Chapter 1 Safety Guidance

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

WARNING

Type B 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 explosion-proof and can 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 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. 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 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.

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).
When cleaning the machine:

Δ CAUTION: Don’t use strong solvent, for example, acetone.

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

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

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

Δ CAUTION: Don’t remain any cleaning solution on the surface of the device.

When disinfecting the machine:

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

Δ Refer to accompanying documents.

Chapter 2 Introduction

2.1 Overview

Pocket Fetal Doppler is a hand-held obstetrical unit, which can be used in hospital, clinic and home for daily self-check by pregnant woman.

It contains components of ultrasonic signal transmitter and receiver, analog signals processing unit, FHR calculating unit, LCD display control unit etc. The Pocket Fetal Doppler model is a high performance model with fetal heart rate) LCD digital display. It has 3 work modes: real-time FHR display mode, averaged FHR display mode, and manual mode. All three models have audio output, and can be connected with earphone or recorder with audio input. It uses standard 1.5V DC alkaline batteries (2 pieces).

2.2 Features

* Battery status indicator
* Low power inspection of the battery
* Built-in speaker
* Output for headphones
* 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.

Chapter 3 Outlook

3.1 Front Panel

3.1.1 Display

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

![Fig.3-4 LCD Display](image)

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

![Power Button](image)

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 Button](image)

Mode selection button.

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

3.2.3 Backlight Control Button

![Backlight Control Button](image)

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 Control Indicator](image)

Volume adjusting direction indicator.

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

3.3 Introduction to Top Panel

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

Ω: The socket, terminal post, or switch that connected with the headphones.

⚠️ 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 950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC60601-1-1. 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 IEC60601-1-1. 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 shown on LCD screen.

④ Turn off the machine For the Pocket Fetal Doppler, keep pressing the power button 3 seconds to turn off.

⚠️ CAUTION⚠️: 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.

Chapter 5 Product Specification

Product Name: The Pocket Fetal Doppler Pocket Fetal Doppler

Safety: Complies with IEC60601-1-1: 2006

Classification:
- Anti-electroshock Type: Internally powered equipment.
- Harmful Liquid Proof Degree: Ordinary equipment (sealed equipment without liquid proof)

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

Suitable Using Range: Suitable for use after the 12th week of pregnancy

Physical Characteristic
- Size: 130mm (Length) x 100mm (Width) x 36 (Height) mm
- Weight: About 250g (including batteries)

Environment
- Working:
  - Temperature: +5℃～+40℃
  - Humidity: ≤80%
- Atmospheric Pressure: 70kPa～106kPa
Transport and Storage:
Temperature: -10°C ~ +55°C
Humidity: <95%
Atmospheric Pressure: 50kPa ~ 106kPa

Display: 44.5mm × 23mm LCD display
Backlight: The two statuses can be alternated: turn off/on the backlight.

FHR Performance
FHR Measuring Range: 50~240 BPM (BPM: beat per minute)
Resolution: 1 BPM
Accuracy: ±2 BPM

Power consumption: <0.8W
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).

Probe:
Nominal Frequency: 3.0MHz
Working Frequency: 3.0MHz±10%
P×: <0.5kPa
I×p×: <0.1mW/cm²
Ultrasonic Output Intensity: Isata=5mW/cm²
Working Mode: Continuous wave Doppler
Effective Radiating Area of Transducer: 208mm²±15%

Chapter 6 Maintenance
6.1 Maintenance
The probe acoustic surface is fragile 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 ensure 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 identify baby, by recording FHR changes can display the symptoms such as fetus anoxia. Testing the FHR at this time can display the healthy status for the fetus best.

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.

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.

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.

1) CAUTION: Don’t use strong solvent, for example, acetone.
2) CAUTION: Never use an abrasive such a steel wool or metal polish.
3) CAUTION: Do not allow any liquid to enter the product, and do not immerse any parts of the device into any liquids.
4) CAUTION: Avoid pouring liquids on the device while cleaning.
5) CAUTION: Don’t remaim 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.

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

Chapter 7 Solutions for possible problems
If it appears below problems when you use the Pocket Fetal Doppler, please solve them as below:

<table>
<thead>
<tr>
<th>Problems</th>
<th>Possible reasons</th>
<th>Solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>No sound</td>
<td>volume is too low</td>
<td>adjust the volume louder</td>
</tr>
<tr>
<td></td>
<td>power is low</td>
<td>change the battery</td>
</tr>
<tr>
<td>Weak sound</td>
<td>volume is too low</td>
<td>adjust the volume louder</td>
</tr>
<tr>
<td></td>
<td>power is low</td>
<td>change the battery</td>
</tr>
<tr>
<td></td>
<td>did not daub the gel</td>
<td>daub the gel</td>
</tr>
<tr>
<td>Noise</td>
<td>probe is too near from the main unit</td>
<td>make the distance between the probe and the main unit a little further</td>
</tr>
<tr>
<td></td>
<td>disturbance from the outside signal</td>
<td>keep far away from the outside signal</td>
</tr>
<tr>
<td></td>
<td>power is low</td>
<td>change the battery</td>
</tr>
<tr>
<td>Low sensitivity</td>
<td>position of the probe is not correct</td>
<td>adjust the position of the probe</td>
</tr>
<tr>
<td></td>
<td>did not daub the gel</td>
<td>daub the gel</td>
</tr>
</tbody>
</table>

Appendix 1
Essentiality of Fetal Domestic Monitor
Modern medicine think that:
FHR is an important gist to identify fetal health, by recording FHR changes can observe fetal hypoxaemia, 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 for fetus above twelve 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 Pocket Fetal Doppler is intended for use in the electromagnetic environment specified below. The customer of the Pocket Fetal Doppler should assure that it is used in such an environment.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RF emissions CISPR 11</td>
<td>Group 1</td>
<td>The Pocket Fetal Doppler 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.</td>
</tr>
<tr>
<td>RF emissions CISPR 11</td>
<td>Class B</td>
<td>The Pocket Fetal Doppler 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.</td>
</tr>
<tr>
<td>Harmonic emissions IEC 61000-3-2</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td>
<td>Not applicable</td>
<td></td>
</tr>
</tbody>
</table>

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

Guidance and manufacture's declaration – electromagnetic immunity

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
</table>
| 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 Pocket Fetal Doppler, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 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).

- 80 MHz to 800 MHz: \( d = \frac{200000}{P} \)
- 800 MHz to 2.5 GHz: \( d = \frac{100000}{P} \)

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol: \( \epsilon \) |

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

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

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment – guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2</td>
<td>±6 kV contact</td>
<td>±6 kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Power frequency (50Hz) magnetic field IEC 61000-4-8</td>
<td>3A/m</td>
<td>3A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

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.

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

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 communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80 MHz to 800 MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>0.1167</td>
</tr>
<tr>
<td>0.1</td>
<td>0.3689</td>
</tr>
<tr>
<td>1</td>
<td>1.1667</td>
</tr>
<tr>
<td>10</td>
<td>3.6893</td>
</tr>
<tr>
<td>100</td>
<td>11.6667</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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 manufacturer.

**NOTE 1**  At 80 MHz and 800 MHz, the separation distance for 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.
## Overall Sensitivity

<table>
<thead>
<tr>
<th>Diameter of Target Reflector (mm)</th>
<th>Distance (d) (mm)</th>
<th>Reflection Loss A(d)</th>
<th>Two-way Attenuation ( B = \sum B_x ) (dB)</th>
<th>( V_x ) (c.m.s) mV</th>
<th>( V_y ) (c.m.s) mV</th>
<th>( C = \frac{20 \log_{10} }{V_x} ) (( V_y )) dB</th>
<th>Overall Sensitivity (S = A + B + C) dB</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.58 A=45.7 dB@2MHz</td>
<td>50</td>
<td>45.7</td>
<td>( \sum B_x ) (T:mm) Bx,dB</td>
<td>0</td>
<td>57.6</td>
<td>186</td>
<td>94</td>
</tr>
<tr>
<td></td>
<td>75</td>
<td>45.7</td>
<td>( \sum B_x ) (T:mm) Bx,dB</td>
<td>0</td>
<td>56.4</td>
<td>175</td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>45.7</td>
<td>( \sum B_x ) (T:mm) Bx,dB</td>
<td>0</td>
<td>56.4</td>
<td>174</td>
<td>89</td>
</tr>
<tr>
<td></td>
<td>200</td>
<td>45.7</td>
<td>( \sum B_x ) (T:mm) Bx,dB</td>
<td>0</td>
<td>49.6</td>
<td>173</td>
<td>90</td>
</tr>
</tbody>
</table>

### Doppler Frequency (Hz)
- 333

### Velocity of Target (cm/s)
- 12.5