



## FETAL HEARTBEAT DETECTOR FEDO

BASIC UDI-DI 590487343900F0Z6

# User manual



Class IIa

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## Application

FEDO is a portable ultrasonic Doppler device designed for monitoring pregnancies and discovering multiple pregnancy. Fetal heartbeat can be detected from the 10th week of pregnancy.

Large and bright three-digit green LED display indicates the heart rate measurement. It is clinically significant from 26<sup>th</sup> week of pregnancy. Detection of different FHR indicates a multiple pregnancy.

Fedo can be used to localize the placenta and it is possible to identify blood-flow through the umbilical cord.





The integrated speaker allows the parents to listen to heartbeat of their child together with the doctor. Listening by the mother to heartbeat of her unborn child also has therapeutic importance - it makes her happy and more calm, as for a moment she stops being anxious of her baby's health. The device allows for the doctor to listen privately - plugging in a set of headphones automatically turns off the speaker. There is a possibility of recording the heartbeat sounds through the audio output.

For the high-mobility applications we offer as an option the Fetal Doppler Speaker. Typically, it serves as additional equipment for FEDO, but it can also be treated as a standalone small fetal heartbeat detector. Its pocketable size makes carrying the device almost everywhere possible. It is perfectly suited to be lent to a patient for home use.





## Using the device



FEDO has 4 sockets:

2.
  - Ultrasound probe socket marked with . Please note that it has a special orientation notch matched by a recess in the probe connector.
  - Battery charger socket marked with 
  - Sound output socket (cinch) for recording marked with 
  - Headphone socket (3,5 mm jack) marked with 



FEDO is controlled with 6 buttons:




- To turn the device on – press the  button.
- To turn off – press the  button.

Buttons on both sides of the loudspeaker symbol control audio volume:

- To increase the volume, press  and to decrease the volume – press the  button.

The display buttons  and  have multiple functions:

- To turn off the heart rate display and to turn it on again – press . When the heart rate display is off, the digit „1” is shown in the middle of the display.
- To freeze the heart rate displayed – press . The frozen result is displayed until this button is pressed again.

- To check the current battery strength, press  and then . The battery state is displayed as percentage of full charge until  is pressed again.

Remaining symbols on the back label:



- Manufacturer, Sonomed LTD



- Please read manual



- According to WEEE2 – don't throw it away, send back to



distributor or give back to recycle center

- Serial number and date of manufacture

-  CE marking with nb of NB.

Charging of the unit is confirmed by the green dot in the upper-left corner of digital display.

When FEDO is turned on, a self-test is run to ensure proper operation. The digit „0” appears at each position of the display and then is displayed in the leftmost and rightmost positions. If no signal is immediately detected, „1” will be displayed.

The software's algorithm is designed to ignore undesirable signals (e.g. reflections from vessel walls, the mother's pulse, and sounds with incorrect amplitude). The measurement is recognized as correct when the signal is repeated at least three times and the pulse value is displayed after averaging five correct samples. This is to avoid showing accidental results and unnecessarily fast changes of displayed pulse value. Please take it into consideration and be patient when reading the heart rate value. The heart rate display range is limited to between 60 and 240 beats per minute, which ensures that only correct results are shown.

To extend the battery operating time, FEDO shuts off after 5 minutes of inactivity. Blinking of all display digits indicates that battery is low (less than 10% charge remaining) and should be recharged as soon as possible. If battery level falls below safety threshold, FEDO will turn off automatically to protect it from damage. In such case, perform full charging immediately. After a few minutes, you can resume using FEDO with the charger still connected. Do not leave the device in discharged state for a prolonged period of time.

## **Medical examination**

3. The front of the probe or the patient's skin should be covered with ultrasound gel to assure good acoustic coupling. It's better to apply an excess of than too little ultrasound gel. The automatic noise control reduces initial noise and strong signals from probe movements but applying Ultrasound Gel to the probe isn't advisable when working with maximum volume. When a good Doppler signal is obtained, the probe should be kept steady to get a FHR result. FEDO software averages five heartbeats and automatically eliminates errors before a result is displayed. It is recommended to avoid use of excessive force when pressing probe to patient's body as it could cause discomfort or pain. In rare cases, the Ultrasound Gel can cause allergic reaction of patient's skin. Please use sterile probe sheath when there is possibility of probe contact with patient's damaged skin.

If a break in the measurement occurs or the signal is weak, the digit "1" is displayed on the right side of the display. If measurement results are not accepted by the program, the „1" appears on the left or moves between the right and left side of the display.

## Terms of use

4. FEDO should be operated within the range of environment temperature from 10°C to 45°C in relative humidity not exceeding 85% and atmospheric pressure 70-106 kPa. Do not expose it to extreme heat or to extreme cold. Do not expose FEDO main unit to liquids.

**Special care is necessary for the probe.** Always ensure that the probe is securely connected to the main unit. Avoid exposing the probe to mechanical shocks. Especially, do not bump the front of the probe against hard surfaces or press on it and protect its surface from scratching. For examinations, use only CE marked ultrasound gel. 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. 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.

Charging can only be performed using the charger supplied with FEDO by manufacturer. First, connect the charger to the socket on the main unit marked with a battery symbol and then connect the charger to mains power outlet. Green lights on the charger and in the upper-left corner of FEDO display indicate proper charging. After 3 months of not being used, FEDO may self-discharge and a full charge is recommended to prevent damage to the battery. Full charging time: 12 – 15 hours.

**Warning:** if the charger is wet or has broken housing, plugging to the mains is forbidden.

Keep in mind that this device has limited resistance to electromagnetic interference (EMI). Avoid using it near EMI sources (e.g. cellphones or diathermy). It is allowed to operate FEDO with the charger connected if no EMC interference is observed.

For shipment and transportation, the probe should be disconnected from the main unit. To disconnect, pull hard on the connector in a straight line. Never pull on the cable to disconnect the probe and do not twist the connector sideways.

In case of damage to any part of the device or of any concerns regarding the correct operation of the device, please contact Sonomed. There are no user-serviceable parts inside the unit. Do not open it as this will cause voiding your warranty and increased service costs post-warranty.

The service check of the device should be performed in the third, fifth and seventh year since purchase. The intended lifetime of the instrument is 10 years.

## Technical tips

5.
  - When the display starts blinking, it is advised to stop using the device and recharge it.
  - When the device is continued to be used when the display is blinking, after some time the automatic shutdown circuit will turn the device off. In such case, it is necessary to perform a full charge cycle.
  - If the device turns off immediately after powering on, perform a full charge cycle.
  - After you finish using the device, make sure it is turned off.
  - If no sound comes from the loudspeaker, make sure that no headphones are connected.
  - If no Doppler signal can be achieved, make sure that a proper amount of ultrasound gel is applied between the probe and skin.
  - Always disconnect the probe by pulling on the connector in a straight line and never twist the connector sideways. Never pull on the cable to disconnect the probe





## Declaration of Conformity EC

no 08/2024/EN

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As a Manufacturer of the

### ***Foetal Heartbeat Detector*** ***FEDO***

BASIC UDI-DI 590487343900F0Z6

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 is a medical device class IIa.

Device 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

President

Paweł Karłowicz



# Attachment 1 – EMC immunity

## Manufacturer's recommendations


### Ultrasonic Fetal Heartbeat Detector FEDO

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
The device 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.			
<b>Immunity test</b>	<b>IEC 60601 Test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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
<b>Voltage dips, short interruptions and voltage variations on power supply input lines</b> 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

Guidance and manufacturer's declaration – electromagnetic immunity

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Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance:</b></p> <p><math>d = 1,2 \sqrt{P}</math>      80 MHz to 800 MHz</p> <p><math>d = 2,3 \sqrt{P}</math>      800 MHz to 2,5 GHz</p> <p>where <b>P</b> is the maximum output power rating of the transmitter in watts (<b>W</b>) according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in metres (<b>m</b>).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device

## Specifications

6. Ultrasonic frequency: 2MHz, continuous wave

### FEDO detector:

Heart rate display range: 60 – 240 bpm  
Audio output: >500 mW (>10W PMPO)  
Rechargeable battery: 6V, 3Ah  
Dimensions WxLxH: 16x18x10cm (6x7x4in.)  
Weight: 1,3 kg (45 oz.)  
Construction: ABS plastic case  
Outputs: headset 3.5mm jack, line-out cinch  
Charger input: 5.5mm, 12V DC 400mA

### Fetal Doppler speaker:

Audio output: 200 mW  
Rechargeable: alkaline battery 9V, 6LR61  
Dimensions WxLxH: 6.5x9.0x3.0cm (2.5x3.5x1.2 in.)  
Weight: 0,2 kg

**FEDO set contains:** main unit, ultrasonic probe CW 2 MHz, battery charger, User Manual, Ultrasound Gel.

Optionally: Fetal Doppler speaker, headphones, audio cable, wall mount.



MDD Directive 93 / 43 EEC

**Class IIa**