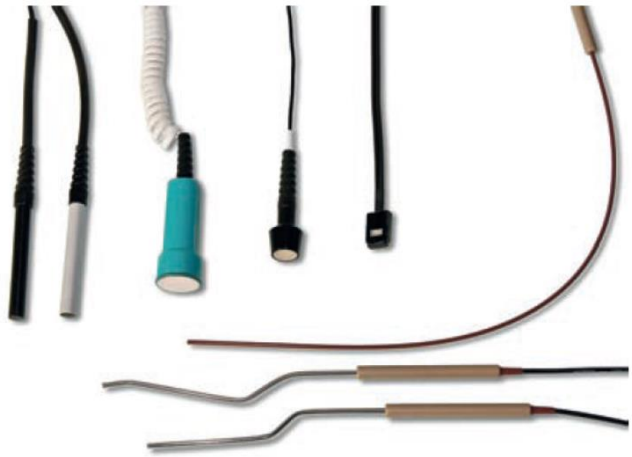
ULTRASOUND PROBES



CW2, PW2, CW4, CW5, CW8, FCW8, SPW16

to the family of Sonomed Doppler products
BASIC UDI-DI 590487343900C2YZ

User manual

CE
2274

KLASA IIa

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1. Application

The ultrasound probe is an application part for non-invasive diagnostics intended for use with the Sonomed Doppler device.

PROBE	PRODUCT NAME
	OB/GYN DIAGNOSTICS
• CW2	• Fetal heartbeat detect
	VASCULAR DIAGNOSIS
• CW4, CW8, SPW16 • CW4, CW8 • CW5	• VENO Vascular Doppler flow meter • Ultrasonic Doppler UD 48V • SONOMED Doppler Blood Flow Detector Type MD4
• CW8, FCW8	• SONOMED Doppler Blood Flow Detector Type MD4-CW8
• PW2	• Ultrasonic Doppler digiTDS

2. Operation

Note: Before starting use, read the manual for use of the device and check the compatibility of the ultrasound probe with the appropriate Doppler sockets (connector type, frequency designation).

Pay attention to the markings of the probe sockets when there are more to choose from, e.g. UD 48V. Incorrect insertion of plugs (e.g. CW8 - 8 MHz probe into 4 MHz sockets) will not cause device failure, but will result in the inability to perform the examination.

Before examination, the working part of the probe should be disinfected with certified liquid preparation according to manufacturer's instruction. Please use sterile probe sheath when there is possibility of probe contact with patient's damaged skin.

3. Exploitation conditions

For examinations, use only CE marked ultrasound gel.

Mechanical shock is to be avoided, and special precautions are needed with the ultrasonic probe since it can get damaged when hit by a hard surface.

Especially, do not bump the front of the probe against hard surfaces or press on it and protect its surface from scratching.

It is a recommended practice to always wipe the probe with a damp swab immediately after use, ensuring that any remaining gel is removed. Do not use organic solvents. Only mild cleaning and disinfecting liquids are recommended (water and alcohol based). Before examination, the working part of the probe should be disinfected with certified

liquid preparation according to manufacturer's instruction. All hot disinfection processes are excluded. Do not soak cables and connectors. When putting the probe away on the holder, orient it face-down and always make sure that it is fixed in a stable way.

The output cable from the probe is carried the weight of the decaying strain relief. Please do not bent it at work or in transport or storage. The figure shows at the bottom of the inadmissible way bending the cable, at the top the course correct.

4. Medical examination

Doppler blood flow or structure movement study is an effective, non-invasive, repetitive and cheap. It is the basis for the diagnosis of vascular diseases and assessment of pregnancy condition.

Ultrasonic probe position over the blood vessel. The probe or skin in the place of study should be moistened with ultrasound gel, liberally so as to ensure good contact. More, it is advisable to use excessive than too small amount of gel. You should beware of unnecessary pressure with probes on the surface of the patient's skin in order to avoid unnecessary unpleasant sensations and do not interfere with the flow in the diagnosed the blood vessels. In addition, it should be remembered that in the few cases where ultrasound gel can cause allergic reaction of the skin, you should warn the patient. In the case of the risk of contact with damaged skin should apply a sterile protective on the probe.

5. Exploitation

5.1. STORAGE AND TRANSPORT CONDITIONS::

Temperature	-10 ÷ 50 °C,
Relative humidity	< 90 %,
Atmospheric pressure	500 ÷ 1060 hPa.

5.2. ENVIRONMENTAL CONDITION

Ambient temperature	recommended 16 ÷ 26 °C, acceptable 10 ÷ 40 °C
Humidity	30 ÷ 85 %
Vibrations	avoid

Declaration of Conformity EC

no 09/2024/EN

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As a Manufacturer of the

Ultrasonic transducers

- CW2, PW2, CW4, CW5, CW8, FCW8, SPW16

BASIC UDI-DI 590487343900C2YZ

Declares under the sole responsibility that According rule 10, MDD 93/42 and Rozporządzenie Ministra Zdrowia dated 5 11 2010; DZ U 215 poz. 1416 with updates are a medical devices class IIa.

Devices has been designed and manufactured in a way to conform Medical Devices Directive 93/42/EEC, as in Annex II excl. sec 4, and respective European Union harmonized standards

The assessment was done with Notified Body No 2274 (TÜV Nord Polska Sp. z o.o., ul. Mickiewicza 29, 40-095 Katowice, Poland

signed

Warszawa, 24 10 2024

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President

Paweł Karłowicz