



Rev. 02

July 2015

**ADDENDUM TO PROBES USER MANUALS FOR
VETERINARY**

350005250

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Introduction

This manual is an addendum to the “Transducers and Consumables” or “Probes and Consumables & ProbeAgents” manuals and provides information about the additional probes that can be used with the Esaote MyLabVET devices.

Always refer to the below mentioned manuals prior to use your MyLab system and probes:



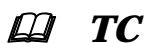
SS

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



GS

Carefully read the “Getting Started” manual: all system keys and their functions, clinical applications, cautions and warnings listed also apply to the use of these probes.



TC

Carefully read the “Transducers and Consumables” or “Probes and Consumables & ProbeAgents” manual: all care information, cleaning and disinfecting procedures, cautions and warnings listed also apply to the use of these probes.



PC &

ProbeAgents

Never refer exclusively to this addendum when operating with MyLab and the probes here described.

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.



GS

The MyLab systems have multiple configurations and feature sets. All are described in this user manual but not every option may apply to your system. Refer to “Getting Started” manual for configurations and feature sets available on specific MyLab model.

System features are dependent on your system configuration, transducer and exam type. Not all the system features are approved in all countries.

Keep this manual with the equipment for future reference.

1 - Probes Description



Refer to “Transducers and Consumables” or “Probes and Consumables” manual for information regarding handling, control, store and protect the probe and for its use.

WARNING

Do not use a probe if any damage to the probe has occurred.

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.

LV513, SV3513 and TL 5-10 Probes

LV513, SV3513 and **TL 5-10** are Linear Array probes dedicated for endorectal veterinary examinations. They are a Type BF part. As per directive EN60601-1, the probes must be physically intact and the system correctly grounded for the electrical safety of the patient and operator.

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 **LV513, SV3513** and **TL 5-10** probes incorporate a high frequency linear transducer for sagittal and transverse endorectal scanning. The **LV513, SV3513** and **TL 5-10** probes are also suitable for equine tendon examinations.

The probe is delivered with the following accessories:

- Storage case

Examination Safety

Endorectal 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 animal, 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 “Transducers and Consumables” or “Probes and Consumables” 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 animal. Protective sheaths DO NOT provide protection against such damages 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. DO NOT USE the probe if you know or suspect that it has been damaged.

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.

Preparation of the LV513, SV3513 and TL 5-10 Probe for Endorectal examinations
Follow the instructions below for preparing the probe for endorectal scanning.

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 endorectal 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. 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 endorectal 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).

- Apply a sufficient quantity of ultrasound gel inside the sheath.
- Completely unroll the sheath along the probe body and part of the cable, making it adhere in the lens area, so as to avoid air pockets.
- Secure the sheath if needed.
- To make it easier to insert the endorectal probe, use only water-based lubricating gel with the probe.

 **SS**

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

During the Endorectal Examination

WARNING

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

During the examination Esaote recommend the operator to:

- Clean the rectum of all faeces.
- Cover your arm with a plastic glove.
- Cover the probe handle with a disposable cloth during examinations in which the presence of pathogenic micro-organisms is suspected.
- Place the 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.

- Never force the probe during insertion or removal.

WARNING

Forced insertion or removal may wound the animal.

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 left or right or move the probe forwards or backwards to get another view.

Electric scalpels used during the examination may interfere with the 2D and 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.

At the End of the Examination

At the end of an endorectal examination with **LV513**, **SV3513** or **TL 5-10**, Esaote recommends the Operator to:

- Unplug the endorectal probe from the system.
- Wipe any residual ultrasound transmission gel off the probe with a soft cloth, then gently wipe the probe dry using a new tissue or dry cloth.
- If the probe is very dirty, scrub the probe with your hands with water or with water and mild detergent. Use a dampened soft cloth or towel. NEVER use any abrasive sponge.
- When using running water be sure you always have the probe tip pointing upwards and the cable downwards. Wipe the probe dry with a soft cloth or towel.
- Clean and disinfect the probe, according to the instructions provided in “Transducers and Consumables” or “Probes and Consumables” manual.
- Store the probe as indicated in “Transducers and Consumables” or “Probes and Consumables” manual.

WARNING

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 **LV513**, **SV3513** and **TL 5-10** probes:

- Autoclaving
- Soaking the probe in chlorine bleach

The **LV513**, **SV3513** and **TL 5-10** probes can be disinfected by using disinfection agents indicated in the next paragraph and according to 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 the "Transducers and Consumables" or "Probes and Consumables" manual. Make sure that the disinfecting fluid is not in contact with the connector and the connector grommet or can drip via the grommet into connector. Follow the disinfecting agents manufacturer's instruction for use.

2 - Probes 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.

WARNING

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.

Probe ID	LV513, SV3513	TL 5-10
Technology	Linear Array	Linear Array
Maximum immersion level	Up to 10 cm from transducer head	Up to connector
Type	BF	BF

Immersing the probes in liquid beyond to the **Maximum Immersion Level** can compromise the 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.

3 - Cleaning, Disinfection and Sterilization



Refer to “Transducers and Consumables” or “Probes and Consumables” manual for instructions to clean, disinfect and sterilize the probe.

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

The symbol “√√” means that the agent/system has been tested as both **chemical compatibility and biological efficacy** with the probe.

The symbol “√” means that the agent/system has been tested as **chemical compatibility** with the probe.

“N” means that the agent/system has been tested as **NOT compatible** with the probe.

The symbol “⊗” means **not tested**.

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



Refer to the “Transducers and Consumables” or “Probe and Consumables” manual for detailed information on how to clean, disinfect and sterilize the probes.

CAUTION

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

Note

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

WARNING

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

The tables in the next pages indicate which agents/systems have been positively tested for 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 the acoustic lens. Esaote takes no responsibility for damage caused by using non-approved products.

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

Overexposure to the disinfection fluid can damage the probe.

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

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

Cleaning Agents

	LV513, SV3513 TL 5-10
Accel RTU	√
Alkazyme	√
Anios Detergent Desinfectant	√
Asepti-Wipes II	√√
Cavicide	√√
Caviwipes	√√
CidezymeXTRA	√√
Cleanisept-wipes	√√
Cleanisept wipes forte	√√
Deconex 3- zyme	√
Enzol	√√
Gigazyme	√
Hexanios G+R	√
Klenzyme	√
Medi-Prep	√
Mediclean	√
Metrizyme	√√
Mikrozyd AF wipes	√√
Mikrozyd PAA wipes	√√
Mikrozyd sensitive wipes	√√
Milton	⊗
PerCept RTU	√
Prolystica	√
Protex wipes	√√
Salvanios	⊗
Sani-Cloth Active	√
Sani-Cloth HB	√√
Sani-Cloth Plus	√√
Sani-Cloth Super	√√
SaniZide plus	√√
Septi Wipes	⊗
Sono ultrasound wipes	√√
Trionic D	√√
T-Spray	√
T-Spray II	√
Transeptic	√
Tristel Duo	⊗
Tristel Sporocidal Wipes	⊗

	LV513, SV3513 TL 5-10
Virusolve +	√

Disinfection agents

	LV513, SV3513 TL 5-10
Anioxyde 1000	⊘
Cidex	√√
Cidex OPA	√√
Cidex Plus	√√
Compliance	⊘
Gigasept	√√
Gigasept AF	N
Gigasept FF	N
Korsolex extra	⊘
Metricide OPA	√√
Mikrobac tissues	√
Mikrozid Sensitive	√
Neodisher	⊘
NuCidex	√
Omnicide 14 NS	√√
Omnicide 28 NS	√√
Peraction	√√
Perasafe rely on	√√
Resert XL HLD	√√
Sekusept Aktiv	⊘
Ster-bac Blu	⊘
Steranios	√
Tristel Stella 5	⊘
Virkon	√
Wavicide-01	√

Disinfection systems

Follow the guidelines and recommendations of the manufacturer for the correct use of the system.

	LV513, SV3513 TL 5-10
Antigermix S1 (UV-C) ^a	√√
Trophon	√√

- a. The frequent use of Ultraviolet C (UVC) may cause a yellowing of the cable and of the plastic parts, though not compromising the safety and reliability of the probe.

Sterilization Systems

	LV513, SV3513	TL 5-10
Steris V Pro-1	√√	N
Sterrad 100S	√√	N
Sterrad 100NX	√√	N
Sterrad NX	√√	N