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PROBES AND CONSUMABLES

141003500

Forewords

This manual provides information about the probes and consumables that can be used with the Esaote **MyLab** devices.

WARNING

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

CAUTION

The word CAUTION describes the precautions necessary to protect the equipment.

NOTE

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

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

The **MyLab** devices have multiple configuration and feature sets. All of them are described in this user manual but not every option may apply to your device.

Available features are dependent on your **MyLab** configuration, probe, and exam type. Not all the features are approved in all Countries.

Keep the manual with the equipment for future reference.

Manufacturer's Address



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

Important Information



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

Esaote probes are devices in Class IIa according to the Medical Device Directive.

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

EC Declaration of Conformity

esaote

DICHIARAZIONE DI CONFORMITÀ CE
EC DECLARATION OF CONFORMITY

Noi costruttori
We manufacturer

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

dichiariamo, sotto la nostra responsabilità, che le sonde per sistemi per diagnostica ad ultrasuoni
declare, under our sole responsibility, that the probes for ultrasonic medical diagnostic systems

Convex, Microconvex	AC2541; C 1-8; C5-2 R13; CA123; CA133; CA421; CA430E; CA431; CA541; CA621; CA631; CA1123; CA1421; mC 3-11; SC3121; SC3123; SC3421; C 2-9
Lineari/*Linear*	AL2442; AL2443; AL2445; L 3-11; L 4-15; L 8-24; LA332E; LA424; LA435; LA522E; LA523; LA523E; LA532E; LA533; LA923; SL1543; SL2325; SL3116; SL3235; SL3323; SL3332
Phased Array	P 1-5; P2 3-11; P2 5-13; P 3-11; P 5-13; PA023E; PA121E; PA122E; PA230E; PA240; PA250; SP2430; SP2442; SP2730; SP3630; P 2-9; PX 1-5; PX 1-5B
Volumetriche/*Volumetric*	BC431; BC441; BE1123; BL433; SB2C41; SB3123
Doppler	2 MHz CW; 5 MHz CW; HF CW; S2MCW; S2MPW; S5MCW; SHFCW
Endocavitarie/*Endocavity*	E8-5 R10P; EC123; EC1123; SE3123; SE3133; E 3-12
Transesofagee/ *Transesophageal*	ST2612; ST2613; TEE022; TEE122; TEE132
Intraoperative e Speciali/ *Intraoperative & Special*	CAB411A; IH 6-18; IL 4-13; IOE323; IOT332; IOT342; LP 4-13; LP323; SI2C41; TLC 3-13; TRT33; IHX 6-18

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

Classificazione: *Classification:*	Classe IIa secondo l'allegato IX della Direttiva 93/42/CEE *Class IIa according to Annex IX of 93/42/EEC Directive*
Numero identificativo dell'Organismo Notificato: *Notified Body identification number:*	**0123**
Nome e indirizzo dell'Organismo Notificato: *Notified Body name and address:*	TÜV Süd Product Service GmbH, Ridlerstr.65, D-80339 Munich – Germany
N° Certificato CE/ *EC Certificate No.:*	G1 095545 0023 Rev. 00
Procedura di conformità: *Conformity procedure:*	Allegato II della Direttiva 93/42/CEE, emendata con la Direttiva 2007/47/CEE, escluso punto 4. *Annex II without point 4 of the 93/42/EEC Directive as amended by the 2007/47/EEC Directive.*
Luogo e data/*Place and date*	Firenze/*Florence* – Italy 2019-11-11

Ing. Massimo Polignano
Responsabile Assicurazione Qualità
Chief Quality Officer

Dichiarazione/*Declaration* 834 0101 000 - 31

1/1

Product Life Cycle

Life Time

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

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

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

Maintainability Time

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

End-of-Life Disposal

MyLab probes 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 probe must be disposed of in a separate collection from urban waste.

CAUTION

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

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Chapter 1

1. Care of Probes and Needle Guide Kits

Handling Probes

Damages caused by dropping or knocking a probe against other objects, stepping on or twisting a cable or a cable becoming entangled, are not covered by the warranty.

Incorrect handling can seriously damage any probe. Both the acoustic lens and the crystal elements can be damaged if the probe is dropped or struck against another object. Cuts on the probe cable or breakage of the housing may jeopardize the electrical safety of the probe.

There are several ways a probe can be damaged, for example:

- dropping or knocking against another object;
- contact with sharp edged objects;
- contact with chemical agents;
- contact with hot surfaces;
- immersion in liquid substances;
- exposure to high voltage discharge;
- exposure to environmental conditions out of allowed range.

WARNING

Do not use a probe if any of the above listed events occurs until it has been established if any electrical damage to the probe has occurred by measuring the current leakage (see Appendix B for further details). Contact the Esaote Service personnel.

CAUTION

Do not tug the probe cable or bend it. If the probes are carried around on a trolley, make sure that the wheels do not roll over the cable.

Periodic Control Schedule

The following table describes the periodic control that must be made on the probes and needle guide kits. The frequency suggested for non-invasive probes is considered to be the minimum; very frequent usage requires more frequent controls.

Table 1-1: Periodic Control Schedule

Operation to be performed	Frequency
Physical inspection of non-invasive probes	Every month or when the probe is dropped or struck against another object.
Physical inspection of endocavity, transesophageal, intraoperative and laparoscopic probes	Before every examination.
Physical inspection of the needle guide kit	Before every examination and if dropped or struck against another object.

WARNING

Never use a probe, if it has been dropped or if any of the above listed events, that could damage the probe, has happened, until you are sure that no electrical damage has occurred to the probe. This can be done by performing a leakage current test (see Appendix B for further details). Contact Esaote Service Personnel for advise.

Probe Inspection

The inspection must be made on all probes to ensure that:

- there are no holes, bulges, abrasions or dents along the entire surface of the probe;
- there are no irregularities on the lens and that the lens is not broken;
- the probe cable is not broken or damaged. Cuts or holes in the cable may jeopardize electrical safety;
- the connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

CAUTION

If any damage is found, DO NOT USE the probe until it has been inspected by Esaote Service personnel.

WARNING

Breaks to the probe casing or to the cable could result in risks to electrical safety.

Do not use a probe if it has been dropped. A leakage current test (see Appendix B for further details) must be performed prior to re-use to ensure that no electrical damage to the probe has occurred.

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective covers DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if it is known or suspected that it has been damaged; contact Esaote Service Personnel immediately.

CAUTION

Do not try to dismantle the probe; any attempt to dismantle the probe may damage it and will void the warranty.

In order to minimize the probability of damaging the probe, the following operations are suggested:

- **do not touch the lens** at the end of the probe, and never exert force on the lens;
- the connector is not waterproof and shall always be kept dry. The probe, although waterproof, should be immersed not beyond the maximum immersion level (refer to Appendix A for further details).

After use, clean and disinfect or sterilize the probe as specified in this manual.

Store the probe as specified in the next paragraphs when not in use.

Specific Inspection for Transesophageal and Laparoscopic Probes

In addition to the above listed inspections perform:

- a manual and visual check of the endoscope while bending the tip in all possible directions; deflection must function according to characteristics and the guides must not protrude during these movements;
- check that the deflection mechanism functions in both modes (free and with friction).

WARNING

In case of incorrect operation of the flexion, do not use the probe and contact the Esaote Service Personnel.

In order to minimize the probability of damaging the probe, add the following operation to the ones suggested above:

- before inserting the probe, **do not rub or spray the tip** of the probe with an **anesthetic agent**.

Storing and Protecting the Probes

Daily Storage and Protection (short term)

Storing and Protecting non-critical Probes

Non Invasive Probes

The special probes slot can be used for short-term storage of non-critical probe types, e.g. linear and convex probes. The special probes slot on the system should be cleaned regularly following local guidelines. If all the available slots are full, place the probe in its case. In any way they are stored (slot or case), all gels must always be cleaned off the probe (see the next chapter for the relative instructions). The probe must always be cleaned/ disinfected following the instructions provided further in this manual.

Storing and Protecting Semi-critical Probes

The Transesophageal Probe

The probe must always be cleaned and sterilized/high level disinfected following the instructions provided further in this manual. The probe must be kept in a way that maintains reprocessing level (e.g. sterile, high-level disinfected as per related instruction further in this manual) and with the endoscope straight. In particular, it is recommended to use:

- wall-mounted supports,
- a storage drawer that is large enough to house the endoscope, bending it as little as possible.

The Endocavity Probe

The probe must always be cleaned and sterilized/high level disinfected following the instructions provided further in this manual. When not in use, the special probes slot on the machine can be used for short-term storage of the endocavity probe. The special probes slot on the system should be cleaned regularly following local guidelines. If all the available slots are full, place the probe in its case.

The probe must be kept in a way that maintains reprocessing level: once reprocessed, store the probe in packaging ensuring to preserve the sterility status (wrapped trays on heat-sealable non-woven, polyethylene sterilization pouches) as indicated in reprocessing IFU above reported. Place the packaged probe in its case or in equivalent place that keeps the probe protected at all

times from sharp objects that may damage the probe or packaging and from humidity.

CAUTION **For short term storage always keep the probe in its case or in the slot. Otherwise it could be accidentally dropped or damaged.**

Storing and Protecting Critical Probes

The Intraoperative and Laparoscopic Probes and any other probe critical by application.
The probes must always be cleaned and sterilized following the instructions provided further in this manual. When not in use, place the probe in its case. The probe must be kept in a way that maintains reprocessing level (e.g. sterile, high-level disinfected as per related instruction further in this manual).

CAUTION **Always keep the probe in its case. Otherwise it could be accidentally dropped or damaged.**

Long-Term Storage or Transport and Protection

All probes are supplied with their own case that must always be used both when transporting the probe and for long-term storage. All probes must at least be thoroughly cleaned and thoroughly dried prior to storage, following the procedures described in the following chapter before putting the probe away in its case.

For long-term storage, check that the environmental requirements indicated on the label of the case are observed. The probe must be stored in a way that maintains reprocessing level (e.g. sterile, high-level disinfected). Probes must be stored in a clean and dry place. Keep the probe protected at all times from sharp objects that may damage the probe or packaging. The watertight connector lid, if any, should not be left on for an extended storage period.

CAUTION **Always use the original case to store the intraoperative and the transesophageal probes. The special shape of these cases prevent damage to the probe due to excessive bending.**

Shipping the Probe

Contact Esaote Service Personnel to ensure that the probe is correctly packed before shipping it.

Needle Guide Kit Control

Always check that:

- the adaptor is not bent. Do not use the adaptor if it has been damaged;
- the needle guide is not bent. Do not use the guide if it has been damaged.

Storing and Protecting Needle Guide Kit

All needle guide kits are supplied with their own case. It is recommended to leave any unused needle guides in the case. The kits must always be sterilized after use (refer to next chapter for procedures). Please refer to the procedures used on-site for storing sterile parts.

Chapter 2

2. Reprocessing Probes and Needle Guides

All Esaote probes require proper reprocessing before each usage. This section contains information and instructions to help you effectively clean and disinfect or sterilize the probes that are compatible with your ultrasound scanner. Additionally, these instructions help avoiding damage during cleaning and disinfection or sterilization, which could void your warranty.

NOTE ***Reprocessing methods are harsh and can shorten the life of the equipment. Equipment that undergoes reprocessing should be checked regularly.***

Reasonable reprocessing includes inspection, cleaning, and disinfection or sterilization, as necessary.

Reprocessing may cause cosmetic changes to the device material that do not necessarily impact the functionality of the device. The most usual cosmetic changes are color changes in the device materials.

To choose an appropriate reprocessing method for your probe, you must first determine the classification of the probe, based on its use. The reprocessing method for your probe determines the appropriate agents/processes that could be used for your probe.

Probes must be reprocessed before first use and after each use.

WARNING **Esaote recommends to reprocess the probe before use, if the probe was not kept, since last reprocessing, at the requested disinfection/sterilization level.**

Table 2-1: Reprocessing Methods for different type of probe

Probe's type	Contacted tissues	Classification	Reprocessing Method
Convex, linear and phased non-invasive probes	Contacts intact skin	Non-critical	Cleaning and Low-level disinfection
Transesophageal (TEE)	Contacts intact mucous membranes	Semi-critical	Cleaning and High-level disinfection or sterilization[1]
Endocavity	Contacts intact mucous membranes	Semi-critical	Cleaning and High-level disinfection or sterilization[1]
Intraoperatory	Contact blood or otherwise sterile tissue	Critical	Cleaning and Sterilization[2]
Laparoscopic	Contact blood or otherwise sterile tissue	Critical	Cleaning and Sterilization
Probe's Needle Guide Kit	Contact blood or otherwise sterile tissue	Critical	Cleaning and Sterilization[2]

1. High-level disinfection and the use of a sterile gel and a probe cover, as described in the instructions provided with the probe cover, is an accepted method of infection control for ultrasound probe. See the WHO guidelines (issued on 2016): "Decontamination and Reprocessing of Medical Devices for Health Care Facilities"
2. Sterile probe covers with sterile ultrasound transmission gel are required for intraoperative and biopsy procedures. Please note that the use of covers does not change the type of processing that is recommended for the probe. See same reference of note (1).

If non-critical probes are used in critical applications (surgical typically), they should be undergone to the same reprocessing and usage condition applied for critical probes as the intraoperatory one.

NOTE ***Probe and needle guide supplied by Esaote are neither disinfected nor sterilized.***

Safety

Probe

All probes that comply with Safety Standard EN60601-1 (IEC60601-1) Type



BF must be checked once a year to ensure that they still comply with the requirements of this standard. Probes that need to be checked have the letters BF or the symbol shown above printed on them. This check must be carried out by qualified personnel. Contact Esaote Service personnel if you need any help checking your probe.

The probe can be inserted in water or other liquid up to the Maximum Immersion Level. (see Appendix A). Damages caused by immersion over the Maximum Immersion Level are not covered under the warranty.

WARNING

Do not immerse the probe in water or other liquid over the Maximum Immersion level. Immersion may compromise the probe integrity and its electrical safety features.

WARNING

Connector immersion in water or other liquid can compromise the safety feature of the probe. Damage caused by the probe immersion is not covered under the warranty.

WARNING

Do not use a probe for neurosurgical applications if the patient is suspected of having Creutzfeldt-Jakob disease. If a neurosurgical probe has been used on a patient suspected of or diagnosed as being Creutzfeldt-Jakob positive, the probe must be destroyed, following approved procedures for your facility.

Agents and system

Refer to Appendix C for a list of recommended cleaning, disinfection and sterilization agents and systems.

Safety information that applies only to a specific reprocessing task is included in the procedure for that task.

The instructions provided further in this chapter have been validated by Esaote as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.

For maximum safety when using reprocessing agents and systems, observe the following warnings and cautions:

WARNING

Do not use agents/systems that have not been recommended by Esaote for chemical compatibility. Damages linked to the use of not recommended systems/agents are not covered under product warranty or service contract.

WARNING

When reprocessing a probe, ensure that the solution's strength and duration of contact are appropriate for reprocessing. Be sure to follow the manufacturer's instructions.

WARNING

Probe may be damaged by use or reprocessing. It is important to check it at least once a month (or more often, if it undergoes sterilization) to ensure that it can be effectively reprocessed. If there are any pits or cracks on any probe surfaces, reprocessing may not give a sterile or disinfected product.

WARNING

Never attempt to clean or disinfect the probes while they are connected to MyLab.

CAUTION

Probes are resistant to ultrasound gel, alcohol, and disinfectants, but if you use those substances, you must wipe them off after each use to prevent permanent damage.

CAUTION

Follow the recommendations of the agent/system manufacturer.

CAUTION

Using non-recommended agent/system, using incorrect solution strengths, or immersing a probe deeper or longer than recommended can damage or discolor the probe and void the probe warranty.

Probe cover

For using procedures of probe covers, see the instructions provided with the covers.

WARNING

Sterile probe covers with sterile ultrasound transmission gel are required for intraoperative and biopsy procedures. Protective covers are recommended for transrectal and intravaginal procedures; in China and Japan, the covers are mandatory. Esaote recommends the use of qualified covers. Please note that the use of covers does not change the type of processing that is recommended for the probe.

WARNING

Probes that contact brain tissue and cerebrospinal fluid should always be used with a sterile, endotoxin-free cover because the disinfectant/sterilant residue left on the probe is neuro-toxic and endotoxin is pyrogenic (e.g., cause fevers).

WARNING

In intraoperative applications, sterilized probes should be used with sterile gel and a sterile probe cover.

WARNING

Inspect probe covers before and after use.

WARNING

Do not apply the probe cover until you are ready to perform the procedure.

WARNING

Sterile probe covers are disposable and must not be reused.

Latex Product Alert

Esaote probes do not contain natural rubber latex that contacts humans.

WARNING

Some probe covers can contain latex. Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises health-care professionals to identify latex-sensitive patients and be prepared to treat allergic reactions promptly.

Personnel

WARNING

Personnel in Sterile Processing Departments, as well as nurses, physicians, sonographers and others, may be responsible for reprocessing medical devices. Anyone who reprocesses medical devices should be thoroughly trained in the proper procedures.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection, and sterilization process. Follow the procedures

established in your facility for the protection of both the staff and its next usage on the patient.

WARNING

Always wear gloves when you handle probes used in TEE, endocavity, intraoperative, and biopsy procedures that have contacted infected patients and have not been yet disinfected.

WARNING

If the device becomes contaminated internally with bodily fluids carrying pathogens, components inside the device cannot be disinfected. In that case, the device must be disposed of as biohazardous material in accordance with local or federal laws and you must immediately notify it following the procedures established in your facility.

Reprocessing of Probes Used in Non-critical Applications

The procedures described in this paragraph explain how to reprocess probes used in non-critical applications. An application is considered non-critical when the probe is used on intact skin.

Both Cleaning and Low-Level or Medium-Level disinfection are reprocessing methods sufficient for these applications. The probes can be cleaned/ disinfected using the recommended agents, following the manufacturer's instructions. For a list of agents compatible with your probe see Appendix C.

WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

WARNING

Immediately after use, you must pre-clean the device until visually clean. Conduct the thorough cleaning process as soon as possible after use in order to prevent bioburden drying on the surface. Dried bioburden can lead to inefficient cleaning, disinfection and sterilization, causing a risk of cross-contamination. If pre and thorough cleaning cannot be done immediately, keep the device moist until cleaning.

WARNING

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

WARNING **Do not soak the probe in the disinfection solution for periods beyond the time required to achieve a disinfection.**

CAUTION **When cleaning and disinfecting probes, do not allow any fluid to enter the connector through the electrical contacts, strain reliefs, connector housing, or areas surrounding the locking lever shaft. On TEE probes, do not allow any fluid to enter the handle or steering mechanism. When wiping or spraying connector or handle housings, wipe or spray only the outer surfaces. If available, place a connector-cover splash guard over the electrical contacts to help preventing fluid from entering the connector housing. Damage due to fluids in these areas is not covered by the warranty or your service contract.**

CAUTION **When cleaning the probe using spray agent, DO NOT spray the probe while it is placed on its holder. Over spray can damage the device: the use of wipe cleaner is suggested in these cases.**

CAUTION **Do not try to sterilize probes using the autoclave, ultra-violet rays, gamma rays or gas, steam or heat sterilization techniques. These sterilization methods can permanently damage the probe. Any damage to the probe caused by substances or methods not approved by Esaote is not covered by the warranty.**

CAUTION **When disinfecting the probe using spray agent, DO NOT spray the probe while it is placed on its holder.**

NOTE ***Probes can be disinfected using the wipe method only if the product labeling of the compatible disinfectant that you are using indicates it can be used with a wipe method.***

Cleaning procedure

Probe must be cleaned immediately after it is used.

Cleaning Procedure

1. Disconnect the probe from **MyLab**;
2. Remove the protective cover, if any;
3. Remove all residues of ultrasound gel from the probe using a soft cloth;
4. Using one of the suggested agents, wipe/spray the probe thoroughly, paying attention to clean grooves and exposed

parts, if present. When a liquid agent is used, wet a clean cloth/paper towel with cleaner to wipe the probe;
Always follow the product label recommendations to operate the cleaning;

5. Carefully dry the probe with a clean paper towel or soft, dry cloth, removing foam when present;
6. Examine the probe for damage, such as cracks, splitting, fluid leaks, deformation, peeling or sharp edges or projections. If damage is evident, discontinue use of the probe and contact Esaote Service personnel.

Disinfection procedure

Probe must be disinfected immediately after it is used.

Disinfection procedure

1. Disconnect the probe from **MyLab**;
2. Remove the protective cover, if any;
3. Remove all residues of ultrasound gel from the probe using a soft cloth;
4. Disinfect the probe using the disinfection agent compatible with your probe. For a list of disinfectants compatible with your probe see Appendix C.
Apply the agent to the probe following disinfectant label instructions for temperature, and duration of disinfectant contact. Ensure that the disinfectant solution does not enter the device or the connector. When disinfecting the connector housing, do not allow any type of fluid to enter through the strain relief, electrical contacts;
5. Air dry or towel dry with a soft sterile cloth according to the instructions on the disinfectant label;
6. Examine the probe for damage, such as cracks, splitting, fluid leaks, deformation, peeling or sharp edges or projections. If damage is evident, discontinue use of the probe and contact Esaote Service personnel.

Reprocessing of Probes Used in Semi-critical Applications

The procedures described in this paragraph explain how to reprocess probes used in semi-critical applications. An application is considered semi-critical when the probe is used in contact with intact mucous membranes.

In order to reduce risk of contamination, the use of sterile covers for this type of applications is recommended.

Being products destined to be used in contact with intact mucous membranes but do not enter sterile cavities, semi-critical device shall be used decontaminated from all microorganisms except, eventually, for bacterial spores because intact mucous membranes are resistant to infection by common bacterial spores but are susceptible to other organisms, such as bacteria, mycobacteria, and viruses.

To ensure that the device is safe and effective for its intended use, as requested by ISO 17664, semi-critical device shall be subjected to a reprocessing that ensures a decontamination (Log reduction) of at least 6.0 with the whole microorganism family except, eventually, for bacterial spores. The efficacy of a decontamination process is proof if it achieves Log reduction >6.0 with the microorganism family having the higher resistance to germicidal activity after bacterial spores i.e. mycobacteria (condition of High Level Disinfection as from WHO definition).

The probe must be cleaned and disinfected before it is used for the first time. The probe must be always cleaned and disinfected after every examination.

WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

WARNING

Immediately after use, you must pre-clean the device until visually clean. Conduct the thorough cleaning process as soon as possible after use in order to prevent bioburden drying on the surface. Dried bioburden can lead to inefficient cleaning, disinfection and sterilization, causing a risk of cross-contamination. If pre and thorough cleaning cannot be done immediately, keep the device moist until cleaning.

WARNING

Esaote recommends to reprocess the probe before use, if the probe was not kept, since last reprocessing, at the requested disinfection/sterilization level.

WARNING

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

WARNING

After any reprocessing cycle check the integrity of the probe, performing a manual and visual inspection of the entire probe before using it again. DO NOT use further the probe if it has been damaged or if any damage is found. Contact Esaote Service personnel if you need any help checking your probe.

CAUTION

When cleaning the probe using spray agent, DO NOT spray the probe while it is placed on its holder. Over spray can damage the device: the use of wipe cleaner is suggested in these cases.

CAUTION

When cleaning and disinfecting probes, do not allow any fluid to enter the connector through the electrical contacts, strain reliefs, connector housing, or areas surrounding the locking lever shaft. On TEE probes, do not allow any fluid to enter the handle or steering mechanism. When wiping or spraying connector or handle housings, wipe or spray only the outer surfaces. If available, place a connector-cover splash guard over the electrical contacts to help preventing fluid from entering the connector housing. Damage due to fluids in these areas is not covered by the warranty or your service contract.

Physical damage to the probe may cause electrical or mechanical injury to the patient. DO NOT USE the probe if it is known or suspected that it has been damaged; contact Esaote Service Personnel immediately.

CAUTION

To minimize the effects from residual OPA, or any other disinfectant, Esaote recommends to follow the disinfectant manufacturer's instructions very carefully. For example, the manufacturer of Cidex OPA recommends rinsing probes by immersing them three times in fresh water. Limit the time that probes are soaked in the disinfectant solution to the minimum time recommended by the disinfectant manufacturer. For example, the manufacturer of Cidex OPA recommends a minimum of 12 minutes.

CAUTION

Any damage to the probe caused by substances or methods not approved by Esaote, such as steam (autoclave), ethylene oxide or radiation, are not covered by the warranty. These sterilization methods can permanently damage the probe.

NOTE ***Handle any examination waste (for example protective cover, gloves) as if potentially infected and treat it accordingly.***

NOTE ***For the detailed handling procedures for an agent, refer the documentation provided by the manufacturer.***

NOTE ***In order to maintain the effectiveness of the agent, confirm the concentration, replacement interval, working temperature, etc. specified in the documentation provided by the manufacturer.***

Cleaning procedure

Proper cleaning is essential to the success of any disinfection or sterilization procedure. Probe must be cleaned immediately after it is used and before it is disinfected or sterilized.

Use the following cleaning procedure after each examination and prior of any disinfection or sterilization procedure.

Cleaning Procedure

1. Disconnect the probe from **MyLab**;
2. Remove the protective cover, if any;
3. Remove all residues of ultrasound gel from the probe using a soft cloth;
4. Step for endocavity probes. The endocavity probes have two communicating holes, one at the tip and one at the base, this channel has to be cleaned first, following this specific cleaning instruction for lumen:
    a Using a 60cc syringe and the kit supplied together with the probe, connect a section of the IV tube to one end of the tap; the other end of the IV tube must be inserted into the probe-filling hole;
    b Followed by filling the 60cc syringe with the recommended (cleaning/disinfectant) agent;
    c Clean the channel with the recommended (cleaning/disinfectant) agent with some applied pressure using the mentioned 60cc syringe and kit;
    d Rinse the channel with sterile water with some applied pressure using the mentioned syringe and kit;

5. Clean the probe using the agent compatible with your probe (refer to Appendix C). Use the prepared wipe cleaner or wet a clean cloth/paper towel with cleaner to wipe the probe. Always follow the product label recommendations to operate the cleaning;
6. Carefully dry the probe with a sterile soft, dry cloth or leave it to air dry;
7. Examine the probe for damage, such as cracks, splitting, fluid leaks, deformation, peeling or sharp edges or projections. If damage is evident, discontinue use of the probe and contact Esaote Service personnel.

Disinfection procedure

The below listed procedure grants to disinfect the probe with the indicated agent/method to reduce the number of viable microorganisms to the level previously specified as being appropriate for this class of device.The probes can be disinfected using the recommended agents/methods, following the manufacturer's instructions.

Disinfection procedure (manual process)

1. Clean the probe using the procedure described in the previous paragraph;
2. Step for endocavity probes. Disinfect the channel following this specific disinfection instruction for lumen:
   a Using a 60cc syringe and the kit supplied together with the probe, connect a section of the IV tube to one end of the tap; the other end of the IV tube must be inserted into the probe-filling hole;
   b Followed by filling the 60cc syringe with the recommended disinfection agent;
   c Clean the channel with the recommended disinfection agent with some applied pressure;
3. Disinfect the probe using the disinfection agent compatible with your probe. For a list of disinfectants compatible with your probe see Appendix C.
   Apply the agent to the probe following disinfectant label instructions for temperature, and duration of disinfectant contact. Ensure that the disinfectant solution does not enter the device or the connector. When disinfecting the connector housing, do not allow any type of fluid to enter through the

strain relief, electrical contacts, or areas surrounding the locking-lever shaft.
Immerse very carefully the probe into the recommended agents up to the limit and, in case of endocavity probes, with channel filled with disinfectant, using the mentioned 60cc syringe to be sure to have the lumen fill;

4. Minimize the effect of residual disinfectant following the manufacturer's instructions. Residual disinfectant may remain on your probes if you do not carefully follow the manufacturer's instructions. Confirm that the disinfectant has been completely removed. Do not reuse the sterile water or deionized water;
Extract the probe and minimize the effects of residual disinfectant following the manufacturer's instructions. If you use an OPA-based disinfectant, residual solution may remain on your probes if you do not carefully follow the manufacturer's instructions;
5. Step for endocavity probes. Ensure to clean the channel with sterile water with some applied pressure using the mentioned 60cc syringe and kit. Step not necessary if probe was used with a sheath resulting not perforated or broken after examination;
6. Rinse the probe surface with sterile water;
7. Carefully dry the probe with a sterile soft, dry cloth or leave it to air dry for at least 30 minutes. In case of endocavity probe, the lumen can be dried only leaving it to air for at least 30 minutes;
8. Examine the probe for damage, such as cracks, splitting, fluid leaks, deformation, peeling or sharp edges or projections. If damage is evident, discontinue use of the probe and contact Esaote Service personnel;
9. Store the probe in packaging ensuring to preserve the disinfection status (wrapped trays on heat-sealable non-woven, polyethylene sterilization pouches).

Disinfection procedure (automatic process)

1. Disconnect the probe from **MyLab**;
2. Remove the protective cover, if any;
3. Remove all residues of ultrasound gel from the probe using a soft cloth;

4. Step for endocavity probes. The endocavity probes have two communicating holes, one at the tip and one at the base, this channel has to be cleaned/disinfected first, following this specific reprocessing instruction for lumen:

    a Using a 60cc syringe and the kit supplied together with the probe, connect a section of the IV tube to one end of the tap; the other end of the IV tube must be inserted into the probe-filling hole;

    b Followed by filling the 60cc syringe with the recommended (cleaning/disinfectant) agent;

    c Clean the channel with the recommended (cleaning/disinfectant) agent with some applied pressure;

    d Once this step is done, fill the channel with liquid recommended (disinfectant) agent and leave the channel filled for the time indicated by the disinfectant manufacturer's instruction. Step not necessary if probe was used with a sheath resulting not perforated or broken after examination;

    e Clean the channel with sterile water with some applied pressure using the mentioned 60cc syringe and kit. Step not necessary if probe was used with a sheath resulting not perforated or broken after examination;

    f Rinse the probe surface with sterile water using sterile soft cloth or gauze. Step not necessary if probe was used with a sheath resulting not perforated or broken after examination;

    g Carefully dry the probe with a sterile soft, dry cloth or leave it to air dry for at least 30 minutes. The lumen can be dried only leaving it to air for at least 30 minutes;

5. Disinfect the probe using the disinfection agent compatible with your probe. For a list of disinfectants compatible with your probe see Appendix C;

6. Minimize the effect of residual disinfectant following the manufacturer's instructions. Residual disinfectant may remain on your probes if you do not carefully follow the manufacturer's instructions. Clean the channel with sterile water with some applied pressure using the mentioned 60cc syringe and kit. Confirm that the disinfectant has been com-

pletely removed. Do not reuse the sterile water or deionized water;

7. Carefully dry the probe with a sterile soft, dry cloth or leave it to air dry for at least 30 minutes. In case of endocavity probe, the lumen can be dried only leaving it to air for at least 30 minutes. Do not use heat to dry the probe;
8. Examine the probe for damage, such as cracks, splitting, fluid leaks, deformation, peeling or sharp edges or projections. If damage is evident, discontinue use of the probe and contact Esaote Service personnel;
9. Store the probe in packaging ensuring to preserve the sterility status (wrapped trays on heat-sealable non-woven, polyethylene sterilization pouches).

Sterilization procedure

Sterilization is not required nevertheless it is still an acceptable decontamination process, alternative to the other high level disinfection methods above specified being able to ensure the same reprocessing level.

In the event, use the following sterilization procedure after each examination.

Sterilization procedure

1. Clean the probe using the procedure described in the previous paragraph, including the additional steps to clean the channel in case of endocavity probe;
2. Prior to sterilization, cleaned and dried probes have to be packaged using aluminium containers compatible with hydrogen peroxide, eventually in combination with disposable polypropylene filters;
3. Sterilize the probe using the methods compatible with your probe. For a list of sterilizing agents compatible with your probe see Appendix C;
4. Follow sterilizer manufacturer IFU to have control over sterilizer, load and packaging and, eventually, minimize the effect of residual sterilant. Residual solution may remain on your probes if you do not carefully follow the manufacturer's instructions.
5. After exposure, the packages have to be opened under aseptic conditions using a certified laminar flow hood.

6. If requested, dry the surface of the probe using sterile soft cloth or gauze. Do not use heat to dry the probe.
7. Examine the probe for damage, such as cracks, splitting, fluid leaks, deformation, peeling or sharp edges or projections. If damage is evident, discontinue use of the probe and contact Esaote Service personnel;
8. Store the probe in packaging ensuring to preserve the sterility status (wrapped trays, polyethylene sterilization pouches).

Reprocessing of Probes Used in Critical Applications

The procedures described in this paragraph explain how to reprocess probes used in critical applications. An application is considered critical when the probe comes into contact with blood or compromised tissue. Sterilization is required for this type of procedure.

The probe must be cleaned and sterilized before it is used for the first time. The probe must be always cleaned and sterilized after every examination.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses) as stated by its own facility procedure.

WARNING

Esaote recommends to reprocess the probe before use, if the probe was not kept, since last reprocessing, at the requested disinfection/sterilization level.

WARNING

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics.

WARNING

Do not leave the probe immersed in the agent for longer than the time indicated by the manufacturer for sterilization.

WARNING

Do not immerse the entire body of the probe. The probe is not waterproof and immersion may compromise the electrical safety characteristics (see Appendix A for Maximum Immersion Level).

CAUTION

Any damage to the probe caused by substances or methods not approved by Esaote, are not covered by the warranty. Not recommended sterilization methods can permanently damage the probe.

Cleaning and Sterilization Procedure

Proper cleaning is essential to the success of any sterilization procedure. Probe must be cleaned immediately after it is used and before it is sterilized.

After cleaning, choose the sterilization agent/method compatible with your probe. For a list of sterilizers compatible with your probe, see Appendix C.

Cleaning Procedure

1. Disconnect the probe from **MyLab**;
2. Remove the protective cover, if any;
3. Remove all residues of ultrasound gel from the probe using a soft cloth;
4. Using one of the suggested agents, wipe/spray the probe thoroughly, paying attention to clean grooves and exposed parts, if present. When a liquid agent is used, wet a clean cloth/paper towel with cleaner to wipe the probe;
   Always follow the product label recommendations to operate the cleaning;
5. Extract the probe, carefully rinse it with sterile water to remove cleaning agent residuals;
6. Carefully dry the probe with a clean soft, dry cloth or leave it to air until it is thoroughly dried;

Sterilization Procedure with Agents

7. Sterilize the probe using the methods compatible with your probe. For a list of sterilizing agents compatible with your probe see Appendix C;
8. Follow sterilizer manufacturer IFU to have control over sterilizer, load and packaging and, eventually, minimize the effect of residual sterilant. Residual solution may remain on your probes if you do not carefully follow the manufacturer's instructions.
   Immerse the probe very carefully up to maximum level into the recommended agents, following the manufacturer's instructions;
9. Extract the probe and rinse it with sterile water;
10. Carefully dry the probe with a clean soft, dry cloth or leave it to air until thoroughly dried;
11. Examine the probe for damage, such as cracks, splitting, fluid leaks, deformation, peeling or sharp edges or projections. If damage is evident, discontinue use of the probe and contact Esaote Service personnel;
12. Store the probe in packaging ensuring to preserve the sterility status (wrapped trays, polyethylene sterilization pouches).

For information on how to store sterilized parts, refer to the locally applicable procedures.

Precautions for probes used in Neurosurgery Application

GS

Refer to the "Getting Started" manual to know which probe can be used in Neurosurgery application with your **MyLab**.

Probes used in Neurosurgery application should be cleaned and sterilized before the first use and after use even if a sterile cover was used. Covers can fail during use and the level of resulting contamination may not be easily visible.

In Neurosurgery the use of sterile non-pyrogenic cover is required. After use, the single-use cover should be removed and properly discarded.

WARNING

When in direct contact with the brain or with the central nervous system, the probes have to be enclosed in a sterile non-pyrogenic cover.

The covers must be in Class III according to Council Directive 93/42/EEC and successive amendments.

Probes that contact brain tissue and cerebrospinal fluid should always be used with a sterile, endotoxin-free cover because the disinfectant/sterilant residue left on the probe is neuro-toxic and endotoxin is pyrogenic (e.g., cause fevers).

If the probe is used on a patient with known or suspected Creutzfeldt-Jakob Disease (CJD or vCJD) the probe shall be destroyed.

Do not reuse, reprocess or resterilize single use device. Reuse, reprocessing or resterilization may create a risk of contamination of the device, cause patient infection or cross-infection.

Dispose of single-use components as infectious waste.

Use only sterile saline or other non-pyrogenic coupling media.

Disposable components are packaged sterile and are single-use only. Do not use if integrity of packaging is violated or if expiration date has passed.

Cleaning and Sterilization of Needle Guide Kits

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes

into contact with blood or compromised tissue. Sterilization is required for this type of procedure.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses) as stated by your own facility procedures.

WARNING

The kit must be sterilized before it is used for the first time. The kit must be cleaned and sterilized after every examination.

Esaote recommends sterilizing the kit before it is used for the first time or after storage periods if it was not kept at the requested sterilization level.

- Dismantle the kit from the probe.
- Clean the kit carefully using the same procedure for probe in non-critical application.
- Carefully rinse the device with sterile water to remove any residual cleaning agent.
- Carefully dry the kit until it is thoroughly dry.

For information on how to store sterilized parts, refer to the locally applicable procedures.

- After cleaning, choose the sterilization agent/method compatible with your kit. For a list of sterilizers compatible with your probe, see Appendix C.
- Follow the sterilizer's manufacturer instructions.

Vacuum steam sterilization mode

After cleaning and drying, the kit must be packed in permeable to steam, water repellent, resistant to tears and impermeable to microorganisms bag. Packing serves to protect the disinfected kit from contamination before the use.

Appliance used

Steam autoclave based on fractional vacuum moist heat sterilization. Any steam autoclave models allowed to operate in the framework of specifications below reported can be used.

Sterilization by saturated steam under pressure (autoclave) should be performed according to standard protocol.

Operational specifications

Steam sterilization is achieved by the combined intervention of three factors:

Factors	Value for kit
Pressure	2.1 bar
Temperature	134°C
Time	7 minutes

Chapter 3

3. Examinations with Endocavity Probes

The endocavity (**BE1123**, **E 3-12, EC1123, EC123, SB3123**, **SE3123** and **SE3133**) and transrectal (**TRT33** and **TLC 3-13**) probes are Type BF applied parts. As per IEC EN60601-1 Safety Standard, the probe must be physically intact and **MyLab** correctly grounded for the electrical safety of the patient and operator.

SS

Read the "Safety and Standards" manual carefully: all the listed safety characteristics, caution and warning messages also apply to the use of these probes.

In particular, remember that:

WARNING

MyLab must be correctly grounded: it must be supplied from a socket equipped with a protective ground connection.

Mobile configurations are fitted with insulated supply sockets for supplying documentation systems without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

In case of doubts about the protective ground connection, DO NOT use the probe and contact Esaote Service Personnel immediately.

Characteristics and Components

The **E 3-12, EC1123**, **EC123, SE3123** and **SE3133** probes incorporate a high frequency convex transducer for sagittal (transverse) endorectal or endovaginal scanning.

The **TRT33** and **TLC 3-13** probes incorporate both a convex transducer and a linear transducer for longitudinal and transversal scanning.

Refer to 3D/4D section for further information on the use of Bi-Scan probes.

The **BE1123** and **SB3123** probes are Bi-Scan probes incorporating a high frequency convex transducer for sagittal (transverse) endorectal or endovaginal scanning.

Examination Safety

Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

WARNING

Endocavity probes must be used by operators who have been specially trained to insert the probe and interpret the images.

Before the Examination

Before each examination Esaote recommends the operator to:

- Perform a manual and visual inspection of the entire probe before using it (see previous chapter of this manual). DO NOT use the probe if it has been damaged or if any damage is found.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective cover DO NOT provide protection against these damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if you know or suspect that it has been damaged.

WARNING

The operator is recommended to wear gloves during the probe preparation procedure and during the examination.

WARNING

Protective covers are recommended for transrectal and intravaginal procedures. In China and Japan covers are mandatory. Esaote recommends use of qualified covers.

WARNING

The probe covers may contain natural rubber latex which may cause allergic. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

If the protective cover is damaged during the endocavity exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the

Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

Refer to next chapters for recommended gels and covers.

- Apply enough ultrasound sterile gel inside the cover.
- Completely unroll the cover along the probe body, making it adhere, so as to avoid air pockets.
- Secure the cover with the rubber band.
- To make it easier to insert the endocavity probe use only water based lubricant gel on the probe.

SS

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

During the Examination

WARNING

Before probe use, be sure that the probe name shown on the monitor is correct.

During the examination Esaote recommends the operator to:

- Never force the probe during insertion or removal.

WARNING

Forced insertion or removal may wound the patient.

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels used during the examination may interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels, and other devices that introduce radio frequency or electro-magnetic current fields into the patient, interfere with ultrasound images.

While using **MyLab** in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to the probe 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

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective covers DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically.

Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends the operator to:

- Clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual.
- Store the probe as indicated in Chapter 1 of this manual.

Water Stand-Off for E 3-12, EC1123, EC123, SE3133, TRT33 and TLC 3-13 Probes

The **E 3-12, EC1123**, **EC123**, **SE3133**, **TRT33** and the **TLC 3-13** endocavity probes have two communicating holes, one at the tip and one at the base, that make it possible to use water stand-off to optimize probe adherence in transrectal examinations. The probe is equipped with a 60 cc syringe with tubes that allow water to be injected.

- Cover the part of the probe that can be immersed with the stand-off cap and attach it with the rubber band provided at about 5 cm. from the tip; make sure the water intake hole is below the band.
- Fill a 60 cc syringe with sterile water.
- Apply the tap valve to the syringe.
- Connect a section of the IV tube to one end of the tap; the other end of the IV tube must be inserted into the probe-filling hole.
- Open the tap; inject about 30 cc of water into the stand-off.

Eliminate the air bubbles between the probe and the cover; air bubbles impede the transmission of ultrasound.

- To eliminate air bubbles, turn the probe upwards holding it by the handle; the bubbles will rise towards the water intake hole.
- Suck air back into the syringe; close the tap to remove the syringe and expel the air.
- Repeat this procedure until all the air bubbles have been eliminated.
- Replace water, without air, back into the syringe and close the valve; leave the tube and the syringe connected.

- Apply ultrasound examination gel to the tip of the stand-off.
- Cover the portion of the probe that is to be inserted with the protection cover.

WARNING

The protective covers available on the market may contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

- To make it easier to insert the endocavity probe, use only water-based lubricating gel with the probe.

Once the probe is in the correct position, fill the stand-off with water again. To optimize image quality, use enough water to ensure that the probe adheres as well as possible to the rectal wall.

WARNING

Do not remove the probe from the rectum if the probe tip is still full of water.

Chapter 4

4. Examinations with Intraoperative Probes

The intraoperative probes (**IH 6-18**, **IL 4-13**, **IOE323** and **IOT342**) are Type BF applied parts. The probes must be physically intact and **MyLab** properly grounded for the electrical safety of the patient and operator.

SS

Carefully read the Safety and Standards Manual: all safety characteristics, cautions and warnings listed also apply to the use of these probes.

In particular, remember that:

WARNING

MyLab must be correctly grounded: it must be supplied from a socket equipped with a protective ground connection.

Mobile configurations are fitted with insulated supply sockets for supplying documentation systems without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise electrical safety.

In case of doubts about the protective ground connection, DO NOT use the probe and contact Esaote Service Personnel immediately.

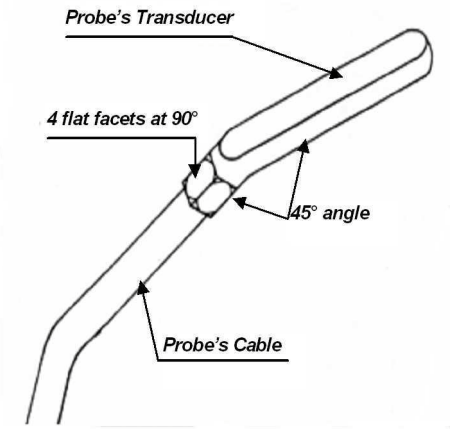
Characteristics and Components

The **IH 6-18**, **IL 4-13**, **IOE323** and **IOT342** probes incorporate a high frequency linear transducer for intraoperative scanning.

The **IL 4-13** and **IOE323** probes are designed to form an angle of 45° between the head, which houses the transducer and the terminal portion where the cable is connected. The terminal portion of the **IL 4-13** and **IOE323** probes has a square shape to accommodate accessories available for use with the probe, offering maximum comfort during surgical ultrasonography (see Fig. 4-1).

The probe accessories are shaped in a manner to prevent rotation and to improve patient safety.

Fig. 4-1: IL 4-13 and IOE323 Probes



The terminal portion of the **IOT342** probe incorporates a finger attachment: the probe can be handled in different ways allowing compression on specific target and offering maximum comfort during surgical ultrasonography.

Fig. 4-2: IOT342 Finger attachment



Examination Safety

Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

WARNING

The intraoperative examination is to be carried out by operators who have been specially trained to use the probe and interpret the images.

WARNING

Do not use the intraoperative probe in direct contact with the heart, the central circulatory system and the central nervous system.

Before the Examination

Before each examination:

- perform a manual and visual inspection of the entire probe prior to use (see previous chapters of this manual). DO NOT use the probe if it has been damaged or if any damage is suspected;

WARNING

Probe is used in a sterile environment so accurately check the integrity of the probe itself before use. The effectiveness of sterilization may be compromised by a not intact probe. DO NOT use the probe in case of a verified or suspected damage.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective covers DO NOT provide protection against such damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if damage is known or suspected.

- wear sterile gloves during probe handling at any time.

WARNING

Personnel should adopt all necessary protective measures during probe handling to ensure the required level of device sterilization as stated by its own facility procedure.

- probes should be used sterile and covered with a sterile cover to reduce the level of contamination on the probe and the risks of infection. If this is not possible, at a minimum the probe should be high level disinfected and covered with a sterile probe cover.

WARNING

Esaote recommends to process probe before use if the probe was not kept, since last reprocessing, at the requested sterilization level.

WARNING

The probe covers may contain natural rubber latex which may cause allergic reactions. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

- Apply enough ultrasound sterile gel inside the cover. See next chapter on consumables for selecting the gel.
- Completely unroll the cover along the probe body, making it adhere, so as to avoid air pockets.
- Secure the cover with the sterile rubber band.

WARNING

If the protective cover is damaged during the intraoperative exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

SS

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

During the Examination

WARNING

Before probe use, be sure that the probe name shown on the monitor is correct.

Electric scalpels used during the intraoperative examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electro-magnetic current fields into the patient interfere with ultrasound images.

While using **MyLab** in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to 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

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective covers DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends that the operator:

- clean and sterilize the probe, according to the instructions provided in chapter 2 of this manual;
- store the probe as indicated in chapter 1 of this manual.

Using the IL 4-13 and IOE323 Probes

The probe is delivered with the following accessories:

- handle attachment;
- finger attachment;
- sled attachment;
- biopsy attachment.

Follow the instructions below for preparing the intraoperative probe.

Handle Attachment

The handle attachment, is inclined 30 degrees, and can be placed on the probe in four different positions to form four different shapes (profiles) A, B, C and D as shown below and on the following pages:

Fig. 4-3: Handle attachments

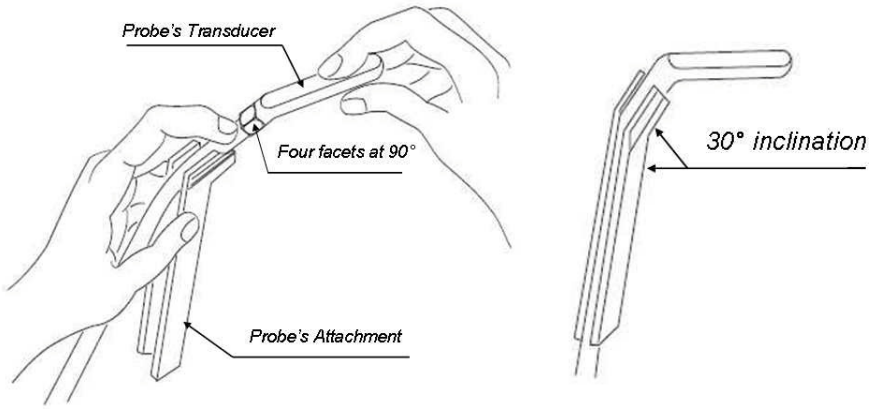
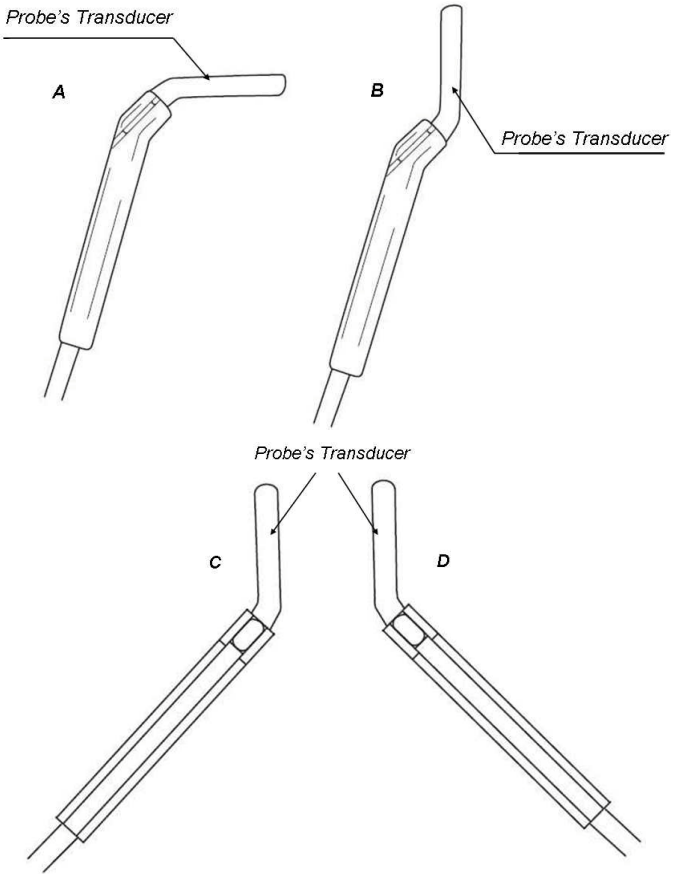


Fig. 4-4: Attachment positions

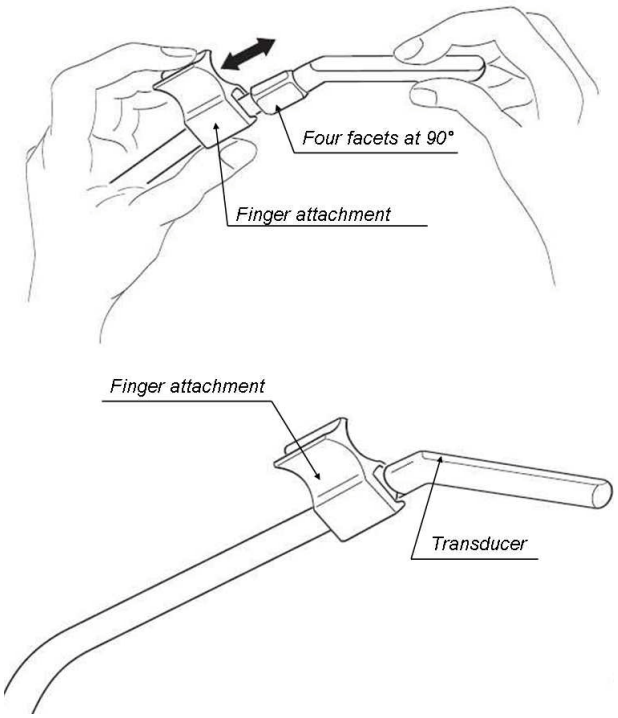


Finger Attachment

The Finger Attachment allows manipulation of the IL 4-13 and IOE323 intraoperative probes for use with only two fingers.

The 4 facets, at 90 degrees, allow the user to obtain four different insertion methods with the probe.

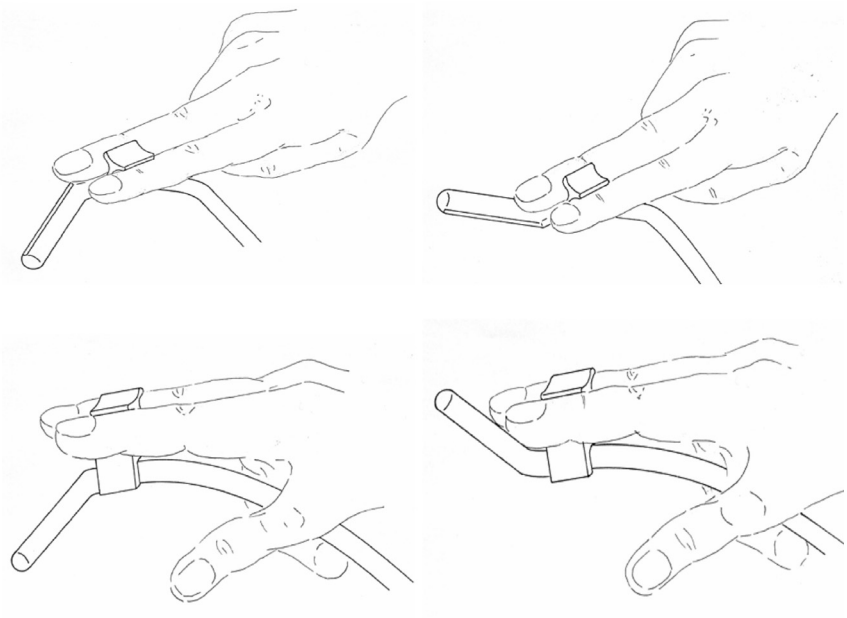
Fig. 4-5: Finger attachment



The finger attachment can be used in four different configurations in order to more closely adapt to the surface being evaluated. In intraoperative applications, it is possible to insert the probe below, adjacent to, or on top of the structure of interest.

Following are the four different IL 4-13 and IOE323 probes attachment designs.

Fig. 4-6: Finger attachment configurations

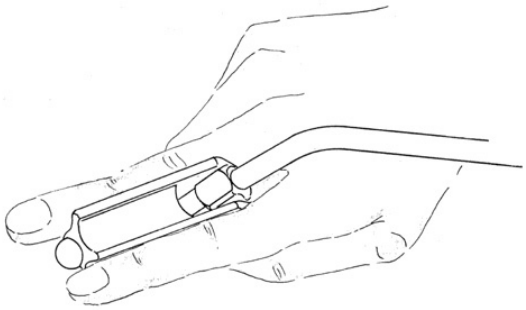


Slide Attachment

The slide attachment has been developed to provide easier manipulation of the probe during both intraoperative and superficial scanning. The attachment corresponds to the ergonomics of the probe, and is the same length as the probe.

The correct position of the Slide attachment is shown below.

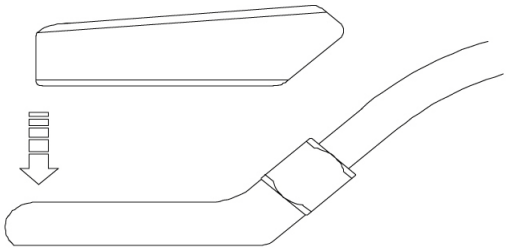
Fig. 4-7: Slide attachment



To place the attachment on the probe, follow the procedure described below. The sequence is also shown in the following design.

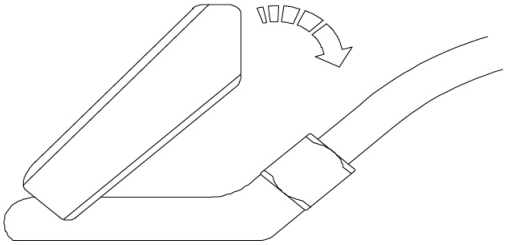
1. Place the slide attachment at the tip of the probe.

Fig. 4-8: Slide position



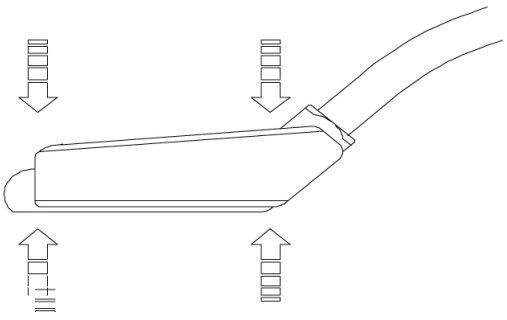
2. Rotate the slide attachment around the probe until it is safely in place between the two lateral extensions of the attachment.

Fig. 4-9: Slide rotation



3. Press the probe inside the holder, hearing a click, to assure secure and complete insertion.

Fig. 4-10: Securing the slide



4. To remove the sled attachment, reverse the procedure.

Chapter 5

5. Examinations with Transesophageal Probes

The transesophageal probes (**ST2612**, **ST2613** and **TEE022**) are Type BF applied parts. The probe must be physically intact and **MyLab** properly grounded for the electrical safety of the patient and operator.

SS

Carefully read the "Safety and Standards" manual: all safety characteristics, cautions and warnings listed also apply to the use of these probes.

In particular, remember that:

WARNING

MyLab must be properly grounded: it must be supplied from a socket equipped with a protective ground connection;

mobile configurations are equipped with insulated sockets to supply power without increasing the leakage current. Incorrect connections or failure to use insulated sockets may compromise the electrical safety;

if in doubt about the protective ground connection, DO NOT use the probe and contact Esaote Service Personnel immediately.

Characteristics and Components

The transesophageal probes are designed for transesophageal imaging of the heart in adult patients (**ST2612** and **TEE022**) and pediatric patients (**ST2613**).

The **ST2612** probe shaft has a length of roughly 110 cm. The shaft is labeled in 10 cm increments.

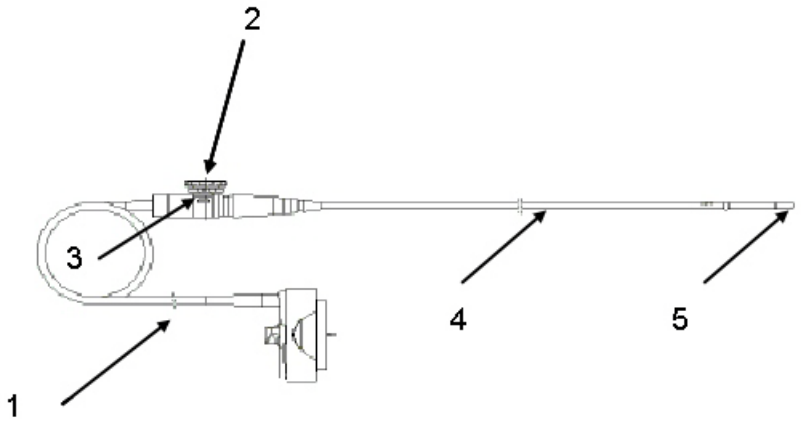
The **ST2613** probe shaft has a length of roughly 80 cm. The shaft is labeled in 10 cm increments.

The **TEE022** probe shaft has a length of roughly 100 cm. The shaft is labeled in 10 cm increments.

The transesophageal probe incorporates a motorized array transducer which can be rotated of 180° to easily obtain all imaging planes. The probe tip can also be deflected for optimal coupling.

The probe is equipped with a temperature sensor; **MyLab** models are designed to use this sensor thermal data to prevent probe tip overheating: **MyLab** constantly samples and displays the probe temperature.

Fig. 5-1: Transesophageal probe components



Legenda

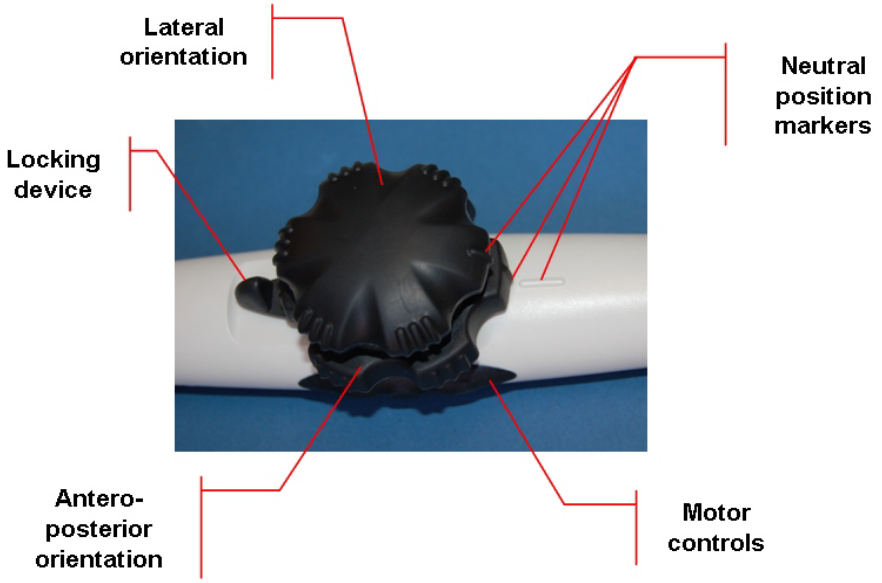
1:	Probe cable and connector
2:	Probe handle with the probe tip deflection control and the transducer rotational knob
3:	Locking device
4:	Shaft
5:	Probe tip with ultrasound transducer

Probe Orientation for ST2612 and ST2613

ST2612 Probe

The ST2612 probe handle wheels can be used to orientate the tip anteriorly, posteriorly and laterally. The motor controls allow to rotate the transducer inside the tip.

Fig. 5-2: ST2612 - Tip orientation



The probe tip can be oriented to optimize tissue contact. The antero-posterior orientation is controlled by the largest wheel and it is adjustable from -40°÷120°.

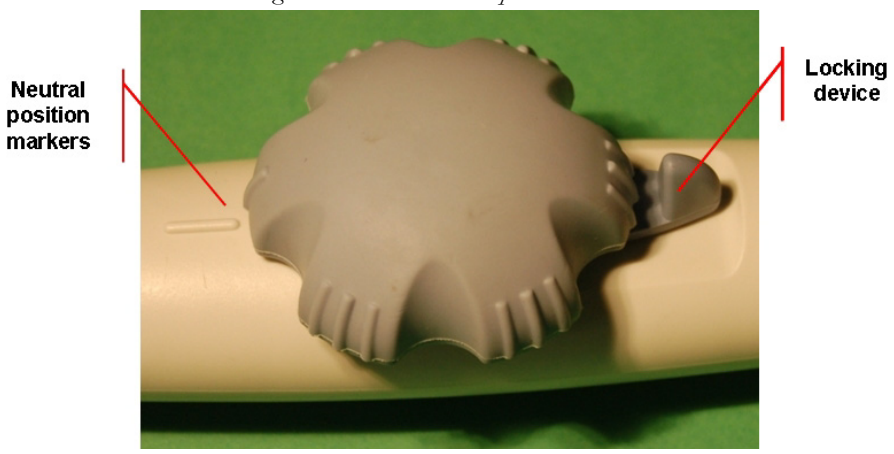
The lateral orientation is controlled by the smallest wheel and it is adjustable in a range left-right of 50° ±10°.

The wheels can be locked into positions by rotating the locking device, located below the wheels. During probe insertion, make sure that the tip is unlocked.

ST2613 Probe

The ST2613 probe handle wheel can be used to orientate the tip antero-posteriorly. The motor controls allow to rotate the transducer inside the tip.

Fig. 5-3: ST2613 - Tip orientation



The probe tip can be oriented to optimize tissue contact. The antero-posterior orientation is controlled by the largest wheel and it is adjustable from -40°÷110°.

Probe Rotation

The rotation of the transducer is motor-driven. The three motor control buttons, placed in both the endoscope handles, allow to change the rotation.

The central button forces the transducer position to 0°. The upper and lower buttons respectively increases and decreases the transducer position by step of 1°, up to the maximum of 180°; keeping the button pressed continuously changes the transducer position.

MyLab screen displays the probe's current orientation.

Probe Orientation for TEE022

The probe handle wheels can be used to rotate the transducer inside the tip or to change the tip position.

Probe Rotation

The rotation of the transducer is controlled by the largest knob and is adjustable from 0° to 180°. In the zero position, the transducer will scan the transversal plane. The zero, 90° and 180° positions are marked on the knob.

MyLab screen displays the transducer's current orientation.

Tip Position

The probe tip can be oriented to optimize tissue contact. The articulation of the flexible part of the probe is controlled by the smallest knob; up- and backwards adjustments are feasible:

- 120° upwards (clockwise rotation of the knob),
- 90° backwards (counter- clockwise rotation of the knob).

The zero position is marked on the knob. This knob can be locked into position by engaging the locking device, located next to the knob. This locking device has two color coded positions: on red the tip is locked, on grey the tip is loose.

During probe insertion, make sure that the tip is unlocked (grey locking device).

Fig. 5-4: Locking device



Examination Safety

The user must know how to recognize contra-indications to the examination and any possible complications, such as tip buckling.

WARNING

The transesophageal examination is to be carried out by operators who have been specially trained:

- **to safely insert, operate and remove the transesophageal probe;**
- **to properly use the device and the transesophageal probe;**
- **to interpret the transesophageal images;**
- **to properly clean, disinfect and storage the transesophageal probe.**

Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

Before the Examination

WARNING

Manually and visually check the probe shaft for holes, protrusions, or dents.

Manually and visually check the entire shaft while gently deflecting the tip in all possible positions to verify that the deflection mechanism works properly and to ensure that a wire is not protruding through the outer material of the shaft.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. To protect the probe shaft from the patient's teeth, use a bite guard for all transesophageal procedures.

Protective covers DO NOT provide protection against such damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if damage is known or suspected.

CAUTION

Damage caused to the probe due to failure to use a protective mouthpiece is not covered by the warranty.

WARNING

Personnel should adopt all necessary protective measures during probe handling to ensure the required protection of the contamination level for himself and for the patient as stated by his own facility procedure.

Before each examination:

- perform a manual and visual inspection of the entire probe (see previous chapters of this manual). DO NOT use the probe if it has been damaged or if damage is suspected;
- wear sterile gloves during probe handling at any time.
- check that the probe deflection controls function correctly in all directions and that they have not jammed;
- make sure that the probe tip is free to move; the probe handle is equipped with locking device which must be set to "loose" position;
- use protective covers during the examination. These covers are mainly composed of latex (natural rubber).
- verify the sterilization effectiveness of the probe before use.

NOTE

The probe used in a semi-critical application like TEE should be cleaned and sterilized or at least receive high level disinfection after use even if a cover was used. This level of freedom from contamination should be preserved up to the next usage.

WARNING

Esaote recommends to reprocess probe before use, if the probe was not kept, since last reprocessing, at the requested sterilization level.

WARNING

The probe covers may contain natural rubber latex which may cause allergic reactions. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

See chapter on Consumables for selecting these accessory kits.

The use of probe covers is strongly recommended, along with a bite guard to protect the probe shaft. These items are available as accessory kits, which also contain items that facilitate placement of the cover on the probe.

- Place the tip of the probe in a straight position and release it.
- Apply a sufficient quantity of ultrasound gel inside the cover.
- Completely unroll the cover along the probe body, making it adhere, so as to avoid air pockets.
- Secure the cover with the rubber band provided.
- Always use a bite-proof mouthpiece to protect the probe from the patient's teeth.

SS

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

During the Examination

WARNING

Before probe use, be sure that the probe name shown on the monitor is correct.

WARNING

Insertion, manipulation or forced removal can seriously damage the patient's esophagus.

Never apply force when operating with the probe and when using the deflection controls: the endoscope could be damaged if excessive force is applied.

Never use force when manipulating the probe; if resistance is met when introducing or advancing the probe, stop the procedure. Make sure that the probe tip is straight and unlocked prior to inserting or removing the probe from the patient's esophagus.

To prevent esophageal wall damage from prolonged pressure, do not lock the probe tip to rest against the esophagous wall.

Esaote recommends the operator to:

- never force the probe during manipulation and extraction; if there is any resistance in introducing the probe, interrupt the

examination. Make sure that the tip is straight and released before inserting or removing the probe.

- Do not leave the probe against the esophagus wall for prolonged periods.
- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.
- If it is necessary to use the defibrillator, disconnect and remove the probe from the patient.

Electric scalpels used during the transesophageal examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electro-magnetic current fields into the patient interfere with ultrasound images.

High frequency signals used by ultrasound can interfere with the functioning of pacemakers.

WARNING

Even if the possibility of interference is remote, interrupt the examination immediately if interference with a pacemaker is noticed.

While using **MyLab** in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to 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

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective covers DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends the operator to:

- clean and disinfect the probe, according to the instructions provided in Chapter 2 of this manual;
- store the probe as indicated in Chapter 1 of this manual.

Screen Information (before start exam)

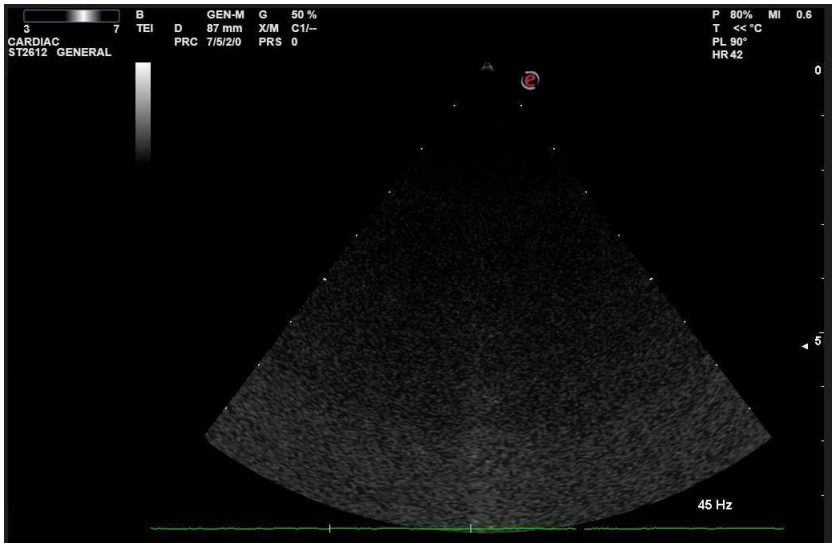
When the initialization phase is finished, the device is ready to work.

The following additional information should be displayed while working with the transesophageal probes (see Fig. 5-5):

- tip temperature;
- transducer orientation.

If not, stop exam and contact Esaote Service Personnel.

Fig. 5-5: Screen information



Tip Temperature

The probe tip temperature is displayed, and continuously updated, in the upper right side of the screen. **MyLab** displays:

Displayed on the screen	
<< ^{o} C	When the temperature is below 35.5^{o} C
Temperature value	When the temperature is between 35.5^{o} C and 41.5^{o} C
>> ^{o} C	When the temperature is higher than 41.5^{o} C

Refer to next paragraph for information on temperature control as essential reference parameters for safe operations.

Tip Orientation

The motor plane ("PL" field) orientation is displayed under the tip temperature.
A 0º plane is equivalent to the longitudinal plane and a 90º plane is equivalent to the transversal plane.

Temperature Control

Once the probe is connected, the temperature is displayed on the screen.

To ensure patient safety, the ultrasound scanner "allows" a maximum temperature of 41.5° C; if the probe reaches this limit, **MyLab** automatically de-activates and displays the following warning message:

Warning: the probe is overheating!
Please refer to the User Manual or wait for the system to restart. To be able to use another probe, disconnect the transesophageal probe.

As soon as the temperature goes down below the thermal limit, the message disappears and the probe starts working again. The operator should either wait for the probe to cool down or interrupt the procedure and remove the probe from the patient.

If the tip temperature reaches the value of 45° C the following warning message is displayed:

Warning: the probe is overheating!
Please disconnect the probe at once from the system.

How to Minimize Probe Heating

In normal conditions, the probe does not reach the thermal limit; the limit may be reached in patients with fever or due to breakage of the thermal sensor. A list of recommendations follows to prevent the probe from over-heating:

- set the B-Mode angle at maximum;
- the color mode is the greatest heat "generator"; limit the use of the color as much as possible in patients with a high body temperature;
- trans-gastric projections reduce heat dissipation; repositioning the probe in the esophagus may make the probe cool down quickly.

Chapter 6

6. The Laparoscopic Probes

The laparoscopic probes (**LP 4-13** and **LP323**) are a Type BF applied parts. As per IEC EN 60601-1 Safety Standard, the probe must be physically intact and **MyLab** properly grounded for the electrical safety of the patient and operator.

📖 ***SS*** **Carefully read the Safety and Standards manual: all safety characteristics, cautions and warnings listed also apply to the use of these probes.**

In particular, remember that:

WARNING

MyLab must be correctly grounded: it must be supplied from a socket equipped with a protective ground connection.

Mobile configurations are fitted with insulated supply sockets for supplying documentation systems without increasing the leakage current. Incorrect connections or failure by using insulated sockets may compromise electrical safety.

In case of doubts about the protective ground connection, DO NOT use the probe and contact Esaote Service Personnel immediately.

Characteristics and Components

The **LP 4-13** and **LP323** incorporate a high frequency linear transducer for laparoscopic scanning.

Fig. 6-1: LP323 Probe



The **LP 4-13** and **LP323** probes have an articulation that allows a double movement of its extremity in order to position the transducer directly on to the surface of the organ under evaluation. This movement is adjustable by two control levers located on the probe handle.

Examination Safety

Carefully review current medical provisions and follow their precautions and recommendations concerning the preparation and positioning of the patient, probe insertion and manipulation techniques.

WARNING

The laparoscopic examination is to be carried out by operators who have been specially trained to use the probe and interpret the images.

WARNING

Do not use the laparoscopic probe in direct contact with the heart, the central circulatory system and the central nervous system.

Before the Examination

Before each examination:

- perform a manual and visual inspection of the entire probe prior to use (see previous chapters of this manual). DO NOT use the probe if it has been damaged or if damage is suspected;

WARNING

Probe is used in a sterile environment, so accurately check the integrity of the probe itself before use. The effectiveness of sterilization may be compromised by a not intact probe. DO NOT use the probe in case of a verified or suspected damage.

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective covers DO NOT provide protection against such damages nor do they guarantee that the probe is insulated electrically. DO NOT USE the probe if damage is known or suspected.

- wear sterile gloves during probe handling at any time.

WARNING

Personnel should adopt all necessary protective measures during probe handling to ensure the required level of device sterilization as stated by its own facility procedure.

- probes should be used sterile and covered with a sterile cover to reduce the level of contamination on the probe and the risks of infection. If this is not possible, at a minimum the probe should be high level disinfected and covered with a sterile probe cover.

WARNING

Esaote recommends to process probe before use if the probe was not kept, since last reprocessing, at the requested sterilization level.

WARNING

The probe covers may contain natural rubber latex which may cause allergic reactions. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such reactions. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

- Apply enough ultrasound sterile gel inside the cover. See next chapter on consumables for selecting the gel.
- Completely unroll the cover along the probe body, making it adhere, so as to avoid air pockets.
- Secure the cover with the sterile rubber band.

WARNING

If the protective cover is damaged during the laparoscopic exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

SS

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

During the Examination

WARNING

Before probe use, check to be sure that the probe name shown on the monitor is correct.

During the examination, Esaote recommends that the Operator:

- never force the probe during insertion or removal.

WARNING

Before introducing the laparoscopic probe into the Trocar verify that there is no mechanical play of the tip of the probe.

While inserting the laparoscopic probe into the Trocar, the tip of the probe should be in a straight position.

Forced insertion or removal may harm the patient.

- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.

Electric scalpels used during the LP examination interfere with the 2D and make it impossible to use Doppler procedures.

Electric scalpels and other devices that introduce radio frequency or electro-magnetic current fields into the patient interfere with ultrasound images.

While using **MyLab** in combination with high frequency devices (like electro-surgical units), be aware that a failure in the surgical device or a damage to 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

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective covers DO NOT provide protection against such damage nor do they guarantee that the probe is insulated electrically. Perform a manual and visual check before each examination to ensure that the probe is intact.

At the End of the Examination

At the end of the examination, Esaote recommends that the operator:

- clean and sterilize the probe, according to the instructions provided in Chapter 2 of this manual.
- store the probe as indicated in Chapter 1 of this manual.

7. Needle Guide Kits

AO See the **MyLab** "Advanced Operations" manual for correct use of the needle guide.

Reusable Needle Guides

Reusable Needle Guides by Esaote

Esaote supplies a series of optional adaptors for the needle guide kits, all equipped with specific adaptor to be attached to the probe. The following table lists the available kits.

Table 7-1: Reusable Needle Guides by Esaote

Probe	Adaptor	Angle	Gauge
CA430E CA431	ABS421	20°/30°	14, 18, 20, 21, 22
CA631	ABS621	25°/35°	14, 18, 20, 21, 22
LA523	ABS523	45°	14, 18, 20, 21, 22
LA435 SL2325	ABS424	45°	14, 18, 20, 21, 22
LA332E SL3332	WBSL33X	35°	14, 18, 20, 21, 22
TLC 3-13 TRT33	ABS33A	90°	14, 16, 18, 20
EC123	ABS123	3.8°	16
IL 4-13 IOE323	ABS15	45°	14, 18, 20, 21, 22
AC2541 C 1-8	WBAC54X	20°/30°	14, 18, 20, 21, 22
AC2541	AC2541	15°/25°/35°	11-23
SI2C41	ABSIC4X	0°/5°/15°	14-15, 16-17, 18-19, 20-21

See Appendix A in this manual for probes characteristics.

G12 and G19 needle guides are available for the ABS kits to be used with CA, LA and IOE probes and for the WBAC kit for AC probe.

WARNING

Do not use needle guides other than those described in this manual.

ABS15, ABS421, ABS424, ABS523, ABS621, WBAC54X and WBSL33X kits are composed of stainless steel; the ABS123 and ABS33A needle guide kits are composed of titanium; the ABSIC4X kit is composed of anodized aluminum.

The above mentioned kits can be sterilized with saturated steam under pressure (Autoclave).

WARNING

Follow the instructions provided in next dedicated paragraphs to properly mount and reprocess them. Follow MyLab "Advanced Operations" manual for their current use.

Reusable Needle Guides by Civco[1]

In addition to the above mentioned reusable needle guides, Esaote supplies the following kits produced by Civco.

Table 7-2: Reusable Needle Guides by Civco

Probe	Adaptor	Angle	Manufacturer's Kit P/N
C 1-8	CBC5XR	15°/25°/35°	639-058
L 4-15 LA533 SL1543	CBSL53R	40°/60°	639-059

CBC5XR and CBSL53R kits are composed of stainless steel.

WARNING

Follow the instructions provided by the manufacturer of the kits to properly mount and use them and to clean, disinfect and sterilize them.

WARNING

Due to the symmetric shape of the probe the bracket can be locked also in the mirrored way even if the design itself suggests the proper position

Reusable Needle Guides by Protek[2]

In addition to the above mentioned reusable needle guides, Esaote supplies the following kits produced by Protek.

Table 7-3: Reusable Needle Guides by Protek

Probe	Adaptor	Angle	Gauge	Manufacturer's Kit P/N
E 3-12 EC1123 SE3123 SE3133	DBSE12X	0°	16	6360

DBSE12X kit is composed of stainless steel.

WARNING

Follow the instructions provided by the manufacturer of the kits to properly mount and use them and to clean, disinfect and sterilize them.

1. www.civco.com
2. www.protekmedical.com

Disposable Needle Guides

Disposable Needle Guides by Civco[1]

In addition to the above mentioned reusable needle guides, Esaote probes can be equipped with optional kits composed of sterilizable mounting adaptors and disposable needle guides produced by Civco.

Table 7-4: Fixed Angle and Multi-Angle Disposable Needle Guides by Civco

Probe	Adaptor	Angle	Gauge	Manufacturer's Kit P/N
AC2541 C 1-8	CBAC54X	15°/25°/35°	(12), 14, 15, 16, 17, 18, 20, 21, 22, 23	639-049
CA430E CA431	CBSC43X	20°/30°	(12), 14, 15, 16, 17, 18, 20, 21, 22, 23	639-018
CA631	CBSC63X	20°/30°	(12), 14, 15, 16, 17, 18, 20, 21, 22, 23	639-019
CA541	CBSC54X	15°/25°/35°	(12), 14, 15, 16, 17, 18, 20, 21, 22, 23	639-032
LA523	CBSL52X	40°/55°/70°	(12), 14, 15, 16, 17, 18, 20, 21, 22, 23	639-022
LA435 SL2325	CBSL43X	50°/60°/70°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-023
LA332E SL3332	CBSL33X	25°/40°/50°	(12), 14, 15, 16, 17, 18, 20, 21, 22, 23	639-015
EC123 EC1123 SE3123 SE3133	-	3,8°	16-18	610-693
E 3-12 EC1123 SE3123 SE3133	CBSE12X	0°	16	639-012
CA123	CBSC12X	20°/35°	(12), 14, 15, 16, 17, 18, 20, 21, 22, 23	639-028
BC441 SB2C41	CBSB44C	25°/35°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-020

1. www.civco.com

Probe	Adaptor	Angle	Gauge	Manufacturer's Kit P/N
L 4-15 LA533 SL1543	CBSL53X	40°/60°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-034
SC3123 mC 3-11	CBSC23X	20°/35°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-045
AL2442 L 3-11	CBSL44X	25°/35°50°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-036

Table 7-5: Free Insertion Angle Disposable Needle Guides by Civco

Probe	Adaptor	Insertion Angle	Gauge	Manufacturer's Kit P/N
AC2541 C 1-8	IKAC54X	42°÷60°	14, 18, 20, 21/22, 25	639-047
CA430E CA431	IKC43X	42°÷64°	14, 18, 20, 21/22, 25	639-014
CA631	IKC63X	42°÷68°	14, 18, 20, 21/22, 25	639-024
LA523	IKL53X	42°÷80°	14, 18, 20, 21/22, 25	639-016
SL3323	IKL3323	42°÷81°	14, 18, 20, 21/22, 25	639-025
LA435 SL2325	IKL43X	42°÷80°	14, 18, 20, 21/22, 25	639-021
LA332E SL3332	IKL33X	42°÷79°	14, 18, 20, 21/22, 25	639-026
CA541	IKC54X	42°÷60°	14, 18, 20, 21/22, 25	639-033
L 4-15 LA533 SL1543	IKL533	42°÷75°	14, 18, 20, 21/22, 25	639-035
SC3421	IKC3421	42°÷57°	14, 18, 20, 21/22, 25	639-027
AL2442 L 3-11	IKL44X	0°÷42°	14, 18, 20, 21/22, 25	639-037
IOT342	IKI33X	42°÷80°	14, 18, 20, 21/22, 25	639-051

The Infinity needle guide kits listed in the table above allow the user to have a free insertion angle: this can be any angle within the range edged by the guide back wall, on one side, and by the probe itself, on the other side. The

kit allows the user to keep the needle on the same scanning plane of the probe.

WARNING

Follow the instructions provided by the manufacturer of the kits to properly mount and use them and to clean, disinfect and sterilize them.

Disposable Needle Guides by Protek[1]

In addition to the above mentioned reusable needle guides, Esaote probes can be equipped with optional kits composed of sterilizable mounting adaptors and disposable needle guides produced by Protek.

Table 7-6: Disposable Needle Guides by Protek

Probe	Adaptor	Angle	Gauge	Manufacturer's Kit P/N
CA123	DBSC12X	15°	13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23	7356
CA430E CA431	DBS421/431	20°/30°	13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23	7352
CA631	DBS621/631	25°/35°	13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23	7354
EC1123 EC123 SE3133	DBSE12P	3.8°	16	5145
LA523	DBS523	45°/60°/75°	13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23	7357
LA435 SL2325	DBS424/435	45°	13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23	7350
SI2C41	DBSI2C	0°/15°/25°	14 – 15	5362
			16 – 17	5363
			18 – 19	5364
			20 – 21	Ref 5365

WARNING

Follow the instructions provided by the manufacturer of the kits to properly mount and use them and to clean, disinfect and sterilize them.

1. www.protekmedical.com

Disposable Needle Guides by Leapmed[1]

In addition to the above mentioned reusable needle guides, Esaote probes can be equipped with optional kits composed of sterilizable mounting adaptors and disposable needle guides produced by Leapmed.

Table 7-7: Disposable Needle Guides by Leapmed

Probe	Adaptor	Angle	Gauge	Manufacturer's Kit P/N
TLC 3-13 TRT33	LPUBKE06	3.8°	18	102040 (including needle guide only)
				10650602 (including needle guide, gel and cover)

WARNING

Follow the instructions provided by the manufacturer of the kits to properly mount and use them and to clean, disinfect and sterilize them.

Examination Safety

The biopsy procedures are to be carried out by operators with adequate experience.

SS

All safety information related to the use of the needle guide kits is in addition to the safety procedures described for **MyLab** and for the probes. Consult **MyLab** "Safety and Standard" manual for additional safety information.

WARNING

Personnel should adopt all necessary protective measures during probe and kit handling to ensure his own and patient safety as stated by its own facility procedure.

Before the Examination

Before each examination, Esaote recommends that the operator:

- Handle the needle guide kit and the probe with sterile gloves;

1. www.leapmed.com

- Perform a visual check of the adaptor and needle guides: do not use them if any damage or distortion is found;
- Make sure that the probe has been duly reprocessed (see Chapter 2);
- Make sure that the needle kit is sterile (see manufacturer's instructions);
- Use protective cover for the probe during the examination. This cover could be composed of latex (natural rubber).

WARNING

The probe covers may contain natural rubber latex which may cause allergic reactions. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

NOTE ***Using sterile cover is recommended for intraoperatory and biopsy procedures.***

- Apply ultrasound examination gel to the probe or to the tip of the protective cover.
- Completely unroll the cover along the probe making it to adhere so to avoid air pocket.
- Secure the cover with the sterile rubber band.
- Mount the needle kit following manufacturer's instructions (see in the following paragraphs for Esaote made kit, see instruction with kit package for those manufactured by CIVCO and PROTEK).

During the Examination

Pay particular attention to the ultrasound image during the insertion of the needle into the body, checking that the needle follows the displayed line.

WARNING

The lines displayed on the monitor only provides an indication of the needle direction, according to the selected guide. Pay particular attention

to the ultrasound image during the insertion of the needle into the body and be sure that the needle always stays within the displayed area.

Before performing the biopsy-test, check for the correct assembly and positioning of the needle guide kit. Also, check that the insertion angle is equal to the angle selected using the user interface software.

Needle insertion in a guide with an insertion angle other than that of the selected angle involves risks to patient safety.

At the End of the Examination

At the end of the examination Esaote recommends that the operator:

- reprocess the kit as per kit manufacturer's instructions;
- reprocess the probe used during the biopsy as per instructions in chapter 2.

Mounting the ABS Needle Guide for Linear Array and Convex Array Probes

The ABS needle guide kits for linear and convex probes are composed of two parts: the adaptor to be connected to the relative probe and the needle guide device.

Kit Assembly

- First refer to the above "Before the examination" paragraph.
- Connect the adaptor to the probe, positioning the two alignment pins on the special notches on the probe.

NOTE ***The adaptor for needle insertion must be on the same probe side of the LED. The adaptor must click into the special notch on the probe.***

When using the disposable needle guide, the adaptor has to be mounted after inserting the protective cover.

Fig. 7-1: ABS523 / ABS424 kit



Fig. 7-2: ABS421 / ABS621 kit



WARNING

Make sure that the bottom cone shaped part (at the bottom of the adaptor) is screwed into the indentation at the bottom of the top curved portion of the probe. If the user does not perform this procedure correctly, the insertion angle can be wrong thus causing a risk to patient safety.

For disassembly of the needle guide kit, reverse the previous procedure.

Reprocessing ABS421, ABS424, ABS523, ABS621

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is mandatory for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

Esaote recommends sterilizing the kit before it is used for the first time after prolonged storage periods.

The kit must be sterilized before it is used for the first time. The kit must be cleaned and sterilized after every examination.

- Dismantle the kit from the probe.
- Clean the kit carefully with mild soap.
- Carefully dry the kit with a clean soft, dry cloth or leave it to dry air until it is thoroughly dry.
- Sterilize the kit. ABS421, ABS424, ABS523, ABS621 needle guide kits, manufactured by Esaote, are composed of stainless steel (AISI 316) and can undergo all the sterilization methods used for surgical instruments operating to a temperature lower than 250° C.

WARNING

The maximal admitted temperature to sterilize ABS421, ABS424, ABS523, ABS621 kits is 250° C.

For information on how to store sterilized parts, refer to the locally applicable procedures.

WBSL Needle Guide on LA Probes

The WBSL33X needle guide kit is composed of two parts: the adaptor device to be connected to the probe and the needle guide.

Kit assembly

- First refer to above "Before the examination" paragraph.
- Connect the coupling device to the probe, by placing its grooved side on the probe's ridge.

Fig. 7-3: Adaptor device position



- Close the adaptor device by hitching it to the opposite side of the probe.

Fig. 7-4: Securing the adaptor device



NOTE ***The guiding device for needle insertion must be on the same probe side of the LED. The coupling device must click into the special notch on the probe.***

WARNING **If the user does not perform this operation correctly, the insertion angle can be wrong causing a risk to patient safety.**

To disassemble the needle guide kit, reverse the previous procedure.

Reprocessing WBSL33X

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is mandatory for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING **Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).**

Esaote recommends sterilizing the kit before it is used for the first time after prolonged storage periods.

The kit must be sterilized before it is used for the first time. The kit must be cleaned and sterilized after every examination.

- Dismantle the kit from the probe.
- Clean the kit carefully with mild soap.
- Carefully dry the kit with a clean soft, dry cloth or leave it to air dry until it is thoroughly dry.
- Sterilize the kit. WBSL33X needle guide kits, manufactured by Esaote, are composed of stainless steel (AISI 316) and can undergo all the sterilization methods used for surgical instruments operating to a temperature lower than 250° C.

WARNING

The maximal admitted temperature to sterilize WBSL33X kits is 250° C.

For information on how to store sterilized parts, refer to the locally applicable procedures.

ABS123 Needle Guide on the EC123 Endocavity Probe

The ABS123 needle guide kit is composed of two parts: the adaptor to be connected to the probe and the needle guide device.

Fig. 7-5: ABS123 Needle guide



Kit assembly

- First refer to above "Before the examination" paragraph.
- Connect the kit to the probe, positioning the two alignment pins on the special notches on the probe.

Fig. 7-6: Mounting the needle guide



- Close the clamp and tighten it using the special ratchet.
- Insert the needle guide and tighten it onto the coupling.

To disassemble the needle guide kit, reverse the previous procedure.

Reprocessing ABS123

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is mandatory for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

Esaote recommends sterilizing the kit before it is used for the first time after prolonged storage periods.

The kit must be sterilized before it is used for the first time. The kit must be cleaned and sterilized after every examination.

- Dismantle the kit from the probe.
- Clean the kit carefully with mild soap.
- Carefully dry the kit with a clean soft, dry cloth or leave it to air dry until it is thoroughly dry.
- Sterilize the kit. ABS123 needle guide kits, manufactured by Esaote, are composed of titanium ASTM grade 5 and can undergo all the sterilization methods used for surgical instruments.

For information on how to store sterilized parts, refer to the locally applicable procedures.

WBAC Needle Guide on AC Probes

The WBAC needle guide kit is composed of two parts: the adaptor device to be connected to the probe and the needle guide.

Kit assembly

- First refer to above "Before the examination" paragraph.
- Connect the coupling device to the probe, by placing its grooved side on the probe orientation marker.

Fig. 7-7: Adaptor device



- Close the adaptor device by hitching it to the opposite side of the probe.

Fig. 7-8: Adaptor device



NOTE ***The guiding device for needle insertion must be on the same probe side of the LED. The coupling device must click into the special notch on the probe.***

WARNING **If the user does not perform this operation correctly, the insertion angle can be wrong causing a risk to patient safety.**

To disassemble the needle guide kit, reverse the previous procedure.

Reprocessing WBAC54X

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is mandatory for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING **Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).**

Esaote recommends sterilizing the kit before it is used for the first time after prolonged storage periods.

The kit must be sterilized before it is used for the first time. The kit must be cleaned and sterilized after every examination.

- Dismantle the kit from the probe.
- Clean the kit carefully with mild soap.
- Carefully dry the kit with a clean soft, dry cloth or leave it to air dry until it is thoroughly dry.
- Sterilize the kit. WBAC54X needle guide kits, manufactured by Esaote, are composed of stainless steel (AISI 316) and can undergo all the sterilization methods used for surgical instruments operating to a temperature lower than 250° C.

WARNING

The maximal admitted temperature to sterilize WBAC54X kits is 250° C.

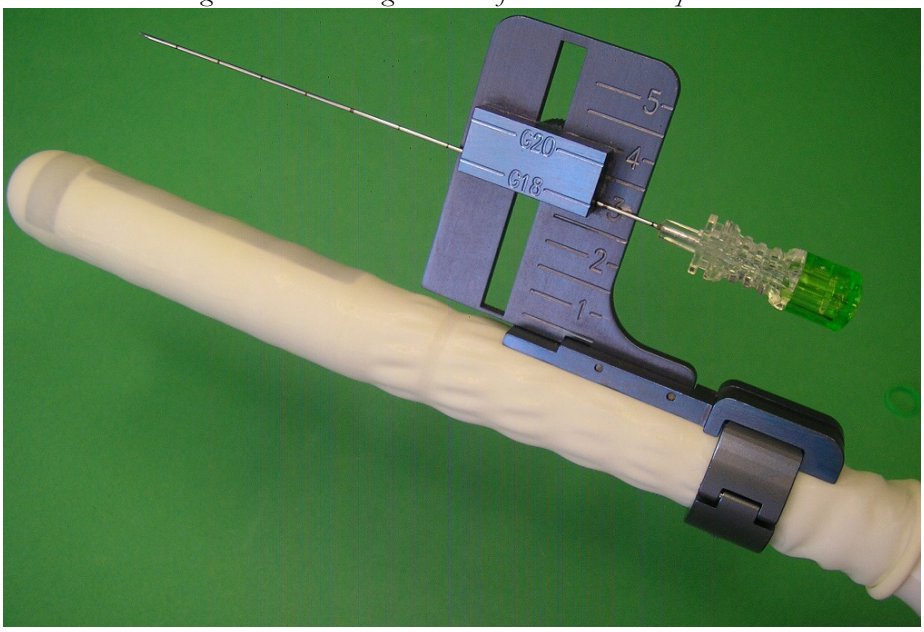
For information on how to store sterilized parts, refer to the locally applicable procedures.

ABS33A Transrectal Probe Needle Guide

The ABS33A transrectal needle guide kit is composed of two parts: the adaptor to be connected to the probe and the needle guide device.

Due to the fact that the TLC 3-13 and TRT33 probes have two different arrays, one convex and one linear, it should be taken in account that the ABS33A works with the linear array only.

Fig. 7-9: Needle guide kit for transrectal probes



The position of the needle guide is adjustable both in length and in depth.

The position of the needle guide, in longitudinal direction, is regulated by moving the whole kit along the probe using the channel on the probe and the two matching pins on the kit. To ensure the mechanical stability, fasten the fixing screw of the clamp.

The vertical adjustment allows the user to change the needle depth in the linear probe field of view and is performed by sliding the needle guide along the vertical track. To guarantee the precision of the adjustment, the vertical guide has a scale in centimeters (0,5 cm to 5 cm) corresponding to the depth shown in the ultrasound image; the needle guide has two notches to indicate each of the two guides for the supported needles. By rotating the needle guide the user can select the gauge. The needle guide fixing screw holds the guide in place.

Kit assembly

- First refer to above "Before the examination" paragraph.
- Connect the horizontal guide to the probe, positioning it on the groove on the probe and screwing the attachment system.
- Adjust the needle guide on the vertical guide to choose the correct depth for the exam.
- Slide the vertical guide on the horizontal one so that it fits in the desired position.
- Attach the vertical guide with the "longitudinal position sliding screw".
- Insert the needle into the guide paying particular attention to choose the correct needle guide hole.

To disassemble the needle guide kit, reverse the previous procedure.

Reprocessing ABS33A

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is mandatory for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

Esaote recommends sterilizing the kit before it is used for the first time after prolonged storage periods.

The kit must be sterilized before it is used for the first time. The kit must be cleaned and sterilized after every examination.

- Dismantle the kit from the probe.
- Clean the kit carefully with mild soap.
- Carefully dry the kit with a clean soft, dry cloth or leave it to air dry until it is thoroughly dry.
- Sterilize the kit. ABS33A needle guide kits, manufactured by Esaote, are composed of titanium ASTM grade 5 and can

undergo all the sterilization methods used for surgical instruments.

For information on how to store sterilized parts, refer to the locally applicable procedures.

ABS15 Needle Guide for Intraoperative Probe

The ABS15 needle guide kit consists of two components: one bracket to hook the needle guide to the probe handle attachment and a needle guide to attach to the bracket. These two components can be disassembled to enable easier cleaning and sterilization.

Kit assembling

The ABS15 needle guide kit can only be placed on the probe handle attachment as shown below.

Check the integrity of the probe and needle guide and assemble the needle guide kit as follow:

- First refer to above "Before the examination" paragraph except last point.
- Fix the handle attachment as shown in Fig. 7-10.

Fig. 7-10: Adaptor positioning



- Apply ultrasound examination gel to the probe or to the tip of the protective cover. This cover could be composed of latex (natural rubber).

WARNING

The probe covers may contain natural rubber latex which may cause allergic reactions. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction. Refer to the package indications to identify whether the product contains Latex (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

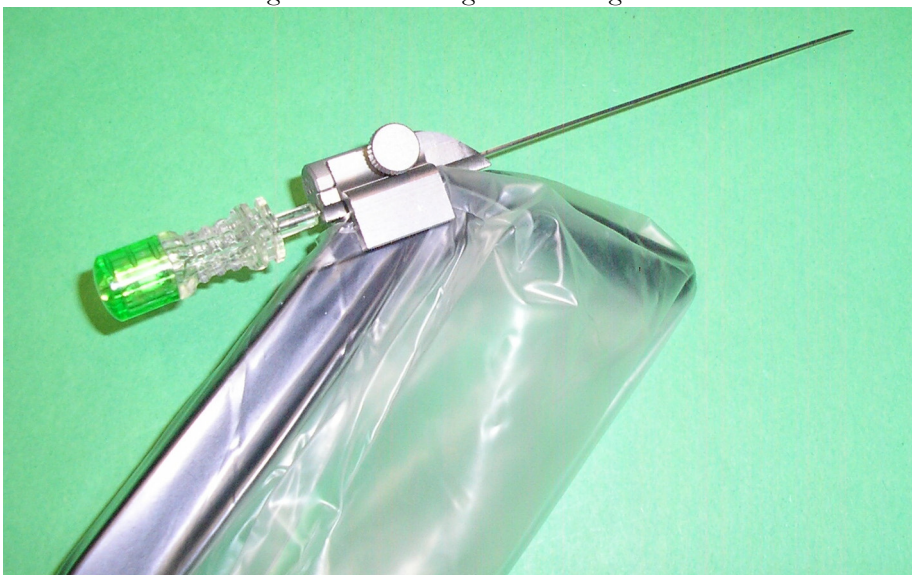
- Completely unroll the cover along the probe.
- Secure the cover with the sterile rubber band.
- Insert the bracket into the grooves on the handle attachment by sliding the bracket to the end of the groove. Attach the bracket with the screw provided.

Fig. 7-11: Adaptor positioning on the cover



- Choose the needle guide acceptable for the diameter of the needle to be used and insert it into the bracket.
- Attach the needle guide to the bracket with the screw provided.
- The needle can then be inserted into the hole formed between the bracket and the attached needle guide.

Fig. 7-12: Securing the needle guide



If necessary, the needle guide attachment can be removed from the handle attachment without removing the needle.

To disassemble the needle guide kit reverse the previous procedure.

Reprocessing ABS15

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is mandatory for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

Esaote recommends sterilizing the kit before it is used for the first time after prolonged storage periods.

The kit must be sterilized before it is used for the first time. The kit must be cleaned and sterilized after every examination.

- Dismantle the kit from the probe.
- Clean the kit carefully with mild soap.

- Carefully dry the kit with a clean soft, dry cloth or leave it to air dry until it is thoroughly dry.
- Sterilize the kit. ABS15 needle guide kits, manufactured by Esaote, are composed of stainless steel (AISI 304) and can undergo all the sterilization methods used for surgical instruments including autoclavable ones.

For information on how to store sterilized parts, refer to the locally applicable procedures.

ABSIC4X on SI2C41 Probes

SI2C41 is a special probe designed for biopsy. Each ABSIC4X adaptor consists of two parts, an adaptor with three different insertion angles (0°, 5° and 15° degrees) and a safety catch. Each adaptor supports 14-15, 16-17, 18-19 and 20-21 gauge needles.

NOTE ***Needle guide kits supplied by Esaote are neither disinfected nor sterilized.***

The use of protective covers is recommended in all clinical situations where there is a risk of infection. Specific covers are available on the market, please refer to chapter 9 for further information.

Kit assembly

The procedure below gives general rules on how to use covers; refer to the manufacturer's instruction for the covers characteristics and detailed information on how to use it.

- Refer to above "Before examination" paragraph up to the use of a protective cover.
- Make sure that the probe has been disinfected.
- Insert the adaptor into the gap on the scan head paying attention to push it into the special safety catch on the probe.

NOTE ***Both adaptor and safety catch can be outside or inside the cover: check that they are safely fixed.***

- Apply enough ultrasound gel inside the cover.
- Completely unroll the cover along the probe body, making it adhere, so as to avoid air pockets.
- Secure the cover using all the rubber bands enclosed to the kit.
- Insert the Safety Catch as depicted in the image below:

Fig. 7-13: Safety Catch Insertion



- Close the Safety Catch by the dedicated screw.

Fig. 7-14: Safety Catch Closed



- Fix the Safety Catch on the probe covered with the cover as depicted in the image below.

Fig. 7-15: Kit fixed on the probe and needle inserted



- Insert the needle in one of the three holes paying attention to choose the correct insertion angle.

Using the cover in this way during the biopsy procedure, the cover will be perforated by the needle. Anyway it is suggested to use the cover to better protect the probe from any contamination.

For disassembly of the needle guide kit, reverse the previous procedure.

Reprocessing ABSIC4X

The procedures described in this paragraph apply to all the kits used in critical applications. The application is considered critical when the device comes into contact with blood or compromised tissue. Sterilization is mandatory for this type of procedure.

Wearing gloves is recommended during cleaning and sterilization operations.

WARNING

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

Esaote recommends sterilizing the kit before it is used for the first time after prolonged storage periods.

The kit must be sterilized before it is used for the first time. The kit must be cleaned and sterilized after every examination.

- Dismantle the kit from the probe.
- Clean the kit carefully with mild soap.

- Carefully dry the kit with a clean soft, dry cloth or leave it to air dry until it is thoroughly dry.
- Sterilize the kit. ABSIC4X needle guide kits, manufactured by Esaote, are composed of anodized aluminium and can undergo all the sterilization methods used for surgical instruments, including autoclavable ones.

For information on how to store sterilized parts, refer to the locally applicable procedures.

8. Accessories and Consumables

Stand Off for LA533 Probe

The Stand Off for LA533 Probe allows to keep some distance between the probe head and the skin, thus moving the focus area of the probe.

The stand-off's water balloon interface can generate artifacts on the ultrasound image; for this reason dedicated presets for LA533 probe have been added to improve the imaging quality and reduce artifacts to the minimum.

WARNING

The stand-off is made of natural latex, so it is not latex free. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the operator should be prepared to handle such a reaction (for further information refer to the FDA Medical Alert, March 29, 1991, "Allergic Reactions to Latex-Containing Medical Devices").

Using the Stand-Off

Inspect balloon for damage such as abrasion. If damage is evident, discontinue use of the balloon and substitute it with a new one.

Inspect the plastic frame for damage such as cracks or breakage. If damage is evident, discontinue use of the frame and contact Esaote or your local representative.

- Insert the closed end of the balloon into one of the holes of the plastic frame as depicted in the first image.
- Insert the fillable end of the balloon into the other hole of the plastic frame.
- To get the desired distance, fill with water the balloon. The balloon can be filled and emptied using a syringe which perfectly suits into the balloon open side. It is suggested to do fill only at 50% the balloon to assure the maximum breast contact with the minimum image reverberation. It is also suggested to use water without air bubbles and at a temperature of about 37°C.
- Close the open end with the suitable stopper.

CAUTION

During the exam, check that the balloon is perfectly closed and correctly mounted on its frame, to avoid fluid leaks or air bubbles.

- Apply ultrasound gel on the probe.
- Place the stand-off on the probe sliding it till some gel comes out.
- Apply ultrasound gel on the stand-off (between the balloon and the patient).

CAUTION

When the stand off is not used, it is recommended to store it far from light sources, to avoid early aging of the natural latex.

Cleaning

1. Disassemble the stand-off from the probe.
2. Disassemble the balloon and the plastic frame.
3. Remove visible contaminants from balloon and plastic frame surface using a small, soft brush.
4. Soak balloon and plastic frame for a minimum of five minutes in a neutral pH, low foaming enzymatic detergent (i.e. Johnson & Johnson Enzol Enzymatic Detergent). Follow manufacturer's directions for use and recommendations for concentrations. While immersed, use a brush to remove trapped contaminants from surfaces.
5. Remove balloon and plastic frame from cleaning solution and remove any remaining residue thoroughly rinsing them with water.

Disinfecting

1. Disassemble the stand-off from the probe.
2. Disassemble the balloon and the plastic frame.
3. Remove visible contaminants from balloon and plastic frame surface using a small, soft brush.
4. Mix the disinfectant solution using AMUCHINA or equivalent product. Follow manufacturer's direction for use and recommendations for concentration, time of contact (exposure) and post-process procedure.

CAUTION

The use of germicidal lamps and/or disinfectant agents containing quaternary ammonium compound is not recommended as they could damage the stand-off.

Sterilizing

According to its intended use, the stand-off sterilization is not required.

Gel

Transmission gel must always be applied to probes to obtain correct probe-patient contact. Esaote recommends only using water or glycerine-based ultrasound gel.

WARNING

Check the composition of the gel before using it on the patient in order to eliminate the possibility of allergic reactions.

CAUTION

Do not use gels containing the substances listed below. The probe could be damaged if such gels are used.

Always verify the gel composition before using it.

NOTE

Any damage caused by the use of gels containing the below listed components is not covered by the warranty.

Substances to Be Excluded

- Acetone,
- methanol, ethanol, isopropyl alcohol, isooctyl alcohol,
- denatured ethyl alcohol,
- mineral oil,
- iodine,
- any lotion or gel containing perfume,
- glycol.

The following table indicates ultrasound gels that have tested compatibility with **MyLab** probes and their level of compatibility rank.

Table 8-1: Gels tested with Esaote Probes

	Product	Supplier	Compatibility Rank
	Sonogel	Sonogel Vertriebs GmbH (www.sonogel.de)	• [a]
	Scan MV	MV Groupe	•• [a]
	G006	Fiab	•• [a]
	GuangonPai	GuangonPai	•• [a]
	Ecosupergel	Ceracarta	••• [b]
Recommended	Scan®	Parker Laboratories, Inc., USA (www.parkerlab.com)	••• [b]
Recommended	Aquasonic® Clear	Parker Laboratories, Inc., USA (www.parkerlab.com)	••• [b]
Recommended	Aquasonic® 100	Parker Laboratories, Inc., USA (www.parkerlab.com)	•••• [b]
Recommended	Clear Image	NEXT Medical Products Company (former Sonotech) (www.nextmedicalproducts.com)	••••• [c]

a. • and ••: possible damage after 40 hours of continuous use.
b. ••• and ••••: possible damage after 80 hours of continuous use.
c. •••••: no damage for more than 100 hours of continuous use.

Covers

The use of protective covers is recommended in all clinical situations where there is a risk of infection. Specific covers are available on the market for most types of Esaote probes. The covers listed below are produced by CIVCO[1].

Refer to the manufacturer's instructions for the characteristics and use of the kits.

WARNING

In neurosurgery application the use of sterile non-pyrogenic covers is required.

The procedure below gives general rules on how to use the cover; refer to the manufacturer's instructions for the cover characteristics and detailed information on how to use it.

Procedure

- Apply enough ultrasound gel inside the cover.



- Completely unroll the cover along the probe body, making it adhere, so as to avoid air pockets.



- Secure the cover using all the rubber bands enclosed to the kit.



1. www.civco.com

Table 8-2: Civco Covers for Esaote Probes

Probes	CIVCO P/N	Measurements	Sterile	Latex
L 3-11, L 4-15, L 8-24, LA332E, LA533, AL2442, LA435, LA523, SL1543, SL2325, SL3116, SL3323, SL3235, SL3332	610-001	8.9 x 61 cm	Yes	No
C 1-8, C 2-9, CA431, CA541, CA631, BL433, AC2541, BC441, CA430E, SB2C41, SC3123, SC3421, SI2C41	610-002	14x61 cm	Yes	No
BE1123 E 3-12 EC1123 EC123 SE3123 SE3133 TLC 3-13 TRT33	610-006	Can be reduced from 11.9 to 4.6 x 61 cm	Yes	No
	610-007	Can be reduced from 11.9 to 4.6 x 61 cm	No	No
	610-214	3.5 x 20 cm	Yes	Yes
	610-010	3.5 x 20 cm	No	Yes
	610-075	2 x 20 cm	Yes	Yes
	610-039	2 x 20 cm	No	Yes
IH 6-18, IOT332, IOT342	610-023	7.6 x 244 cm	Yes	No

Table 8-3: Civco Covers for Transesophageal Probes

Probes	CIVCO P/N	Kit composition	Sterile	Latex
ST2612 ST2613 TEE022	610-840	Bite-guard and cover with application kit (for adult probe)	No	No
	610-979	Pediatric Bite-guard (pediatric probe)	No	No

Appendix A - MyLab Probes

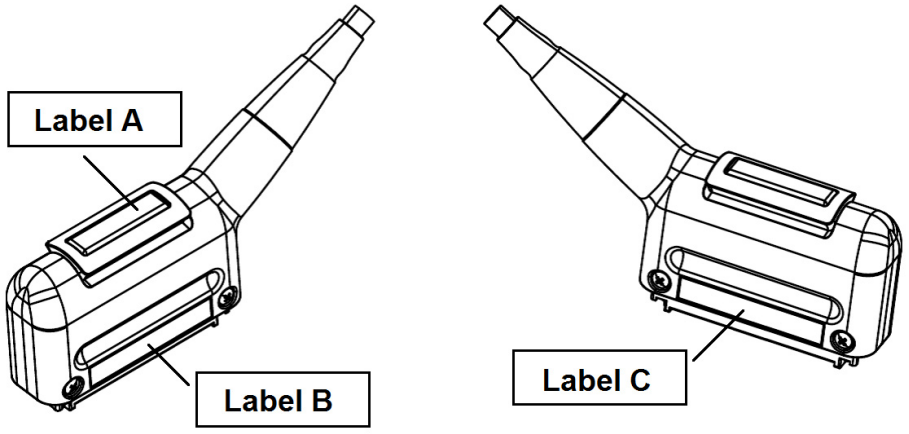
This chapter provides information on probe labeling and a list of **MyLab** probes with their main characteristics.

Probe Labels

The probe labels are stuck on the probe connector. Probe may have two types of connectors: small connector and big connector.

Small Connector Probes

Fig. A-1: Probe Connector: three labels are stuck on the connector

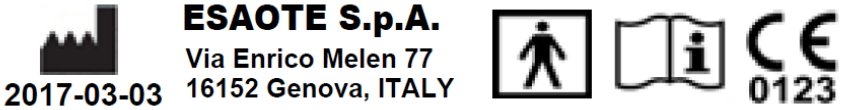


Label A — **Probe ID Label**



The label contains the Company logo and the name of the probe (Probe ID).

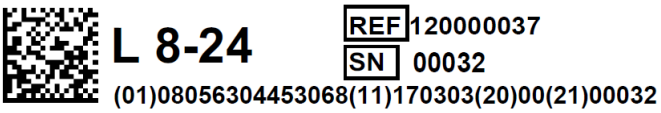
Label B **Company Label**



The company label contains the following information:

- Manufacturing date,
- Manufacturer name and address,
- Type BF applied part symbol,
- Operating instruction symbol: carefully read he user manual,
- CE Mark of Conformity.

Label C **Reference Label**

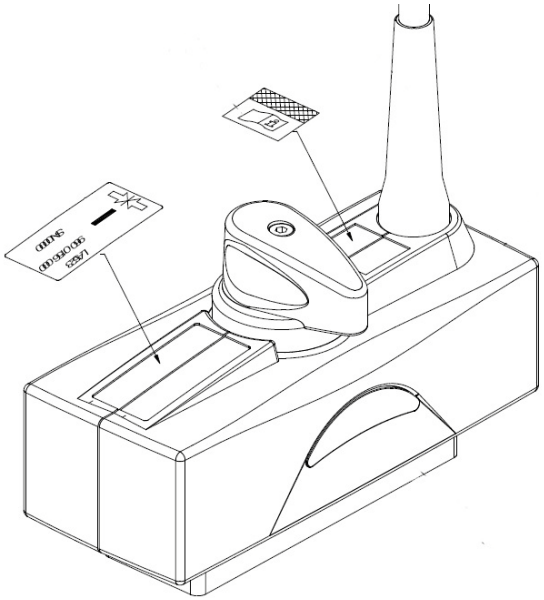


The reference label contains the following information:

- Probe UDI optical code,
- Probe name,
- Probe UDI human readable code,
- Probe part number (REF field)
- Probe serial number (SN field),

Big Connector Probe

Two labels are stuck on the connector.



Probe ID and Reference Label



The probe name (Probe ID) and reference label contain the following information:

- Manufacturing date,
- Company name and address,
- Type BF applied part symbol,
- CE Mark of Conformity,
- Locking position symbol,

- Probe name, part number (REF field) and serial number (SN field),
- Probe UDI optical code,
- Probe UDI human readable code.

Instruction Label



This label contains the operating instruction symbol: carefully read he user manual.

Probes Denomination and Maximum Immersion Level

The user manual and the display always identify the probe by using the Probe ID.

Esaote probes are protected against the effects on temporary immersion in liquids (IPX7) up to the maximum immersion level indicated in the tables below.

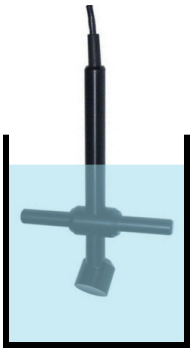
CAUTION **Esaote probe protection against the effects on temporary immersion is not granted.**

All other parts of Esaote probes are protected against vertical drop of water drops (IPX1).

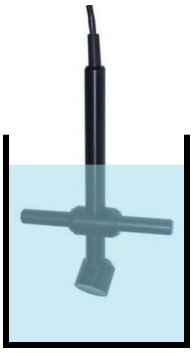
CAUTION **Esaote probe connector is not protected against any liquid drop or immersion.**



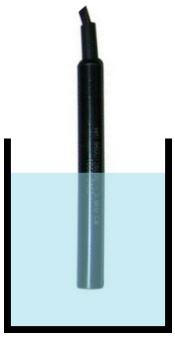
In the next pages the agent level is represented as shown in the beside image.



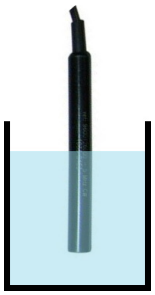
Probe ID:	2 MHz CW
Technology:	Pencil
Type:	BF
Connector type:	LEMO
Maximum immersion level:	Up to 9 cm from the contact surface



Probe ID:	2CWS
Technology:	Pencil
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 7 cm from the contact surface



Probe ID:	5 MHz CW
Technology:	Pencil
Type:	BF
Connector type:	LEMO
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	5CWS
Technology:	Pencil
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



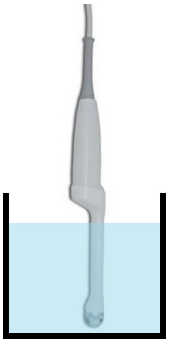
Probe ID:	AC2541
Technology:	Convex Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	AL2442
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	BC441
Technology:	Convex Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 9,5 cm from the contact surface



Probe ID:	BE1123
Technology:	Convex Array
Imaging plane:	Sagittal
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 17,5 cm from the contact surface



Probe ID:	BL433
Technology:	Linear Array
Type:	BF
Connector type:	Big/Small
Maximum immersion level:	Up to 8 cm from the contact surface



Probe ID:	C 1-8
Technology:	Convex Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	C 2-9
Technology:	Convex Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	CA123
Technology:	Convex Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 5 cm from the contact surface



Probe ID:	CA430E
Technology:	Convex Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 3 cm from the contact surface



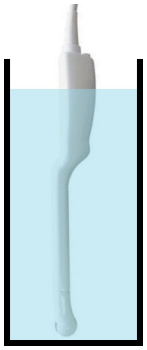
Probe ID:	CA431
Technology:	Convex Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 5 cm from the contact surface



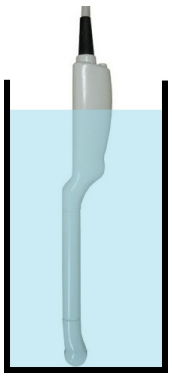
Probe ID:	CA541
Technology:	Convex Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 5 cm from the contact surface



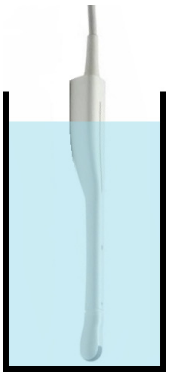
Probe ID:	CA631
Technology:	Convex Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 5 cm from the contact surface



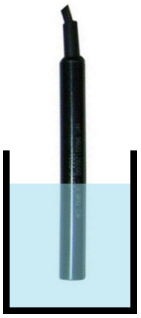
Probe ID:	E 3-12
Technology:	Convex Array
Imaging plane:	Sagittal
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 25 cm from the contact surface



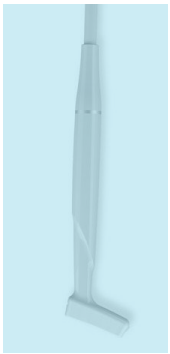
Probe ID:	EC1123
Technology:	Convex Array
Imaging plane:	Sagittal
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 25 cm from the contact surface



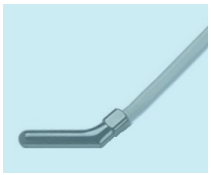
Probe ID:	EC123
Technology:	Convex Array
Imaging plane:	Sagittal
Type:	BF
Connector type:	Big/Small
Maximum immersion level:	Up to 25 cm from the contact surface



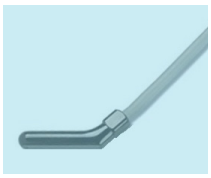
Probe ID:	HF CW
Technology:	Pencil
Type:	BF
Connector type:	LEMO
Maximum immersion level:	Up to 4,5 cm from the contact surface



Probe ID:	IH 6-18
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



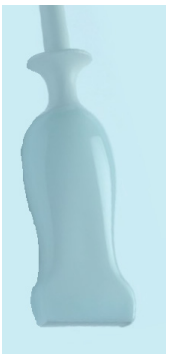
Probe ID:	IL 4-13
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	IOE323
Technology:	Linear Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	IOT342
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	L 3-11
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	L 4-15
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	L 8-24
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



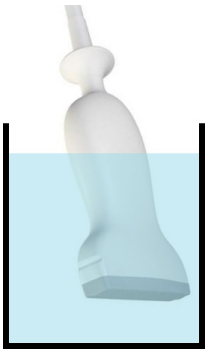
Probe ID:	LA332E
Technology:	Linear Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 8 cm from the contact surface



Probe ID:	LA435
Technology:	Linear Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 5 cm from the contact surface



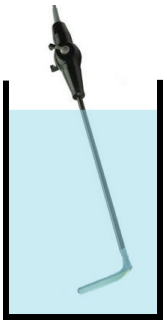
Probe ID:	LA523
Technology:	Linear Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 5 cm from the contact surface



Probe ID:	LA533
Technology:	Linear Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	LP323
Technology:	Linear Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 50 cm from contact surface



Probe ID:	LP 4-13
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 50 cm from contact surface



Probe ID:	mC 3-11
Technology:	Convex Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 8 cm from the contact surface



Probe ID:	P 1-5
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	P 2-9
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	P 3-11
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



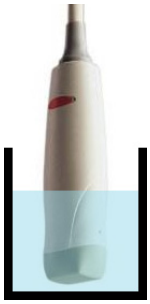
Probe ID:	P2 3-11
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	P2 5-13
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 3 cm from the contact surface



Probe ID:	PA023E
Technology:	Phased Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 3 cm from the contact surface



Probe ID:	PA121E
Technology:	Phased Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 9 cm from the contact surface



Probe ID:	PA122E
Technology:	Phased Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 3 cm from the contact surface



Probe ID:	PA230E
Technology:	Phased Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 3 cm from the contact surface



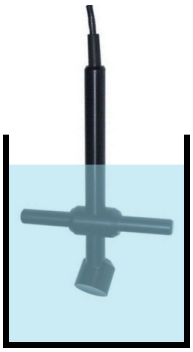
Probe ID:	PA240
Technology:	Phased Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 3 cm from the contact surface



Probe ID:	PA250
Technology:	Phased Array
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 200 cm from the contact surface



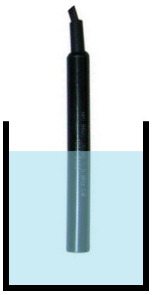
Probe ID:	PX 1-5
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 200 cm from the contact surface



Probe ID:	S2MCW
Technology:	Pencil
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 9 cm from the contact surface



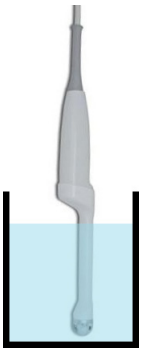
Probe ID:	S2MPW
Technology:	Pencil
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 4 cm from the contact surface



Probe ID:	S5MCW
Technology:	Pencil
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	SB2C41
Technology:	Convex Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 9,5 cm from the contact surface



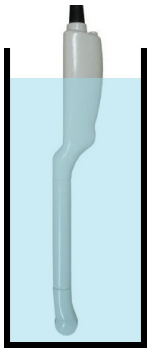
Probe ID:	SB3123
Technology:	Convex Array
Imaging plane:	Sagittal
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 17,5 cm from the contact surface



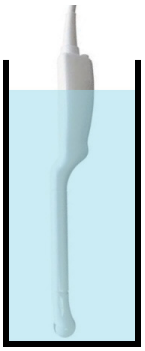
Probe ID:	SC3123
Technology:	Convex Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 8 cm from the contact surface



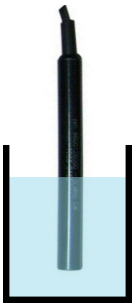
Probe ID:	SC3421
Technology:	Convex Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 8,5 cm from the contact surface



Probe ID:	SE3123
Technology:	Convex Array
Imaging plane:	Sagittal
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 25 cm from the contact surface



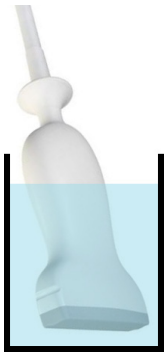
Probe ID:	SE3133
Technology:	Convex Array
Imaging plane:	Sagittal
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 25 cm from the contact surface



Probe ID:	SHFCW
Technology:	Pencil
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 4,5 cm from the contact surface



Probe ID:	SI2C41
Technology:	Convex Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	SL1543
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



Probe ID:	SL2325
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 5 cm from the contact surface



Probe ID:	SL3116
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



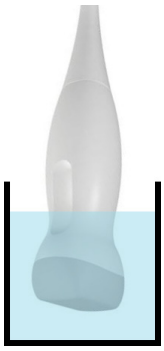
Probe ID:	SL3235
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 7 cm from the contact surface



Probe ID:	SL3323
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 7,5 cm from the contact surface



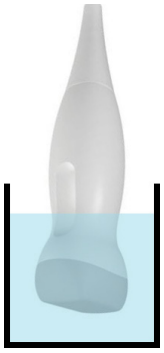
Probe ID:	SL3332
Technology:	Linear Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 7 cm from the contact surface



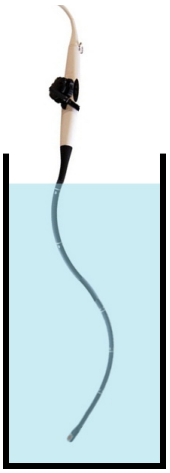
Probe ID:	SP2430
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 3 cm from the contact surface



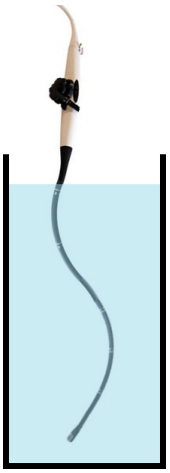
Probe ID:	SP2442
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 6 cm from the contact surface



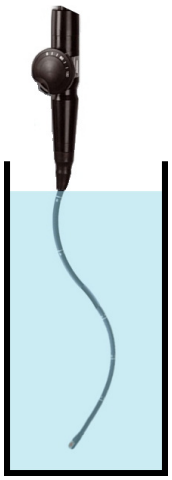
Probe ID:	SP2730
Technology:	Phased Array
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 3 cm from the contact surface



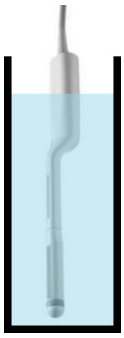
Probe ID:	ST2612
Technology:	Phased Array
Imaging plane:	0-180°
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 110 cm from the contact surface



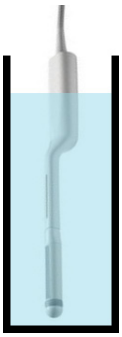
Probe ID:	ST2613
Technology:	Phased Array
Imaging plane:	0-180°
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 80 cm from the contact surface



Probe ID:	TEE022
Technology:	Phased Array
Imaging plane:	0-180°
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 100 cm from the contact surface



Probe ID:	TLC3-13
Technology:	Convex + Linear Array
Imaging plane:	Transversal and longitudinal
Type:	BF
Connector type:	Small
Maximum immersion level:	Up to 22 cm from the contact surface



Probe ID:	TRT33
Technology:	Convex + Linear Array
Imaging plane:	Transversal and longitudinal
Type:	BF
Connector type:	Big
Maximum immersion level:	Up to 22 cm from the contact surface

Appendix B - Probes Electrical Safety

The endocavitary, intraoperative and transesophageal probes, produced by Esaote, are classified as Type BF applied parts. To ensure electrical safety both to the patient and the operator, the physical integrity of the probe must be checked and the **MyLab** must be correctly grounded.

NOTE ***Normal leakage current testing frequency should be based on the procedures established by the hospital for operating-room-based equipment.***

It is important to check on a regular basis the electrical safety of probes used in semi-critical (for example endocavity) and critical (for example intraoperative) applications, according to what is stated by the IEC EN 60601-1 Safety Standard. This means that the procedures adopted to check probes must also include a leakage current measurement.

WARNING **Do not use a probe which underwent any kind of shock or whose integrity has been compromised (carefully read Chapter 1 of this manual), until its electrical integrity has been defined by a leakage current measurement. Contact your local Esaote Service Personnel.**

The leakage current measurement must be performed by a qualified person, using some test equipment complying with the standards.

NOTE ***Before performing the measurement, make sure that the test equipment is correctly calibrated.***

The below described procedure refers to ULT800 (www.flukebiomedical.com) measurement device: for further details on its use, please refer to the manufacturer's user manual. Any other equipment complying with the standards can be used, referring to the corresponding user manuals.

NOTE ***Probe with small connector (for instance SL, SC probes) requires a proper adaptor to be connected to the measurement device.***

WARNING

During the test do not touch either the electrodes or the liquid where the probe is immersed. During the test a high voltage is applied on the electrodes.

Do not immerse the probe cable or connector into water or other liquids. Immersion may compromise the electrical safety features. The probe can be inserted in water up to its Maximum Immersion Level (see Appendix A).

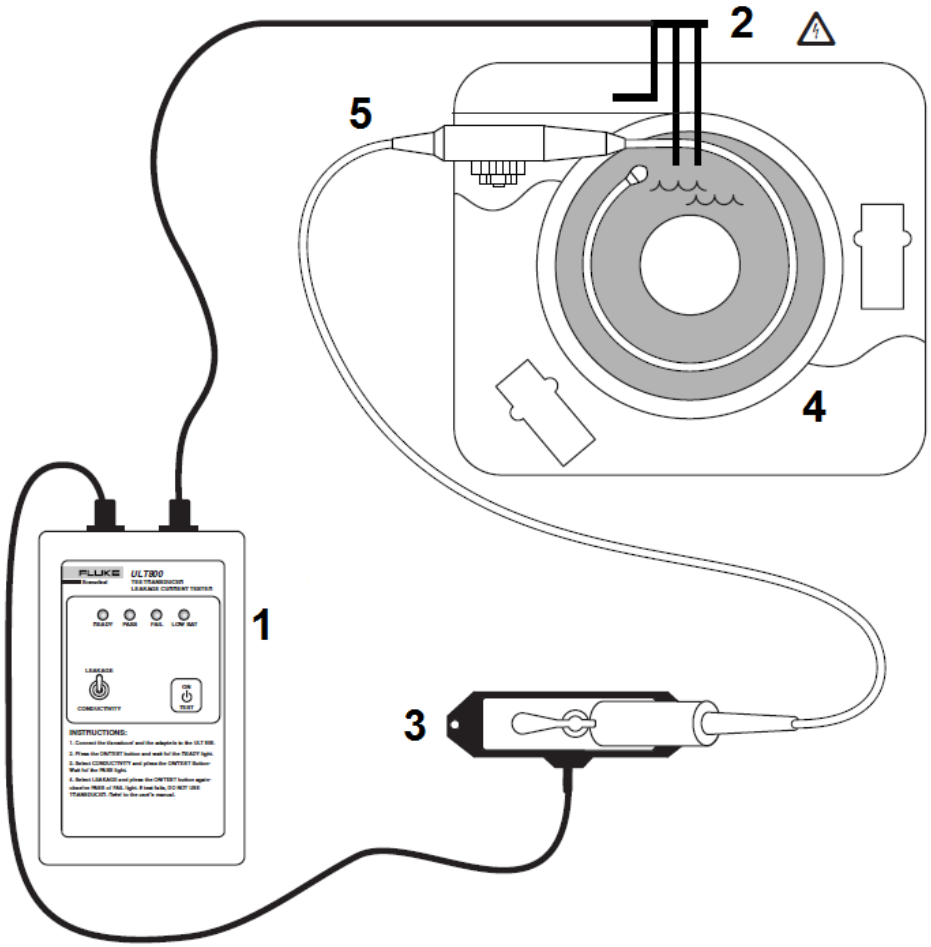
Procedure

- Connect the probe to the adapter available on the measurement device.
- Turn the measurement device on and wait till it is ready to work.
- Immerse the probe into a saline solution or Cidex®.
- Place the electrodes into the saline solution.
- Connect both the electrodes and the probe adaptor to the tester.
- Run first the conductivity test and then the leakage current test.

WARNING

If the leakage current test gives a negative result, do not use the probe and contact your local Esaote representative.

Fig. B-1: Probe leakage test



Legenda

1:	Measuring device
2:	Conductivity electrodes
3:	Probe adapter
4:	Water tank filled with Cidex or saline solution
5:	Probe to be examined

Appendix

C

Appendix C - Probes and Agents

Agents and Systems

The following tables list the **MyLab** probes and the recommended cleaning, disinfection and sterilization agents and systems.

The tables show both chemical (and physical) compatibility and biological effectiveness of the method.

NOTE ***The listed products may not be available in all regions. For probe availability, please contact your local representative; for cleaning, disinfectant or gel availability, contact the cleaning agent or gel manufacturer.***

OK means the use of the agent/system is permitted.

- means the use of the agent/system is not permitted.

CAUTION **Do not use not tested agents/systems either to clean or to disinfect or to sterilize the probe. The probe could be damaged if such agents are used.**

Cleaning, disinfection and sterilization are allowed up to the immersible part limit.

NOTE ***Any damage caused by the use of not recommended agents/systems is not covered by the warranty.***

WARNING **The listed disinfection/sterilization agents and systems are recommended because of chemical compatibility with the probe materials.**

The tables in the next pages indicate which agents/systems have been positively tested for chemical compatibility only. Follow the guidelines and recommendations of the manufacturer for the biological effectiveness of agents/systems.

Use of solutions other than those referenced is not recommended. They may damage the probe housing or the acoustic lens. Esaote takes no responsibility for damage caused by using non-approved products.

Follow the instructions provided by the manufacturer of the agent for proper use. Observe specifically soak times and dilution rates.

Overexposure to the disinfection fluid can damage the probe.

Personnel should adopt all necessary protective measures during the probe cleaning, disinfection and sterilization processes (for example gloves, protective glasses).

Never attempt to clean or disinfect the probes while they are connected to MyLab.

The probes have resulted compatible, in terms of chemical aggression, with reprocessing agents/methods listed in the tables below for average use of at least 7 years corresponding to not less than 4000 cycles. For sterilization, compatibility test evaluation is limited to 100 cycles.

In any case reprocessing methods are harsh and can shorten the life of the equipment owing to many unpredictable factors.

Equipment that undergoes reprocessing should be checked regularly.

Table C-1: Cleaning Agents

	2 MHz CW	5 MHz CW	AC2541	AL2442	BC441	BE1123	BL433	C 1-8	C 2-9	CA123	CA430E	CA431	CA541	CA631	E 3-12[a]	EC1123[a]
Accel RTU wipes	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	OK
Asepti-wipe II	-	-	OK	OK	OK	-	-	OK	OK	OK	-	OK	-	OK	OK	OK
Cavicide	OK	OK	OK	OK	OK	-	-	OK	-	OK	-	OK	-	OK	-	-
Caviwipes	OK	OK	OK	OK	OK	-	-	OK	-	OK	-	OK	-	OK	-	-
Cidezyme	-	-	OK	-	OK	-	-	OK	-	OK	OK	OK	-	OK	-	-
CidezymeXTRA	-	-	OK	-	OK	-	-	OK	-	OK	OK	OK	-	OK	-	-
Cleanisept-wipes forte	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Enzol	-	-	OK	-	OK	-	-	OK	-	OK	OK	OK	-	OK	-	-
Hexanios G+R	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Klenzyme	-	-	OK	-	-	-	-	OK	-	OK	OK	-	-	-	-	-
Metrizyme	-	-	OK	-	OK	-	-	OK	-	OK	OK	OK	-	OK	-	-
Microzid AF wipes	-	-	OK	-	-	-	-	OK	-	OK	OK	-	-	-	-	-
Microzid PAA wipes	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	OK
Microzid Sensitive wipes	-	-	OK	OK	OK	-	-	OK	OK	-	-	OK	-	OK	OK	OK
Mild soap	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Percept RTU cleaner	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	OK
Prolystica	-	-	OK	-	-	-	-	OK	-	OK	OK	-	-	-	-	-
Protex wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Sani-Cloth Active wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Sani-Cloth HB wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Sani-Cloth plus wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	-	-
SaniZide plus spray	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
SaniZide plus wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Sono wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Super Sani Cloth wipes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Transeptic	-	-	-	-	OK	-	-	-	-	OK	-	OK	-	OK	-	-
Trionic D wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Trionic D spray	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Trophon Companion Cleaning wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Umonium medical tissue	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Virusolve + wipes	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
Wip'anios Excel	-	-	OK	OK	OK	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK

a. Whole probe, lumen excluded

Table C-2: Cleaning Agents

	EC123[a]	HF CW	IH 6-18	IL 4-13	IOE323	IOT342	L 3-11	L 4-15	L 8-24	LA332E	LA435	LA523	LA533	LP323	LP 4-13	mC 3-11
Accel RTU wipes	OK	OK	OK	-	-	OK	OK	OK	-	OK	-	-	OK	-	-	OK
Asepti-wipe II	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Cavicide	OK	OK	OK	-	-	OK	OK	OK	-	OK	-	-	OK	-	-	-
Caviwipes	-	OK	OK	-	-	OK	OK	OK	-	OK	-	-	OK	-	-	-
Cidezyme	OK	-	OK	OK	OK	-	-	-	-	OK	-	-	-	OK	OK	-
CidezymeXTRA	OK	-	OK	OK	OK	-	-	-	-	OK	-	-	OK	OK	OK	-
Cleanisept-wipes forte	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Enzol	OK	-	OK	OK	OK	-	-	-	-	OK	-	-	OK	OK	OK	-
Hexanios G+R	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Klenzyme	OK	-	OK	OK	OK	-	-	-	-	OK	-	-	OK	OK	OK	-
Metrizyme	OK	-	OK	OK	OK	-	-	-	-	OK	-	-	OK	OK	OK	-
Microzid AF wipes	-	-	-	-	-	-	-	-	-	OK	-	-	OK	-	-	-
Microzid PAA wipes	OK	OK	OK	-	-	OK	OK	OK	-	OK	-	-	OK	-	-	OK
Microzid Sensitive wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Mild soap	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Percept RTU cleaner	OK	OK	OK	-	-	OK	OK	OK	-	OK	-	-	OK	-	-	OK
Prolystica	OK	-	OK	OK	OK	-	-	-	-	OK	-	-	OK	OK	OK	-
Protex wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Sani-Cloth Active wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Sani-Cloth HB wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Sani-Cloth plus wipes	-	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
SaniZide plus spray	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
SaniZide plus wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Sono wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Super Sani Cloth wipes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Transeptic	OK	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	-
Trionic D wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Trionic D spray	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Trophon Companion Cleaning wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Umonium medical tissue	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Virusolve + wipes	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK
Wip'anios Excel	OK	-	OK	-	-	OK	OK	OK	-	OK	OK	OK	OK	-	-	OK

a. Whole probe, lumen excluded

Table C-3: Cleaning Agents

	P 1-5	P 2-9	P 3-11	P2 3-11	P2 5-13	PA023E	PA121E	PA122E	PA230E	PA240	PA250	PX 1-5	S2MCW	S2MPW	S5MCW	SB2C41
Accel RTU wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK
Asepti-wipe II	OK	OK	OK	OK	-	-	-	-	-	OK	OK	-	-	-	-	OK
Cavicide	OK	OK	OK	OK	-	-	-	-	-	OK	OK	-	OK	OK	OK	OK
Caviwipes	OK	OK	OK	OK	-	-	-	-	-	OK	OK	-	OK	OK	OK	OK
Cidezyme	OK	-	OK	-	OK	OK	-	OK	OK	OK	OK	OK	-	-	-	OK
CidezymeXTRA	OK	-	OK	-	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Cleanisept-wipes forte	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	OK
Enzol	OK	-	OK	-	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Hexanios G+R	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Klenzyme	OK	-	OK	-	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	-
Metrizyme	OK	-	OK	-	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Microzid AF wipes	OK	-	OK	-	-	-	-	-	-	OK	OK	-	-	-	-	-
Microzid PAA wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK
Microzid Sensitive wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Mild soap	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK
Percept RTU cleaner	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK
Prolystica	OK	-	OK	-	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	-
Protex wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Sani-Cloth Active wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Sani-Cloth HB wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	OK
Sani-Cloth plus wipes	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
SaniZide plus spray	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
SaniZide plus wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Sono wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	OK
Super Sani Cloth wipes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Transeptic	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	OK
Trionic D wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Trionic D spray	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Trophon Companion Cleaning wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	OK
Umonium medical tissue	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Virusolve + wipes	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK
Wip'anios Excel	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	OK

Table C-4: Cleaning Agents

	SB3123	SC3123	SC3421	SE3123[a]	SE3133[a]	SHFCW	SI2C41	SL1543	SL2325	SL3116	SL3235	SL3323	SL3332	SP2430	SP2442	SP2730
Accel RTU wipes	OK	OK	OK	OK	OK	OK	OK	OK	-	-	-	-	OK	OK	OK	OK
Asepti-wipe II	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Cavicide	-	-	OK	-	-	OK	OK	OK	-	OK	-	-	OK	OK	OK	OK
Caviwipes	-	-	OK	-	-	OK	OK	OK	-	OK	-	-	OK	OK	OK	OK
Cidezyme	-	-	OK	-	-	-	-	OK	-	OK	-	-	OK	OK	-	OK
CidezymeXTRA	-	-	OK	-	-	-	-	OK	-	-	-	-	OK	OK	-	OK
Cleanisept-wipes forte	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Enzol	-	-	OK	-	-	-	-	OK	-	-	-	-	OK	OK	-	OK
Hexanios G+R	-	OK	OK	OK	OK		OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Klenzyme	-	-	-	-	-	-	-	OK	-	-	-	-	OK	OK	-	OK
Metrizyme	-	-	OK	-	-	-	-	OK	-	-	-	-	OK	OK	-	OK
Microzid AF wipes	-	-	-	-	-	-	-	OK	-	-	-	-	OK	OK	-	OK
Microzid PAA wipes	OK	OK	OK	-	OK	OK	OK	OK	-	-	-	-	OK	OK	OK	OK
Microzid Sensitive wipes	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Mild soap	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Percept RTU cleaner	OK	OK	OK	-	OK	OK	OK	OK	-	-	-	-	OK	OK	OK	OK
Prolystica	-	-	-	-	-	-	-	OK	-	-	-	-	OK	OK	-	OK
Protex wipes	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Sani-Cloth Active wipes	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Sani-Cloth HB wipes	-	OK	OK	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Sani-Cloth plus wipes	-	OK	OK	-	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
SaniZide plus spray	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
SaniZide plus wipes	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Sono wipes	-	OK	OK	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Super Sani Cloth wipes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Transeptic	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	-
Trionic D wipes	-	OK	OK	OK	OK	-	OK	OK	OK		OK	OK	OK	OK	OK	OK
Trionic D spray	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Trophon Companion Cleaning wipes	-	OK	OK	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Umonium medical tissue	-	OK	OK	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Virusolve + wipes	-	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK	OK	OK	OK
Wip'anios Excel	-	OK	OK	OK	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK

a. Whole probe, lumen excluded

Table C-5: Cleaning Agents

	ST2612	ST2613	TEE022	TLC 3-13[a]	TRT33[a]
Accel RTU wipes	OK	OK	OK	OK	OK
Asepti-wipe II	-	-	-	OK	OK
Cavicide	-	-	-	-	-
Caviwipes	-	-	-	-	-
Cidezyme	-	-	OK	-	-
CidezymeXTRA	-	-	OK	-	-
Cleanisept-wipes forte	-	-	-	OK	OK
Enzol	-	-	OK	-	-
Hexanios G+R	-	-	-	OK	OK
Klenzyme	-	-	-	-	-
Metrizyme	-	-	-	-	-
Microzid AF wipes	-	-	-	-	-
Microzid PAA wipes	OK	OK	-	OK	OK
Microzid Sensitive wipes	-	-	-	OK	OK
Mild soap	OK	OK	OK	OK	OK
Percept RTU cleaner	OK	OK	-	OK	OK
Prolystica	-	-	OK	-	-
Protex wipes	-	-	-	OK	OK
Sani-Cloth Active wipes	-	-	-	OK	OK
Sani-Cloth HB wipes	-	-	-	OK	OK
Sani-Cloth plus wipes	-	-	-	-	-
SaniZide plus spray	-	-	-	OK	OK
SaniZide plus wipes	-	-	-	OK	OK
Sono wipes	-	-	-	OK	OK
Super Sani Cloth wipes	-	-	-	-	-
Transeptic	-	-	-	-	-
Trionic D wipes	-	-	-	OK	OK
Trionic D spray	-	-	-	OK	OK
Trophon Companion Cleaning wipes	-	-	-	OK	OK
Umonium medical tissue	-	-	-	OK	OK
Virusolve + wipes	-	-	-	OK	OK
Wip'anios Excel	-	-	-	OK	OK

a. Whole probe, lumen excluded

Table C-6: Low-medium Disinfection Agents

	Amuchina soluzione concentrata	Cavicide	Caviwipes	Cleanisept wipes	Mikrobac tissues	Sani Cloth HB wipes	Sani Cloth plus wipes	Sono wipes	Transeptic	Trophon Companion Cleaning wipes	Umonium medical tissue	Wip'anios Excel
2 MHz CW	-	OK	OK	-	-	-	-	-	-	-	-	-
5 MHz CW	-	OK	OK	-	-	-	-	-	-	-	-	-
AC2541	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
AL2442	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
BC441	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
BE1123	-	-	-	-	-	-	-	-	-	-	-	-
BL433	-	-	-	-	-	-	-	-	-	-	-	-
C 1-8	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
C 2-9	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
CA123	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
CA430E	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
CA431	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
CA541	-	-	-	-	-	-	-	-	-	-	-	-
CA631	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
E 3-12[a]	-	-	-	OK	-	OK	-	OK	-	OK	OK	OK
EC1123[a]	-	-	-	OK	-	OK	-	OK	-	OK	OK	OK
EC123[a]	OK	OK	-	OK	-	OK	-	OK	OK	OK	OK	OK
HF CW	-	OK	OK	-	-	-	-	-	-	-	-	-
IH 6-18	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
IL 4-13	-	-	-	-	-	-	-	-	-	-	-	-
IOE323	-	-	-	-	-	-	-	-	-	-	-	-
IOT342	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
L 3-11	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
L 4-15	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
L 8-24	-	-	-	-	-	-	-	-	-	-	-	-
LA332E	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
LA435	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
LA523	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
LA533	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
LP323	-	-	-	-	-	-	-	-	-	-	-	-

	Amuchina soluzione concentrata	Cavicide	Caviwipes	Cleanisept wipes	Mikrobac tissues	Sani Cloth HB wipes	Sani Cloth plus wipes	Sono wipes	Transeptic	Trophon Companion Cleaning wipes	Umonium medical tissue	Wip'anios Excel
LP 4-13	-	-	-	-	-	-	-	-	-	-	-	-
mC 3-11	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
P 1-5	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
P 2-9	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
P 3-11	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
P2 3-11	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
P2 5-13	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
PA023E	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
PA121E	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
PA122E	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
PA230E	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
PA240	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
PA250	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
PX 1-5	OK	-	-	OK	-	OK	-	OK	-	OK	-	OK
S2MCW	-	OK	OK	-	-	-	-	-	-	-	-	-
S2MPW	-	OK	OK	-	-	-	-	-	-	-	-	-
S5MCW	-	OK	OK	-	-	-	-	-	-	-	-	-
SB2C41	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
SB3123	-	-	-	-	-	-	-	-	-	-	-	-
SC3123	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
SC3421	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
SE3123[a]	-	-	-	OK	-	OK	-	OK	-	OK	OK	OK
SE3133[a]	-	-	-	OK	-	OK	-	OK	-	OK	OK	OK
SHFCW	-	OK	OK	-	-	-	-	-	-	-	-	-
SI2C41	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
SL1543	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
SL2325	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
SL3116	OK	OK	OK	OK	-	OK	OK	OK	-	OK	OK	OK
SL3235	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
SL3323	-	-	-	OK	OK	OK	OK	OK	-	OK	OK	OK
SL3332	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK

	Amuchina soluzione concentrata	Cavicide	Caviwipes	Cleanisept wipes	Mikrobac tissues	Sani Cloth HB wipes	Sani Cloth plus wipes	Sono wipes	Transeptic	Trophon Companion Cleaning wipes	Umonium medical tissue	Wip'anios Excel
SP2430	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
SP2442	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
SP2730	-	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK
ST2612	-	-	-	-	-	-	-	-	-	-	-	-
ST2613	-	-	-	-	-	-	-	-	-	-	-	-
TEE022	-	-	-	-	-	-	-	-	-	-	-	-
TLC 3-13[a]	-	-	-	OK	OK	OK	-	OK	-	OK	OK	OK
TRT33[a]	-	-	-	OK	OK	OK	-	OK	-	OK	OK	OK

a. Whole probe, lumen excluded

Table C-7: High-Level Disinfection (HLD) Agents

	Amuchina soluzione concentrata	Anioxyde 1000	Antigermix E1	Antigermix S1	Cidex	Cidex OPA	Cidex Plus	Compliance	Gigasept AF	Gigasept FF	Hypernova Chronos	Metricide 14	Metricide 28	Metricide OPA	Nu-Cidex	Omnicide 14 NS	Omnicide 28 NS	Peraction	Rely+On Perasafe	Revital Ox Resert	Sekusept Aktiv	Steranios	Tristel sporicidal wipes	Trophon 2	Trophon EPR	Umonium38	Virkon	Wavicide-01
2 MHz CW	-	OK	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	OK	-	OK	-	-	-	-	-	-	-	-
2CWS	-	-	-	-	-	OK	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5 MHz CW	-	OK	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	OK	-	OK	-	-	-	-	-	-	-	-	-
5CWS	-	-	-	-	-	OK	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
AC2541	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
AL2442	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	OK	-	-	OK	-	OK	OK	-	-	-	-	-	-	-
BC441	OK	OK	OK	OK	-	OK	-	OK	-	OK	OK	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
BE1123	-	OK	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	OK	-	OK	-	-	-	OK	OK	-	-	-
BL433	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	-	-	-	OK	OK	-	-	-
C 1-8	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
C 2-9	-	OK	-	-	-	OK	-	OK	-	-	-	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
CA123	OK	OK	-	-	OK	OK	OK	OK	-	OK	-	OK	-	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK	-	OK
CA430E	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	-	-	-	OK	-	OK	-	-	-	OK	OK	OK	OK	-
CA431	OK	OK	-	-	-	OK	-	OK	-	OK	-	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
CA541	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	-	OK	-	OK	OK	OK	-	OK	-	-	-	OK	OK	OK	-	OK
CA631	OK	OK	-	-	OK	OK	OK	OK	-	OK	-	-	-	OK	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	-	OK
E 3-12[a]	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	-	-	-	OK	OK	OK	-	-
EC1123[a]	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-
EC123[a]	OK	-	-	-	OK	OK	OK	-	-	-	-	OK	-	-	-	OK	OK	-	OK	-	-	-	OK	OK	OK	OK	-	OK
HF CW	-	OK	-	-	-	-	-	OK	-	-	-	-	-	OK	-	-	-	OK	-	OK	-	-	-	-	-	-	-	-
HFCWS	-	-	-	-	-	OK	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

PROBES AND CONSUMABLES

	Amuchina soluzione concentrata	Anioxyde 1000	Antigermix E1	Antigermix S1	Cidex	Cidex OPA	Cidex Plus	Compliance	Gigasept AF	Gigasept FF	Hypernova Chronos	Metricide 14	Metricide 28	Metricide OPA	Nu-Cidex	Omnicide 14 NS	Omnicide 28 NS	Peraction	Rely+On Perasafe	Revital Ox Resert	Sekusept Aktiv	Steranios	Tristel sporicidal wipes	Trophon 2	Trophon EPR	Umonium38	Virkon	Wavicide-01
IH 6-18	OK	OK	-	-	OK	OK	OK	OK	-	OK	-	OK	OK	OK	OK	-	-	OK	OK	OK	OK	-	-	-	-	OK	-	-
IL 4-13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	-	-	-	-	-
IOE323	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	-	-	-	-	-
IOT342	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	OK	-	-	OK	-	OK	OK	-	-	-	-	-	-	-
L 3-11	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
L 4-15	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
L 8-24	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	-	-	-	OK	OK	-	-	-
LA332E	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
LA435	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	OK	-	-
LA523	-	-	OK	OK	-	OK	-	-	-	-	OK	-	-	OK	-	-	-	-		-	-	OK	-	OK	OK	OK	-	-
LA533	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
LP323	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	-	-	-	-	-
LP 4-13	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	-	-	-	-	-
mC 3-11	-	OK	-	-	-	OK	-	OK	-	-	-	-	-	OK	OK	-	-	OK	OK	OK	OK	-	OK	OK	OK	OK	-	-
P 1-5	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
P 2-9	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
P 3-11	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
P2 3-11	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
P2 5-13	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	-	-	-	OK	-	OK	-	-	-	OK	OK	OK	-	-
PA023E	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	-	-	-	OK	-	OK	-	-	-	OK	OK	OK	OK	-
PA121E	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	-	-	-	OK	-	OK	-	-	-	OK	OK	OK	-	OK
PA122E	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	-	-	-	OK	-	OK	-	-	-	OK	OK	OK	OK	-
PA230E	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	-	-	-	OK	-	OK	-	-	-	OK	OK	OK	OK	-

	Amuchina soluzione concentrata	Anioxyde 1000	Antigermix E1	Antigermix S1	Cidex	Cidex OPA	Cidex Plus	Compliance	Gigasept AF	Gigasept FF	Hypernova Chronos	Metricide 14	Metricide 28	Metricide OPA	Nu-Cidex	Omnicide 14 NS	Omnicide 28 NS	Peraction	Rely+On Perasafe	Revital Ox Resert	Sekusept Aktiv	Steranios	Tristel sporicidal wipes	Trophon 2	Trophon EPR	Umonium38	Virkon	Wavicide-01
PA240	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	OK	OK
PA250	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
PX 1-5	-	OK	OK	OK	-	OK	-	-	-	OK	OK	-	-	-	-	-	-	-	OK	-	-	-	-	-	-	OK	-	-
S2MCW	-	OK	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	OK	-	OK	-	-	-	-	-	-	-	-
S2MPW	-	OK	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	OK	-	OK	-	-	-	-	-	-	-	-
S5MCW	-	OK	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	OK	-	OK	-	-	-	-	-	-	-	-
SB2C41	OK	OK	OK	OK	-	OK	-	OK	-	OK	OK	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
SB3123	-	OK	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	OK	-	OK	-	-	-	OK	OK	-	-	-
SC3123	-	OK	-	-	-	OK	-	OK	-	-	-	-	-	OK	OK	-	-	OK	OK	OK	OK	-	OK	OK	OK	OK	-	-
SC3421	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	-	-	OK	-	-
SE3123[a]	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-
SE3133[a]	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-
SHFCW	-	OK	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	OK	-	OK	-	-	-	-	-	-	-	-
SI2C41	-	OK	-	-	-	OK	-	OK	-	-	-	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	-	-	OK	-	-
SL1543	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
SL2325	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	OK	-	-
SL3116	OK	OK	-	-	-	OK	-	-	-	OK	-	-	-	-	-	-	-	-	OK	-	-	-	-	-	-	OK	-	-
SL3235	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	OK	OK	-	-
SL3323	-	-	OK	OK	-	OK	-	-	-	-	OK	-	-	OK	-	-	-	-	-	-	-	OK	-	OK	OK	OK	-	-
SL3332	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK
SP2430	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	-
SP2442	-	OK	OK	OK	-	OK	-	OK	-	-	OK	-	-	OK	OK	-	-	OK	OK	OK	OK	-	-	OK	OK	OK	-	-
SP2730	-	OK	OK	OK	OK	OK	OK	OK	-	-	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	-	OK	OK	OK	-	OK

PROBES AND CONSUMABLES

	Amuchina soluzione concentrata	Anioxyde 1000	Antigermix E1	Antigermix S1	Cidex	Cidex OPA	Cidex Plus	Compliance	Gigasept AF	Gigasept FF	Hypernova Chronos	Metricide 14	Metricide 28	Metricide OPA	Nu-Cidex	Omnicide 14 NS	Omnicide 28 NS	Peraction	Rely+On Perasafe	Revital Ox Resert	Sekusept Aktiv	Steranios	Tristel sporicidal wipes	Trophon 2	Trophon EPR	Umonium38	Virkon	Wavicide-01
ST2612	-	OK	OK	-	-	OK	-	-	-	-	-	-	-	OK	OK	-	-	-	OK	-	OK	OK	-	-	-	-	-	OK
ST2613	-	OK	-	-	-	OK	-	-	-	-	-	-	-	OK	OK	-	-	-	OK	-	OK	OK	-	-	-	-	-	OK
TEE022	-	-	-	-	OK	OK	OK	-	OK	OK	-	OK	OK	-	-	OK	OK	-	OK	-	-	OK	OK	-	-	-	OK	OK
TLC 3-13[a]	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	-	-	-	OK	OK	OK	-	-
TRT33[a]	-	-	-	-	-	OK	-	-	-	-	-	-	-	-	-	-	-	-	-	OK	-	-	-	OK	OK	OK	-	-

a. Whole probe, lumen included for liquid agents, lumen excluded for Trophon systems. To effective disinfect lumen use liquid HDL agents following the instruction on chapter 2.

Table C-8: Sterilization Agents

	Steris VPro Family	Sterrad 100S	Sterrad NX	Sterizone VP4
AC2541	OK	OK	OK	-
AL2442	OK	OK	OK	-
C 1-8	OK	OK	OK	-
E 3-12	-	-	-	OK
EC1123	OK	-	OK	OK
EC123	-	OK	OK	OK
IH 6-18	OK	-	OK	-
IL 4-13	OK[a]	-	-	-
IOE323	OK	-	-	-
IOT342	OK	OK	OK	-
L 3-11	OK	OK	OK	-
L 4-15	OK	OK	OK	-
LA332E	OK	OK	OK	-
LA523	-	-	-	OK
LA533	OK	OK	OK	-
LP323	OK	-	-	-
LP 4-13	OK	-	-	-
mC 3-11	OK	-	OK	OK
P 1-5	OK	OK	OK	-
P 2-9	OK	OK	OK	-
P 3-11	OK	OK	OK	-
P2 3-11	OK	OK	OK	-
PA240	OK	OK	OK	-
PA250	OK	OK	OK	-
SC3123	OK	-	OK	OK
SE3123	OK	-	OK	OK
SE3133	OK	-	OK	OK
SI2C41	OK	OK	OK	-
SL1543	OK	OK	OK	-
SL3116	OK	-	-	-
SL3323	-	-	-	OK
SL3332	OK	OK	OK	-

	Steris VPro Family	Sterrad 100S	Sterrad NX	Sterizone VP4
SP2430	OK	OK	OK	-
SP2442	OK	OK	OK	-
SP2730	OK	OK	OK	-
TLC 3-13	-	-	-	OK
TRT33[a]	-	-	-	OK

a. Probes accessories included

Table C-9: Additional information on agents

Trade name	Type	Chemical type	Manufacturer
Accel RTU wipes	Cleaning	Hydrogen peroxide	Virox Technologies
Amuchina Soluzione concentrata	Medium Disinfection	Sodium Hypochlorite	Amuchina / Angelini
Anioxyde 1000	HLD	Hydrogen peroxide	Laboratoires Anios
Antigermix E1	HLD	UV Radiation	Germitec
Antigermix S1	HLD	UV Radiation	Germitec
Asepti-wipe II	Cleaning	Isopropanol3, 2-butoxyethanol, n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	Ecolab
Cavicide	Disinfection	Isopropanol, Ethylene Glycol, Quaternary Ammonium	Metrex Research Corporation
Cavicide1	Disinfection	Isopropanol, Ethylene Glycol, Quaternary Ammonium, Ethanol	Metrex Research Corporation
Caviwipes	Disinfection	Isopropanol, Ethylene Glycol, Quaternary Ammonium	Metrex Research Corporation
Caviwipes1	Disinfection	Isopropanol, Ethylene Glycol, Quaternary Ammonium, Ethanol	Metrex Research Corporation
Cidex	HLD	Glutaraldehyde	Advanced Sterilization Products (ASP)
Cidex Plus	HLD	Glutaraldehyde	Advanced Sterilization Products (ASP)
Cidex OPA	HLD	Orto-phthalaldheyde	Advanced Sterilization Products (ASP)
Cidezyme	Cleaning	Enzimatic detergent	Advanced Sterilization Products (ASP)
CidezymeXTRA	Cleaning	Enzimatic detergent	Advanced Sterilization Products (ASP)
Cleanisept wipes	Disinfection	Quaternary Ammonium	Dr.Schumacher Gmbh
Cleanisept wipes forte	Cleaning	Quaternary Ammonium NH_4Cl[a]	Dr.Schumacher Gmbh

Trade name	Type	Chemical type	Manufacturer
Compliance	HLD	Hydrogen peroxide, peracetic acid	Metrex Research Corporation
Enzol	Cleaning	Enzimatic detergent	Advanced Sterilization Products (ASP)
Gigasept AF	HLD	Dimethyldioctyl-ammonium chloride, Phenoxypropanols, Alkylguanidine acetate, Laurylpropylenediamine	Schülke&Mayr GmbH
Gigasept FF	HLD	Reaction product of DMO-THF, ethanol and water	Schülke&Mayr GmbH
Hexanios G+R	Cleaning	Quaternary Ammonium NH_4Cl^a based	Laboratoires Anios
Hypernova Chronos	HLD	UV Radiation	Germitec
Klenzyme	Cleaning	Enzymatic detergent	Steris Corporation
Metricide 14	HLD	Glutaraldehyde	Metrex Research Corporation
Metricide 28	HLD	Glutaraldehyde	Metrex Research Corporation
Metricide OPA	HLD	Orto-phtalaldheyde	Metrex Research Corporation
Metricide Plus 30	HLD	Glutaraldehyde	Metrex Research Corporation
Metrizyme	Cleaning	Enzymatic detergent	Metrex Research Corporation
Microzid AF wipes	Cleaning	Ethanol, Propan-1-ol	Schülke&Mayr GmbH
Microzid PAA wipes	Cleaning	Hydrogen peroxide, peracetic acid	Schülke&Mayr GmbH
Microzid Sensitive wipes	Cleaning	Quaternary Ammonium NH_4Cl^a	Schülke&Mayr GmbH
Mild soap	Cleaning		Various
Nu-Cidex	HLD	Orto-phtalaldheyde	Advanced Sterilization Products (ASP)
Omnicide 14 NS	HLD	Glutaraldehyde	Metrex Research Corporation
Omnicide 28 NS	HLD	Glutaraldehyde	Metrex Research Corporation
Peraction	HLD	Hydrogen peroxide	Biosteril
Percept RTU cleaner	Cleaning	Hydrogen peroxide	Virox Technologies
Prolystica	Cleaning	Enzymatic detergent	Steris Corporation
Protex wipes	Disinfection	Quaternary Ammonium NH_4Cl^a	Parker Laboratories Inc.
Rely+On Perasafe	HLD	Sodium Percarbonate, Citric acid, Sodium Carbonate	Chemours
Revital Ox Resert XL	HLD	Hydrogen peroxide	Steris Corporation
Sani-Cloth Active wipes	Cleaning	Quaternary Ammonium NH_4Cl^a	Nice-Pak / Professional Disposables International (PDI)
Sani Cloth HB wipes	Disinfection	Quaternary Ammonium NH_4Cl^a	Nice-Pak / Professional Disposables International (PDI)

Trade name	Type	Chemical type	Manufacturer
Sani Cloth plus wipes	Disinfection	Quaternary Ammonium NH_4Cl^a, Isopropanol	Nice-Pak / Professional Disposables International (PDI)
SaniZide plus (spray, wipes)	Cleaning	Quaternary Ammonium NH_4Cl^a	Safetec
Sono wipes	Disinfection	Quaternary Ammonium NH_4Cl^a	Advanced Ultrasound Solutions
Sekusept Aktiv	HLD	Sodium Percarbonate, Citric acid, Sodium Carbonate	Ecolab
Steranios	HLD	Glutaraldehyde	Laboratoires Anios
Steris VPro Family	Sterilization	Hydrogen peroxide	Steris Corporation
Sterrad 100S	Sterilization	Hydrogen peroxide	Advanced Sterilization Products (ASP)
Sterrad NX	Sterilization	Hydrogen peroxide	Advanced Sterilization Products (ASP)
Sterizone VP4	Sterilization	Hydrogen peroxide, Ozone	TSO_3
Super Sani Cloth wipes	Disinfection	Quaternary Ammonium NH_4Cl^a, Isopropyl Alcohol	Nice-Pak / Professional Disposables International (PDI)
Transeptic	Disinfection	Isopropyl alcohol	Parker Laboratories Inc.
Trionic D (spray, wipes)	Cleaning	Quaternary Ammonium NH_4Cl^a	Ebiox
Tristel sporicidal wipes	Cleaning HLD	Chlorine dioxide	Tristel Solution Ltd.
Trophon 2	HLD	Hydrogen peroxide	Nanosonic Ltd.
Trophon Companion Cleaning wipes	Disinfection	Quaternary Ammonium NH_4Cl^a	Nanosonic Ltd.
Trophon EPR	HLD	Hydrogen peroxide	Nanosonic Ltd.
Umonium38	HLD	Quaternary Ammonium NH_4Cl^a	Laboratoire Huckert's International
Umonium medical tissue	Disinfection	Quaternary Ammonium NH_4Cl^a	Laboratoire Huckert's International
Virusolve + wipes	Cleaning	2-Aminoethanol, Quaternary Ammonium NH_4Cl^a	Amity International
Virkon	HLD	Pentapotassium bis(peroxymonosulphate) bis(sulphate)	Day-Impex Ltd
Wavicide-01	HLD	Glutaraldehyde	Wave Energy Systems
Wip'anios Excel	Disinfection	Quaternary Ammonium NH_4Cl^a	Laboratoires Anios

Appendix D - Civco Stepper

The CIVCO Stepper[1] is designed to perform multiple percutaneous prostate biopsies through the transperineal access.

The CIVCO Stepper works with TRT33 transrectal probe when a dedicated licence has been activated on **MyLabClass**, **MyLabEight** or **MyLabTwice** family's devices.

The manufacturer's kit code for TRT33 CIVCO Stepper is 639-055.

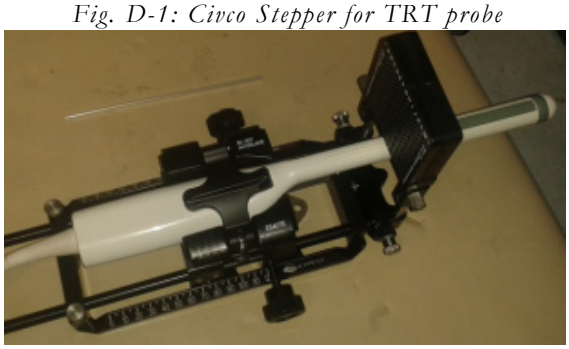
The CIVCO Stepper kit includes: stepper, fixation system, probe adapter and disposable template grid.

Due to the fact that the TRT33 probe has two different arrays, one convex and one linear, it should be taken in account that the CIVCO Stepper works with the convex array while ABS33A works with the linear one. Refer to the Chapter 7 in this manual to information about the biopsy with ABS33A and transrectal probes.

NOTE ***The stepper requires a specific licence.***

WARNING **Follow the instructions provided by the manufacturer of the kit to properly mount and use it and to clean, disinfect and sterilize it.**

Fig. D-1: Civco Stepper for TRT probe



1. Civco Stepper is not supplied by Esaote but directly by Civco. Esaote is giving only clearance and compatibility of its use with probe model TRT33.

The CIVCO Classic Stepper supports a variety of procedures from simple biopsy to cryotherapy and also brachytherapy. It could happen that **MyLab** images are imported in a dedicated planning software for the supporting of below procedure. The grid displayed on **MyLab** images can be shifted/rotated in order to maximize the accuracy of the overall system composed by stepper, grid and probes as defined further.

Planning software that do not manage translation or rotation of the grid could show a displacement between **MyLab** grid and their grid. This displacement does not affect the accuracy of **MyLab** systems but will be anyhow reflected on the planning software itself. You are requested to evaluate the reliability of the planning and any other outcome from external software that are used in combination with the **MyLab**.

Procedure

To correctly operate the CIVCO Stepper the next procedure has to be followed:

1. Start a new exam selecting the TRT33 probe, Urology application and any preset.

2. Select the convex array of TRT33 probe;

3. Flip the image upside/down pressing **REVERSE** to display the image like in figure D-2;

4. Activate the biopsy pressing **BIOPSY**, a pop up window warns to check different safety aspects:

   - Always verify that the whole working area of the needle, from its insertion point up to its target, does not include anatomical structures that could be involved and damaged, thus compromising the patient's safety.
   - Always verify that the proper side of the template (grid) corresponds to the visualized one.
   - The S label displayed on the monitor shall correspond to the one present on the template side in front of the operator.
   - Verify the proper assembling of the stepper before starting any procedure.
   - Verify that the probe cradle is not inclined. The cradle should have a 0 degree inclination. Do not perform any percutaneous procedure before calibrating the stepper.

5. Press OK to continue, a biopsy grid is superimposed on the ultrasound image to guide the biopsy insertion and additional Software Keys are available.

6. Before proceeding with the biopsy, verify the system accuracy in water bath. Refer to the next paragraph for CIVCO Stepper calibration.

The superimposed grid is a matrix of 13 rows and 13 columns having the same references present on the disposable template grid.

Each point is equidistant far 5.16 mm each other.

Rows are labeled from 12 to 1 with the upper row without label (row 1 to the probe array side).

Columns are labeled from A to M.

Rotating **ROW** allows to navigate among the rows, while rotating **COL** allows to navigate among the columns.

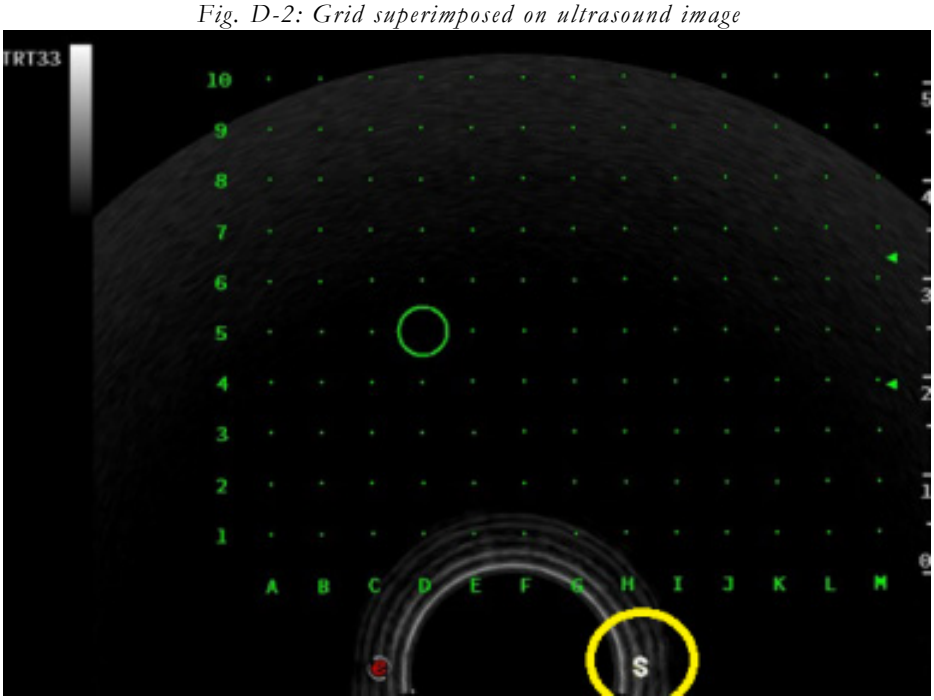
The navigation among rows and columns can be enable/disabled pressing **SELECT**. When the navigation is disabled, **ROW** and **COL** are disabled too.

In real time, the superimposed grid is yellow dotted while the selected column and row are white dotted with a circle at their intersection. In Freeze everything is green for both layouts.

The superimposed grid layout can be changed pressing **LAYOUT**. In the alternative layout, the grid has small grey balls instead of yellows dots, while the selected column and row are white with a bigger ball at their intersection.

Together with the grid, an S label is also displayed on the screen, indicating the related side of the template grid.

Fig. D-2: Grid superimposed on ultrasound image



During calibration and use of Civco Stepper, the superimposed grid must be seen as depicted in the above picture, and you have to be sure that:

- the ultrasound image is flipped upside/down; the skin level is at the bottom of the image,
- the S is on the right of the image,
- the numbers on the left increase from bottom up,
- the letters are on down side and increase from left to right.

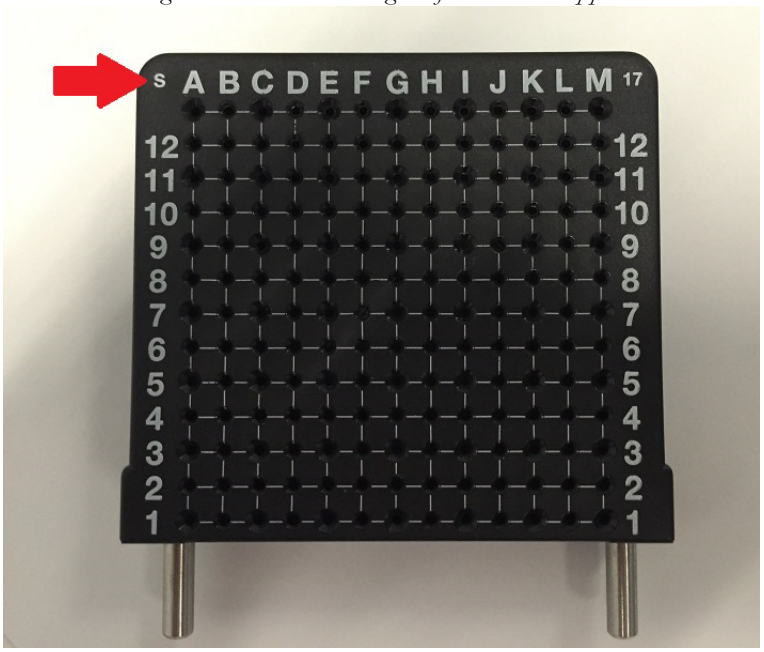
CIVCO Stepper calibration

Be sure the TRT33 probe is correctly mounted on CIVCO Stepper following the manufacturer's instructions.

The CIVCO Stepper template grid has two faces; the face with an S label on top-left has to be turned towards the operator to be correctly mounted.

The S label superimposed with the grid on the screen, indicates the related side of the template grid.

Fig. D-3: Calibration grid for Civco Stepper



WARNING

Verify the proper assembly of the stepper before starting any procedure. Verify that the probe cradle is not inclined. The cradle has to be in the 0 degree inclination.

WARNING

Always verify that the proper template side corresponds to the visualized one. The S label displayed on the monitor shall correspond to the one present on the template side in front of the operator.

Procedure

- Prepare a water bath to perform the calibration.
- Press **CALIBRAT**, the calibration procedure to verify the system accuracy begins.
- A message window asks to insert the needle in a fixed point giving its coordinates.
- Press OK to begin the procedure.
- Insert the needle in the given hole and click on its reverberation on the ultrasound image. On the screen info area, until a double click is performed, a text mentions the point where the needle is requested to be inserted. This point is recorded and a message window is displayed asking to insert the needle in a new point.
- Press OK to continue the procedure. Insert the needle in the new hole and double click on the related reverberation point on the ultrasound image.
- If the calibration is correct, after the double click the software re-arranges the grid with horizontal and vertical shift minimizing the error among the real points and their reverberations.

WARNING

The software calibration procedure must be repeated for any new probe or any mechanical calibration.

If the distance between the click on the reverberation and the expected point is higher than 5 mm, the message "Please select the proper points, if error persists contact Esaote personnel" is displayed.

The calibration accuracy can decrease in points far from the area where calibration has been performed. At the end of calibration it is suggested to verify the accuracy on the points at the edge of the template grid using the water bath.

WARNING

Verify the system accuracy in water bath before proceeding with percutaneous procedure.

Please verify the overall accuracy selecting more points just placing the needle in the grid.

In case the accuracy is not satisfactory, proceed with the calibration procedure.

WARNING

Take in account that the accuracy can be reduced far from the region where calibration is performed and can change among the points. If the accuracy is not satisfactory, repeat the procedure. If it is impossible to reach a satisfactory accuracy, please contact Esaote personnel.