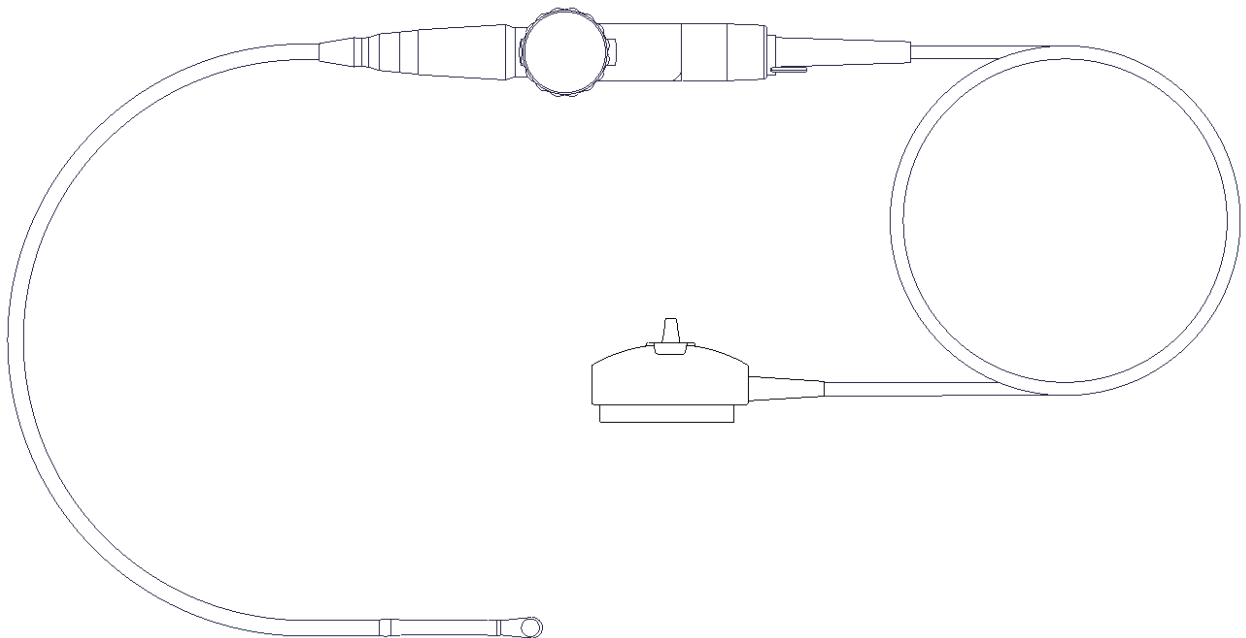




User Manual

Oldelft Motorized Multiplane TE Probes

Type numbers 171M-



WARNING / CAUTION



- Before using the equipment, carefully study this manual. Keep this manual at hand for quick reference. Reread it periodically for warnings, safety precautions and maintenance requirements.
 - **A damaged probe may cause an electrically hazardous condition when coupled to the human body.**
 - **Do not use a damaged probe.**
 - The multiplane TE probe is a precision instrument, which must be handled with care. It may be damaged when dropped or abused. In particular, do not allow the ultrasonic window in the tip to come into contact with a sharp object. Do not touch this window unnecessarily. Never exert force onto the window.
 - **Only a qualified physician who has received appropriate training should perform examinations with the probe.**
 - The connector is not watertight, and should always be kept dry. The control unit, although spray-watertight, should not be immersed.
 - **This equipment contains no operator serviceable components. To prevent electric shock, do not remove any covers or panels.**
 - **Inspect the probe for damage, cracks or bite-marks prior to each use.**
 - Before introducing the probe: do not rub or spray the tip of the probe with an anaesthetic agent.
 - **Please, do use the bite-guard, supplied with the probe.**
 - Only use water-based coupling gel.
 - As with all diagnostic ultrasound procedures keep exposure levels and duration to the minimum necessary for the examination, especially in the Doppler modes.
 - **Avoid forceful manipulations and excessive force in using the probe, which could result in patient injury.**
- Withdraw the probe only with the deflection control in the unlock mode and with the distal end of the probe straight.**
- Under normal conditions at full acoustic power the temperature of the tip does not exceed 43°C. Follow the instruction in this user manual to check this regularly.
 - **Clean and disinfect as described in this user manual.**
 - **Do not use methods not described in this user manual like Ethanol, Iodine, Steam, Heat or Ethylene Oxide.**
 - **The up/down and/or left/right deflection may after prolonged use develop an unwanted amount of free play. In that case, contact the service organization to re-adjust the steering of the probe. In this way, the risk of "buckling" or "U-turning" of the probe in the esophagus is minimized.**

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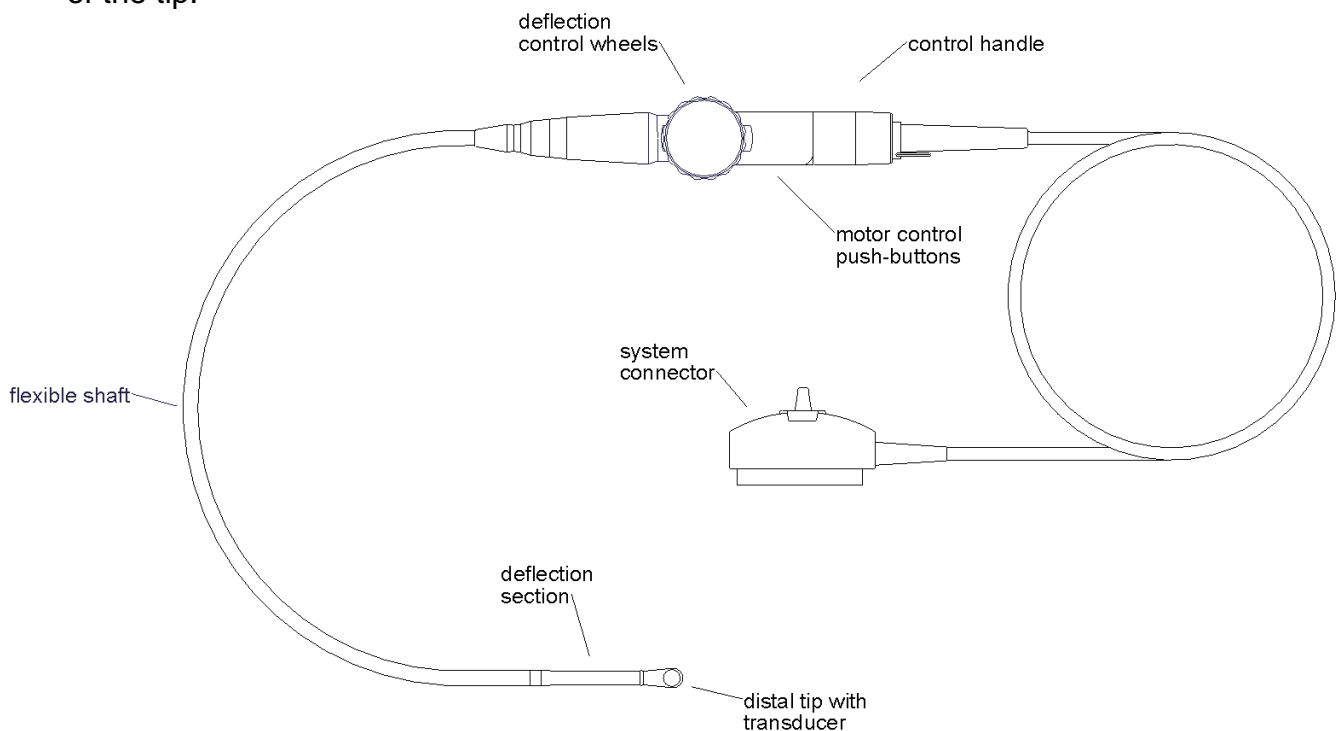
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1 Introduction


This document is written as such that it is conform the EN 1041:2008 standard.

1.1 Multiplane TE Probes

Oldelft manufactures several types of multiplane TE Probes with 32 - 64 elements, center frequency between 5 and 7MHz. All are phased array transducers, mounted in a sealed tip at the end of a gastroscope. The probes are intended for imaging of the heart through the esophagus and the stomach. The array can be rotated 180°. Scan plane rotation is controlled by two push-buttons on the control handle or via the ultrasound system. The deflection control wheels on the handle of the probe controls the deflection of the tip.



1.2 Intended use of the multiplane TE Probe.

WARNING  **The multiplane TE Probe should be used only by a qualified physician who has received appropriate training in proper operation of the probe and in endoscopic techniques as dictated by current relevant medical practices.**

The physician conducting the examination must exercise sound medical judgement in the selection of patients for this probe and be skilled in interpreting the data obtained from the examination with the multiplane TE Probe.

The probe can be used to form images of the heart to detect abnormalities, to evaluate the velocity of the blood flowing in the heart and to obtain a color depiction of the velocities of the blood flowing in the heart.

1.3 Intention of this manual

This manual gives the user all information necessary to guarantee a safe and satisfactory use of the multiplane TE Probe. It also describes how to handle the probe during all stages: before, during and after the examination.

2 Preparing the multiplane TE Probe for Use

2.1 Visual examination

Visually examine and feel all portions of the probe before use, especially the gastroscope shaft and the flexible section at the distal end of the gastroscope. Perform the inspection of the flexible section both with the probe deflection straight and deflected. There should be no discontinuities, bumps, dents, holes, abrasions, bite-marks or any other evidence of wear or damage found.

The hard plastic section at the distal end of the probe should be smooth and firmly attached to the gastroscope shaft.

The cable and the connector that attach the probe to the ultrasound console should be free from evidence of damage.

Check the proper mechanical operation of the probe. Rotate the scan plane with the push-buttons on the handle (see §3.2). Make sure that the rotation is smooth for all scan planes. Deflect the tip in both up/down and left/right direction using the deflection control wheel on the handle (see §3.2). Make sure the deflection operates smoothly.

Electrical Hazard **Any evidence of damage indicates the probe cannot be used and should be returned to Oldelft for evaluation and repair.**

2.2 Safety precautions

- a. The multiplane TE probe is a precision instrument, which must be handled with care. It may be damaged when dropped or abused.
In particular, do not allow the ultrasonic window in the tip to come into contact with a sharp object.
Do not touch this **window** unnecessarily. Never exert force onto the window.
- b. Only a qualified physician who has received appropriate training should perform examinations with the probe.
- c. The connector is not watertight, and should always be kept **dry**.
The control unit, although spray-watertight, should not be immersed.
- d. This equipment contains no operator serviceable components.
To prevent electric shock, do not remove any covers or panels.
- e. Before introducing the probe: **do not rub or spray** the tip of the probe with an **anaesthetic agent**.
- f. Avoid forceful manipulations and excessive force in using the probe, which could result in patient injury.
- g. Withdraw the probe only with the deflection control in the unlock mode and with the distal end of the probe straight.
- h. Never manually deflect the distal tip of the probe; use only the deflection control wheels.
- i. Do not kink, tightly coil, or apply excessive force on the probe cable or shaft.
Insulation failure may result.
- j. Under normal conditions at full acoustic power the temperature of the tip does not exceed 43°C. To check that the temperature increase of the tip is within limits:
 - Connect the probe to the Ultrasound system.
 - Adjust the Acoustic Power to the highest value possible.
 - Select Color Doppler mode.
 - Wait for 2 minutes.
 - Feel at the distal end of the probe if there is a relevant temperature increase, which could be harmful for the patient.

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|------------------------------------------|
| <input type="radio"/> Daily |
| <input type="radio"/> Weekly |
| <input checked="" type="radio"/> Monthly |
| <input type="radio"/> Other |

2.3 Preparation for Use

Inspect the probe as described in §2.1.

Clean and disinfect the probe and the bite-guard as described in §4.

Make sure the system connector is plugged into the Ultrasound system and is locked by means of the locking handle on the connector.

For patient protection a sterile, single-use, latex sheath can be used.

CAUTION



Ensure that the sheath's sterile surface is maintained.

Devices containing latex may cause severe allergic reaction in latex sensitive individuals. Refer to FDA's March 29, 1991, "Medical Alert on Latex Products".

Place the bite guard on the probe so that after insertion of the probe the bite guard can easily be placed in the patient's mouth. The bite guard can also be placed in the patient's mouth before inserting the probe.

WARNING



The use of a bite-guard is mandatory. Failure to use the bite-guard may result in damage to the probe, which could result in a safety hazard. Damage to the probe due to biting is not covered by the probe's warranty.

Apply a sufficient amount of water-soluble acoustic coupling gel on the probe acoustic window.

CAUTION



Only use water-soluble acoustic coupling gel. Other coupling gels containing ingredients like ethanol, mineral oil, Iodine, lotions, lanolin, aloe vera or methyl or ethyl parabenzoic acid can cause probe damage.

If used, place the latex sheath over the probe and gastroscop shaft up to but not covering the handle. Rub the tip carefully to ensure that all air bubbles have been removed from the probe's acoustic window area. In addition to the gel on the acoustic window, apply a sufficient amount of acoustic coupling gel on the outside of the sheath at the tip of the probe.

CAUTION



Do not exert force on the window area.

3 Use of the multiplane TE Probe

3.1 Patient selection

Although the multiplane TE probe can provide clinical data not available from other instruments, there are some considerations to be made in patient selection for safe use of the probe.

CAUTION



The ability of a patient to swallow or accommodate the probe should be considered.

Any history of gastro-esophageal diseases must be determined and considered as well as the possible effects of other therapies the patient is undergoing.

All gastro-esophageal abnormalities must be considered as well.

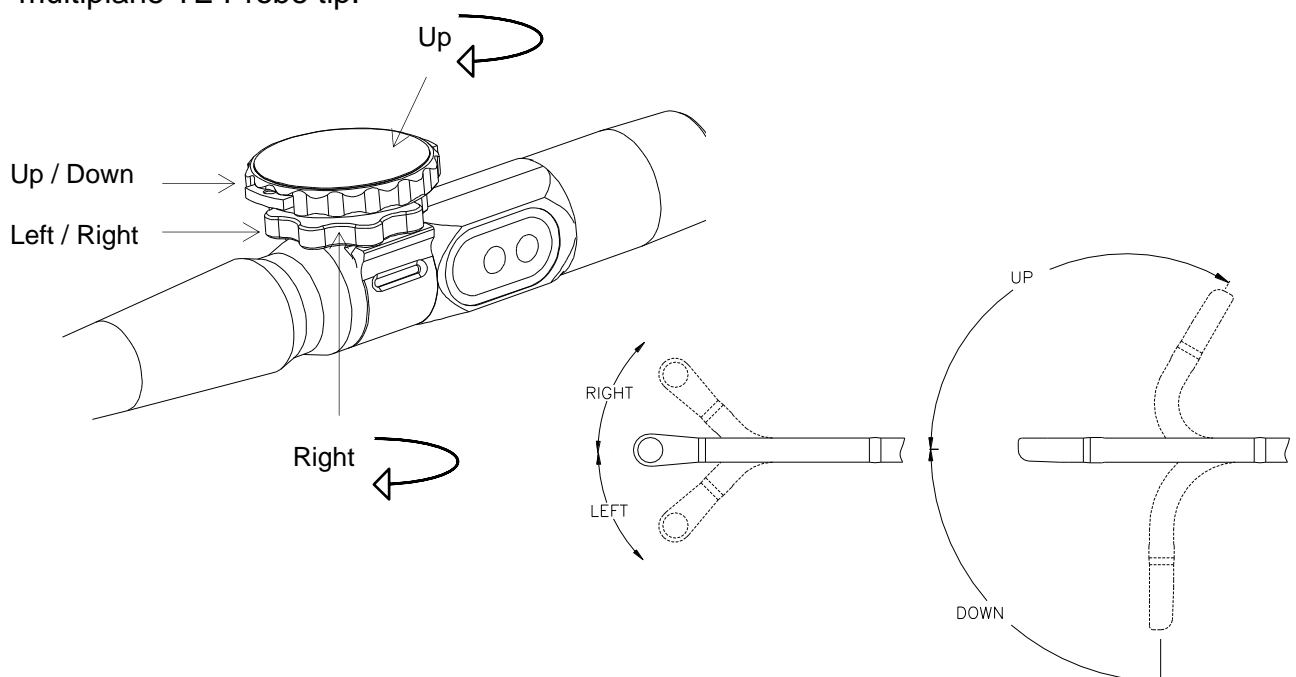
3.2 Deflection and scan plane rotation control

The control handle is designed for one-hand operation. Normally the operator takes the control handle in his left hand. Thumb, first and second fingers control the deflection control wheels and scan plane rotation push-buttons.

The smallest wheel on the handle is for controlling the probe left/right tip deflection. The largest wheel on the handle is for controlling the probe up/down tip deflection. Both wheels have a locked and freely moving mode. In the locked mode the movement of the deflection wheel is restrained. This is used to hold the tip in a certain position. A metallic ring around the body of the handle, which clicks on/off, controls the lock of the left/right tip deflection. A shifting bar in the largest knob controls the lock of the up/down tip deflection.

Tip deflection control

The deflection control wheels found on the handle of the probe control deflection of the multiplane TE Probe tip.



Tip deflection control

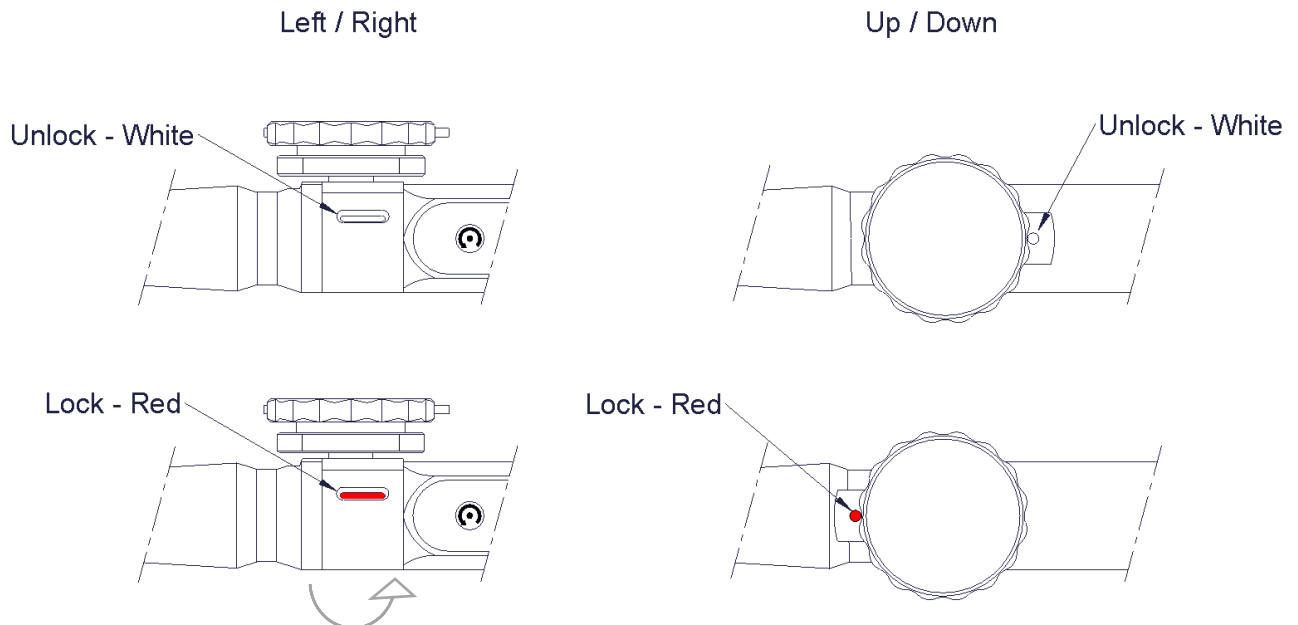
WARNING



Check if the maximum deflection of the tip is 90° to 120° upward, 60° to 90° downwards and 30° to 45° left/right. If the deflection shows an unwanted amount of free play or exceeds the maximal deflection angles given above, do not use the probe. Contact the service organization to re-adjust the steering of the probe. In this way, the risk of "buckling" or "U-turning" of the probe in the esophagus is minimized.

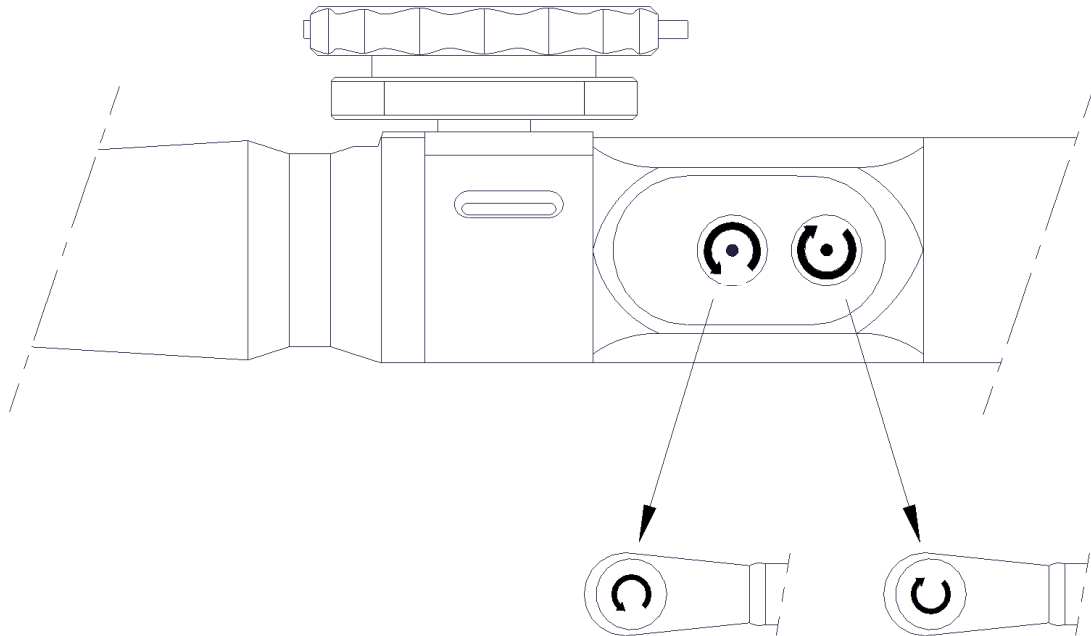
Lock operation

To protect the patient and the probe, unlock the deflection controls when inserting or withdrawing the probe.



3.3 Transducer scan plane rotation control

The transducer scan plane can be rotated from 0° (transversal plane) via 90° (longitudinal plane) to 180° (transversal plane, left/right inverted). All planes in between can also be chosen. This makes it possible to scan a conical imaging volume



3.4 Examination

The actual examination with the multiplane TE Probe is beyond the scope of this manual. There are many medical articles and books, which very thoroughly address this topic. There are however specific cautions that should be considered.

CAUTION



Long-term exposure to ultrasound should be minimized. Although there have been no confirmed adverse effects produced by diagnostic levels of ultrasound, unnecessary patient exposure to ultrasound energy should be avoided, especially in the Doppler mode.

Prolonged pressure on the esophagus by the tip of the probe may lead to a Pressure Necrosis phenomenon. Thus in monitoring applications the tip should be removed from the esophagus wall when you are not scanning by releasing it in the neutral position. If continuous monitoring is required, the probe tip should often be re-positioned.

Whenever active scanning is not desired 'freeze' the image and release the deflection control.

Position the array such, that good acoustical contact is made. Before rotating the array, actuate the friction ('brake') on the up/down movement. If this is not done, rotating the array can mean loss of acoustical contact!

4 Cleaning and disinfecting the multiplane TE Probe

Biological Hazard

Adequate cleaning and, if necessary disinfection are carried out to prevent disease transmission. It is the responsibility of the user to verify and maintain the effectiveness of the procedure used. A single-use, sterile disposable sheath for TE purposes can be used.

CAUTION



Keep the control handle and system connector out of any cleaning or disinfection solutions. The control handle and cable may be cleaned with a damp cloth, but only the distal end of the probe up to the 100cm marker on the shaft may be placed into a disinfection solution.

- | |
|----------------------------------------|
| <input type="radio"/> Daily |
| <input type="radio"/> Weekly |
| <input type="radio"/> Monthly |
| <input checked="" type="radio"/> Other |
| After each use |

For approved cleaning and disinfection agents, visit www.oldelft.com.

4.1 Manual cleaning

Sterile purified lukewarm water shall be used (maximum 26°C), unless otherwise stated by the cleaner manufacturer.

Perform the following steps, unless otherwise stated by the manufacturer of the selected cleaning agent:

1. Rinse the soiled probe (1 minute).
2. Soak the probe as prescribed by the manufacturer of the cleaning agent. Take care that only the distal end up to the 100cm marker is immersed.
3. Gently scrub the probe using a soft-bristled brush (or wipes).
4. Rinse the probe for at least one 1 minute until there is no sign of blood or soil.
5. Dry the probe by means of a dry sterile wipe.

CAUTION



Do not clean any portion of the probe with methanol or ethanol. Such substance can cause irreparable damage to the probe.

4.2 Automated cleaning

Sterile purified lukewarm water shall be used (maximum 26°C), unless otherwise stated by the cleaner manufacturer.

Before running automated cleaning, residual debris should be removed by immersing the used products in lukewarm water for 1 minute while removing coarse contamination with a fine, soft nylon brush or wipe. Take care that only the distal end up to the 100cm marker is immersed.


Automated cleaning shall be performed in accordance with the instructions of the manufacturer of the cleaning agent and automated cleaner, using a validated cleaning cycle. Only the distal end of the TE probe shall be placed in the automated cleaner.

4.3 Manual disinfection

Sterile purified lukewarm water shall be used (maximum 26°C), unless otherwise stated by the manufacturer of the disinfection agent.

Perform the following steps, unless otherwise stated by the manufacturer of the disinfection agent:

1. Rinse the contaminated probe for at least one 1 minute.
2. Soak the probe for 12 minutes (or spray the probe if prescribed by the manufacturer of the disinfectant). Take care that only the distal end up to the 100cm marker is immersed.
3. Gently wipe the probe.
4. Rinse the probe for at least one 1 minute.
5. Dry the probe by means of a dry sterile wipe.

CAUTION  The probe should never be left in the disinfection solution for more than 1 hour.
Do not forget to rinse the probe directly after disinfection.

4.4 Automated disinfection

Automated disinfection shall be performed in accordance with the instructions of the manufacturer of the disinfection agent and automated disinfectant / reprocessor, using a validated disinfection cycle for thermo-labile products.

The maximum allowable temperature is 50°C using peracetic acid based sanitizing solutions. Only the distal end of the TE probe shall be placed in the automated disinfectant / reprocessor.

4.5 Tristel Trio Wipes system

Cleaning and disinfection of the probe using the Tristel Trio Wipes system shall be performed in accordance with the instruction supplied with the wipes, except for the duration of the disinfection.

To obtain high level disinfection the duration of the disinfection step should be increased to 60s.

Take care that only the distal end up to the 100cm marker is exposed to the wipes.

WARNING  **Do not use other disinfection methods like Iodine, Steam, Heat or Ethylene Oxide.**

5 Labeling

The device should be labeled by our customer in such way that the labeling includes the following items. Preferably the symbols used are conform the EN 980.

- CE mark of the vendor
- Reference to the Instruction for use
- Serial number
- Catalog number
- Date Of Manufacture
- Manufacturer
- BF applied part symbol
- Warning symbol

6 Storing the multiplane TE Probe

The multiplane TE Probe is a sensitive and expensive instrument. Use great care when storing the probe. Make sure the probe is adequately cleaned and disinfected prior to storage.

The probe can be stored in its original case.

WARNING



Avoid damage to the probe by allowing nothing to protrude beyond the case when closing the lid.

A wall mounted probe hanger can also be used for storage. Make sure the probe control handle, cable and connector are adequately supported. The shaft should hang down freely.

The storage environmental conditions must fall within the following range:

- Temperature between -25°C and 55°C .
- Humidity between 5% and 95%, non-condensing.

7 Specifications

The probe has been designed to take into account all relevant provisions of the European Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC. The probe is categorized in Class IIa.

The probe is classified according to IEC 60601-1 as class I, type BF, defibrillator-proof.

Motorized Multiplane	
Mechanical dimension	171M-
» Shaft external diameter	11.2 mm
» Shaft length	100 cm
» Probe tip width	14.3 mm
» Probe tip height	10.6 mm
» Probe tip length	30.6 mm

Transducer	
» Center frequency	5.0 MHz
» Type	phased array
» Number of elements	64
» Aperture	9 mm
» Focus	50 mm

Scan plane rotation	» minimum 180°
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Tip deflection	
» Up	120° + 10°
» Down	90° + 10°
» Left	45° + 5°
» Right	45° + 5°

Leakage current / dielectric strength	» Meet the requirements of IEC 60601
----------------------------------------------	--------------------------------------

Biocompatibility	» All materials used in the patient applied part meet the requirements of ISO 10993
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Environmental requirements	
» Operating temperature	0°C to 45°C
» Storage temperature	-25°C to 55°C
» Relative humidity	5 to 95%, non-condensing

8 Annex A. Whom to Contact.

8.1.1.1.1.1.1.1 Manufacturer

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