

multiDOPPY

**Ultrasound
blood flow
detector**

Operating Manual

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1 Field of application

The *multiDOPPY* is a battery operated, pocket instrument for cardiovascular ultrasound diagnostics. It has been designed for examining blood flow and/or cardiac action, with the help of one of the replaceable sensors using different operating frequency.

Ultrasounds of various frequency penetrate into human body at different depth. Those of lower frequency penetrate deeper, and higher frequency to the surface only. Using a sensor of 8 MHz or higher frequency the vessels near the surface, while a sensor of 4 MHz the vessels located deeper can be examined. The deep penetration depth of a sensor operating at the frequency of 2 MHz makes it capable for monitoring primarily the vessels located at deeper regions (e.g. the aorta), or the fetal cardiac action.

2 Application examples of sensors using various frequencies

2 MHz – observation of deep-seated vessels, or fetal heart sound

- Reliable indication of the existence of foetus.
- Monitoring the live foetus, from the 11th-12th week after the latest menstrual period at the earliest.
- Estimation of the fetal cardiac action during pregnancy.
- Localization of the placenta.
- Determination of twin pregnancy.
- Examination of cardiac action or blood flow of adult patients.

8 MHz - superficial blood flow detection

4 MHz - deep blood flow detection

- Measurement of low systolic blood pressure in obese adult patients and in neonates.
- Measurement of blood pressures on shock patients.
- Detection of occlusions in the extremities.
- Evaluation of patient condition.

- Determine location of patient vessels for injection or cannulation.
- Checking the shunts (Cimino-fistula) in artificial kidney dialysis.
- Assessment of vascular integrity in burn patients..
- Observation of vascular flow after tissue transplants.
- Evaluation of valvular incompetence and assessment of therapeutic progress in postphlebitic patients.
- Diagnosis of tescular varicoceles.

3 Operation

During the examination, low intensity ultrasound is beamed into the body from a small transducer, and is scattered back from all interfaces between tissues of different types. These backscattered signals are picked up by the transducer. If such interfaces are in motion the backscattered ultrasound is shifted in frequency, the shift is within the human audible range. The amount of the Doppler shift, which in this case means the pitch of the acoustic signal, corresponds to the velocity of blood flow in the examined tissue:

| | | |
|------------|---|--------------|
| high pitch | = | rapid motion |
| low pitch | = | slow motion |
| no signal | = | no motion |

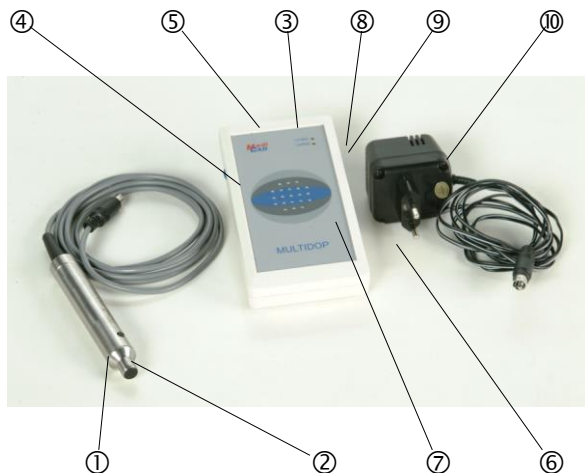
The motion of tissue walls or the variations in blood velocity throughout the cardiac cycle can thus be observed by listening to the alterations in the pitch of the sound. Sharp, short signals suggest high flow resistance (rapid flow in constricted vessel), a pitch rising and falling slowly and regularly indicates good patency of a vessel.

The procedure is non-invasive, and does not cause any stress or discomfort for the patient, and may be repeated at will.

With the optional cable and program the instrument can be connected to a computer and is also capable for displaying and documenting (storage, printing) the flow velocity curve.

4 Controls

- ① Transducer
- ② Pushbutton (On/Off switch)
- ③ Transducer/battery charger connector (**PROBE/CHARGE**)
- ④ Volume control (**VOLUME**)
- ⑤ Computer connector (**PC**)
- ⑥ Headphone jack (**PHONE**)
- ⑦ Speaker
- ⑧ Low battery indicator (***battery***)
- ⑨ Battery charge indicator (***charge***)
- ⑩ Mains charger adapter



5 Using of the instrument

To use, place the sensor on the skin and push the ② button for a short time on the sensor to activate the device. The **green** light of the **battery lamp** ⑧ indicates the ON status. **You do not have to keep the button depressed** during measurement! By pushing the button ② on the sensor again the instrument can be turned off, or when it is not used for **approx. one minute, it is automatically.**

The diagnosis is based on the observation and analysis of the acoustic signals obtained. Adjust volume with **VOLUME** control ④.

Attention! Volume control is not an on/off switch, the turning knob serves only for adjusting the volume!

In order to ensure optimal transmission of sound, some contact gel should be applied on the patient's skin in the entire examination area and, in certain cases, a certain amount of contact gel should also be applied on the transducer tip.

Do not use saline gels, which are applied for ECG, because they may damage the ultrasound sensors!

The **multiDOPPY** operates independently from electric mains, with 1 piece 9 V-rechargeable battery. For the information concerning the battery charging see **4.2**.

One or fully charged battery will last for at least 3 hours of uninterrupted operation, with normal signals and average acoustic volume. Taking into account the actual examination time per patient and the usual interruptions, a charged battery will last for at least one complete workday, even when the instrument is in constant use.

6 Check of both battery and instrument

The **multiDOPPY** is in working condition, if after turning it on whispering noise is heard from the speaker (at full volume setting), and the rubbing or touching of the (dry!) surface of the sensor creates rubbing sound.

Difference from these above sounds – choking, dim, rasping - ***can mean*** either: failure of the instrument; or in many case: ***extreme exhausting of the battery!***. You must require repairing only if after recharging the battery according to **4.2** of the battery, the repeated checking is also unsuccessful.

7 Recharging the battery

When the instrument is on the running down of the battery is indicated by the colour change of the **battery lamp** ⑧ from green to **yellow**. If the **battery lamp** ⑧ continuously lights in **yellow** colour, then turn off the device, and start charging the battery as follows:

After unplugging the ultrasound transducer, insert the 8-pin connector ⑩ of the mains battery charger *supplied by the manufacturer* into the socket marked **PROBE/CHARGE** (in the place of the connector of probe), and then after inserting the plug into the wall outlet the charging of the battery starts, which is indicated by the yellow light of **charge** lamp ⑨. (*The continuous yellow light is interrupted with very short green flashes! This is not an error, it arises from the operation of the charger circuit.*) The completion of the charging is indicated by the continuous green light of the **charge** lamp ⑨ of the device. Then torn the device on and check its operation!

*Do not start charging the battery while the **battery** lamp lights in **green**, and do not interrupt the charging of the battery while **charge** lamp*

*lights in **yellow**, because it may result in the reduction of the battery capacity! Considering this is especially important during the first three discharge-charge cycle (battery „formatting”), that is: 1. Do not recharge a partially discharge battery, and 2. Do not interrupt charging until reaching the full charging!*

The extended storage of the device with a run-down battery in it may result in the damage of the battery, so prior to extended storage it is advisable to fully charge the battery!

The battery charging is controlled by the electronics built in the device, which ensures the optimal charging of the battery and also prevents its overcharging.

8 Notes on diagnostic technique

Transmission of ultrasound is very poor in air. Therefore good coupling must be ensured. The entire space between transducer tip and skin should ALWAYS be filled with a sufficient amount of gel.

For obtaining the blood flow velocity, the angle between transducer and vessel axis should be approximately 45° . If the transducer is perpendicular to the vessel the only movements that will be detected are those of the vessel walls; movements of the blood cells would not be picked up. Since the 8 MHz ultrasound beam of the transducers of **multiDOPPY** is very narrow, a small vessel might be easily missed if the transducer is moved too fast over the skin while searching for the vessel.

The transducers of both the 4 and 8 MHz versions should be placed on the skin very lightly so as not to impede flow by compression!

In the case of vessels that are immediately beneath the skin, e.g. with the digital arteries, the transducer tip may have to be drawn back a bit from the skin surface. Particularly in this case there should be no air-gap in the sound path.

The characteristic arterial and venous sound are easily distinguishable from each other. The artery has a strong pulsatile sound, whereas venous flow is characterized by a continuous gale or wind-like sound which typically is in phase with the patient's respiration. Venous flow can be stopped by deep inspiration or a Valsalva manoeuvre; distal compression will accelerate it.

As certain arteries and veins are in close proximity to each other it is possible, depending on the angle of the transducer, to detect the arterial sound with venous flow superimposed on it from one transducer position.

9 Cleaning, sterilization

Use soft, water-wetted cloth to clean the **multiDOPPY** device and the transducers. During the cleaning make sure that no water or other liquid can leak into the interior of the instrument or the sensor through the clearances of the instrument case and the sensor (e.g. speaker grill, connector, switch).

Never immerse the transducer or main unit in any liquid (e.g. water, alcohol, oil) because they may irreversibly damaged!

Sterilization in hot air or water vapour will also damage the transducer and instrument irreparably!

The front face of the transducer and its surrounding should be cleaned and with isopropyl alcohol and sterilized prior to each examination!

10 Ambient and other conditions of the use, storage and transport of the instrument

Temperature:

| | |
|------------------------------|-----------------|
| Operating temperature range: | +10 °C - +40 °C |
| Transport temperature range: | -40 °C - +55 °C |
| Storage temperature range: | -20 °C - +55 °C |

Humidity:

| | |
|---|------------|
| Operating humidity: | 30% - 95 % |
| Transport, storage humidity: (non-condensing!) | max. 95 % |

The instrument must not be exposed to direct sunlight for a period exceeding 30 minutes!

During use, transport and storage the device should be protected from shocks and from other extreme mechanical stresses (e.g. dropping)!

The transducers contain fragile ceramic ceramic crystals, which may damage in case of shock or dropping!


11 Technical specification

Transducers:

| Frequency: [MHz] | Model | Rated diameter [mm] | Max. ultrasound power output: [mW/cm ²] |
|---------------------|-------|---------------------------|---|
| 2±10% | MD-02 | 20 | 20 |
| 5±10% | MD-05 | 8 | 20 |
| 4±10% | MD-04 | 8 | 20 |
| 8±10% | MD-08 | 8 | 20 |

Classification:

Device supplied from internal power
source

BF  type patient section

Power supply: 9 V rechargeable NiMH battery (PP3)

Battery charger:

Type: NA 120P030P GS or its equivalent

Input: 240V-50Hz

Output: 12VDC; 3.6VA

Operating time: min. 3,5 hours
(with fully charged battery)

Dimensions: main unit: 114 x 72 x 34 mm
transducers: Ø20 x 120 mm

Weight:

main unit: approx. 200 g

transducers:

approx. 100 g

each

charger:

approx. 250 g

| |
|---|
| Manufacturer reserves the right to |
|---|

12 Contents of the kit

| | |
|----------------------|---|
| main unit | 1 piece |
| transducer(s) | 1 to 4 piece(s) (depending on order) |
| battery charger unit | 1 piece |
| carrying case | 1 piece |
| manual | 1 piece |
| PC cable | 1 piece (depending on order) |
| PC software | 1 piece (depending on order) |

13 Installation of *multiDOPPY* monitor program

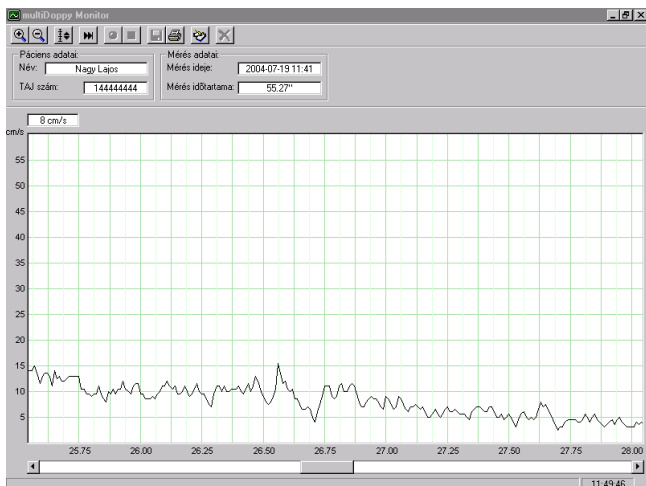
1. Install the program on the computer by running **multiDOPPY.exe** located on the disk!
2. Start the Help of **multiDOPPY** (Start / Programs / multiDOPPY / multiDOPPY Help) ! It provides detailed description about the connection of the multiDOPPY unit and the use of the a program.

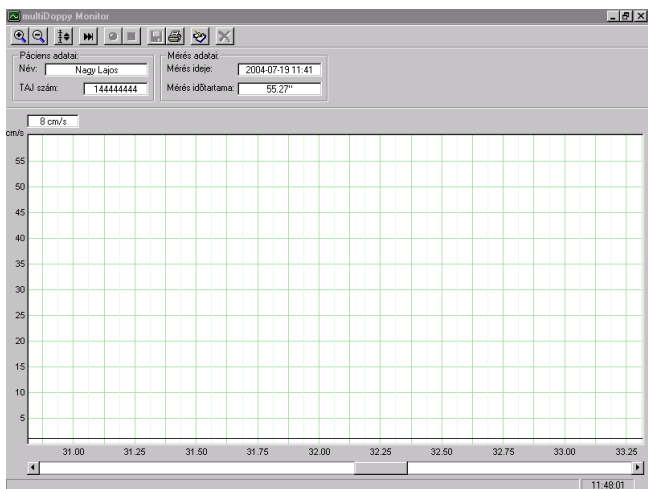
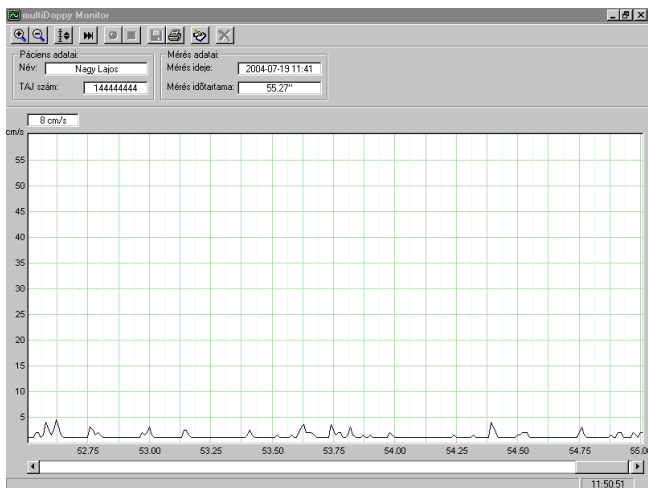
14 Measuring and recording the flow velocity

1. Connect the PC communication cable to the MultiDOPPY and the computer!
2. Connect the transducer, necessary for the examination, to MultiDOPPY!
3. Start **multiDOPPY** program on the computer (Start / Programs / multiDOPPY / multiDOPPY) !
4. Turn on MultiDOPPY with the pushbutton located on the transducer!

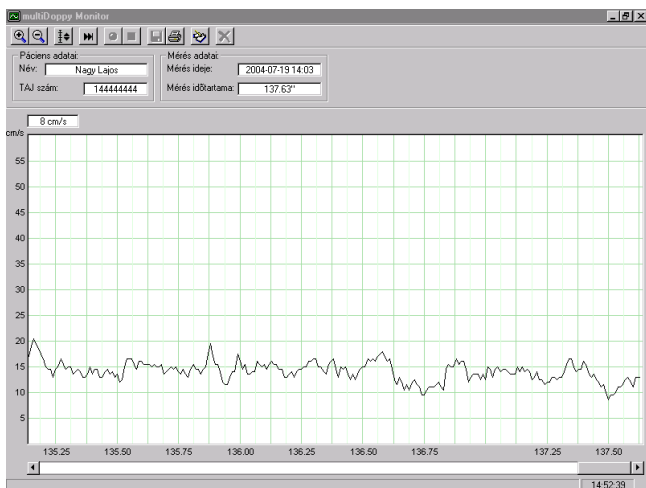
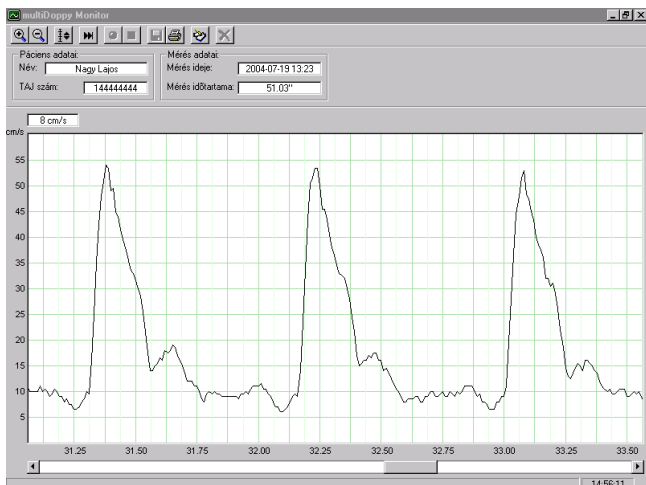
5. Put the sensor in resting position! The front face of the transducer should be dry and clean! Adjust the volume necessary for recording the flow curve with the turning knob VOLUME so that the slightly rippled (noisy) baseline just can be seen at the bottom of the image field.

The figures below illustrate volume in case of proper and wrong adjustment:





6. Now it is possible to record the flow curve.



15 Repair, maintenance

Service and maintenance must be carried out only by Medi-CAD staff or by such other persons that are authorized by Medi-CAD.

Address:

Medi-CAD Kft.

H-3529 Miskolc, Lázár Vilmos u. 4., Hungary

Phone: +36 46 369-377

Declaration of Conformity

We herewith declare that above mentioned product meet the provisions of the Council Directive 93/42/EEC for medical devices.

Manufacturer:

Medi-CAD Kft.

H-3529 Miskolc, Lázár Vilmos u. 4.

Hungary

Tel: +36 46 369 377

Fax: +36 46 560 423

Product: Ultrasonic fetal heartbeat detector

Type: **multiDOPPY**

Applied Standards:

MSZ EN 60601-1

MSZ EN 60601-1-2

MSZ EN 61266

MSZ EN ISO 10993-1

MSZ EN ISO 14971

MSZ EN ISO 13485

Classification: Class II a. (Rule 10)

Notified body:

National Institute of Pharmacy and Nutrition

Directorate of Device Testing and Clinical Engineering

H-1125 Budapest, Diós árok u. 3.

CE 1011

• **Quality certificate / Warrantee**

Product designation: **multiDOPPY**

Serial numbers:

Device:

MD-02:

MD-04:

MD-05:

MD-08:

Based on the performance of an inspection, the product conforms to the specified parameters contained in the user's manual.

We provide a **24 month** warrantee for the aforementioned device, calculated from the time of purchase. For the duration of this period we will repair the device free of charge in the case of a possible malfunction.

Place of fulfillment:

Medi-CAD Kft.

3529 Miskolc, Lázár Vilmos u. 4.

The warrantee is not valid for malfunctions originating from the device's use not in accordance with its intended purpose, and in the case of impact damage.

Date of purchase:

Sales clerk (signature and stamp):