



User Manual

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EZD-100B

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 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 waranted 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. A WARNING label advises against certain actions or situations that could result in personal injury or death. \triangle CAUTION: \triangle

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.

Section 1 : Safety Guide

1.1 Safety Terms And Conditions

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 cannot be used in the presence of flammable anesthetics.

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

⚠ WARNING: ⚠ Do not throw batteries in fire as this may cause them to explode. riangle WARNING: riangle Do not touch signal input or output connector and the patient

⚠ WARNING: ⚠ Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 9 50 for data processing equipment and IEC60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC60601-1-1. Everybody who connects additional equipment to the signal input connector or signal output connector configures a medical system

technical service department or your local distributor.

or gamma radiation sterilization.

and should not be used in place of normal fetal monitoring.

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

⚠ **WARNING:** ⚠ This Fetal Doppler is a tool to aid the healthcare professional

⚠ 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. \triangle **CAUTION:** \triangle 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

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△ 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.

(3) Consult instructions for use of the product and/or it's accessories. Warning Information \triangle CE Mark: The product system conforms to essential requirements (€0482

SN Specifies serial number of the product LOT Production batch

> It indicates that the equipment should be sent to the special agencies according to local regulation for separate collection

of the Medical Device Directive 93/42/EEC

Date of manufacture.

after its useful life.

CLASS II equipment

Type B applied part

Ingress Protection.

Section 2: Introduction

سرا

IPX4

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

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 (A):

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

1) Plug in the Probe to the socket at the bottom of the device.

Take out another probe, Repeat 4.1.1 Installing the probe.

Function: increase the volume. 3 Volume Decrease button $\textcircled{\forall}$:

3.4 Battery

Section 4: Operation 4.1 Installation

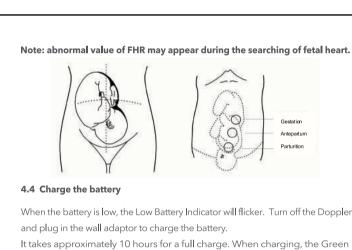
Function: reduce the volume.

4.1.1 Installing the probe

4.1.2 Replace probe

6

② Place the Probe into the Probe stand.



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

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

Section 5: Cleaning and Maintenance

Recommended cleaning product:

• Isopropyl alcohol (70% solution in water)

5.1 Cleaning

• Mild soap and water

gases may result.

Cleaning instructions:

• Visual Inspection

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product.

• 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

• Do not clean electrical contacts or connectors with bleach.

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

• 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

Note: The following specifications are subject to change and are only noted as a

Safety: Complies with IEC 60601-1, EN 60601-1, EN60601-1-2, IEC 61266

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

Anti-electric Shock Type: Internally powered equipment

Protection against electric shock: Class II equipmen Anti-electric Shock Degree: Type B applied part Degree of Protection against Harmful Ingress of Wat 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

Ultrasonic emitting frequency: 2.5 MHz

operated at room temperature.

Mode: EZD-100B

Classification:

Physical Dimensions:

Technical parameters:

Output power: 7.9mW

Ultrasound:

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Appendix 1

Fetal Doppler.

RF emissions

RF emissions

IEC 61000-3-2

IEC 61000-3-3

Voltage dips,

interruptions

and voltage

variations on

power supply

IEC 61000-4-8

Immunity test

Conducted RF

IEC 61000-4-6

14

short

12

Harmonic emissions

Voltage fluctuations/ flicker emissions

CISPR 11

CISPR 11

other equipment.

Section 6: Product Specifications

Product name: Portable Fetal Doppler

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

CAUTION: Fetal Doppler needs special precautions regarding EMC and

CAUTION: Portable and mobile RF communications equipment can affect

CAUTION: the Fetal Doppler should not be used adjacent to or stacked with

Guidance and manufacturer's declaration-electromagnetic emissions

The Sweetiesong Fetal Doppler is intended for use in the electromagnetic

its internal function. Therefore, its

RF emissions are very low and are

not likely to cause any interference in nearby electronic equipment.

The Sweetiesong Fetal Doppler

EZD-100B is suitable for use in all

establishments and those directly

buildings used for domestic

purposes.

establishments, including domestic

connected to the public low-voltage power supply network that supplies

Mains power quality should

environment. If the user of

Doppler requires continued

environment - quidance Portable and mobile RF

communications equipment

should be used no closer to any part of the Sweetiesong Fetal Doppler including

be that of a typical c

ommercial or hospital

the Sweetiesong Fetal

operation during power

provided for in the ACCOMPANYING DOCUMENTS.

needs to be installed and put into service according to the EMC information

Overall sensitivity at the distances 200mm from the face of the probe (Doppler

frequency: 500±50Hz, Target velocity: 10cm/s~40cm/s): 92.4dB

Effective area of the ultrasonic transducer active element: 3.07cm2

Spatial-peak temporal-peak acoustic pressure: 20.1kPa

environment specified below. The customer of the user of the Sweetiesong Fetal Doppler should assure that it is used in such an environment. Electromagnetic environment-Compliance **Emissions** guidance The Sweetiesong Fetal Doppler EZD-100B uses RF energy only for

Group 1

Class B

Class A

<5%UT

(>95% dip in

cycle 40% UT

(60% dip in

5cycles 70%

IEC 60601

test level

3 Vrms

UT)for 0.5

UT)for

Not applicable

input lines IEC UT (30% dip UT (30% dip mains interruptions, it is 61000-4-11 in UT)for 25 in UT)for 25 recommended that the cycles <5% cycles <5% Sweetiesong Fetal Doppler UT (>95% UT (>95% is powered from an dip in UT) dip in UT) uninterruptible power for 5sec for 5sec supply or a battery. Power frequency (50/60 Hz) 3 A/m applicable magnetic fie**l**d Not applicable

NOTE UT is the a.c. mains voltage prior to application of the test level.

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.

level

Compliance

<5%UT

(>95% dip in

cycle 40% UT

(60% dip in

5cycles 70%

UT)for

UT)for 0.5

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 Sweetiesong Fetal Doppler EZD-100B is
used exceeds the applicable RF compliance level above, the Sweetiesong Fetal
Doppler should be observed to verify normal operation. If abnormal performance
is observed, additional measures may be necessary, such as re-orienting or
relocating the device.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less
than 3 V/m.

Recommended separation distances between portable and mobile RF

The customer of the user of the Sweetiesong Fetal Doppler can help prevent electromagnetic interference by maintaining a minimum distance between

portable and mobile RF communications equipment (transmitters) and the

Sweetiesong Fetal Doppler as recommended below, according to the maximum

Separation distance according to frequency of

80 MHz to

800 MHz to

communications equipment and the Sweetiesong Fetal Doppler.

The Sweetiesong Fetal Doppler EZD-100B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

output power of the communications equipment.

150 kHz to

transmitter (m)

Rated maximum

Doppler frequency Target Velocity

Target Velocity

acoustic pathway

C: Signal-to-noise Ratio

S: Overall Sensitivity

Supplementary information: --

A(d): Target reflection loss

B: two-way attenuation over the

output power

of transmitter

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

w	80 MHz d=1.2×P1/2	800 MHz d=1.2×P1/2	2,5 GHz d=2.3×P1/2	
0.01	0.12	0.12	0.23	
0.1 0.38		0.38	0.73	
1	1.2	1.2	2.3	
16				
Distance for the probe face Nominal acoustic working frequency		75mm		
		2.5MHz		

293Hz

12cm/s

12cm/s

44.5dB

46.8dB

Vs: 227mV

Vn: 109mB

C=20log(Vs/Vn)=6.4dBSS=A+B+C=97.1db

,	
A(d): Target reflection loss	44.5dB
B: two-way attenuation over the acoustic pathway	47.2dB
C: Signal-to-noise Ratio	Vs: 229mV Vn: 110mB C=20log(Vs/Vn)=6.4dB
S: Overall Sensitivity	S=A+B+C=97.1db
Supplementary information:	
Distance for the probe face	100mm
Nominal acoustic working frequency	2.5MHz
Doppler frequency	293Hz

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⚠ 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

⚠ CAUTION: ⚠ Please use the Fetal Doppler under the environment without

△ CAUTION: △ Do not use unauthorized Probe or any other unauthorized

strong electromagnetic field, which may influence measure result.

⚠ CAUTION: ⚠ Do not use strong solvent, for example, acetone.

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

⚠ **WARNING**: ⚠ Never try to sterilize the probe or equipment by low

The following symbols may appear in this manual, on the product, or on its

accessories. Some of the symbols represent standards and compliances

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⚠ 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

 \triangle CAUTION: \triangle Remove any residual cleaning solution on the surface of the

device may be damaged.

When cleaning the machine:

device.

1.2 Symbols

3.1 Appearance

1. Charge Socket

3. Charging Indicator Light

4. ON Indicator Light

3.2 Display Panel

4.2 Operation

4.2.1. Turn on

4.2.2. Detect FHR

will also turn off.

4.3 Detecting

2. LCD display

any parts of the device into any liquids.

When disinfecting the machine:

associated with the product and its use.

⚠ WARNING: ⚠ Refer to accompanying documents.

Section 3: Product Description

Indicator **FHR Display:** It displays the fetal heart rate in bpm (beats per minute) When the FHR is out of normal scope, the symbol 👃 will display.

⚠ CAUTION: ⚠ The Doppler must be turned off when installing or replacing

Press ON/OFF button @ down, 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

5. Power ON/OFF Button

6. Volume up button

8. Probe plug

7. Volume down button

9.Probe

10. Battery Cover

11. Headset socket

Apply gel on the probe head, then place it on the detecting position softly and ensure it has good contact with the abdomen. When the probe is in 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

▲ CAUTION: ▲ Do not use unauthorized Probe.

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

exterior surfaces of the device. **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 **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.

the device into and liquids.

5.2 Maintenance

dry or clean with a clean, dry cloth.

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

* Avoid pouring liquids on the device while cleaning.

The acoustic coupling medium for normal use: ph: 5.5~8, Acoustic impedance: ≤1.7*105g/cm2·s Working mode: Continuous wave doppler Audio output:

Audio output power: <0.5 W

Charge limit: DC 12V 300mA

Adapter: The input voltage see the label

Audio out Socket: Φ 3.5mm Recommended battery type:

9.6V NI-MH,300mAh

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

Rechargeable 9.6V NI-MH,300mAh

Symptom

Audio Static

Interference

Weak sound

output

Appendix 2

discharge (ESD)

IEC 61000-4-2

Section 7: Troubleshooting

Guidance & Declaration-electromagnetic immunity Guidance & Declaration-electromagnetic immunity 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. IEC 60601 Compliance Electromagnetic **Immunity test** test level environment-quidance level Floors should be wood, Electrostatic ±6 kV ±6 kV concrete or ceramic tile. If

contact

+8 kV air

13 3 V/m Radiated RF recommended separation 80 MHz distance calculated from the IEC 61000-4-3 equation applicable to the 3 Vrms frequency of the transmitter. 80 MHz to Recommended separation 2.5 GHz

	electromagnetic site surveya should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol:
	determined by an
	Tri transmitters, as

1	rrequency 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.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher

3.8

12

3.8

12

10

100

Overall sensitivity(2.5MHz Probe)

A(d): Target reflection loss

C: Signal-to-noise Ratio

acoustic pathway

B: two-way attenuation over the

C=20log(Vs/Vn)=6.4dB S=A+B+C=103.2db S: Overall Sensitivity Suppleme

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

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

* Do not allow any liquid to enter the product, and do not immerse any parts of

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 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

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* Remove any residual cleaning solution on the surface of the device. * Wipe the surface of sensor of transducer with 70% ethanol or alcohol, self-air

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:

Stand-by Time: >8hours Performance: Sensitivity: 16 weeks gestation FHR Measuring Range:50bpm -210bpm (beat per minute) Resolution: 1bpm Accuracy: ±2bpm

Cause

Audio volume too high

Battery is exhausted

Battery is exhausted

Insufficient gel

Audio volume too low

Too much gel on the probe

Remedy

• Turn down the volume

Charge the battery

• Turn up the volume

Charge the battery

floors are covered with s

ynthetic material, the relative

11

• Use less gel

Add gel

			humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for Input/output lines	±2kV for power supply lines	Mains power quality should be that of atypical commerci- or hospital environment
Surge IEC 61000-4-5	±1kV line to line ±2kV line to earth	±2kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

contact

±8 kV air

		3V d=1.2×P1/2 80MHz to 800 MHz d=1.2×P1/2 800MHz 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 should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marke with the following symbol:
--	--	--

15

7.3

23

Temperature: 77°F(24.9°C), Relative Humidity : 68%		
Distance for the probe face	50mm	
Nominal acoustic working frequency	2.5MHz	
Doppler frequency	293Hz	
Target Velocity	12cm/s	

44.5dB

52.3dBay

Vs: 235mV

Vn: 113mB

Supplementary information: –		
Distance for the probe face	200mm	
Nominal acoustic working frequency	2.5MHz	
Doppler frequency	293Hz	
Target Velocity	12cm/s	
A(d): Target reflection loss	44.5dB	
B: two-way attenuation over the acoustic pathway	41.4dB	
C: Signal-to-noise Ratio	Vs: 225mV Vn: 106mB C=20log(Vs/Vn)=6.5dB	
S: Overall Sensitivity	SS=A+B+C=92.4db	
Supplementary information: –		

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