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Edition: V1.0

Issue Date: December 10, 2010

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CHAPTER 1 Introduction

1.1 Brief Introduction

Thank you for purchasing the Fetal Doppler. The device adopts ultrasound to detect the heart rate of fetus. The purpose of this manual is to guide users in the operation and care of the Fetal Doppler. Please read the manual carefully before using the device.

Note: The illustrations applied in the manual may differ slightly from the actual unit.

1.2 Safety Information

Conception of Warning, Caution and Note

The Warning, Caution and Note at this document are special information in favor of user's operation.

Warning - Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.

Caution - Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

Note - Provides application tips or other useful information to ensure that you get the most from your product.



Warnings!

- Users should follow all instructions listed in this manual. Our company will assume no warranty for using the device improperly.
- The device is not intended for treatment. If you have any doubt about the fetal health status after using this device, please use other methods for further examination immediately.
- Self-diagnosis and treatment is dangerous. Never use the device in critical situations! Please consult professional doctors.
- Do not use the equipment in the presence of flammable anesthetics, vapors or liquids, otherwise it may cause the risk of explosion.
- Do not use the equipment in an MRI or CT environment.
- This equipment is intended only as an adjunct in patient assessment, and the measurement results only serve as a reference for any relevant treatment.
- The surface of the device can be wiped with alcohol gently. The device is strictly forbidden to contact with strong acid or alkali.
- Operation of the Fetal Doppler may be affected by the use of an electrosurgical unit (ESU).
- This device is not intended for use on or around the eyes.
- This device is not for invasive use.
- Connect the probe correctly; please see the directions for use of any accessories.
- The malfunction of probe or worn-out data cables may cause inaccurate measurement results, so the user should inspect them frequently and make sure that they are in good working state.
- The disposable accessories should not be cycled.
- The Fetal Doppler can assist users to diagnose the fetal viability basically, but it cannot be used for medical training.
- Damage may result if the Fetal Doppler is knocked or dropped.

Cautions

- Clean the probe with an H₂O solution and a neutral detergent.
- Don't submerge the probe into any liquid. Do not use in autoclave (sterilizer).
- Before cleaning or disinfecting the probe, unplug it from the device to prevent probe or device from being damaged, and to protect users under safety situation.
- To avoid an electrical hazard, never immerse the device in any liquid or attempt to clean it with liquid cleaning agents.
- The materials that contact with human bodies are all non-toxic.
- Under poor signal conditions, the fetal heart sounds and readings may not be accurate.
- If the specification or function of the device is abnormal during measuring, stop measuring immediately and consult us.

Notes

- Application of this device in the background of electromagnetic areas may influence the measuring accuracy such as in the environment of electro-surgery.
- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.
- Dispose of the device or its accessories end of life in accordance with the local ordinances and regulations, otherwise, discarding them as you like may cause pollution to the environment.
- Our company will only provide the schematic, components list, legend and correction details for the qualified technical personnel authorized by our company.
- Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.
- The circuit diagrams, the list of components, the illustration of diagrams, and the detailed rules of calibration, are provided exclusively to professional personnel authorized by our company.
- As to the other concerns for attention, please carefully look through the specific chapter in this instruction.

1.3 Intended Use

The Fetal Doppler is a non-invasive hand-held device with a speaker. This device is used for the pregnant as early as 10 weeks in pregnancy to detect fetal heart rate (FHR) through the principle of ultrasound in hospital or homecare environment.

1.4 Electromagnetism Interference

This device is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the electronic medical device - IEC 60601-1-2. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (e.g. cellular phones, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

This apparatus complies with the IEC 60601-1-2 international standard. The requirements of this international standard are: CISPR11, GROP1, and CLASS B.

1.5 Explanation of Symbols

Symbol	Explanation
	Attention, consult the accompanying documents.
	Type BF applied part
	Date of Manufacture
	Manufacturer's information.
	The battery power indication
IPX4	Protected against water
	Volume indication
	Probe off
	Heart beat indication
FHR	Fetal Heart Rate
SN	Serial number
	Prevent from rain
	Storage temperature and relative humidity

Note: The degree of protected against water IPX4 is only applied for the probe, and the main body of the device doesn't have the capacity of waterproof.

1.6 Product Features

- Compact design and light in weight;
- Portable and easy to operate;
- Three measurement modes: real time, average and manual;
- TFT display screen with adjustable backlight;
- Shown in red when the heart rate beyond normal range.
- Powered by two AA alkaline batteries;
- Headphone and audio connector;
- Suitable for pregnant women as early as 10 weeks.

1.7 Ultrasound Safety

Diagnostic ultrasound has been in use for over 25 years with no confirmed adverse effects on patients or instrument operators at the intensities typical of present diagnostic instruments. Although the total absence of adverse effects to human subjects after such extensive use at diagnostic power levels is gratifying, available data are not conclusive and the possibility that biological effects may be identified in the future remains. It is therefore deemed desirable by medical and other scientific authorities in this field that exposure to ultrasound should be limited to the duration and intensity appropriate for the clinical objective. Because fetal tissue could be more sensitive to biological effects by reason of pregnant subjects be kept to a minimum. At present, there is a clear consensus that the benefits to patients of prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

CHAPTER 2 General Description

The MD800 Fetal Doppler has three measurement modes: real-time FHR measurement mode; average FHR measurement mode and manual counting mode. It adopts TFT screen, which can display the FHR value, volume indication, battery power indication, the connection status of probe and so on.

The MD800 Fetal Doppler has audio output and can connect with headphones. It is equipped with 2MHz ultrasound probe.

2.1 Appearance

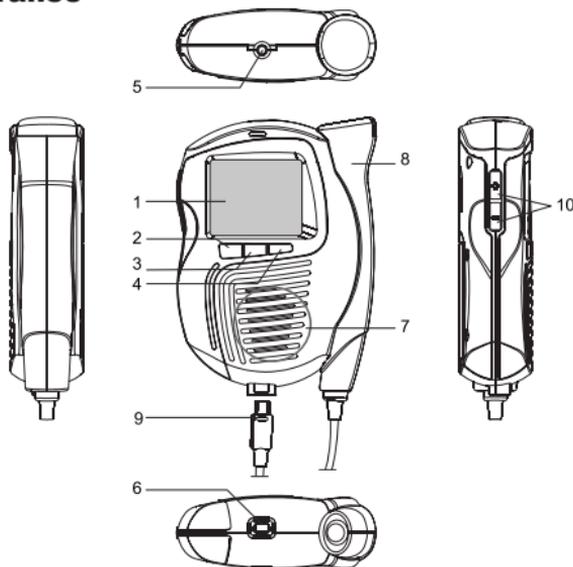


Fig.2-1

Description of Fig.2-1:

- (1) **Display screen** ;
 - (2) **Mode button**: the button for changing the measurement mode, each time this button is pressed the mode switches to the next. Every time you power on the device, it will enter the measurement mode which the device is in the last shutdown.
 - (3) **Power button**: press and hold it for 3 seconds to power the device on, and for 4 seconds to turn the device off.
- Note:** The device will power off automatically when there is no signal for 1 minute.
- (4) **Backlight button**: this button is a double-use key, when in mode 1 and mode 2 the button is used for adjusting the brightness; when in mode 3 this button is used for starting or terminating a time.
 - (5) The socket for connecting headphones.
 - (6) The socket for connecting probe.
 - (7) Speaker.
 - (8) The ultrasound probe.
 - (9) The connector of the probe.
 - (10) The buttons for adjusting volume.

2.2 Power Supply

The device can be powered by 2 AA alkaline batteries.

Batteries Installation:

- 1) Open the battery cover and you can see the battery polarities as shown in Fig.2-2.
- 2) Install 2 AA alkaline batteries lightly as indicated by the polarity signs in the battery compartment.



Warnings!

- DO NOT USE Ni-MH rechargeable and alkaline batteries together, otherwise, that may damage the device or injury users.
- Make sure the polarities of the batteries are correct.

- 3) Close the battery cover.

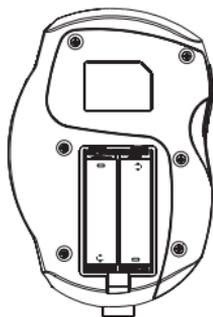


Fig.2-2

Battery life

When the battery power is lower than 2.2V the battery indication will become empty and keep flashing, which means little of battery capacity remains. You should replace the batteries with new ones in time.

The device will shut down automatically after the battery indication flashes for 10 seconds.

Cautions:

- Do not use batteries not specified for this unit.
- Do not dispose of batteries in fire.
- If battery fluid gets on your skin or clothing, rinse with plenty of clean water immediately.
- Take out batteries from the unit when you are not going to use it for a long period of time (approximately one month).
- Keep a certain distance (further than 1.5m) from patients when replacing batteries.
- Do not use batteries of different types together.
- Do not use new and used batteries together.
- Dispose of batteries in accordance with the local ordinances and regulations.

CHAPTER 3 Take a Measurement

3.1 Connect the Probe

Before taking measurement, you should connect the ultrasound probe firstly as shown in the following figure.

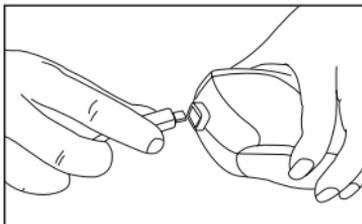


Fig.3-1

3.1.1 Probe Detection

When there is no probe or the probe is not connected well, the probe off indication () will be displayed in the screen, and the "----" will flash in red simultaneously.

When the probe is connected well but no signal is detected, the "----" will be displayed in red without flashing.

3.1.2 Replacement of Probe

The Fetal Doppler will be connected with a probe before leaving factory. If necessary, you can change the probe for another one compatible with the Fetal Doppler. Unplug the connected probe from the probe socket, and then connect the needed probe with the device.

Notes:

- Please take care of the temporary idle probe, prevent from dropping, splashing, strong weight and so on.
- If you are not going to use the probe for a long period of time, it is recommended to connect the probe to a device, and then put the device together with the probe into the package box.

3.1.3 Remove and Place the probe

(1) Remove the probe

Hold the Fetal Doppler with one hand, and hold the probe with the other hand, remove the probe as shown in the following figure.

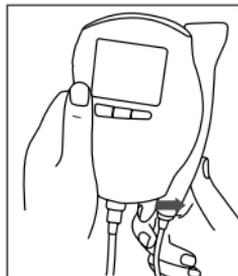


Fig.3-2

(2) Place the probe

The operation of placing the probe is as shown in the following figure. Place the probe into its notch until you hear the click sound, which means the probe is placed well.



Fig.3-3

3.2 Detection of Fetal Heart Rate

1. Power on the device

Press and hold the Power button for 3 seconds to power the device on, the TFT screen will display as shown in Fig.3-4.

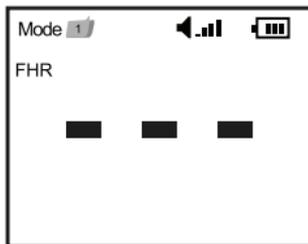


Fig.3-4

2. Find the fetal position

Firstly feel the fetal position with your hands to find the best test site. And then smear amount of ultrasound coupling agent evenly on the acoustic surface of the probe, attach the probe to the abdomen of pregnancy. Adjust the position or angle of the probe to obtain the best fetal heart signal.

Notes:

- You may hear noise when taking measurement if the test site is not good, and also you may get an inaccurate measurement result.
- Although the Fetal Doppler can detect fetal movement signals as early as 10 weeks in pregnancy, you might not get the desired result due to different individual development.

3. Display of the fetal heart rate

The value of the fetal heart rate will be displayed on the screen. It will display “---” if there is no signal for 3 seconds.

The measuring screen is as follows:

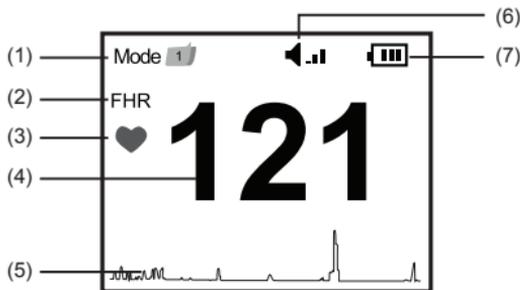


Fig.3-5

- (1) Measuring mode;
- (2) FHR, fetal heart rate;
- (3) Heart beat indication, when the device detects signals, that icon will flash with the fetal heart beat in the same frequency;
- (4) The current measured value of fetal heart rate;
- (5) Fetal movement waveform;
- (6) Volume indication, you can adjust the volume via the two side buttons;
- (7) The battery power indication;

The value of fetal heart rate will be displayed in red when the detected value is out of the normal range of 120~160bpm.

4. Power off the device

After operation press and hold the Power button for 4 seconds to power the device off.

5. Cleaning

Clean the coupling agent on the surface of the probe with a piece of soft cloth.

Notes:

- The probe should contact with the abdomen closely.
- Search for fetal heart position. Only the probe is placed on the best position the accurate measurement result will be obtained.
- Do not place the probe on the position where the stronger placental tone or the wave sound of the umbilical blood flow can be heard.
- Unless the fetal heart sound signal is heard, it is impossible to detect the fetal heart rate.

3.3 Measurement Modes

There are 3 measuring modes for the device.

Mode 1: real-time measuring mode

At the moment that the fetal heart signal is detected, the heart beat indication will flash and at the same time the instantaneous fetal heart rate will be displayed on the TFT screen.

Mode 2: average measuring mode

You can obtain a more stable fetal heart rate through this measurement mode. The value displayed on the TFT screen is the average of the latest 8 fetal heart rate. In this mode the fetal heart rate displayed on the screen changes slowly.

Mode 3: manual measuring mode

The device begins counting once enters this mode, the "--" will be shown at the display area of fetal heart rate. When the fetal heart signal is detected, the heart beat indication will flash on the screen. Press the Backlight button to stop counting. The device will calculate the average of the fetal heart rate automatically obtained during the period from the beginning to stopping counting, and display the results. If more measurements are needed, you can press the Backlight button to beginning counting, and press it again to stopping counting. The value of fetal heart rate will be kept until the next measurement is taken or the measurement mode is changed.

Note: The degree of brightness can not be changed in mode 3.

CHAPTER 4 Maintenance and Cleaning

4.1 Maintenance

The acoustic surface of the ultrasound probe is a precision substance, so it must be handled with care. You should wipe away the remaining coupling agent on the probe after using the device. Those maintenance steps may extend the service life of the device.

Before using, users should inspect the device for damages that may affect the patient safety or the device's performance obviously. The recommended inspection cycle is one time per month. It is suggested to replace the damaged parts before using the device if you find the obvious damage.

Safety testing and leakage current measurement should be performed on the device periodically to ensure the insulation of leakage current. The recommended test cycle is one time every two years (or perform the test following the inspection procedure specified by public institutions).

The accuracy of the fetal heart rate measurement is determined by the device, and it can't be adjusted by users. If the measurement result is not credible, please adopt other methods such as stethoscope to verify the result, or contact the local agent or manufacturer for help.

Battery maintenance

Please take out battery if you will not use the device for a long time.

If any abnormal phenomena occurs, you should stop using immediately and reuse after inspection by technical person.

- f) Inspect the equipment and accessories for mechanical and functional damages.
- g) Inspect the safety relevant labels for legibility.
- h) Verify that the device functions properly as described in the instructions for use.

Safety Checks

Before every use, or after your Fetal Doppler has been used for 6 to 12 months, or whenever your device is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability. Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Make sure that only specified accessories are applied.
- Make sure that the Fetal Doppler is in good working condition.

In case of any damage or abnormality, do not use the device. Contact your hospital's biomedical engineers or your service personnel immediately.

4.2 Cleaning

Power off the device and take out batteries before cleaning.

Keep the surface of the device clean, no dust and dirt. You can clean the surface of the device as well as its TFT screen with a piece of soft and clean cloth. Dip the cloth with soapy water if necessary. Wipe off all the cleaning solution with a dry cloth after cleaning.

Wipe off the remaining coupling agent on the probe. The probe can be cleaned with water or soapy water or ethanol (70%), and dry it in a ventilated, cool place.

Cautions

- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).
- Do not allow any liquid to enter the case.
- Do not immerse any part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not left any cleaning solution on the surface of the device.
- Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damages caused by unapproved substances or methods.

4.3 Disinfecting

The applied parts touching the patients' body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

Disinfection may cause damages to the device, and therefore is not recommended for this device unless special provisions are indicated in your hospital's servicing schedule. Clean the device before disinfecting.

Cautions

- Never use EtO or formaldehyde for disinfection.
- Do not use low-temperature steam or other methods for sterilization.
- Do not use high-temperature sterilization or radiation to disinfect the device.

CHAPTER 5 Warranty and Repair

5.1 Maintenance Method

- a) Maintenance responding time: 9:00am ~ 17:30pm, Monday to Friday
- b) Service support: Our company will offer user telephone and e-mail technology support and parts change.
Parts change: our company will change parts if it is necessary free of charge in the warranty period.
Because parts are the sources of maintenance, user should send them back to our company if not specified.
- c) Update the system software free of charge.

5.2 Exempt and Limitation

- a) Our company isn't responsible for such damage caused by natural disaster. For example: fire, thunder flash, flood, cyclone, hail, earthquake, house collapse, commotion, plane failing and traffic accident, deliberate damage, lack of fuel or water, labor and capital bother, strike and stop-working etc.
- b) No-service offer
The corresponding fee and insurance fee of disassembly, refurbishment, repackaging and conveying of the device or the part of it doesn't comply with the instruction manual.
The damage is caused by the third company which is not commended by our company adjusting, installing or replacing the parts of the device.
The damage and failure caused by user or its representative doesn't comply with the instruction manual.
- c) The unit is installed or connected with external devices such as printer, computer, internet line and so on without our company's permission, which leads to the failure of the device. Our company will charge for the maintenance.
- d) Responsibility limitation
During the period of maintenance contract validity, if user changes the parts manufactured by other manufacturers without our company permission, our company is entitled to stop contract.

5.3 User Guarantee

- a) Please read the instruction manual completely before operation.
- b) Please operate and make daily maintenance as request of manual and guarantee.
- c) Power supply and environment.

5.4 No-guarantee Principle

There is no-dispelled smut and not-original mark in the crust.

- There is physical damage on the unit and its accessory.
- There are liquid and eyewinker leftover on the unit which lead to short circuit and plugboard failure.
- All the probe and accessories belong to consumption and beyond free change range.
- Such damage of probe caused by mechanical force doesn't belong to free change range.
- Maintenance seal of the unit are not opened.
- Not-original package leads to damages to the unit during transportation.
- Not-professional person operation leads to measurement failure. Not our company professionals or authorized personnel disassemble the unit and lead to its failure.
- Not carefully read this manual and wrong operation leads to damage and failure.

5.5 Repackage

- Take all the accessories and put them into plastic cover
- Try to use original package and packing material. The user will be responsible for such damage caused by bad package during transportation.
- Please offer guarantee list and copy of invoice to standby with the period of guarantee.
- Please describe failure phenomenon in detail and altogether offer the device.

5.6 Storage and Transportation

Storage: Storage Temperature -20°C~55°C ; Relative Humidity ≤93%, no condensation.

Transportation: Transport by airline, train or vessel after packing according to request.

Package: We pack the product with the hard bag. We put the foam between the inner box and the cartoon to alleviate the shake.

CHAPTER 6 Troubleshooting

Problem	Cause	Solution
The voice is too low.	The volume is turned too low.	Turn up the volume.
	The battery capacity is insufficient.	Replace the batteries.
	Poor location of the probe.	Adjust the probe for a better test site.
	The probe is not coated with sufficient coupling agent.	Add the coupling agent.
No voice	Probe off.	Plug the probe well.
	Sound off.	Turn up the volume.
Noise	The probe is kept too closely to the device.	The probe should be kept at a certain distance from the device.
	Interference come from external signals.	Keep away from external signals.
	Poor location of the probe.	Adjust the probe for a better test site.
The screen gets dark.	<p>Batteries might not be installed or installed incorrectly.</p> <p>The battery capacity may be exhausted.</p> <p>The TFT screen or the Fetal Doppler is damaged.</p>	<p>Please check if the batteries is installed correctly.</p> <p>Please replace batteries.</p> <p>Contact local Customer Technical Service.</p>

Appendix Specifications

Notes:

- Specifications may be changed without prior notice.
- The circuit diagrams, the list of components, the illustrations of diagrams, and the detailed rules of calibration are provided exclusively to professional personnel authorized by our company.

Display

TFT screen;

Data: FHR (fetal heart rate), fetal movement waveform;

Others: measuring mode, probe off indication, volume indication, battery power indication and heart beat icon;

Data update time: less than 30 seconds;

FHR

Display range: 40~230bpm

Measurement range: 50~210bpm

Resolution: 1bpm

Accuracy: ± 2 bpm

Working Current: <300mA ;

Probe

Standard frequency: 2.0MHz;

Working frequency: 2.0MHz $\pm 10\%$;

Peak negative pressure: $P_- < 1$ Mpa;

Output beam intensity: $I_{ob} < 20$ mW/cm²;

Spatial peak, temporal average: $I_{spta} < 100$ mW/cm²;

Ultrasonic output intensity: $I_{sata} < 10$ mW/cm²;

Ultrasonic output power: $P < 20$ mW;

Working mode: continuous Doppler;

Valid emission area of ultrasonic: 208mm² $\pm 15\%$.

Classification

According to the method of sterilization or disinfection:

Non-sterilizable: Use of Liquid surface disinfectants only;

According to the type of protection against electric shock:

Internal powered equipment;

According to the degree of protection against electric shock:

Type BF applied part;

According to the degree of protection against ingress of water:

The 2MHz ultrasound probe: IPX4;

The main body of the device doesn't have the capacity of waterproof.

Operation mode:

Continuous operation mode.

Environment Requirements

- Operation temperature: 5°C~40°C
Operation humidity: ≤80%, no condensation
Storage temperature: -20°C~55°C
Storage humidity: ≤93%, no condensation
Power supply: Two AA alkaline batteries
Working time: work for 6 hours at least continuously
Ambient atmosphere: 86~106kPa

Outline of product

- Dimension: 150.7mmX99.3mmX36.5mm
Weight: 278g (including the batteries)

Accessories:**Standard accessories:**

1. Two AA alkaline batteries;
2. One instruction manual;
3. One ultrasound probe;
4. 30ml of ultrasound coupling agent for medical use.

Manufacturer address:

Beijing Choice Electronic Technology Co.,Ltd.

Bailangyuan Building B

Rm. 1127-1128, Fuxing Road, A36

100039 Beijing

PEOPLE'S REPUBLIC OF CHINA