patient ID.
DISPLAY LIBRARIES ON TOUCHSCREEN	When checked, MyLibrary protocols are displayed on the touchscreen instead of main screen.
LUNG ULTRASOUND	When checked, it enables Lung Ultrasound (LUS) protocol.

Table 6–3 Control Panel Folder (cont'd.)

Fields	Action
DIRECT PROBE SELECTION	When checked, it allows to show on the touchscreen work flow area icons of connected probes for quick change. If the current application is available on the new probe, the application is maintained, otherwise it will be changed to the default one at probe switching.
AUTO QUERY IN ARCHIVE	When checked, only the exams belonging to the patient entered in the Patient ID screen are retrieved from archive.
DICOM Q/R CURRENT PATIENT DATA	When checked, it enables the DICOM query/retrieve with query field automatically filled with the current patient name. It extend to the PACS archive the retrieving of data belonging to the current patient available through AUTO QUERY IN ARCHIVE.
SHOW CONTROL PANEL COMMANDS ON MONITOR	When checked, functions related to joysticks (or encoders) and 1, 2, 3, 4 buttons are displayed on monitor.
TOUCHSCREEN	Sets the brightness of the touchscreen.
CONTROL PANEL	Sets the brightness of the control panel.

6.4.1.5.1. Field SHUTDOWN TYPE

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

Table 6–4 Shutdown types

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

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

NOTE

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

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

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

6.4.1.5.2. Field AVAILABLE QWERTIES

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

Fig. 6–5 Qwerty keyboard

6.4.1.6. CINE MODE Folder

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

6.4.1.7. APPLICATION PRESET Folder

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

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

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

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

Table 6–5 Application Preset Folder

Fields	Action
ABSOLUTE ANGLE	The angle correction factor of linear probes can be correlated either to the line cursor or to the line perpendicular to the transducer surface (absolute angle). In the first case the angle correction is kept constant when the line is moved; in the latter case an angle correction is calculated whenever the line is moved.
SHOW SWEEP VELOCITY	When checked, this option allows to display the Sweep Velocity (cm/s) below the PW/CW/M scroll area.
SAMPLE VOLUME SWIVELING STEERING	When checked, the Doppler line can be oriented by using the center of the sample gate as rotation axis.
SHOW ZOOM REFERENCE WINDOW	When checked, the zoom navigation window is displayed on the screen just as the zoom has been activated.
USE REFERENCE BOX ON DUAL COLOR DOPPLER	When checked, in dual visualization, the ROI box is overlaid to the B-Mode image as a reference.
IMAGE SIZE	Sets the default dimension for reference image in split format for the selected application.
ACTION ON FREEZE	Sets the action after **FREEZE** pressure.
AUTO BUTTON SETUP	Sets the action after **AUTO** pressure: AUTOADJUST (to automatically adjust the B-Mode image), ECFM (to automatically optimize CFM image) or BOTH of them.
EASYTRACE ENABLED	When checked, this option allows to enable easyTrace.
IMAGE AUTOFITTING	When checked, for linear probes and superficial depths, it adapts the size to the width of the screen.
ENABLE SMARTOUCH	When checked, it enables the smarTouch for the selected application.
INVERT CFM SCALE WITH STEERING	When checked, this option allows to automatically invert the Doppler scale when inverting the steering with reference to the vertical line.
USE REFERENCE BOX ON DUAL ELAXTO	When checked, in dual visualization, the ROI box is overlaid to the B-Mode image as a reference.
AVF ENABLED	When checked, this option enables AVF that makes the focus positioning automatic, improving the focus management. When enabled, all controls related to focus management are disabled.
1-CLICK CHANGEOVER ENABLED FOR PW, CW, M-MODES	When checked, pressing PW from B-Mode, **MyLab** switches to B-Mode frozen + Doppler live at once. When not checked, pressing PW from B-Mode, **MyLab** switches to B live + PW frozen. This step allows to position the beamline into the target vessel and it is necessary then to press PW once again. The same behaviour applies to CW and M modes.
INVERT CFM AND DOPPLER SCALE	When checked, it makes the palette/scale inversion completely independent, even when the automatic inversion controlled by the steering is enabled (i.e. invert PW spectrum without inverting the CFM scale).
HD ZOOM DENSITY	When checked, it increases the resolution in HD zoom.
FIXED BOX IN ATTENUATION IMAGING	When checked, it fixes the acquisition ROI in the middle of the screen.
SHOW ZOOM CALIPER WINDOW	When checked, it enlarges the area of image around the caliper during measurements.

WARNING

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

6.4.1.7.1. Field ACTION ON FREEZE

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

Table 6–6 Actions on freeze

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

6.4.1.8. LANGUAGE SETTINGS Folder

This option is used to set which language is used for the user interface and for the on-board user manuals. Select your preferred language from the drop-down menus.

6.4.1.9. FOOTSWITCH Folder

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

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

6.4.1.10. PROBE BUTTONS Folder

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

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

6.4.1.11. TOOL BUTTONS Folder

This option is used to set which tools among the available are displayed on the dedicated touchscreen area.

Select one item in the list, then press **ADD** or **REMOVE** it.

Through **MOVE UP** and **MOVE DOWN** you can change the order of visualization.

6.4.1.12. RAW DATA Folder

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

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

6.4.1.13. KEYBOARD BUTTONS Folder

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

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

NOTE

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

6.4.1.14. SECURITY Folder

Antivirus

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

DEFINITION VERSION lets you know the version number installed.

You can update the antivirus on your own through:

UPDATE FROM FILE if you have already downloaded the upgrade on a USB pen drive. Download the antivirus upgrade from the following web page

https://go.microsoft.com/fwlink/?LinkID=121721&arch=x64

UPDATE FROM THE WEB to automatically search on the web any available update and install them. The update from the web requires a web access and it can take long time to finish, so a message warns you before starting.

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

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

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

Encryption

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

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

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

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

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

Encryption can be enabled by Esaote Service personnel only.

6.4.1.15. AUTOMATIC DELETION Folder

This option is used to set automatic deletion of archived data.

Table 6–7 Automatic Deletion Folder

Fields	Action
ENABLE AUTOMATIC DELETION	When checked, it enables automatic deletion of archived data older than the number of months set by MANAGE CONSERVATION PERIOD (IN MONTHS). Examinations older than the number of months set will be irrevocably deleted from the archive.
MANAGE CONSERVATION PERIOD (IN MONTHS)	Sets the number of months after which the archived data will be deleted.
DELETE UNSENT STUDIES	When checked, it enables automatic deletion of examinations not sent to pacs after the number of months set by MANAGE CONSERVATION PERIOD (IN MONTHS). Examinations older than the number of months set will be irrevocably deleted from the archive.

6.4.1.16. TRANSDUCER CHECK Folder

This option is used to set a periodic automatic check of a probe when connected.

Three levels are available:

- MAXIMUM LEVEL: the transducer check procedure is activated each time a probe is selected for the examination.

- MEDIUM LEVEL: the transducer check procedure is activated on periodical base. You can select the frequency as BOOT, DAILY or WEEKLY.
- FAST LEVEL: the transducer check procedure is activated on user demand.

During the check the probe must be clean and in the air.

6.4.2. Security

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

6.4.3. Licenses Manager

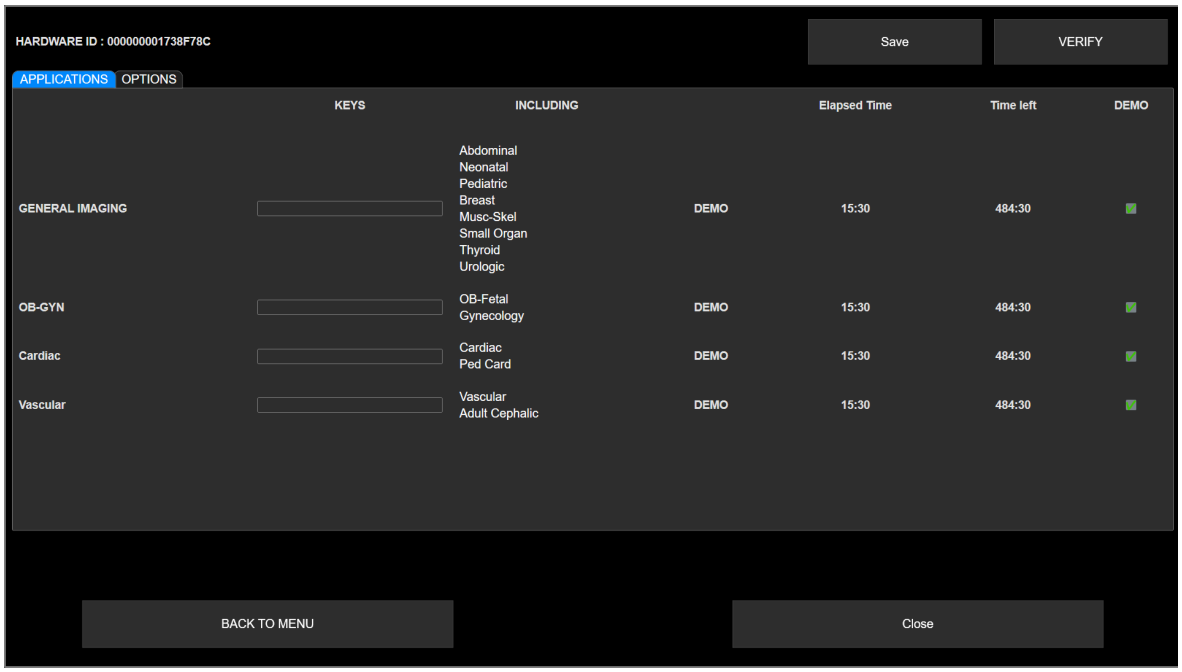
Licenses Manager allows to install optional licenses and to check the status of a demo license.

NOTE

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

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

Fig. 6–6 License Configuration Menu



6.4.3.1. License Activation

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

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

License Activation

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

NOTE

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

Demo License

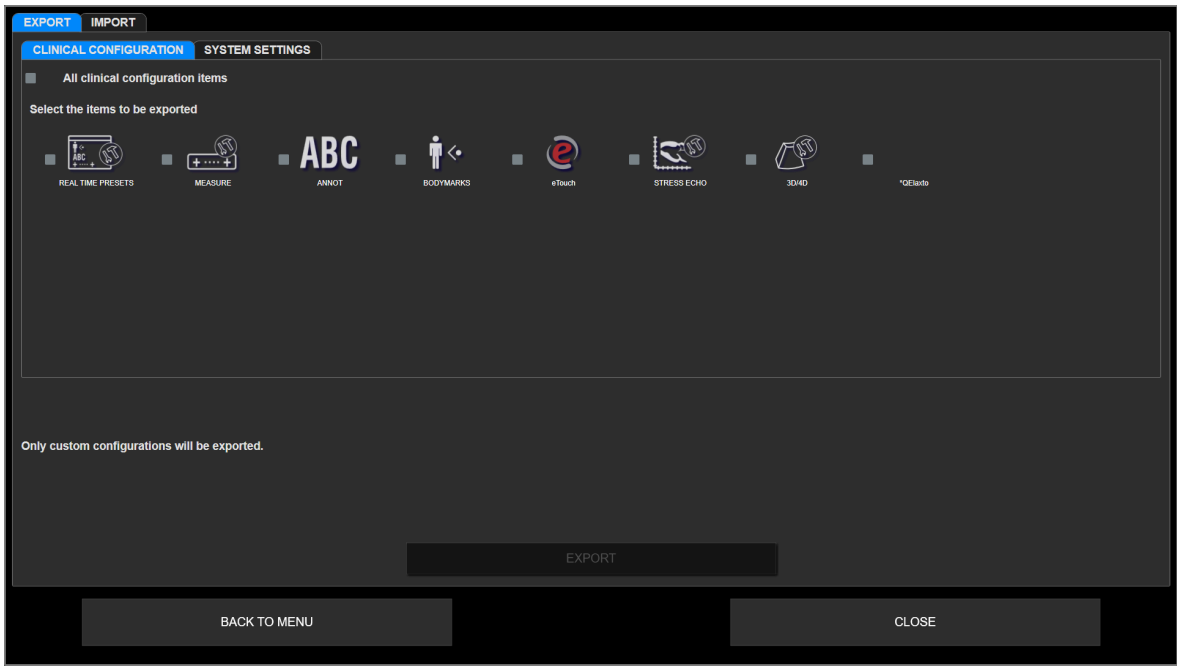
If a demo license has been activated (DEMO box checked), EXPIRATION DATE shows the expiration date of each demo licence.

SAVE saves the configuration, activating the licenses.

6.4.4. Import/Export Menu

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

Fig. 6–7 Import/Export Menu



6.4.4.1. EXPORT Folder

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

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

Clinical Configuration Folder

The clinical settings that can be exported are:

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

System Settings Folder

The system configuration settings that can be exported are:

- customized DICOM configuration;
- customized SAVING OPTIONS;
- customized center configuration (CENTER ID);
- customized MULTIMEDIA export settings;

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

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

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

NOTE

Only custom configurations will be exported.

6.4.4.2. IMPORT Folder

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

Procedure

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

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

NOTE

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

6.4.5. System Info

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

- the model name and serial number;

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

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

6.4.5.1. Encryption Mode

Encryption allows to preserve health data storage confidentiality.

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

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

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

NOTE

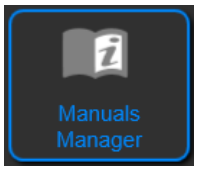
To make effective use of encryption it is strongly advised to use it with security access enabled.

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

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

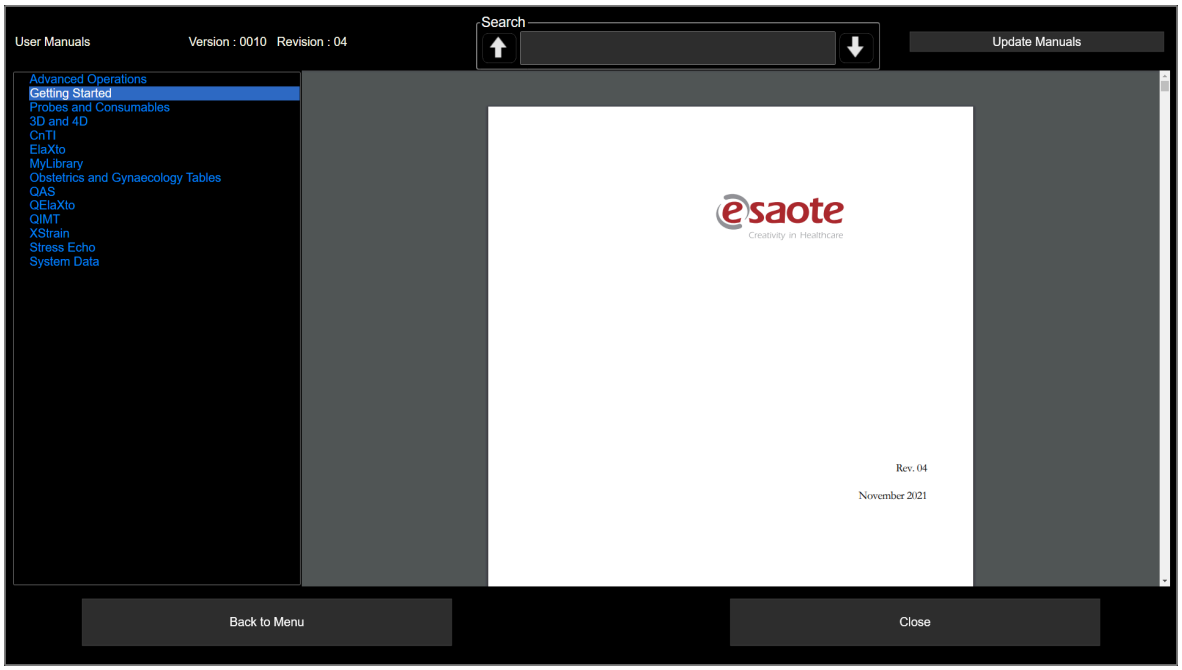
When an encrypted USB memory device is connected to a different system, data will remain locked and then not accessible.

6.4.6. Manuals Manager



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

Fig. 6–8 User manual display



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

NOTE

The PDF reader is already integrated in MyLab.

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

6.4.6.1. Electronics manuals on Esaote website

To access the manuals on Esaote website you have to:

1. Access the website https://eifu.esaote.com.
2. If you are not registered yet, you have to register in e-manual reserved area following the instruction provided on website; to complete the registration you need the Serial Number, which you can find on the label placed on the lower back of your **MyLab**.

3. Click on the dropdown menu CHOOSE THE MEDICAL SYSTEM;
4. Select the **MyLab** for which the manuals are needed;
5. Once the page related to the selected **MyLab** is displayed, select the manuals corresponding to the software version installed on your **MyLab**;
6. Select the language you desire;
7. Click on the manual to open it or click on  to download it.

NOTE

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

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

6.4.6.2. How to request a printed copy of the manuals

You can request the instructions for use in paper form, at no additional cost, by contacting:

- the subsidiary or the local distributor;
- Esaote S.p.A., at the email address ordini.interpro@esaote.com

It is necessary to clearly communicate the software version installed on your system, available in System Info (press **MENU** then select **SYSTEM INFO**).

The instructions for use in paper form can be requested for the whole period of the life time of your **MyLab**.

7

7. PERFORMING AN EXAM

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

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

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

NOTE

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

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

NOTE

Improper use of MyLab can result in serious injury.

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

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

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

NOTE

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

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

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

7.1. Starting an Exam

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

CAUTION

MyLab is a PC based device; do not turn MyLab off while working (for example saving data) or during the initialization phase: data loss or hard disk damage may occur.

Fig. 7–1 Patient ID screen

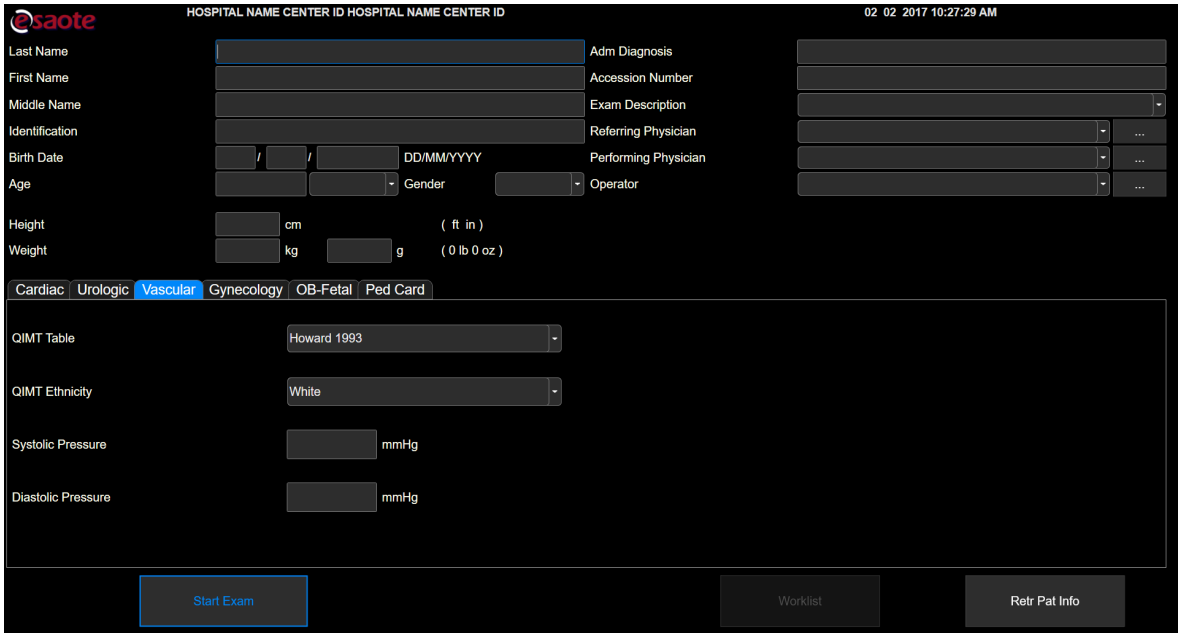
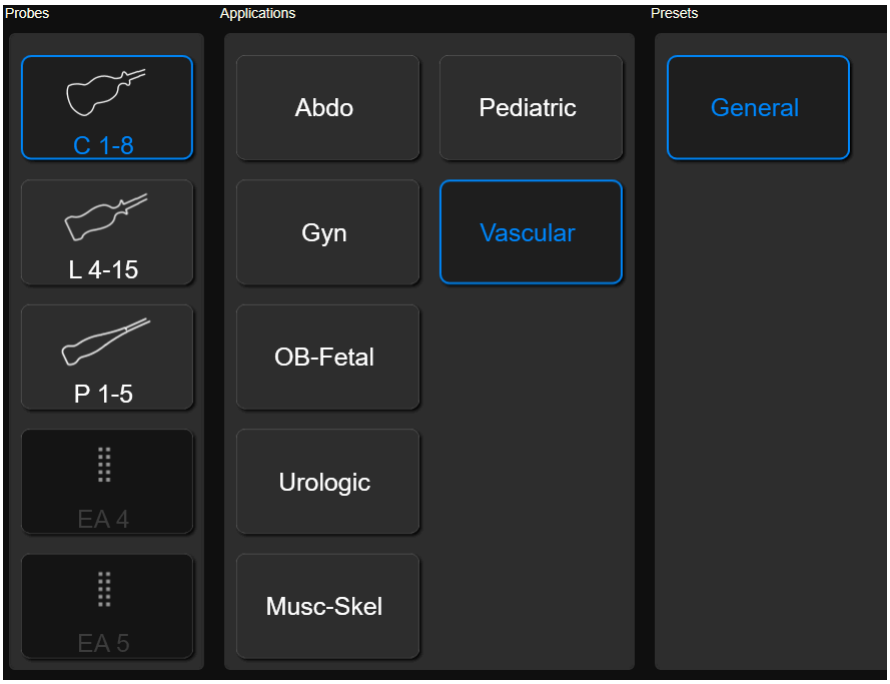


Fig. 7–2 Probe, Application, Preset touchscreen



Starting exam procedure

The steps to be followed to start an exam are:

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

7.1.1. Entering Patient and Application data

There are two ways to enter patient data:

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

7.1.1.1. Filling the Patient ID screen

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

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

The Application data are additional information required for specific application for calculation purposes.

7.1.1.2. Retrieving data from archive

CURRENT retrieves the patient data of the last exam.

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

NOTE

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

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

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

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

Unsupported character setting!

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

WARNING

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

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

WARNING

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

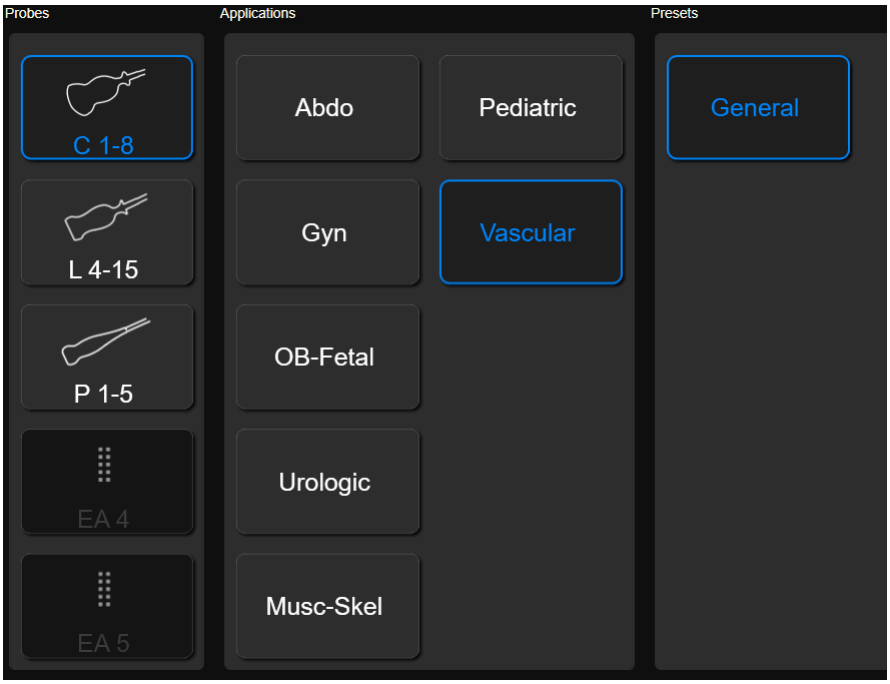
7.1.2. Selecting Probe

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

Tap the probe image to select it.

The blue highlighted key indicates the active probe.

Fig. 7–3 Probe, Application, Preset touchscreen



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

7.1.3. Selecting Application

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

The blue rounded application indicates the active one.

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

7.1.4. Selecting Preset

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

The blue rounded preset indicates the active one.

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

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

WARNING

Before beginning the exam, ensure that the probe name displayed on the screen is the same of the probe you intend to operate with.

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

NOTE

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

7.1.4.1. Smart Preset

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

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

7.2. Performing the Exam

MyLab offers a set of imaging modes to cover a variety of imaging needs. By pressing the different mode buttons (B, M, C, PD/TVM, PW, CW) the specific mode is activated in real time. If the same button is pressed again, **MyLab** automatically returns to the previous presentation.

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

Touchscreen buttons change according to the activated mode.

When more modes are active, the navigation tabs (**B-MODE**, **M-MODE**) allow the operator to scroll among the specific mode menu. If the displayed menu has several levels, swipe left/right to scroll through all functions.

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

7.3. Acquiring images

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

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

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

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

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

7.3.1. Freeze and Scrolling Memories

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

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

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

7.3.2. Reviewing Images

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

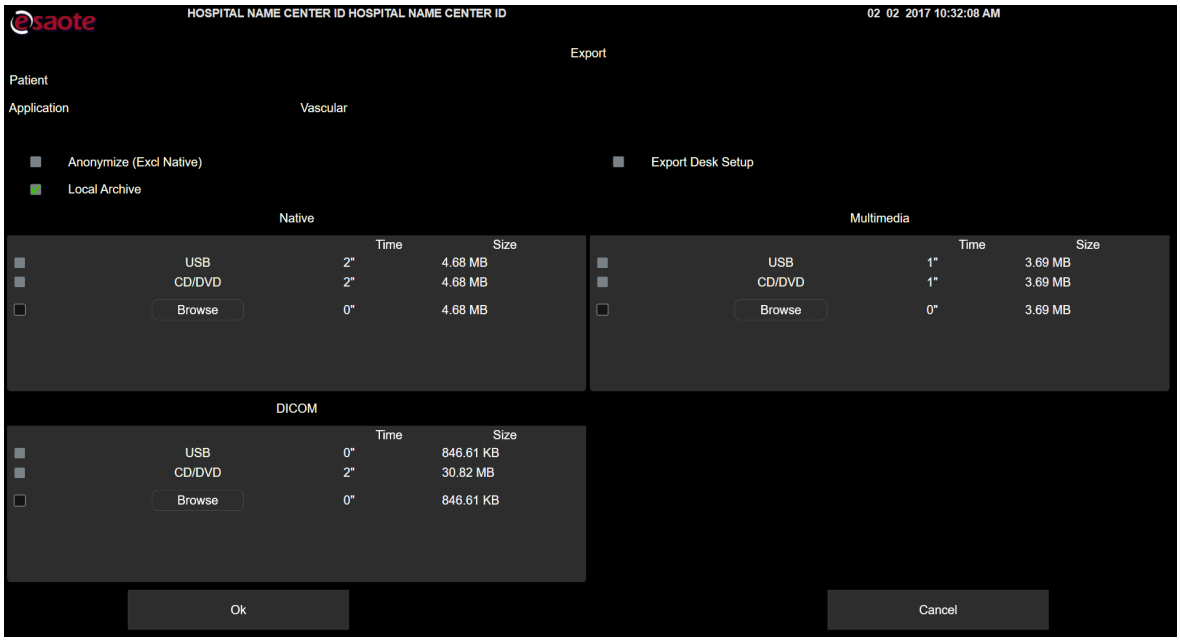
The selected image or sequence is shown on the screen.

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.

7.4. Ending the Exam

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

Fig. 7–4 End Exam Window



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

NOTE

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

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

NOTE

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

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

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

NOTE

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

7.5. Monitor adjustments

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

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

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

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

8. MAINTENANCE

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

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

Table 8–1 Maintenance Operations

Maintenance	Minimum frequency	Performed by
cleaning the probes	after use	user
checking the probes	every week	user
cleaning control panel and device	every week	user
cleaning touch screen	every week	user
cleaning probe and gel holders	every week	user
cleaning LCD case and screen	every week	user
checking device housings for any damage	every month	user
checking control panel and keyboard for defects	every month	user
checking equipment for loose or missing hardware	every month	user
checking movements of all parts composing the device	every month	user
checking LCD and touchscreen status	every month	user
checking trackball movement	every month	user
cleaning trackball	every month	user
checking connectors on cables for any mechanical defects	every month	user
checking entire length of electrical and power cables for cuts or damages	every month	user
checking the device integrity, functionality and cleaning (including internal components)	every year	Esaote personnel
Electrical Safety Tests	every two years	Esaote personnel or authorized personnel

WARNING

Turn MyLab off and unplug it before any maintenance operation.

NOTE

Frequency of cleaning can change depending on environment cleanliness.

NOTE

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

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

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

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

Contact Esaote personnel for any problem found during inspection.

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

8.1. Cleaning Operations

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

Users have to follow local Healthcare Institutions infection control guidelines for reprocessing of ultrasound scanners and related parts taking into consideration manufacturer's IFU.

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

Table 8–2 **MyLab** *compatible cleaning agents*

Product	Supplier
Cavicide Caviwipes Metrizyme	**Metrex Research Corporation** (www.metrex.com/company/contact/index.cfm)
Mid Soap	-
Mikrozid AF wipes Mikrozid PAA wipes Mikrozid sensitive wipes	**Schülke&Mayr GmbH**, (www.schuelkemayr.com/int/en/contact/smi044_adresses.htm)
Sani-Cloth HB Sani-Cloth Plus Sani-Cloth Super	**Professional Disposable International** (www.pdipdi.com)
Trionic D	**Ebiox** (www.ebiox.co.uk)

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

WARNING

Turn MyLab off and unplug it before any cleaning operation.

NOTE

The cleaning operation should be performed accordingly to the equipment environment requirements in terms of temperature, pressure and humidity. Check the instructions supplied by the manufacturer of the cleaning agents for possible stricter limitation. Do not use hot cleaning agents for cleaning the equipment.

CAUTION

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

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

8.1.1. Cleaning control panel and device

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

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

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

WARNING

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

CAUTION

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

8.1.2. Cleaning the QWERTY keyboard

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

CAUTION

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

NOTE

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

8.1.3. Cleaning the trackball

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

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

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

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

WARNING

Never look directly or stare into the trackball's light when on. Do not use optical viewing aids.

WARNING

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

8.1.4. Cleaning Probe and Gel Holders

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

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

8.1.5. Cleaning the Touchscreen

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

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

WARNING

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

CAUTION

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.

8.1.6. Cleaning the LCD Screen

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

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

WARNING

Overspray or liquid may cause electrical shock.

8.1.7. Cleaning the LCD case

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

CAUTION

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

9. TECHNICAL SPECIFICATIONS

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

NOTE

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

9.1. MyLab Characteristics

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

9.1.1. Licenses

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

Additional features can be added buying the related license.

Applications

MyLab can be equipped with the following application licenses.

Table 9–1 Applications licenses

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

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

Features

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

Table 9–2 Features

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

Table 9–2 Features (cont'd.)

Feature	Description
microV	It automatically recognizes the lowest speeds with ultra sensitivity for small vessels and slow flow detection.
MView	It is an ultrasound technique which applies beam-line steering and acquires several coplanar scans of an organ from different view angles.
MyLab Tablet	Mobile application which allows to remotely review **MyLab** images on tablet or mobile
MyLibrary	Dedicated libraries for Rheumatology, MSK, Regional anesthesia, Physioterapy and Advanced vascular. Live Preview features allow to scan in real-time while using anatomical references and scanning guidance.
Needle Enhancement Imaging	It increases the needle visibility.
Protocols	Clinical protocols[3]
QAS	Quality Arterial Stiffness
QElaXto - (pSWE)	It allows to perform a Quantitative Elastosonographic analysis of tissues.
QIMT	Quality Intima Media Thickness calculation automatically measures the Carotid Intima-media thickness in real-time
QPack - Quantification	Time/Intensity analysis
Raw Data Processing	It enables raw data management in post-processing allowing to act on the raw data of captured images and clips by modifying some of the parameters represented.
Stress-Echo	Stress-Echo allows to acquire multiple views of the left ventricle (LV) under stress, using customizable protocols.
TEI	Tissue Enhanced Imaging improves the signal-to-noise ratio and enhances contrast resolution.
TPView	It enlarges the field-of-view.
TVM	Tissue Velocity Mapping provides a complete Wall Motion Analysis for both systolic and diastolic myocardial function evaluation.
VPan	Panoramic Imaging merges multiple B-Mode images in one complete panoramic image.
Virtual Biopsy	Virtual Biopsy combined with Intelligent Positioning increases confidence during ultrasound real-time biopsy procedures, thanks to virtual tracking of the needle.
XSTIC	It is a three-dimensional technique which allows the acquisition of a volume of data from fetal heart, displayed as a cineloop of a single cardiac cycle.
XStrain	XStrain allows to quantify endocardial velocities of contraction and relaxation and local deformation of the heart (Strain/Strain Rate analysis).

Table 9–2 Features (cont'd.)

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

1. Refer to www.esaote.com for further details on supported DICOM classes.
2. www.elesta-echolaser.com
3. Refer to the corresponding Sales Area manager for further information.

NOTE

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

9.2. Technical Characteristics

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

9.2.1. Display

- Built-in color LCD, WVGA resolution
- Full HD LED 24.1" monitor (16:9 aspect ratio)
- 10.1" LCD (touchscreen)

9.2.2. Probe connectors

- 5 electronic probes

9.2.3. Connectivity

- I/O connectors
  - LAN RJ45
  - 2 USB 2.0 on keyboard control panel
  - 2 USB 3.0 on left side
  - Wi-Fi (802.11.A,B,G,N)
- Video Output

    - Display port[2]
- Dedicated connectors
    - ECG input
- Other
    - Laser/Ink jet printers
- Complies with IHE integration profiles[3]

9.2.4. Image Files

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

9.2.5. Software

- Operating system: Windows 10
- Multi-lingual

9.2.6. Biometry

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

9.2.7. Keyboard

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

2. Auxiliary monitors connected to this input have not to be used for diagnostic purposes.
3. Refer to www.esaote.com for further details.

- Pull out alphanumeric QWERTY keyboard

9.2.8. Dimensions

- Closed (approximately): 605 (W) x 1135 (H) x 730 (D) mm
- In working position: 605 (W) x 773÷1035 (H) x 730 (D) mm (height of trackball)
- In working position: 605 (W) x 940÷1202 (H) x 730 (D) mm (at top of Control Panel)
- In working position: 605 (W) x 1315÷1577 (H) x 730 (D) mm (at top of the monitor)

9.2.9. Weight

- < 85 kg (basic configuration without peripheral units)

9.2.10. IP Grade

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

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

9.2.11. Power supply

- Voltage operative range:
  - 100 ÷ 120 V
  - 200 ÷ 240 V
- Voltage limit range:
  - 90 ÷ 132 V
  - 180 ÷ 264 V
- Working frequency range: 47 ÷ 63 Hz

9.2.11.1. Available power on peripherals

Depending on the configuration, your **MyLab** can be equipped with one of the following Power Supply models: V1 model or V2 model.

To know which type of power supply is mounted on your system, press **MENU**, then **SYSTEM INFO**. POWER SUPPLY will show the type of power supply as described in the table below.

Fig. 9–1 Power supply type: V1 on the left and V2 on the right

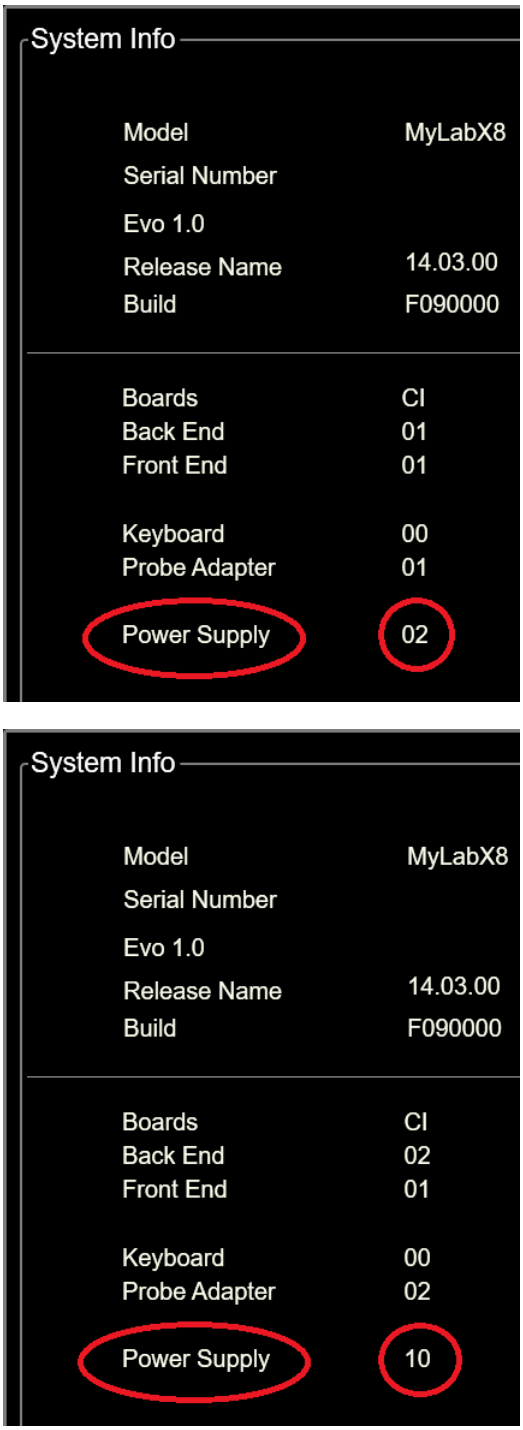


Table 9–3 Power supply types

First digit	Second digit	Power Supply model	Example
0	any	V1 model	02
1	any	V2 model	10

The table below shows the total power available on the three power outlets for peripheral devices.

Table 9–4 Maximum power available on peripheral outlets

	MyLab equipped with V1 model power supply	**MyLab** equipped with V2 model power supply
110V range	230VA	320VA
220V range	230VA	450VA

9.2.11.2. Power consumption

Table 9–5 Maximum power available on peripheral outlets

	MyLab equipped with V1 model power supply	**MyLab** equipped with V2 model power supply
MyLab only	≤ 250VA	≤ 300VA
MyLab + peripherals	≤ 600VA	≤ 800VA

9.2.11.3. Fuses

Table 9–6 Fuses used on MyLab

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

9.2.12. Operating Requirements

- Temperature: 15 ÷ 35 ℃
- Humidity:
  - 20 ÷ 85% (not condensing) without standby batteries
  - 20 ÷ 80% (not condensing) with standby batteries
- Pressure:
  - 795 ÷ 1060 hPa for V1 systems

- 700 ÷ 1060 hPa for V2 systems

9.2.13. Storage requirements

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

9.2.14. Probe Storage Requirements

- Probe storage requirements are indicated in the probe case.

9.2.15. Batteries

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

9.2.16. Opti-Light

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

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

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

9.3. Power Cables

Table 9–7 Power Cables

	Connector (MyLab side)	Plug Type (Mains side)	Cord Type	Length
Italy	EN60320/C13	I/3G CEI 23-50	H05VVF3G Section 1 mm² 3 conductors 10A-250V	4,5 m
Europe France Germany Spain	EN60320/C13	Type VII G CEE (7) VII	H05VVF3G Section 1 mm² 3 conductors 10A-250V	4,5 m
USA North America	C13M EN60320/C13	HG (Hospital grade) NEMA 5-15	SJT3x14AWG 3 conductors 15A-125V	4,5 m
UK	EN60320/C13	BS13/13 BS 1363/A	H05VVF3G Section 1 mm² 3 conductors 10A-250V	4,5 m
Brazil	EN60320/C13	BR/3 NBR14136	H05VVF3G Section 1 mm² 3 conductors 10A-250V	4,5 m

9.4. European and international standards

MyLab ultrasound scanners comply with:

Table 9–8 Standards

Number and Edition	Title
Regulation (EU) 2017/745 and successive amendments	Medical Device Regulation (MDR)
Directive 2011/65/EU and successive amendments	Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
Directive 2014/53/EU and successive amendments	Radio Equipment Directive (RED)
EN IEC 63000:2018–12	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances (RoHS)
EN 60601-1:2006 + AC:2010 + A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Table 9–8 Standards (cont'd.)

Number and Edition	Title
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Compatibility - Requirements and tests
EN 60601-1-6:2010 + A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 60601-2-37:2008	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
ETSI EN 301 489–1 v2.2.3	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
ETSI EN 301 489–17 v3.2.0	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
ETSI EN 300 328 v2.1.1	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
ETSI EN 301 893 v2.1.1	5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
IEC 61157:2007 IEC 61157:2007/A1:2013	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment
EN 62304:2006 EN 62304:2006/A1:2015 IEC 62304:2006 IEC 62304:2006/A1:2015	Medical device software - Software life cycle processes
EN 62366:2008 IEC 62366:2015	Medical devices - Application of usability engineering to Medical Devices
EN ISO 10993-1:2009 EN ISO 10993-1:2009/AC:2010 ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2019+A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016 ISO 15223-1:2016, Corrected version 2017-03	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General Requirements

Table 9–8 Standards (cont'd.)

Number and Edition	Title
IEC 60601–1–9 and successive amendments	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design
AIUM/NEMA UD-2:2004 (R2009)	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.
AIUM/NEMA UD-3:2004 (R2009)	Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
ANSI/AAMI ES60601-1: 2005/(R)2012	Medical Electrical Equipment - Part 1: General Requirements for Safety

A. PROBES USED IN OPTIONAL FEATURES

A.1. CnTI

Table A–1 Probes that can be used in CnTI with **MyLabX8 Family**

Probe	Application
BL433	Abdominal, Breast, Musculo-skeletal, Small Organ, Thyroid, Vascular
C 1-8	Abdominal, Gynecology, Musculo-skeletal, Urology, Vascular
C 2-9	Abdominal, Gynecology, Musculo-skeletal, Urology, Vascular
E 3-12	Gynecology, Urology
EC123	Gynecology, Urology
IOT342	Abdominal, Musculo-skeletal, Small Organ, Vascular
L 3-11	Abdominal, Breast, Musculo-skeletal, Small Organ, Thyroid, Vascular
L 4-15	Abdominal, Breast, Musculo-skeletal, Small Organ, Thyroid, Vascular
mC 3-11	Abdominal, Small Organ, Thyroid, Vascular
P 1-5	Abdominal, Adult Cephalic, Vascular
PX 1–5	Abdominal, Adult Cephalic, Vascular
SB2C41	Abdominal, Gynecology, Musculo-skeletal, Urology
SB3123	Gynecology, Urology
SI2C41	Abdominal, Gynecology, Musculo-skeletal, Urology
TLC 3-13	Gynecology, Urology

A.2. ElaXto

Table A–2 Probes that can be used in ElaXto with **MyLabX8 Family**

Probe	Application
BL433	Breast, Musculo-skeletal, Thyroid
C 1-8	Abdominal, Gynecology, Musculo-skeletal, Urology
C 2-9	Abdominal, Gynecology, Musculo-skeletal, Urology
E 3-12	Gynecology, Urology
EC123	Gynecology, Urology
IH 6-18	Abdominal, Musculo-skeletal, Small Organ

Table A–2 Probes that can be used in ElaXto with **MyLabX8 Family** *(cont'd.)*

Probe	Application
IOT342	Abdominal, Musculo-skeletal
L 3-11	Abdominal, Breast, Musculo-skeletal, Small Organ, Thyroid
L 4-15	Breast, Musculo-skeletal, Small Organ, Thyroid
L 8-24	Breast, Musculo-skeletal, Small Organ, Thyroid
mC 3-11	Small Organ, Thyroid
SB2C41	Abdominal, Musculo-skeletal, Urology
SB3123	Gynecology, Urology
SI2C41	Abdominal
SL2325	Breast, Musculo-skeletal, Small Organ, Thyroid
SL3116	Breast, Musculo-skeletal, Small Organ, Thyroid
TLC 3-13	Urology

A.3. QAS

Probes that can be used in QAS with **MyLabX8 Family**:

- L 3-11
- L 4-15

A.4. QElaXto 2D

Probes that can be used in QElaXto 2D with **MyLabX8 Family**:

- C 1-8
- L 3-11
- L 4-15

A.5. Virtual Navigator

Table A–3 Virtual Navigator applications

Feature	Main Application	Districts	Probes
Virtual Navigator Fusion Imaging 3D	General Imaging	Abdominal	C 1-8, CX 1-8, L 3–11, L 4-15, LMX 4-20, LX 3-15, mC 3–11, P 1–5, PX 1–5, SI2C41
		Breast	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15
		Musculo-skeletal	C 1-8, CX 1-8, L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, SI2C41
		Thyroid	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11
		Urology	C 1-8, CX 1-8, E 3-12, SI2C41, TLC 3-13
	Vascular	Adult Cephalic	P 1–5, PX 1–5
		Vascular	C 1-8, CX 1-8, L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11, P 1–5, PX 1–5
	Women Health	Gynecology	C 1-8, CX 1-8, E 3-12, SI2C41, TLC 3-13

Table A–3 Virtual Navigator applications (cont'd.)

Feature	Main Application	Districts	Probes
Virtual Biopsy	General Imaging	Abdominal	C 1-8, CX 1-8, L 3–11, L 4-15, LMX 4-20, LX 3-15, mC 3–11, SI2C41
		Breast	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15
		Musculo-skeletal	C 1-8, CX 1-8, L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, SI2C41
		Pediatric	C 1-8, CX 1-8, L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11, SI2C41
		Small Organs (Testicles)	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11
		Thyroid	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11
		Urology	C 1-8, CX 1-8, E 3-12, SI2C41, TLC 3-13
	Vascular	Adult Cephalic	P 1–5, PX 1–5
		Vascular	C 1-8, CX 1-8, L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11, P 1–5, PX 1–5
	Women Health	Gynecology	C 1-8, CX 1-8, E 3-12, SI2C41, TLC 3-13
		OB/Fetal	C 1-8, CX 1-8, E 3-12, L 3–11, mC 3–11, SI2C41

Table A–3 Virtual Navigator applications (cont'd.)

Feature	Main Application	Districts	Probes
Fusion Imaging 2D Body Map	General Imaging	Abdominal	C 1-8, CX 1-8, L 3–11, L 4-15, LMX 4-20, LX 3-15, mC 3–11, P 1–5, PX 1–5, SI2C41
		Breast	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15
		Musculo-skeletal	C 1-8, CX 1-8, L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, SI2C41
		Pediatric	C 1-8, CX 1-8, L 3–11, L 4-15, L 8-24, mC 3–11, LMX 4-20, LX 3-15, SI2C41
		Small Organs (Testicles)	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11
		Thyroid	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11
		Urology	C 1-8, CX 1-8, E 3-12, SI2C41, TLC 3-13
	Vascular	Adult Cephalic	P 1–5, PX 1–5
		Vascular	C 1-8, CX 1-8, L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15, mC 3–11, P 1–5, PX 1–5
	Women Health	Gynecology	C 1-8, CX 1-8, E 3-12, SI2C41, TLC 3-13
		OB/Fetal	C 1-8, CX 1-8, E 3-12, L 3–11, mC 3–11, SI2C41
Breast Navigation	General Imaging	Breast	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15
Breast Nav MRI	General Imaging	Breast	L 3–11, L 4-15, L 8-24, LMX 4-20, LX 3-15
Urofusion	General Imaging	Urology	CX 1-8, E 3–12, TLC 3–13

B

B. ULTRASOUND SAFETY

B.1. Introduction

Esaote has adopted the more recent requirements and recommendations established by the USA Food and Drug Administration and by the American Institute of Medicine and Biology. **MyLab** is equipped with the **Acoustic Output Display** feature to provide the user with real time, on-line information on the actual power of the scanner. The following paragraphs describe the rationale of this methodology. Esaote recommends the use of the **ALARA** principle described in this appendix.

Refer to the glossary at the end of this appendix for specific terms.

B.2. Safety Statements for diagnostic ultrasound

In the USA, in more than three decades of use, there has been no report of injury to patients or operators from medical ultrasound equipment.

The **ALARA** (**A**s **L**ow **A**s **R**easonably **A**chievable) principle is the guideline for prudent use: during an exam, the user should use for the shortest duration the least amount of acoustic output to obtain the necessary clinical information for diagnostic purposes.

B.2.1. American Institute for Ultrasound in Medicine (AIUM) Statement on Prudent Clinical Use and Safety of Diagnostic Ultrasound (released in 2012 and revised in 2017 and 2019)

The whole statement is reported on AIUM web site: https://www.aium.org/officialStatements/34

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use. No independently confirmed adverse effects caused by exposure from present diagnostic ultrasound instruments have been reported in human patients in the absence of contrast agents. Biological effects (such as localized pulmonary bleeding) have been reported in experimental mammalian systems at diagnostically relevant exposures, but the clinical relevance of such effects is either not significant or is not yet know. Increased outputs and time of exposure can increase the likelihood of bioeffects. Ultrasound should be used only by qualified health professionals to provide medical benefit to the patient. Ultrasound exposures during examinations should be as low as reasonably achievable (ALARA).

B.2.2. American Institute for Ultrasound in Medicine (AIUM) Statement on Prudent Use and Safety of Diagnostic Ultrasound in Pregnancy (released in May 2020)

The whole statement is reported on AIUM web site: https://www.aium.org/officialStatements/79

Based on the epidemiologic data available and on current knowledge of interactive mechanisms, there is insufficient justification to warrant conclusion of a causal relationship between diagnostic ultrasound and recognized adverse effects in humans. Some studies have reported effects of exposure to diagnostic ultrasound during pregnancy, such as low birth weight, delayed speech, dyslexia, and non–right-handedness. Other studies have not demonstrated such effects. The epidemiologic evidence is based primarily on exposure conditions before 1992, the year in which acoustic limits of ultrasound machines were substantially increased for fetal/obstetric applications. In addition, the absence of conclusive studies demonstrating causal relationships does not constitute proof that adverse effects are impossible. Therefore, prudent use and safety of diagnostic ultrasound in pregnancy should involve a conservative approach that obtains necessary diagnostic information at minimal exposure.

The American Institute of Ultrasound in Medicine (AIUM) advocates the responsible use of diagnostic ultrasound and strongly discourages the nonmedical use of ultrasound. The use of ultrasound without a medical indication to view the fetus, obtain images of the fetus, or identify the fetal external genitalia is inappropriate and contrary to responsible medical practice.

The AIUM recommends that appropriately trained and credentialed medical professionals who have received specialized training in fetal imaging perform all fetal ultrasound examinations. These individuals have been trained to recognize medically important image patterns, such as may be present with congenital anomalies, as well as artifacts associated with ultrasound scanning that may mimic pathology. Furthermore, they should be proficient in the use of techniques to avoid unnecessary ultrasound exposure to the fetus. The AIUM emphasizes that all imaging requires proper documentation and a final report for the patient medical record signed by a physician or an advanced clinical provider legally responsible for interpretation.

Although the general use of ultrasound for medical diagnosis is considered safe, ultrasound energy has the potential to produce biological effects. It is the responsibility of the operator to minimize the possibility of ultrasound bioeffects by limiting exposure and dwell times, by monitoring the output display indices (thermal index [TI] and mechanical index [MI]), and by using Doppler and elasticity imaging and measurement appropriately only for a medical indication.

B.2.3. British Medical Ultrasound Society (BMUS) Statement for the General Public on the Safety of Medical Ultrasound Imaging (released in September 2017)

The whole statement is reported on BMUS website: https://www.bmus.org/static/uploads/resources/Statement_for_the_General_Public_on_the_Safety_of_Medical_Ultrasound_Imaging_Sept_2017.pdf

Ultrasound has been widely used in medical imaging since the 1960s. In medical circles it is recognised as an extremely useful and safe tool; it has benefits to the patient that greatly outweigh any potential risks when used for a justified medical purpose and by a suitably trained operator.

There is no evidence that diagnostic ultrasound has ever produced any harm to adults, children or the human foetus and embryo. However, laboratory tests have shown that ultrasound can cause heating and other potentially harmful effects inside the human body if used at inappropriate power levels or for prolonged periods.

To safeguard against these risks, guidelines exist to ensure the operator minimizes the exposure levels, keeping them within a safe range.

Hence, the British Medical Ultrasound Society (BMUS) considers medical imaging to be safe when it is performed:

- for a clear clinical indication or for appropriate and recognised training of health care practitioners,
- using well maintained equipment,
- by properly trained professionals,
- and that the ultrasound exposure is kept as low as reasonably achievable (ALARA principle).

All unnecessary exposure to the human body should be avoided as it provides no medical benefit to outweigh any potential harm. In particular, ultrasound should not be used on pregnant women solely for 'entertainment' or 'bonding' purposes.

B.2.4. European Committee for Medical Ultrasound Safety (ECMUS) and the European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB)'s Committee for Medical Ultrasound Safety: EFSUMB Clinical Safety Statement for diagnostic Ultrasound- (2019 revision)

DOI: 10.1055/a-1010-6018

In this statement ECMUS and EFSUMB affirm that:

- Diagnostic ultrasound has been widely used in clinical medicine for many year with no proven deleterious effects.
- Ultrasound examinations should be performed by competent personnel who are trained and updated in safety matters.
- It's important that ultrasound devices are CE (European Conformity) approved and appropriately maintained.
- Available safety information during clinical scanning. Ultrasound produces heating, pressure changes and mechanical disturbances in tissue. Diagnostic levels of ultrasound are capable of producing temperature rises that may be hazardous to sensitive organs and the embryo/fetus. Biological effects of nonthermal origin have been reported in animals, but

to date, no such effects have been demonstrated in humans, except when a microbubble contrast agent is present.

- Ultrasound exposure during pregnancy. The embryo/fetus in early pregnancy is known to be particularly sensitive. In view of this and the fact that very little information is currently available regarding possible subtle biological effects of diagnostic levels of ultrasound on the developing human embryo or fetus, care should be taken to limit the exposure time.

  Based on scientific evidence of ultrasound-induced biological effects to date, there is no reason to with-hold diagnostic scanning during pregnancy, provided it is medically indicated and is used prudently by fully trained operators.

- Safety considerations in scanning neonates or the eyes: particular care should be taken to reduce risk of thermal and nonthermal effects during investigation of the eyes and during cardiac, pulmonal and cranial investigations of neonates. When scanning the neonatal brain, the TI should never exceed 3.0 and the duration of ultrasound exposure should be restricted if TI > 0.7.

- Safety information concerning Ultrasound Contrast Agents: the use of contrast agents can potentially produce cavitation or microstreaming, the risk of which increases with mechanical index. Data from small animal models suggest that microvascular damage or rupture is possible. Caution should be considered in use of ultrasound contrast agent in tissue where damage to microvasculature could have serious clinical implications such as brain and the eye, and in the neonate.

B.3. Ultrasound Bioeffects

Although diagnostic ultrasound has an excellent history of safety, it has been known for a long time that ultrasound, at certain levels, can alter biological systems. The AIUM Bioeffects Committee describes two fundamental mechanisms by which ultrasound may induce biological effects:

- Mechanical bioeffects or non-thermal mechanisms[1]
- Thermal bioeffects.

B.3.1. Mechanical Bioeffects

Mechanical bioeffects, also referred to as non-thermal bioeffects, seem to be caused by the tissue alternate expansion and contraction induced when ultrasound pressure waves pass through or near gas. The majority of these non-thermal interactions, also known as cavitation, deal with the generation, growth, vibration, and possible collapse of microbubbles within the tissue. The occurrence of cavitation depends on a number of factors, such as the ultrasonic pressure and frequency, the ultrasonic field (focused or unfocused, pulsed or continuous), the nature and state of the tissue and boundaries. Mechanical bioeffects are a threshold phenomenon, occurring only when a certain level of output is exceeded. However, the threshold level varies depending on the tissue. The potential for mechanical effects is thought to increase as peak rarefactional pressure increases, but to decrease as the ultrasound frequency increases.

1. American Institute of Ultrasound in Medicine Bioeffects Comittee "Bioeffects Considerations for the Safety of Diagnostic Ultrasound"; J:Ultrasound Med, 1988, 7 Suppl.

Although there have been no adverse mechanical bioeffects in humans from diagnostic ultrasound exposure, it is not possible to specify thresholds at which cavitation will occur in mammals.

B.3.2. Thermal Bioeffects

Thermal bioeffect is the rise in temperature of tissue when exposed to acoustic energy. The acoustic energy is absorbed by body tissue; absorption is the conversion of this energy into heat. If the rate of energy deposition in a particular region exceeds the ability to dissipate the heat, the local temperature will rise. The rise in temperature will depend on the amount of energy, the volume of exposure, and the thermal characteristics of the tissue.

B.4. Acoustic Output Display

Until recently, application-specific output limits[2] established by the USA Food and Drug Administration (FDA) and the user's knowledge of equipment controls and patient body characteristics have been the means of minimizing exposure. Now, more information is available through a new feature, named the Acoustic Output Display. The output display provides users with information that can be specifically applied to ALARA. It eliminates some of the guesswork and provides both an indication of what may actually be happening within the patient (i.e. the potential for bioeffects), and what occurs when system control settings are changed. This makes it possible for the user to get the best image possible while following the ALARA principle and thus to maximize the benefits/risks ratio.

MyLab incorporates a real-time acoustic output display according to the AIUM[3]/NEMA[4] "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" publication, adopted in 1992 by both institutions. This **output display standard** is intended to provide on-screen display of these two indices, which are related to ultrasound thermal and cavitation mechanisms, to assist the user in making informed risk (i.e. patient exposure)/benefit (diagnostically useful information) decisions. Considering the type of exam, patient conditions and the case study level of difficulty, the operator decides how much acoustic output to apply for obtaining diagnostically useful information for the patient; the thermal and mechanical indices real-time display is intended to provide information to the operator throughout the examination so that exposure of the patient to ultrasound can be reasonably minimized while maximizing diagnostic information.

For ultrasound equipment with an output display, the FDA currently regulates only the maximum output. **MyLab** has been designed to automatically default the proper range of intensity levels for a particular application. However, within the limits, the user may override the application specific limits, if clinically required. The user is responsible for being aware of the output level that is being used. The **MyLab** real time output display provides the user with relative information about the intensity level.

2. Also known as the pre-amendments limits, those values were established on the basis of acoustic output of equipment on the market before 1976.
3. American Institute for Ultrasound in Medicine.
4. National Electric Manufacturers Association.

B.4.1. On-screen Real-Time Acoustic Output Display

The acoustic output indices are displayed during live scanning to the top right of the screen, together with the transmit power setting.

The following abbreviations are used:

Index	Abbreviation
Soft Tissue Thermal Index	TIS
Bone Thermal Index	TIC
Bone Thermal Index	TIB
Mechanical Index	MI

The output display is organized to provide meaningful information to implement ALARA without "distracting" the user with unnecessary data. During the entry of the patient ID, the user is provided with a choice of applications (Cardio, Vascular, OB, etc.); depending on the selection, the system will default the appropriate indices.

NOTE

Index values below 0.4 are NOT displayed by this system.

To optimize ALARA, index values equal or higher than 0.4 are displayed even if the maximal index value does not exceed 1.0.

The following table shows the indices used for each clinical application. Indices are displayed in 0.1 increments.

Application	MI	TIS	TIB	TIC
OB/Fetal	Yes	Yes	Yes	No
Neonatal[1]	Yes	Yes	Yes	Yes
Adult Cephalic	Yes	Yes	No	Yes
All others	Yes	Yes	Yes[2]	No

1. Includes Neonatal Head studies
2. Only when TIB≠TIS

In combined modes (i.e.: B–Mode+Doppler), the indices will show the highest value between the two modes.

B.4.1.1. The Mechanical Index

The Mechanical Index (**MI**) is related to mechanical bioeffects. It is defined as the peak rarefactional pressure in MPa (derated by a tissue attenuation coefficient of 0.3dB/cm/MHz) divided by the square root of the probe central frequency in MHz.

With the MI, the user can keep the potential for mechanical bioeffects as low as reasonably achievable while obtaining diagnostically adequate images. The higher the index, the larger the potential. However, there is not a level to indicate that bioeffect is actually occurring: the index is not intended to give an "alarm" but to use it to implement the ALARA principle.

B.4.1.2. The Thermal Index

The Thermal Index is related to thermal bioeffects and its purpose is to keep the user aware of conditions that may lead to a temperature rise under certain defined assumptions. It is the ratio between the total acoustic power to the power required to raise tissue temperature by 1°C, estimated on thermal models. There are currently three thermal indices (each based on a specific thermal model) used to estimate temperature rise whether at the surface, within the tissues, or at the point where the ultrasound is focusing on bone:

1. The Soft Tissue Thermal Index (**TIS**) provides information on temperature increase within soft homogeneous tissue.
2. The Cranial Bone Thermal Index (**TIC**) indicates temperature increase of bone at or near the surface, as may occur during a cranial exam.
3. The Bone Thermal Index (**TIB**) provides information on temperature increase of bone at or near the focus after the beam has passed through soft tissue.

As with the Mechanical Index, the thermal indices are relative indicator of temperature rise: a higher value represents a higher temperature rise; they indicate that the possibility for an increase in temperature exists and they provide a relative magnitude that can be used to implement ALARA.

B.4.1.3. The Output Default Settings

System default settings depend upon the probe, the mode of operation and the application which is selected during the patient ID procedure. The **MyLab** defaults the transmit power to obtain output levels that are below the historic Ispta limits established by the FDA for the selected application.

B.5. Methodology and Accuracy of Display

The displayed indices values must be interpreted as relative information to help the user to achieve the ALARA principle.

Initial data are derived from laboratory measurements based on the AIUM standard. Then the indices are calculated beginning from these measurements according to the AIUM/NEMA "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment" publication. Many of the assumptions used for measurements and calculation are conservative in nature. The measured water tank values are derated using the conservative attenuation coefficient established by the standard (0.3 dB/cm/MHz). Over-estimation of actual in-situ exposures is thus part of the calculation process.

B.5.1. Indices Accuracy

A number of factors influence the estimation of the accuracy of the displayed indices, the most significant ones being the variability between probes and the laboratory measurements accuracy (hydrophone, operator, algorithms, etc.) itself, while variability of the system pulsar and efficiency is a minor contributor.

The accuracy estimate, based on the variability range of probes and devices, and on the inherent modeling and measurements errors, is:

- ±15% for the MI
- ±30% for the TI

This accuracy estimate does not consider errors in/or caused by measuring with the AIUM standard.

B.6. Maximum Acoustic Output

This device does not use the historic FDA limits for Isppa and Imax, but rather the MI, which is now considered a better relative indicator of non-thermal bioeffect mechanisms. The maximum MI is below 1.9; the FDA has recognized this value as equivalent to pre-amendments Isppa limits. The maximum output for Ispta is limited to the pre-amendments FDA limit for peripheral vascular applications (720 mW/cm^2).

Other application limits have been established as per this table:

Application	Preamendments Ispta Limits (mW/cm^2)	**MyLab** Maximum(mW/cm^2)
OB/Fetal	94	430
Cardiac	430	720
Pediatric	94	430
Peripheral Vascular	430	720
Other	94	720

The maximum output for a given probe can be less than the system limit, since the maximum depends on various elements (for example crystal efficiency, mode of operation).

B.7. Acoustic Output Controls

In an ultrasound equipment controls may be divided into three categories:

1. controls which directly affect the acoustic output (**direct** controls),
2. controls which indirectly affect the acoustic output (**indirect** controls),
3. controls which do not affect the acoustic output, such as the gains and the processing curves.

B.7.1. Direct controls

Controls which directly affect the acoustic output include:

- the application selection, which establishes the appropriate range of intensities (see maximum output section); the application also establishes the indices to be displayed;
- the **POWER** control, which allows an increase or decrease in the output intensity within the range of the selected application. This parameter will affect both the MI and the TI values.

B.7.2. Indirect controls

Controls which indirectly affect the acoustic output include:

- PRF
- Focal Point
- Frequency
- CFM Process
- Sample Volume

This category includes controls, which change several aspects of the transmitted ultrasonic field rather than the intensity. Intensity is affected because of the field variations. Each mode has its own pulse repetition frequency (PRF) and intensity level; moreover, for each mode, a number of parameters will indirectly affect the transmitted field.

NOTE

The TI index display depends on the application and on the mode.

B–Mode

The MI may increase whenever the PRF is decreased, i.e. when the field of view is increased.

MyLab allows the user to set the transmit focal point which will affect both indices by varying the beam profile. Generally, higher MI's and TI's will occur with closer focal points. If more than one transmit focal point is activated, MI and TI values will each correspond to the zone with the largest value. In addition, all system probes can image at two frequencies; both indices are usually different, depending on the probe bandwidth.

Tissue Enhancement Image (TEI)

The same controls described for 2D affect the acoustic output. Because the tissue response is a non-linear phenomenon, this modality usually **requires higher acoustic outputs** than conventional imaging. While using this mode, the **MI** is your primary concern; a deeper transmit focal point helps to keep the MI value as low as possible.

M-Mode

In M-Mode, the transmitted field is only affected by the transmit focal point and the frequency. If M-Mode is displayed with 2D and the 2D is updated, the system may show the latter mode MI (and TI if available) if higher.

Color Flow Mapping (CFM)

The MI is primarily dependent on 2D settings, i.e. the depth (which will determine the 2D and color PRF) and the transmit focal point. The MI may also be increased by a decrease in the color PRF.

The TI may be increased by increasing the color CFM. Increasing the color frame rate may increase the TI while decreasing the MI. Finally, probes can provide color at two frequencies; the outcome in terms of transmitted field is marginal and largely unpredictable.

Tissue Velocity Mapping (TVM)

This mode optimizes CFM settings in order to image the movement of tissue, thus the same controls described for 2D-CFM affect the acoustic outputs.

Pulsed Wave Doppler (PW)

In PW, the sample volume depth automatically sets the Doppler PRF and the focal point. Deeper sample volumes will cause lower PRF; the MI may, however, not increase since the focal point is far, while the TI is generally reduced. The TI may, however, change if the sample volume size is varied. This factor accounts generally for a MI modification.

Tissue Velocity (TV)

The TV Doppler optimizes your settings to analyse tissue motion.

Finally, most probes provide Doppler at two frequencies; the outcome in terms of transmitted field is marginal and largely unpredictable.

Continuous Wave Doppler (CW)

In CW, the only "variable" factor is the Doppler frequency. As stated before, most probes provide Doppler at two frequencies; the outcome in terms of transmitted field is marginal and largely unpredictable. The user can vary the spectral velocity range; this does NOT, however, change the system's PRF.

NOTE

In Doppler modes, if the tracings are displayed with an updated 2D, the 2D values are used if higher than the Doppler indices.

B.8. Implementing ALARA with MyLab

Prudent use implies that during an exam the user should use for the shortest time the least amount of acoustic output to obtain the necessary clinical information for diagnostic purposes. In other words, the goal is to keep the TI and the MI indices as low as possible for the shortest time while obtaining the necessary clinical information.

This paragraph does not cover the patient and technique factors, which may influence the indices such as the patient body size, the tissue perfusion characteristics, the presence or the absence of fluid, etc.

ALARA Guidelines

- Select the appropriate application when you enter the patient data.

- Depending on the patient characteristics and the type of exam, select the appropriate probe and frequency.
- Use the system capabilities to preset **MyLab** to default each mode according to your needs or specific applications; this will reduce the need for real time interactions and help to quickly obtain useful images, thus reducing ultrasound exposure.
- Start scanning with a low output level and optimize the focusing, the gains and all other adjustments; if this is not adequate for diagnostic purposes, then increase the output level. In cardiac studies, use Tissue Enhancement Imaging if acoustic noise is affecting the images' readability.
- Use the output display feature to guide your settings; remember that the indices do not consider TIME exposure: the higher your indices, the shorter the patient exposure should be.

Which Index When

In **cardiac, vascular** and general purpose (**abdominal, small organ, musculoskeletal**) exams, **MyLab** displays the TIS in addition to the MI. In imaging and CFM modes, the primary concern is in keeping the "cavitation" predictor as low as possible. You can minimize the MI by reducing the power to the lowest possible level, and adjusting the TGC and general gain controls. Use the transmit focal point to enhance resolution and sensitivity in the area of interest: this may increase the MI, but because of the enhanced sensitivity, you may be able to reduce the transmit power, thus reducing the MI. Decreasing the imaging depth as low as possible may allow the system to increase the PRF and thus reduce the MI.

In Doppler modes, if you are working with a B–Mode + Doppler display, the MI will show the B–Mode value (because it is higher than the Doppler one) and the Doppler TIS; the latter parameter should be your primary concern: the MI value reflects the energy to which the patient is exposed only for a minimal time, i.e. between every sweep. You may want however to remember that whenever varying the Doppler speed: increasing the speed will cause the B–Mode to be refreshed more often. You may eventually freeze the B–Mode or switch to a full screen mode; however, this will probably increase the time to actually find the desired signal, and therefore the exposure time.

In **OB** exams, **MyLab** displays both the MI and the TIB in imaging and CFM modes. While the MI will remain your primary concern in those modes, you should also consider the TIB in imaging a second or third trimester fetus as a conservative estimate of the actual temperature rise. In PW Doppler, the latter value is the primary parameter to consider for second or third trimesters pregnancies while the TIS is a more reliable indicator for earlier exams. The general guidelines already expressed for the previous exams remain valid.

For **Neonatal Head** studies, the MI and the TIB may be significant in imaging and CFM modes, while the MI and both TIS and TIB are displayed for Doppler modes. Because of the chance of focusing near the base of the skull, the TIB should be conservatively considered the ideal thermal index. As usual the MI is the primary concern in imaging modes, and the TIB in Doppler. The general guidelines expressed above are valid. In **Adult Cephalic**, because of the skull, the TIC is considered the most significant index for this application. The general guidelines expressed above are valid.

B.9. Acoustic Output Tables

According to the IEC61157 and EN 60601-2-37, the acoustic output tables give the acoustic output data for each probe in every operating mode. These tables are in the System Data section of the user manual.

B.10. British Medical Ultrasound Society (BMUS) recommendation

B.10.1. Initial power setting

Scanners should be set up so that the default (switch-on) setting of the acoustic output power control is low. If a low default setting cannot be achieved, a low setting should be selected after switching on. A low setting should be selected for each new patient. The output should only be increased during the investigation if this is necessary to produce a satisfactory result.

B.10.2. Exposure time

The overall examination times should be kept as short as necessary to produce a useful diagnostic result.

B.10.3. Stationary probe

The probe should not be held in a fixed position for any longer than necessary, and should be removed from the patient whenever there is no need for a real-time image or spectral Doppler acquisition. For example, using the freeze frame or cine loop facilities allows images to be reviewed and discussed without continuing the exposure.

B.10.4. Probe self-heating

Endo-cavitary probes (e.g. vaginal, rectal or esophageal probes) should not be used if there is noticeable self-heating of the probe when operating in air. This applies to any probe, but particular care should be taken if trans-vaginal probes are to be used to investigate a pregnancy during the first 10 weeks after LM.

B.11. Glossary and Definition of Terms

B.11.1. “In Situ” Intensities Calculations

The intensity measurements made in water in the laboratory must be derated to reflect the effects of attenuation.

When determining the possible effects of the ultrasound beam on tissue, the intensity encountered at the tissue site must be calculated. Because of attenuation of the beam within the body,

the intensity at the tissue site ("in situ") may be 10 to 100 times less than if it was measured at the same location in water. The amount of attenuation from experience by an ultrasound beam as it travels through the body tissue is determined by three factors:

1. Type of tissue along the beam path,
2. Frequency of the ultrasound energy,
3. Distance covered by the beam.

In order to achieve a conservative approximation of attenuation due to these three factors, the FDA requires the application of the following formula:

$$Id = Iw \exp^{(-0.23\ a\ f\ z)}$$

- I_d is the estimated "in situ" intensity at the tissue site,
- I_w is the intensity measured in water at a distance "z", measured in cm,
- a is the attenuation coefficient[5] expressed in dB/cm/MHz,
- f is the acoustic frequency in MHz of the ultrasound beam.

B.11.2. Definition of Terms

The **acoustic intensity** generated by an ultrasound probe is usually described as follows:

Ispta

The Spatial Peak Time Average Intensity is an ultrasound intensity averaged over time at the point in the acoustic field where the pulse average intensity is at maximum.

Isppa

The Spatial Peak Pulse Average Intensity is an ultrasound intensity averaged over the pulse transmission time at a point in the acoustic field where the pulse average intensity is at maximum.

Imax

The Maximum Intensity is an average intensity during the half-cycle with the greatest amplitude during the pulse.

Mechanical Index

The Mechanical Index is defined as the peak rarefactional pressure in MPa (derated by a tissue attenuation coefficient of 0.3 dB/cm/MHz) divided by the square root of the probe central frequency in MHz.

5. As per the FDA, this coefficient is equal to 0.3dB/cm/MHz

Thermal Index

The Thermal Index is the ratio between the acoustic power and the power required to raise tissue temperature by 1 ℃, estimated on thermal models.

Peak Rarefactional Pressure

The peak rarefactional pressure (pr in MPa) is the temporal peak rarefactional pressure amplitude at a specified point.

Pulse Intensity Integral

The Pulse Intensity Integral (PII) is the time integral of instantaneous velocity for any specific point and for any specific pulse, integrated over the time in which the envelope of acoustic pressure or the envelope of hydrophone signal for the specific pulse is non-zero. It is equal to the energy fluence per pulse.

B.12. Equations

Table B–1 Indices Equations

Parameter	Equation
Soft Tissue at Surface TIS (scanned[6]) TIB (scanned[6])	$\frac{W_{01}}{\frac{210}{f_c}}$
Large Aperture (A_{aprt}> 1 cm^2) TIS (unscanned[7])	$\frac{max_{z>zbp}[min(W_{.3}(z);I_{TA.3}(z)\times 1cm^2)]}{\frac{210}{f_c}}$
Small Aperture ($A_{aprt}\leq$1 cm^2) TIS (unscanned[7])	$\frac{W_0}{\frac{210}{f_c}}$
Bone at Focus TIB (unscanned[7])	$min\left\{\frac{\sqrt{W_{.3}(Z_{B.3})I_{TA.3}(z_{B.3})}}{50};\frac{W_{..3}(z_{B.3})}{4,4}\right\}$ where $z_{B.3}$ is the depth that maximizes $W_{.3}(z)I_{TA.3}(z)$, or, equivalently, the depth of $I_{SPTAB.3}$.

6. The scanned mode (or autoscanning) is the electronic or mechanical steering of successive ultrasonic pulses or series of pulses, through at least two dimensions.
7. The unscanned mode (or nonautoscanning) is the emission of ultrasonic pulses in a single direction, where scanning in more than one direction would require moving the transducer assembly manually.

Table B–1 Indices Equations (cont'd.)

Parameter	Equation
Bone at Surface TIC	$\frac{W_o}{40D_{eq}}$
Mechanical Index (MI)	$\frac{p_{r.3}(z_{sp})}{\sqrt{f_c}}$ where $p_{r.3}(z_{sp})$ is the peak rarefactional pressure (in MPa) derated by 0.3dBcm^{-1}MHz^{-1} to the point on the beam axis z_{sp} where pulse intensity integral (PII.3) is maximum, and f_C is the center frequency (in MHz).

Table B–2 Symbols Used in Indices Equations

Symbol	Definition
A_{aprt} (cm^2)	Active aperture area
$d_{eq}(z)$ (cm)	Equivalent beam diameter $\sqrt{\frac{4W_{.3}(z)}{\pi I_{TA.3}(z)}}$
D_{eq} (cm)	Equivalent aperture diameter $\sqrt{\frac{4A_{aprt}}{\pi}}$
f_c (MHz)	Center frequency.
$I_{SPTAB.3}$ (mW/cm^2)	Equivalent to the spatial peak temporal average derated (0.6 dBcm^{-1}MHz^{-1}) intensity
$I_{TA.3}$ (z) (mW/cm^2)	Temporal average intensity derated to depth z
W_0 (mW)	Time average acoustic power at source
W_{01} (mW)	Time average acoustic power at the source emitted from the central centimeter of the active aperture
W.3 (z) (mW)	Time average acoustic power derated to depth z
(mW/cm)	Acoustic power per unit linear length (for example of a linear array)
z (cm)	Depth from the surface along the beam axis
z_{bp} (cm)	Break point depth (minimum depth for intensity measurements in the TIS (unscanned) models) $z_{bp} = 1.5D_{eq}$

Table B–2 Symbols Used in Indices Equations (cont'd.)

Symbol	Definition
$z_{B.3}$ (cm)	Depth of the maximum temperature rise in the bone at focus model
$p_{r.3}(zsp)$	Peak rarefactional pressure (in MPa) derated by 0.3 $dBcm^{-1}MHz^{-1}$ to the point on the beam axis z_{sp} where pulse intensity integral (PII.3) is maximum

C

C. ULTRASOUND RESIDUAL RISKS

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

This appendix contains additional information about possible contraindications, undesired side effects or residual risks associated with the clinical use of ultrasound medical devices as reported in the scientific literature and highlighted by the state of the art review conducted from Esaote.

The information provided in this appendix represents the best of Esaote's current knowledge; in any case they are not intended, nor should be used, to establish the correct clinical approach because the ultimate judgment and responsibility regarding any specific procedure must be made by the healthcare practitioner in light of all known circumstances among which the patient's health status and medical conditions and the adherence to the best clinical practices.

Therefore, the potential benefits and risks associated with each ultrasound examination should be always carefully considered by the ultrasound practitioner ahead its conduction.

The information reported in the following sections has been organized to cover the main clinical applications defined in Esaote medical device indications for use:

- Cardiac
- Vascular
- General Imaging
- Women Health (OB/GYN)

C.1. Cardiac Application

C.1.1. Transthoracic Echocardiography (TTE)

Transthoracic echocardiography (TTE) is an established and safe method for assessment of the heart structure and function not only in cardiology (ischemic heart disease, valvular disease, cardiomyopathies, congenital heart disease) but also in pre-operative and intraoperative settings and in intensive care unit. It can be also used to tune cardiovascular risk assessment in specific types of patient.

New echocardiographic techniques, like myocardial strain, were introduced to better assess local and regional LV function.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

Contraindications

There are not absolute contraindications for transthoracic echocardiography.

However it is important to underline that this modality may yield only limited information in patients at the extremes of adult body weight, because a thick chest wall (in markedly obese) or overcrowded ribs (in severely underweight patients) may limit the penetration of ultrasound waves.

Hazards and Undesirable Side Effect

Transthoracic echocardiography has no known risk of complications.

C.1.2. Contrast-enhanced ultrasound (CEUS)

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

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

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

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

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

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

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

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

Contraindication

There are not absolute contraindications to CEUS in echocardiography.

Abundant literature exists supporting the safety of ultrasound enhancing agents (UEAs) use in nonpregnant adults.

The use of UEAs is contraindicated in patients with a history of allergy to the agent or its constituent gas or shell. Hypersensitivity events are due to anaphylactoid (allergic-like) reactions to

the gas or shell. Anaphylactoid reactions include hypotension with tachycardia, bronchospasm, urticaria, and pruritus.

The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions.

For this reason, the use of UEAs is also contraindicated in multiple diseasestate subjects.

These disease-state contraindications include: presence of acute myocardial infarction or acute coronary syndromes, worsening or decompensated heart failure, serious ventricular arrhythmias, or patients at high risk for arrhythmias on the basis of QT-interval prolongation, as well as respiratory failure, severe emphysema, pulmonary emboli, or other conditions that may cause pulmonary hypertension.

Precautions for use

The potential benefits and risks of each examination should be carefully considered.

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

Real-time Very Low MI (VLMI) and low-MI harmonic imaging techniques, usually less than 0.3 for continuous imaging, should be used.

Although anaphylactoid reactions are rare (a rate of 0.001% has been reported in literature for life-threatening anaphylactoid reactions), laboratories that routinely use UEAs should have policies in place for emergent resuscitation of patients who may experience serious side effects.

Precautions related to the use of ultrasound enhancing agents (UEAs) in specific vulnerable populations

- **Pregnant women**

  Even tough currently there're no evidences, attributable solely to direct effects on fetus of the ultrasound enhancing agents (UEAs), that their use might be harmful during pregnancy in humans, teratogenic effects have been demonstrated in animal studies.

  As such the use of contrast agents is still off-label in pregnancy and guidelines recommends caution specifying that ultrasound enhancing agents (UEAs) be used in pregnancy only if benefit outweighs the risk.

- **Breastfeed infant**

  Currently there are no data on the presence of ultrasound enhancing agents (UEAs) in human milk, the effects on the breastfed infant, or the effects on milk production.

  However any potential adverse effects on the breastfed infant from of ultrasound enhancing agents (UEAs) or from the underlying maternal condition should be considered along with the mother's need for contrast enhanced ultrasound examination. In such a circumstances milk can be pumped and discarded within 24 hours of contrast administration as a precautionary measure.

C.1.3. Stress Echocardiography (Stress Echo)

Stress echocardiography is an established method for monitoring global and regional myocardial function under stress in order to detect myocardial ischemia and myocardial reserve regional. Its sensitivity, specificity, positive and negative predictive values for coronary stenosis were established in different studies and are considered adequate for routine diagnostic testing.

Stress echocardiography was also compared with other non-invasive diagnostic methods, like SPECT, CT and Radionuclide emission tomography.

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

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

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

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

Absolute contraindications

- Acute myocardial infarction within 48 hours.
- Acute pericarditis/Myocarditis.
- Symptomatic severe aortic stenosis.
- Uncontrolled Arrhythmias causing symptoms or instability.
- Acute aortic dissection.
- High-risk Unstable Angina.
- Decompensated or unstable heart failure with left ventricle ejection fraction (LVEF) less than 35%.
- Acute pulmonary embolism or pulmonary infarction.

Relative contraindications

- Left main coronary artery stenosis.
- High degree atrioventricular (AV) block.
- Severe hypertension (greater than 180/100mm Hg).
- Electrolyte abnormalities.
- Mental or physical disability.
- Tachycardia or bradyarrhythmia.
- Moderate stenotic valvular heart disease.

Specific contraindications

Specific contraindications to dipyridamole (or adenosine) and dobutamine stress echocardiography include severe conduction abnormalities (highdegree AV block without pacemaker), active bronchospasm, Sick sinus syndrome without a pacemaker, systolic blood pressure less than 90 mmHg, and tachyarrhythmias such as atrial fibrillation.

Generic contraindications

It is important to underline that this modality may yield only limited information in patients at the extremes of adult body weight, because a thick chest wall (in markedly obese) or overcrowded ribs (in severely underweight patients) may limit the penetration of ultrasound waves.

Hazards and Undesirable Side Effect

Minor, but limiting, side effects preclude the achievement of maximal pharmacological stress in 10% of patients with dobutamine and in 5% in patients with dipyridamole stress.

These side effect include palpitation, arrhythmias, headache, dizziness, hypotension. More detailed data are reported in table below.

Table C–1 Side effects

Events	Dobutamine	Dipyridamole
Submaximal test (%)	10	5
Side effects	1/300	1/1000
Ventricular tachycardia and fibrillation	++	+
AV block	+	++
Death	1/5000	1/10000

C.1.4. Transesophageal Echocardiography (TEE)

Tranesophageal Echocardiography (TEE) is a semi-invasive method used for diagnosis and description of specific cardiac pathologies, like congenital heart disease, intracardiac sources of ischemic stroke, infective endocarditis and thoracic aorta dissection. It is also valuable like for intraoperative monitoring, both during cardiac and noncardiac surgical procedures. In cardiac surgery it allows to check an effectiveness of intervention with patient still on operating table under anesthesia. In noncardiac surgery it allows noninvasive monitoring of cardiac and ventilator stability.

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

Examinations should be performed with caution since heating of the transducer has the potential to produce additional heat to adjacent tissue, which may cause esophageal burning and perforation. The probe tip temperature must be monitored during entire examination.

The TEE transducer system has a upper thermal limit set at 41.5°C. If the temperature of the transducer tip reaches the limit a warning appears on the screen and the system freezes unconditionally.

Byte-block must always be used to protect patient's teeth and prevent patient's biting the endoscope.

Byte-blocks and sterile sheaths/covers may contain rubber latex which may cause allergic reactions in some individuals.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

Contraindications

TEE as a semi-invasive technique has several absolute and relative contraindications as indicated in the table below.

Table C–2 List of absolute and relative contraindications to transesophageal echocardiography

Absolute contraindications	Relative contraindications
Perforated viscus	History of radiation to neck and mediastinum
Esophageal stricture	History of GI surgery
Esophageal tumor	Recent upper GI bleed
Esophageal perforation, laceration	Barrett's esophagus
Esophageal diverticulum	History of dysphagia
Active upper GI bleed	Restriction of neck mobillty (severe cervical arthritis, atlantoaxial joint disease)
	Symptomatic hiatal hernia
	Esophageal varices
	Coagulopathy, thrombocytopenia
	Active esophagitis
	Active peptic ulcer disease

The probability of complications increases in perioperative TEE monitoring, when the probe is introduced in esophagus for a longer period and when the patient under anesthesia cannot complain the discomfort.

In addition, it is important that ultrasound transducer is adequately cleaned and disinfected after each examination and procedure, according to recommendations indicated in guidelines.

Other possible issues related to the safety of the procedure

- Byte -block must always be used to protect patient's teeth and prevent patient's biting the endoscope.
- Byte-blocks and sterile sheaths/covers may contain rubber latex which may cause allergic reactions in some individuals.

Hazards and Undesirable Side Effect

The following Table listed risk of TEE and their incidence.

Table C–3 List of complications reported with TEE and the incidence of there complications during diagnostic TEE and intraoperative TEE

Complication	Diagnostic TEE	Intraoperative TEE
Overall complication rate	0.18–2.8%	0.2%
Mortality	<0.01–0.02%	0%
Major morbidity	0.2%	0–1.2%
Major bleeding	<0.01%	0.03–0.8%
Esophageal perforation	<0.01%	0–0.3%
Heart failure	0.05%	
Arrhythmia	0.06–0.3%	
Tracheal intubation	0.02%	
Endotracheal tube malposition		0.03%
Laryngospasm	0.14%	
Bronchospasm	0.06–0.07%	
Dysphagia	1.8%	
Minor pharyngeal bleeding	0.01–0.2%	
Severe odynophagia		0.01%
Hoarseness	12%	0.1%
Lip injury	13%	
Dental injury	0.1%	0.03%

C.2. Vascular Application

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

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

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

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

C.2.1. Extracranial and Peripheral Vessel

Vascular ultrasound is established and safe method for assessment of vascular structure and function. Its value has been established for detection of vascular stenosis both in extracranial vessel and peripheral vessels. It is an established screening method for patients with stroke and claudication. It is also used for monitoring of patients undergoing vascular surgery. In recent

years vascular ultrasound established its role also in primary and secondary prevention of CV diseases. The performance of vascular ultrasound has been tested against other methods. Normalcy values have been established in large multicenter populations.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

C.2.1.1. Abdominal Aorta Vascular Ultrasound Examinations

Contraindications

There are not absolute contraindications to ultrasound of the aorta.

If aortic rupture or dissection is clinically suspected, ultrasound is usually not the examination of choice.

C.2.1.2. Renal Duplex Sonography

Hazards and Undesirable Side Effect

Vascular Ultrasound has no additional known hazards and undesirable side effect.

C.2.2. Cephalic (Adults and Children)

Current guidelines and scientific literature clearly demonstrate that Transcranial Doppler (TCD) can be used to measure flow velocity in the basal arteries of the brain to assess relative changes in flow, diagnose focal vascular stenosis, or to detect embolic signals within these arteries. TCD can also be used to assess the physiologic health of a particular vascular territory by measuring blood flow responses to changes in blood pressure (cerebral autoregulation), changes in end-tidal CO2 (cerebral vasoreactivity), or cognitive and motor activation (neurovascular coupling or functional hyperemia). TCD has established utility in the clinical diagnosis of a number of cerebrovascular disorders such as acute ischemic stroke, vasospasm, subarachnoid hemorrhage, sickle cell disease, as well as other conditions such as brain death.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

Contraindications

There are not absolute contraindications.

However, the use of Transcranal Doppler (TCD) is also hampered by the 10 to 15% rate of inadequate acoustic windows prevalent in Blacks, Asians, and elderly women.

Hazards and Undesirable Side Effect

TCD has no known hazards or undesirable side effects.

C.2.3. Cephalic (Neonatal)

Cranial sonography has an important place in neonatal care. Attributes favorable to sonography that make it almost indispensable for routine care of the newborn includes easy access, low cost, portability, lack of ionizing radiations and exemption from sedation or anesthesia.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

Contraindications

There are no absolute contraindications to neurosonography.

Precautions for use

The potential benefits and risks of each neonatal cranial examination should be considered. The ALARA (as low as reasonably achievable) principle should be observed when adjusting controls that affect the acoustic output and by considering transducer dwell times and a limited use of Color Doppler should be done.

Hazards and Undesirable Side Effect

Ultrasound exposure of the fetal or neonatal brain may lead to a significant temperature elevation at the bone-brain that can potentially affect neuronal structure and function and may also affect behavioral and cognitive function. Approximately 90% of the maximum temperature increase in these studies occurred between 30 and 60 s, reaching equilibrium within 120 s and plateauing thereafter. The temperature rise reported in all three studies is above the threshold recommended by the World Federation for Ultrasound in Medicine and Biology. According to the recommended standards, a diagnostic exposure that elevates fetal in situ temperature above 41°C (4°C above normal temperature) for ≥5 min should be considered potentially hazardous.

C.3. General Imaging

C.3.1. Abdominal

Abdominal US is well-established non-invasive safe method for assessment of intraabdominal organs and abdominal aorta, even in children and in emergency room. In this section were evaluated its indication for diagnosis of diseases involving liver, pancreas, bowel, spleen, and abdominal aorta. Kidney are included in Urology. The use of contrast agent is also well established.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

C.3.1.1. Abdomen and/or retroperitoneum

Hazards and Undesirable Side Effect

There are no known hazards or undesirable side effects.

C.3.1.2. Contrast-enhanced ultrasound (CEUS) in Abdominal organs

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

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

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

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

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

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

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

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

Contraindications

There are not absolute contraindications to CEUS.

Abundant literature exists supporting the safety of Contrast Media use in nonpregnant adults.

The use of Contrast media is contraindicated in patients with a history of allergy to the agent or its constituent gas or shell. Hypersensitivity events are due to anaphylactoid (allergic-like) reactions to the gas or shell. Anaphylactoid reactions include hypotension with tachycardia, bronchospasm, urticaria, and pruritus. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions.

For this reason the use of Contrast media is also contraindicated in multiple disease-state subjects.

These disease-state contraindications include: presence of acute myocardial infarction or acute coronary syndromes, worsening or decompensated heart failure, serious ventricular arrhythmias, or patients at high risk for arrhythmias on the basis of QT-interval prolongation, as well as respiratory failure, severe emphysema, pulmonary emboli, or other conditions that may cause pulmonary hypertension.

Precautions for use

The potential benefits and risks of each examination should be considered.

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

Real-time Very Low MI (VLMI) and low-MI harmonic imaging techniques, usually less than 0.3 for continuous imaging , should be used.

Although anaphylactoid reactions are rare (a rate of 0.001% has been reported in literature for life-threatening anaphylactoid reactions), laboratories that routinely use Contrast Media should have policies in place for emergent resuscitation of patients who may experience serious side effects.

Precautions related to the use of ultrasound enhancing agents (UEAs) in specific vulnerable populations

- **Pregnant women**

  Even tough currently there're no evidences, attributable solely to direct effects on fetus of the ultrasound enhancing agents (UEAs), that their use might be harmful during pregnancy in humans, teratogenic effects have been demonstrated in animal studies.

  As such the use of contrast agents is still off-label in pregnancy and guidelines recommends caution specifying that ultrasound enhancing agents (UEAs) should be used in pregnancy only if benefit outweigh the risk.

- **Breastfeed infant**

  Currently there are no data on the presence of ultrasound enhancing agents (UEAs) in human milk, the effects on the breastfed infant, or the effects on milk production.

  However any potential adverse effects on the breastfed infant from of ultrasound enhancing agents (UEAs) or from the underlying maternal condition should be considered along with the mother's need for contrast enhanced ultrasound examination. In such a circumstances milk can be pumped and discarded within 24 hours of contrast administration as a precautionary measure.

Hazards and Undesirable Side Effect

Use of US contrast agent can induce some light side effects. The most frequent adverse events are headache (2.1%), nausea (0.9%), chest pain (0.8%) and chest discomfort (0.5%). All other adverse events occurred at a frequency of <0.5%.

C.3.1.3. Advanced techniques - Elastosonography (Elaxto© and QElaxto©)

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

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

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

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

Contraindications

SWE have not known contraindications.

Precautions for use

The potential benefits and risks of each examination should be considered.

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

The scanning times should be kept short, especially when exposing vulnerable tissues such as plaques.

Hazards and Undesirable Side Effects

There are no known hazards or undesirable side effects.

However, due to the current lack of dedicated model for TI and MI estimation while SWE mode, the value displayed for these applications may represent an underestimate of the temperature rises and mechanical effects to be expected. With SWE the temperature has its maximum usually at its focus while in standard B-mode is close to the transducer and significant temperature rises may occur if bones lie in the beam. Therefore, it is advisable to adopt the precaution set in the previous paragraph wherever performing SWE imaging (either pSWE or 2DSWE).

C.3.1.4. Urology

In urologic application, US is safe method for detection of infective diseases, tumors and lithiasis. It is also the method of first choice in traumatic lesions and in infants/neonates. The use of echo-contrast is well established in urologic diagnosis. Biopsy of prostate is performed under US control.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

WARNING

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

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

Contraindications

Coagulation problems in US-guided biopsies.

Precautions for use

The potential benefits and risks of each examination should be considered.

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

Transrectal probes, after ultrasound gel application, must be covered by a disposable sheath before insertion. After the examination and disposal of the sheath, the probe must be disinfected. The method of disinfection may vary with institutional practices in force. Disposable items used during the study must be discarded after each examination.

Hazards and Undesirable Side Effect

Trans-rectal US-guided biopsy has to be performed having in place policies and procedure for cleaning and disinfection the infection control under sterile conditions.

C.3.1.5. Intraoperative and Laparoscopic Abdominal

Intraoperative US (IOUS), including fusion imaging, provides crucial diagnostic and staging information to the surgeon during surgery. The technique has a demonstrated positive effect on patient care, surgical planning, and clinical outcome. Current applications for intraoperative US include tumor staging, metastatic survey, guidance for metastasectomy and various tumor ablation procedures, documentation of vessel patency, evaluation of intrahepatic biliary disease, and guidance for whole-organ or split-liver transplantation as well as for neurosurgery.

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

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

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

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

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

Contraindications

Coagulation problems in patients affected by coagulopathy or under anticoagulant/antiplatelet therapy.

Precautions for use

The potential benefits of performing IOUS or LUS examinations and risks of induced contamination or cross-contamination should be considered.

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

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

Hazards and Undesirable Side Effect

Laparoscopic US (LUS) -related morbidity is low and has been reported to range between 0% and 4%. Most complications are minor and consist of wound infections, bleeding at port sites, or skin emphysema. There are no available studies that compare complications between a short-duration procedure only with inspection (DL) and a more extended procedure that combines DL and LUS.

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

C.3.1.6. Musculo-skeletal Conventional and Superficial

US is established method in evaluation of all parts of musculoskeletal system, including inflammatory, degenerative, traumatic and neoplastic diseases.

It has also a growing role in regional anesthesia, pain treatment and as realtime imaging guidance during mini-invasive procedures.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

C.3.1.6.1. Musculoskeletal Ultrasound

Hazards and Undesirable Side Effect

No hazards and undesirable effects are known.

C.3.1.6.2. Regional Anesthesia and other Ultrasound-Guided Procedures

Contraindications

Although there are no known contraindications to the appropriate use of ultrasound guidance to perform a procedure, the following general procedural contraindications apply.

General Contraindications

The appropriate medical history should be reviewed, and a focused physical examination performed to ensure that there are no contraindications to performing the procedure considering.

Absolute contraindications

- Known allergy to the injectate (when applicable).
- Lack of appropriate equipment or skill to complete the procedure.
- Inability of the patient to cooperate with the procedure.

Relative contraindications

- Coagulopathy or anticoagulant/antiplatelet therapy. Patients with coagulopathy or who are taking anticoagulant or antiplatelet therapies have an increased risk of bleeding complications. Clinicians should be familiar with appropriate national, regional, and practice-specific guidelines. Regardless, bleeding risk can be minimized by using Doppler ultrasound with light transducer pressure to evaluate for regional vasculature before the procedure and by using ultrasound to guide the smallest gauge needle possible toward the target structure (optimally with a single pass) while avoiding adjacent vasculature. After the procedure, the area can be monitored with ultrasound for post procedure bleeding and hematoma formation.
- Underlying medical condition that may be affected by the injectate (eg, diabetes mellitus that may be affected by corticosteroids).
- Local infection, rash, or skin breakdown.

Precautions for use

The potential benefits and risks of each examination should be considered.

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

Ultrasound-guided procedures should be performed in accordance with the institutional/hospital approved infection-control guidelines utilizing vendorrecommended disinfection products. The patient's skin should be cleansed with an antiseptic cleanser. The ultrasound transducer may represent a potential source of contamination. Probes should be disinfected between each procedure according to manufacturer recommendations and practicespecific infection control guidelines.

Hazards and Undesirable Side Effect

Depending on targeted anatomical district, ultrasound-guided procedures can lead to major and/or minor complications, although rare, such as hematoma, edema and localized abscess.

If appropriate aseptic and clinical precautions are not respected, bacterial and viral infections are also potential undesirable adverse side effects.

C.3.1.7. Small Organs, Breast and Thyroid

US is established method in evaluation of breast and thyroid nodules and for assessment of testicles, where it could provide information on trauma, inflammation, tumors and disorder of sexual development. It also serves as an imaging method during guided biopsies. Its sensitivity, specificity, positive a negative predicted value has been established and technique of examination, indication and risk has been established by scientific societies. Established reporting of breast and thyroid US, according to ACR is available with Esaote US systems.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

C.3.1.7.1. Breast ultrasonography

Hazards and Undesirable Side Effect

The risk of bleeding and infection has to be considered during biopsies, yet these side-effects are related to the bioptic procedure and not to US technique itself.

Undesirable side effects: Coagulation problems in US-guided biopsies.

C.3.1.7.2. Thyroid and Parathyroid Ultrasound Examination

Hazards and Undesirable Side Effect

The risk of bleeding and infection has to be considered during biopsies, yet these side-effects are related to the bioptic procedure and not to US technique itself.

Undesirable side effects: Coagulation problems in US-guided biopsies.

C.3.1.7.3. Testicles and Scrotal Ultrasound Examination

Hazards and Undesirable Side Effect

No hazards and undesirable effects are known.

C.3.1.8. Neonatal

Neonatal US is optimal non-invasive method for early detection of malformation of brain, spine, heart, hip, GI system, kidney and for assessment of lung development.

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

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

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

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

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

C.3.1.8.1. Neurosonography in neonates and infants

Precautions for use

The potential benefits and risks of each examination should be considered.

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

Neonatal cranial ultrasound should be as short as possible, with limited use of Color Doppler.

Hazards and Undesirable Side Effect

Ultrasound exposure of the fetal or neonatal brain may lead to a significant temperature elevation at the bone-brain that can potentially affect neuronal structure and function and may also affect behavioral and cognitive function. Approximately 90% of the maximum temperature increase in these studies occurred between 30 and 60s, reaching equilibrium within 120s and plateauing thereafter. The temperature rise reported in all three studies is above the threshold recommended by the World Federation for Ultrasound in Medicine and Biology. According to the recommended standards, a diagnostic exposure that elevates fetal in situ temperature above 41°C (4°C above normal temperature) for ≥5 min should be considered potentially hazardous.

C.3.1.8.2. Neonatal and infant spine examination

Contraindications

- Preoperative examination of an open spinal dysraphic defect. However, in such cases the closed portion of the spinal canal away from the open defect can be examined for other suspected abnormalities, such as syrinx or diastematomyelia. These latter abnormalities should be identified preoperatively.
- Examination of the contents of a closed neural tube defect if the skin overlying the defect is thin or no longer intact.

Precautions for use

The potential benefits and risks of each examination should be considered.

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

Neonatal cranial ultrasound should be as short as possible, with limited use of Color Doppler.

Hazards and Undesirable Side Effect

No hazards and undesirable effects are known.

C.3.1.8.3. Assessment of developmental Dysplasia of the Hip

Contraindications

There are not absolute contraindications to ultrasound on infant hip.

However, the diagnostic value of ultrasound diminishes as the femoral head ossifies; therefore, radiography of the hip is preferable for patients 6 months of age or older.

Precautions for use

The potential benefits and risks of each examination should be considered.

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

Hazards and Undesirable Side Effect

No hazards and undesirable effects are known.

C.3.1.8.4. Lung ultrasound in neonates and infants

Hazards and Undesirable Side Effect

No hazards and undesirable effects are known.

C.4. Women Health (OB-Gyn) Application

C.4.1. Gynaecology — Transvaginal

US pelvic and transvaginal has an established role in gynecology, it is mandatory for detection of tumors and assessment of endometrium. where it could provide important information also on hormonal status, infertility, guide interventions including assisted fecundation. New imaging techniques, like CEUS and elastography are also used in gynecologic application.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

WARNING

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

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

C.4.1.1. Ultrasound examination of female pelvis

Contraindications

There are no absolute contraindications to performing ultrasound examination of the female pelvis.

Precautions for use

The potential benefits and risks of each examination should be considered.

The ALARA (as low as reasonably achievable) principle should be observed when adjusting controls that affect the acoustic output, transducer dwell times and total scanning time should be considered.

In case an examination is conducted on a pregnant woman, spectral Doppler ultrasound should not be used on fetus unless clinically indicated.

The use of transvaginal probe during pregnancy should be adequately valuated.

The use of contrast agents is still off-label in pregnancy.

Hazards and Undesirable Side Effect

There is no known risk or hazard.

The use of intravaginal probe should follow the recommendation for proper use of cover sheets and adequate infection control procedures.

C.4.1.2. Pelvic floor ultrasound (PFUS) examination

Contraindications

There are no absolute contraindications to Pelvic floor ultrasound (PFUS) examination.

Relative contraindications

Patients who are unable to consent to the procedure and in situations that would breach infection control guidelines, such as the presence of an open wound or severe vulvovaginal pain and discomfort.

Precautions for use

The potential benefits and risks of each examination should be considered.

The ALARA (as low as reasonably achievable) principle should be observed when adjusting controls that affect the acoustic output, transducer dwell times and total scanning time should be considered. In case an examination is conducted on a pregnant woman, spectral Doppler ultrasound should not be used on fetus unless clinically indicated and the overall scanning time and ultrasonic exposure to gain the necessary diagnostic information should be kept as low as possible.

The use of transvaginal probe during pregnancy should be adequately evaluated.

Hazards and Undesirable Side Effect

There is no known risk or hazard.

The use of intravaginal probe should follow the recommendation for proper use of cover sheets and adequate infection control procedures.

C.4.2. Gynecology - Shear Wave Elastography

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

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

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

C.4.3. Obstetric and Fetal Application

Obstetric and Fetal US is an established method for the detection and confirmation of pregnancy, for the detection of multiple pregnancies, congenital diseases, for the follow-up of fetal growth and well-being, for the assessment of placental/ uterine abnormalities.

This paragraph resumes the most important indications, contraindications, precaution, hazard and undesirable side effect from guidelines documents.

Precautions for use

The potential benefits and risks of each examination should be considered.

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

The overall scanning time and ultrasonic exposure to gain the necessary diagnostic information should be kept as low as possible.

Spectral Doppler ultrasound should not be used on fetus unless clinically indicated.

The use of transvaginal probe during pregnancy should be adequately valuated.

Hazards and Undesirable Side Effect

There are no known hazards and undesirable side effects and diagnostic ultrasound studies of the fetus are generally considered safe during pregnancy.

The use of intravaginal probe should follow the recommendation for proper use of cover sheets and adequate infection control procedures.

C.4.4. Fetal

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

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

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

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

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

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

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

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

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

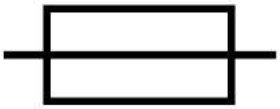
The ALARA (as low as reasonably achievable) principle should be observed when adjusting controls that affect the acoustic output and transducer dwell times should be considered.

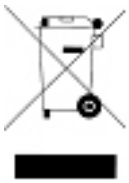
D. DEVICE LABELS

MyLab devices use the EN60601-1 safety symbols for medical electronic devices to classify a connection or to warn of any potential hazard.

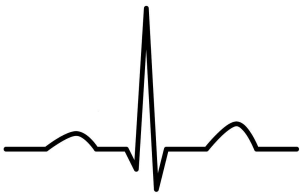
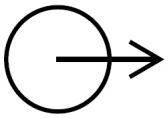
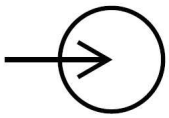
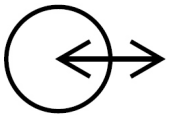
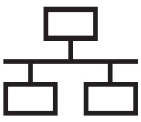
The following tables describe the labels that may be used on the equipment and the packaging.

D.1. Equipment Labels

Symbol	Explanation
	On (Mains Power) In some cases a green light replaces this symbol
	Off (Mains Power)
	Stand-by (Mains Power)
	Fuse
	Type CF applied part
	Type B applied part

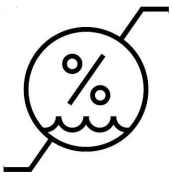
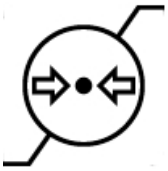
Symbol	Explanation
	Type BF applied part
	Equipotential connection
	Dangerous Voltage
	This symbol generically means “Caution”. Consult the appropriate sections of user manuals.
	General Warning
	Operating instructions. This symbol indicates to carefully read the user manuals.
	Operating instructions. This symbol advises to carefully read the user manuals.
	Device contains radio module fully compliant with CFR47 Part 15 Sub.C (under FCC rules). Device meets requirements of CFR47 Part 18 (under FCC rules).
	Separate collection for electrical and electronic equipment. This symbol indicates to dispose of the equipment as special waste according to the applicable local regulations.

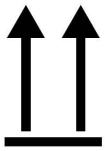
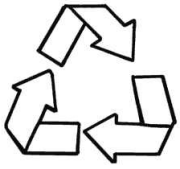
Symbol	Explanation
IP	This symbol indicates the degree of protection provided by the enclosure per IEC 60529. **IPX1:** Protected against vertically falling water drops. **IPX7:** Protected against the effects of temporary immersion in water. **IPX8:** Protected against the effects of continuous immersion in water.
MOD.	Device model
REF	Device part number
SN	Device serial number
	Date of manufacture. The date is located adjacent to the symbol.
	Manufacturer. The date of manufacture can be combined with this symbol.
	CE Mark of Conformity
	Product certified by CSA for U.S. and Canadian markets
	Data matrix barcode (UDI compliance)
	USB connection
	USB 3.0 connection
	HDMI connection

Symbol	Explanation
	VGA connection
	DVI connection
	Headphone connection
	Microphone connection
	ECG connection
	Output connection
	Input connection
	Combined Input/Output connection
	LAN connection
	Direct current

Symbol	Explanation
	Alternating current
	Radio frequency signal
	Esaote logo

D.2. Packaging Labels

Symbol	Explanation
	Temperature limit
	Humidity limit
	Atmospheric pressure limitation
	Stacking limit
	Fragile: handle with care

Symbol	Explanation
	Keep away from rain
	This way up. It indicates the correct upright position.
	Use no hooks
	Recycling material
	Recycling material. The packaging material complies with the RESY requirements.