

ESAOTE

Rev. G

October 2011

MyLabFive INTRODUCTION

Doc # 41B02EN07

User's kit

The box contains the licenses, the USB pen drive and the "Operator Manuals" disk.

Licenses

The licenses enable specific functions of the system, e.g. the Clip. Licenses are linked to the system's serial number and are, therefore, unique. They should be carefully stored. The system is delivered by ESAOTE, with the licenses installed.

MyLab Pen Drive

The appliance is supplied with a customised USB pen drive. The pen drive can be used as a digital support for data. For further information on how to use it, please read the Getting Started manual.

"Operator Manuals" Disk

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

Operator Manuals

These manuals refer to the **MyLabFive** product, indicated by the name **MyLab** inside the manuals. The Operator Manuals consist of four Sections:

Getting Started

The manual describes how to install the system and provides the main instructions for using it.



This symbol is used to indicate this section of the manual. Whenever it is shown, it indicates that further information on the specific subject is available in this section.

Transducers and Consumables

The manual describes the cleaning, disinfecting and maintenance procedures for the probes and their accessories. Information is also supplied on the consumables that can be used.



This symbol is used to indicate this section of the manual. Whenever it is shown, it indicates that further information on the specific subject is available in this section.

Safety and Standards

The manual contains information about the patient and operator's safety. The system's conformity standards are also indicated.



This symbol is used to indicate this section of the manual. Whenever it is shown, it indicates that further information on the specific subject is available in this section.

Advanced Operations

The manual contains information about all additional features not mentioned in the getting started manual.



This symbol is used to indicate the "Advanced Operations" Manual, available in the "Operator Manuals" CD.

Note

The Operators Manuals describe all operations relating to the correct and safe use of **MyLab** systems. Any system malfunctioning caused by uncorrect operations is considered as falling under the user's responsibility.

Veterinary Use

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

However, the user should be aware of the limitations in calculations and results.

Please contact Esaote personnel for information on the correct maintenance procedures to be followed in case of use in veterinary environment.

MANUFACTURER'S RESPONSIBILITY

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

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

Product Life Cycle

Life Time

The safety and effectiveness of **MyLab** ultrasound systems are guaranteed for at least six years from the purchase date, provided that:

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

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

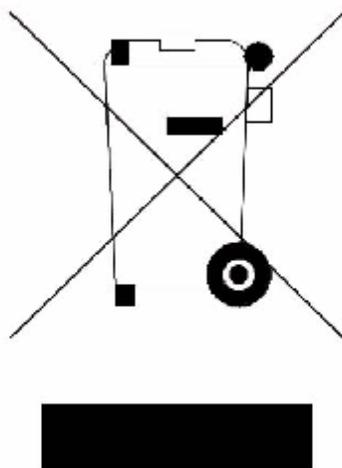
Maintainability Time

Esaote ensures maintainability of **MyLab** ultrasound systems for six years from the purchase date.

End-of-Life Disposal

MyLab ultrasound systems fall within the application field of the 2002/96/EC Directive on waste electrical and electronic equipment (WEEE).

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



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

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

Caution

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

DICHIARAZIONE CE DI CONFORMITA' - Direttiva 93/42/CEE - allegato II
CE DECLARATION OF CONFORMITY - 93/42/EEC Directive - annex II
DECLARATION DE CONFORMITÉ - 93/42/CEE - annexe II
KONFORMITÄTSEKTLÄRUNG - 93/42/EWG - Anhang II
DECLARACIÓN DE CONFORMIDAD CE - Directiva 93/42/EEC

Noi costruttori:

We manufacturer:

Nous les Constructeurs:

Wir, die Hersteller:

Nosotros, los fabricantes

ESAOTE EUROPE – Philipsweg 1 – 6227AJ Maastricht – The Netherlands

dichiariamo, sotto la nostra responsabilità, che il sistema:

declare under our sole responsibility that the system:

déclarons sous notre responsabilité que le système:

erklären, daß das System, unter unserer Verantwortung:

declaramos, bajo nuestra responsabilidad, que el producto:

MyLabFive

è stato costruito applicando il sistema di garanzia della qualità approvato per la progettazione, fabbricazione e controllo finale del prodotto e risponde alle disposizioni presenti dell'Allegato II della direttiva 93/42/CEE sui dispositivi medici.

has been manufactured by applying the quality system approved for the design, manufacture and final inspection and meets the provisions of the 93/42/EEC-Annex II medical devices directive.

a été construit en appliquant le système de qualité approuvé pour le projet, production et contrôle final du produit et répond aux dispositions de la directive 93/42/CEE-Annexe II pour les appareils médicaux.

mit der Anwendung des geprüften Qualitätssystems für das Projekt, die Fertigung und die Schlußkontrolle des Produkts gefertigt wurde und daß es die Anordnungen der Richtlinie 93/42/EWG-Anhang II für medizinische Geräte erfüllt.

ha sido fabricado aplicando el sistema de garantía de la calidad aprobado para el diseño, fabricación y control final del producto y responde a los requisitos presentes en el Anexo II de la directiva 93/42/EEC sobre los dispositivos médicos.

Il rappresentante legale ESAOTE EUROPE.
ESAOTE EUROPE legal representative.
Le représentant légal de ESAOTE EUROPE.
ESAOTE EUROPE autorisierter Bevollmächtigter.
El representante legal de ESAOTE EUROPE.

USE LICENSE AGREEMENT FOR THE SOFTWARE INCLUDED IN THE APPARATUS

Attention

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

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

PROPRIETARY RIGHTS

You have acquired a device ("DEVICE") which includes Esaote proprietary software and/or software licensed by Esaote 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 or its Software Suppliers.

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

LICENSE RIGHTS AND LIMITATIONS

With this license, Esaote 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.

PRODUCT TRACEABILITY

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

Product Traceability Form

To: ESAOTE EUROPE
Quality Assurance Department
Philipsweg 1
6227AJ Maastricht
The Netherlands

ESAOTE system/device name:

REF:

SN:

Name and address of the original owner:

.....

Name and address of the new owner:

.....

Date:

Signature

VIGILANCE SYSTEM

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

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

Post-Marketing Vigilance Form

To: ESAOTE EUROPE
Quality Assurance Department
Philipsweg 1
6227AJ Maastricht
The Netherlands

ESAOTE system/device name:

REF:

SN:

Description of the potential/real hazard:

.....

Notes and suggestions:

.....

Contact Person/Department:

Address:

Phone: Fax:

Date:

Signature

Important Information



0344

This mark complies with the Medical Device Directive 93/42/EEC.

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

SYSTEM CONFIGURATIONS AND OPTIONS

Standard Configuration

97154411410 **MyLabFive 100-240V/50-60Hz**

Multipurpose mobile digital console including large TFT LCD very high resolution color monitor , General Imaging, TEI, B-Steer, TP-View, Auto-Adjust for B mode and Doppler

Multipurpose platform allowing QIMT technology (opt)

Transmission:

Probes have independent digital delay. Variable multiple focal points position.

Reception:

Full digital beam former for Imaging, CFM (Optional) and Doppler (Optional). Variable aperture and dynamic focusing.

General:

Dual processors, Unix and WindowsXP O.S.

High sensitivity CFM and Power Doppler processing (Optional)

PW, HPRF, and steerable CW Doppler (Optional)

Windows formats (BMP, AVI) for still images and clips

2 Probe connectors (1 for PA/LA/CA probes,1 for Doppler probe) + 1 Connector optional

Advanced Technology (Real Time Archive)

External CD and DVD Reader and Writer Optional

Internal Hard Disk

USB storage memory kit

Video Signals (S-VGA, RGB, S-VHS, Composite)

Video Standard NTSC/PAL

Software (multi-lingual, CD upgrading capability)

Biometry (cardiac and vascular reports) optional

On/Off-line basic measurements

Safety (EN 60601-1, EN 60601-1-2, EN 30993-1, EN 61157).

Battery operated (Optional)

The above system will be provided with Quick Reference Guide and Electronic-User Manual

The above system must be ordered specifying one of the following power settings:

97154411418 Mains Cable Euro

97154411420 Mains Cable Italy

97154411766	Mains Cable United Kingdom
97154411767	Mains Cable Australia
97154411768	Mains Cable China
97154411770	Mains Cable USA Medical
	The above system must be ordered specifying one of the following language settings:
97154312948	English setting
97154312949	German settings
97154312950	Italian setting
97154312951	French setting
97154312952	Spanish setting
	The above system must be ordered specifying one of the following Video settings:
97154311931	PAL setting
97154311932	NTSC setting

Options

Optional Trolley

9807310000	Docking station trolley 200-230 V
9807310001	Docking station trolley 100-115 V
9707320010	Collapsable trolley
9103286000	Shorter height support for docking station trolley
9707315000	Height-Adjustable Trolley
9730680004	UPS group 35 minutes autonomy
9103156000	Rechargeable battery pack for collapsable trolley

Optional Modules

97154411590	Internal Battery kit
97154411450	External CD/ DVD writer

Optional Licenses (s/n required)

97154411431	Cardio License
97154411425	Vascular License
97154411426	Ob-Gyn License
97154411427	Urology License
97154411430	DICOM License
97154411690	Doppler PW License
97154411691	Doppler CW License
97154411423	CFM License
97154411434	CnTi License
97154411449	2nd Probe Connector
97154411429	Clips Archive License
97154411436	QIMT License (Real time based on RF input), Vascular License required
97154411692	Fetal Weight Index License (OB-GYN License required)
97154411437	X-View License
97154411435	Compass M-Mode License
97154411432	TVM License
97154411428	Stress Echo License (Cardio License required)

97154411695 X-Strain license for MyLab Desk
97154411694 M-View

Electronic Probes

97154411664 PA121E Phased Array Probe
97154411665 PA122E Phased Array Probe
97154411666 PA023E Phased Array Probe
97154411675 PA230E Phased Array Probe
97154411381 LA523P Linear Probe
97154411669 LA523 Linear Probe
97154411674 LA522E Linear Probe
97154411679 LA435 Linear Probe 18-6
97154411686 LA332 Linear Appleprobe
97154411671 CA123 14R Microconvex Probe 9 5
97154411681 CA 431 Convex Probe 8 1
97154411395 CA1421 R40 Convex Probe
97154411008 C5-2 R13 Microconvex probe
97154411683 CA631 – Convex probe 8-1
97154411677 CA430E Convex Probe 35 50
97154411678 TEE022 Multi-plane Transesophageal Probe 7 3
97154411684 TEE122 Pediatric Multi-plane Transesophageal Probe 7 3
97154 411780 TEE132 Pediatric Multi-plane Transesophageal Probe 7 3
97154411672 IOE323 Intraoperative probe 10 5
97154411673 LP 323 Laparoscopic probe 10 5
97154411670 EC123 End-Fire Cavity Probe
97154411312 EC1123 End-Fire Cavity Probe
97154411280 E8-5 R10P End-Fire Cavity Probe
97154411696 TRT33 biplane Probe

Doppler Probes

97154411661 2.0 MHz Probe (PW/CW)
97154411662 5.0 MHz Probe (PW/CW)
96002 14000 HF CW Probe (PW/CW)

Cables

97154402184 VTR S-VHS CABLE
97154402185 RGB THERMAL PRINTER CABLE
97154402197 B-W PRINTER CABLE
8830747000 B-W/RGB SPLITTER CABLE
9630028000 ECG Cable IEC
9360028010 ECG Cable AHA
8830749000 USB double cable shielding
8830915000 Printer cable

Biopsy Kit

9102157000 ABS523 (biopsy angle of 45 deg.)

9102159000	ABS421 (biopsy angle of 20, 30 deg.)
9101699000	ABS15 (biopsy angle of 45 deg.)
9102199000	ABS123 (biopsy angle of 3.8 deg.)
9102158000	ABS621 (biopsy angle of 25, 35 deg.)
9102156000	ABS424 (biopsy angle of 45 deg.)
97154410662	NG TYPE T (biopsy angle of 36 deg.)
97154401795	NG TYPE O (biopsy angle of 3 deg.)
97154411057	NG TYPE X (biopsy angle of 3.8 deg.)
9103431000	WBSL33X (Biopsy angle 35 deg.)
9650052000	DBSC12X (Biopsy angle 15 deg.)
9650056000	DBS523 (Biopsy angle of 45, 60, 75 deg.)

For information about prices and further options please refer to the MyLabFive Pricelist.

