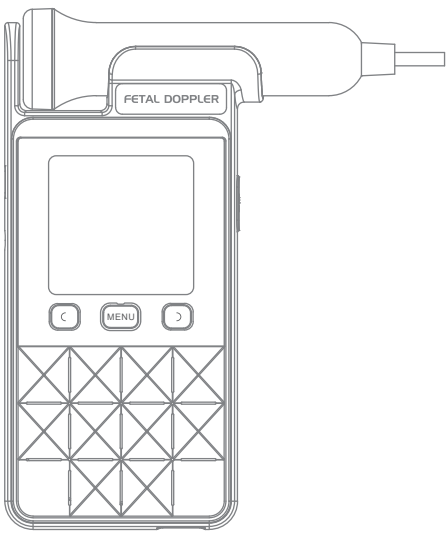


Fetal Doppler

USER MANUAL



The revision Number: V1.0

Notice

The Company will not supply any kind of guarantee, including(without limitation) supply the implied marketing guarantee for some specified purpose. The Company will not be responsible for the following cases like the wrong information in this user manual, the actual performance and incidental or consequential damages during use which provided by this user manual. This manual contains proprietary information protected by copyright law. All right reserved, without written consent by the Company , any part of this user manual can not be photographic reproduced, copied,or translated into another language. The content contained in this user manual can make any changes without public notice.

Responsibilities of manufacturer

The Company will only be responsible for the following cases like objective security and reliable performance of the instrument. For example, the assemble operation maintenance must be done by the approved people from the Company. The instrument must be operated according to the user manual.

Warning

This instrument is intended for clinical application, it is not for treatment. If the fetal heart rate results unreliable, please use other methods, such as using stethoscope to verify.

This user manual instructions

Warning:

You should know how to avoid patients with the medical staff been hurt.

Caution:

You should know how to avoid this instrument been damaged.

Notice:

You should know some more information.

CHAPTER1 SAFETY GUIDE

Safety Guide

To avoid the possibility of being hurt, please be sure to obey the following safety regulations.

Warning: Do not use it in the natural gas environment, for example anesthetic environment it can lead to explode.

warning: Do not touch the signal input or output connectors and patients at the same time.

warning: Do not monitor patients when charging battery.

caution: The instrument must be repaired by a qualified engineer who authorized by our company.

caution: The instrument is continuous working type. It is common equipment. Avoid water on the machine.

caution: Keep the instrument clean and avoid it oscillation.

caution: Do not do high-temperature sterilization processes or uses electron beam and y radiation sterilization.

caution: Make sure the instrument not be used in strong sources of electromagnetic environment, such as wireless transmitters or mobile telephone interference.

caution: Before use, the user must check the equipment may not significantly affect the patients' safety or performance of equipment.Recommended inspection period is once a month or less.If you find obvious damage, it is recommended to replace the damaged parts before use.

caution: The following safety examination must be done by people who have been trained and have some knowledge and experience. It is recommended that test it every two years or test it according to the inspection procedures and specified by public bodies.

- ◆ Make sure this instrument no mechanical and functional damage.

- ◆ Make sure the safety-related labeling easy to identify.

- ◆ Make sure the device functionality and the manual is the same description.

caution: After the effective life of the instrument in the period, it should be handled in accordance with local laws.

caution: When the batteries scrapped, it should be handled in accordance with local laws.

caution: The instrument is a hand-held fetal heart rate check device, it can not replace the standard fetal monitoring.

caution: We recommend that when it meet the clinical needs, the ultrasonic irradiation time on the patient should be as little as possible.

caution: In storage, please do not make metal objects mixed together with the battery. It may lead to accidental short circuit.

CHAPTER 2 PRODUCT INTRODUCTION

Intended use

Fetal Doppler uses the principle of ultrasonic Doppler to obtain fetal heart movement information from pregnant women's abdomen, amplify the signal and output it from the loudspeaker, and calculate the fetal heart rate.It is for fetal heart rate measurement.

Contraindication

Not found yet

Product features

- ◆Color 2.4 inch display
- ◆Calculating FHR with the same DSP techniques as used in Fetal Heart Monitor, and ensure the FHR accuracy and reliability.
- ◆High sensitive transducer, the transducer is 2.5MHz with continuous wave work mode, Low ultrasound power, safe to the fetal.
- ◆Friendly man-machine interface, easy to use.
- ◆Built-in speaker and earphone output.
- ◆3.7V lithium battery and battery status indicator.
- ◆Under the normal working mode, auto power off if there is no signal more than two

Signs and symbols

	BF type application part		Avoid sunlight
	Up toward		Humidity range
	Reference manual		Keep dry
	Cautions		On / Off key
	Serial number		Waterproof grade
	Date of manufacture		Temperature range
	Manufacturer		
	To protect the environment,dispose of empty batteries at appropriate collection sites according to national or local regulations.		

CHAPTER 3 OPERATION

Connection probe

The probe is not connected in our machine when out of factory. The probe can be directly connected into mainframe during use, please refer to the following Figure:



Figure3-1

Take out and put the probe

Taking out: one hand holds the Doppler, another hand holds the probe head and slightly pull up the probe as follows.

Putting in: one hand holds the Doppler, another hand takes the probe and insert it into the machine, if it sound "Kaca" and it means that the probe is in the right position.



Figure3-2

Power on and power off operation

Before each inspection with the Fetal Doppler, check whether there is any mechanical damage or crack on the surface of the main engine and probe. If there is any sign of damage or abnormality, do not use the Fetal Doppler for inspection. Please contact the manufacturer or dealer.

Press and hold the "⌂" button of the fetal doppler, and wait for the screen to start displaying. At this time, release the button to start the machine, and the Fetal Doppler will enter the normal use state. If you need to shut down, just press and hold the "⌂" button and wait for the display to go out.

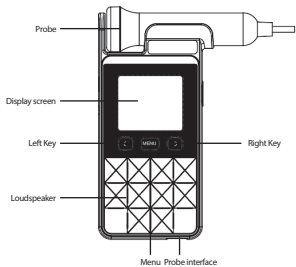
In order to prevent accidental operation from turning on and off the machine, the '⌂' keys of the fetal doppler need to be pressed continuously for more than 2 second to turn on and off the machine.

To extend the battery life, the fetal heart meter will automatically shut down when there is no fetal heart rate value for two consecutive minutes and no key operation.

1

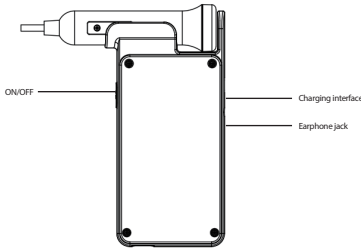
Panel Introduction

Front panel



Panel Introduction

Back panel



Display

Display screen under the normal working mode as following Figure 2-1

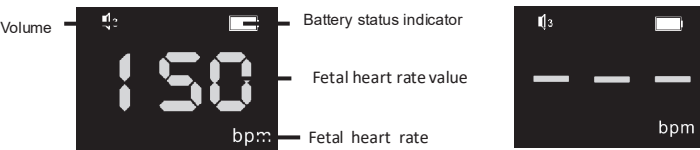


Figure2-1

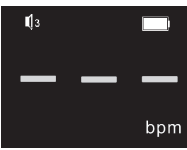


Figure 2-2

2

In the above Figure, the fetal heart rate is 150, it means that the fetal heart beat 150 times. If there is no FHR, it will display horizontal line in the above area. Please refer to Figure 2-2.



Volume of speaker, 8 steps can be adjusted.



Battery status indicator

Key

There are four keys in our machine as follows:

⌂ Power On/Off

Boot press about 2 seconds, shut down need to keep pressing this key for about 2 seconds before loosening the button.



Left key

At normal operation, increase the volume one level when pressed and released.



Right Key

At normal operation, decrease the volume one level when pressed and released.

Menu key

There are two mode in our machine: numerical mode and curve mode . Short press can switch the two modes.

Side panel introduction

Charging interface: it is used to charge the lithium battery.

Earphone jack : it can insert the ear-phone.

Probe interface: it is used to connect doppler probe.

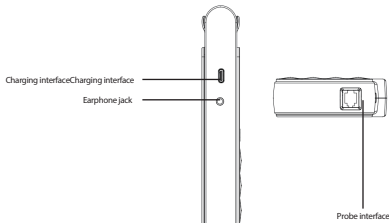


Figure2-3

5

6

4

Fetal heart rate detection

Before fetal heart rate detection, turn on the fetal doppler, adjust the volume to the appropriate gear, evenly apply an appropriate amount of ultrasound couplant on the pregnant woman's abdominal fetal heart rate position, align the ultrasonic probe acoustic face to the pregnant woman's abdominal fetal heart rate position, and properly adjust the probe position and probe angle until a clear and resonant fetal heart rate sound is heard. Generally, the heartbeat position of the fetus with small gestational age is on the upper edge of pudendal hair, and moves up with the increase of gestational age, and slightly to the left or right with different fetal position. When the gestational age increases, the movement of the fetus in the body may lead to a large range of movement of the fetal heart position. At this time, to find the accurate fetal heart position should be operated patiently. The location of fetal heart in different gestational weeks can be shown in Figure 3-3. The small dots in the figure indicate the possible fetal heart location.

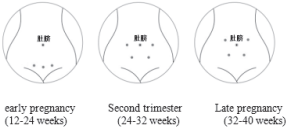


Figure3-3 Schematic diagram of fetal heart position at different gestational weeks

When using the fetal doppler, the surrounding environment should be relatively quiet. Pregnant women should keep flat or half lying posture, try to keep calm and less activity. When moving the probe, make sure there is enough coupling agent between the probe surface and pregnant women's abdomen. The probe should be close to the abdomen, slowly move the probe, and carefully look for fetal heart sound, After hearing the weak fetal heart sound, you should continue to move the probe until you find the most sonorous and clear position. After finding this position, keep the probe still. After 3-5 seconds, the fetal heart rate displayed on the screen will be accurate.

Insufficient couplant may result in failure to hear fetal heart sounds or very weak fetal heart sounds. When listening to fetal heart sound, we should pay attention to exclude the abdominal blood flow sound of pregnant women. The frequency of blood flow sound is significantly higher than that of fetal heart sound, and the rhythm is also significantly slower than that of fetal heart rhythm.

The value of fetal heart rate and the sound of fetal heart rate measured by fetal doppler are only for clinical reference. If medical staff or users doubt this, other medical means should be taken to confirm.

otherwise it may cause interference to the fetal heart rate meter, resulting in abnormal sound output or even abnormal measured value.

- The fetal heart rate meter is a portable device. Please operate it carefully to prevent falling, and pay attention to the safety of the fetal heart rate meter and personnel.
- The fetal heart rate meter should be operated by doctors, nurses and other professionals; When using the fetal heart rate meter, family users should read the manual carefully and consult the medical staff, dealers or manufacturers before using it.
- The ultrasonic probe used in the fetal heart rate meter is a sensitive device. Please handle it with care, do not knock or impact it, and pay attention to prevent accidental damage such as falling.
- The ultrasonic output power of fetal heart rate meter is very small, which has no effect on pregnant women and fetus. Please feel free to use it. On the premise of meeting the clinical needs, we suggest to control the frequency of use.
- When fetal heart rate meter is used to measure adult heart rate or fetal heart rate below 12 gestational weeks, the accuracy of measurement results is not guaranteed.
- Fetal heart rate meter only uses radio frequency energy for its internal function, so its electromagnetic radiation is very low, and it may not interfere with nearby electronic equipment, and has no effect on pregnant women and fetus. Please rest assured to use it.
- When the fetal heart rate meter is used normally, there may be slight temperature rise in the ultrasonic probe, which is a normal phenomenon and has no effect on pregnant women and fetus. Please rest assured to use it.
- When there is any quality or technical problem with the fetal heart instrument, we do not recommend the user to repair and maintain it by themselves. If the user needs technical data such as circuit diagram, component list, drawing note, calibration rules, internal wiring diagram and so on for maintenance and maintenance purposes, the user can contact the dealer or the manufacturer for request.
- The main machine of fetal heart rate meter can only be connected with the probe provided by our company.
- The fetal heart rate meter can only be connected with 3.5mm earphone.

Pregnant women with too small gestational age or too obesity may have inaccurate fetal heart rate or unclear fetal heart sounds when using fetal doppler. Due to lack of experience, it is difficult for family users to distinguish between pregnant women's abdominal blood flow sound and fetal heartbeat sound, and pregnant women's blood flow sound is often detected by mistake. The rhythm of pregnant women's blood flow is slow and synchronized with pregnant women's heartbeat. If the user observes that the value displayed on the screen is in the range of 70 ~ 100 beats / min, it is likely that it is pregnant women's blood flow. At this time, the probe should be moved to continue searching until the real fetal heart position is found.

Volume adjustment

he volume of fetal doppler can be adjusted by the "⏮" and "⏭" keys. The volume is divided into 9 levels from 0 to 8. 0 means to turn off the sound output (i.e. mute), and 8 is the maximum volume. Each time you press the "⏮" and "⏭" keys, the volume will increase or decrease by one gear. When the volume is the eighth gear of the maximum volume, continuing to press the "⏮" key will no longer work. When the volume is the zero gear of the minimum volume, continuing to press the "⏭" key will no longer work.

Display mode switching

There are two display modes: numerical mode and curve mode. The numerical mode display interface is shown in Figure 3-4, and the curve mode display interface is shown in Figure 3-5. Short press the "menu" button (less than 1 second) to switch back and forth between numerical mode and curve mode. The curve mode can display the fetal heart rate curve for about 4 minutes, which is convenient for users to view the historical data of fetal heart rate measurement.



Figure 3-4 numerical mode

This interface display FHR value and convenient to use.
150: Real-time FHR value. It means that the fetal heart beat 150 times per minute.

⏮: Volume of speaker: 8 steps can be adjusted by the up&down key.

🔋: Battery status indicator

CHAPTER 4 PRODUCT SPECIFICATIONS

Product Name	Fetal Doppler
Model	YK-90S
Classification:	
Protection against electric shock Type:	Internal power supply.
Degree of protection against electric shock	BF type.
Protection the liquid level	IP22
the safety level of combustible gas	not suitable for use in environments where there is flammable gases.
operating mode	continuous work.
Physical properties	
Machine size	about 155(L)x68 (W) x25.5 (H) mm
weight	184g (including battery)
Lithium battery specifications	3.7V 680mAh
Environment	
Working environment	Temperature: +5℃ ~+40℃ humidity: 30% ~<80% Atmospheric pressure: 60kPa ~110kPa
Transportation and storage environment:	Temperature: -20℃ ~+55℃ Humidity: 10% ~<93% Atmospheric pressure: 50kPa ~110kPa
Display:	2.4inch
FHR measurement	50 ~240BPM (BPM: times/minute)
Accuracy	±2BPM
Loudspeaker specification	8Ω1W
Auto power off:	there is no signal more than 2 minute .
Working frequency	2.5MHz±5%
Comprehensive sensitivity(at a distance of 200 mm from the probe surface)	≥90dB
Output beam intensity	<20mW/ c m²
Peak negative sound pressure	≤1Mpa
Spatial peak time average derived sound intensity	Ispta<100mW/ c m²

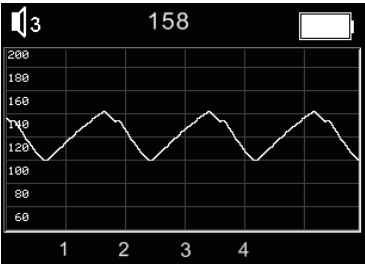


Figure3-5curve mode

The FHR value will be display in the form of the curve. It is convenient to analysis the fetal heart rate during this period changes.

Battery power detection

The Fetal Doppler automatically monitors the battery power and displays and updates it on the screen. The battery power is divided into four levels, namely 🔋, 🔋, 🔋, 🔋. When the battery power symbol is displayed 🔋, the user should charge in time. When the battery power symbol starts flashing 🔋, the user is prompted to charge immediately. Otherwise, the user may shut down automatically at any time due to low battery power.

Charging

When the battery power of the fetal doppler is low, the user should charge it in time. When charging, insert the type C interface of the USB cable into the charging interface on the left side of the fetal doppler, and insert the other end of the USB cable into the USB power supply. After connecting the USB power supply, the fetal doppler will automatically enter the charging state. When charging, the screen flashes 🔋 to indicate that it is charging, and the battery power symbol 🔋 indicates the current battery power; When the battery is full, the battery charge symbol 🔋 stops flashing. When the battery is fully charged, pull out the USB cable directly, and the fetal doppler will automatically enter the shutdown state. To ensure safety, the fetal heart rate detection function is not available when the fetal doppler is charged. There is no response when pressing the on / off button. You must unplug the USB cable to start the machine.

CHAPTER 5 MAINTENANCE AND PURCHASE INFORMATION

Maintenance

The surface of the probe is very precise and must be handled with care. The excess gel on the probe must be wiped off after use. These maintenance will extend the life of the instrument.

Before use, the user must check the equipment may not significantly affect the patients' safety or performance of equipment.Recommended inspection period is once a month or less.If you find obvious damage, it is recommended to replace the damaged parts before use. Safety examination should be periodically tested to ensure insulation leakage current, including the leakage flow. It is recommended that test it every two years or test it according to the inspection procedures and specified by public bodies. The accuracy of fetal heart rate is controlled by the device. It can not be adjusted by the users. If the fetal heart rate results unreliable, please use other methods such as using stethoscope to verify, or contact your local dealer or manufacturer for help.

Cleaning

Before cleaning, please make sure the machine is off and the battery is out. Keep the appearance of the machine clean and there is no dust. The main unit including LCD screen can be cleaned with a dry and soft cloth. If necessary, Clean the cabinet only with a soft cloth which moistened in soap or clean water. Clean the excess gel on the probe with a soft cloth. Clean the probe with soap and water only.

Caution:Do not use strong solvents such as acetone.

Caution:Do not use wear material (such as steel wool or silver polish).

Caution:Do not let any liquid into the cabinet, nor can any part of the instrument immersed into liquid.

Caution:Do not pour the liquid into the equipment while cleaning.

Caution:Do not let any cleaning fluid left on the instrument's surface.

Note:The probe surface can be wiped by 70% alcohol or isopropyl alcohol, natural air-dry or use clean and dry cloth to clear.

Disinfection

Clean the cabinet and probe according to the above methods. The probe surface can be wiped by 70% alcohol or isopropyl alcohol. Use dry and soft cloth to clean the probe.

Caution:The probe and instrument can not be allowed to do low temperature steam sterilization or other methods to sterilizate.

Warning

- Charger specification: output voltage DC 5V. It is forbidden to use USB cable with type C interface at both ends to charge the fetal heart meter, otherwise it will be damaged.
- After the battery is fully charged, the USB cable should be pulled out in time. It is forbidden to charge the battery continuously for a long time.
- Please use the couplant provided by regular manufacturers (with medical device registration certificate and production license), otherwise the performance of fetal heart rate instrument may be affected and the probe of fetal heart rate instrument may be damaged. For users allergic to couplant, please choose to use water or olive oil instead of couplant.
- After each use, please press the on / off button to turn off the probe, wipe the couplant on the probe surface with a soft cloth or paper towel, and then store it properly.
- The couplant remaining on the surface of the probe may corrode the probe, resulting in poor performance or damage. It should be wiped clean in time after use.
- Fetal doppler is a kind of device for checking fetal heart rate in a short time, which is not suitable for monitoring the fetus for a long time and can not replace the traditional fetal monitor. If the user doubts the measurement results of fetal heart rate monitor, other medical means should be taken to confirm.
- Please use ultrasonic probes and accessories provided by the manufacturer. Using probes and accessories from other sources may cause the fetal heart meter to be unable to use normally or its performance is degraded, damaged and other safety risks may be caused.
- Fetal heart rate meter can not be used with high-frequency surgical equipment at the same time, can not be used with fetal monitor at the same time, can not be used with two or more fetal heart rate meters at the same time.
- In normal use, the fetal heart rate meter and probe should not be immersed in water or other liquids.
- It is not allowed to modify this equipment.
- When using the fetal heart rate meter, it is not allowed to carry out maintenance.
- It is forbidden to use the probe when it contacts the skin or is bleeding. The probe used by patients with skin diseases should be disinfected.
- The probe surface contacting with the patient may cause discomfort to the patient due to biocompatibility; Couplants may cause skin allergy; If the patient feels unwell or allergic, stop using immediately and seek medical treatment if necessary.
- The operation of the fetal heart rate meter may be affected by portable or mobile radio frequency communication devices (such as mobile phones). It is necessary to avoid using portable or mobile radio frequency communication devices near the fetal heart rate meter,

Product configuration list

Item name	Quantity
host	1
Probe	1
User manual	1
USB charging line	1
Couplant	1
earphone	1

CHAPTER 6 WARRANTY AND MANUFACTURER INFORMATION

Warranty

This machine can not be repaired by user himself. All the repairment should be done by the technical people who approved by our company. Our company will provide guarantee of one year for the whole machine(From the purchase date). We warranty all the troubles caused by material failure or manufacturing process failure. During the warranty, all the broken parts can be repaired and replaced for free. Our company will not provide free service for the faults resulting by users' damage.