Fetal Doppler

Operation Manual

Part No.: VTF-FDLB-OM-03
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Contents

Preface

0.1 Copyright

0.2 Attention

For any modifications and upgrades, the information in this document is subject to change without notice.

This operation manual includes special documents which are under protection of copyright law.

0.3 Manufacturer's Responsibility

The manufacturers only consider itself responsibility for any effects on safety, reliability and performance of the device if : Assembly operations, extensions, readjustments, modifications or reparation are carried out by persons authorized by manufacturer, and the electrical installation of the relevant room compiles with national standard, and the document is used in accordance with the instruction for use. If necessary, we can provide necessary circuit diagram and other documents to help qualified technicians to maintain and repair the device.

⚠**WARNING**⚠: The device is not intended for treatment. The intended use is for inspecting of FHR. If the FHR result is distrustful, please use other methods such as stethoscope to verify immediately.

0.4 Warranty

The unit can not be repaired by users. All service must be done by the engineers approved by manufacturer. We warrant that each product is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product does not

function as warranted during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty.

0.5 Explanation

 : The label refers to follow operation manual.

NOTE: Provide useful information of a function or a procedure.

WARNING: The label advises against certain action or situation that could result in personal injury or death.

CAUTION : The label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate procedure.

Section 1 Safety Guidance and Symbols

1.1 General Safety

The device is internal power supply equipment, electrode protection class is BF type. BF type meant patient contact should meet the rule of allow the leakage current and dielectric strength in IEC 60601-1.
Before using the device, carefully examine the Fetal Doppler (hereinafter called device) and the accessories to ensure the main unit and accessories do not have any visible damage evidence that may affect patient safety and device performance. The recommended examination period is once per week.
The device is used for fetal heart rate test, and not intended for any treatment. If the test FHR result is useless, please try to test by other clinical test methods.
Installment, adjustment, maintenance and reparation can be carried out only by qualified or authorized personnel from manufacturer.

⚠**WARNING**⚠: The device uses very low power ultrasound doppler. It is confirmed by design calculation, laboratory test, clinical test and clinical application that the device doppler energy is safe for fetus, pregnant women and other personnel. Even so, it is not appropriate to use the device continuously or with long term.

NOTE: Before using the device, please read this manual carefully and assure to be familiar with the controls, displays, features and operating techniques.

1.2 Warnings

⚠**WARNING**⚠: This device is not explosion-proof and can not be used in the presence of flammable an anaesthetics equipment.

⚠**WARNING**⚠: Do not throw battery into fire as this may explode and cause danger.

⚠**WARNING**⚠: Do not attempt to recharge normal dry-cell battery, which may leak and cause fire or even explosion.

⚠**WARNING**⚠: Use the adapter complying with IEC60950.All configuration should conform with IEC60601-1-1

⚠**WARNING**⚠: Do not touch signal input/output connector and the patient simultaneously to avoid device damage.

⚠**WARNING**⚠: Accessory and equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards.

⚠ **WARNING** ⚠: The battery must be taken out if the device will not be used for a long time.

⚠ **WARNING** ⚠: The operator does not contact patient when changing battery and opening battery cover.

⚠ **WARNING** ⚠ : The device is a tool to aid the FHR inspection 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 specialized probes provided by the manufacturer.

⚠**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 device.

⚠**WARNING**⚠: The device is designed for interval operation and is ordinary. Do not drip, splash and immerse in any

liquid .

⚠**WARNING**⚠: Keep the device clean. Avoid vibration.

⚠ **WARNING** ⚠ : Do not use high or low temperature sterilizing process and E-beam or gamma radiation sterilization.

⚠**WARNING**⚠: The device is not subject to any sources of strong electromagnetic interference from radio transmitters, mobile telephones,etc.

⚠**WARNING**⚠: The user must check that the equipment does not have visible 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.

⚠**WARNING**⚠: The device can not be used when some equipment is used, such as high frequency electrical generator, microwave oven and mobile phone.

⚠**WARNING**⚠**:** Do not use the device in the presence of flammable anesthetic mixture with oxygen or other flammable agents.

⚠ **WARNING** ⚠ **:**The device is designed for interval operation with short time.

⚠**WARNING**⚠**:** Please stop using the device to deal with properly if the device construction is not integrated, such as the battery cover is lost.

⚠**WARNING**⚠**:** The operator, responsible organization and environmentalist who are related with this device do not need special skills, training and knowledge.

⚠**WARNING**⚠**:** This operation manual is written at a level without special education, training and other needs of individual for whom they are intended. For using in hospital and clinic, the operator needs to have relative qualification certificate such as nurse certificate. For using at home, when the test data are used to diagnose, it should be analysed by specialized medical

working personals.

⚠**WARNING**⚠**:** This minimum qualification of service personnel is to be familiar with our device operation and service technique.

⚠ **WARNING** ⚠ : The following safety checks should be performed once every half a year 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.

(1) Inspect the equipment for mechanical and functional damage.

(2) Inspect the safety relevant labels for legibility.

(3) Verify that the device functions properly as described in the instructions for use.

(4) Test the patient leakage current according to IEC 60601-1: limits less than 100uA (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 device conforms to IEC60601-1-2 requirement.

For battery installment or replacement, please follow this document.

Portable and Movable RF communication will affect the equipment performance, avoid the strong EM such as approach the telephone, microwave oven.

1.3 Cautions

⚠ **CAUTION** ⚠ : The battery must be properly disposed

according to local regulation after use.
⚠ **CAUTION** ⚠ : The device shall only be used when 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 battery before first use.Normally, battery must be continuously charged over 2 hours or charged according to the guidance displayed on the battery.
⚠**CAUTION**⚠: Please do not set anode and cathode of the battery wrongly.
⚠ **WARNING** ⚠: Device full charging can be continuously used for 4 hours.
⚠**WARNING**⚠: Please use the adapter according relevant national standard. Do not use the device when charging.
⚠**CAUTION**⚠: The information in this manual is subject to modify without notice.
⚠**CAUTION**⚠The device usage life is 5 years, after which please treat according to relative regulations.
⚠ **CAUTION** ⚠ : Do not use strong solvent (for example, acetone) and abrasion material to clean the device.
⚠ **CAUTION** ⚠ : Please choose the accessories and expendable authorized by manufacturer.
⚠**CAUTION**⚠: Air, sea and land transportation are allowed after package.In the process of transportation,it is not allowed to be stored in open air.

1.4 Symbols

Symbol	Explanation
	Type BF
	Refer to the operation manual

	Attention, refer to the accompanying documents
	Waste electrical and electronic equipment alone processing signs (please comply with local laws and regulations)
	Avoid the rain
	Headphone socket
ON/OFF	ON/OFF
	Fetal heart signal symbol
P/N	Part number
S/N	Serial number
IP22	Liquid protection degree
PC220	Probe frequency 2.0MHz
PC225	Probe frequency 2.5MHz
PC230	Probe frequency 3.0MHz
	Date of manufacture
	Manufacturer
	This item is compliant with Medical Device Directive 93/42/EEC
	Authorized representative in the European community

Section 2 Introduction

2.1 Overview

The device is high performance fetal heart rate detector which satisfies the requirement of hospital，clinic，community and home FHR examination.
The device consists of ultrasonic signal emitter and receiver, computer process unit, LCD display, speaker, keystroke and power supply.

2.2 Product Features

Different models have different features as follows.

Function	A	B	D	G	C
Display	No	B/W	B/W	Colour	Colour
Back light	No	Yes	Yes	Yes	Yes
Build-in speaker	Yes	Yes	Yes	Yes	Yes
Battery indicator	Yes	Yes	Yes	Yes	Yes
Curve display	No	No	No	Yes	Yes
Auto power off	Yes	Yes	Yes	Yes	Yes
Alkalinity battery	Yes	Yes	No	Yes	No
Ni-MH battery	No	No	Yes	No	Yes
Adapter	No	No	Optional	No	Optional
USB charging line	No	No	Optional	No	Optional
Voice	Optional	Optional	Optional	Optional	Optional
2.0MHz probe	Yes	Yes	Yes	Yes	Yes
2.5MHz probe	Optional	Optional	Optional	Optional	Optional
3.0MHzprobe	Optional	Optional	Optional	Optional	Optional

Remark: “B/W” means Black and White.
“Yes” means the device has the function.
“No” means the device don’t have the function.
“Optional” means can choose this function.

2.3 Intended Use

The device is used to detect the fetal heart rate. The device can be used by health care professionals including nurses, midwives, specialized technicians in hospital, clinic, community, and nonprofessionals at home.
The 2MHz, 2.5MHz and 3MHz probe are used to detect fetal heart rate.

2.4 Contraindications for Use

Normally none, as a particular case, please consult your doctor.

2.5 Product Description

Fetal Doppler is a device prescribed by health care professionals and nonprofessionals including nurses, midwives, and specialized technicians in hospital, clinic, community and at the homecare environment. It is a hand-held, battery powered audio Doppler device integrated with 2MHz, 2.5MHz and 3MHz probe, used for detecting fetal heart beats. And the device is for prescription use and is intended for use at or after 12 weeks gestation.
Fetal Doppler is non-sterile.

2.6 Working Principle

Fetal Doppler detects fetal heart rate externally utilizing the principle of Doppler shift of an ultrasound that the frequency shift of the reflected signal is proportional to the velocity of the reflecting structure—in this case, the fetal heart. The ultrasound is transmitted from the probe to patient body that can transmit ultrasonic signal. When this ultrasonic energy is

reflected back from the tissues, the reflected ultrasound is received by the probe and is converted into electric signals. The signals data are applied to the CPU for signals processing on LCD Display such as FHR, FHR waveform and recording and an audible FHR (Display and Voice Sound).

2.7 Standard Configuration

2.7.1 Main body 1pc
2.7.2 Battery 2pcs
2.7.3 2MHz probe 1pc

Section 3 Appearance

3.1 Display

3.1.1 A does not have display function.
3.1.2 B, D display FHR digit and working parameter.
3.1.3 G, C display menu, FHR digit, FHR curve and working parameter.
3.1.4 The explanation of display content

NO.	Mark	Explanation
1		Fetal heart signal.It twinkles with fetal heart beat
2	**MHz**	Frequency unit of probe
3	**bpm**	Fetal heart rate unit,byte per minute
4		Battery volume
5		No FHR value, it indicates the probe does not connect well with main unit or there is not fetal heart signal
6		Signal strength
7		Alam ON/OFF
8		Voice volume

3.2 Controlling Keys

3.2.1 Volume Turning down Key
When the device is power on, if the sound is too high, press DOWN key, the volume will be lower.
3.2.2 Volume Turning up Key
When the device is power on, if the sound is too low, press UP key, the volume will be higher.
3.2.3 Turning on/off
Press the key , the device will be turned on, and press the key for 3 seconds, the device will be turned off.
3.2.4 Menu Setting
When the device is power on, press the key once, the mode code symbol flashes, this means the modes can be set.
3.2.5 Mode Selection
When mode mark flashes, press the key once to select mode.

3.3 Indicating Light

3.3.1. Charge Indicator Light
When the battery is charged, the indicating light is orange color. When the battery is full, the indicating light becomes green.
3.3.2. Working Indicator Light
When the device is power on, this indicator light will be on with blue color.

3.4 Probes

The basic probe frequency is 2MHz. 2.5MHz and 3MHz probe are optional.

Section 4 Basic Operation

4.1 Preparing to Use

Carefully check if the device has any damage and if the accessories are integrated. If so, please contact with manufacturer or local distributor immediately.
Keep the package for future transportation or storage.

4.2 Using Battery

4.2.1. Taking out Battery
Turn the rear panel up. Hold the main unit with one hand. Press the battery cover with another thumb.
Then slide the battery cover down to remove the battery.
4.2.2.Open the battery cover,put into the battery according to the sign direction.
4.2.3. Closing the Battery Compartment
Put the battery cover; slide the cover along the reverse direction of opening cover to close the battery compartment.

4.3 Operating Probe

Hold the main unit of the device with one hand and hold the top of the probe with another hand. Take out the top of the probe and take out the whole probe from the probe slot.

4.4 Turning on the Device

Turn on by pressing the power key  . The working indicator light is bright.

4.5 Setting Work Modes

4.5.1 Work Modes

For A, the FHR is manually calculated.
For B and D, the work modes and codes are:1- real-time mode, 2-average mode, 3-manual mode, 4-freeze mode, 5-Back Light Switch, 6-alarm mode, 7-Voice Switch.
For G and C, the work modes are: real-time mode, average mode, manual mode, freeze mode,curve mode

and demo mode.

1) Real-time Mode

In this mode, the heart symbol on LCD will flash, and real-time FHR is displayed on LCD simultaneously.

2) Average Mode

This mode is used to get more stable FHR. The LCD displays the flashing heart symbol when displaying FHR.

3) Manual Mode

When finishing selecting this mode, press ▲ to start to count the FHR till the ▲ is pressed again.The FHR will be automatically displayed on LCD.

4) Freeze Mode

When working under one of the mode of real-time mode, average mode, manual mode, and curve mode, selecting freeze mode, the FHR or FHR curve on LCD will be freezed. This will keep to next measurement starts or the mode is changed.

5) Curve Mode

In this display mode, the device display FHR curve and relative parameters.

6) Back Light Switch

Be used to set the back light.

7) Alarm Switch

Be used to set the alarm function.

8) Voice Switch

Be used to set voice function. At the open condition, device will announce FHR every 5 seconds

9) Demo Mode

In this mode,the LCD screen will continuously display FHR digit and/or curve.

4.5.2 Selecting Modes

Press ⏻ key once by once, the work modes will change seasonally. The default mode is real-time mode.

Together press ▲ and ▼ for 3 seconds, the demo mode work starts/stops, or enter into menu to turn on/off the demo mode.Press ▲ or ▼ to change the demo work mode.

4.6 Mode and Menu Setting

4.6.1 For A, the FHR is manually calculated.

4.6.2 For B, D, setting is as below：

(1) Mode Selection

Short press ⏻ to enter into mode selection which is mode code.

(1) Work Mode Setting

Press ▲ or ▼ to set work modes including "ON" or "off".

4.6.3 Detail setting parameter for G, C is as below:

No.	Parameter	Explanation	Selectable value	Default value
1	FHR-ALM-HI	FHR alarm up limit	50—230bpm	160bpm
2	FHR-ALM-LOW	FHR alarm down limit	50—230bpm	120bpm
3	ALARM SWITCH	Alarm voice switch	ON or OFF	ON
4	LANGUAGE	Selectable language	Chinese or English	English
5	RETURN	Return to working state	/	/

(1) Display Mode Setting

Press ⏻ to enter into digital mode and curve mode setting.

(2) Menu Parameter Setting

-- Synchronously press ▲ and ▼ to enter into menu setting interface.

-- Press ▲ or ▼ key to select the menu item.

-- Press ⏻ to confirm menu item.

-- Press ▲ or ▼ key to set the parameter.

-- Press ⏻ to exit the current menu item.

-- Synchronously press ▲ and ▼ to exit the menu setting.

4.7 Turning off the Device

When the device is power on, press the key again for 3 seconds to turn off the device.

NOTE: The device will automatically turn off in1 minute if it is not used.

4.8 Replacing or Charging the Battery

When the device warns the battery volume is not enough, please turn off the device and replace or charge the battery.

For charging the rechargeable battery in the machine, insert the DC plug into the device charge socket, and connect the device AC plug to the AC110-240V, 50/60Hz power supply.

It will take about 2 hours to fully charge the battery. When charging, the LED of the charger is orange; when the battery is fully charged, the LED turns to green.

CAUTION: When working, the rechargeable battery can not be recharged. You must turn off the Doppler before charging the battery.

CAUTION : The device can be used only when the charger is disconnected with the device.

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

CAUTION : Charge the battery with the adaptor accompanying with Doppler. Don’t charge the battery over 12 hours.

Section 5 Inspecting and Recording

5.1 Inspecting FHR

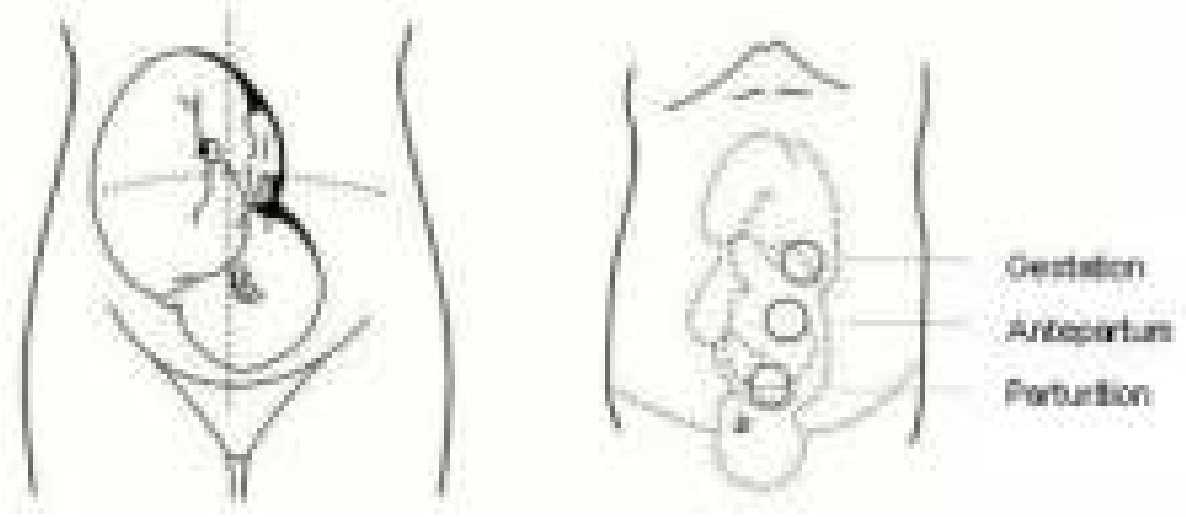
5.1.1 Gel Usage

Daub ultrasonic gel on the probe face plate to decrease noise and boost up test result.

5.1.12 Finding the Position of Fetus

Firstly, please feel the fetal position by hand. Place the working faceplate on abdomen with feasible tight contact. Adjust the probe position to obtain an optimum audio signal. Wait until the sounds is clear and consecutive seconds later, the LCD screen will display the right FHR.

Generally, the site of heart of fetus is 1/3 below of navel line at its earlier stage, it then moves upward with increasing of gestational period, and the site of heart of fetus will be a little deviation to left or right with different fetus. Pls. make sure that the surface of probe should be contacted fully with the skin. After the sound become clear and stays stable for a few seconds, the FHR value will appear on the LCD in real time.



NOTE: Do not compress probe too tightly on abdomen surface to avoid to weaken signal.

NOTE: When searching for the fetal heartbeat, do not pull the probe on the abdominal surface to avoid the noise.

NOTE: Do not put the probe on the position where there is strong Placental Blood Sound or strong Umbilical Sound.

5.1.3 FHR Inspecting

Finish setting mode and parameters, press power on/off key

to start work, press power on/off key again to stop working.
NOTE: Do not measure FHR unless audible and identifiable fetal sound has been heard, usually it needs 5 seconds.
NOTE: The normal value of the fetal heart rate is 120-160bpm.100-120bpm and 160-180bpm is the critical values which should be paid some attention to. And lower than 100bpm and more than 180bpm are danger values which should be paid more attention to.

5.1.4 Adjusting Volume

When device is working, you can adjust volume by pressing  or  key to adjust volume.

5.1.5 Cleaning Work

After finishing using the device, please turn off the equipment in time and wipe the gel on the probe and skin, put the probe into the probe clamp.

5.2 Recording, Re-playing

5.2.1 Recording

Insert one end of the double channel audio line into port of the audio output behind the mainframe.Turn on the computer. Start the recording. Click on the "start"-"procedure"-"accessory"- -"entertainment"-"recording". Monitoring the fetal heart signal, after detected high quality fetal heart signal, remove the earphone plug, insert the other end of the audio line into device earphone jack, and click "start" to recording. After the recording get enough, click "stop" to finish recording.

Click "document"-"storage", enter the document name, select the folder, click "confirm", stored the file of wav format in computer.

5.2.2 Re-playing Recording

Start the voice recorder, click "document"- "open", select Sound document, click "open" load document, click "play" to start play sound document.

5.2.3 Copy the data to CD or sent by email
Computers save standard audio files of image of cardiac ultrasound which can copy the data to CD or sent by email.

Section 6 Cleaning and Disinfecting

6.1 Cleaning

Before cleaning the device, switch off and take out the battery from main unit.

Keep the outside surface of the device clean and free of dust and dirt.Clean exterior surface with a dry, soft cloth. Wipe off the remaining coupling agent on the probe then clean the probe at least 4-5 times slowly with a soft cloth soaked in alcohol (70%) and wipe dry with a clean cloth immediately.

Dry it in a ventilated, cool place.

⚠**CAUTION**⚠:

Never use abrasive materials (such as steel wool or silver polish), or erosive cleansers (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 section to clean or disinfect your equipment. Warranty does not cover damages caused by unapproved substances or methods.

The remaining coupling agent (or gel) should be removed prior to the actual cleaning process.

6.2 Disinfecting

Clean the equipment case, probe, etc. as above, and then wipe the probe surface with an alcohol impregnated soft cloth (70% alcohol) at least 4-5 times with at least 3 cycles using a clean an alcohol impregnated soft cloth

(70% alcohol).
Wipe the probe with a clean, dry cloth to remove any remaining moisture.

⚠CAUTION⚠:

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.

CAUTION: Cleaning liquids: DO NOT submerge the device in liquids or pour cleaning liquids over, into or onto the device.

Section 7 Maintenance and Troubleshooting

7.1 Maintenance

The device is precision equipment, and the probe acoustic surface is frangible, you need to handle the device especially probe with enough care.

Gel and dirty dunghill must be wiped from the probe after using. These precautions will prolong the life of the unit and keep the examination precision.

Before using, the user must check that the equipment does not have visible evidence of damage that may affect patient safety or device capability. The recommended inspection interval is once per week. If damage is evident, reparation is recommended before use.

The device 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 device 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 manufacturer to get help. The device will be not calibration when suspicious of its accuracy.

7.2 Troubleshooting

When using, if it appears following problems. Please treat by following instruction. If fail to treat, please contact local distributor or manufacturer.

7.2.1 No Sound

Main reasons: (1) The battery volume is serious insufficient; (2) The equipment is damaged; (3) The battery connection line is damaged.

Solution: (1) Charge the battery or change battery; (2)

Inspect the device; (3) Contact dealer or manufacturer.

7.2.2 Weak Sound

Main reasons: (1) Voice volume is too low; (2) Battery volume is too low; (3) Without or insufficient gel.

Solutions: (1) Adjust higher voice volume; (2) Change or charge the battery; (3) Add sufficient gel on probe inspecting surface.

7.2.3 Noise

Main reasons: (1) Probe is too near from the main unit; (2) Disturbance from the outside signal; (3) Battery volume is too low.

Solutions: (1) Keep the probe far enough from main unit; (2) Be away from the outside signals; (3) Change or charge the battery.

7.2.4 Low Sensitivity

Main reasons: (1) Probe position is incorrect; (2) Without or insufficient gel.

Solutions: (1) Keep the probe at right position; (2) Daub sufficient gel.

Section 8 Warranty and After-sale Service

8.1 Warranty

Manufacturer obligation under this warranty is limited to repair any part or whole unit upon manufacturer examination to prove they are within warranty period and range. If the product does not function during the warranty period, we will repair or replace it free of charge. The device usage life is 3 years, after which please treat according to relative regulations.

Limit of warranty:

1. Trouble resulting from misuse, negligence, accident or transportation.
2. Opening, modification or repairing by unauthorized persons from manufacturer.
3. Replacing or removing serial number label or manufacturer label.

8.2 After-sale Service

If you have any questions about use, maintenance, technical specifications or malfunction of device, please contact local distributor or manufacturer service department.

Section 9 Product Specifications

9.1 Product Name: Fetal Doppler
9.2 Models: A, D, B, G and C
9.3 Standard: IEC60601-1:2005, IEC 60601-1-2:2014, IEC60601-1-11：2015，IEC61266：1994，NEMA UD 2-2004 IEC 60601-2-37:2015

9.4 Classification

9.4.1 Anti-electroshock type: internal power supply equipment

9.4.2 Anti-electroshock Degree: Type BF equipment 
9.4.3 Liquid Proof Degree: IP22

9.5 Physical Characteristic

9.5.1 Size: 135mm* 95mm*35mm
9.5.2 Weight: approximately 500g (including battery)

9.6 Environment

9.6.1 Working: Temperature: 5℃~40℃
Humidity: 25-80%
Atmospheric Pressure: 86~106KPa
9.6.2 Transport and Storage:
Temperature:-25℃~70℃
Humidity: ≤ 93%
Atmospheric Pressure: 70~106KPa

9.7 Recommend Battery

9.7.1 2 pieces of 1.2V rechargeable battery (D, C)
9.7.2 2 pieces of 1.5V AA alkaline battery (A, B, G)

9.8 Performance Parameter

9.8.1 Working Frequency of Ultrasonic
Working frequency of ultrasonic is 2.0MHz (2.5MHz and 3.0MHz optional), ±10%nominal standard
9.8.2 Overall Sensitive
200mm distance from probe, integrated

sensitive≥90db
9.8.3 Output Power: 10-45 mW
9.8.4 Acoustic Pressure: 20-55 kPa

9.9 Acoustic Output Parameter

9.9.1 Work frequency 2.0MHz: I_{SATA}:10.23 mW/cm^2
9.9.2 Work frequency 2.5MHz: I_{SATA}:11.37 mW/cm^2
9.9.3 Work frequency 3.0MHz: I_{SATA}:10.52 mW/cm^2

9.10 Mechanical Index (MI)

9.10.1 2.0MHz: 0.014
9.10.2 2.5MHz: 0.024
9.10.3 3.0MHz: 0.018

9.11 Overall Sensitivity at the Distances 200mm from the Face of the Probe (Doppler frequency: 332Hz, Target velocity: 4.8cm/s)

9.11.1 2.0MHz: 104.3 dB
9.11.2 2.5MHz: 95.8 dB
9.11.3 3.0MHz: 95.9 dB

9.12 Acoustic Pressure, Output power and Effective Area of the Ultrasonic Transducer Active Element

9.12.1 2.0 MHz

Spatial-peak temporal-peak acoustic pressure: 20.0kPa

Ultrasonic output power: 13.1mW

Effective area of the ultrasonic transducer active element: 1.54cm^2

9.12.2 2.5 MHz

Spatial-peak temporal-peak acoustic pressure: 54.7kPa

Ultrasonic output power: 41.8mW

Effective area of the ultrasonic transducer active element: 1.54cm^2

9.12.3 3.0 MHz

Spatial-peak temporal-peak acoustic pressure:

42.0kPa

Ultrasonic output power: 14.0mW

Effective area of the ultrasonic transducer active element: 1.54cm^2

9.13 Measurement uncertainties for ISATA:±16.6%

9.14. Ultrasonic gel

9.14.1 pH: 5.5~8

9.14.2 Acoustic impedance: ≤1.7*106Pa.s/m

9.14.3 Acoustic Velocity: 1520-1620m/s

9.15 Working Mode: Continuous Wave Doppler

9.16 Measuring Performance

FHR Measuring Range: 50-230 bpm (beat per minute)

Resolution: 1bpm

Accuracy: ± Bpm

Section 10 Appendix

Guidance and Declaration of EMC

Guidance and manufacturer's declaration – electromagnetic emissions The Fetal Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal Doppler should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions **CISPR 11**	Group 1	The 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.
RF emissions CISPR 11	Class B	The Fetal Doppler is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supple network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity The Fetal Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal Doppler should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common	±1 kV differential mode ±2 kV common	Mains power quality should be that of a typical commercial or hospital environment.

	mode	mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0,5 cycle 0 UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (100 % dip in UT) for 250/300 cycles	0 % UT (100 % dip in UT) for 0,5 cycle 0 UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (100 % dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [EQUIPMENT or SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [EQUIPMENT or SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz (6V in ISM and amateur radio bands between 0.15 MHz and 80MHz) 10 V/m	3 Vrms 150 kHz to 80 MHz (6V in ISM and amateur radio bands between 0.15 MHz and 80MHz) 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 800 MHz to 2,5 GHz

	80MHz to 2.7 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 range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between Portable and mobile RF communications equipment and the Fetal Doppler

The Fetal Doppler is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Fetal Doppler can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fetal Doppler as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{p}$	80 MHz to 800 MHz $d = 1.2\sqrt{p}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{p}$
0.01	1.2	0.12	0.23
0.1	3.8	0.38	0.73
1	12	1.2	2.3
10	38	3.8	7.3
100	120	12	23

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.