ULTRASOUND
BLOOD - FLOW DETECTOR

SONOMED DOPPLER
Type MD4 and MD4-CW8

USER MANUAL
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Application

The pocket size Doppler blood flow detector is a simple device enabling a wide range of easy and reliable diagnosis of blood flow in the vessels.

The Doppler probe is positioned over the examined vessel. The pencil type probe should be between 45 and 60 degree to the skin surface.

The Doppler signal detected in normal arteries generally contains easily differentiated flow phases; first, louder with higher frequency (higher pitch) and next, with lower intensity and frequency (lower pitch). First sound is like a strong whistle of wind, remaining two are like more silent noise. In a little narrower arteries second phase disappear. In extremely narrow arteries (more than 50 %) there is heard only first phase suited to systole. One-phase signal has usually high frequency and sounds like hiss. Under narrowing, sound has complex character. It's contained from high frequency suited to acceleration of flow with put, loud, booming tone which is connected with disturbing flow from narrowing.

The Doppler signal from the stenosed vessels has higher frequency in the first, systolic phase. The successive phases are considerably faded down or they disappear completely.

The Doppler diagnosis helps to investigate blood flow, localize the stenosis and occlusions. The unit is applicable, helpful and it can successfully replace the stethoscope for measurements of blood pressure in patient with difficult to hear Korotkoff sounds. This application is especially important in detecting of peak systolic pressure (measured with cuffs and sphygmomanometer). The most common application is ABI (ankle brachial index) calculation.

Operation

Sonomed Doppler is easy and handy to use. The unit design was though to simplify its use reducing to minimum controls - volume up/down and on/off switches.

The front of the probe or patients skin should be covered with Ultrasound Gel in the way assuring good acoustic coupling. It's better to use more than less Ultrasound Gel. The automatic noise control reduces initial noise and strong signals from probe movements. Despite of this during putting Ultrasound Gel at the probe it isn't advisable work with maximal volume. It is recommended to avoid use of an excessive force pressing probe on patient's body during examination by probe's head as it could cause a pain. Sometimes Ultrasound Gel can also breed skin's allergy.

For shipment and transportation probe could be disconnected from main unit. Push-pull probe connectors are marked  and situated on side of the main unit. A pair of connectors is symmetrical, generally do not care to the connecting order (with flat transducer, due the geometry, and only in difficulties it is worth to check both positions). The self-latching mechanism of connectors protects of pulling out by the cable. **To disconnect always pull the metal part of the connector!**

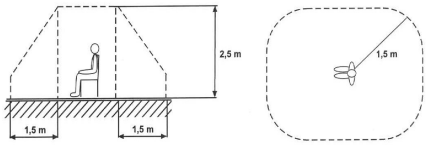
The basic version operates at ultrasonic frequency 5MHz that is the most common to cover wide range of applications. 8MHz model is also offered. The pencil type transducers are offered as standard, other shapes like flat one with "pre-set" Doppler angle are available.

To turn on the device – press button **ON**, to turn off - press **OFF.** To increase the volume - press  to decrease .

The continuous green LED light indicates that the unit is turned on. The pulsating green light shows that the batteries should be recharged. When the unit is not used for a few minutes or batteries are low, it will be turned off automatically.

To charge plug the chargers mini-jack to the main unit and connect to the mains. The red LED near connector should shine. While charging the use of the device is excluded. If battery is completely discharged turning on in correct way won't be possible. It's forbidden to continue work with pressing button ON. First of all battery should be charge. The full battery charging time is 15 hours.
During charging the red light near headphone socket becomes weaker and disappears.

Charging must be performed outside the patient area. A sample of such area is shown on the drawing.



The integrated speaker allows listen to the signal of blood flow but the device also allows the doctor to listen privately - plugging in the headphones automatically turns off the speaker. To connect the headphones there is the same mini-jack socket as for the charger.

Maintenance

Sonomed Doppler should be operated within the range of environment temperature from 10°C to 45°C by relative humidity not exceeding 85% and atmospheric pressure 70-106 kPa. Do not expose it neither to extreme heat nor to extreme cold.

Special care is necessary for the probe. 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. The probe can be cleaned by means of a soft tissue, dampened with water or weak alcohol. Do not scratch. Do not use organic solvents. Only mild cleaning and disinfecting liquids are recommended (with water or alcohol). Probe should be cleaned immediately after use. Before examination working part of the probe should be disinfected by certificated liquid preparation according to producer's instruction (don't soak cables and connectors). In case of risk that probe may contact with hurt skin it's advice to use a sterile cover on the probe.

Advices

When SONOMED DOPLER couldn't be turned on it's helpful to charge the battery.
When there isn't any noise from speaker it must be checked if the headphones are not plugged.
When it's difficult to obtain a Doppler signal it' s important to check if correct probe is used and Ultrasound Gel applied in satisfying quantity.

Repairs to the device

In case of damage or of any queries whatsoever, concerning the correct operation of the device, please contact service. There are no user serviceable parts inside unit. Do not open it.
The service check of the device should be performed in third, fifth and seventh year since purchase. The intended lifetime of the instrument is 10 years.

Attention: when charger is wet, poured a liquid over or with broken housing plugging to the mains is forbidden. The proper operation of the charger is confirmed by shining diode. Battery can by charge only by charger which is delivered by the Manufacturer. While device charging it's use is forbidden.
The device has limited immunity to electromagnetic disturbance. Avoid operation near of their sources (for example mobile phones) recommended protecting distances are mentioned in the tables.

EMC-information

The Sonomed DOPPLER meets the requirements of the EMC-standard IEC 60601-1-2 for Medical electrical equipment. Medical electrical equipment needs special precautions regarding EMC and need to be installed and put into service according to the EMC information provided here.

Fixed RF transmitters, portable and mobile RF communications equipment can affect to Sonomed DOPPLER and the tables 3 and 4 are guiding to prevent from interferences.

The device is suitable for use in all establishments, including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Table: Emission

Guidance and manufacturer's declaration – electromagnetic emissions		
The SONOMED DOPPLER is intended for use in the electromagnetic environment specified below. The customer or the user of the type device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishment, including domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2, Class D	Not applicable, active input power <50 W	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table: Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The SONOMED DOPPLER is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	< ±1 kV for input/output lines	Occasional false echoes may occur even with mains power quality of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_t (>95% dip in U_t) for 0.5 cycle 40 % U_t (60% dip in U_t) for 5 cycle 70 % U_t 30 % dip in U_t) for 25 cycle <5 % U_t (>95% dip in U_t) for 5 sec	<5 % U_t (>95% dip in U_t) for 0.5 cycle 40 % U_t (60% dip in U_t) for 5 cycle 70 % U_t 30 % dip in U_t) for 25 cycle <5 % U_t (>95% dip in U_t) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note: U_t is the a.c. mains voltage prior to application of the test level

Table: Immunity in RF-field

Guidance and manufacturer's declaration – electromagnetic immunity			
The SONOMED DOPPLER is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the SONOMED DOPPLER, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHZ to 800 MHZ $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz where **P** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (**m**). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SONOMED DOPPLER is used exceeds the applicable RF compliance level above, the SONOMED DOPPLER should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SONOMED DOPPLER.			

Table: Separation distances

Recommended separation distances between portable and mobile RF communications equipment and Sonomed DOPPLER			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances arecontrolled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Sonomed DOPPLER as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance***d*** in meters (**m**) can be estimated using the equation applicable to the frequency of the transmitter, where***P*** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Declaration of Conformity EC

no 08/2017/EN

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As a Manufacturer of the

SONOMED Doppler Blood Flow Detector MD4, MD4-CW8

Declares that According rule 10 MDD 93/42 and Rozporządzenie Ministra Zdrowia dated 5 11 2010; DZ U 215 poz. 1416 is a medical device class IIa

Device has been designed and manufactured in a way to conform Medical Devices Directive 93/42/EEC and to the following European Union harmonized standards

- PN-EN 60601-1: 2011 / A1:2014-02
- PN-EN 60601-1-2: 2007 / AC:2010
- PN-EN 60601-1-6: 2010
- PN-EN 60601-2-37: 2008
- PN-EN ISO 14971: 2012
- PN-EN 62366-1:2015
- PN-EN 980: 2010
- PN-EN 1041: 2010

The assesment was done with Notified Body 2460

signed

Warszawa, 30 08 2017

CE 2460

President

Paweł Karłowicz

The device is offered in a dedicated plastic suitcase.

Standard package includes:
the Doppler unit, ultrasonic transducer CW5 (for MD4-CW8: CW8 option FCW8)
, battery charger, gel, user manual, headphones.

MDD Directive 93 / 43 EEC
Class IIa

CE
2460

Specification

Ultrasonic frequency	
model MD-4	5 MHz
model MD4-CW8	8MHz
Audio output-loudspeaker	>200mW
Frequency response	300 Hz-6 kHz
Ultrasound output	P_<1MPa, Iob<20mW/cm^2, Ispta<100mW/cm^2
Rechargeable battery	3.6V, 1500mAh
Operating time (continuous)	approx. 6 - 15h
Charging time	15 h
Dimensions	170x75x25mm.
Weight with battery	280 g
Headphone acoustic output	mini jack 3.5
