Model : JPD-300E

Fetal Monitor

Instruction Manual

Version: V1.0

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Shenzhen Jumper Medical Equipment Co., Ltd.

Statement

This manual prepared fully in accordance with the “General Instructions for operating manual of GB/T9969 industrial products” conforms to the national standards.

The contents of this manual are completely consistent with the actual situation of this monitor.

This Manual includes Technical Specifications and Instruction Manuel.

WARRANTIES

In the event that the following conditions are met, Jumper Company will be responsible for the safety, reliability and performance of the product:

（1）Use this product in accordance with the Instruction Manuel/Technical Specifications.

（2）The installation, maintenance and upgrade of the product shall be carried out by the personnel of Jumper Company.

（3）The storage environment, working environment and electrical environment of the product are in accordance with the manual.

（4）The serial number tag or manufacturing mark of the product shall be clear and identifiable. It is verified through the appraisal of Jumper Company that this product is manufactured by Jumper Company.

（5）Damage caused by non-human factors

The products that are under the warranty service regulations of Jumper Company shall enjoy free service. As for the products that are beyond the warranty service regulations, Jumper Company shall charge for the service. If the products are transported to Jumper Company for maintenance, the user shall bear the freight (including the customs expenses).

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Foreword

Confirm the fetus is alive before using the monitor

Current Fetal Monitoring technology cannot always distinguish the fetal heart rate (FHR) signal source from the maternal heart rate signal (MHR) source under all circumstances. Therefore, you must use other methods to verify that the fetus is alive before using the Fetal Monitor, such as out-patient fetal movement, or using a fetal stethoscope, a fetal heart meter, or a wooden earpiece for fetal heart sounds. If you hear no fetal heart sounds or feel no fetal movements, verify whether the fetus is still alive by means of ultrasonic obstetrical examination. Then confirm that the fetus is the source of the FHR that you are monitoring.

It is to be understood that:

- MHR traces can present features that are very similar to FHR traces, and even include acceleration and deceleration phenomenon. Do not solely rely on the trend characteristics of the trace to identify the heart rate source of the fetus.

- Only automatic fetal movement (AFM) markers on fetal traces do not consistently ensure that the fetus is still alive. The dead fetus also moves and causes the monitor to mark the fetal movement.

Here are a few examples of how MHR is mistakenly identified as FHR.

- **When using ultrasonic sensors:**

△ Can detect the mothers signal source, such as the mother’s heart, aorta or other large blood vessels beat.

△ When MHR is higher than normal values (especially over 100 bpm), false identification can occur.

Contents

FCC Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and

(2) This device must accept any interference received, including interference that may cause undesired operation.

Notes:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions,may cause harmful interference to radio communications.However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

■ Reorient or relocate the receiving antenna.

■ Increase the separation between the equipment and receiver.

■ Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

■ Consult the dealer or an experienced radio/TV technician for help.

Caution: Any changes or modifications to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

1. Introduction

1.1. Product Introduction

Thank you for purchasing the Fetal Monitor. This product is a portable wireless Fetal Monitor. The data is transmitted to the host by Bluetooth technology instead of the traditional wired connection. The probe captures the fetal heart signal from the abdomen of the pregnant woman by using the principle of ultrasonic Doppler, its unique manufacturing technique makes the fetal heart sound clearer. You don't need to remember the pair relationship between the host and the probe, it can be used as soon as you pick it up. The monitoring data is uploaded in real-time through wireless WIFI, nurse central monitoring station can view the real-time monitoring information of the fetus and keep abreast of the Fetal Monitoring situation.

This Fetal Monitor is applicable to external monitoring, it is equipped with an ultrasonic probe, a uterine contraction pressure probe and a fetal movement pen. Its performance conforms to the latest international standards. The whole machine design is simple, reliable and easy to use. The main features of this product are as follows:

- The portable Fetal Monitor can be used in the hospital or at home.
- The host and the probe can be freely paired. It is free to pair the probe. It can be used immediately after pairing.
- It can be placed freely, or hung on the wall. The probe will not fall down even if the host rotates 360°.
- The host will show the current pregnant woman's name and the corresponding bed number so that the doctors no longer worry about "checking the wrong number".
- Data is real-time uploaded to the central station which can simultaneously connect to more than 30 beds.
- 1MHz fetal heart probe of 9-chip wide beam uses the unique manufacturing technology, making small noise and clear fetal heart sound.
- The probe has built-in lithium battery, which can continuously work for more than 10 hours.
- Fetal heart probe will automatically shut down after 3 minutes without signal, which can save energy.
- It supports effective transmission within 10 meters between probe and host.

Working Principles

Fetal Monitor is the fetal heart rate detection through the noninvasive ultrasonic Doppler. We know that a certain

frequency of ultrasonic wave will reflect when it encounters obstacles during the transmission. If the object is stationary, the reflected wave frequency is the same as the transmitted wave frequency. Once the object is moving, the reflection frequency will change, and the greater the movement rate of the object, the greater the change of the frequency. So we put the ultrasonic probe on the abdomen surface of the pregnant woman. Since the fetal heart beat has movement relative to the ultrasonic probe, the reflected wave will cause frequency offset after the transmitting wave encounters the heart, so as to calculate the frequency of the fetal heart beat per minute (fetal heart rate), and so on. Uterine contraction pressure is to detect the uterine contraction pressure change of the pregnant woman through uterine contraction probe sensor, and draw the curve. Fetal movement frequency is manually recorded by fetal movement pen button according to the pregnant women feel their own fetal movement.

- Monitoring all stages after pregnancy.

- Fetal Monitor is not applicable to monitor water birth.

Intended Usage

It is provided for medical institutions to monitor the fetal heart rate, the fetal movement and uterine contraction pressure.

Product Composition

It consists of the host and the ultrasonic probe.

1.2. Safety Guide

Classification according to anti-electric shock type and anti-electric shock degree:

JPD-300E is class-II power supply BF type, a mobile ordinary equipment. Classification according to the degree of protection against liquid inlet: a mobile ordinary equipment. The waterproof grade of the probe is **IPX4**.

 Application part to BF type.

BF-type protection indicates that the patient connection should comply with the stipulation of IEC60601-1 to allowable leakage current and dielectric strength.

Safe Operation Instructions

In order to avoid possible injury, you are highly recommended to observe the following safety instructions when operating the device.

Warning: Please do not completely rely on the alarm system of the monitor when the pregnant women being monitoring. Too low alarming setting or closing alarming voice may be harmful to patients. The most reliable monitoring method is medical staff can monitor and operate the monitor closely and correctly. The alarm function of the monitor has to be regularly verified. When several devices are used on the same patient at the same time, the danger of leakage current may be greater. It is suggested that before connecting each other, the leakage testing should be conducted by qualified personnel professional to ensure the leakage current is within safety range, that is to say, it will not cause harm to the patient, the operator and the surroundings. The user should consult the manufacturer about the correct operating method if any further doubts. Before using this monitor, the operator must confirm that the instrument is in normal working condition and operating environment. When using a high-frequency electrotome, the lead wires and guide wires for patient should be placed as far from the surgery as possible to keep the cables away from other devices, thereby reducing the risk of burns caused by poor neutral connection of high-frequency electrotome. Regularly check whether the repeated use of accessories are damaged, whether the sensor is damaged, whether cable connections are reliable, replace if necessary, and properly handle the damaged accessories according to medical waste.

Warning: Do not use in areas with flammable gases such as anesthetics, which has a danger of explosion.

Warning: Never dispose of batteries into the fire because they may explode.

Warning: Please do not touch the signal input or output connector and pregnant women at the same time.

Caution: The repair of the device has to be conducted by the authorized qualified engineer.

Caution: The design of the instrument is continuous working type. It is a closed anti-drop equipment, be watch out of wetting.

Caution: Keep the instrument clean and avoid oscillation.

Caution: Do not make high temperature disinfection treatment or use electronic bean or radiation Y to sterilize.

Caution: Electromagnetic interference --- ensure that the original use environment of the instrument is not affected by strong electromagnetic interference sources, such as wireless transmitter or mobile phone.

Caution: User must check if there is the damage that may affect the personal safety of patient or the performance of device before use. The recommended inspection period is once a month or less. If no obvious damage is found, it is recommended to change the damaged parts before use.

Caution: The following safety checks must be executed by the person who has been trained, has certain knowledge

and practical experience. Generally the safety check should be made every two years or according to the inspection regulations formulated by the public organization. Test according to the inspection rules designated by public agency.

- ✧ Check if there is mechanical or functional damage;
- ✧ Check if the label related to the safety is legible.
- ✧ Check if the function is consistent with the description of the manual.

Caution: The instrument is returned to the manufacturer for disposal in accordance with local regulations after the effective life of the instrument.

Caution: Dry batteries of fetal movement pen should be handled properly after use in accordance with local regulations.

Caution: It must be stored in a cool and dry environment.

Caution: Please do not mix metallic objects with batteries during storage to avoid accidental short circuit.

Caution: We suggest that under the premise of meeting the clinical needs, the ultrasound irradiation time to pregnant women should be as short as possible.

Caution: Do not use instrument immediately when it is transferred from a cold environment to a warm and humid place.

Caution: Keep the operating environment free from vibration, corrosion, flammable substances, and avoid too high or too low temperature and humidity.

Caution: Stop the operation if the instrument is wet or has water condesation.

Caution: Although the Fetal Monitor is designed to be firm, dropping and shaking resistant, and to meet complicated clinical working needs, it should be handled carefully during its usage, especially, the ultrasonic probe wafer is ceramic, shall not be dropped, bumped or surface scratched. But it should be careful when using.

Caution: It is recommended to use water-based coupling agent. Oil-based coupling agent may damage the probe surface, which should be prohibited.

Caution: After each use, wipe the couplant on the surface of the ultrasonic probe. The user can scrub the probe and

the device by using a wet rag dipped with a neutral disinfectant or detergent.

Caution: Wet a soft cloth with 1000ppm sodium hypochlorite solution to wipe and sterilize.

Caution: The complete machine and probe parts cannot be sterilized by steam.

Caution: The pressure probe is not waterproof and cannot use coupling agent. It must be absolutely prevented from flowing into any liquid.

Caution: Do not use a bad socket when plugged in.

Caution: Please do not turn off speaker volume during monitoring, because fetal heart sound monitoring is very important.

Caution: The accuracy of the fetal heart rate is controlled by the device and cannot be adjusted by the user. If FHR result is not accurate, please use other methods. For example, use a stethoscope to verify, or contact a local agent or manufacturer for assistance.

1.3. Symbol and text description

Symbol	Description
	Class II equipment
	Type BF applied part
	Note! Please refer to this Manual
	Non-ionizing radiation
IPX4	Probe waterproof grading of 4
	When discarding the product, it must be taken to the separation and collection place for recycling.
WARNING	You should know the information about how to avoid pregnant women and medical personnel being injured.
NOTE	Some important information that you should know

2. Recommended clinical application

The Fetal Monitor is suitable for external monitoring applications.

- Prenatal monitoring at all levels of the hospital
- Prenatal monitoring at home or in community
- Examination before hospitalization

3. Product Description

3.1. Standard Configuration

- The host

The host has a liquid crystal display module (LCD) electronic circuit – microprocessor, signal processing system, audio system, display system and power supply. Monitoring curve and monitoring state are displayed on the LCD screen, selection and other functions can be conducted through the shuttle keys, including system parameter settings, freeze display, volume control and alarm control and so on.

- Ultrasound fetal heart probe US

Ultrasound (US) fetal heart probe is fixed on the abdomen of pregnant women by elastic bandage.

- Uterine contraction probe TOCO

Uterine contraction pressure (TOCO) probe is fixed on the abdomen of pregnant women by elastic bandage.

- Fetal movement pen FM

Pregnant women hold the fetal movement pen, and press the fetal movement pen button to record the fetal movements when pregnant women feel fetal movements or uterine contractions.

- AC Adapter

Input: AC 100-240V，50/60Hz 0.8A Max.

Output: DC 12V, 2.5A

3.2. Product Introduction

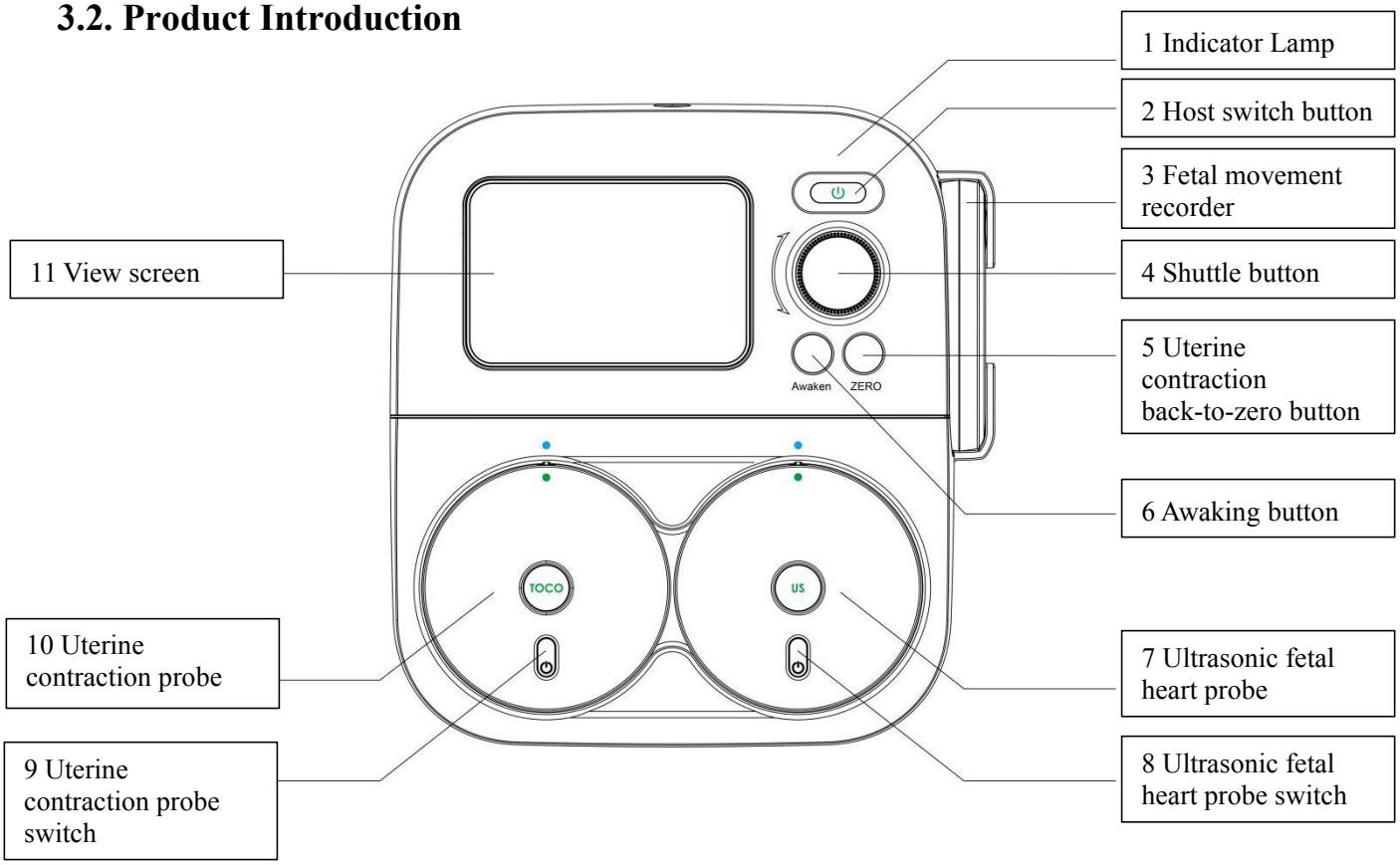

Figure 1 Product appearance

3.2.1 Indicator Lamp

1) Green on: indicates that the instrument is powered on normally.

2) Orange blinking: indicates low battery. Please charge as soon as possible.

3) Orange on: indicates that the instrument is charging.

3.2.2. Host switch button

1) In the power-off state, press switch button and hold it for 2 seconds to turn on the device.

2) In the power-on state, press switch button and hold it for 2 seconds to turn off the device

3) In power on state, each short press the switch button to update the monitoring.

3.2.3. Fetal movement pen

1) The fetal movement pen will automatically shut down when it is put into the side of the host.

2) The fetal movement pen will automatically turn on when it is removed from the side of the host.

3) When used, pregnant women press the fetal movement pen button when they feel fetal movements or uterine contractions, the host will record the fetal movement. It records once only if it is repeatedly pressed within 15 seconds.

3.2.4. Shuttle button

1) Adjust the volume: in monitoring mode, select the shuttle button to adjust the volume. There are eight grades totally from 0 to 7. The corresponding system volume is from silent to the strongest, which can be adjusted by shuttle button, reducing sound through rotating to the left and increasing sound through rotating to the right.

2) Freeze playback: in monitoring mode, short press the shuttle button to enter the freeze playback function. The monitoring information can be played back by rotating the shuttle button (fetal heart sound does not support playback).

3) Selection and confirmation: in setting mode, rotating shuttle button is the selection function. The cursor will move when shuttle button rotates. Short press the shuttle button to confirm if enter the submenu or select a parameter.

3.2.5. Uterine contraction back-to-zero button

1) In monitoring mode, short press this button after the uterine contraction probe is fixed by bandage, the pressure display value is reset to 10.

3.2.6. Awaking button

1) Press once to awake fetal heart probe once, the awaking icon is displayed once on the pressed time 

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3.2.7. Ultrasonic fetal heart probe

1) When the host is in power on state, the ultrasonic fetal heart probe is taken out and turned on automatically. The probe will show the current electric quantity and it will disappear after 3 seconds, then the signal light is on. During the monitoring process, the signal light flashes with the signal strength of the ultrasonic fetal heart probe;

2) The ultrasonic fetal heart probe is put into the host, making the metal contact of the fetal heart probe touch the sub-contact of the host charging terminal. The probe will automatically pair with the host, all power indicator lights are on, indicating the pairing is successful. The host will automatically charge for the probe;

3) The probe cannot be used during charging;

4) The total electric quantity of the probe displays 3 grades. When it is in low power, only one grade will display and flash continuously. Please charge as soon as possible at this time;

5) Ultrasonic fetal heart probe will automatically shut down if there is no signal for 3 consecutive minutes;

6) Long press ultrasonic fetal heart probe switch button for about 2 seconds to turn on / shut down.

3.2.8. Uterine contraction probe

1) The uterine contraction probe will automatically turn on when it is taken out, the probe displays the current electric quantity and it will disappear after 3 seconds;

2) The uterine contraction probe is put into the host, making the metal contact of the uterine contraction probe touch the sub-contact of the host charging terminal. The probe will automatically pair with the host, all power indicator lights are on, indicating the pairing is successful. The host will automatically charge for the probe;

3) The probe cannot be used during charging;

4) The total electric quantity of the probe displays 3 grades. When it is in low power, only one grade will display and flash continuously. Please charge as soon as possible at this time;

5) Uterine contraction will automatically shut down if the uterine contraction keeps the same contraction value for 3 consecutive minutes;

6) In turn-on state, long press the uterine contraction probe switch for about 2 seconds to shut down.

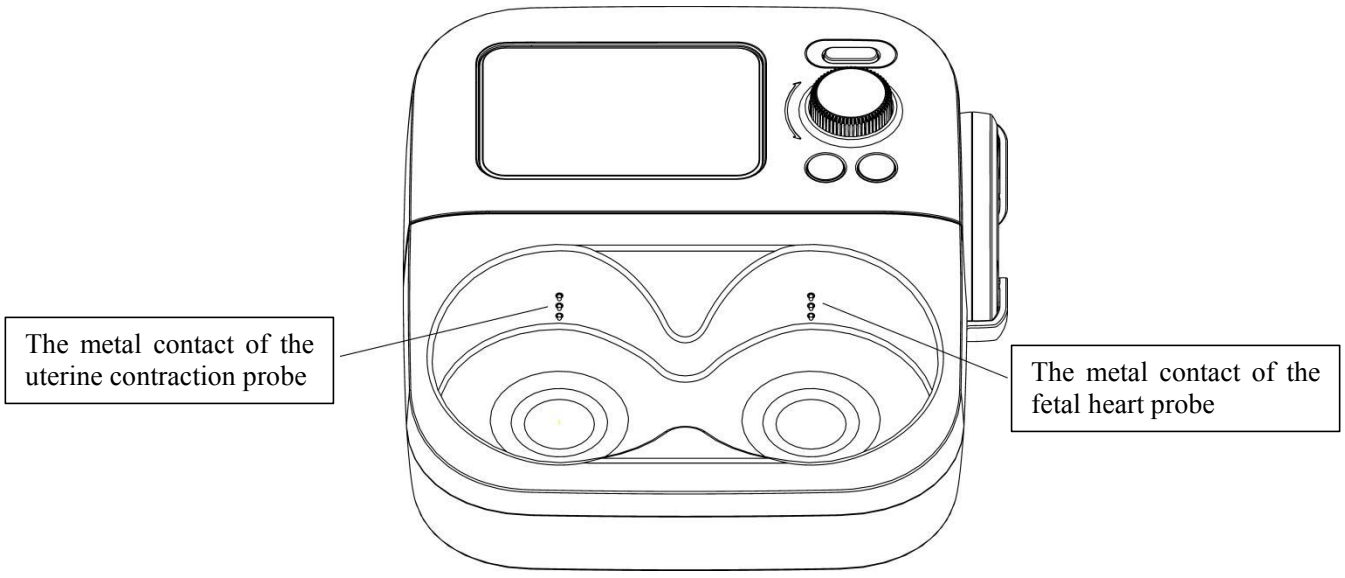

Figure 2 Sub-contact schematic diagram of the host charging terminal.

3.2.9. Viewing screen

3.3. Main interface (monitoring interface) description

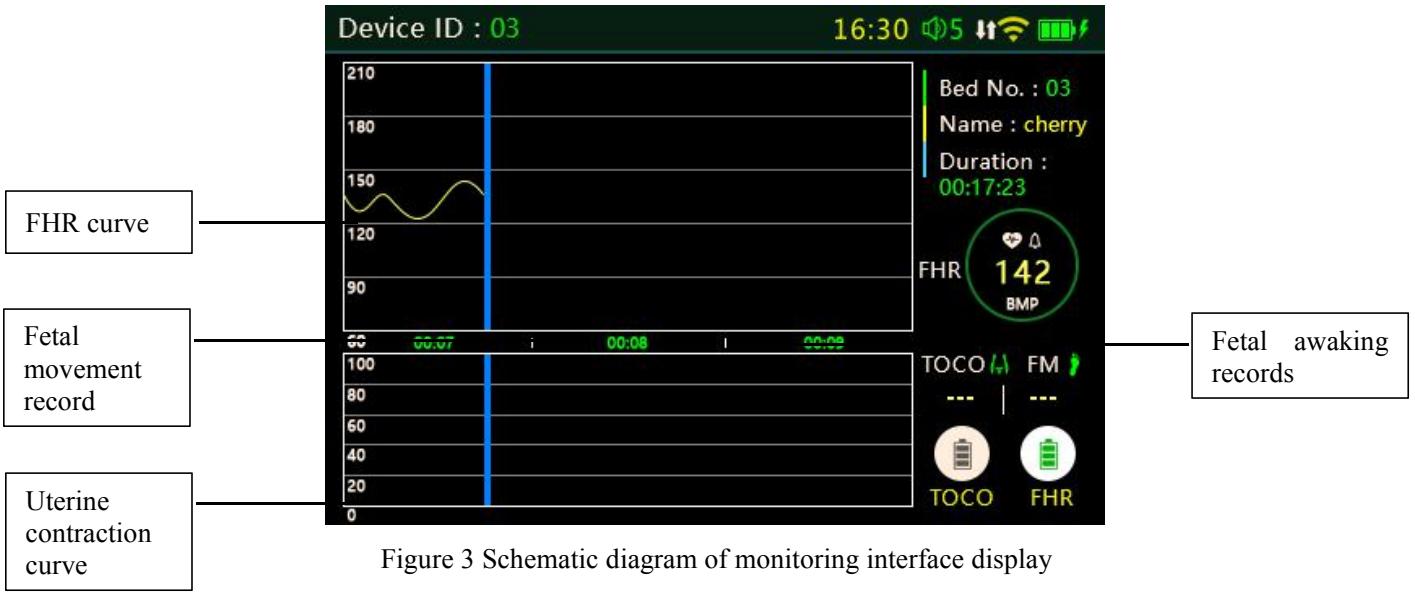

Figure 3 Schematic diagram of monitoring interface display

Main Interface Description

Device ID: display the device ID of the current device. The device ID can be set, with range of 00-99.

Time: The current time, update time with the central station when connecting the central station, calculate the time from the starting up if there is no connection with central station.

Volume: speaker volume indicator, eight grades display from 0 to 7. The corresponding system volume is from silent to the strongest, which can be adjusted by rotating the shuttle button, reducing sound through rotating to the left and increasing sound through rotating to the right.

Data: the state of the data that is currently connected to the central station. The icon is displayed when the connection to the central station is successful and the data is being sent and received. Otherwise, the data is grayed out.

WiFi: indicates the WiFi connection state of the device. When the connection between the device and the central station is successful, the indicator will be green. When the connection between the device and the router is successful, the indicator will be yellow. The indicator will be gray if WiFi is off.

Electric quantity of the built-in power supply: indicates the current electric quantity and charging state of the built-in power supply of the device.

1. Normal work: display the current electric quantity;

2. Low electric quantity tip: when the electric quantity is too low, it will flash continuously;

3. Charging: it displays charging when access to the power adapter, the charging symbol flashes;

Bed No.: displays the current bed number. the bed number is consistent with the device ID.

Name: displays the name of the pregnant woman who is currently being monitored (connection to the central station is required).

Duration: the monitoring duration is started from pressing the start key.

Fetal heart rate: displays the current fetal heart rate. The abnormal icon will light up if the current fetal heart rate exceeds the upper and lower limits of 15 seconds.

Uterine contraction: displays the current uterine contraction value.

Fetal movement: press a fetal movement mark to calculate the fetal movements. It records once only if it is repeatedly pressed within 15 seconds.

Fetal heart probe connection label: indicates the state label connected with the ultrasonic fetal heart probe. When the host is paired with the ultrasonic fetal heart probe and the probe is on, the white background of the label will be on and the current electric quantity of the fetal heart probe will be displayed. When the fetal heart probe is taken out from the host box, the label will become green, indicating that automatic matching is complete. You can use the probe for fetal heart monitoring.

Uterine contraction probe connection label: indicates the state label connected with the uterine contraction probe. When the host is paired with the uterine contraction probe and the probe is on, the white background of the label will be on and the current electric quantity of the uterine contraction probe will be displayed. When the uterine contraction probe is taken out from the host box, the label will become green, indicating that automatic matching is complete. You can use the probe for uterine contraction monitoring.

 Fetal movement record: indicates that the user presses the fetal movement pen at that time.

 Awaking record: indicates that the awaking function has been used once at that time.

3.4. Setting interface specification

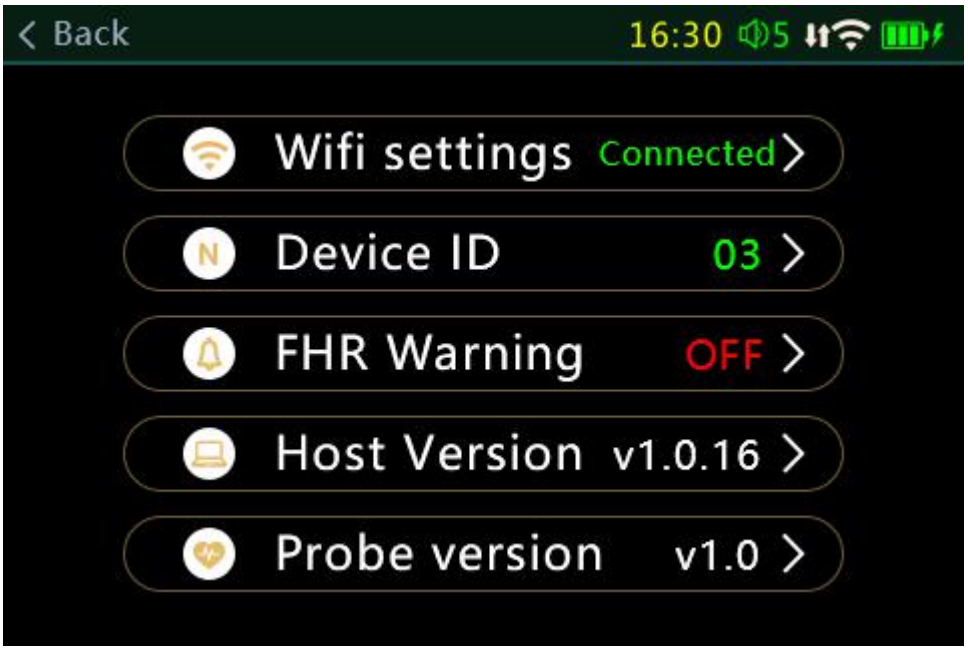

Figure 4 Setting Up the Interface

Setting interface specification

WiFi settings: access to WiFi settings, the searched or type in hotspot can be connected, and the password of WiFi needs to be entered.

Setting ID: access to set the Device ID of this device, the default ID is 00, and the optional range is 00 to 99.

FHR Warning: warning settings include upper FHR limit, lower FHR limit, warning switch, etc.

Host Version: View the current version of the host.

Probe version: view the current version of ultrasonic FHR probe.

Return: Return to the main interface.

Reset Password: Reset the password that entered the setup interface.

3.4.1. Access to Setup Interface

Long press shuttle button for 2 seconds to access to setting interface after entering 4 numbers of password on the password entry screen (the default password is 1234), after the success of the password authentication, access to setting interface from the main interface.

Figure 5 Input Password Interface

3.4.2. WiFi settings

1) Access to the WiFi configuration interface, automatically search the nearby WiFi, rotate the shuttle button to select the hotspot to connect, enter the password, and select OK to connect

Figure 6 WiFi Search Interface

Figure 7 WiFi Configuration Interface

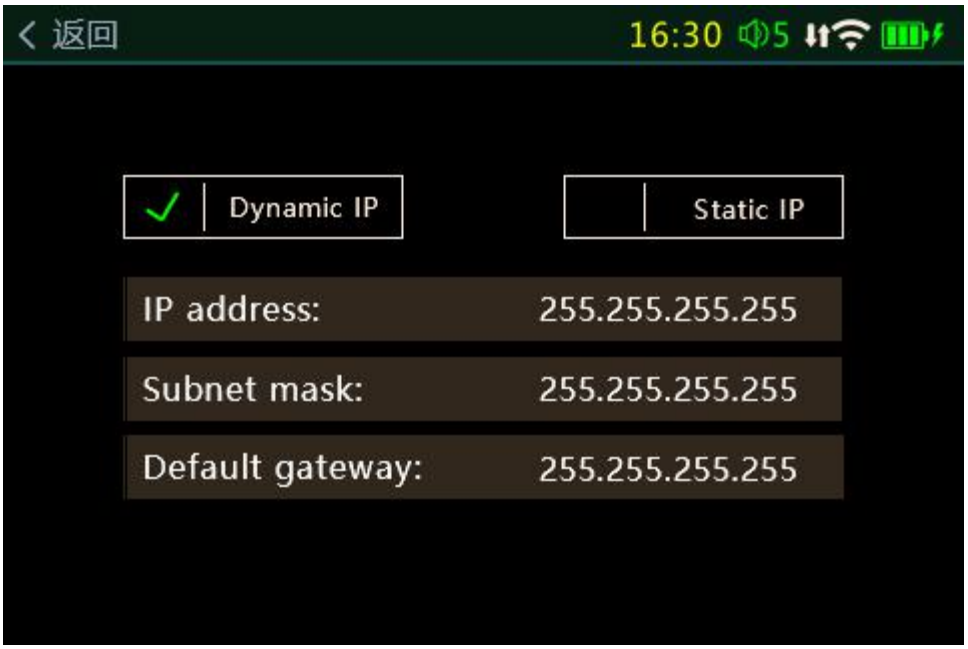

Figure 8 Static IP Setting Interface

2) After selecting the dynamic IP by default, the local area network will be automatically distributed IP to the device. Select static IP, it will skip to the setting static IP interface, then could set fixed IP, subnet mask and default gateway.
3) IP and port number in the configuration process are IP address and port number connected with the central station.
4) Select type in, enter SSID and the corresponding password through virtual keyboard.
5) If there is no WiFi hotspot can be searched, select Re-Scan or exit the list.
6) Select “Back” to return back to the main interface (monitoring interface).

3.4.3. Device ID

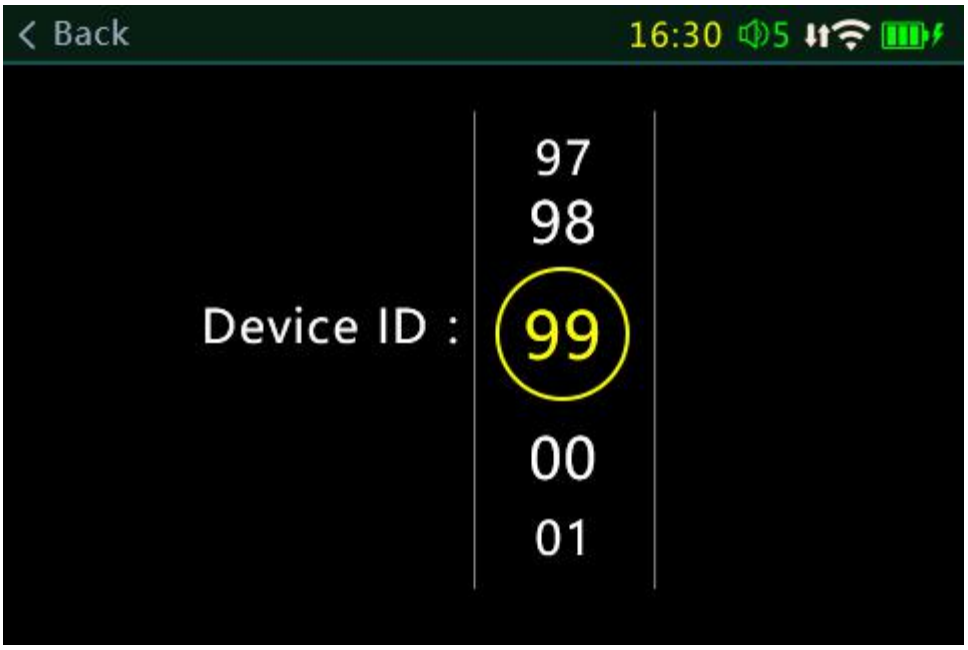

Figure 9 Device ID Interface

To distinguish different devices, set the number of the devices, select the different numbers by rotating the shuttle button, after the selection, pressing the button to confirm exit by pressing Back to set the number of the device, the settable range is 00 to 99.

3.4.4. FHR Warning

Figure 10 FHR Warning Interface

FHR Warning selects on, when the rate of FHR is abnormal for 15 seconds consecutively, exceeding the upper limit and lower limit range of setting, the system makes warning sound, select off, and close the warning.

Upper FHR limit: the adjustable range is 150bpm to 180bpm, and the default is 160bpm.

Lower FHR limit: the adjustable range is 90bpm to 120bpm, and the default is 110bpm.

Return: Return to the setup interface.

3.4.5. Host Version

View the software version of the host.

3.4.6. Probe version

View the software version of ultrasonic FHR probe.

3.4.7. Reset Password

Access to setting interface, select Reset password, enter the new password, the new password allows the maximum number of characters to be entered in 10 bits, click OK after the completion of entry to complete password reset.

4. Setting of monitor

This section tells you how to

- ❖ Disassembly and Installation
- ❖ Connection to Power Supply

4.1. Disassembly and installation and list of accessories

4.1.1. Carefully remove the host and accessories from the packing box.

4.1.2. Check to see if there is any loss or damage in the packing box according to the following table.

♦ Fetal Monitor host X 1

♦ FHR ultrasonic probe X 1

♦ TOCO pressure probe X 1

♦ FM pen X 1

♦ Probe bandage X 2

♦ Power adapter X 1

♦ Gel X 1

♦ Instruction Manual

♦ Warranty Card (included in this specification)

♦ Certificate of Conformity

4.2. Connect the power supply Charge

4.2.1. Insert the DC plug of the power adapter into the power socket behind the device.

4.2.2. Insert the AC plug of the power cable into the power socket of Extranet.

4.2.3. The screen displays charging and this device can be used in charge.

5. Operational Guidelines

5.1. Preparation before Use

Long press the switch button for 2 seconds, the screen enters the main monitoring interface, remove the ultrasonic probe, the TOCO probe and the FM pen from the host, if the FHR probe connection identifier and TOCO probe connection identifier of the screen light up, it indicates the success of matching with the probe (if the match fails, please rematch the probe back to the contact point).

5.2. FHR monitoring

5.2.1. Pregnant women should maintain an easy-to-monitor position, usually in a semi-supine position.

5.2.2. Pass the strap down the waist (two straps are required to monitor fetal heart rate and uterine pressure).

5.2.3. Apply proper amount of couplant on the surface of the ultrasonic probe, put the probe on the abdomen of the pregnant woman, and make sure the probe and the abdomen of the pregnant woman are in good contact.

Move the probe slowly to find the best position. The fetal heart sound in the speaker is strongest at this time, and the fetal heart rate is shown continuously on the screen.

5.2.4. After finding the best position, the probe is fixed at the position and the strap is fixed. If the probe moves, adjust the probe's position again to seek for the best signal.

5.2.5. During monitoring, please do not turn off the speaker's volume; when the fetal heart rate signal is very weak, you can hardly hear the fetal heart sound from the speaker. Note that the digital fetal heart rate displayed on the screen now might be meaningless.

5.2.6. After fixing the ultrasonic probe, rotate the shuttle to adjust the volume to the appropriate volume.

5.3. TOCO monitoring

5.3.1. Pass the strap through the back of the pressure probe, place the sensor at the pregnant woman's uterine fundus, fix the strap, adjust the position; the tightness of the strap should be appropriate.

5.3.2. Press the uterine contraction pressure reset button on the host, at which point the uterine contraction position shows the uterine contraction pressure reset value 10.

5.4. Manual FM monitoring

Remove the FM pen from the host, when use, press the button of the FM pen when the pregnant woman feels FM, the host will record the FM, repeatedly press in 15 seconds, only recorded once, place back the FM pen to the side of the host after use, and the FM pen will be automatically turned off.

If the FM icon of the interface turns gray, place the FM pen to the side again for re-adsorption, then remove the FM pen out again, if the icon lights up, the match is successful.

5.5. Monitoring information update

During the monitoring process, short press the switch button, refresh the monitoring information, and restart the monitoring.

5.6. Restore Factory Settings

Simultaneously press the awakening button and the UC zeroing button on the main interface for one second to restore the factory setting.

6. Maintenance and clean of Fetal Monitor

6.1. Product Handling

Although the design of Fetal Monitor is strong enough to be used for clinical use, it is important to be careful in use and pay attention to maintenance, especially the wafer of ultrasonic probe is precise and cannot be rammed and fallen.

6.2. Maintenance

In addition to cleaning, the Fetal Monitor does not require additional maintenance. Keep the outer surface of the device clean and free of dust. Clean the outer surface of enclosure (including LCD display) with a dry and soft cloth. If necessary, clean the enclosure with only soft rag soaked with soap water. Use a soft cloth to wipe off the excess gel on probe. Use only soap and water to clean probe.

Caution: Do not use acetone and other strong solvents.

Caution: Do not use wearable material (such as steel wool or silver polishing agent).

Caution: Do not allow any liquid to enter the enclosure or immerse any part of the instrument into the liquid.

Caution: Do not pour the cleaning liquid into the instrument.

Caution: Do not make cleaning liquid leave on the surface of instrument.

Note: The surface of the probe can be wiped with 70% alcohol or isopropanol, naturally dried or cleaned with clean and dry cloth.

6.3. Cleaning and Disinfection

Clean the outer surface of the device and the probe according to the above method, then wipe the surface of the probe with 70% alcohol or isopropanol. Wipe the probe with a dry, soft cloth to remove the liquid on the surface.

Caution: Do not sterilize the device or probe with low temperature steam or other methods.

6.4. Gel

It is recommended to use random-carrying water-based gel. It is absolutely prohibited to use oil-based gel, if the

probe is damaged because of using oil-based gel, the warranty of the device will be automatically terminated.

7. Packaging, transportation and storage

7.1. Packaging

The monitor is sealed in a plastic bag and filled with sponge or foam, then packaged in the packaging box and sealed firmly.

7.2. Transport

The monitor can be transported by usual transportation, such as airplane, train, and automobile, which should prevent violent collision and not be mixed with corrosive objects in transportation. Transportation, climate and environment should be in accordance with:

a) Ambient temperature range: -20 ℃ ~ + 55 ℃;

b) Relative humidity range: ≤ 95%;

c) Atmospheric pressure range: 50kPa ~ 106kPa.

7.3. Storage

Packed monitors must be stored in well ventilated room with temperature of -20℃~+55℃, relative humidity no more than 80％, and without corrosive gas.

8. Fault finding and eliminating

The quality and reliability of antenatal monitor are high. If you have any problems, please find the problems and eliminate the faults according to the table below.

Symptom	Possible cause	Troubleshooting method
No display at boot time	The host is powered off.	Connect the power adapter for charge.
Abnormal FHR	The probe is not connected to the device well The location of the probe is incorrect, the fetal heart is not found No couplant or too little couplant	Reconnect Readjust the probe position Readjust the probe position after signal restoration Add couplant

	Probe damaged	Change the probe
Abnormal uterine contraction pressure	The probe is not connected to the device well Incorrect probe position No pressure reset Pregnant woman has no uterine contraction	Reconnect Readjust the probe position Process pressure reset Wait for pregnant woman's uterine contraction
Press the pressure probe, the value of uterine contraction has no change or little change.	Circuit drift in pressure probe Pressure probe damaged	Contact the manufacturer for maintenance or Change the pressure probe
No response when press the FM pen	The FM pen is not successfully matched with the host	Place the FM pen in the side of the device for re-adsorption, and then take out the FM pen again
Speaker silence	Too low volume adjustment	Volume up
WiFi icon shows gray	Turn off WiFi function Disconnect from the router	Access to setting interface, open the WiFi function and configure WiFi Check the router
The screen displays the probe icon in gray	Unpaired The probe is charging	Retake the probe and align to the contact point for matching. Normal phenomenon

9. Warranty Period and Maintenance

We provide the one-year warranty and lifelong maintenance for this product. **If the device fault occurs to device fails to work, the manufacturer shall be contacted in time, any form of maintenance or other disposal of the device is prohibited.**

The service life of this device is five years.

Please contact the manufacturer for repair or replacement if any problem occurs in the following accessories:

Probe: When the probe line appears to be damaged, broken or in bad contact, please contact the manufacturer in time to consult for maintenance or replacement.

Power line: When the power line appears to be damaged, broken or in bad contact, please immediately stop to use, and consult the manufacturer to undertake timely replacement.

About after-sales service, maintenance and any other involved problem or any problems involving the company's

other products, please contact us, when you want to return this product, please follow the local disinfection process for disinfection and provide corresponding document to indicate the current state of the product. Please enclose the document in the product packing box.

Note: Our company shall not assume responsibility for the incidental or consequential damages resulting from the errors in this manual or from the provision, actual performance and use of this manual.

This manual contains the proprietary information which is protected by copyright law. All rights reserved, no one is allowed to photocopy or duplicate any part of this manual or translate it into any other language without the prior written consent of our company.

The content in this manual may be subject to change without further notice.

Warning: The intended use of this device is clinical and cannot be used for treatment. If the FHR result is not reliable, please use other methods immediately, such as using a stethoscope.

Annotation notes of this manual are as follows:

Warning: You should know the information about how to avoid pregnant women and medical personnel being injured.

Caution: You should know the information about how to avoid being hurt by the device.

Note: Important information you should know

.


: Refer to accompanying documents.

10. Technical Parameters

Product Name: Fetal Monitor

Product Model: JPD-300E

Fetal Heart Rate (FHR)

Probe: multi-chip, wide beam, pulse working mode, high sensitivity.

Ultrasonic intensity: less than 5mW/cm^2

Working frequency: 1.0MHz±5%

Signal processing: special digital signal processing unit

Measuring range: 60bpm to 210bpm

Alarm Range:

Upper limit: the adjustable range is 150bpm to 180bpm, the default is 160bpm

Lower limit: the adjustable range is 90bpm to 120bpm, the default is 110bpm

Maximum audio output power: 2W

UC pressure

Measuring range: 0-100mmHg

Display

The LCD screen shows the monitoring state of FHR curve, UC pressure curve, FM symbols, volume and so on, which can be frozen and replayed.

Power supply: AC 100-240V 50/60Hz, internal battery: lithium battery3.7V 3000mAh

Input Power: 20VA

Work mode: continuous working for more than 10 hours after full power supply

Size: 89.2mm (length)*202mm(width)*75.9mm (height)

Net weight: 882.5g (power adapter and accessories are not included)

Environment

Working environment: temperature: +5℃ to +40℃ humidity: ≤ 80% atmospheric pressure: 86KPa to 106KPa

Transportation and storage environment: temperature: -20℃ to +55℃ humidity: ≤ 95% atmospheric pressure: 50KPa to 106KPa

Probe sound output: According to the regulations of international standard IEC 61157, the peak negative acoustic pressure shall not exceed 1 MPa, and the output beam sound intensity shall not exceed 20mW/cm^2. The

average sound intensity of space peak time shall not exceed 100mW/cm^2. The sound intensity of the device type shall not exceed 5mW/cm^2.

Gel: viscous water-based compound is not irritative and allergic to skin.

Sound output report form

Product model: JPD-300E

Working mode of probe: pulse wave

Probe Frequency: 1.0MHz

Index Name			MI	TIS			TIB	TIC
				Scanning	Non-scanning		Non-scanning	
					$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
Maximum Index			0.02	-	-	0.002	0.03	-
Parameters	$p_{r.a}$		0.017					
	P			-	-		4	-
	Minimum of $P(z_s)$ and $I_{ta,}(z_s)$					0.46		
	z_s					2.0		
	z_{bp}					1.8		
	z_b						2.0	
	z at maximum I_{pi}		2.0					
	$d_{eq}(z_b)$						1.2	
	f_{awf}		1.0	-	-	1.0	1.0	-
	Diameter of A_{aprt}	X		-	-	Φ1.2	Φ1.2	-
		Y		-	-	Φ1.2	Φ1.2	-
OthersInformation	t_d		903.9					
	prr		1250					
	p_r at maximum I_{pi}		0.018					
	d_{eq} at maximum I_{pi}						1.2	
	$I_{pa.3}$ at maximum MI		0.00					
Operation ControlCondition	Control 1		×	×	×	×	×	×
	Control 2		×	×	×	×	×	×
	Control 3		×	×	×	×	×	×
	…		…	…	…	…	…	…

Note 1: For the maximum number of TIS not produced in this mode, no information about TIS formula is required.

Note 2: For any transducer component that is not used in the head of a transcranial or newborn baby, no information about TIC is required.

Note 3: If the device satisfies the exemption clauses of both 51.2aa) and 51.2dd), no information about MI and TI is required.

Appendix Ⅰ—Electromagnetic Compatibility Declaration

This device is capable of generating, using, and radiating RF energy. This equipment may cause the electromagnetic interference between other medical devices or non-medical devices, as well as radio communications. According to the statement of IEC 60601-1-2, this product belongs to the medical device with the emission limit of B-grade in first group, so as to provide corresponding protection measures for avoiding interference. Nevertheless, it cannot be fully guaranteed that the electromagnetic interference will not occur under specific installation conditions.

When it is discovered that this equipment causes an interference phenomenon, (it needs to be confirmed by the switch-on and switch-off of the equipment), the operators (or the maintenance personnel) can eliminate the interferences based on the following measures:

- Adjust or reposition the affected device;
- Increase the distance between the device and the affected device;
- Use another power supply to provide power for the device;
- Consult maintenance engineers for more advice.

⚠**Note:** Before using this device, please make sure that all of the requirements for EMC in this section are met.

⚠**Note:** This Chapter shall list the contents described in IEC 60601-1-2, and the users are obliged to ensure that this equipment and its nearby equipment conform to the RF interference parameters as indicated in the general safety requirements.

⚠**Note:** Near this device, do not using the devices that purposely transmit RF signals (mobile phones, radio receiver and transmitter or radio controlled products), for this may cause operation to exceed the specified values. When it is near this device, please switch off such types of the device. The operator shall have the responsibility to prompt the patient or other personnel near the device to comply fully with the above requirements.

⚠**Note:** The manufacturer will not be responsible for any interference caused by the use of non-recommended internal connecting cables or any unauthorized changes or modifications to this equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The JPD-300E is intended for use in the electromagnetic environment specified below. The customer or the user of the JPD-300E should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic**

		environment – guidance
RF emissions CISPR 11	Group 1	The JPD-300E 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 JPD-300E 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	Complies	
Voltage fluctuation/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The JPD-300Eis intended for use in the electromagnetic environment specified below. The customer or the user of the JPD-300E should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharges (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 (EFT) 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

Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	hospital environment.
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 25/30cycles 0 % 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 25/30cycles 0 % 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 JPD-300E requires continued operation during power mains interruptions, it is recommended that the JPD-300E be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels haracteristic of a typical location in a typical commercial or hospital environment.
Note: U_T means AC network voltage before applied with test voltage.			

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

Guidance and manufacturer’s declaration – electromagnetic immunity			
The JPD-300E is intended for use in the electromagnetic environment specified below. The customer or the user of the JPD-300E 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	3 Vrms 150 kHz to 80 MHz（6V in ISM and amateur radio bands between 0.15MHz and 80MHz）	3 Vrms 150 kHz to 80 MHz（6V in ISM and amateur radio bands between	Portable and mobile RF communications equipment should be used no closer to any part of the JPD-300E, including cables, than the recommended separation distance calculated

		0.15MHz and 80MHz）	from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	Recommended separation distanced = 1.2 x $\sqrt{P}$ d = 1.2 x $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 x $\sqrt{P}$ 800 MHz to 2.5GHz 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 EQUIPMENT or SYSTEM – For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between Portable and mobile RF communications equipment and the JPD-300E			
The JPD-300E is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the JPD-300E can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the JPD-300E as recommended below, according to the maximum output power of the communications equipment.			
Ratings of the transmitter	Separation distance according to frequency of transmitter m		
Max. Output Power	150kHz -80MHz	80MHz -800MHz	800MHz -2.5GHz

(W)	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	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.

JUMPER

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