



MEDIZINTECHNIK BASLER AG
 Lindauerstrasse 15
 CH-8317 Tagelswangen
 Switzerland
 Phone 0041 44 884 06 00
 Fax 0041 44 884 06 10
 Email info@mtb-sonic.com

Leaflet for sterile disposable ultrasound probes for invasive applications

CE 0123



The ultrasound probes will be delivered in sterile packages



The ultrasound probes are single use products and are not intended to be reprocessed. A reprocessed ultrasound probe may pose a high-risk regarding cleanliness and sterility, mechanical integrity and electrical safety for the patient and the user.

1. Intended use of the ultrasound probes:

The ultrasound probes are intended to measure blood flow in small vessels at different locations 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 the application. However, the primary application is the assessment of the cerebral blood supply.

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

The ultrasound probes may be used whenever the blood flow in a small, superficial, surgically exposed or endoscopically accessible vessels must be assessed. For this purpose, 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 only light pressure to avoid injuries of the delicate vessels.

The application time is usually limited to a couple of minutes. Accumulated, the application time does not exceed 20 minutes per patient (Limited Contact Duration according to EN/ISO 10993-1).

Contraindications are not known so far.

Side effects are currently not unknown.

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	Datum	Initialen	Datum	Initialen	Datum	Initialen	Version/Revision
Erste	17.10.2014	BA	17.10.2014	BA	17.10.2014	BA	2.00
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Furthermore, the following points have to be considered:

Electrical Safety: The Doppler device must be fitted with an insulation of 2 MOPPs!

The Amplitude of the transmit signal must not exceed $30V_{RMS}$!

- The sterile single use ultrasound probes are manufactured for a certain Doppler device or a certain group of devices and must be used with those only. Information regarding the use is included in the manual of the Doppler device. The ultrasound probes are only operative when connected to a Doppler device. The performance data for the Doppler measurements is given in the manual of the Doppler device.
- Attention must 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 designed and manufactured for single use invasive applications and is delivered in a sterile package.
- The functionality can be tested by dipping the probe into liquid (e.g. sterile saline solution). The Doppler device must show the characteristic acoustic and optical signals. A calibration of the probe is not necessary. In case the characteristic acoustic or optical signals do not appear or are too weak, the probe must not be used. In this case the configuration of the Doppler device has 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 alone.
- 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. Eliminating the interferences (e.g. switching off the electrocautery) the measurements will work perfectly again.
- Performance data: the ultrasound doppler probes are pure physical measurement devices. The technical data of the 16MHz and 20MHz probes are given on page 3 of this leaflet. Performance data regarding the measurements are given in the manual of the Doppler device.
- Ultrasound probes are high precision, delicate electromechanical devices and are to be handled with appropriate care.
- The tip of the probe is particularly delicate. This applies for a length of 10mm measured from the tip. This area must not be bended, folded or squeezed. Special caution is required if the tip is held with a tweezer.
- Storage/Lifespan: The lifespan is indicated on the package ("use by date"). The indicated expiration date is valid provided that the products are properly stored 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. In this case the probe must not be used anymore and must be disposed of.
- Ultrasound probes contain a small amount of lead. They must be disposed of as hazardous waste.

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2. 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:	Coax 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):	25 Ohm +/- 10 Ohm, Phase 45° +/- 20°
Frequency range:	16MHz +/- 5%
Bandwidth:	> 3MHz
Sensibility:	> -26dB (insertion loss)

3. 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:	Coax 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%
Bandwidth:	> 3MHz
Sensibility:	> -26dB (insertion loss)



Note: the specification corresponds to the current state of development of the products and can be changed by MTB at any time.

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Protocol: Leaflet for Sterile Single Use Probes

- Below is a summary of the most important issues to keep in mind regarding the handling of the probes:

The probes must:

- not be dropped
- not be crushed
- not be bended (minimal bending radius = 15 mm) or folded
- not be immersed in liquids for a longer period (>15 minutes)
- not be exposed to temperatures exceeding 60 °C
- not be exposed to cold (below 0 °C)
- not to be exposed to solvents
- not to be exposed to high humidity (exceeding 90% rel. humidity) for a longer period (> 1 hour)
- not to be operated for a long period of time without being coupled to tissue (danger of damage due to overheating)

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

Symbol:

Explanation:



„CONFORMITÉ EUROPÉENNE. THE APPLICABLE REQUIREMENTS OF THE EUROPEAN DIRECTIVE MDD 93/42/EEC ARE FULFILLED“



„NOT FOR RE-USE“



„BATCH CODE“



„SERIAL NUMBER“



„STERILE“, „STERILIZED USING IRRADIATION“



„DATE OF MANUFACTURE“



„CATALOG NUMBER“



„CAUTION“ (Pay attention to additional accompanying documents of the Doppler device)



„MANUFACTURER“



„USE BY DATE“

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	Datum	Initialen	Datum	Initialen	Datum	Initialen	Version.Revision	BA.doc
Erste	17.10.2014	BA	17.10.2014	BA	17.10.2014	BA	Copyright by	Medizintechnik Basler AG
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