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PROBES AND CONSUMABLES

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Introduction

This manual provides information about the probes and consumables that can be used with the Esaote **MyLab** devices. The manual is divided into the following chapters:

- Chapter 1: Care of Probes and Needle Guide Kits

The chapter describes how to handle, control, store and protect Esaote probes and needle guide kits.

- Chapter 2: Cleaning and Disinfecting Probes and Needle Guide Kits

The chapter describes how to clean and disinfect non-invasive probes and those probes and needle guide kits used in semi-critical and critical applications.

- Chapter 3: Examinations with Endocavity Probes

This chapter lists the specific safety requirements for examinations with endocavity probes. A description is also given on how to prepare the probe for the examination.

- Chapter 4: Examinations with Intraoperative Probes

This chapter lists the specific safety requirements for examinations with intraoperative probes. A description is also given on how to prepare the probe for the examination.

- Chapter 5: Examinations with Transesophageal Probes

This chapter lists the specific safety requirements for examinations with transesophageal probes. A description is also given on how to prepare the probe for the examination.

- Chapter 6: The Laparoscopic Probes

This chapter lists the specific safety requirements for examinations with the laparoscopic probe. A description is also given on how to prepare the probe for the examination.

- Chapter 7: Needle Guide Kits

This chapter explains the procedure for assembling the kits.

- Chapter 8: Accessories and Consumables

The chapter describes how to check, clean and disinfect the ECG cable. The chapter also gives information about the characteristics of the consumables.

- Appendix A: **MyLab** Probes

The appendix details available probes and their main characteristics.

- Appendix B: Probes Electrical Safety

The appendix explains how to check the electrical safety of the probes.

WARNING

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

CAUTION

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

Make sure you understand and follow these instructions.

Keep this manual with the equipment for future reference.

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Chapter 1

1 - Care of Probes and Needle Guide Kits

Handling Probes

Damage 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 guarantee.

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 tables describe 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.

Operation to be performed	Frequency
Physical inspection of non-invasive probes	Every month or when the probe is dropped
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

WARNING

Never use a probe, if it has been dropped, until you are sure that no electrical damage to the probe has occurred. This can be done by performing a leakage current test (see Appendix B for further details).

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.

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 sheaths 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 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 Never exert force on the lens;
- the connector is not waterproof and should 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/or disinfect/sterilized 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 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

Non Invasive Probes

When not in use, the probe must be stored in the special probes slot on the machine. If all the available slots are full, place the probe in its case. All gel must always be cleaned off the probe (see the next chapter for the relative instructions).

CAUTION

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

Storing and Protecting the Transesophageal Probe

The probe must always be cleaned and disinfected following the instructions provided in the next chapter. The probe must be kept in a clean environment 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.

Storing and Protecting the Endocavity Probe

The probe must always be cleaned and disinfected following the instructions provided in the next chapter.

When not in use, the endocavity must be stored in the special probes slot on the machine. If all the available slots are full, place the probe in its case.

CAUTION

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

Storing and Protecting the Intraoperative and Laparoscopic Probes

The probes must always be cleaned and sterilized following the instructions provided in the next chapter.

When not in use, place the probe in its case.

CAUTION

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

Transport or Long-Term Storage 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. Clean the probe carefully, 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.

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

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 - Cleaning and Disinfecting Probes and Needle Guide Kits

Periodic Cleaning and Disinfecting Schedule

The following table describes the periodic maintenance to be carried out on probes and needle guide kits depending on their application. The risk of infection establishes the type of operation.

Application	Operation	Frequency
Non-critical[a]	Cleaning	Before the first use and after each exam
Non-critical[a]	Disinfection	When necessary
Semi-critical[b]	Cleaning and disinfection	Before the first use and after each exam
Critical[c]	Cleaning and sterilization	Before the first use and after each exam

a. The application is considered non-critical when the device is used on intact skin.
b. The application is considered semi-critical when the device is used on the mucous membrane.
c. The application is considered critical when the device comes into contact with blood or compromised tissue

If non-invasive probes are used in semi-critical/critical applications and in a sterile field, apply protective sheaths during the examination. These sheaths are usually composed of latex (natural rubber).

WARNING

The probe sheath 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").

Esaote recommends disinfecting the probe, if the probe has not been used for an extended period.

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

Note

Probes and needle guides supplied by Esaote are neither disinfected nor sterilized.

Agents and Systems

Refer to the manual "Probes - Cleaning, Disinfection, Sterilization" for a list of recommended cleaning, disinfection and sterilization agents and systems.

Note

Any damage caused by the use of not recommended agents or by immersing the probe over its maximum level is not covered by the warranty.

WARNING

The disinfection/sterilization agents and systems listed in the "Probes - Cleaning, Disinfection, Sterilization" manual are recommended because of chemical compatibility with the probe materials.

The "Probes - Cleaning, Disinfection, Sterilization" manual clearly indicates which agents/systems have been positively tested for both biological effectiveness and chemical compatibility and which for chemical compatibility only. In the latter case 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 acoustic lens.

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 the system.

Probes Tightness to Liquids

See Appendix A for description of probes Maximum Immersion Level.

Do not immerse the probe cable or connector in water or other liquid. The probes can be inserted in water up to the **Maximum Immersion Level** that will not compromise a probe's integrity:

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.

Cleaning Probes Used in Non-Critical Applications

The cleaning procedures described in this paragraph apply to all the probes used in non-critical applications. An application is considered non-critical when the device is used on intact skin.

Probes must be cleaned at regular intervals to ensure that they work properly. Esaote recommends removing the gel from the probe between one examination and the other; this keeps the probes clean between one complete cleaning procedure and the next.

Cleaning Procedure

- Disconnect the probe from the system;
- Remove all residues of ultrasound gel from the probe using a soft cloth;
- 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.

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 system: the use of wipe cleaner is suggested in these cases.

- Wait approximately 1 minute for cleaner to operate.
- Carefully dry the probe with a clean paper towel or soft, dry cloth, removing foam when present.

Disinfecting Probes Used in Non-Critical Applications

The disinfection procedures described in this paragraph apply to all probes used in non-critical applications. The application is considered non critical when the device is used on intact skin. Low-level disinfection is sufficient for these applications. The probes can be disinfected using the recommended agents, following the manufacturer's instructions.

Disinfection Procedure

- Disconnect the probe from the system.
- Clean the probe using the procedure for non-critical application.
- Immerse the probe casing in the recommended agent, up to the maximum immersion level, following the manufacturer's instructions very carefully.
- Leave the probe immersed for longer than 10 minutes and less than 30 minutes, at room temperature (20° - 30° C).

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).

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

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.

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

- Extract the probe, rinse it with sterile water and clean the probe handle and cable using the recommended agents or with a mild detergent solution.

- Carefully dry the probe with a clean soft, dry cloth or leave it to air dry for at least 30 minutes.

Cleaning and Disinfecting Probes Used in Semi-Critical Applications

The procedures described in this paragraph apply to all probes used in semi-critical applications. The application is considered semi-critical when the device is used on the mucous membranes. The use of sterile sheaths for this type of application is recommended, and high-level disinfection is necessary. Wearing gloves are recommended during probe cleaning and disinfecting operations.

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

Esaote recommends disinfecting the probe before it is used for the first time after prolonged storage periods.

- Disconnect the probe from the system.

- Remove the protective sheath; clean the probe handle, the probe lens and the endoscope with the recommended agent, using the procedure for non-critical application.

Note

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

- Immerse the probe casing in the recommended agent, up to the maximum immersion level, following the manufacturer's instructions very carefully.

- Leave the probe immerse for longer than 10 minutes and less than 30 minutes, at room temperature (20° - 30° C).

WARNING

Do not leave the probe immersed in the disinfectant for longer than the time indicated by the manufacturer for high-level disinfection.

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).

- Extract the probe, rinse it with sterile water and clean the probe handle and cable with a soft cloth dampened with a mild detergent solution.

- Carefully dry the probe with a clean soft, dry cloth or leave it to air dry for at least 30 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.

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

Cleaning and Sterilization of Probes Used in Critical Applications

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

Wearing gloves are recommended during cleaning and sterilization procedures.

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 probe before it is used for the first time after prolonged storage periods.

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

Cleaning Procedure

- Disconnect the probe from the system.

- Remove the sheath.

- Clean the probe using the procedure for non-critical application.

WARNING

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

- Extract the probe, carefully rinse it with water to remove cleaning agent residuals.
- Carefully dry the probe with a clean soft, dry cloth or leave it to dry air for at least 30 minutes.

Note

Dry the IOT332 and IOT342 probes using compressed air and then leave them in oven for 30 minutes at 60°C.

Sterilization Procedure with Agents

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

- Immerse very carefully the probe into the recommended agents, following the manufacturer's instructions.

WARNING

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

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).

- Extract the probe and rinse it with sterile water.
- Carefully dry the probe with a clean soft, dry cloth or leave it to dry air for at least 30 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.

Sterilization Procedure with Systems

Refer to the agents manual for information on STERRAD manufacturer.

Sterilization Procedure with STERRAD®

- Follow the above procedure to clean the probe.
- Place the probe inside a pack compatible with sterilization process.
- Follow the STERRAD® instructions loading the sterilization chamber at the following conditions:
  - temperature: 55°C;
  - time: 54 min;
  - minimum pressure: 400 mtorr;
  - maximum pressure: 760 torr.

CAUTION

Before proceeding with the process, verify that the settings of the sterilization chamber comply with the indicated conditions, otherwise the probe may be possibly damaged.

Refer to the agents manual for information on Steris manufacturer.

Sterilization Procedure for with Steris V-Pro 1

- Follow the above procedure to clean the probe.
- Place the probe inside a pack compatible with sterilization process.
- Follow the Steris instructions loading the sterilization chamber at the following conditions:
  - Temperature: < 55°C (typically 50°C),
  - Time: 55 min,
  - Minimum pressure: 200-300 mtorr,
  - Maximum pressure: 760 torr.

CAUTION

Before proceeding with the process, verify that the settings of the sterilization chamber comply with the indicated conditions, otherwise the probe may be possibly damaged.

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 stipulated 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.
- Follow the instructions of the manufacturer of the sterilization agent.

Note

The material used for the ABS needle guide kits, manufactured by Esaote, can undergo all the sterilization methods used for surgical instruments.

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

Chapter 3

3 - Examinations with Endocavity Probes

The endocavity (**BE1123**, **EC1123, SB3123**, **SE3123** and **SE3133**) and transrectal (**TRT33** and **TLC 3-13**) probes are Type BF parts. As per directive EN60601-1, the probe must be physically intact and the system 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 this probe.

In particular, remember that:

WARNING

The system must be correctly grounded: it must be supplied from a socket equipped with a protective earth 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 earth connection, DO NOT use the probe and contact Esaote immediately.

Characteristics and Components

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

The **EC1123** probe mounts a big connector while the **SE3123** and **SE3133** probes have a small connector.

The **TRT33** and **TLC 3-13** probes incorporate both a convex transducer and a linear transducer for longitudinal and transversal scanning. The **TRT33** probe mounts a big connector, while the **TLC 3-13** probe mounts a small connector.

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.

The **BE1123** probe mounts a big connector while the **SB3123** probe has a small connector.

Examination Safety

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

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 sheaths 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.

Note

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

- Use protective sheaths during the examination. These sheaths are mainly composed of latex (natural rubber).

Note

Esaote recommends use of sterile sheaths in transvaginal examinations.

WARNING

The probe sheaths 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 sheaths.

- Apply enough ultrasound gel inside the sheath.
- Completely unroll the sheath along the probe body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band.

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 recommended 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 the system 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 the system 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 sheaths 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.

Preparation of the Endocavity Probes

Follow the instructions below for preparing the endocavity probe.

Note

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

See next chapter on consumables for selecting the gel and sheathes.

- Apply a sufficient quantity of ultrasound gel inside the sheath.

WARNING

The probe sheaths 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").

- Completely unroll the sheath along the probe body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.
- To make it easier to insert the endocavity probe, use only water-based lubricating gel with the probe.

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

The **EC1123**, **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 transducer and the sheath; 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 sheath.

WARNING

The protective sheaths available on the market often 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.

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, IOT332** and **IOT342**) are Type BF parts. The probes must be physically intact and the system 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 this probe.

In particular, remember that:

WARNING

The system must be correctly grounded: it must be supplied from a socket equipped with a protective earth 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 earth connection, DO NOT use the probe and contact Esaote immediately.

Characteristics and Components

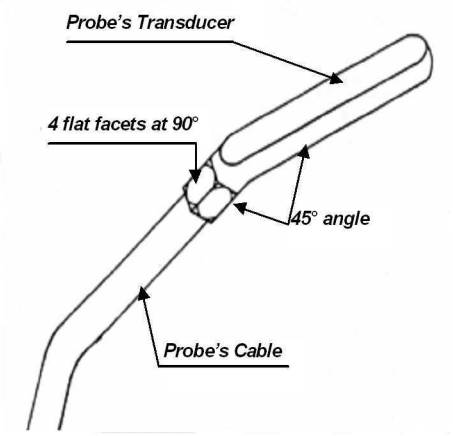
The **IH 6-18**, **IL 4-13**, **IOE323, IOT332** and **IOT342** probes incorporate a high frequency linear transducer for intraoperative scanning.

The **IOE323** and **IOT332** mount a big connector while the **IH 6-18**, **IL 4-13** and **IOT342** have a small connector.

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.

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

Fig. 1: IL 4-13 and IOE323 Probes



The terminal portion of the **IOT332** and **IOT342** probes 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. 2: IOT332 and IOT342 Finger attachment

Examination Safety

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

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;
- if the probe has to be used in sterile environments, Esaote recommends both to sterilize the probe using one of the methods described in this manual and to use sterile sheaths.

WARNING

If the probe is used in a sterile environment, accurately check the integrity of the probe itself. 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.

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

Using the Probe in Sterile Environments

When the probe is used in sterile environment, complete the procedure above with the following instructions:

- wear sterile gloves during the probe preparation procedure;
- if the probe has not been sterilized, make sure that the probe has been disinfected, following one of the methods described in this manual, and use sterile sheath during the exam. See next chapter on consumables for selecting the sheathes.

WARNING

The probe sheaths 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 sheath. See next chapter on consumables for selecting the gel.
- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath 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 the system 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 the system 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 sheaths 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. 3: Handle attachments

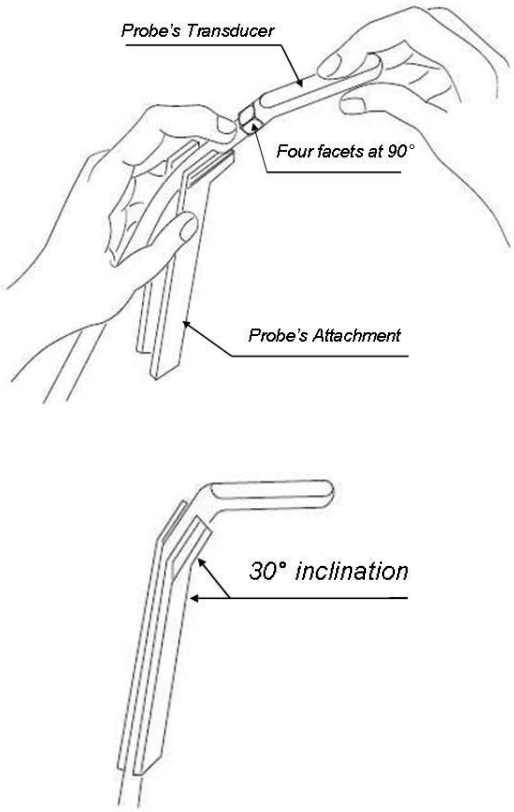
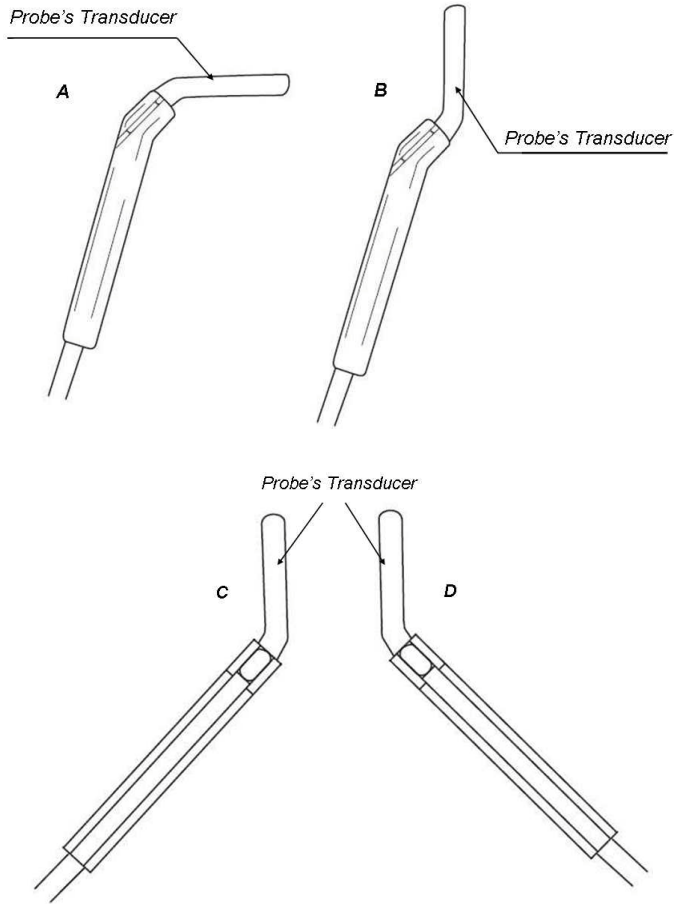


Fig. 4: Attachment positions

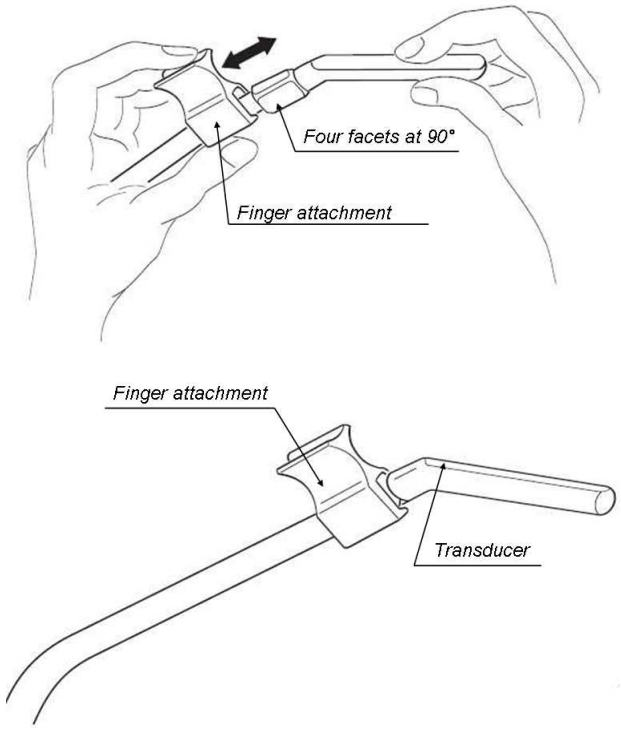


Finger Attachment

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.

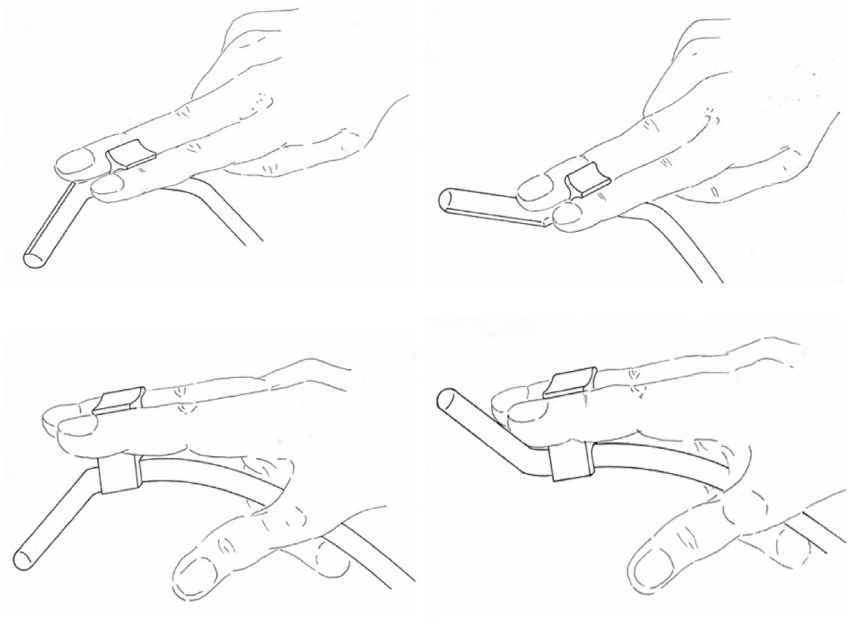
Fig. 5: Finger attachment



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. 6: Finger attachment configurations

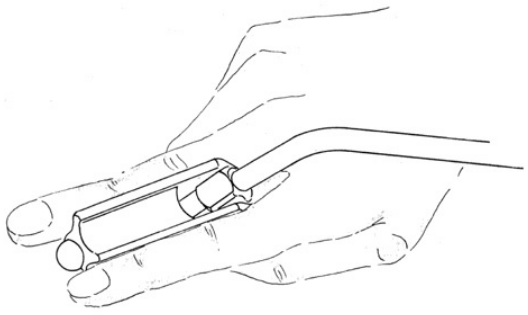


Slide Attachment

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 transducer.

The correct position of the Slide attachment is shown below.

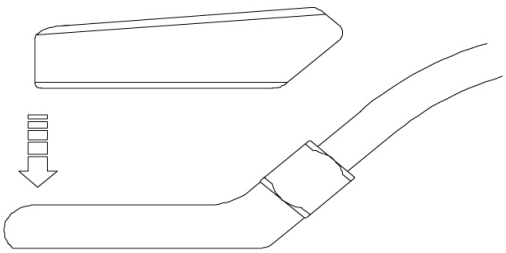
Fig. 7: Slide attachment



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

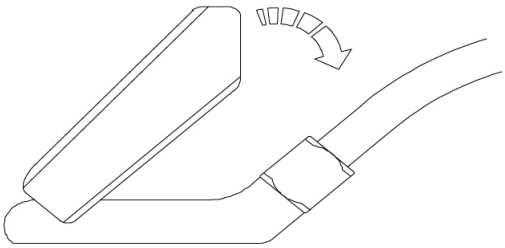
1. Place the slide attachment at the tip of the transducer.

Fig. 8: Slide position



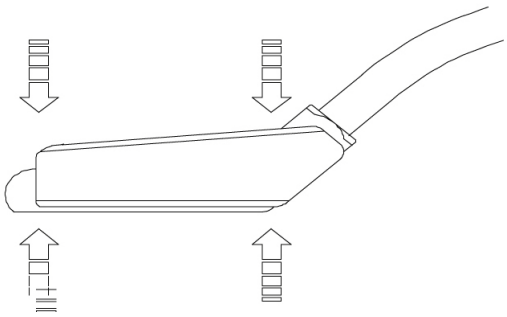
2. Rotate the slide attachment around the probe until it is safely in place between the two lateral extensions of the attachment.

Fig. 9: Slide rotation



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

Fig. 10: Securing the slide



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

Chapter 5

5 - Examinations with Transesophageal Probes

The transesophageal probes (**ST2612** and **ST2613**) are Type BF part. The probe must be physically intact and the system 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 this probe.

In particular, remember that:

WARNING

the system 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 immediately.

Characteristics and Components

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

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

The **ST2613** probe shaft has a length of roughly 80 cm. The shaft is labelled 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.

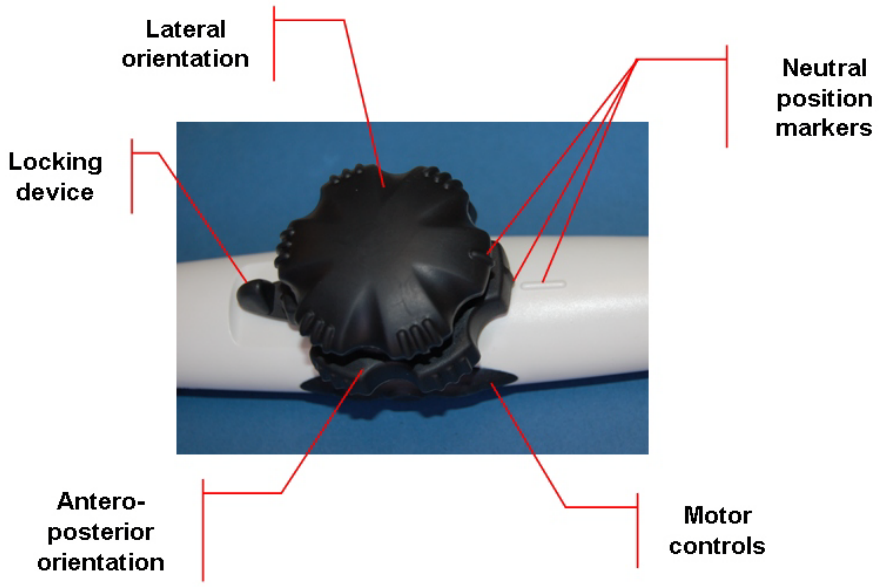
The probe is equipped with a temperature sensor; **MyLab** models are designed to use this sensor thermal data to prevent probe tip overheating: the system constantly samples and displays the probe temperature.

Probe Orientation

ST2612 Probe

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

Fig. 1: 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°.

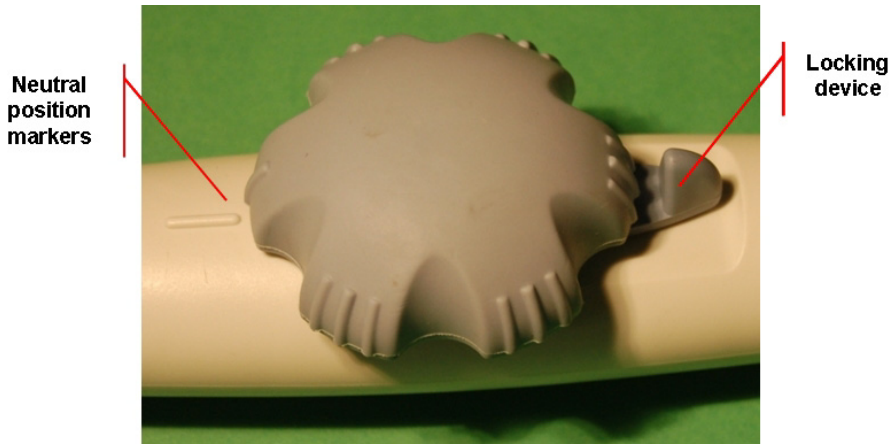
The lateral orientation is controlled by the smallest wheel and it is adjustable from ±60°.

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. 2: 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°.

Probes 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.

The **MyLab** system screen displays the probe's current orientation.

Examination Safety

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

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 system 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

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;

WARNING

Physical damage to the probe may cause electrical or mechanical injury to the patient. Protective sheaths DO NOT provide protection against such damage 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.

- 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 sheaths during the examination. These sheaths are mainly composed of latex (natural rubber).

WARNING

The probe sheaths 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").

If the protective cover is damaged during the transesophageal 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).

- Always use a bite-proof mouthpiece to protect the probe from the patient's teeth.

WARNING

Physical damage to the probe can cause electrical or mechanical injury to the patient.

CAUTION

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

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.

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.

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.

- 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 the system 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 the system 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 sheaths 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.

Preparation of the Transesophageal Probe

Follow the instructions below to prepare the transesophageal probe.

Note

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

See chapter on Consumables for selecting these accessory kits.

The use of latex 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 sheath.

WARNING

The probe sheaths 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").

- Completely unroll the sheath along the probe body, making it adhere, so as to avoid air pockets.
- Secure the sheath with the rubber band provided.

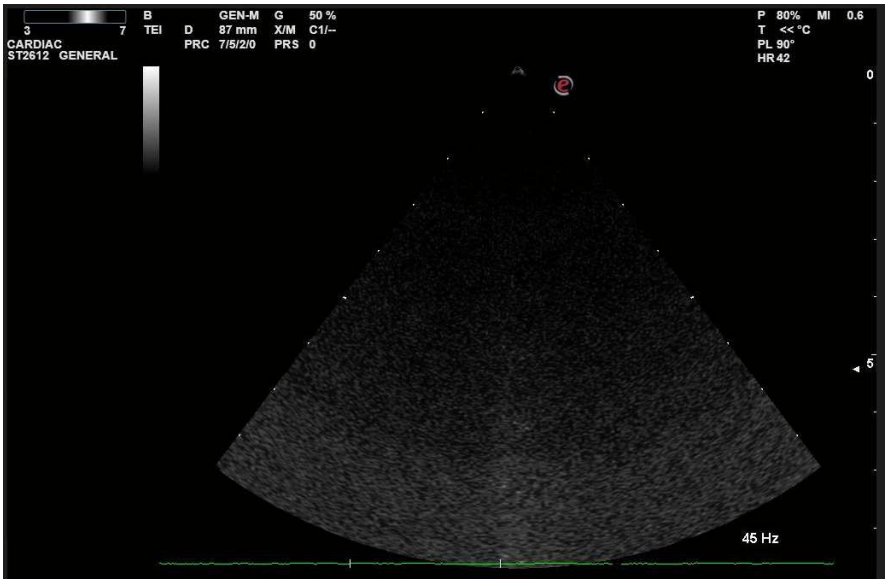
Screen Information

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

The following additional information is displayed while working with the transesophageal probes:

- tip temperature;
- transducer orientation.

Fig. 3: Screen information



Tip Temperature

The probe tip temperature is displayed, and continuously updated, in the upper right side of the screen. The system 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.

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, the system 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 part. As per directive EN60601-1, the probe must be physically intact and the system 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 this probe.

In particular, remember that:

WARNING

The system must be correctly grounded: it must be supplied from a socket equipped with a protective earth 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 earth connection, DO NOT use the probe and contact Esaote immediately.

Characteristics and Components

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

The **LP323** mounts a big connector while the **LP 4-13** has a small connector.

Fig. 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

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

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;
- if the probe has to be used in sterile environments, Esaote recommends both to sterilize the probe using one of the methods described in this manual and to use sterile sheaths.

WARNING

If the probe is used in a sterile environment, accurately check the integrity of the probe itself. 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.

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

Using the Probe in Sterile Environments

When the probe is used in sterile environment, complete the procedure above with the following instructions:

- wear sterile gloves during the probe preparation procedure;
- if the probe has not been sterilized, make sure that the probe has been disinfected, following one of the methods described in this manual, and use sterile sheath during the exam. See next chapter on consumables for selecting the sheathes.

WARNING

The probe sheaths 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 sheath. See next chapter on consumables for selecting the gel.
- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath 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 the system 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 the system 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 sheaths 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.

Chapter 7

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.

Probe	Biopsy adaptor	Angle	Gauge
CA430	ABS421	20°/30°	14, 18, 20, 21, 22
LA523	ABS523	45°	14, 18, 20, 21, 22
LA435 SL2325	ABS424	45°	14, 18, 20, 21, 22
TLC 3-13 TRT33	ABS33A	90°	14, 16, 18, 20
IL 4-13 IOE323	ABS15	45°	14, 18, 20, 21, 22
AC2541	WBAC54X	20°/30°	14, 18, 20, 21, 22
SI2C41	ABSIC4X	0°/5°/15°	12-13, 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, and WBAC54X kits are composed of stainless steel; the ABS33A needle guide kit is composed of titanium; the ABSIC4X kit is composed of anodized aluminum.

Reusable Needle Guides by Protek[1]

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

Probe	Biopsy adaptor	Angle	Gauge
EC1123	DBSE12X	0°	16

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.

Disposable Needle Guides

Disposable Needle Guides by Civco[2]

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

Table 1: Fixed Angle and Multi-Angle Kits

Probe	Biopsy adaptor	Angle	Gauge	Manufacturer's Kit P/N
CA430	CBSC43X	20°/30°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-018
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
EC1123 SE3123	-	3,8°	16-18	610-693
	CBSE12X	0°	16	639-012
BC441 SB2C41	CBSB44C	25°/35°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-020

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

Probe	Biopsy adaptor	Angle	Gauge	Manufacturer's Kit P/N
AL2443 SL1543	CBSL53X	40°/60°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-034
SC3123	CBSC23X	20°/35°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-045
AL2442	CBSL44X	25°/35°50°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-036
AC2541	CBAC54X	15°/25°/35°	12, 14, 15, 16, 17, 18, 20, 21, 22, 23	639-049

Table 2: Free Insertion Angle Kits

Probe	Biopsy adaptor	Insertion Angle	Gauge	Manufacturer's Kit P/N
CA430	IKC43X	42°÷64°	14, 18, 20, 21/22, 25	639-014
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
AC2541	IKAC54X	0°÷42°	14, 18, 20, 21/22, 25	639-047
AL2443 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	IKL44X	0°÷42°	14, 18, 20, 21/22, 25	639-037
IOT332 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 biopsy kits composed of sterilizable mounting adaptors and disposable needle guides produced by Protek.

Probe	Biopsy adaptor	Angle	Gauge	Manufacturer's Kit P/N
CA430	DBS421/431	20°/30°	13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23	7352
LA523	DBS523	45°/60°/75°	13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23	7351
LA435 SL2325	DBS424/435	45°	13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23	7350

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 the system and for the probes. Consult **MyLab** "Safety and Standard" manual for additional safety information.

Before the Examination

Before each examination, Esaote recommends that the operator:

- handle the needle guide kit and the probe with sterile gloves;
- perform a visual check of the adaptor and needle guides: do not use them if any damage or distortion is found;

1. www.protekmedical.com

- use protective sheaths during the examination. These sheaths are primarily composed of latex (natural rubber).

Note

Using sterile sheaths is recommended for intraoperative and biopsy procedures.

WARNING

The probe sheaths 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").

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 biopsy 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:

Chapter 2 provides cleaning, disinfection and sterilization instructions.

- clean and sterilize the kit;
- clean and disinfect the probe used during the biopsy.

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.

- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection sheath.
- Cover the probe with the protective sheath securing it with the rubber band provided.

WARNING

The protective sheaths available on the market often 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 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").

If the protective cover is damaged during the 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).

- Connect the adaptor to the probe, positioning the two alignment pins on the special notches on the probe.

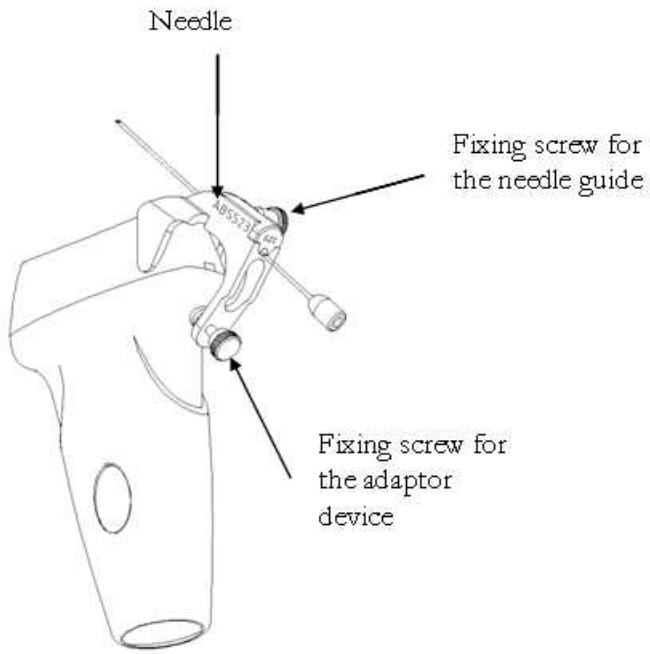
Notes

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 before inserting the protective sheath; this will allow to safely use the same adaptor in different exams.

The following figures show an example of how the ABS523 is assembled on the LA523.

Fig. 3: ABS523 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.

Mounting the WBAC Needle Guide on AC Probes

The WBAC needle guide kit for AC541 probe is composed of two parts: the adaptor device to be connected to the probe and the needle guide.

- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection cap.

- Cover the probe with the protective cap securing it with the rubber band provided.

WARNING

The protective sheaths available on the market often 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 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").

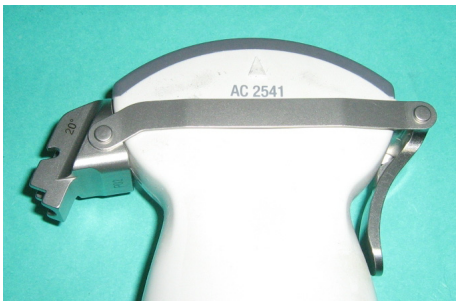
If the protective cover is damaged during the exam on patients affected by a spongiform encephalopathy (for instance Creutzfeldt-Jacob disease), refer to the guidelines provided by the Centers for Disease Control and Prevention (www.cdc.gov) and by World Health Organization (www.who.int).

- Connect the coupling device to the probe, by placing its grooved side on the probe orientation marker.

Fig. 4: Adaptor device

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

Fig. 5: 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

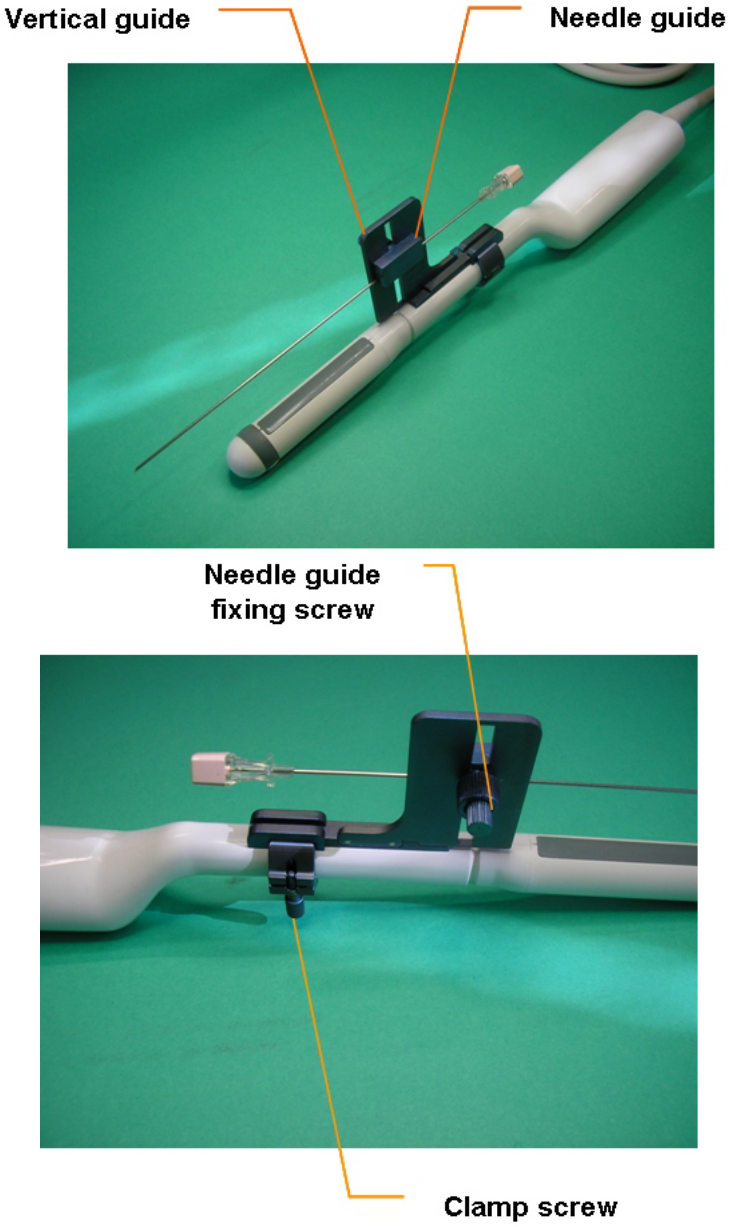
If the user does not perform this operation correctly, the insertion angle can be wrong causing a risk to patient safety.

To disassemble the biopsy kit, reverse the previous procedure.

Mounting the ABS Transrectal Probe Needle Guide

The ABS33A transrectal needle guide kit for TLC 3-13 and TRT33 is composed of two parts: the adaptor to be connected to the probe and the needle guide device.

Fig. 6: 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.

- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe or to the tip of the protection sheath.
- Cover the probe with the protective sheath; secure with the rubber band provided.

WARNING

The protective sheaths available on the market often 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 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").

If the protective cover is damaged during the 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).

- 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.

Mounting the ABS Intraoperative Probe Needle Guide

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

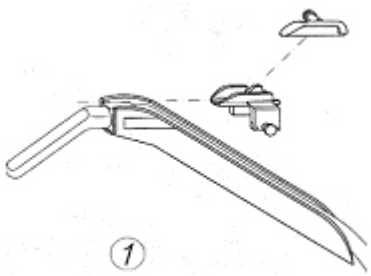
The ABS15 needle guide kit can only be placed on the probe handle attachment as shown below.

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

- Once the adaptor has been positioned on the handle attachment as shown in figure 1, insert the biopsy bracket into the grooves on the handle attachment by sliding the

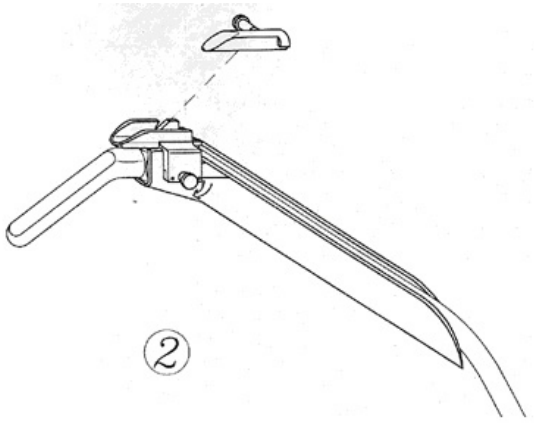
biopsy bracket to the end of the groove. Attach the bracket with the screw provided.

Fig. 7: Adaptor positioning



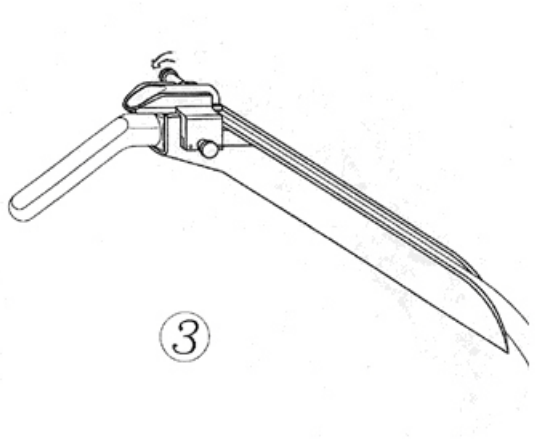
- Choose the needle guide acceptable for the diameter of the needle to be used and insert it into the bracket.

Fig. 8: Needle guide positioning



- Attach the needle guide to the bracket with the screw provided.

Fig. 9: Securing the needle guide



- The needle can then be inserted into the hole formed between the bracket and the attached needle guide.

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

To disassemble the biopsy kit reverse the previous procedure.

Mounting the Needle Guide for SI2C41 Probes

SI2C41 is a special probe designed for biopsy. Each adaptor for SI2C41 biopsy probe consists of two parts, one adaptor with three different insertion angles (0°,

5° and 15° degrees) and a safety catch. Each adaptor supports needles: 12-13, 14-15, 16-17, 18-19 and 20-21 gauge needles.

Fig. 10: SI2C41 Probe with Adaptor

The design allows the removal of the biopsy adaptor while the needle is inserted in the tissue.

Note

Adaptors supplied by Esaote are neither disinfected nor sterilized.

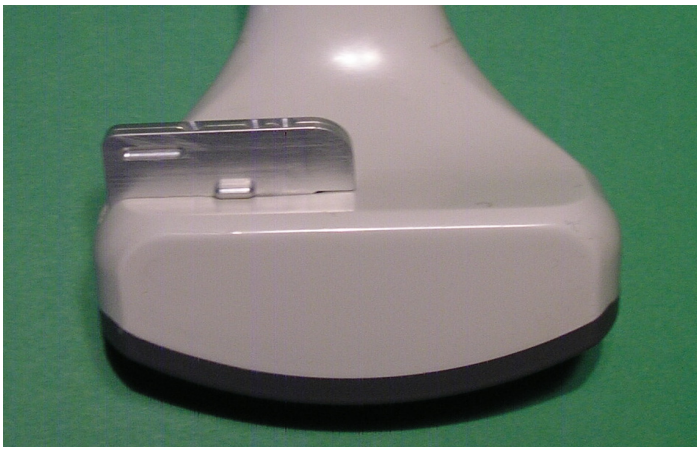
- Make sure that the probe has been disinfected.
- Apply ultrasound examination gel to the probe.

WARNING

Since the probe design allows the removal of the biopsy adaptor, it is recommended not to apply a strength force to the probe/adaptor/needle in order to avoid undesired kit disconnection and/or dislodge and consequently possible injury to the patient.

- Insert the adaptor into the gap on the scan head paying attention to push it into the special safety catch on the probe.

Fig. 11: Adaptor Inserted



- Insert the Safety Catch as depict in the image below

Fig. 12: Safety Catch Insertion

- Close the Safety Catch trough the dedicated screw

Fig. 13: Safety Catch Closed

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

Note

Esaote suggests the use of SI2C41 probe without any protective sheaths.

For disassembly of the biopsy kit, reverse the previous procedure.

Chapter 8

8 - Accessories and Consumables

ECG Cable

The ECG cable supplied by Esaote includes leads which are equipped with a pliers terminal.

Refer to the system documentation for ECG capabilities.

Reference	Description
141003100	3-Leads ECG Cable - Black, yellow and red colors (IEC Standard) [a]
141011200	3-Leads Pediatric ECG Cable - Black, yellow and red colors (IEC Standard) [a]
141003101	3-Leads ECG Cable - Black, green and white colors (AHA Standard) [a]

a. IEC: International Electrotechnical Commission; AHA: American Heart Association

Each button electrode can be used with the ECG cable. Esaote recommends using disposable Ag/AgCl electrodes. Read the manufacturer's instructions carefully for the correct use of the electrodes.

Checking the ECG Cable

A check of the ECG cable and leads should be made periodically.

ECG Cable Inspection

Disconnect the cable from the system and check that there are no breaks or slits.

Note

Esaote recommends to replace the ECG cable if there are breaks or slits.

Cleaning and Disinfecting the ECG Cable

Periodically clean the ECG cable and leads so that they remain in optimal working order.

WARNING

Never clean or disinfect the ECG cable when it is still connected to the system.

Equipment

The equipment listed in the following table will be necessary for periodic maintenance procedures.

CIDEX OPA® is a Johnson&Johnson Ltd. Registered brand.

Agent	Destined for
Solution of mild soap and water	Cleaning the ECG cable and leads
CIDEX OPA	Disinfection of the ECG cable and leads
Indicated by the manufacturer	Disinfecting the electrodes

Cleaning Procedure

- Disconnect the cable from the system.
- Dust the cable connector with a soft cloth.
- Clean the cable and the leads by rubbing them gently with a soft cloth dampened with water and a mild detergent.
- Rub the cable and the leads gently with a soft cloth slightly dampened with a mild detergent solution.
- Dry the cable and the leads by rubbing them gently with a clean soft, dry cloth.

Disinfection Procedure

The ECG pliers (that are attached to the electrodes) can be disinfected using CIDEX OPA, following the manufacturer's instructions.

- Disconnect the cable from the system.
- Clean the cable and the leads.
- Immerse the ECG pliers in Cidex OPA. When using the disinfectant substance, carefully follow the manufacturer's instructions.

CAUTION

Do not immerse the ECG cable. The ECG cable is not waterproof. To disinfect the ECG pliers (that are attached to the electrodes) immerse only the pliers and a part of the leads (closest to the pliers) in the disinfection solution. Do not allow the connector of the ECG cable to become wet.

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.

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.

Product	Supplier	Compatibility Rank
Sonogel	Sonogel Vertriebs GmbH (www.sonogel.de)	• [a]
Scan MV	MV Groupe	•• [a]

	Product	Supplier	Compatibility Rank
Recommended	G006	Fiab	•• [a]
	GuangonPai	GuangonPai	•• [a]
	Ecosupergel	Ceracarta	••• [b]
	Scan®	Parker Laboratories, Inc., USA (www.parkerlab.com)	••• [b]
	Aquasonic® Clear	Parker Laboratories, Inc., USA (www.parkerlab.com)	••• [b]
	Aquasonic® 100	Parker Laboratories, Inc., USA (www.parkerlab.com)	•••• [b]
	Clear Image	Sonotech (www.sonotech-inc.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.

Sheaths

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

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

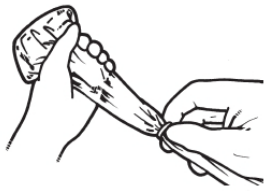
Procedure

- Apply enough ultrasound gel inside the sheath.

1. www.civco.com

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

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



Convex and Linear Probes

Probes	Manufacturer's kit ref.	Measurements	Sterile	Latex
AL2442, AL2443, LA435, LA523, SL1543, SL2325, SL3116	610-001	8.9 x 61 cm	Yes	No
AC2541, BC431, BC441, CA430, SB2C41, SC3123, SI2C41	610-002	14x61 cm	Yes	No

Endocavity Probes

Manufacturer's kit ref.	Measurements	Sterile	Latex
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

Manufacturer's kit ref.	Measurements	Sterile	Latex
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

Intraoperative Probes

The IL 4-13 and IOE323 intraoperative probes use Esaote sterilized sheaths Ref.1000000065.

The IOT332 and IOT342 intraoperative probes use CIVCO sterilized sheaths Ref. 610-023.

LP 4-13 and LP323 Probes

The Laparoscopic probe uses Esaote sterilized sheaths Ref.7900000210.

Transesophageal Probes

The kits listed below are produced by CIVCO[1]. Refer to the manufacturer's instructions for the characteristics and use of the kits.

Manufacturer's kit ref.	Kit composition	Sterile	Latex
610-840	Bite-guard and sheath with application kit (for adult probe)	No	No
610-979	Pediatric Bite-guard (pediatric probe)	No	No

Appendix A

Appendix A - MyLab Probes

GS

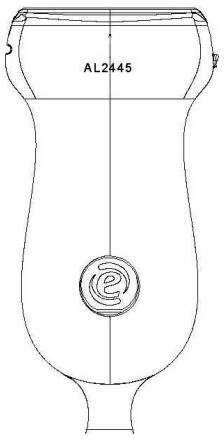
This chapter provides information on probe labeling and a list of **MyLab** probes with their main characteristics.

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 Probe

Probe Housing

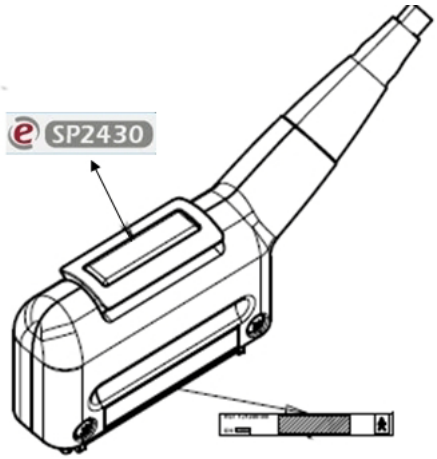


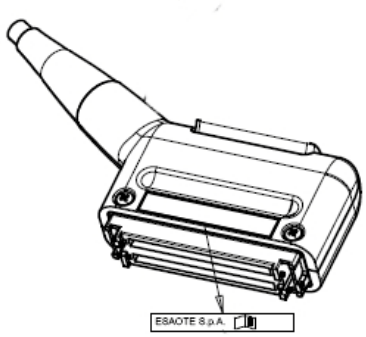
The probe housing is labeled with the following information:

- the Company logo,
- the name of the probe (Probe ID).

Probe Connector

Three labels are stuck on the connector.

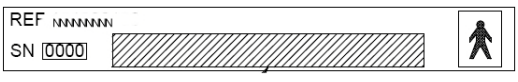




Probe ID Label

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

Reference Label



The reference label contains the following information:

- Probe part number (REF field) on the upper left side of the label,
- Probe serial number (SN field) on the lower left side of the label,
- Type BF applied part symbol on the right side of the label,

- Bar code on the center of the label.

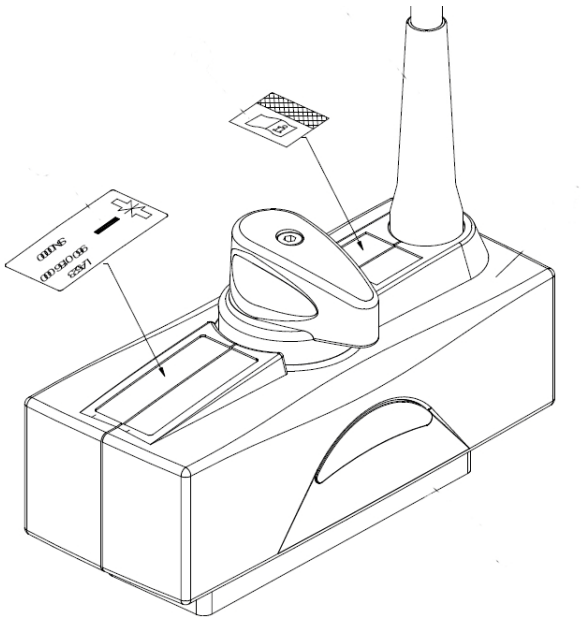
Company Label

The company label contains the following information:

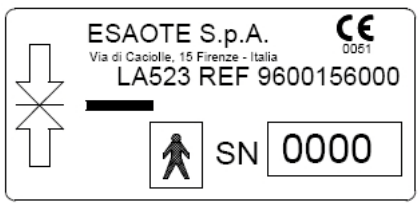
- Company name and manufacturing address on the left side of the label,
- CE Mark of Conformity on the right side of the label,
- Operating instruction symbol on the center of the label.

Big Connector Probe

Two labels are stuck on the connector.



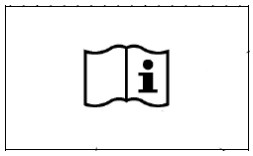
Probe ID and Reference Label



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

- Company name and manufacturing address on the upper side of the label,
- CE Mark of Conformity on the upper right side of the label,
- Probe name (Probe ID) and part number (REF field) below the company name,
- Locking symbol on the left side of the label,
- Type BF applied part symbol on the lower side of the label,
- Probe serial number (SN field) on the lower right side of the label.

Instruction Label



This label contains the operating instruction symbol.

Probes Denomination and Maximum Immersion Level

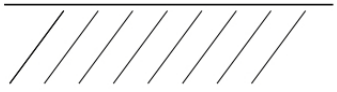
The user manual and the display always identify the probe by using the Probe ID.

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

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

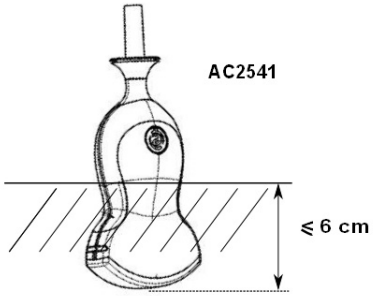
Note

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

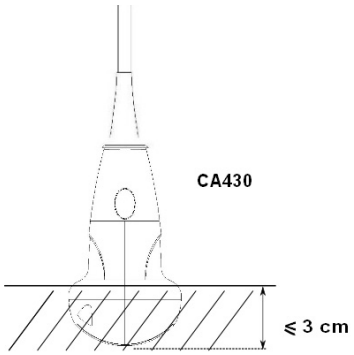


In the next pages the agent level is represented as shown in the beside image.

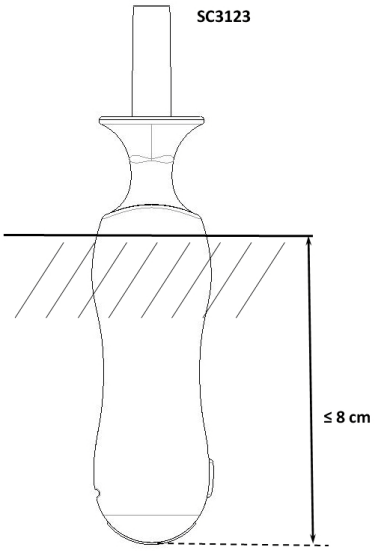
Convex Probes



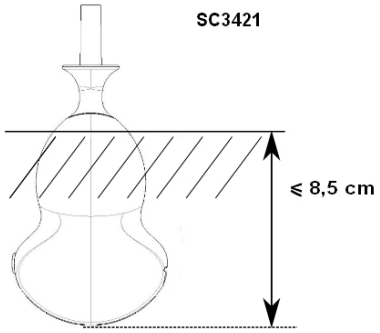
Probe ID	AC2541
Maximum immersion level	Up to 6 cm from transducer head
Type	BF



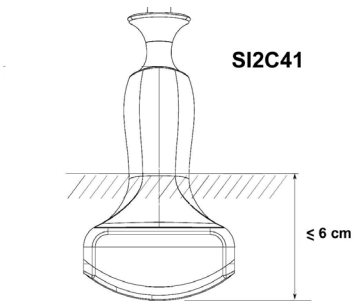
Probe ID	CA430
Maximum immersion level	Up to 3 cm from transducer head
Type	BF



Probe ID	SC3123
Maximum immersion level	Up to 8 cm from transducer head
Type	BF

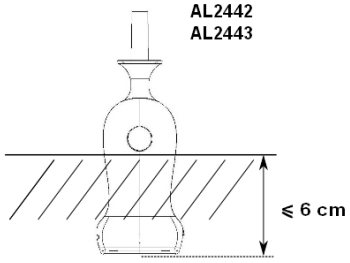


Probe ID	SC3421
Maximum immersion level	Up to 8,5 cm from transducer head
Type	BF

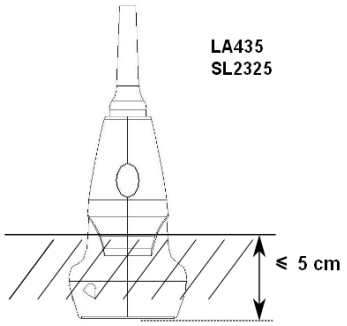


Probe ID	SI2C41
Technology	Convex Array
Maximum immersion level	Up to 6 cm from transducer head
Type	BF

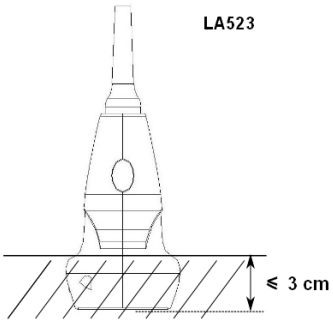
Linear Probes



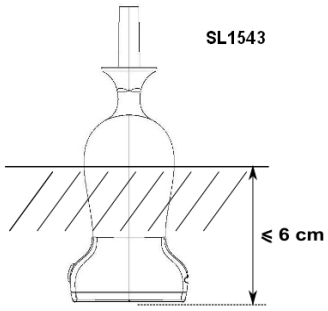
Probe ID	AL2442, AL2443
Maximum immersion level	Up to 6 cm from transducer head
Type	BF



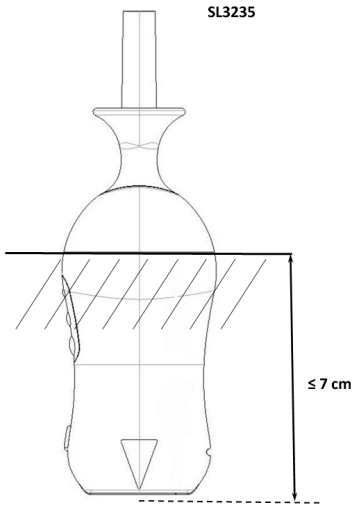
Probe ID	LA435, SL2325
Maximum immersion level	Up to 5 cm from transducer head
Type	BF



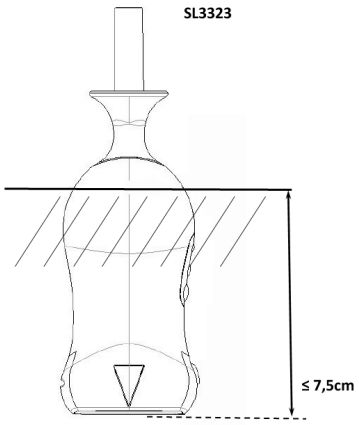
Probe ID	LA523
Maximum immersion level	Up to 3 cm from transducer head
Type	BF



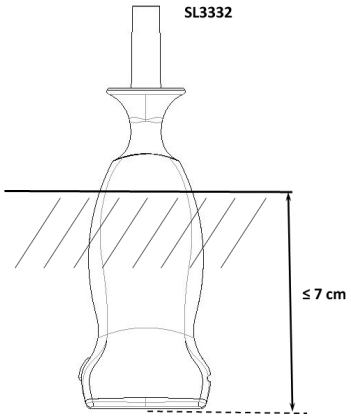
Probe ID	SL1543
Maximum immersion level	Up to 6 cm from transducer head
Type	BF



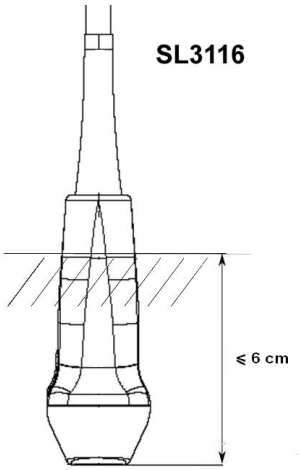
Probe ID	SL3235
Maximum immersion level	Up to 7 cm from transducer head
Type	BF



Probe ID	SL3323
Maximum immersion level	Up to 7,5 cm from transducer head
Type	BF

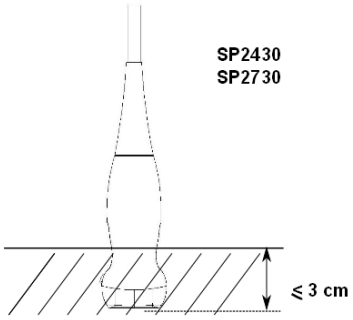


Probe ID	SL3332
Maximum immersion level	Up to 7 cm from transducer head
Type	BF

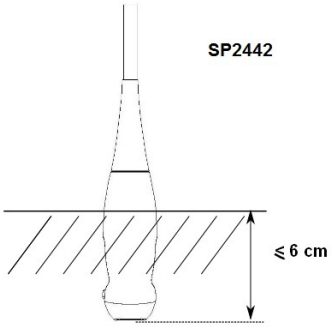


Probe ID	SL3116
Maximum immersion level	Up to 6 cm from contact surface
Type	BF

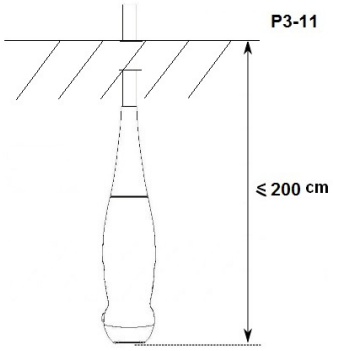
Phased Array Probes



Probe ID	SP2430, SP2730
Maximum immersion level	Up to 3 cm from transducer head
Type	BF

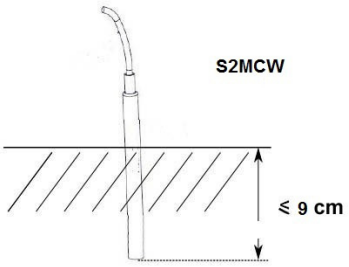


Probe ID	SP2442
Maximum immersion level	Up to 6 cm from transducer head
Type	BF

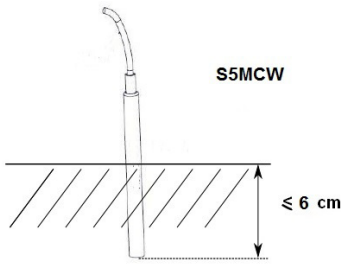


Probe ID	P3-11
Maximum immersion level	Up to 200 cm from contact surface
Type	BF

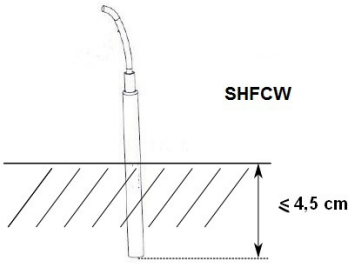
Doppler Probes



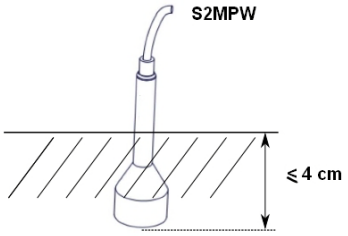
Probe ID	S2MCW
Maximum immersion level	Up to 9 cm from transducer head
Type	BF



Probe ID	S5MCW
Maximum immersion level	Up to 6 cm from transducer head
Type	BF



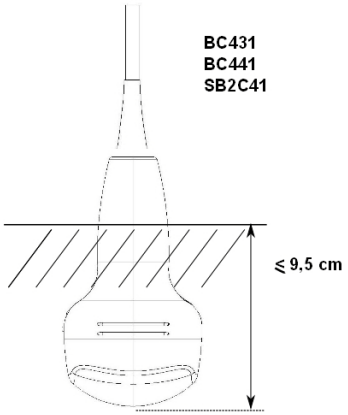
Probe ID	SHFCW
Maximum immersion level	Up to 4,5 cm from transducer head
Type	BF



Probe ID	S2MPW
Maximum immersion level	Up to 4 cm from transducer head
Type	BF

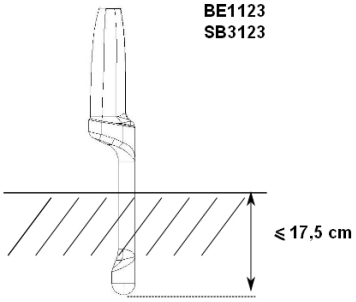
Specialty Probes

Bi-Scan Probes



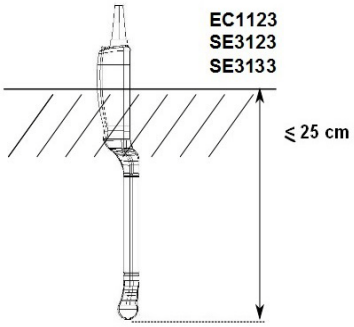
Probe ID	BC431, BC441, SB2C41
Transducer	Convex Array
Maximum immersion level	Up to 9,5 cm from transducer head
Type	BF

Bi-Scan Endocavity Probe

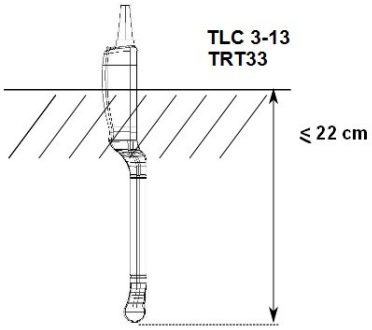


Probe ID	BE1123, SB3123
Transducer	Convex Array
Imaging plane	Sagittal
Maximum immersion level	Up to 17,5 cm from transducer head
Type	BF

Endocavity Probes

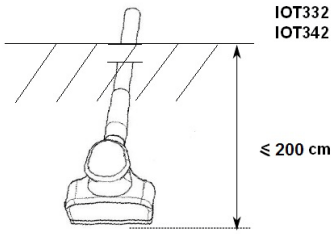


Probe ID	EC1123, SE3123, SE3133
Transducer	Convex Array
Imaging plane	Sagittal
Maximum immersion level	Up to 25 cm from transducer head
Type	BF

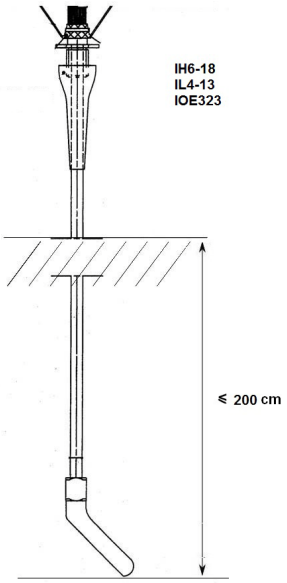


Probe ID	TLC 3-13, TRT33
Transducer	Convex + Linear Array
Imaging plane	Transversal and longitudinal
Maximum immersion level	Up to 22 cm from transducer head
Type	BF

Intraoperative Probes

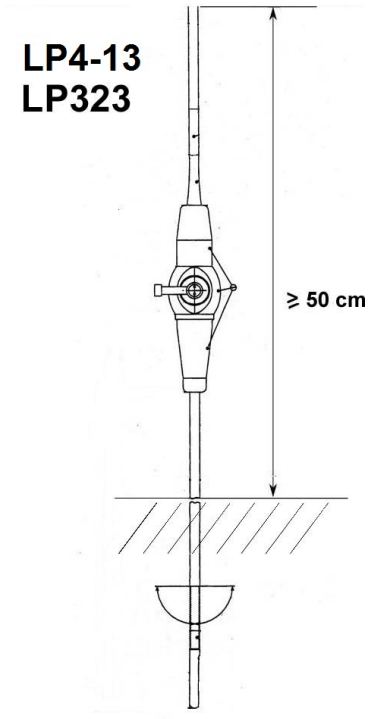


Probe ID	IOT332, IOT342
Transducer	Linear Array
Maximum immersion level	Up to 200 cm from contact surface
Type	BF



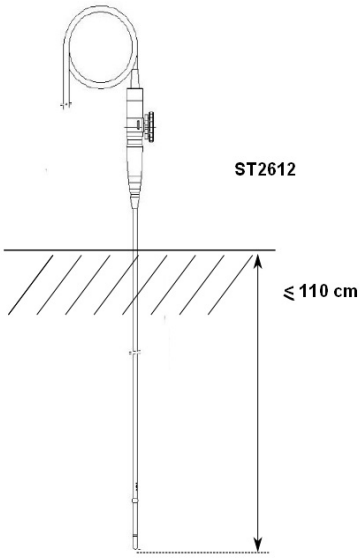
Probe ID	IH6-18, IL 4-13, IOE323
Transducer	Linear Array
Maximum immersion level	Up to 200 cm from contact surface
Type	BF

Laparoscopic Probes

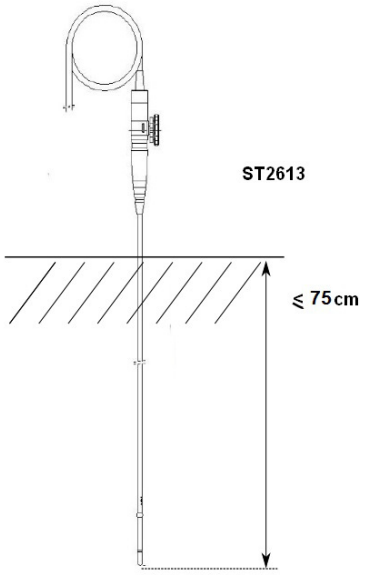


Probe ID	LP 4-13, LP323
Transducer	Linear Array
Maximum immersion level	Up to 50 cm from connector
Type	BF

Transesophageal Probes



Probe ID	ST2612
Transducer	Phased Array
Imaging plane	0-180°
Maximum immersion level	Up to 110 cm from transducer head
Type	BF



Probe ID	ST2613
Transducer	Phased Array
Imaging plane	0-180°
Maximum immersion level	Up to 75 cm from transducer head
Type	BF

Appendix B

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 system 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 EN60601-1 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 representative.

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.

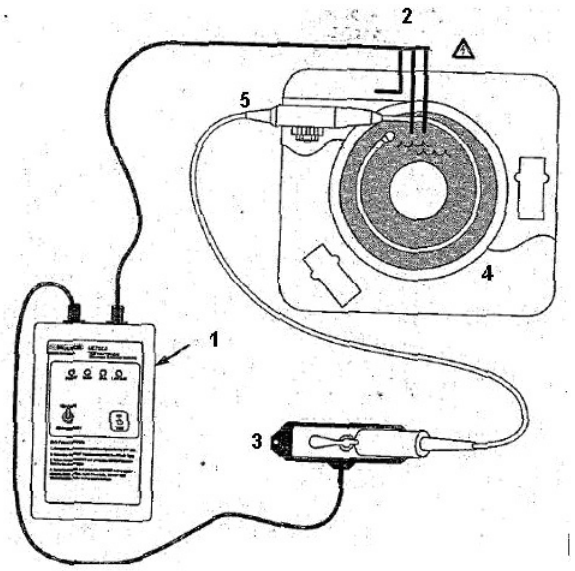
Do not immerse the probe cable or connector into water or other liquids. Immersion may compromise the electrical safety features. The probe can be inserted in water up to its Maximum Immersion Level (see Appendix A).

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.



Legenda

1: Measuring device

2: Conductivity electrodes

3: Probe adapter

4: Water tank filled with Cidex or saline solution

5: Probe to be examined