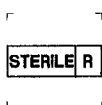




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Instruction sheet for sterile disposable ultrasound probes, for invasive application

CE 0123



The ultrasound probes will be delivered in sterile packages



The ultrasound probes are one-way products and are not allowed to be recycled. A recycled ultrasound probe cannot guarantee the security regarding cleanliness and sterility, mechanical integrity and electrical security.

Intended use of the ultrasound probes:

The ultrasound probes are intended to measure blood flow in small vessels at different positions on/in the body. As a medical class III product, the heart, the central circulatory system as well as the central nervous system are not excluded from application. The primary application lies in recording the hemodynamics in the vessels providing the brain.

Warning: the ultrasound probes are not for intravascular use.
The insertion of the ultrasound probe in a vessel could have catastrophic consequences for the patient.

The ultrasound probes may only be used by appropriate qualified doctors.

It is at the discretion of the doctor to decide about the use of the ultrasound probe. A complementary use with angiographic methods should be considered.

The ultrasound probes may be used wherever the blood flow in a small, superficial, operational exposed or endoscopic accessible vessels has to be determined. For that matter the probe will be brought in contact with the outside of the vessel wall or the tissue located above it. It is important to apply gentle pressure only. To avoid injuries the vessel must not be pressured too intense.

The application time is usually a couple of minutes in the maximum. Accumulated the application time does not exceed 20 minutes (short time application according to EN/ISO 10993-1).

Contraindications are not known so far.

Side effects are not known to this day.

Furthermore the following points have to be considered:


- **The sterile disposable ultrasound probes are manufactured for a certain device or a certain equipment group and must only be used with those. Information regarding use is included in the manual of the Doppler device. The ultrasound probes are only functional in connection with the Doppler device. The performance data for the Doppler measurements is to be taken from the manual of the Doppler device.**
- **Attention should be paid to all safety regulations specified in the manual of the Doppler device, in particular the implementation of the required insulation voltage. The ultrasound probes must only be used with a certified safety transformer.**
- **this type of ultrasound probe is manufactured for intra operative applications for single use and will be delivered in a sterile package.**
- **The functionality can be tested by dipping the probe in some liquid (e.g. sterile saline solution). On the devices the characteristic acoustic and optical signals have to appear. A calibration of the probe is not necessary. If the characteristic acoustic or optical signals do not appear or are too low, the probe must not be used. In this case the configurations of the Doppler device have to be checked. The procedure has to be repeated with a new probe. The probe without satisfactory function is to be returned to the manufacturer accompanied by a description of the problem.**
- **The accuracy of the measurements depends on the Doppler device. The accuracy of the measurements cannot be specified for the probe only.**
- **Strong electromagnetic fields (e.g. created by electrocautery) can interfere with measurements. Those interferences can be clearly detected as such. A misinterpretation of the measurements is therefore excluded. By disappearance of the interferences (e.g. switching off the electrocautery) the measurements work perfectly again.**
- **Performance data: the ultrasound doppler probes are pure physical measuring probes. The technical data of the 16MHz and 20MHz probes are described on page 4 of this information sheet. Performance data regarding the measurements are described in the manual of the Doppler device.**
- **Ultrasound probes are high precision, sensitive electromechanical components and are to be handled appropriately.**
- **The tip of the probe is particularly sensitive. This applies for a length of 10mm measured from the tip. This area must not be bended, folded or preassured. Caution is demanded if the tip is hold with a tweezer.**
- **Storage/Life period: The life period is indicated on the package. The indicated expiration date is valid as long as the products are stored properly in designated locations with the following environmental conditions: Temperature 18°C to 25°C, rel. humidity 40% to 70%.**
- **The sterility of the ultrasound probe is no longer guaranteed if the sterile package is damaged. Thus the probe must not be used anymore and must be disposed of.**
- **Ultrasound probes contain a small amount of lead. They have to be disposed of properly as hazardous waste.**

Technical data 16MHz-Version

Article no.:	02.0004.1601.02
Type of probe:	PW probe for invasive application
Frequency:	16MHz
Active diameter:	0.8mm
Outer diameter:	1.3mm (Tube diameter)
Length:	2.5m
Tube material:	PEBAX blue, USP class VI
Cover:	Epoxy black, USP class VI
Cable:	Koax caable, 50 Ohm, OD 0.45mm, length 2.5m
Connector:	2.5mm phone jack connector stereo, with protective sleeve
Measurement range:	0 to 8mm
Sound field:	unfocussed
Impedance (at connector):	25 Ohm +/- 10 Ohm, Phase 45° +/- 20°
Frequency range:	16MHz +/- 5%
Bandwidth:	> 3MHz
Sensibility:	> -26dB (insertion loss)

Technical data 20MHz-Version

Article no.:	02.0004.2001.02
Type of probe:	PW probe for invasive application
Frequency:	20MHz
Active diameter:	0.8mm
Outer diameter:	1.3mm (Tube diameter)
Length:	2.5m
Tube material:	PEBAX blue, USP class VI
Cover:	Epoxy black, USP class VI
Cable:	Koax cable, 50 Ohm, OD 0.45mm, length 2.5m
Connector:	2.5mm phone jack connector stereo, with protective sleeve
Measurement range:	0 to 8mm
Sound field:	unfocussed
Impedance (at connector):	35 Ohm +/- 10 Ohm, Phase 50° +/- 20°
Frequency range:	20MHz +/- 5%
Bandwith:	> 3MHz
Sensibility:	> -26dB (insertion loss)











 Remark: the specified data correspond to today's development status of the products and may be modified by MTB at any time.

- Below is a summary of the most important points to bear in mind regarding the handling :

The probes must:

- not be dropped
- not be crushed
- not be bended strongly (minimal bending radius = 15 mm) or folded
- not be dipped in liquid over a longer period (>15 minutes)
- not be heated over 60 °C
- not be exposed to cold (under 0°C)
- not to be exposed to solvent
- not to be exposed to high humidity (over 90% rel. humidity) over a longer period (> 1 hour)
- not to be used over a longer period of time without connection to tissue (danger of overheating)

The symbols below are used in connection with the ultrasound doppler probes:

<u>Symbol:</u>	<u>Explanation:</u>
	„CONFORMITÉ EUROPÉENNE. THE APPLICABLE REQUIREMENTS OF THE EUROPEAN DIRECTIVE MDD 93/42/EEC ARE FULFILLED“
	„NOT FOR REUSE“
	„IDENTIFICATION“
	„SERIAL NUMBER“
	„STERILE“, „RADIATION STERILISATION“
	„DATE OF MANUFACTURE“
	„PURCHASE ORDER NUMBER“
	„WARNING“ (Pay attention to additional accompanying documents of the Doppler device)
	„MANUFACTURER“
	„USABLE UNTIL“

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