



User Manual

Oldelft Motorized Multiplane TE Probes

Type numbers 19xM-

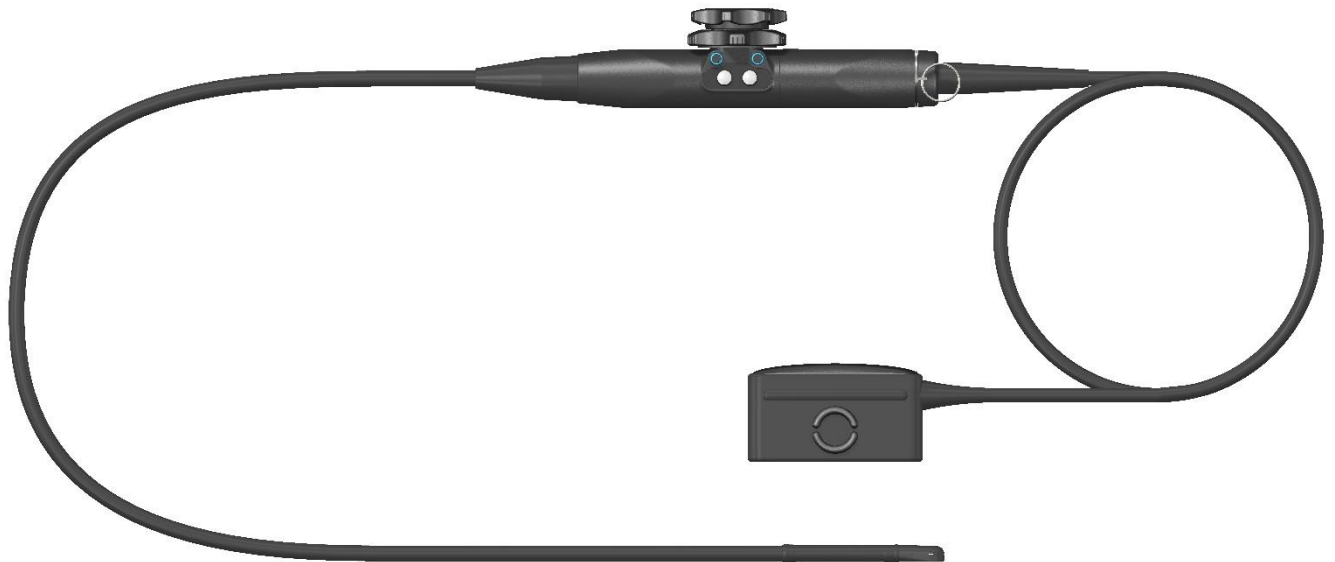


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1. Introduction

This document is written as such that it is conform the EN 1041:2008 standard. Before using the equipment, carefully study this manual. Keep this manual at hand for quick reference. Reread periodically for warnings, safety precautions and maintenance requirements.

1.1. Scope

This manual is applicable for Oldelft Multiplane TE probes with part numbers in the 19xM- range. These probes have 64 elements and center frequency around 5 MHz. 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 articulation of the tip is controlled by rotary knobs on the handle of the probe.

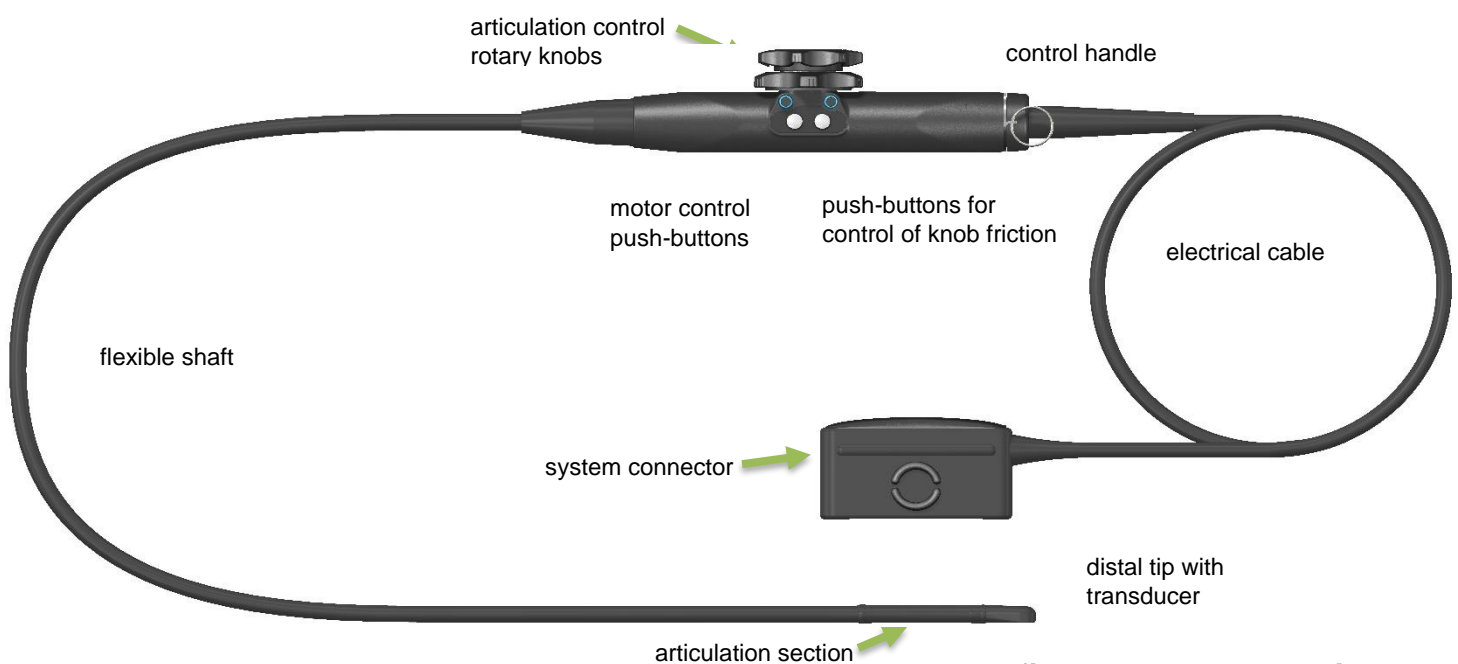



figure 1. probe overview

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

The rigid tip at the distal end of the probe should be smooth and firmly attached to the gastroscope.

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

2.2. Functional examination

Check the proper mechanical operation of the probe. Rotate the scan plane with the push-buttons on the handle. Make sure that the rotation is smooth. Articulate the tip in both up/down and left/right direction using the rotary knobs on the handle. Make sure the articulation operates smoothly.

Electrical
Hazard



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

2.3. 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 keep sharp objects away from the acoustic window. Do not touch this window unnecessarily. Never exert force onto the window.
- b) Do not use a damaged probe. A damaged probe may cause an electrically hazardous condition when coupled to the human body. Inspect the probe for damage, cracks or bite-marks prior to each use.
- c) To avoid the risk of electric shock, this equipment must only be connected to a supply with protective earth.
- d) Only a qualified physician who has received appropriate training should perform examinations with the probe.
- e) The connector is not watertight, and should always be kept dry. The control handle, although spray-watertight, should not be immersed.
- f) This equipment contains no operator serviceable components. To prevent electric shock, do not remove any covers or panels.
- g) Never rub or spray the tip of the probe with an anesthetic agent.
- h) Avoid forceful manipulations and excessive force in using the probe, which could result in patient injury.
- i) Use a bite guard to prevent damage to the probe by the patients teeth.
- j) Only use water-based coupling gel.
- k) Withdraw the probe only with the friction deactivated and with the articulating section straight.
- l) Never manually articulate the distal tip of the probe directly; always use the articulation controlling rotary knobs.
- m) Do not kink, tightly coil, or apply excessive force on the probe cable or shaft. Insulation failure may result.
- n) The up/down and/or left/right articulation may after prolonged use develop an unwanted amount of free play. In that case, contact the service organization to re-adjust the articulation of the probe. This way, the risk of "buckling" or "U-turning" of the probe inside the esophagus is minimized.
- o) As with all diagnostic ultrasound procedures keep exposure levels and duration to the minimum necessary for the examination, especially in the Doppler modes.
- p) 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.
- q) 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:

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

- 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.

2.4. Preparation for use

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

Inspect the probe as described in §2.1 and §2.2.

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

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 para benzoic acid can cause probe damage.

If used, place the latex sheath over the probe and gastroscope 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.

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. Introduction and withdrawal of the probe

To protect the patient and the probe, unlock the knob friction on both knobs when introducing or withdrawing the probe and make sure the articulating section is straight.

3.3. Articulation and scan plane rotation control

The handle is designed for one-hand operation. Thumb, first and second fingers control the articulation controlling rotary knobs and scan plane rotating push-buttons.

Tip articulation control

The rotary knobs found on the handle of the probe, control the articulation of the TE probe tip. The smallest rotary knob on the handle is for controlling the probe left/right tip articulation. The largest rotary knob on the handle is for controlling the probe up/down tip articulation. When rotating the knob a click is felt at the central position, indicating the tip is in a straight position (no articulation).

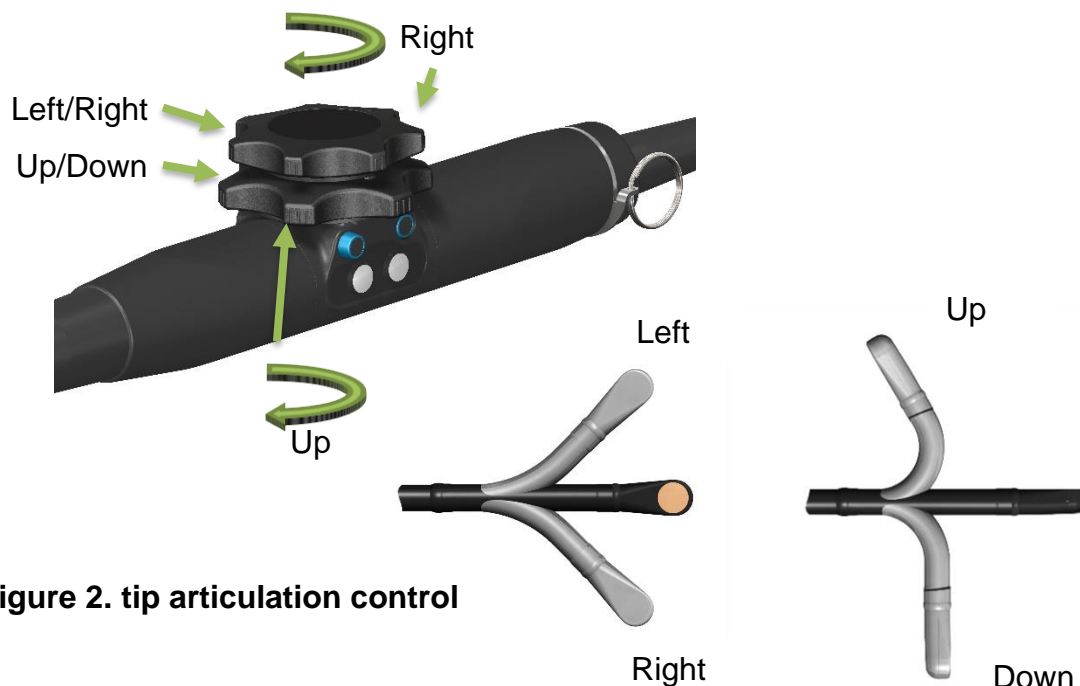


figure 2. tip articulation control

WARNING



Check if the articulation of the tip is according specifications. If the articulation shows an unwanted amount of free play or exceeds the maximal articulation angles, 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 articulating section in the esophagus is minimized.

Knob friction ('brake') operation

Both rotary knobs have a freely moving mode and a mode where the knobs have friction. In the friction mode the movement of the articulation rotary knob is restrained. This can be used to hold the articulation in a certain position. The push buttons directly underneath the rotary knobs, control the friction function for the tip articulation.

If the sliding bar shows blue¹ as depicted in the left picture below the friction is active. The sliding bar on the distal end (where the tip is) controls the friction of the left/right articulation (smallest rotary knob, upper), while the sliding bar on the proximal end (where the connector is) controls the friction of the up/down articulation (largest knob, closest to the handle).

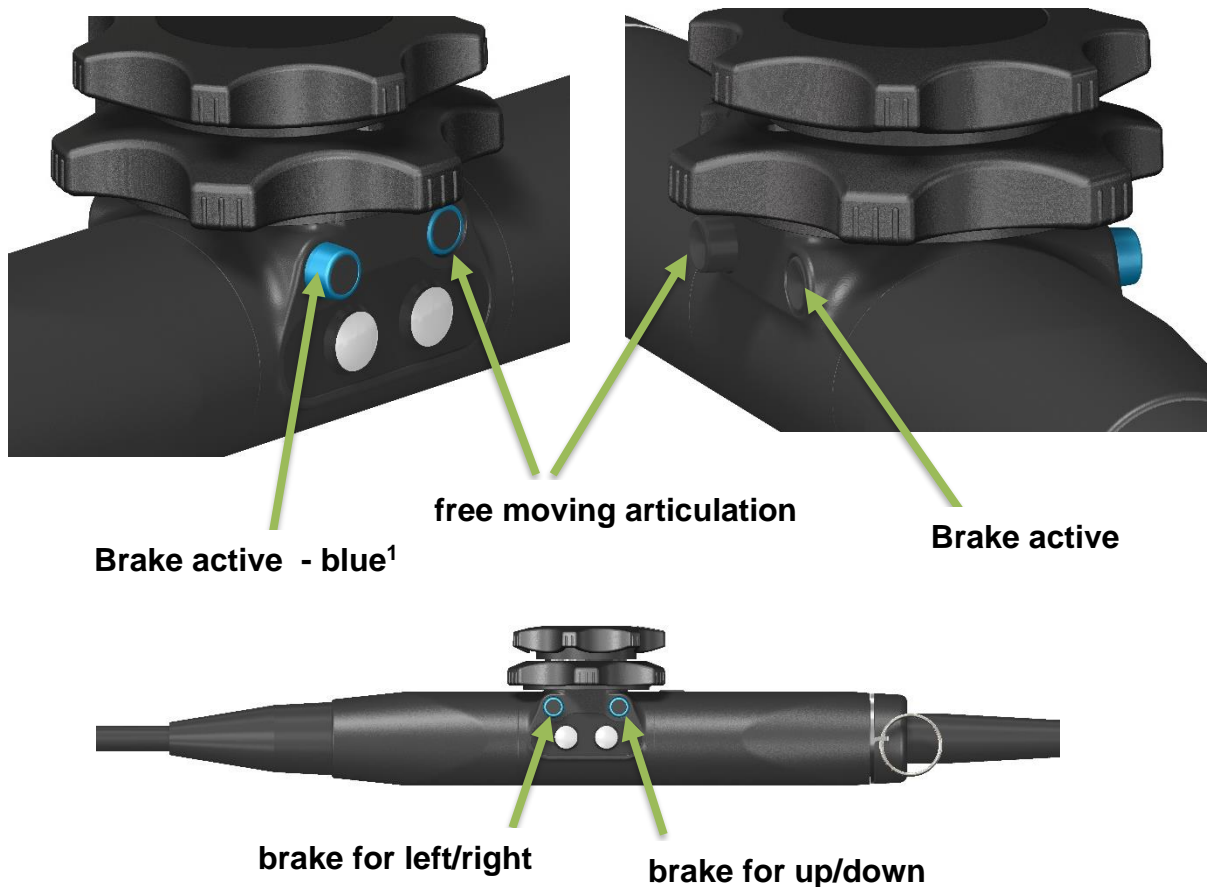


figure 3. function of brake control buttons

¹ The color can be different, depending on the probe type.

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.

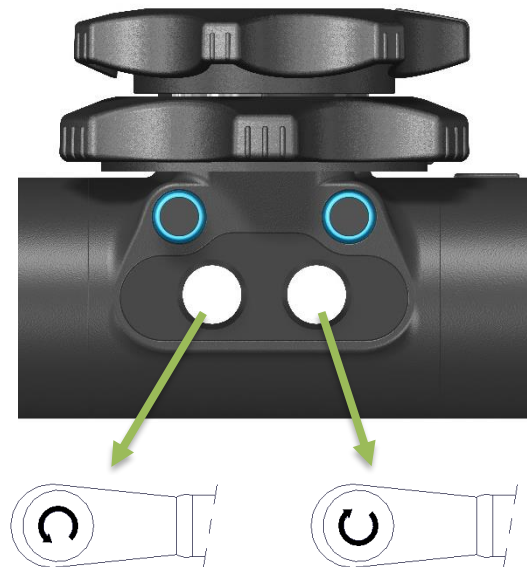


figure 4. function of the motor control buttons

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 articulation control.

Position the array such, that good acoustical contact is established. 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.

- Daily
- Weekly
- Monthly
- Other

After each use

Probe cleaning

- a. Clean the tip and flexible shaft with gauze pads soaked in mild soapy lukewarm water (below 26°C is recommended). For other authorized cleaning agents, see Oldelft's website (www.oldelft.com).
- b. Remove any materials that could interfere with the disinfection procedure.
- c. Rinse the distal tip and shaft with lukewarm water, in which one can hold one's hand without pain. Proceed until all visible soap residue has been removed.

CAUTION



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

- d. Air-dry or dry with a soft cloth.

Probe disinfection

When necessary, ultrasound probes can be disinfected using liquid chemical germicides. For authorized disinfection liquids which have been tested for compatibility with the materials used to construct the probe, see Oldelft's website (www.oldelft.com). Follow the disinfectant manufacturer's recommendations for solution preparation, immersion time and rinsing.

- e. Place the cleaned and dried probe surface in contact with the disinfection solution. Take care that only the distal end up to the 100cm marker is immersed.
- f. Rinse the probe tip and shaft with water and dry prior to storage.

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.

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. Furthermore the labelling for products marketed in the USA should comply to UDI regulations.

- 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	19xM-
» 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
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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

Annex A. Whom to Contact

Manufacturer

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Heertjeslaan 10,
2629 JG Delft,
The Netherlands.

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