

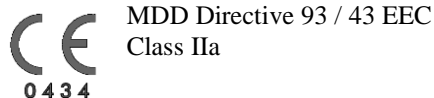
Advices

When FEDO 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.

The basic version is equipped with ultrasound probe 2MHz with 20 mm crystal the wide beam nine crystals probe is available

FEDO set contains: main unit, ultrasonic probe CW2, battery's charger, User Manual, Ultrasound Gel.

Optionally: amplifier with speaker - battery operated, headphones.



Specifications:

Ultrasonic frequency:	2MHz, continuous wave
<u>Fetal heartbeat with probe:</u>	
Heart rate display range:	60 – 240 bpm + - 2 digits
Audio output:	>500 mW sinus; >10W PMPO
Rechargeable battery:	6V, 3Ah
Dimensions wxdxh:	16x18x10cm (6x7x4in.)
Weight:	1,3 kg (45 oz.)
Construction:	ABS plastic case
Outputs:	headset 3.5mm jack, tape-recorder chinch
Charger input:	5.5mm, 12V DC 400mA
<u>Fetal Doppler speaker:</u>	
Audio output:	>200 mW
Rechargeable:	alkaline battery 9V, 6LR61
Dimensions wxdxh:	6.5x9.0x3.0cm (2.5x3.5x1.2 in.)
Weight:	0,2 kg

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Ultrasonic Fetal Heartbeat Detector

FEDO

User Manual



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 three digit bright green LED display indicates the heart rate measurement. It is clinically significant from the 26th week. The detection of different FHR indicates the multiple pregnancy.

The placenta may be localized with the Fedo and it is possible to identify blood-flow through the umbilical cord.


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

Functions of the keypad



To turn on the device – press button **I**


To turn off - press button **0**.

Buttons on both sides of loudspeakers symbol control audio volume.


To increase the volume - press 

To decrease 



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 displayed in the middle.

To freeze the heart rate displayed - press button 

The frozen result is displayed till this button is pressed again.

To check the current battery strength - press button  and then button 

The battery state is displayed as percentage of full charge until  is pressed again.

Declaration of conformity

Sonomed Ltd.
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Ul. Pruszkowska 4 d
Poland
Tel. (022) 654 15 06
Fax. (022) 654 15 07

as manufacturer of:

Fetal Detector FEDO

declares that:

according rule 10 MDD 93/42 and Ministry of Health order dated 05 11 2010 the device is class II a, and conforms the following EU directives and standards
Medical Devices Directive 93/42/EEC

- 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 62304:2010
- PN-EN 62366-2008
- PN-EN 980: 2010
- PN-EN 1041: 2010

In the assessment participated Notified Body
Det Norske Veritas 0434



President



Paweł Karłowicz

For the high mobility applications we offer as an option The Fetal Doppler Speaker. Typical it is an additional equipment for FEDO, but it is also accepted as a small fetal heartbeat detector. Fully pocket size make possible carrying the device almost everywhere. It may be lend to the patient for home use.



Maintenance

FEDO should be operated within the range of environment temperature from 10oC to 45oC 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. Avoid shocks; do not apply excessive force to the transducer. Dried rests of gel remove with wet cloth, do not scratch. Do not use organic solvents. Only mild cleaning and disinfecting liquids are recommended. Probe should be cleaned immediately after use.

When operating probe under the water be sure that the unit and connectors remain in dry conditions. Do not allow to soak a moisture into the FEDO. Putting the probe on the holder (frontal surface should be directed down) it's important to check out that it is fixed in stable way. After 3 months not using FEDO it's possible self-discharge. To charge a battery one must use only a charger which is supplied with FEDO by manufacturer. A cable of a loader should be connected to a socket marked with a signs of battery. When the loader is switched on to net 230V green point which signs loading should be light in the left upper corner.

There are no user serviceable parts inside unit. Do not open it, as the special tools are required to disassemble.

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. Charging of the unit is confirmed by the green dot on upper left part of the digital display. It's accepted to operate FEDO with connected charger if there is no EMC interference observed.


FEDO has limited immunity to electromagnetic disturbance. Avoid operation near of their sources (for example mobile phones) recommended protecting distances are mentioned in the attachment. 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.

Attachment 1 EMC immunity Manufacturers recommendations

Ultrasonic Fetal Heartbeat Detector FEDO

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
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 _i (>95% dip in U _i) for 0.5 cycle 40 % U _i (60% dip in U _i) for 5 cycle 70 % U _i 30 % dip in U _i) for 25 cycle <5 % U _i (>95% dip in U _i) for 5 sec	<5 % U _i (>95% dip in U _i) for 0.5 cycle 40 % U _i (60% dip in U _i) for 5 cycle 70 % U _i 30 % dip in U _i) for 25 cycle <5 % U _i (>95% dip in U _i) 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_i is the a.c. mains voltage prior to application of the test level

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
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 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2 \sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
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.			
<p>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</p>			

Operation

FEDO is easy and handy to use.

For shipment and transportation probe could be disconnected from main unit. Push-pull, key guided, self-latching probe connector is situated in the back of main unit. When the device is turned on the selftest program is run. Meanwhile digit „0” appears in each position of the display and then „1” in the most left and most right positions.

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. When good Doppler signal is obtained the probe should be kept steady to get FHR result. Program averages five beats and automatically eliminates errors before result is displayed.

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

The front of the probe or patients skin should be covered with Ultrasound Gel in the way assuring good acoustic coupling. The automatic noise control reduces initial noise and strong signals from probe movements. When good Doppler signal is obtained the probe should be kept steady to get FHR result. Program averages five beats and automatically eliminates errors before result is displayed.

The software's algorithm is fit in a way which finds undesirable signals (e.g. echoed from vessel- walls mother's pulse, sounds with different amplitude or signals appearing in other moment) as false and ignores them. The measurement is recognized as correct when the signal is repeated at least three times. It has to be also showed after calculation current medium result for five correct measurements. It helps to avoid in efficiently way projection of accidental results and unnecessary blinking of display but it takes a little more time. The Heart rate display range is limited to 60 to 240 beats per minute what also guarantees correct results.

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. In case of risk that probe may be in contact with hurt skin it's advice to use a sterile cover on the probe. To extend the battery operating time FEDO shuts off after 5 minutes of no Doppler activity The instruments has a function self-control of power. Blinking of all display digits warns that battery is week (less than 10% fully charged) and should be recharged. Examination should be limited to minimum. The battery must be charged as soon as it possible. If battery level is lower than acceptable the instrument will be turned off automatically. FEDO could be turned on again only after plugging the mains power supply and some minutes delay. Full battery-charging time: 12 – 15 hours.