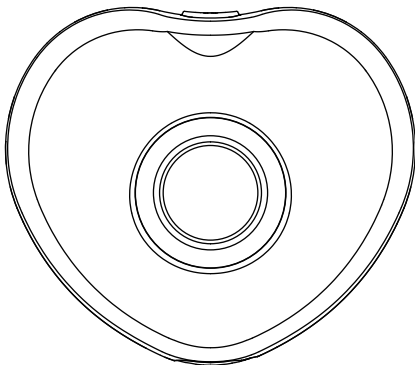


TX-05-01

TX-05-02

ENGLISH

All for Healthcare



FETAL DOPPLER

INSTRUCTION MANUAL

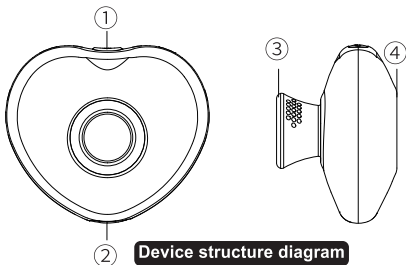
1. Product name

Ultrasonic fetal heart rate monitor.

2. Model and specifications

TX-05-01, TX-05-02: The parameters of different models are exactly the same, only the color matching is different (TX-05-01 (white shell and green handle), TX-05-02 (pink shell and white handle)).

3. Structure and composition



Button

There is a power switch button on the top of the instrument. When it is off, press the power switch button to turn it on. When it is on, press and hold the power switch button for two seconds to turn it off.

Display

The status light is located in the center of the handle, and its display status is as follows:

1. The orange light is always on when the instrument is turned on;
2. The orange light is off when looking for the fetal heart rate, and the blue light flashes (flashing according to the speed of the fetal heart rate);
3. The green light is always on when charging;
4. The orange light is always on when fully charged;
5. The orange light flashes for about 10 seconds to turn it off when the battery is low.

Headphone/charging jack

Type C socket, dual-purpose for charging and headphones, you can insert a charger to charge the battery, or insert headphones to listen to the fetal heart rate.

Application part

Ultrasound probe.

4. Scope of application

For fetal heart rate measurement.

5. Product performance

Technical specifications

Acoustic operating frequency: $2.0\text{MHz} \pm 10\%$

Comprehensive sensitivity (200mm from the probe surface): $>90\text{dB}$

Power supply: $\equiv 3.7\text{V}$ internal power supply, rechargeable lithium battery

Charging power supply: TypeCUSB ($\equiv 5\text{V}/500\text{mA}$)

Communication method: Ultra-low power consumption BT 4.0

Basic performance

Heart rate display range: $50\sim 220\text{bpm}$

Resolution: 1bpm

Fetal heart rate error: 2bpm

Basic safety

Main unit dimensions: 76mm (length) x 66.5mm (width) x 45 (height) mm

Main unit net weight: about 50g

Coupling agent characteristic requirements: Impedance $<1.7 \times 10^5 \text{g}/\text{cm}^2 \cdot \text{s}$

Attenuation $\leq 0.02\text{dB}/\text{mm}$

Acoustic output parameters : $P_{-} < 1\text{MPa}$; $I_{ob} < 20\text{mW}/\text{cm}^2$; $I_{spta} < 100\text{mW}/\text{cm}^2$

Normal working conditions

Ambient temperature: 5°C~40°C

Relative humidity: <80%

Atmospheric pressure: 70kPa~106kPa

Safety category and waterproof and dustproof level

Power supply type: Internal power supply equipment

Protection against electric shock: BF type application part

Waterproof and dustproof level: IP22

Safety classification when used in flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide:

It does not belong to AP type or APG type equipment

Classification by operation mode: Continuous operation

Acoustic output report form

Probe working mode: continuous wave

Probe frequency: 2.0MHz $\pm 10\%$

Index Name		MI	TIS		TIB		TI C
			Body surface	Under the body surface	Under the body surface	Body surface	
Maximum index value		0.020	9.5		0.0095		-
Maximum index value			-	-	-	-	
Sound parameters	$Z_{M} \text{ At } P_{CA}/\text{MPa}$	0.028					
	P/mW		-	-	-	-	-
	P_{LX1}/mW		-		-		
	Z_s/cm			-			
	Z_b/cm					-	
	Z_M/cm	-					
	$Z_{PI1.2}/\text{cm}$	-					
	f_{ave}/MHz	2	2		2		-
Other information	p_{rr}/Hz	-					
	s_{rr}/Hz	-					
	n_{pps}	-					
	$Z_{PI1.0} \text{ At } I_{PS1.0} / (\text{W}/\text{cm}^2)$	-					
	$Z_{PI1.0} \text{ Or } Z_{SI1.0} \text{ At } I_{SPT1.0} / (\text{mW}/\text{cm}^2)$	-					
	$Z_{PI1.0} \text{ Or } Z_{SI1.0} \text{ At } I_{SPT1.0} / (\text{mW}/\text{cm}^2)$	-					
	$Z_{PI1.0} \text{ At } p_r/\text{MPa}$	-					
Operational control conditions	Control 1	x	x	x	x	x	x
	Control 2	x	x	x	x	x	x
	Control 3	x	x	x	x	x	x
	...	...	...	...	...	...	...

- Note 1: Each index has only one operating condition.
- Note 2: The data is entered in the "body surface" and "below the body surface" in the relevant TIS or TIB column.
- Note 3: No information about TIC is required for any transducer assembly not intended for transcranial or neonatal head use.
- Note 4: If the requirements of 201.12.4.2a) are met, no data is required to be entered in the TIS, TIB or TIC columns.
- Note 5: If the requirements of 201.12.4.2b) are met, no data is required to be entered in the MI column.
- Note 6: "√" indicates that a value should be entered in this unit, and the equipment settings related to the index should be filled in the operation control section.
- Note 7: Depths Z_{pii} and $Z_{pii,\alpha}$ apply to non-scanning mode, and depths Z_{sii} and $Z_{sii,\alpha}$ apply to scanning mode.

6. Taboos

At present, no discovery has been made.

7. Precautions, warnings, and prompts

- This device is a fetal heart rate detection device, and the detection results cannot be used as the sole basis for determining the fetal health status. During use, factors such as the usage environment, the pregnant woman's own conditions, and the operator should be taken into account to comprehensively judge the fetal health status.
- The patient is the expected operator who can use all functions and perform cleaning and maintenance. Before use, please carefully read the user manual/technical manual, operate the instrument according to the correct usage method, and if necessary, seek professional medical guidance for use. The interior of the instrument is a precision electronic circuit, please do not open it without authorization.
- The equipment should be left unused for at least 3 hours from -20 ° C to an ambient temperature of 20 ° C.
- Equipment with an ambient temperature of 55 ° C to 20 ° C should be left for at least 3 hours before use.
- The appearance of the instrument can be wiped and cleaned with non corrosive cleaning agents. Do not use high-temperature disinfection or corrosive cleaning agents for cleaning. The probe can be disinfected by wiping with a small amount of alcohol.
- Before daily use, please clean the ultrasound probe section of the product. It is recommended that a dedicated person use it exclusively to avoid cross use; Please use coupling agents with legal and valid medical device qualifications; After each monitoring, please use a soft cloth or tissue soaked in water and wrung dry to clean any remaining lotus root agent on the product. When the battery is fully charged, it can be used for 180 minutes.

- When the battery is low, please charge it in a timely manner. The number of times the battery can be charged and discharged is about 300 or more. Please use a charger that complies with the standard for charging; In daily use, please turn off the charger promptly after use to avoid unnecessary consumption of battery power.
- The instrument is an ultrasonic product, please do not use it outside the human abdomen.
- The instrument probe cannot be replaced and can only be used for measuring fetal heart rate on this device.
- The instrument is prohibited from collision and violent vibration to avoid damage.
- Please note that the instrument is waterproof and moisture-proof. \Do not place it in water or rinse it with water. Do not place the product in boiling water for sterilization or in boiling water; Do not perform ultrasonic cleaning, as it may cause malfunctions.
- Do not use volatile agents, diluents, gasoline, etc. to remove dirt; Before cleaning, please turn off the power and keep it dry after cleaning;
- Do not use a dryer, hair dryer, etc. to dry it, otherwise it may cause malfunctions.

 Warning:

- No modification of this equipment is allowed.
- Cannot be used together with high-frequency devices.
- Do not use this instrument in environments with flammable and explosive anesthetic gases, high or low temperatures and humidity.
- Potential electromagnetic interference may affect the effectiveness of the fetal heart rate monitor. To avoid these interferences, please use this instrument in an environment far away from the interference source.
- This device is equipped with a rechargeable lithium battery that cannot be disassembled. Do not forcefully disassemble or damage the battery, heat it up, or throw it into a fire, as it may cause the battery to explode.

- After the service life of the host and accessories expires, please do not dispose of them casually. They should be disposed of according to local environmental requirements to avoid causing environmental pollution.
- To avoid the risk of electric shock, this device must be connected to a protected grounded power grid during charging.
- The maximum temperature rise of the probe during use is 5 ° C. When the ambient temperature exceeds 34 ° C, the usage time cannot exceed 10 minutes.
- This device contains a charging cable and should not be choked to prevent injury.
- Please do not place the device in a place that children can come into contact with to avoid putting it into the mouth or swallowing body parts and causing personal injury.
- Please do not use this device for a long time. Some personnel may have allergic reactions.
- Do not place the device in direct sunlight or in areas with cotton or dust, as it may cause performance degradation.
- Do not place the device in contact with pets or insects to avoid injury.
- High temperatures can cause a decrease in probe performance, and should be avoided when used in environments that exceed the storage environment temperature.

8. Installation and usage instructions or illustrations

Usage Guide

1. Before initial use, connect a charger and fully charge the battery of the fetal heart monitor.
2. Gently press the power switch button to turn on the device. At this time, the status light orange lights up, indicating that the device is turned on.
3. Wear headphones and place the fetal heart rate probe closely against the pregnant woman's abdominal fetal heart position, then slowly move the fetal heart rate probe to detect fetal heartbeat. (To maintain good monitoring results, please apply medical ultrasound coupling agent on the surface of the probe, or evenly apply an appropriate amount of coupling agent on the abdomen. When there is no coupling agent, water or edible oil can be used as a substitute. If the coupling agent dries or coagulates during the measurement process, it can be increased appropriately.)
4. After detecting fetal heartbeat, the breathing light will flash synchronously with the rhythm of fetal heart rate. When the breathing light continues to flash and continuous and regular heartbeat sounds are heard, it indicates that the fetal heart position has been found. At this time, please try to keep the position of the fetal heart monitor unchanged.
5. When hearing unclear or light fetal heart sounds, move the probe around until a clear fetal heart sound is heard.
6. After monitoring, press and hold the power switch button for two seconds to turn off the device, and the breathing light and status light will turn off. If fetal heart rate monitoring is not performed for more than one minute, the fetal heart rate monitor will automatically shut down.
7. After use, wipe off the residual coupling agent on the abdomen and fetal heart rate probe.

Mobile software connection and usage guide

1. Before first use, please scan the QR code on the instruction manual or download the Ziqing Medical mobile software from the website and register as a user.
2. Open the mobile software and log in to the user account.
3. Click to enter the fetal heart rate monitor interface, press the power switch button of the fetal heart rate monitor to turn on the device, and click the device connection button on the APP interface, and the device will automatically connect.
4. After the device is connected, there is no need to connect headphones, adjust the volume of the mobile phone, and use the same method as the stand-alone and usage guide to find the fetal heart. During the search process, you can see that the average heart rate and current heart rate values will change, and the mobile phone speaker will output a heartbeat sound.
5. After detecting a stable heart rate, click the screen prompt button to start drawing the fetal heart rate graph, and you can choose whether to save the drawn graph.
6. After the monitoring is completed, turn off the graph drawing on the mobile software and turn off the fetal heart rate monitor, and wipe off the residual coupling agent on the abdomen and the fetal heart rate monitor probe. The graphics and related data saved on the mobile software can be called up and viewed at any time.

Charging

- When the orange light flashes when the device is turned on or during the test, it means that the battery is low. Please charge as soon as possible.
- When the device cannot be turned on, please charge as soon as possible before measuring.
- Insert the charging cable into the charging socket, and the display window turns green to indicate that it is in charging state.
- After charging is completed, the display window turns orange.

The correct way to find the fetal heart sound

1. The simplest way is to pay attention to the doctor's listening to the fetal heart in the hospital, and then listen to it again after returning home to determine the location of the fetal heart.

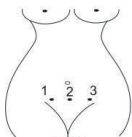
2. Since the fetus moves in the abdomen at any time, the position of the fetal heart may also change. There are usually the following methods to find the position of the fetal heart:

A. Before 24 weeks of pregnancy, the fetal heart is often in the middle or slightly off the navel.

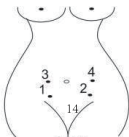
B. After 26 weeks of pregnancy, the fetal heart is most clearly heard on the side where the fetal back is located.

C. Since fetal movement is usually the movement of the fetus's hands and feet, when the right side feels frequent fetal movement, the fetal heart is generally on the left; conversely, the fetal heart is generally on the right.

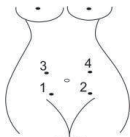
D. Head position and breech position will also affect the position of the fetal heart. In head position, the fetal heart is on the left or right below the navel, and in breech position, the fetal heart is on the left or right above the navel.



Early pregnancy
16-24 weeks



Mid-pregnancy
24-32 weeks



Late pregnancy
32-40 weeks

Note:

The normal fetal heart rate fluctuates between 120 and 160 beats per minute. If it is confirmed to be greater than 160 beats per minute or less than 120 beats per minute, you should go to the hospital for treatment. If you find that you can't hear the fetal heart rate in the original position, but you can feel the fetal movement, it means that the fetal position has changed. Please follow the above method to carefully find the fetal heart rate. If the fetal movement is not obvious, please go to the hospital immediately.

Common troubleshooting

Symptoms	Causes	Solution
No sound	Volume too low Battery insufficient	Turn up the volume Replace the battery
Howling	Sound too loud Too much coupling agent on the probe surface Battery insufficient	Turn down the volume Clean the probe surface Replace the battery
Weak sound	Sound too low No coupling agent Battery insufficient	Turn up the volume Apply more coupling agent Replace the battery
Low sensitivity	Wrong probe position No coupling agent	Adjust the probe position Apply more coupling agent

9. Product maintenance and care methods, special storage and transportation conditions, maintenance suggestions

- When the battery is low, please charge it in time.
- Check regularly to confirm that the instrument's ultrasonic probe has no cracks, and the connecting cable and plug are intact to ensure the safety and performance of the instrument.

Cleaning and disinfection

- This device is recommended to be used by one person only to avoid cross-use.
- Clean before use.
- Turn off the instrument before cleaning.
- After use, wipe off the excess coupling agent on the ultrasonic probe with a dry, soft cloth. Be careful not to let the coupling agent or any liquid enter the interior to avoid damage to the machine.
- When the dirt on the ultrasonic probe is serious, please use a neutral detergent or a cloth dampened with water to wring it dry, and then wipe it dry with a soft cloth.
- When disinfecting the ultrasonic probe, dip the absorbent cotton in 75% medical disinfectant alcohol and wipe it gently.
- After each cleaning and disinfection, carefully check whether the instrument's ultrasonic probe and components have cracks to ensure the safe use and performance of the instrument.

Transportation and storage conditions

General transportation means, such as airplanes, trains, and cars, can be used for transportation. During transportation, it should be prevented from violent collisions and should not be mixed with corrosive objects. The transportation climate and the transportation and storage environment conditions between two uses after removing the protective packaging should meet the following requirements:

- Ambient temperature: $-20^{\circ}\text{C}\sim+55^{\circ}\text{C}$;
- Relative humidity: 10%~93%;
- Atmospheric pressure: 50kPa~106kPa.
- The packaged fetal heart rate monitor should be stored in a room with a temperature of $-20^{\circ}\text{C}\sim+55^{\circ}\text{C}$, a relative humidity of 10%~93%, no corrosive gases, and good ventilation.

10. Production date, expiration date or expiration date

The production date of the product is shown on the label, and the expiration date is 3 years.

11. Configuration list

1. Host*1
2. Instruction manual (including warranty card and certificate of conformity)*1
3. Charging cable *1

Please open the package carefully, check the list, check whether the accessories are complete, whether the parts are damaged due to transportation, and install and operate strictly in accordance with the instructions. If there is any damage or operational questions, please contact our dealer or contact us directly.

In order to protect your rights, please ask the salesperson for invoices, receipts and other relevant documents when purchasing the product.

The warranty period of this product is one year. Our company promises to provide warranty for non-human quality problems within one year.

Outside the warranty period, only transportation and component costs are charged (see the warranty card for details).

12. Explanation of graphics, symbols, abbreviations, etc. used on medical device labels

Graphic, symbol and text description

Symbol	Description
	Wireless transmitter
	BF type application part
	Warning
	Follow the operating instructions
IP22	Dust and water resistance level
	The transport package should be transported vertically upwards
	The transport package contains fragile items, so be careful when handling
	The transport package is afraid of rain
	Indicates the maximum number of layers that can be stacked with the same transport package.
	The transport package cannot be exposed to direct sunlight.
	When the end user discards the product, it must be sent to the designated collection and separation location for recycling
	DC voltage

13. Network security instructions

1. Operating environment

1.1 Hardware configuration

Processor: Android: Dimensity 700 octa-core and above;
IOS: A10 and above.

Memory: Android: 6GB and above; 10S: 2GB and above

1.2 Software environment.

1.2 Software environment: Android: Android 12 and compatible versions;
IOS: IOS 15.7.9 and compatible versions.

1.3 Network conditions

Network type: 4g/5g network, WiFi network.

2. Security software

2.1 Antivirus software

Antivirus software that runs normally on the phone, such as
(Mobile Security Manager, Tencent Security Manager).

2.2 Firewall

The protection monitoring in the mobile phone manager can be turned on normally.

3. Data and device (system) interface

Data interface: Bluetooth communication.

Transmission protocol: Standard BLE4.0 standard protocol when BT is connected.

4. User access control mechanism

- (1) User identity authentication method: Login through SMS verification
- (2) User type and authority: The software has only ordinary user authority, and users can log in to use the APP through the mobile phone verification code.

5. Security software update

Updated normally with the mobile phone antivirus software.

13. Appendix | Electromagnetic compatibility statement

Warning:

- Users should install and use the unit according to the electromagnetic compatibility information provided in the accompanying documents.
- Portable and mobile radio frequency communication equipment may affect the performance of this unit. Avoid strong electromagnetic interference when using it, such as near mobile phones, microwave ovens, etc.
- For detailed instructions and manufacturer's statements, please see the attachment.

Warning:

- This device should not be used close to or stacked with other devices. If it must be used close to or stacked, it should be observed and verified to operate normally in the configuration it is used in.
- Except for cables sold by the manufacturer of this device as spare parts for internal components, the use of accessories and cables other than those specified may result in increased emissions or reduced immunity of this device.
- Using accessories or cables other than those specified with this device may result in increased emissions or reduced immunity of this device.
- Operating this device below the minimum amplitude or minimum value mentioned above may result in inaccurate results.
- This device uses Bluetooth 4.0 technology, with a transmit and receive frequency of 2400-2483.5MHz. The modulation type is: GFSK, and the effective radiated power is 0.03mW.

- Even if other devices meet the emission requirements of the corresponding national standards, this device may still be interfered with by other devices. The following cables must be used to meet the requirements of electromagnetic emission and interference immunity:

NO.	Cable Name	Length	Shielded
1	USB charging cable	0.7	No