

1.1 Overview

Fetal Doppler applies ultrasonic doppler principle to obtain the movement information of fetal heart from abdomen of pregnant women, enlarge the signals, and output from the built-in speaker, through the calculation to get value of the fetal heart rate.

1.2 Intended use

This instrument is applicable to listen to the fetal heart sounds from the bodies of pregnant women and obtain the value of fetal heart rate so as to provide reference for clinical diagnosis.

1.3 Contraindication

Not yet found

1.4 Features

- (1) The probe and the main engine are integrated design;
- (2) Slim shape, light, smart, beautiful;
- (3) Headphone design, mothers can listen to fetal heart sound on same time;
- (4) High sensitivity ultrasonic transducer;
- (5) High precision FHR LCD digital display;
- (6) Low ultrasonic output intensity, far less than the national standard, to ensure safe using, has a high safety quality;
- (7) Low energy consumption, two units standard No.7 alkaline batteries can support long time test.

1.5 Product structure

The instrument is consisted of the host and the ultrasonic probe. Please refer to Figure 1-1 for the detailed structures of all parts of instrument.

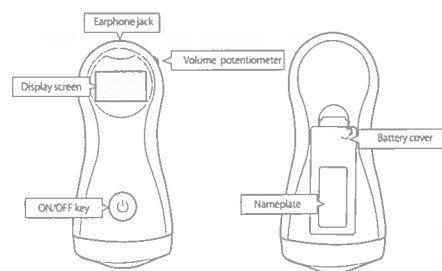


Figure 1-1 Front and rear view of instrument

1.6 Display

The display of all parts of liquid crystal display is shown in Figure 1-2.



Figure 1-2 Introduction of display content of liquid crystal display

In the figure, 145 refers to the measured value of fetal heart rate, which means that fetal heart beats for 145 times. If there is no fetal heart rate, the corresponding value area displays horizontal line.

Notice

Since liquid crystal display has limit visual angle range, please observe the display content of liquid crystal display from the front and keep the line of sight be perpendicular to liquid crystal display so as to ensure the best visual effect. In case of observing from other angle, the visual angle may cause blurring or reading error.

Caution

- Keep away from electromagnetic interference—Make sure that the operational environment is not interfered by relatively strong electromagnetic interference source, for instance X machine, multifunctional microwave therapeutic instrument and other equipments.
- Before use, user must check that the equipment has no obvious damages that may affect patient safety or instrument performance. The recommended inspection cycle is once a month or shorter time. In case of obvious damages, it is recommended to use the damaged component replaced previously.
- The following safety inspection must be executed by properly trained persons with certain knowledge and practical experience. In general, test shall be conducted once every two years or designated by public institution in accordance with the inspection procedures.
 - ① Check that whether the equipment has mechanical and functional damages.
 - ② Check that whether label related to safety is easily recognizable.
 - ③ Verify whether equipment functions are consistent with those described on manual.
- After effective of service life, this instrument shall be disposed in accordance with local laws.
- After using, battery shall be disposed in accordance with local laws.
- This instrument is a handheld tool for the examination of fetal heart rate and it cannot replace standard fetal monitoring.
- This instrument can be used only after closing battery holder.
- In case of using battery, please do avoid short circuit or reversely install positive and negative electrodes.
- At the time of storage, please do not put metal object together with battery so as to avoid accidental short circuit.

Chapter 2 Instrument operation and usage

2.1 Turn on/off

Before using fetal doppler to conduct examination, it is required to check whether there is any mechanical damage or crack on host, surface of probe and earphone cable. In case of damage or normal sign, this instrument shall not be used for examination, please contact with manufacturer or dealer. Open the battery cover on the back of the instrument, install the battery in accordance with the direction in battery cabin, and close the battery cover. In the need of turning on, press the ON/OFF key of instrument "U" and wait for the liquid crystal display to begin to display. At the very time, loosen the key and the instrument enters into normal working condition. In case of turning off, it only needs to press the ON/OFF key of instrument "U" and wait for the liquid crystal display to turn off display. At the very time, loosen the key and the instrument is turned off.

To prevent turning on/off caused by accidental operation, turning on/off of the instrument can be realized by continuously pressing the ON/OFF key for 1 second. Short time of pressing ON/OFF key will be considered to be accidental touch and the instrument will not response.

To prolong the service time of battery, if there is no value of fetal heart rate within continuous two minutes or no key operation, the instrument shuts down automatically.

2.2 Detection of fetal heart rate

Before detection of fetal heart rate, the machine shall be opened firstly, the sound volume shall be adjusted to proper position, and appropriate amount of ultrasonic coupling agent is evenly printed on the acoustic area of probe. Ultrasonic probe is aligned with the fetal heart position in the abdomen of pregnant women. Probe position and probe angle are adjusted properly until the most clear and resonant fetal heart sound can be heard.

Logos and signs

- BF type applied part
- Manufacturer
- Notice, please refer to attached documents
- Level of protecting against liquid inlet

Instructions for safety in use

To avoid possible damages, please abide by the following instructions for safety in use when operating this instrument.

Warning

- Do not use it at places with combustible gas, for instance, anesthetics.
- Please do not throw battery in fire so as to avoid explosion.
- Please do not touch signal input or output connector at the same time or patient.
- Battery shall be replaced in the environment away from patient (about 1.5 meters away from patient).
- Wastes from replacing scrapped components and aging components shall be disposed in accordance with national management provisions for medical wastes and relevant local laws and regulations for scrapped electronic components. Instead of random discarding, they shall be disposed uniformly so as to avoid pollution to environment.

Caution

- This instrument shall be repaired by authorized qualified engineer.
- This instrument is designed to the continuous operation type of common equipment. Pay attention to protect it from water.
- Keep the instrument clean and avoid oscillation.
- Please do not disinfect with high temperature or sterilize with electron beam and γ radiation.

Preface

Notice

The company makes no warranty in any form, including but not limited to implied warranty of marketability and suitability provided it for a specific purpose. The company assumes no responsibility for the error contained in this data, accidental or indirect damages due to the supply of this manual or caused by actual performance and utilization. This manual includes special data protected by copyright law. All rights reserved. Without prior written consent of The company, any part of this manual shall not be photocopied, copied or translated into other language. The content contained in the manual can be changed without notice.

Responsibilities of manufacturer

The company considers that it shall be responsible for the safety and reliability objectively existed in the instrument only under the following situations, namely assembly operation and repair are conducted by personnel recognized by the company and the instrument is used in accordance with the operation guide.

Warning

The intended use of this instrument is clinical application, not treatment. If the result of fetal heart rate is unbelievable, please use other methods immediately, for instance, use stethoscope to conduct verification.

Explanation of annotations in this manual

Warning

The information you should understand on how to avoid possible damages of patients and medical staff.

Caution

The information you should understand on how to avoid possible damages of equipment.

Notice

Important information you should understand.

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20051510 027/3.09.05.0003/ENSM90C201906031

Fetal Doppler
Operation Manual



2.5 Detection of battery level

Fetal Doppler can monitor battery level automatically. When battery level displays as , battery shall be replaced timely. When battery level displays as and begins to flicker, battery shall be replaced timely, or instrument may shut down automatically at any time due to the low battery level.

2.6 Battery replacement

In case of replacing battery, firstly take down the battery on the back of instrument and take battery from the instrument. Put 2 No.7 batteries into battery cabin and close the battery cover.

In case of replacing battery, please pay attention to battery polarity, or it may cause the power-on failure of instrument.

Warning

- If it is not used within a period, the battery shall be taken out.
- The battery replaced or taken from the instrument shall be properly disposed in accordance with relevant national requirement. Please do not discard the battery in fire so as to avoid explosion.

Matters after use

After it is used each time, please press "U" key to shut it down, use soft cloth or paper towel to wipe clean the coupling agent on the surface of probe, and then the instrument is stored properly.

Precautions

Warning

- As an equipment to examine fetal heart rate in a short time, Fetal Doppler is not suitable to conduct monitoring for fetus for a long time and cannot replace conventional fetal monitor. If user suspects the results measured by the instrument, other medical measures shall be taken for confirmation.
- This instrument cannot be used together with high frequency surgical equipment or fetal monitor. Two or more Fetal Doppler cannot be used at the same time.
- In normal use, this instrument and probe part cannot be used by immersing into water or other liquid. In case of performance evaluation, the end face of probe can be vertically immersed into water or other liquid by the depth of 3mm.

Product configuration list

Article name	Quantity
Host	1
Manual	1
Earphone	1

Caution

- If the skin at the place contacting with probe is broken or bleeding, it is forbidden to use the instrument. After being used for patient with skin disease, the probe shall be disinfected.
- Since this instrument is easily to be affected by portable or mobile radio frequency communication equipments (for instance, cell phone) at runtime, it is required to avoid using portable or mobile radio frequency communication equipments near the instrument, or it may cause interference to the instrument so as to lead to the abnormalities of sound output, even abnormal measured value.
- This instrument is portable equipment. During the process of using, please operate carefully so as to prevent falling off and pay attention to the safety of instrument and personnel.
- When family users use this instrument, they shall read this operation manual carefully. If necessary, they shall consult doctors, distributors or manufacturer.
- The ultrasonic probe used in this instrument belongs to susceptible device. When used, please handle it with care. Please do not knock or impact. Pay attention to preventing accidental damages, including falling off.

Notice

- We suggest that the ultrasonic irradiation time for pregnant women shall be minimized under the premise of meeting clinical needs.
- In case of using this instrument, please use the earphones provided by the manufacturer. The utilization of other earphones may cause the decrease of volume or changes of sound quality.
- This instrument cannot be used for the measurement of adult heart rate, or the accuracy of measurement results is not guaranteed.
- In case of using this instrument, it may generate a certain dose of electromagnetic radiation, which may disturb the electronic equipments or instruments near it.
- In case of any quality or technical problems of this instrument, we recommend against repairing it by user. In case users need technical data for the purpose of repair, including circuit diagram, component list and internal wiring diagram, they can contact distributors or manufacturer to obtain them.

transient/burst IEC 61000-4-4	supply lines ±1kV for input/output lines	N/A	that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70% UT (30 % dip in UT) for 25 cycles	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Fetal Doppler requires continued operation during power mains interruptions, it is recommended that the Fetal Doppler be powered from an uninterruptible power supply or a battery.
on power supply input lines IEC 61000-4-11	< 5 % UT (>95 % dip in UT) for 5 sec		
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE	U _T is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

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	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Fetal Doppler including cables, than the recommended separation distance calculated from the equation applicable to

Warning

- It is not allowed to refit this instrument.
- Notice**
- Take account of the effects of dusts and lights on the instrument.
- Take account of the effects caused by children and pets.

Chapter 3 Maintenance

3.1 Maintenance

Since the ultrasonic acoustic area of ultrasonic probe is very precise, it must be handled with care. After the instrument is used, the redundant coupling agent on ultrasonic probe must be wiped off. These maintenance measures can prolong the service life of instrument.

Before use, user must inspect the equipment to check whether there is obvious damage that may affect patient safety or instrument performance. The recommended inspection cycle is one a month or a shorter time. The ultrasonic probe is immersed into conducting liquid to check whether there is crack on probe and damages between probe cable and its plug. In case of obvious damages, it is recommended to use the damaged component replaced previously.

Periodic safety test shall be conducted for instrument to ensure the insulation of leakage current, including leakage current flow. The recommended test cycle is once every two years or test is conducted as designated by public institution in accordance with the inspection procedures. The accuracy of fetal heart rate is controlled by instrument and it cannot be adjusted by user. If the result of fetal heart rate is unbelievable, please use other methods, including using stethoscope, to verify it or contact local distributors or manufacturer for help.

3.2 Instrument maintenance

This instrument needs no special maintenance in process of using. However, if the instrument is stored for over 1 month, the battery shall be taken out of the instrument, or the instrument is likely to be damaged due to battery leakage. Overall inspection shall be conducted for this instrument once every two years so as to ensure normal instrument functions and performance and make sure the safety and effectiveness of product. Inspection shall be conducted by manufacturer or unit with corresponding qualification.

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E} \right] \sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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) b Field strengths from fixed RF transmitters as determined by an electromagnetic site survey ^a should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies
NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Fetal Doppler is used exceeds the applicable RF compliance level above, the Fetal Doppler should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Fetal Doppler
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 2V/m.

3.2.1 Instrument cleaning

Before cleaning the instrument, please shut down firstly and take out the battery. In case of cleaning the instrument, please use soft cloth to dip soapy water or clean water to slightly scrub the surface of instrument and probe. After the surface of instrument is dried up, it can be started up and used.

Warning

Do not let any liquid enter into the instrument or gap, or immerse any part of the instrument into liquid.

Notice

Please do not use strong solvent, including acetone. It is forbidden to use wear materials (for instance, steel wool) to clean the surface of instrument.

3.2.2 Instrument disinfection

Before disinfection, the instrument shall be fully cleaned. Disinfection method: 75% medicinal alcohol or other general disinfectant to scrub the surface of the host and earphones of the instrument to ensure that all contaminated surfaces contact disinfectant. After the surface of instrument is dried up, it can be started up and used. This instrument cannot be disinfected with low temperature, high temperature or y ray.

Chapter 4 Common faults and troubleshooting

4.1 Troubleshooting of common faults

4.1.1 Fault phenomenon: start up failure

Please first make sure whether battery has sufficient electricity and the installation direction is correct. If it is unsure, please replace with new battery and restart it. If it is unable to be started after replacing with new battery, the instrument may be damaged, please contact manufacturer or distributors to handle it.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 MHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
$d = \left[\frac{3.5}{V} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E} \right] \sqrt{P}$	$d = \left[\frac{7}{E} \right] \sqrt{P}$	
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

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

4.1.2 Fault phenomenon: no sound

First, rotate volume potentiometer to adjust the volume to the maximum position, insert and extract earphones again. Slightly knocking the surface of probe with hand, if earphones still have no sound, the instrument may be damaged, please contact manufacturer or distributors to handle it.

4.1.3 Fault phenomenon: Inaccurate value of fetal heart rate

Since instrument displays the real-time fetal heart rate, there may be some difference between it and the average fetal heart rate obtained in accordance with conventional method. This phenomenon belongs to normal situation. The inaccurate value of fetal heart rate may be related with the inaccurate position of fetal heart. Other interference sources or interference signals (for instance, cell phone) near the instrument may also cause inaccurate value of fetal heart rate. The strong interference signals generated from user's moving probe can also cause inaccurate value of fetal heart rate in a short time. If the value of fetal heart rate is still considered to be inaccurate through above judgment, please contact manufacturer or distributors to handle it.

4.1.4 Fault phenomenon: poor signal and bad sound

First, make sure whether appropriate amount of coupling agent is used. Then, move the probe to find the position of fetal heart, make sure that there are no other interference sources or interference signals. Too small gestational age or too fat pregnant women may also have the situations of poor signal or bad sound. If the value of fetal heart rate is still considered to be inaccurate through above judgment, please contact manufacturer or distributors to handle it.

4.1.5 Fault phenomenon: short service time of battery

Please use alkaline battery manufactured by legal manufacturer. Since carbon battery has a low battery capacity, its service time is short, which belongs to normal phenomenon.

Chapter 6 Product Specifications

6.1 Product classification

- A. Classification/Rule of classification
It belongs to IIa, Rule 10.
- B. Classification in accordance with protection against electric shock
It belongs to internal battery, BF type.
- C. Classification in accordance with protection degree of harmful liquid inlet
The liquid inlet level shall be IP22.
- D. Classification in accordance with the safety degree used under the situations with gas mixture of flammable anesthetizing gas and air or gas mixture of oxygen and nitrous oxide
It cannot be used under the situations with gas mixture of flammable anesthetizing gas and air or gas mixture of oxygen and nitrous oxide

6.2 Product size and weight

Size: 117(L)×56.6(W)×34.8(H)mm
Weight: Approx 64g (exclude batteries).

6.3 Performance requirements

6.3.1 Working environment

Temperature: +5 C – +40 C
Humidity: 30%-80%
Atmospheric pressure: 60kPa-110kPa

6.3.2 Transportation and storage environment

The packed instrument shall be stored at – 20 C - + 55 C
Relative humidity shall be 10%-93% (without condensation).
In the room with atmospheric pressure of 50kPa - 110kPa, with no corrosive gas and good ventilation

Chapter 5 Manufacturer's Declaration of the EUT

Guidance and manufacturer's declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission			
The Fetal Doppler is intended for use in the electromagnetic environment specified below. The customer or the user of 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 supply network that supplies buildings used for domestic purposes.	
Harmonic emissions IEC 61000-3-2	N/A		
Voltage fluctuations flicker emissions IEC 61000-3-3	N/A		

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

Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge(ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 10%.
Electrostatic	± 2 kV full power		Mains power quality should be

6.4 Main parameters

6.4.1 Ultrasonic working frequency
Nominal sound working frequency: 2.0MHz/2.5MHz. (Specific to the probe tag)
The deviation between sound working frequency and nominal sound working frequency shall be less than ±5%.

6.4.2 Fetal heart rate
Measuring range: 50-240bpm
Accuracy : ±1% or 1 times/min, take a large value

6.4.3 Integrated sensitivity
The sensitivity at the place 200mm away from the surface of probe: >90dB

6.4.4 Acoustic pressure at space peak value and time peak value P (MPa)
Negative acoustic pressure: P₋ < 1MPa
Acoustic pressure at space peak value and time peak value: < 0.2MPa

6.4.5 Acoustic output power
Ultrasonic output power: < 40mW

6.4.6 Effective area of sensitive element of ultrasonic transducer
Effective area of sensitive element of ultrasonic transducer: 157mm²±10%

6.4.7 Operating mode: continuous wave

6.4.8 The service life is 3 years.

Chapter 7 Warranty

7.1 Warranty

This instrument cannot be repaired by user and all repairs shall be conducted by technicians recognized by the company. The warranty period is one year (calculated from the purchasing date). The scope of warranty includes all equipment faults caused by the failure of material component or production process. Under warranty, all components with faults can be repaired and replaced for free. Artificial damage is not covered in warranty.
Statement: Maintenance data, including circuit diagram, component list, legends and correction, are only provided to qualified repairmen and units trained by the manufacturer.