Pocket Fetal Doppler

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.

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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 B applied part.

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 not explosion-proof and can not be used in the presence of flammable anaesthetics.

⚠**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**⚠: 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 950 for data processing equipment and IEC60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC60601-1-1. 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**⚠: 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).

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 60601-1/1988: Limit: 100 uA (B).

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 insure 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 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.

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

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.

Pocket Fetal Doppler 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 .

It has audio output, and can be connected with earphone or recorder with audio input. They use standard 1.5 V DC alkaline battery (2 pieces). Rechargeable battery and charger can be optionally configured.

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 battery available which can work no less than 10 hours.

Chapter 3 Outlook and Configuration

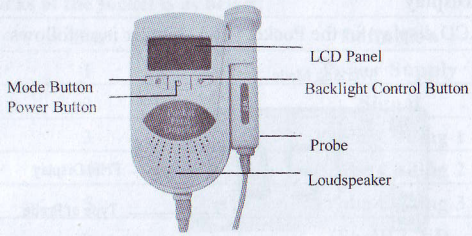

Fig.3-1 Front Panel

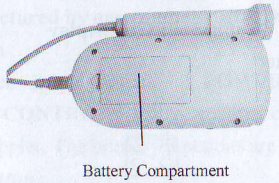

Fig.3-2 Rear Panel

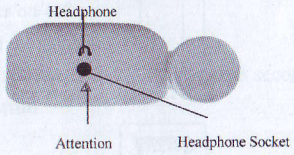

Fig.3-3 Top Panel

3.1 Front Panel

3.1.1 Display

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

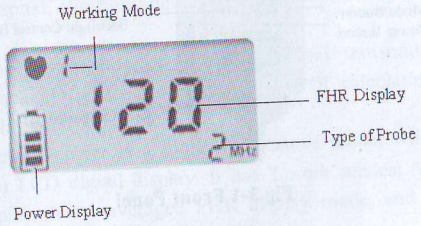

Fig.3-4 LCD Display

3.1.2 Probe Socket

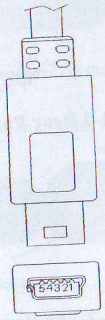

Fig.3-5 Probe Socket

The probe socket is shown as Fig.3-5 above. The definition of the jacks of the socket is as below:

Pin	Definition
1	Power Supply
2	Signal
3	Probe Coding 1
4	Probe Coding 2
5	Probe Coding 3
6	(Shell) GND

⚠WARNING⚠: Do not attempt to connect the probes which are not manufactured by our company with the machine.

3.2 Push 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: Push the button once

Power off: Push 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.

For the Fetal Doppler has memory function, when turning on the machine, it will enter the mode selected before last power off automatically after self testing.

3.2.3 Backlight Control Button

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

②Under 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

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.

3.3.1 Signal Interface

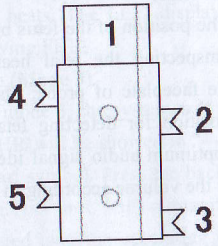

Fig.3-6 Headphone socket for audio output

Headphone socket showed as figure 3-6, the definition of pins showed as below:

Pin	Definition
1	GND
2	Signal
3	Signal
4	Signal
5	Signal

Chapter 4 General Operation

4.1 FHR Inspection

①Power on by pressing the Power button.

It will do self-test when turning on the machine. After self-testing, the LCD display is as Fig.3-4.

②Find the position of fetus.

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.

③FHR Calculation:

The FHR result will be showed on LCD screen.

④Turn off the machine

Keep pressing the power button 3 seconds to turn off.

⚠CAUTION⚠:

①Put the probe on the best detecting position to get better detecting effect.

②Don't put the probe on the position where have strong Placental Blood Sound(PBS) or strong Umbilical Sound(UMS).

③If 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.

④Do 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 8 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 caculating 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 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 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 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

①Taking 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 Probe

②Placing 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

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 or charge the battery (only the chargeable battery can be charged.).

4.5 Replacing Battery

4.5.1Taking 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).

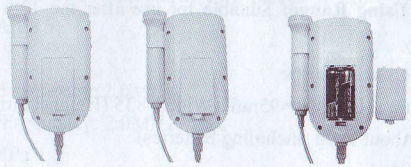

Fig.4-2 Replacing Battery

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: Pocket Fetal Doppler

Safety: Complies with: IEC 60601-1:1988+A1:1991+A2:1995

Classification:

Anti-electroshock Type: Internally powered equipment.

Anti-electroshock Degree: Type B applied part

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: 135mm (Length) ×95mm (Width) ×35 (Height) mm

Weight: About 180g (including batteries)

Environment

Working:

Temperature: +5℃～+40℃

Humidity: ≤80%

Atmospheric Pressure: 70 kPa～106kPa

Transport and Storage:

Temperature: -10℃～+55℃

Humidity: ≤93%

Atmospheric Pressure: 50 kPa～106kPa

Display: 45mm×25mm LCD display

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

FHR Performance

FHR Measuring Range: 50~240BPM (BPM: beat per minute)

Resolution: 1BPM

Accuracy: ±2BPM

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 battery (SIZE AA LR6).

Probe:

Nominal Frequency: 2.0MHz

Working Frequency: 2.0MHz±10%

P-: <0.5MPa

Iob:<10 mW/cm^2

Ispta: <50mW/cm^2

Ultrasonic Output Intensity: Isata<5 mW/cm^2

Working Mode: Continuous wave Doppler

Effective Radiating Area of Transducer: 208mm^2 ± 15%

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 an 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.

WARNING: 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:

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

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 hypoxia, fetal distress and the umbilical cord around the neck, and other symptoms. Fetal domestic monitor test FHR 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 become less. It is easy to arose 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 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

Overall Sensitivity

Overall Sensitivity														
Diameter of Target Reflector (mm)	Distance (d) (mm)	Reflection Loss A(d)	Two-way Attenuation $B=\sum B_s+B_w$						B_w (dB)	B (dB)	V_s (r.m.s.) mV	V_n (r.m.s) mV	$C=20\log_{10}\left(\frac{V_s(r.m.s.)}{V_n(r.m.s.)}\right)$ dB	Overall Sensitivity (S=A(d)+B+C) dB
				$\sum B_s$ (T:mm B_s:dB)										
1.58 A=45.7dB@ 2MHz	50	45.7	T	20	4.8	4.0	-		0	57.6	186	94	5.93	109.2
			B_s	40	9.6	8.0	-							
	75	45.7	T	20	4.8	3.4	-		0	56.4	175	90	5.78	107.8
			B_s	40	9.6	6.8	-							
	100	45.7	T	20	4.8	3.4	-		0	56.4	174	89	5.82	107.9
			B_s	40	9.6	6.8	-							
	200	45.7	T	20	4.8	-	-		0	49.6	173	90	5.68	100.9
			B_s	40	9.6	-	-							
2.38 A=43.2dB@ 2MHz	50	43.2	T	20	4.8	3.4	2.2		0	60.8	178	89	6.02	110.0
			B_s	40	9.6	6.8	4.4							
	75	43.2	T	20	4.8	3.4	1		0	58.4	170	90	5.52	107.1
			B_s	40	9.6	6.8	2							
	100	43.2	T	20	4.8	3.4	-		0	56.4	165	85	5.76	105.3
			B_s	40	9.6	6.8	-							
	200	43.2	T	20	4.8	1	-		0	51.6	160	85	5.49	100.2
			B_s	40	9.6	2	-							
Doppler Frequency (Hz)			333								Velocity of Target (cm/s)		12.5	