Fetal Doppler

User Manual

H5/H5-W-MA/EN
Ver:A-1

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.

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MANUFACTURER'S RESPONSIBILITY

Our company only consider itself responsible for any effects on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustment, modifications or repairs and carried out by persons authorized by our company, the electrical installation must comply with national standard, and the Fetal Doppler is used in accordance with the manual's instructions.

⚠ *WARNING:* This device is not intended for treatment. The proposed procedure is for clinical use. Should the FHR result be suspicious verify immediately using a stethoscope

Warranty.

Maintenance must be done by engineers approved by the manufacturer. The manufacturer warrants that each product is free from defects in labour and materials and will conform to its product specifications as defined in the user documentation. In case of malfunction during the warranty the product will be repaired or replaced free of charge Misuse or improper maintenance will void the warranty.

SECTION 5: SMALL TIPS

Significance of Fetal Domestic Monitor: Modern medicine believes that the FHR is an important way of identitying fetal health. By recording FHR changes , one can observe fetal hypoxia, fetal distress and the umbilical cord around the neck, as well as the heartbeat. Fetal domestic monitor is a powerful guarantee to ensure the safety of your baby.

Fetal heart rate changes are most obvious 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

In these three periad above, due to the change of the body status of pregnant women, the activity of food digesting reguires the body to provide more oxygen,and so fetus'oxyen supply lessens. Therefore, it becomes easy to detect symptoms such as fetus anoxia. Testing the FHR at this time can best display the status for the baby.The above three periods can only be tested at home by pregnant women themselves, so FHR domestic monitor is very important.This product can hear the fetal hearteat for fetus above 16 weeks, and the FHR will displays on the LCD. Pregnant women can record and the FHR will displays on the LCD. Pregnant women can record this data which can be a reference for doctors to ensure the health of the

CLEANING INSTRUCTIONS

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 of the chassis daily with a soft cloth. If necessary, soak the cloth in a solution of soap, or water and wipe dry with a clean cloth immediately.

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

RECYCLING THE BATTERIES

When the battery no longer hold a charge, they should be replaced. Remove the old battery from the product and follow your local recycling guidelines.

AUTHORIZED REPAIR SERVICE

The Product has no user-serviceable internal components. Try to resolve any maintenance issues with the Product by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Service.

⚠ *CAUTION:* The warranty will be void upon unauthorized disassembly or service of the product.

CONTENT

SECTION 1: INTRODUCTION

PRODUCT DESCRIPTION

H5/H5-W Fetal Doppler is a hand held device for inspecting Fetal Heart Rate (FHR) specially designed for expecting women to conduct a daily inspection monitoring and fetus care whilst listening to the fetal heart beat.

►H5 models: The probe with the host through the cable connection

►H5-W models: The probe with the host through 2.4 G wireless communication technology for wireless connection.

Main Features:

◆ Delicate and compact design, portable to use.

◆ High sensitive doppler probe .

◆ Low ultrasound output intensity, much lower than the relative govemment standard, and with very high safe quality.

Intelligent power management, energy saving, save electricity.

◆ Safety and Reliability. When the FHR is not in the safe range (<100 Beats/minute and>160 Beats/minute)for over 10 seconds, the sign "🔔" will flash simultaneously.

The accessories should be disposed of appropriately and replacement parts shall be ordered.

If it appears below problems when you use the , please solve them as below.

Problems	Possible reasons	Solutions
Weak sound	· Volume is too low · Power is low · Daub gel	· adjust the volume louder · change the battery · daub more gel
Noise	· Volume is too high · Power is low · Disturbance from outside signal	· adjust the volume louder · change the battery · change location
Low sensitivity	· Position of the probe is not correct · Daub more gel	· adjust the position of the probe

The recommended inspection interval is monthly. If there is evident damage,replacement is recommended before use.

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

- **Visual Inspection**
- **Cleaning the Product and its accessories**
- **Testing the product Performance**

RECOMMENDED MAINTENANCE AND CARE

The Product and its accessories should be carefully inspected prior to installation, once every 12 months thereafter and each time the equipment is serviced.

- **Carefully inspect the equipment for physical damage**
- **Inspect the graphics display for marks, scratches, or other damage.**
- **Verify that the Safety label on back of the Product is clearly legible**

⚠ ***WARNING:*** **After the visual inspection, if the Product and/or its accessories are damaged please contact Customer Service. The Product will need to be returned back to for repair.**

◆ Can connect to computer or recorder to record the baby heart sound with recording cable at the same time of monitoring fetal heart beat.

◆ The FHR data can be stored in the instrument. The instrument can store ten group FHR data.

◆ After 2 mins without any FHR signal, it will be automatic shutdown.

SAFETY GUIDANCE

To avoid any possible danger, please operate the instrument according to following safety guidance:

1. It is a precision instrument, please don't open it by yourself.
2. This instrument can be cleaned with a non-corrosiveness cleanser. Avoid high temperature, the probe can be cleaned with 70% ethanol.
3. Remove batteries if device is not in use. The used battery should be disposable according to local law of environmental protection.
4. Avoid vident movements to damage device.
5. The instrument should be kept from water and humidity.
6. The service life of this instrument is 3 years.Proper maintenance

can prolong its service life.

IMPAIREMENT TO USE

None normally in a specific case, please consult your doctor.

SAFETY TERMS AND CONDITIONS

The warning signal shown below identify the potential hazard categories. The definition of each category is as follows:

⚠ ***DANGER:*** **This alert identifies hazards that will cause serious personal injury or death.**

⚠ ***WARNING:*** **This alert identifies hazards that may cause serious personal injury or death.**

⚠ ***CAUTION:*** **This alert identifies hazards that may cause minor personal injury, product damage, or property damage.**

SAFETY ALERT DESCRIPTIONS

The following is a list of Product safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the product.

⚠ *DANGER:* Fire and Explosion Hazard

Do not operate the Product in the presence of flammable gases to avoid possible explosion or fire hazard.

⚠ *CAUTION:* Temperature/Humidity/Pressure Extremes

Exposing the Product to extreme environmental conditions

SECTION 4:MAINTENANCE & SERVICE

OVERVIEW

Proper maintenance of the Product is very simple, yet it is an important factor in its reliability. The section describes the maintenance and service required for the Product and its accessories.

MAINTENANCE

⚠ ***WARNING:*** Failure on the part of all responsible individuals, hospitals or institutions, utilizing this device, to implement the recommended maintenance guidance may cause equipment failure and possible health hazards. The manufacturer does not,in any manner, assume the responsibility for performing the recommended maintenance routine.The sole responsibility rests with the individuals, hospitals, or institutions utilizing the device.

The probe acoustic surface is fragible and must be handle with care .Gel must be wiped off 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 effect patient safety or product's capability before use.

P- : <1Mpa

I^{ob} : <20mW/cm²

I^{Spta}: <100mW/cm²

Working Mode: Continuous wave Doppler

Nominal Area of Transducer:1.57cm²±10%

Effective Radiating Area of Transducer(6dB): >40mm²

Testing condition

Doppler Frequency:300± 50Hz

Target velocity:10-40cm/s

Water bath temperature:25± 2℃

Environmental temperature:25± 2℃

Acoustic coupling medium: water/Ultrasound transmission gel (Acoustic impedance: 1. 7×105g/cm²s)

outside of its operating parameters may compromise the ability of the Product to function properly.

⚠ ***CAUTION:*** Battery Disposal. Recycle or dispose of the batteries in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

⚠ WARNING: Use only Approved Equipment

Do not use batteries, gel, cables, or optional equipment other than those approved which may cause the product to function improperly during a rescue.

⚠ *CAUTION:* Possible Radio Frequency (RF) Susceptibility .RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause interference with the product.Do not operate wireless signals in the vicinity of the product – turn power OFF to the cellphone and other like equipment near the product.

⚠ *WARNING:* Adjacent or Stacked Equipment

The Product should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary,the product should be observed to verify normal operation in the configuration in which it will be used.

CAUTION: Systems Statement

Equipment connected to the product must be certified to the respective IEC Standards (i.e. IEC 950 for data processing equipment and IEC 601-1 for medicale quipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for the system complying with the requirements the system standard IEC 601-1-1. The Product Service Port is only intended for use during maintenance by authorized service personnel.

CAUTION: Case Cleaning Solutions

When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

CAUTION: Environment of use

The product is designed for indoor use. Operator must confirm that the environment of use meets the required operating environmental specifications before using.

Transport and Storage:

Temperature:-40℃~+55℃

Humidity:≤90%

Atmospheric Pressure:50kPa~106kpa

Power

Host Internal:1.5V Battery×3(Size:AAA)

Probe Internal:3.7V Lithium polymer battery

External:5V USB equipment power supply.

AC/DC Adaptor:

Input:AC100~240V,50Hz/60Hz,0.2A MAX.

Output:DC 5V,1000mA,5VA.

FHR Performance:

FHR Measuring Range:50-210BPM(Beat per minute)

Resolution:1BPM

Accuracy: ±2BPM

Probe:

Working Frequency:2.5MHz±10%

Output power: <10mW/cm²

Spatial-peak temporal peak acoustic pressure: <0.1Mpa

Ovearll Sensitivity: ≥90dB

SECTION 3: SPECIFICATIONS AND SAFETY

Product Name: Fetal Doppler

Model No.: H5/H5-W

Classification:

Anti-electroshock Type: Internally powered equipment

Anti-electroshock Degree: Type B equipment

Harmful Liquid Proof Degree: IXP4

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

Physical Characteristic:

Main body: 132mm(L)×68mm(W)×34mm(H)

Probe: H5 models:31mm(Ø)×103mm(H)

H5-W models:32mm(Ø)×120mm(H)

LCD Display:38mm(Ø)

Weight: About 200g (including batteries)

Environment:

Working:

Temperature: +5℃~+40℃

Humidity:≤80%

Atmospheric Pressure: 70kpa~106kpa

⚠ *CAUTION:* Cold Environments

If the Product is stored in an environment with a temperature below the operating temperature, the unit should be allowed to

SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the product, or on it's 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 it's accessories.
	Caution: Consult accompanying documents
	Authorized Representative in the European Community
	CE Mark: The Product system conforms to essential requirements of the Medical Device Directive 93/42 /EEC.
	Date of manufacture.
REF	Device Model Number. Battery Model Number.
LOT	Lot Number

	Manufacturer
	Headphone jack
SN	Specifies serial number of the product
	Battery direction identification
	DISPOSAL: Only dispose of this product in specific collection point special treatment is necessary for its disposal.

SAFETY AND PERFORMANCE STANDARDS

The product has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The product conforms to the applicable requirements of the following:

CE 0197 **CE Marked by TUV 0197 per the Medical Device Directive 93/42/EEC of European Union**

Electrical, Construction, Safety and Performance

IEC 60601-1(2005)IEC 60601-2-37(2007)

IEC 60601-1-4(2002)

IEC 1266(1994)

Electromagnetic Compatibility (EMC)

IEC 60601-1-2(2007)

1000mA) for charging. When charging, power light is orange. When fully charged, the power light is green.

⚠ ***CAUTION:*** **The host can't be charged.**

" . "," "cycle changes occur. When pairing, please make sure the host and probe has enough power.

When the probe enter the pairing state, the probe indicator light will stop flashing. The host interface pairing signal identification is shown as " ", means the pairing success. If as shown is as " . ", the pairing is not successful. Pairing successful should be operated again.

⚠ *CAUTION:* The above frequency operation, H5 models do not apply.

CHARGING INSTRUCTIONS

Host section uses 3 AAA batteries.If the battery indication shown " ",it means battery voltage is low and it has to replace the battery as soon as possible.

The Probe is used 3.7 V Lithium polymer battery (H5 models do not apply), when the power indicator light (green) is flashing , show power low, the probe need to recharge. The probe can be used 5V USB output devices to recharge, also can buy power adapter (Input: AC 100 ~ 240V, 50/60Hz, 0.2A MAX; Output: DC5V,

SECTION 2: OPERATION

FHR INSPECTION

1. Before the first use, H5 models please use USB cable to connect the probe and host, H5-W models press the probe power ON/OFF Button for 1 second to turn on the probe.

2.Press the host power ON/OFF Button for 1 second to turn on the product. The LCD display is "---".

3. Find the position of fetus: At first, please feel the fetus by hand. Find out the best direction for inspecting the fetal heart. Apply a generous amount of gel or baby oil to the probe faceplate and place the faceplate in the best position for detecting fetal heart. Adjust the probe to obtain an optimum audio signal ideally by adjusting the angle of the probe. Adjust the volume according to requirements.

⚠ *CAUTION:* Don't adjust the Volume Control Button in very loud volume When finding the fetal heart positions.make sure the sound is kept niuted

4. FHR calculation: The FHR will be displayed on LCD screen .

5. After operation, use a cloth to wipe off the gel or baby oil left on the probe.

BUTTON DESCRIPTION

“ ⏻ ”:Power ON/OFF Button. Turn ON/OFF the host or probe

“ + ” and “ - ” : Volume Control Button. In monitoring interface, these two buttons are used to increase and decrease the audio volume. In playback interface, these two buttons show stored FHR value in the instrument.

“ ↺ ”:Playback Button.Press this button and enter the playback interface. If no any operation, 5 seconds after the instrument will exit the interface.Press this button to 3 seconds, can remove the FHR value which is saved in the instrument.

“ ■ ”:Function Button. Press the button, the instrument will automatically store the current instantaneous value of heart rate. To press these “ ■ ” Button of host and probe at the same time,and hold more than 4 seconds,the instrument will enter into radio frequency pairing.

INTERFACE DESCRIPTION

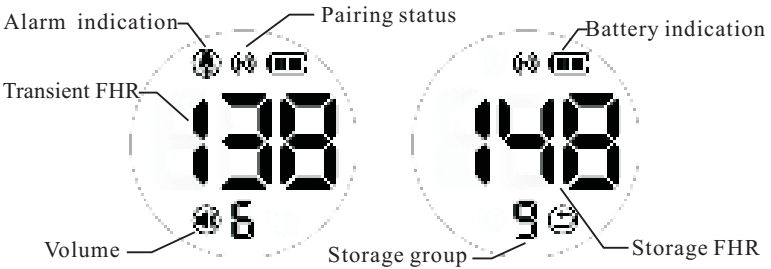

Fig 2.1 The monitoring interface Fig 2.2 The playback interface

MATCHING OPERATION

The probe and host turned on at the same time, if the interface pairing status is shown as " ", said the probe and the host can be worked together, does not need to pair. If pairing signal identification is shown as " . ", said the probe and the host can not worked together, operation need to be paired.

To press these two button of the host and probe at the same time more than 4 seconds, The instrument will enter the radio frequency pairing status. The probe indicator light (green) appear flicker phenomenon, host interface pairing signal identification " ",