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MyLab

TRANSDUCERS AND CONSUMABLES

OPERATOR MANUAL

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Introduction

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

- Chapter 1: Care of transducers
  The chapter describes how to handle, control, store and protect ESAOTE tranducers.

- Chapter 2: Cleaning and disinfecting the transducers
  The chapter describes how to clean and disinfect non-invasive transducers and those used in semi-critical applications.
- Chapter 3: The Endorectal probe
  The chapter lists the specific safety requirements for examinations with the endo probe. A description is also given on how to prepare the probe for the examination.
- Chapter 4: Accessories and Consumables
  The chapter gives information about the characteristics of the consumables.
- Chapter 5: The Intraoperative probe
  The chapter lists the specific safety requirements for examinations with the intraoperative probe. A description is also given on how to prepare the probe for the examination.
- Chapter 6: Needle Guide Kits
  The chapter describes the procedures for assembling the kits.
- Appendix A: **MyLab** Probes
  The appendix details available models and their main characteristics.
- Appendix B: Consumables
  The appendix lists the recommended cleaning, disinfection and sterilization agents.
- Appendix C: Probe Electrical Safety
  The appendix explains how to check the electrical safety of the probes.

In this manual **WARNING** identifies a risk for the patient and/or the operator. The word **CAUTION** describes the precautions necessary for protecting the equipment. **Make sure you understand and follow these instructions.**

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Chapter 1

1 - Care of Transducers

Handling Transducers

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

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

WARNINGS

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

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 Probe Monitoring Schedule

The following tables describe the periodic monitoring that must be made on the probes. The frequency suggested for non-invasive probes is considered to be the minimum; very frequent usage requires more frequent checks.

Operation to be performed	Frequency
Physical check of non-invasive probes	Every month or when the probe is dropped
Physical check of endocavity probes	Before every examination
Physical check of the biopsy 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 current leakage test (see Appendix C for further details).

Transducer Monitoring

Non-invasive Transducers

Non-invasive transducers are intended to be used on the external parts of the body only.

A periodic check must be made on transducers to check that:

- The housing is intact. If cracks or breaks are found, have the probe repaired immediately by contacting an ESAOTE technician.
- The lens does not have any irregularities or is not broken. If any breaks are found on the scanning surface, do not use the probe again and have it repaired.
- The probe cable is not broken or damaged. If any damage is found, do not use the probe again and have it repaired.
- The connector pins are not bent. If the pins are damaged, do not use the probe and have it repaired.

WARNING

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

Do not use a probe if it has been dropped. A current leakage test (see Appendix C 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 control unit, although waterproof, should not be unnecessarily immersed.

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

Invasive Transducers

Invasive transducers penetrate the patient's body through an orifice or through the surface of the body.

Monitoring of the Endocavity Probe

The endocavity probe must be checked before every examination.

- Perform both a visual and manual check to ensure that there are no holes, bulges, abrasions or dents.
- Perform a visual and manual check of the probe cable; 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.

WARNING

Breaks in the probe casing or in the cable could expose the patient and/or operator to an electrical safety risk.

Do not use a probe if it has been dropped. A current leakage test (see Appendix C 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 electric shock 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 attempt to dismantle the probe; any attempt to dismantle the probe may result in damage to the probe and will void the warranty and could compromise its safety.

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

- ***Do not touch the lens*** at the front of the probe. Never exert force on the lens.
- The connector is not waterproof and should always be kept dry.

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

Storing and Protecting the Transducers

Daily Storage and Protection

Non-Invasive Transducers

When not in use, the transducer 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) prior to storage.

CAUTION

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

Storing and Protecting the Endocavity Probe

The probe must always be cleaned following the instructions provided in the next chapter. When not in use, the transducer must be stored 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 transducers are supplied with their own case that must always be used both when transporting the probe and for long-term storage. Clean the transducer 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.

Dispatching the Transducer

Contact Esaote personnel to ensure that the transducer is correctly packed before dispatching it.

Chapter 2

2 - Cleaning and Disinfecting Transducers

Periodic Cleaning and Disinfecting Schedule

The following table describes the periodic maintenance to be carried out on transducers depending on their application. The risk of infection establishes the type of application.

Device	Application	Operation	Frequency
Non-invasive probes	Non-critical[1]	Cleaning	Before the first use and after each exam.
		Disinfection	When necessary
Endocavity probes	Semi-critical[2]	Cleaning and Disinfection	Before the first use and after each exam.

[1] The application is considered non-critical when the device is used on intact skin.
[2] The application is considered semi-critical when the device is used on the mucous membranes.

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

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.

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

Refer to **Appendix B** for a list of recommended cleaning, disinfection and sterilization agents.

Note

Damage caused by the use of not recommended agents is not covered by the warranty.

WARNING

WARNING

The disinfection/sterilization agents listed are recommended because of chemical compatibility with the probe materials, and biological effectiveness. For biological effectiveness of a disinfectant, follow the guidelines and recommendations of the disinfectant manufacturer.

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.

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

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

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.

Cleaning Procedure

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.

- Disconnect the probe from the unit
- Remove all residues of ultrasound gel from the probe using a soft cloth.
- Clean the probe by rubbing it lightly with a soft cloth soaked in a solution of water and mild soap.
- Rub the probe with a soft damp cloth to remove any soap residue.
- Dry the probe by rubbing it with a soft dry cloth.

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 as described in the previous paragraph.
- Immerse the probe casing in the recommended agent, following the manufacturer's instructions very carefully.

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 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 guarantee.

- 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.
- Dry the probe carefully using a soft 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 is recommended during probe cleaning and disinfecting operations. The probe must be disinfected before it is used for the first time. The probe must be 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 transducer and the endoscope with the recommended agent.

Note

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

- If the probe is contaminated by body fluids, disinfect it before and after cleaning.
- Immerse the probe casing into the recommended agents, following the manufacturer's instructions very carefully.

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.
- Dry the probe carefully using a soft 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, is not covered by the guarantee. These sterilization methods can permanently damage the probe.

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

Chapter 3

3 - The Endorectal Probe

The endorectal (**SV3513 and TL5-10**) probe is a dedicated veterinary endorectal probe. It is a Type BF part. 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 safety characteristics, cautions and warnings listed also apply to the use of this probe.

In particular, remember that:

WARNINGS

The system must be correctly grounded: it must be powered from a socket equipped with a protective earth connection.

Mobile configurations are fitted with insulated supply sockets for supplying peripheral systems without increasing the current leakage. Incorrect connection 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 **SV3513 and TL5-10** probe incorporates a high frequency convex transducer for sagittal (transverse) endorectal or endovaginal scanning.

The **SV3513 and TL5-10** probe is delivered with the following accessories:

- Storage case

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 Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if you suspect damage.

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.

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

Note

The use of sterile covers is mandatory for all endocavity scans.

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.

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, check to 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 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.

Make sure that water does NOT get in contact with the connector and connector grommet or that water can drop via the grommet into the connector.

Agents that contain the following chemicals are known to damage the probe:

- Acetone
- Methanol
- Chloride
- Denaturant ethyl alcohol
- Mineral oil
- Iodine
- Any lotions or gel containing perfume

Check with the ultrasound gel manufacturer regarding gel contents. If you have additional questions, please contact your representative.

The following procedures are known to damage the SV3513 and TL5-10 probe:

- Autoclaving
- Soaking the probe in chlorine bleach

The SV3513 and TL5-10 probe can be disinfected by using disinfection agents as indicated in Annex B and according to the manufacturer's directions.

- Unplug the probe from the system
- Clean the probe as described earlier

Immerse the probe and cable (NOT THE CONNECTOR AND GROMMET) in disinfecting agent, as indicated in Annex B. Make sure that the disinfecting fluid is not in contact with the connector and the connector grommet or can drip via the grommet into the connector. Follow the disinfecting agents manufacturer's instructions for use.

Preparation of the Endorectal Probe

Follow the instructions below for preparing the endocavity probe.

Note

The Operator is recommended to wear gloves during the probe preparation procedure

See 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 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.

- Completely unroll the sheath along the transducer body, making it adhere, so as to avoid air pockets.
- Secure the sheath if needed.
- To make it easier to insert the endocavity probe, apply some water-based lubricating gel on the tip of the transducer.

The endorectal examination

- Clean the rectum of all faeces
- Cover your arm with a plastic glove
- Place the SV3513 and TL5-10 probe with enough gel in your hand and enter the rectum. Be sure that the crystal side of the probe is facing downwards when you enter the rectum.

Place the crystal side of the veterinary probe against the rectum wall in order to get a good image. The scan plane is longitudinal. Rotate your arm to the left or right or move the probe forwards or backwards to get another view.

Chapter 4

4 - Accessories and Consumables

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 transducer could be damaged if such gels are used.

Substances to Be Excluded

- acetone
- methanol, ethanol, isopropyl 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.

Product	Supplier
Aquasonic® Scan®	Parker Laboratories, Inc. New Jersey, USA

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 sheaths listed below are produced by CIVCO Medical Instruments Inc., Kalona, IA (USA). Refer to the manufacturer's instructions for the characteristics and use of the protective sheaths.

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.

See the table below for sheaths included in accessory kits.

LA and CA Probes

Probes	Manufacturer's kit code	Measurements	Sterile	Latex
SL3323, SL3116, SL3235, SL3413, SL3332	610-001	8.9 x 61 cm	Yes	No
SV3L11	610-005	22.9 X 61 cm	Yes	No
SC3421, SC3123, SC3121	610-002	14 x 61 cm	Yes	No

5 - The Intraoperative Probe

The intraoperative probe (**IOT342**) is a 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 **IOT342** probe incorporates a high frequency linear transducer for intraoperative scanning.

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

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 Chapter 2 of this manual). DO NOT use the probe if it has been damaged or if damage is suspected.

Note

Esaote recommends to sterilize the probe before its use with one of the authorized methods.

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

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 damage is known or suspected.

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

Note

During the probe preparation procedure the operator is recommended to wear gloves

See Chapter 8 on consumables for choosing gel and sheaths.

- Apply enough 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.

Note

Esaote recommends the use of sterile sheaths in intraoperative examinations.

- Completely unroll the sheath along the transducer body, fitting it tightly so to avoid air pockets.
- Secure the sheath with the rubber band.

WARNING

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).

Note

Esaote recommends use of sterile sheaths in intraoperative examinations.

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:

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

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 6

6 - Needle Guide Kits

For **MyLab** there are a series of optional adaptors for the biopsy needle guide available. These are fitted with special couplings for connection to the probe. The following tables list the available kits.

Biopsy adaptor	Manufacturer's kit code	Probe	Kit contents
WBSL33X	-	SL3332	35° coupling

The WBSL33X kit is composed of stainless steel. 12, 14, 18, 19, 20, 21 and 22 gauge needle guides are available for the WBSL33X.

In addition to the above mentioned biopsy adaptor, Esaote probes can be equipped with sterilized single-use Needle guides[1]. The following table lists the available kits:

Biopsy adaptor	Manufacturer's kit code	Probe	Kit contents
CBSL33X	639-015	SL3332	1 Non-sterile mounting bracket, disposable sterile needle guide and sterile probe cover. (25°, 40° or 50° angle)
IKL3323	639-025	SL3323	Non-sterile bracket with infiniti needle guide and 14x147cm probe cover, (42°÷81° angles)
IKC3421	639-027	SC3421	Non-sterile bracket with infiniti needle guide and 14x147cm probe cover, (42°÷57° angles)
CBSC23X	639-045	SC3123	1 Non-sterile mounting bracket, disposable sterile needle guide and sterile probe cover (20° or 35° angle)
IKI33X	639-051	IOT342	Non-sterile single-angle tracking bracket with Infiniti Plus needle guide-18, 20, 21/22, 25GA (3); 12, 14, 16, 18GA (2) and 14 x 91.5cm CIV-Flex cover (5) and probe clips (25) (42°÷80°angle)

The disposable needle guides are sterile but cannot be re-sterilized.

The CBSL33X utilizes a two-part system consisting of a reusable biopsy bracket and the disposable snap-on needle guide. The needle guide will accept a range of sizes including: 8.5FR, 14-23 gauge (19 GA not available.).

[1] Manufactured Civco Medical Instruments, Kalona Iowa; www.civco.com

The IKL3323 & IKC3421 needle guides accept instruments through 20, 21/22, 25, 14, 18 gauge. These Infiniti needle guide kits 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 transducer itself, on the other side. The kit allows the user to keep the needle on the same scanning plane of the probe.

The CBSC23X needle guide accepts 8.5FR, 14-23 gauge (19 GA not available.) instruments.

See Appendix A in this manual for probes characteristics

WARNING

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

The biopsy adaptors must be attached to the probes using the alignment pivots. Follow the instructions provided by the Manufacturer with these kits to properly use them and to clean, disinfect and sterilize them.

Examination Safety

S&S

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 your **MyLab** "Safety & Standard" manual for additional safety information.

Before the Examination

Before each examination, Esaote recommends that the Operator:

- Handle the biopsy 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.
- 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 reactions.

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 provide 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 via 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 WBSL33X Needle Guide

The WBSL33X adaptor is composed of two parts: the coupling 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

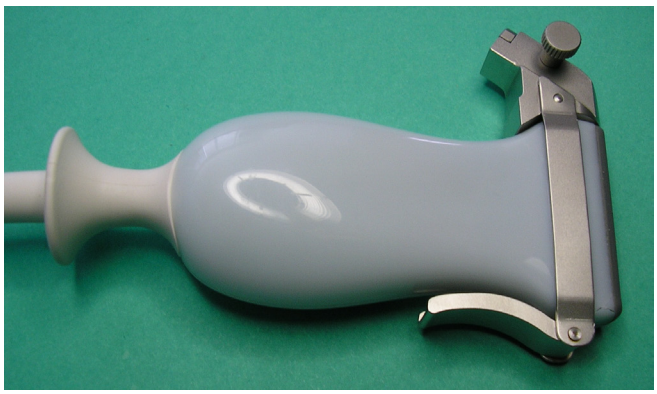
The protective sheaths available on the market often contain latex. Make sure that patients who are allergic to latex are identified before each examination. Serious allergic reactions to latex have been reported; the Operator should be prepared to handle such a reaction.

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's ridge.
- Close the coupling device by hitching it to the opposite side of the probe.

Notes

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.

Appendix A

Appendix A - MyLab Probes

GS

This chapter provides a list of **MyLab** probes with their main characteristics; system dependent features are described in your model documentation.

Probes Denomination

The name of ESAOTE probes includes the following elements from the left to the right:

- A letter indicating the type of connector
- A letter indicating the type of transducer (ex. P = Phased Array, L = Linear Array, C = Convex transducer etc)
- A number indicating the transducer source
- A number indicating the transducer size
- A number indicating the transducer technology
- A number indicating the transducer frequency

The user manual and the display always identifies the probe, by using the prefix and the number only.

Phased Array Probes

Probe ID	Maximum immersion level
SP3630	Up to 60 mm from transducer head

Linear Probes

Probe ID	Maximum immersion level
SL3323	Up to 75 mm from transducer head
SL3116	Up to 60 mm from transducer head
SL3235	Up to 70 mm from transducer head
SL3413	Up to 140 mm from transducer head
SL3332	Up to 70 mm from transducer head

Convex Probes

Probe ID	Maximum immersion level

SC3421	Up to 85 mm from transducer head
SC3123	Up to 80 mm from transducer head
SC3121	Up to 80 mm from transducer head

Vet Endorectal Probe

Probe ID	Maximum immersion level
SV3513	Up to 60 mm from transducer head
TL5-10	Up to connector from trancducerhead

Animal Science Probe

Probe ID	Maximum immersion level
SV3L11	Up to 110 mm from transducer head

Special probes

Probe ID	Maximum immersion level
IOT342	Up to 8 cm from transducer head

Appendix B

Appendix B - Consumables

Cleaning, Disinfection and Sterilization Agents

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

WARNING

Follow the instructions provided by the manufacturer of the agent for proper use.

Cleaning Agents for Convex Array Probes

	SC3121 SC3123 SC3421
Accel RTU	OK
Alkazyme	
Anios Detergent Desinfectant	OK
Asepti-Wipes II	
CaviWipes	OK
Deconex 3-Zyme	OK
Enzol/Cydezime	OK
Hexanios G+R	OK
Klenzyme	
Medi-Prep	OK
Mediclean	OK
Mikrozid	OK
Milton	
PerCept RTU	OK
Salvanios	
Sani Cloth Active	OK
Sani Cloth HB	OK
Septi Wipes	
Super Sani Cloth	
T-Spray	OK
T-Spray II	OK
Transeptic	OK

Disinfection Agents for Convex Array Probes

	SC3121 SC3421	SC3123
Cavicide	OK	OK
Cidex®	OK	OK
Cidex® OPA	OK	OK
Cidexplus®	OK	OK
Cleanisept wipes	OK	OK
Compliance™		
Gigasept (10% vol.)	OK	OK
Gigasept® FF	OK	OK
Korsolex extra		
Mikrobac tissues	OK	OK
Mikrozid Sensitive	OK	OK
Omnicide™ (2.25%)	OK	OK
Resert HLD (ex Secure HLD)		OK
Resert XL HLD		OK
Revital-OX Resert XL HLD		OK
Sporox II		
Ster-bac Blu		
Steranios	OK	OK
Virkon®	OK	OK
Wavicide-01®	OK	OK

Sterilization Agents for Convex Array Probes

	SC3121 SC3421	SC3123
Anioxyde 1000		
Cidex Activated Dialdehyde Solution		OK
Cidexplus®	OK	OK
ComplianceTM		
Hibitane		
Medister		OK
Metricide® 14	OK	OK
NuCidex		
OmnicideTM (2.25%)	OK	OK
Perasafe®		OK
Wavicide-01®	OK	OK

Cleaning Agents for Linear Array Probes

	SL3235	SL3332	SL3323	SL3116	SL3413 SV3513 TL5-10 SV3L11
Accel RTU	OK	OK	OK		OK
Alkazyme		OK	OK		
Anios Detergent Desinfectant	OK	OK	OK		OK
CaviWipes	OK	OK	OK	OK	OK
Deconex 3-Zyme	OK	OK	OK	OK	OK
Enzol/Cydezime	OK	OK	OK		OK
Hexanios G+R	OK	OK	OK		OK
Klenzyme			OK		
Medi-Prep	OK	OK	OK		OK
Mediclean	OK	OK	OK	OK	OK
Mikrozid	OK	OK	OK	OK	OK
Milton	OK	OK	OK		
PerCept RTU	OK	OK	OK		OK
Salvanios		OK	OK		
Sani Cloth Active	OK	OK	OK		OK
Sani Cloth HB	OK	OK	OK		OK
Septi Wipes		OK			
T-Spray	OK	OK	OK	OK	OK
T-Spray II	OK	OK	OK		OK
Transeptic	OK	OK	OK	OK	OK

Disinfection Agents for Linear Array Probes

	SL3235	SL3323	SL3332 SL3413	SL3116	SV3513 TL5-10 SV3L11
Cavicide	OK		OK		
Cidex®	OK	OK		OK	OK
Cidex® OPA	OK	OK	OK	OK	OK
Cidexplus®	OK	OK			OK
Cleanisept wipes	OK	OK			OK
Clidox -S				OK	
Compliance™		OK			
Gigasept (10% vol.)	OK	OK			OK
Gigasept® FF	OK	OK			OK
Korsolex extra					
Mikrobac tissues	OK	OK			OK
Mikrozid Sensitive	OK	OK			OK
Omnicide™ (2.25%)	OK	OK			OK
Resert HLD (ex Secure HLD)		OK			
Resert XL HLD		OK			
Revital-OX Resert XL HLD		OK			
Steranios	OK	OK			OK
Ster-Bac Blu					
Virkon®	OK	OK			OK
Wavicide-01®	OK	OK			OK

Sterilization Agents for Linear Array Probes

	SL3235	SL3323	SL3413	SL3332	SL3116	SV3513 TL5-10 SV3L11
Anioxyde 1000		OK				
Cidex Activated Dialdehyde Solution	OK	OK		OK		OK
Cidexplus®	OK	OK	OK	OK		OK
ComplianceTM		OK				
Medister	OK	OK		OK		
Metricide®	OK	OK	OK	OK		OK
NuCidex		OK				
OmnicideTM (2.25%)	OK	OK	OK	OK		OK
Perasafe®		OK		OK		
Wavicide-01®	OK	OK	OK	OK		OK

Cleaning Agents for Intraoperative Probes

	IOT342
Accel RTU	OK
Alkazyme	
Anios Detergent Desinfectant	OK
CaviWipes	OK
Deconex 3-Zyme	OK
Enzol/Cydezime	OK
Hexanios G+R	OK
Klenzyme	
Medi-Prep	OK
Mediclean	OK
Mikrozid	OK
Milton	OK
PerCept RTU	OK
Salvanios	
Sani Cloth Active	OK
T-Spray	OK
T-Spray II	OK
Transeptic	OK
Tristel Duo	
Tristel Sporicidal Wipes	

Disinfection Agents for Intraoperative Probes

	IOT342
Cavicide	OK
Cidex®	OK
Cidex® OPA	OK
Cidexplus®	OK
Cleanisept wipes	OK
Gigasept (10% vol.)	OK
Gigasept® FF	OK
Mikrobac tissues	OK
Mikrozid Sensitive	OK

	IOT342
Omnicide™ (2.25%)	OK
Resert HLD (ex Secure HLD)	
Resert XL HLD	
Revital-OX Resert XL HLD	
Steranios	OK
Tristel Duo	
Tristel Sporicidal Wipes	
Trophon	OK
Virkon®	OK
Wavicide-01®	OK

Sterilization Agents for Intraoperative Probes

	IOT342
Anioxyde 1000	
Cidex Activated Dialdehyde Solution	OK
Cidexplus®	OK
Ethylene Oxide	
Medister	OK
Metricide®	OK
NuCidex	
OmnicideTM (2.25%)	OK
Perasafe®	OK
Steris V-Pro 1	OK
Sterrad® 100NX	OK
Sterrad® 100S	OK
Sterrad® NX	OK
Tristel Stella 5	
Wavicide-01®	OK

Phased Array Probes

For the SP3630 phased array probe the following agents are recommended:

- Cidex 2%
- Cidex OPA

Cleaning, Disinfection and Sterilization Agents for Needle Guides.

All compatible methods for surgical instruments can be applied for the following kits:

9103525000 - WBSL33X
141009500 - CBSC23X
141002900 - DBSE12X
141009500 - CBSC23X

Approved cleaning agents for all MyLab Systems:
Mid Soap
Caviwipes
Mikrozid Wipes

Details of recommended agents

Agents	Type	Main ingredient	Manufacturer	FDA clearance	Heath Canada Clearance
Accel	Liquid, Wipes	Hydrogen Peroxide	Virox Technologies Inc.	NO	YES
Alkazyme	Powder	Quaternary Ammonium	Alkapharm	NO	YES
Anios Detergent Desinfectant	Liquid	Quaternary Ammonium	Laboratoires Anios	NO	NO
Asepti-Wipes II	Wipes	Alkyl Dimethyl Ethylbenzyl Ammonium Chloride, Benzalkonium Chloride, Isopropyl Alcohol	Ecolab Co.	NO	YES
Anioxyde 1000	Liquid	Peracetic Acid	Laboratoires Anios	NO	NO
Cavicide	Liquid	Isopropyl Alcohol 17.2%, Benzethonium Chloride 0.28%	Metrex Research Corporation	NO	YES
CaviWipes	Wipes	Isopropyl Alcohol 17.2%, Benzethonium Chloride 0.28%	Metrex Research Corporation	NO	YES
Cidex Activated Dialdehyde Solution	Liquid	Glutaraldehyde	ASP	YES	YES
Cidex®	Liquid	Glutaraldehyde	ASP	YES	NO
Cidex® OPA	Liquid	Ortho-phthalaldehyde	ASP	YES	YES
Cidexplus®	Liquid	Glutaraldehyde	ASP	YES	YES
Cleanisept	Wipes	Quaternary Ammonium	Dr. Schumacher GmbH	NO	NO
Clidox-S	Liquid	Chlorine Dioxide	Pharmacal Research Laboratories Inc.	NO	NO
Compliance™	Liquid	Hydrogen Peroxide, Peracetic Acid	Metrex Research Corporation	NO	NO
Deconex 3-Zyme	Liquid	Enzymes	Borer	NO	NO
DisOPA	Liquid	Ortho-phthalaldehyde	ASP	NO	NO
Enzol/Cydezime	Liquid	Enzymes	ASP	NO	NO
Ethylene Oxide	System	Ethylene Oxide	Various manufacturers	NO	NO
Gigasept (10% vol.)	Liquid	Succindialdehyde, formaldehyde	Schülke & Mayr	NO	NO
Gigasept® FF	Liquid	Succindialdehyde	Schülke & Mayr	NO	NO
Hexanios G+R	Liquid	Poliexanide, Quaternary Ammonium Chloride	Laboratoires Anios	NO	NO
Hibitane	Liquid	Chlorhexidine Acetate	Wyeth Animal Health	NO	YES
Klenzyme	Liquid	Proteolytic Enzymes	Steris Corporation	NO	NO
Korsolex extra	Liquid	Quaternary Ammonium	Bode	NO	NO
Mediclean	Liquid	Enzymes	Dr. Weigert	NO	NO
Medi-Prep	Wipes	Cetrimide BP	Seton	NO	NO
Medister	Powder	Hydrogen Peroxide, Peracetic Acid	Euro Trading S.r.l.	NO	NO
Metricide® 14	Liquid	Glutaraldehyde	Metrex Research Corporation	YES	YES
Mikrobac	Tissues	Quaternary Ammonium	Bode Chemie AG	NO	NO
Mikrozid Sensitive	Liquid	Quaternary Ammonium	Schülke & Mayr	NO	NO
Milton	Liquid	Sodium Hypochlorite	Milton Pharmaceutical Ltd.	NO	NO
Neodisher Mediclean	Liquid	Enzymes	Dr. Weigert	NO	NO
NuCidex	Liquid	Peracetic Acid	ASP	NO	NO
Omnicide™ (2.25%)	Liquid	Glutaraldehyde	Cottrell Ltd.	YES	NO
Perasafe®	Powder	Peracetic Acid, Hydrogen Peroxyde	Day-Impex Ltd	NO	NO
PerCept RTU	Wipes, Liquid	Hydrogen Peroxyde	Virox Technologies Inc.	NO	YES
Resert HLD (ex Secure HLD)	Liquid	Hydrogen Peroxyde	Steris Corporation	NO	YES
Resert XL HLD	Liquid	Hydrogen Peroxyde	Steris Corporation	NO	YES
Revital-OX Resert XL HLD	Liquid	Hydrogen Peroxyde	Steris Corporation	NO	YES
Salvanios	Powder	Quaternary Ammonium	Laboratoires Anios	NO	NO
Sani Cloth Active	Wipes	Quaternary Ammonium	PDI	NO	YES
Sani Cloth HB	Wipes	Quaternary Ammonium	PDI	NO	YES
Sekusept Aktiv	Powder	N.A.	Ecolab Co.	NO	NO
Septi Wipes	Wipes	Quaternary Ammonium	Dr. Schumacher GmbH	NO	NO
Sporox II	Liquid	Hydrogen Peroxyde	Sultan Healtcare Inc.	YES	YES
Steam (autoclave)	Steam	Steam	Various Manufacturers	NO	NO

Agents	Type	Main ingredient	Manufacturer	FDA clearance	Heath Canada Clearance
Steranios	Liquid	Glutaraldehyde	Laboratoires Anios	NO	NO
Ster-Bac Blu	Liquid	Quaternary Ammonium	Ecolab Inc.	NO	YES
Steris V-Pro 1	Liquid	Hydrogen Peroxyde	Steris		
Sterrad® 100NX	Liquid	Hydrogen Peroxyde	ASP	NO	YES
Sterrad® 100S	Liquid	Hydrogen Peroxyde	ASP	NO	YES
Super Sani Cloth	Wipes	Quaternary Ammonium, Isopropyl Alcohol	PDI	NO	NO
TD-5/TD-100	Liquid	Glutaraldehyde	Phoenix Airmid Biomedical Corp.	YES	YES
T-Spray II	Spray	Quaternary Ammoniums	Pharmaceutical Innovations Inc.	NO	NO
T-Spray	Spray	Quaternary Ammoniums	Pharmaceutical Innovations Inc.	NO	NO
Transeptic	Spray	Isopropyl Alchohol	Parker Laboratories Inc.	NO	NO
Tristel Duo	Spray	Chlorine Dioxyde	Tristel Solution Ltd	NO	NO
Tristel Sporicidal Wipes	Wipes	Chlorine Dioxyde	Tristel Solution Ltd	NO	NO
Tristel Stella 5	System	Chlorine Dioxyde	Tristel Solution Ltd	NO	NO
Virkon®	Liquid	Potassium Peroximonosulphate	Day-Impex Ltd	NO	YES
Wavicide-01®	Liquid	Glutaraldehyde	Wave Energy Systems Inc.	YES	NO

Manufacturer of recommended agents

Manufacturer	Address	Web site	Country of manufacture
ASP - Advanced Sterilization Products	33 Technology Drive, Irvine, California 92618 USA	www.aspjj.com/	USA
Alkapharm	Parc Biocitech 102 Avenue Gaston Roussel Romainville France 93230	www.alkapharm.fr	France
BODE Chemie GmbH	Melanchthonstraße 27, 22525 Hamburg, Germany Phone: +49 (40) 5 40 06-0; Fax: +49 (40) 5 40 06-200	www.bode-chemie.de/	Germany
Cottrell Ltd.	7399 South Tucson Way, Englewood, CO 80112 USA, Tel: +1 303 799 9401, Free phone (USA only): (800)843-3343, Fax: +1 303 799-9408		USA
Day-Impex Ltd	Station Works Earls Colne Colchester Essex CO6 2ER, UK; Phone: +44 1787 223232 Fax: +44 1787 224171	www.day-impex.co.uk	UK
Dr. Schumacher GmbH	Am Roggenfeld 3, 34323 Malsfeld, Germany Phone: + 49 5664 94960; Fax: +49 5664 8444	www.schumacher-online.com	Germany
Euro Trading S.r.l.	Via Cassia per Siena, 158 – Loc. Bargino – 50023 S.Casciano Val di Pesa; Phone: +39 055 214689; Fax +39 055 210470		Italy
Laboratoires Anios	Pavé du Moulin 59260 Lille-Hellemmes, France; Phone: +33 3 20 67 67 67; Fax:+33 3 20 67 67 68; E-mail: commercialexport@anios.com;	www.anios.com	France
Metrex Research Corporation	1717 West Collins Avenue, Orange, California USA 92867	www.metrex.com	USA
Milton Pharmaceutical Ltd	9, rue Marcel Sembat, Immeuble le St Louis - 3ème étage, 44100 NANTES, France;	www.milton-tm.com/	France
Parker Laboratories Inc	Corporate Headquarters: 286 Eldridge Road Fairfield, NJ 07004 USA; Tel: +1 973-276-9500; Fax: +1 973-276-9510; e-mail: parker@parkerlabs.com Representative for Europe: Parker Laboratories, Inc.; Ninaberlaan 83; 7447 AC Hellendoorn; The Netherlands; Tel: +31 548 659030; Fax: +31 548 659010; e-mail: europe@parkerlabs.eu	www.parkerlabs.com/	USA
Pharmacal Research Laboratories Inc.	Phone: 1-800-243-5350, (203)755-4908; Fax: (203)755-4309 P.O. Box 369 Naugatuck, CT 06770	www.pharmacal.com	USA
Pharmaceutical Innovations, Inc.	897 Frelinghuysen Avenue; Newark, New Jersey 07114-2195; USA; Phone: +1 973-242-2900; Fax: 973-242-0578; E-mail: info@pharminnovations.com	www.pharminnovations.com	USA
PDI Professional Disposables International	Two Nice-Pak Park, Orangeburg, NY 10962, USA; Phone: +1 845 3651700; Canada 800-263-7067; Europe: +44 1 352 763 511; Email:info@pdipdi.com;	www.pdipdi.com	USA
Schülke&Mayr GmbH	Robert-Koch Str. 2, 22851 Norderstedt, Germany; Phone: +49 40 521 000; Fax:+49 40 521 00-318; Email: mail@schuelke-mayr.com ;	www.schuelke-mayr.com	Germany
Seton	Wildmere Industrial Estate, Banbury, Oxfordshire, OX16 3JU, UK; Phone: +44 800 585 501; Fax: +44 800 526 861; E-mail: contactus@seton.co.uk		UK
STERIS Corporation	5960 Heisley Road, Mentor, Ohio 44060-1834 USA, Phone: +1 800 JIT 4 USE or+ 1 440 354 2600	www.steris.com	USA
Sultan Healthcare, Inc.	411 Hackensack, Hackensack, New Jersey Usa 07601		USA

Tristel Solutions Limited	Lynx Business Park, Fordham Road, Snailwell, Cambridgeshire, CB8 7NY, UK Phone: +44 (0) 1638 721500; Fax: +44 (0) 1638 721911	www.tristel.com/	UK
Virox Technologies Inc	2770 Coventry Road, Oakville, Ontario Canada	www.virox.com	USA
Wave Energy Systems Inc.	216 Little Falls Road, Cedar Grove NJ 07009, USA; Phone: +1 201 857-1125		USA
Ecolab Co.	5105 Tomken Road, Mississauga, Ontario Canada	www.ecolab.com	Canada
Wyeth Animal Health	17300 Transcanada Hwy, Kirkland, Québec Canada H9J 2M5	www.wyeth.com	Canada
Borer Chemie AG	Gewerbestrasse 13, 4528 Zuchwil / Switzerland Tel +41 32 686 56 00 Fax +41 32 686 56 90	www.borer.ch	Switzerland
Dr. Weigert	Chemische Fabrik Dr. Weigert GmbH & Co. KG - Telefon: 040-789 60 - 0 – E-mail: info @drweigert.de Mühlenhagen 85, D – 20539 Hamburg Telefax: 040-789 60 -120	www.drweigert.de	Germany

Appendix C

Appendix C - Probes Electrical Safety

The endocavitary probes, produced by Esaote, are classified as Type BF applied parts. To ensure electrical safety both to the patient and the operator, it is necessary to check the physical integrity of the probe and to have the system correctly grounded.

It is important to check on a regular basis the electrical safety of probes used in semi-critical (such as endocavitary) applications, according to what 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.

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..

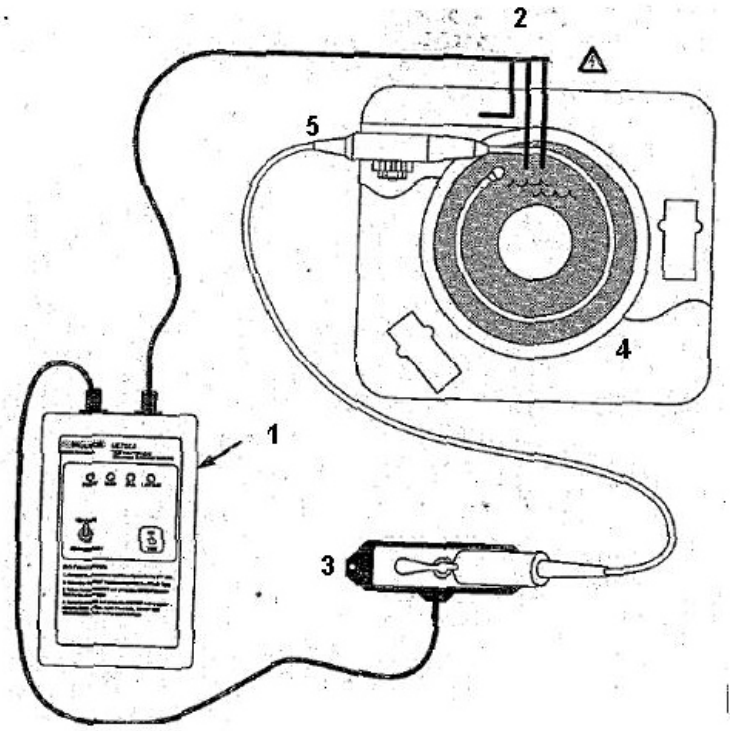
Do not immerse the probe cable or connector into water or other liquids. Immersion may compromise the electrical safety features. The probe can be inserted into water up to its Maximum Immersion Level. (See Appendix A).

Procedure

- Connect the probe to the adapter available on the measurement device.
- Turn the measurement device on and wait till it's 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 sensor
3: Probe adapter
4: Water tank filled with Cidex® or saline solution
5: Probe to be examined