



Questions or comments?

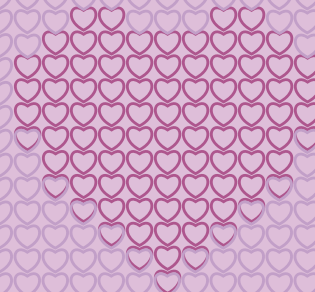
Please call toll-free: 1-855-822-6999

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Easy Healthcare Corporation

360 Shore Dr. Unit B, Burr Ridge, IL USA 60527



pocket fetal doppler
EZD-100S6

User Manual

Attention

This user manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The manufacturer makes no warranty of any kind with regard to this material, including, but not limited to the implied warranties of merchantability and fitness for a particular purpose. The manufacturer assumes no responsibility for any errors that may appear in this document, or for incidental or consequential damage in connection with the furnishing, performance or use of this material.

No part of this document may be photocopied, reproduced or translated to another language without prior written consent of the manufacturer.

The information contained in this document is subject to change without notice.

Responsibility of the Manufacturer

The manufacturer only considers itself responsible for any effects on safety, reliability and performance of the equipment if:

Assembly operations, repairs are carried out by persons authorized by the manufacturer, and the device is used in accordance with the instructions for use.

WARNING :

This device is not intended for treatment. The intended use is for detecting Fetal Heart Rate. If the FHR result is distrustful, please use other methods such as stethoscope to verify immediately.

Warranty

The unit can not be repaired by users themselves. All services must be done by the engineers approved by manufacturer. We warrant that each product we sell you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty.

Using This Label Guide

This guide is designed to give key concepts on safety precautions.

WARNING :

A WARNING label advises against certain actions or situations that could result in personal injury or death.

CAUTION :

A CAUTION label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

Note: A **NOTE** provides useful information regarding a function or procedure.

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Chapter 1 Safety Guidance

This unit is internally powered equipment; the degree of shock protection is type BF applied part.



Type BF applied part protection means that these patient connections will comply with permitted leakage currents, dielectric strengths of IEC 60601-1.

1.1 Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the device.

⚠ WARNING ⚠: This device is not explosion-proof and can not be used in the presence of flammable anesthetics.

⚠ WARNING ⚠: Do not throw batteries in fire as this may cause them to explode.

⚠ WARNING ⚠: Do not attempt to recharge normal dry-cell batteries, they may leak, and may cause a fire or even explosion.

⚠ WARNING ⚠: Don't touch signal input or output connector and the patient simultaneously.

⚠ WARNING ⚠: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC60601-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC 60601-1. If in doubt, consult our technical service department or your local distributor.

⚠ WARNING ⚠: This Pocket Fetal Doppler is a tool to aid the healthcare professional and should not be used in place of normal fetal monitoring.

⚠ WARNING ⚠: Replacing battery shall only be done outside of the patient environment (1.5m away from the patient).

⚠ WARNING ⚠: Please use the Pocket Fetal Doppler probe provided by the manufacturer.

⚠ WARNING ⚠: Do not pull the line of probe longer than 2 meters, or else the probe may break away from the connector of the Pocket Fetal Doppler.

⚠ WARNING ⚠: Potential allergic reactions may occur..

⚠ CAUTION ⚠: The device must be serviced only by authorized and qualified personnel.

⚠ CAUTION ⚠: The device is designed for continuous operation and is

'ordinary'. Do not immerse in any liquid (i.e. not drip or splash- proof).

⚠ CAUTION ⚠: Keep the device clean. Avoid vibration.

⚠ CAUTION ⚠: Do not use high temperature sterilizing process and E-beam or gamma radiation sterilization.

⚠ CAUTION ⚠: Electromagnetic Interference-Ensure that the environment in which the device is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away.

⚠ CAUTION ⚠: The user must check that the equipment does not have visible evidence of damage that may affect patient safety or monitoring capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.

⚠ CAUTION ⚠: The following safety checks should be performed once every two years or as specified in the institution's test and inspection protocol by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- ★ Inspect the equipment for mechanical and functional damage.

- ★ Inspect the safety relevant labels for legibility.

- ★ Verify that the device functions properly as described in the instructions for use.

- ★ Test the patient leakage current according to IEC 60601-1.

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

⚠ CAUTION ⚠: The battery must be properly disposed according to local regulation after their use.

⚠ CAUTION ⚠: The battery must be taken out from the battery compartment if the device will not be used for a long time.

⚠ CAUTION ⚠: The device shall only be used if the battery cover is closed.

⚠ CAUTION ⚠: Battery must be stored in cool and dry place.

⚠ CAUTION ⚠: If use rechargeable battery, to ensure capability and life, please fully charge batteries before first use, normally, batteries must be continuously charged over 14 hours or charged according to the guidance displayed on the battery.

⚠ CAUTION ⚠: Please don't set anode and cathode of the battery wrongly.

⚠ CAUTION ⚠: The valid period of this product is five years.

⚠ CAUTION ⚠: After the service life, please return the products to the manufacture or disposal the products according to local regulations.

⚠ CAUTION ⚠: This device can not be used with defibrillator or high frequency surgical unit.

⚠ CAUTION ⚠: Please choose the accessories authorized by our company or the device may be damaged.

⚠ CAUTION ⚠: Please keep the probe from edge tool.

⚠ CAUTION ⚠: Please use the Pocket Fetal Doppler under the environment without strong electromagnetic field, which may influence measure result.

When cleaning the machine:

⚠**CAUTION**⚠: Don't use strong solvent, for example, acetone.

⚠**CAUTION**⚠: Never use an abrasive such as steel wool or metal polish.

⚠**CAUTION**⚠: Do not allow any liquid to enter the product, and do not immerse any parts of the device into any liquids.

⚠**CAUTION**⚠: Avoid pouring liquids on the device while cleaning.

⚠**CAUTION**⚠: Don't remain any cleaning solution on the surface of the device.

⚠**CAUTION**⚠: It should not be used in life supporting or life sustaining applications.

When disinfecting the machine:

⚠**WARNING**⚠: Never try to sterilize the probe or equipment by low temperature steam or other methods.

⚠: Refer to accompanying documents.

Chapter 2 Introduction

Become familiar with the controls and how to use the PRODUCT properly before operating the product.

2.1 Intended Use

The device is ultrasonic fetal heart beat detector, which can detect the Fetal Heart Rate. The built in speaker of the device allows for listening of the fetal heartbeat. It can display values of fetal heart rate.

2.2 Indications for Use

The Pocket Fetal Doppler is a hand-held, battery powered audio

Doppler device used for detecting fetal heart beats.

Listen to SFH:

Operator can listen to the sound of fetal heartbeat from the headset.

Audio record:

The sound of fetal heartbeats can be recorded by a recorder which is connected with the product. As a safety advisement that can only be connected with a recorder complied with the safety requirements of IEC 60601-1.

2.3 Features

- ★ Battery status indicator
- ★ low power inspection of the battery
- ★ Built-in speaker
- ★ Output for earphone
- ★ The probe can be changeable
- ★ Probe inspection
- ★ Backlight
- ★ Auto shut off
- ★ Two pieces of standard 1.5V alkaline batteries available which can work no less than 10 hours.

2.4 Contraindications for Use

Normally none, as a particular case, please consult your doctor.

2.5 Note for Home Use

This device cannot replace a professional fetal monitor. If the fetal heart rate is abnormal or cannot be located using this monitor, immediately go to the hospital to seek the doctor's help. If fetal movement is not felt by the pregnant woman, immediately go to the hospital to seek the doctor's help.

2.6 Content

1 Device + 1 Manual + 1 Gel + 2 AA Batteries

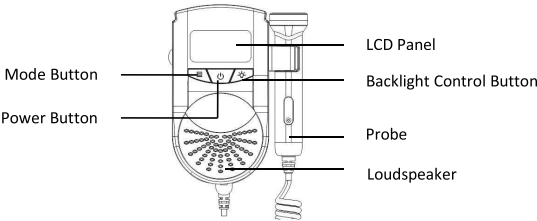


Fig.3-1 Front Panel

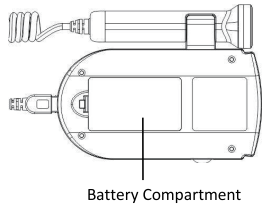


Fig. 3-2 Rear Panel

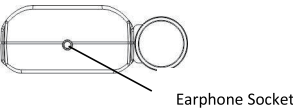


Fig.3-3 Top Panel

3.1 Front Panel

3.1.1 Display

The LCD display for the Pocket Fetal Doppler is as follows:

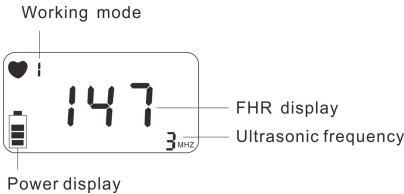


Fig.3-4 LCD Display

3.2 Press Button

There are three push buttons (**POWER**, **MODE**, and **BACKLIGHT CONTROL**) and a Volume control button on Pocket Fetal Doppler. The primary functions are as follows:

3.2.1 Power Button



Function: Power on/off

Power on: Press the button once

Power off: Press down the button and hold 3 seconds to power off

3.2.2 Mode Button



Mode selection button.

Function: mode selection, press once to enter next working mode under working status.

3.2.3 Backlight Control Button



Function: ① Under mode 1 and mode 2, press the button to turn on /off backlight.

② Under mode 3, the button is for start/stop operation, please refer to

4.2.3 manual mode (Mode 3)

3.2.4 Volume Control Indicator



Volume adjusting direction indicator.

From left to right means that the sound level is from high to low.

3.3 Introduction to Top Panel

Earphone Socket: a socket for audio output, and can be connected with earphone or recorder with audio input to record.



The socket, terminal post, or switch that connected with the earphone.



Attention. Refer to the accompanying documents.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC60601-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC60601-1. If in doubt, consult our technical service department or your local distributor.

Chapter 4 General Operation

4.1 FHR Inspection

① Power on by pressing the Power button.

For the Pocket Fetal Doppler, it will do self-test when turning on the machine. After self-testing, the LCD display is as Fig.3-4.

② Find the position of the fetal heart.

At first, please feel the position of the fetus by hand .Find out the best direction for inspecting the fetal heart. Apply a liberal amount of gel to the faceplate of probe; place the faceplate of probe at the best position for detecting fetal heart. Adjust the probe to obtain an optimum audio signal ideally by angling the probe around. Adjust the volume according to requirements.

③ FHR Calculation:

For the Pocket Fetal Doppler, the FHR result will be showed on LCD screen.

- ④ Turn off the machine

For the Pocket Fetal Doppler, keep pressing the power button 3 seconds to turn off.



- ① Put the probe on the best detecting position to get better detecting effect.
② Don't put the probe on the position where have strong Placental Blood Sound (PBS) or strong Umbilical Sound (UMS).
③ If pregnant woman adopts horizontal position and the fetus position is normal, put the probe on the position of lower navel midline to get the clearest FHR sound.
④ Do not measure FHR unless audible fetal sound has been heard.

4.2 Mode Selection

4.2.1 Real-time FHR Display Mode (Mode 1)

At the moment of detecting FHR signal, the LCD will display the flashing heart symbol, and display real-time FHR simultaneously.

4.2.2 Averaged FHR Display Mode (Mode 2)

It is used to obtain more stable heart rate readings. In this mode, FHR is averaged 10 beats. The LCD displays the flashing heart symbol when displaying FHR.

4.2.3 Manual Mode (Mode 3)

When entering into mode 3, the system will automatically counts the audible beats, FHR will be showed in “— — —” Format, and the LCD flashes heart symbol. Press the Backlight Control button to stop calculating. The unit will automatically calculate the derived FHR averaged over the calculating time and display the result. If measure FHR again, press the Backlight Control button to start. Repress it, it will stop calculating.

This rate value is retained until the measurement is repeated or the mode is changed.

4.3 Probe Operation

4.3.1 Inspecting Probe

When the probe falls away from the Pocket Fetal Doppler, the LCD screen

displays the flickering “— — —” and the probe frequency indication data disappeared. At this moment the probe needs to be reconnected. After connected well, LCD screen will stop flickering and display the probe frequency data.

4.3.2 Replacing Probe

There has been a probe connected to the Pocket Fetal Doppler while packaged by the manufacturer. If users need to replace it with another probe, power off the Pocket Fetal Doppler at first, then take out the probe from the parking of the Pocket Fetal Doppler. And then pull out the plug of the probe from its socket. Then connect the plug of the probe which needs to be displaced with the socket.

Note: Place the temporarily unused probe carefully and avoid falling off, stress, etc. When the Pocket Fetal Doppler is not used for a long time, users are recommended to connect the plug of one probe to the Pocket Fetal Doppler socket and put the probe in the parking. Then pack the Pocket Fetal Doppler with the probe in the wrapping box.

4.3.3 Taking out Probe and Placing Probe

- ① Taking out the probe

Hold the main unit with one hand, and hold the handle of the probe with another hand to take out the probe. (See Fig.4-1).

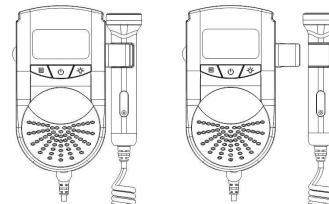


Fig.4-1 Taking out Probes

- ② Placing Probe

It is opposite to take out probe. Hold the main unit with one hand, and hold the top of the probe with another hand, then push the probe into the probe holder.

4.4 Inspection of low power

For the Pocket Fetal Doppler, when it works normally, the LCD screen displays the status of the battery, and the number of the grid in the status represents how much power is left; when the power of the battery is low, the power of the battery displays grid 0 to remind the customer to change another new battery.

4.5 Replacing Battery

4.5.1 Taking out Battery

The rear panel is upturned. First open the battery compartment, then take out the battery from the battery compartment (see Figure 4-2).

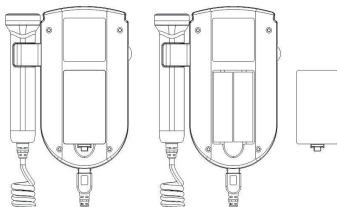


Fig.4-2 Replacing Battery

4.5.2 Replacing Battery

First put two AA size batteries into the battery compartment (as for the direction of battery, please refer to the instruction inside the battery compartment), at last close the battery compartment.

⚠ CAUTION ⚠: The battery must be taken out from the battery compartment if the device will not be used for a long time.

Chapter 5 Product Specification

Product Name: The Pocket Fetal Doppler

Safety: Complies with: IEC60601-1

Classification:

Anti-electroshock Type: Internally powered equipment.

Anti-electric shock degree: Type BF equipment



Degree of protection against Ingress of water and particulate matter: IP22

Degree of Safety in Presence of Flammable Gases: Equipment not suitable for use in presence of flammable gases

Working System: Continuous running equipment

EMC: Group I Class B

Physical Characteristic

Size: 130mm (Length) × 100mm (Width) × 36 (Height) mm

Weight: About 250g (including batteries)

Display: 44.5mm × 23mm LCD display

Backlight: The two statuses can be alternated: turn off/on the backlight.

Suitable Using Range: Suitable for use after the 16th week of pregnancy

FHR Performance

FHR Measuring Range: 50~210BPM (BPM: beat per minute)

Resolution: 1bpm

Accuracy: ±2bpm

Power consumption: ≤0.7W

Auto Shut-off: After 1 minute no signal, power off automatically.

Battery Type Recommended: Two pieces of 1.5 V DC batteries (SIZE AA LR6).

Ultrasonic Probe:

Working Frequency: 3.0MHz ± 10%

Working Mode: Continuous wave Doppler

Overall sensitivity: > 90dB

Spatial-peak temporal-peak acoustic pressure: < 0.1MPa

Output power: < 20mW

Effective area of the ultrasonic transducer active element: 2.08cm²

The acoustic coupling medium for normal use: ph: 5.5~8,

Acoustic impedance: ≤ 1.7 × 10⁵g /cm² · s

The parameters of this product comply with the provisions of exemption, among which are:

Peak negative acoustic pressure: p₋ < 1MPa

Sound intensity of output beam: I_{0b} < 20mW/cm²

Spatial peak time average acoustic intensity: I_{spta} < 100mW/cm²

Environment Requirements:

Operating Conditions:

Temperature: 5°C ~ 40°C (41°F ~ 104°F)

Humidity: ≤ 80%, non-condensing

Atmospheric Pressure: 70kPa ~ 106kPa

Transport and Storage Conditions:

Temperature: -20°C ~ +55°C (-4°F ~ 131°F)

Humidity: 10%-93%, non-condensing

Atmospheric Pressure: 50kPa~106kPa

Product service life: 5 years

Chapter 6 Maintenance

6.1 Maintenance

The probe acoustic surface is frangible and must be handled with care.

Gel must be wiped from the probe after use. These precautions will prolong the life of the unit.

The user must check that the equipment does not have visible evidence of damage that may affect patient safety or Pocket Fetal Doppler capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.

The equipment should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement. The recommended testing interval is once every two years or as specified in the institution's test and inspection protocol.

The accuracy of FHR is controlled by the equipment and can not be adjusted by user. If the FHR result is distrustful, please use other method such as stethoscope to verify immediately or contact local distributor or manufacture to get help.

6.2 Cleaning

Before cleaning, switch off and take out the batteries.

Keep the outside surface of the device clean and free of dust and dirt, clean exterior surface (display screen included) of the chassis with a dry, soft cloth. If necessary, clean the chassis with a soft cloth soaked in a solution of soap, or water and wipe dry with a clean cloth immediately.

Wipe the probe with soft cloth to remove any remaining ultrasound coupling gel. Clean with soap and water only.

 **CAUTION**: Don't use strong solvent, for example, acetone.

 **CAUTION**: Never use an abrasive such as a steel wool or metal polish.

 **CAUTION**: Do not allow any liquid to enter the product, and do not immerse any parts of the device into any liquids.

 **CAUTION**: Avoid pouring liquids on the device while cleaning.

 **CAUTION**: Don't remain any cleaning solution on the surface of the device.

Notes:

Wipe the surface of probe with 70% ethanol, self-air dry, or clean with a clean, dry cloth.

6.3 Disinfecting

Clean the equipment case, probe, etc. as above, and then wipe the probe with an alcohol impregnated wipe (70% ethanol).

Wipe the probe with a clean, dry cloth to remove any remaining moisture.

 **CAUTION**: Never try to sterilize the probe or equipment by low temperature steam or other method.

Chapter7 Solutions for Possible Problems

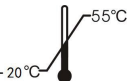
If the following problems appear when you use the Pocket Fetal Doppler, please solve them as below:

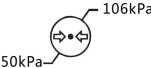
Problems	Possible reasons	Solutions
No sound	☐ volume is too low ☐ power is low	☐ adjust the volume louder ☐ change the battery
Weak sound	☐ volume is too low ☐ power is low ☐ did not daub the gel	☐ adjust the volume louder ☐ change the battery ☐ daub the gel

Noise	☐ probe is too near from the main unit ☐ disturbance from the outside signal ☐ power is low	☐ make the distance between the probe and the main unit a little further ☐ keep far away from the outside signal ☐ change the battery
Low sensitivity	☐ position of the probe is not correct ☐ did not daub the gel	☐ adjust the position of the probe ☐ daub the gel

Chapter 8 Symbols

The following symbols may appear in this manual, on the Product, or on its accessories. Some of the symbols represent standards and compliances associated with the Product and its use.

	Consult instructions for use of the Product and/or its accessories.
	Warning Information.
	Date of manufacture.
	Storage and transport temperature limit

	Humidity limitation
	Atmospheric Pressure limitation
	Type BF applied part.
IP22	Degree of protection against Ingress of water and particulate matter.
	It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.

Appendix 1

Essentiality of Fetal Domestic Monitor

The modern medical science thinks that:

FHR is an important gist to identify fetal health, by recording FHR changes can observe fetal hypoxia, fetal distress and the umbilical cord around the neck, and other symptoms. Fetal domestic monitor test FHR rate changes by listening to fetal heart sound mainly; fetal domestic monitor is a powerful guarantee to improve generational safety.

Fetal heart rate changes most obviously in the following three periods:

- 1) Within 30 minutes after pregnant women get up
- 2) Within 60 minutes after pregnant women finish lunch
- 3) Within 30 minutes before pregnant women go to bed

For the above three periods, because of the change of the body status of pregnant women, the activity of food digesting needs the body to provide more oxygen, relatively, the oxygen for fetus becomes less. It is easy to arise symptoms such as fetus anoxia. Testing the FHR at this time can display the healthy status for the fetus best.

The above three periods can only be tested at home by pregnant women themselves, so FHR domestic monitor is very important.

This Pocket Fetal Doppler can hear the fetal heart sound of fetus above 16 weeks, and calculate the FHR with heart fetal heart sound or check the LCD display. You can listen to the fetal heart sound for 1-2 minutes every time. Pregnant women can take down the record data which can be a reference for doctors to insure the health of the fetus.

Appendix 2

Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The <i>Pocket Fetal Doppler</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Pocket Fetal Doppler</i> should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>Pocket Fetal Doppler</i> 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 emission CISPR 11	Class B	The <i>Pocket Fetal Doppler</i> is suitable for use in all establishments, including domestic establishments 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The <i>Pocket Fetal Doppler</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Pocket Fetal Doppler</i> 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 floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

**Guidance and manufacture’s declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Guidance and manufacture’s declaration – electromagnetic immunity			
The <i>Pocket Fetal Doppler</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>Pocket Fetal Doppler</i> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the <i>Pocket Fetal Doppler</i> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{1}{E} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{1}{E} \right] \sqrt{P}$ 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, ^a should be less than the compliance level in each frequency range. ^b 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 <i>Pocket Fetal Doppler</i> is used exceeds the applicable RF compliance level above, the <i>Pocket Fetal Doppler</i> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <i>Pocket Fetal Doppler</i> . ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Overall Sensitivity