

**Fetal Doppler**  
Model: EZD-100B



User Manual

**Healthcare-Manager.com**

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EZD-100B

**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.

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**Responsibility of the Manufacturer**

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

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.

The unit cannot 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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**Section 1 : Safety Guide**

**1.1 Safety Terms And Conditions**

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

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

**WARNING** : Do not use explosion-proof and cannot be used in the presence of flammable anesthetics.

**WARNING** : Do not touch batteries in fire as this may cause them to explode.

**WARNING** : Do not 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 950 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 60601-1-1. If in doubt, consult our technical service department or your local distributor.

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

**WARNING** : The batteries used in this Fetal Doppler are rechargeable batteries and should not be replaced by the user.

**WARNING** : Do not pull the line of probe longer than 1.5 meters, or else the probe may break away from the connector of the Fetal Doppler.

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

**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 user's safety or monitoring capability before use.

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

**CAUTION** : Do not use unauthorized Probe or any other unauthorized accessories.

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

**When cleaning the machine:**

**CAUTION** : Do not 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** : Remove any residual cleaning solution on the surface of the device.

**When disinfecting the machine:**

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

**WARNING** : Refer to accompanying documents.

**1.2 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
	CE Mark: The product system conforms to essential requirements of the Medical Device Directive 93/42/EEC.
	Date of manufacture.
	Specifies serial number of the product
	Production batch
	It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection after its useful life.
	CLASS II equipment
	Type B applied part
	Ingress Protection.

**Section 2: Introduction**

**2.1 Overview**

The Sweetiesong Fetal Doppler EZD-100B is a hand-held obstetrical unit, which can be used in hospital, clinic and home settings for daily self-check by pregnant women.

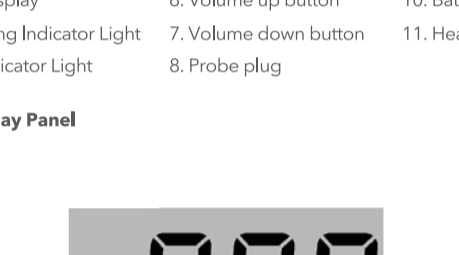
It contains components of ultrasonic signal transmitter and receiver, analog signals processing unit, FHR calculating unit, LCD display control unit etc.

**2.2 Features**

- Rechargeable Battery
- Low Battery Indicator
- Built-in Speaker
- Output for Headphone
- Backlit LCD
- Changeable Probe
- Reliable & High Sensitivity

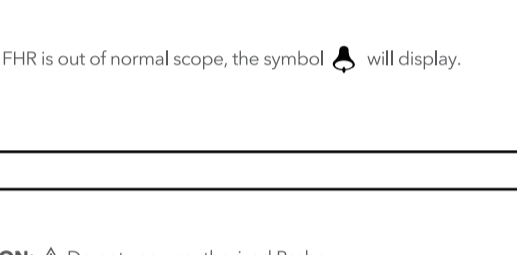
**Section 3 : Product Description**

**3.1 Appearance**



- 1. Charge Socket
- 2. LCD display
- 3. Charging Indicator Light
- 4. ON Indicator Light
- 5. Power ON/OFF Button
- 6. Volume up button
- 7. Volume down button
- 8. Probe plug
- 9. Probe
- 10. Battery Cover
- 11. Headset socket

**3.2 Display Panel**



**FHR Display :**  
It displays the fetal heart rate in bpm (beats per minute)

**Alert:**

When the FHR is out of normal scope, the symbol will display.

**Low Battery Indicator:**

When the battery is low, the symbol will flash.

**3.3 Buttons**

① ON/OFF button :  
Function: switch the Doppler on or off

② Volume Increase button :  
Function: increase the volume.

③ Volume Decrease button :  
Function: reduce the volume.

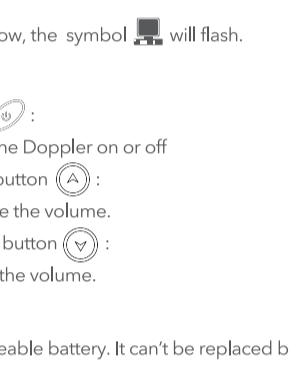
**3.4 Battery**

9.6 V Ni-MH rechargeable battery. It can't be replaced by the user.

**Section 4 : Operation**

**4.1 Installation**

**4.1.1 Installing the probe**



① Plug in the probe to the socket at the bottom of the device.

② Place the Probe into the Probe stand.

**4.1.2 Replace probe**

Take out another probe, Repeat **4.1.1 Installing the probe**.

**CAUTION** : Do not use unauthorized Probe.

**CAUTION** : The Doppler must be turned off when installing or replacing Probe.

**4.2 Operation**

**4.2.1 Turn on**

Press ON/OFF button , the device will turn on and self check, then the blue ON Indicator will light. When the FHR displays "000", the self-check is complete and the device is ready for use.

**4.2.2 Detect FHR**

Apply gel on the probe head, then place it on the detecting position softly and ensure it has good contact with the abdomen. Place the probe at the right position, you can hear the fetal heart beat rate (FHR). Wait until sounds are clear sounding for a few seconds, the LCD screen will then display the detected FHR.

**4.2.3 Volume Control**

Under the FHR display state, you can control the volume by or button.

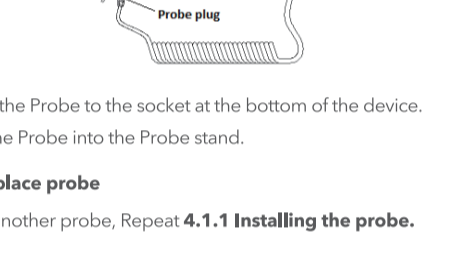
**4.2.4 Turn off**

Press the ON/OFF button , the device will power off, and the Blue ON Indicator will also turn off.

**4.3 Detecting**

Locate the position of the fetus by feeling around the area with your hand; find out the best direction of the fetal heart. Place the top of the probe at the best position for detecting fetal heartbeat. Adjust the probe to obtain an optimal audio signal ideally by angling the probe. Generally, the site of the fetus's heart is 1/3 below of navel line at its earlier stage; it then moves upward further into the pregnancy, and the site of the fetus's heart will be a little deviated to left or right with different fetuses. Please make sure that the surface of the probe head makes full contact with the skin. After the sound is clear and stays stable for a few seconds, the FHR value will appear on the LCD in real time. It is a good practice to apply coupling gel on the probe head to expel air between the probe head and the skin that impedes the sound transmission. If no coupling gel is available, you can use jelly lubricant or clear Aloe vera gel.

**Note: abnormal value of FHR may appear during the searching of fetal heart.**



**4.4 Charge the battery**

When the battery is low, the Low Battery Indicator will flicker. Turn off the Doppler and plug in the wall adaptor to charge the battery.

It takes approximately 10 hours for a full charge. When charging, the Green Indicator light is on.

**Note: Never use the Fetal Doppler while it is charging.**

**Section 5 : Cleaning and Maintenance**

**5.1 Cleaning**

**Recommended cleaning product:**

The following cleaning products may be used to clean the exterior surfaces of the product.

- Isopropyl alcohol (70% solution in water)
- Mild soap and water
- Sodium hypochlorite (chlorine bleach)(3% solution in water)
- Quaternary ammonium compounds (such as Lysol)(10% solution in water)
- Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.
- Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.
- Do not clean electrical contacts or connectors with bleach.

**Cleaning instructions:**

1. Before cleaning, turn the device off and disconnect the power cord.
2. Before cleaning, remove all adherent soil (tissue, fluids, etc) and wipe thoroughly

with a cloth dampened with water before applying the cleaning solution.

3. When cleaning, do not immerse. Keep the exterior surface of the device clean and free of dust and dirt; clean exterior surface of the unit with a dry, soft cloth. If necessary, clean it with a soft cloth soaked in a solution of soap and wipe dry with a clean cloth immediately.

Wipe the transducer body with a soft cloth to remove any remaining coupling gel. Clean with soap only.

4. Wring any excess moisture from the cloth before cleaning.

5. Avoid pouring fluids on the device, and do not allow fluids to penetrate the exterior surfaces of the device.

6. To avoid scratching the display, the use of a soft cloth is recommended.

**CAUTION** : To avoid damaging the equipment, do not clean any part of the product or accessories with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the product or accessories.

**CAUTION** : Cleaning liquids: Do not submerge the device in liquids or pour cleaning liquids over, into, or onto the device.

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

\* Never use an abrasive such as steel wool or metal polish.

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

\* Avoid pouring liquids on the device while cleaning.

\* Remove any residual cleaning solution on the surface of the device.

\* Wipe the surface of sensor of transducer with 70% ethanol or alcohol.

**5.2 Maintenance**

1. The transducer acoustic surface is fragile and must be handled with care. Gel must be wiped off from the transducer 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 the user's safety or product's capability before use. The recommended inspection interval is once per month or less. If damage is evident, replacement is recommended before use.

2. To ensure the product is always functional when required, the following maintenance shall be performed:

- Visual Inspection
- Cleaning the product and its accessories
- Check the battery level
- Test product performance

**Recommended maintenance and care:**

• It is important that the product is stored at the operating temperature range if it is expected to be used. Optimal battery life will be obtained if stored and operated at room temperature.

**Section 6 : Product Specifications**

**Note:** The following specifications are subject to change and are only noted as a point of reference.

**Product name:** Portable Fetal Doppler

**Model:** EZD-100B

**Safety:** Complies with IEC 60601-1, EN 60601-1, EN60601-1-1, IEC 61266

**Physical Dimensions:**

129mm W x 83mm D x 34 mm H, Wt: 8.6 cz (244g, including battery)

**Classification:**

**Anti-electric Shock Type:** Internally powered equipment

**Protection against electric shock :** Class II equipment

**Anti-electric Shock Degree:** Type B applied part

**Degree of Protection against Harmful Influence of Water:**

**Main Unit :** Non-protected

**Probe:** IPX4 Water Ingress Protection Code

**Degree of Safety IN Presence of Flammable Gases:** This device is not suitable for using in presence of flammable gases

**Working Mode:** Continuous operation

**Technical parameters:**

**Ultrasonic:** Continuous emitting frequency: 2.5 MHz

**Overall sensitivity:** at the distances 200mm from the face of the probe (Doppler frequency: 500±50Hz, Target velocity: 10cm/s~40cm/s); 92.4dB

**Spatial-peak temporal-peak acoustic pressure:** 20.1kPa

**Output power:** 7.9mW

**Effective area of the ultrasonic transducer active element:** 3.07cm<sup>2</sup>

The acoustic coupling medium for normal use: ph: 5.5~8, Acoustic impedance: >1.7105g/cm<sup>2</sup>s

Working mode: Continuous wave doppler

Audio output:

Audio output power: <0.5 W

Audio out Socket: Φ 3.5mm

Recommended battery type:

9.6V Ni-MH,300mAh

Adapter: The input voltage see the label

Charge limit: DC 12V 300mA

Stand-by Time: >8hours

Performance:

Sensitivity: 16 weeks gestation

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

Resolution: 1bpm

Accuracy: ±2bpm

**Environmental Requirements:**

Operating Conditions:

Temperature: -41°F to 104°F

Humidity: <80% RH, non-condensing

Atmospheric pressure: 86kPa to 106kPa

Storage and Shipping Conditions:

Temperature: -4°F to 131°F

Humidity: 10%- 93% RH, non-condensing

Atmospheric pressure: 50kPa to 106kPa

Battery

Rechargeable 9.6V Ni-MH,300mAh

**Section 7 : Troubleshooting**

Symptom	Cause	Remedy
Audio/Static Interference	• Audio volume too high	• Turn down the volume
	• Too much gel on the probe surface	• Use less gel
	• Battery is exhausted	• Charge the battery
Weak sound output	• Audio volume too low	• Turn up the volume
	• Insufficient gel	• Add gel
	• Battery is exhausted	• Charge the battery

Low sensitivity	• Incorrect probe position	• Locate at the correct position
	• Insufficient gel	• Add gel

**Appendix 1**

**CAUTION:** Fetal Doppler needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided for in the ACCOMPANYING DOCUMENTS.

**CAUTION:** Portable and mobile RF communications equipment can affect Fetal Doppler.

**CAUTION:** the Fetal Doppler should not be used adjacent to or stacked with other equipment.

**Guidance and manufacturer's declaration—electromagnetic emissions**

The Sweetiesong Fetal Doppler is intended for use in the electromagnetic environment specified below. The customer of the user of the Sweetiesong Fetal Doppler should assure that it is used in such an environment.