CE 0482

Fetal /Maternal Monitor

Usual Manual

(12 Inch LCD)

JUMPER

Manual version : A3

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Preface

Introduction:

It is needed to confirm fetal survival before using the monitor,

Current technology cannot distinguish fetal heart rate (FHR) signal source from maternal heart rate (MHR) signal sources in all circumstances. Therefore, before the monitoring, you must use a different method to confirm that the fetus is still alive, such as palpation fetal movement, a Fetal stethoscope or a pinard. If you can't hear the fetal heart sound, or fail to address the fetal movements, you will need to use the obstetric ultrasound to confirm fetal survival, and confirm that the fetus is the guardianship of the signal source.

Should have known:

- MHR traces and FHR traces can be rendered extremely similar characteristics, as well as acceleration and deceleration.
- Don't just rely on movement of the trace feature to identify sources of the fetal heart rate. There are only traces of the fetus fetal movement on curve (FM) marks does not always guarantee that the fetus is still alive. Deceased fetus also moves the body and lead to a mark of monitor fetal movements.

Here are a few examples, indicates how the MHR will be identified as FHR by error.

- When Ultrasonic transducer is used: you can pick up signals to the mother source, such as a mother's heart, aorta or great vessels of other beats. When the MHR higher than normal (especially above 100bpm), it is possible to identify where the error occurred.
- When enabling AFM curves (AFM):
  the following may be causing fetal death and still appear in the context of FM tags:
  - ✧ dead fetus in utero during exercise or after exercise.
  - ✧ During and after manual palpation of fetal movements (especially if the pressure is too large), the dead fetus will be moving.
  - ✧ Movement of the ultrasonic transducer.
  - ✧ Ultrasonic transducer detects the motion signal source, such as its main artery.

To reduce the possibility of confusion between MHR and FHR, also recommended that monitoring of maternal and fetal heart rate simultaneously.

Contents

1. Brief Introduction

1.1 Instrument Introduction

Thanks for buying this ultrasonic monitor. The monitor is the latest and user-friendly monitor. Due to its easy operation for medical staff and pregnant women, the daily monitoring becomes comfortable and efficient and the expense is lower than before.

The ultrasonic monitor is proper for external monitoring. It is equipped with an ultrasonic probe, a uterine contraction probe and a fetal movement pen. Its performance meets the latest international standards. The design of the instrument is simple and reliable and easy for operation. The main features of the instrument are:

● The large color LCD can show, store and replay the monitoring parameter curve and current monitoring status.

● With more than 20-year MTBF (Mean Time Between Failure), the long-life thermal array recorder can real-time monitor printing and store printing contents. The curve is clear and exquisite.

● Adopt the advanced DSP(Digital Signal Processing) technology to ensure accurate and reliable detected fetal heart rate through real fetal heart rate real-time relevant calculation and model recognition.

● With 1 MHz pulse operation and higher safety standards than national ones, the high-sensitivity and low ultrasonic power probe is safer for monitor fetus.

● Double-mark----Standard event marker used by pregnant women and clinical event mark button used by medical worker.

● Three-in-one probe which can reduce lines winding.

● Operated by the comfortable and convenient encoding board.

● A variety of alarming functions include alarming on too-fast or too-slow fetal movement, reminding monitoring time and alarming on printer out of paper.

Working Principle

The series of 300P ultrasonic monitor detect fetal heart rate through non-invasive ultrasonic Doppler. It is known to us that “Doppler effect” means the ultrasonic wave with certain frequency will reflect when it comes to obstruction when disseminating. If the object is still, then the frequency of reflected wave and the one of object movement are same. Once the object is moving, then the frequency of reflected wave will change. And as the frequency of object movement becomes faster, the frequency of reflected wave will be faster too. Therefore we install the ultrasonic probe in abdominal watch of pregnant women. Since fetal heart is moving as to ultrasonic probe, the frequency (fetal heart rate) of fetal heart of every minute can be calculated due to the deviated frequency (frequency deviation) of reflected wave when it comes to heart.

● Different-stage monitors after pregnancy.

● The ultrasonic fetal monitor does not apply to monitoring childbirth in water.

1.2 Safety Guide

This instrument is Class-II hybrid of internal power supply B and BF. It is mobile ordinary equipment.

 Refers to the BF type application part,  Refers to the B type application part.

BF type protection means connection conducted by patients should comply with IEC60601-1 regulations on allowable leakage current and dielectric strength.

Safe Operation Illustration

In order to prevent probable harms, please abide by the following safe operation illustration before operating the instrument.

Warning: When monitoring pregnant women, please do not totally rely on the alarming system of the monitor. 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 alarming function of the monitor has to be verified regularly. When several equipments are used at the same time on a patient, the danger of leakage current may be greater. It is suggested that before connecting each other, the leakage testing should be conducted by qualified professional to ensure the leakage current is within safety range where patients, operators and surrounding environment will not be harmed. Users should consult accurate operating methods to the producer if they do still have doubts. Before operating the instrument, operators have to ensure the instrument is under normal operating status and environment. When using high-frequency electrotome, the lead wires and guide wires for patient should be put on the place where is away from surgery. And the cable should be away from other equipments to reduce the probable burning risk caused by poor neutral connecting of high-frequency electrotome. Regular inspection into whether usually there is damage for used accessories and sensor and the reliability of cable connection. When necessary, the replacement and proper disposal of broken accessory as medical waste should be conducted.

Warning: Please do not operate in places where there is flammable gas such as anesthetic existing risk of explosion.

Warning: Please do not throw the battery into fire. It is easy to explode.

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

Be Careful: The repair of the instrument has to be conducted by authorized qualified engineer.

Be Careful: The design of the instrument is continuous working type. It is closed anti-drop equipment. Be watch out of wetting.

Be Careful: Keep cleanness of the instrument and prevent it from shocking.

Be Careful: Please do not conduct high-temperature disinfection treatment or electron beam and γ radiation disinfection.

Be Careful: Electromagnetic interference—Ensure that under original operating environment, the instrument will not suffer strong interference of electromagnetic interference source such as wireless transmitter or mobile phone.

Be Careful: Before operating, user has to inspect whether there is evident damage affecting patient's safety or performance of the instrument. Recommended inspection period is once per month or should be more frequent. If there is evident damage, the replacement of broken components before operating is recommended.

Be Careful: The following safety inspections have to be conducted by persons who have gone through proper training and mastered certain knowledge and practical experience. Generally once every two years and should be conducted according to public institutions' designated inspection procedures.

✧ Inspect whether there is mechanical or functional damage of the equipment.

✧ Inspect whether it is easy to recognize relevant safety labels.

✧ Verify whether the practical functions of the equipment are identical with the description on the manual.

Be Careful: After ending the life of the instrument, during returning to producer for recycling, it should be disposed according to local regulations.

Be Careful: After ending the life of the battery, it should be disposed according to local regulations.

Be Careful: If the instrument is not in operation for a long time, please timely remove the battery.

Be Careful: The battery has to be preserved under cool and dry environment.

Be Careful: When preserving the battery, please do not put metal objects and battery together. It is easy for short-circuit.

Be Careful: We suggest that under the premise meeting the clinical needs, the ultrasonic raying time for patients should be as short as possible.

Be Careful: Please do not use the instrument immediately when it is moved from cold place to warm and humid place.

Be Careful: Keep an operation environment containing no vibrative, corrosive and combustible material to prevent too-high or too low temperature and humidity.

Be Careful: Stop operation when the instrument is damp or there is water condensation.

Be Careful: Through ultrasonic fetal monitor is firmly designed and anti-fall and anti-seismic thus meeting the needs of complicated clinical operations. However, you should be careful when using it since especially the ultrasonic probe chip is made of ceramic material. Dropping or collision or scratching the surface is not allowed.

Be Careful: The water-based coupling agent is recommended. The oil-based coupling agent should be prohibited since it may damage the probe surface.

Be Careful: After each using, the coupling agent on the surface of ultrasonic probe should be cleaned. The damp cloth with neutral disinfectant or detergent remover can used to clean the probe and the shell of instrument.

Be Careful: Using the soft damp cloth with 1000ppm sodium hypochlorite solution to clean and disinfect.

Be Careful: Steams are not allowed to disinfect the whole instrument and components such as probe.

Be Careful: Pressure probe is not water-proof, coupling agent is not allowed to use on it. A variety of liquids should absolutely be avoided to inflow.

Be Careful: The power cord should be plugged into the socket with three wires. Do not remove the

earth wire and do not use bad socket.

Be Careful: After using, do not twine the cables on the probe. Avoid breaking!

Be Careful: Do not turn off the volume of the speaker during monitoring since it is quite important to monitor the fetal heart sound.

Be Careful: The accuracy of fetal heart rate is subject to the equipment. It is not adjusted by users. If the result of fetal heart rate is doubtful, please adopt other methods such as using stethoscope to verify the result or consult local agent or producer for solution.

1.3 Motherboard Interface Introduction

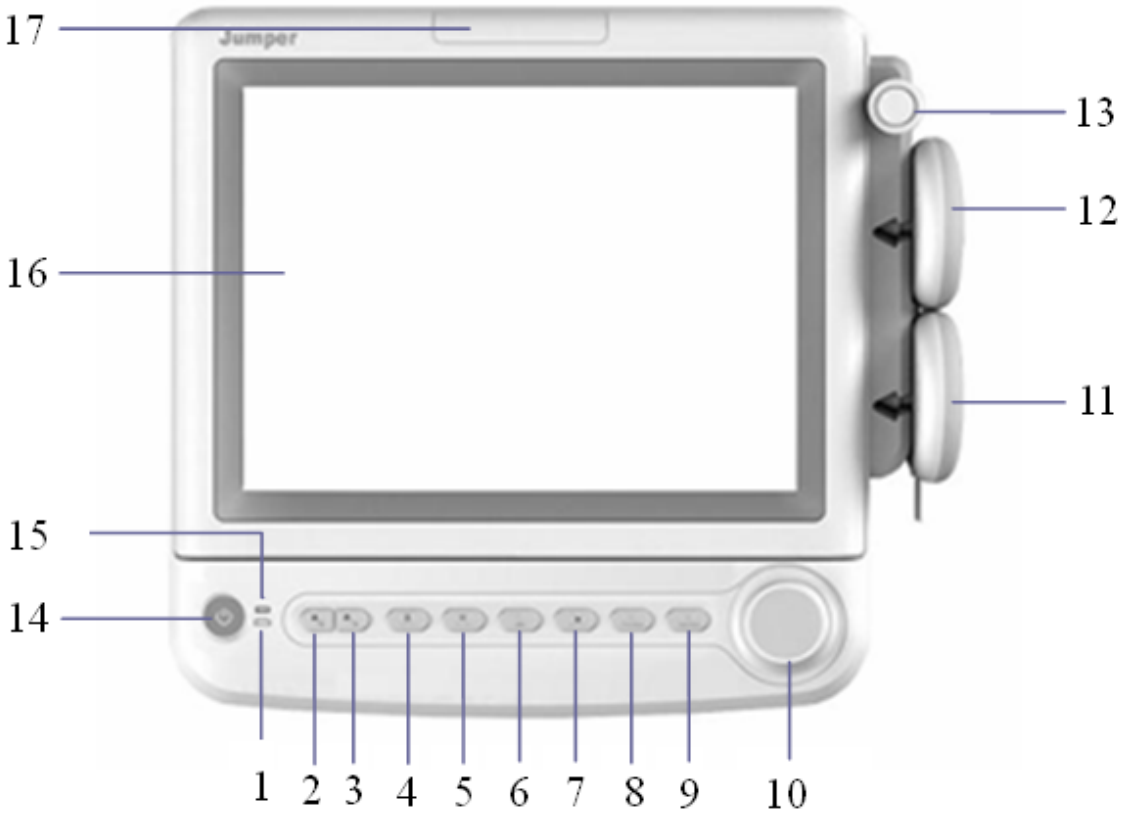


Figure 1-3-1 Front Panel

1. Charging indicator (it is green when charging)
2. Volume increase key (press and hold 2 seconds to switch interface)
3. Volume decrease key
4. Uterine contraction resetting key
5. Freezing key
6. Printing key (long press the paper feed)
7. Blood pressure measuring/stopping key
8. Awakening key
9. Mark key (press and hole 2 seconds to start central monitoring)
10. Encoding board

11.12.13 Probe

14. Turn on/off key

15. Power indicator (power AC is green and power DC is orange)

16. Display

17. Alarming indicator

2. Recommended Clinical Application

Fetal monitor applies for external monitoring.

● Prenatal monitoring in hospitals of different class

● Prenatal monitoring at home or in community

● Inspection before hospitalization

3. Instrument Description

3. 1 Standard Configuration

● Motherboard

● Power cord

● Three-in-one probe (composes of ultrasonic (U/S) probe, uterine contraction probe (TOCO) and one fetal movement pen)

● Motherboard Motherboard contains liquid crystal display module (LCD), printer and electronic circuit - microprocessor, signal processing system, audio system, display system and power.

Monitoring curve and status are both displaying on the LCD and the encoding board can change the corresponding parameters in the menu. There are different kinds of control touch keys on the control panel to set system parameters, freeze display, adjust volume, reset pressure, control printing, paper feed and control alarming etc.

● Probe The probe contains ultrasonic (U/S) probe, uterine contraction (TOCO) probe and one fetal movement pen. The ultrasonic (U/S) probe and uterine contraction (TOCO) probe are fixed on the abdomen of pregnant women by elastic bandage. The pregnant women hold the fetal movement pen, when there is fetal movement or uterine contraction, press the key.

3.2 Display Interface

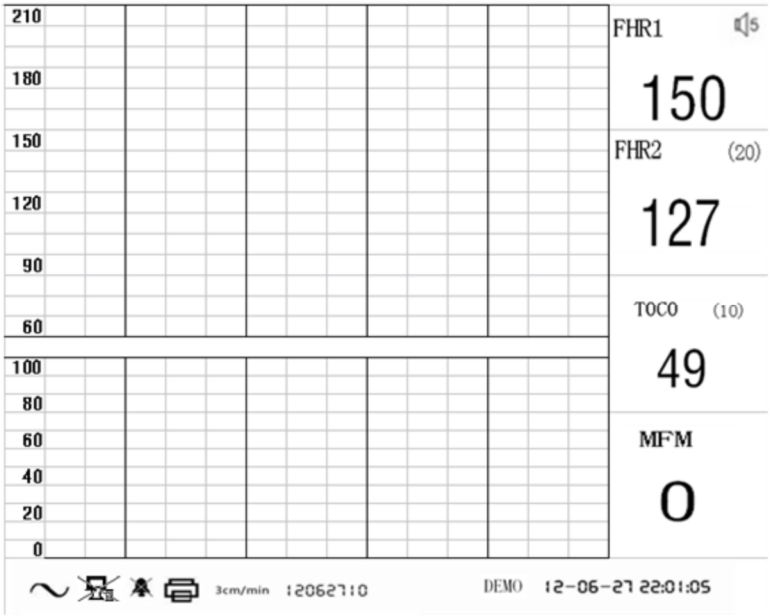


Figure 3-2-1 Sketch drawing of three-parameter standard display

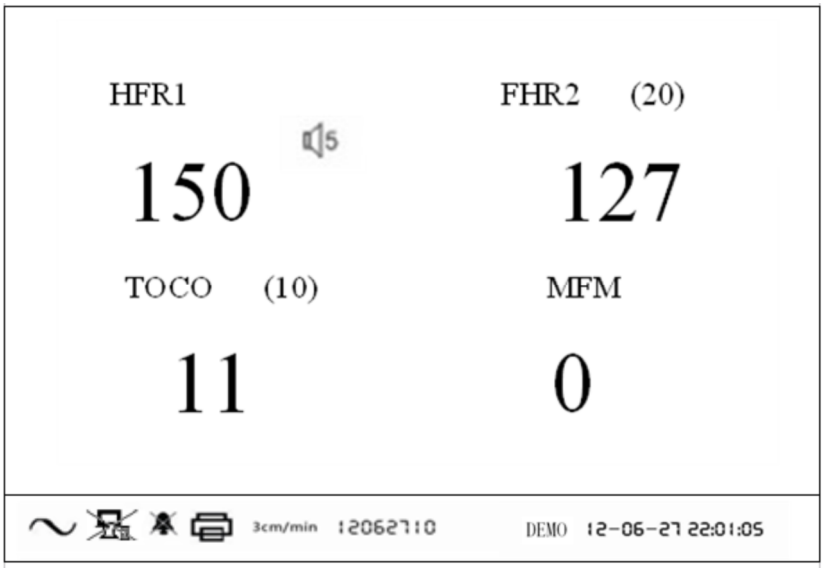


Figure 3-2-2 Sketch drawing of three-parameter large digital display

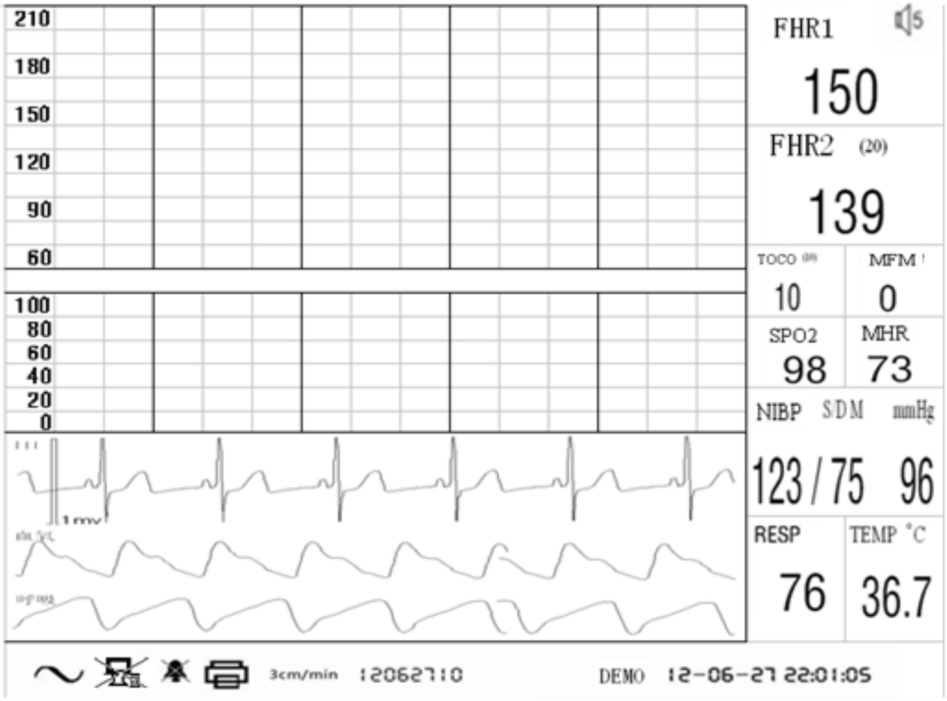


Figure 3-2-3 Nine-parameter display interface

Note: “Interface one” and “Interface two” of three-parameter style can be switched by pressing and holding volume increase key. Nine-parameter style only has one interface.

Below the interface is status indicating area:

Date/Time: Timely monitor date and time. When frozen, show the original date and time of monitoring record.

Printing speed: The current printing speed of the printer has three statuses: 1cm/min, 2cm/min and 3cm/min.

Pregnant women number: Every time when turning on the instrument, the system will automatically produce a serial number according to date and time. The serial number can be changed during monitoring. Change of pregnant women number is only valid for the further data. When there is alarming, the display position will indicate the cause of the alarming. If fetal heart rate is beyond limit, alarming setting shows permit (setting in fetus and pregnant women parameter interface), when the alarming occurs, it shows fetal alarming. When printer is out of paper, the printing door is not closed well or there is something wrong with the printer, there is alarming of system, then it shows printing alarming which indicates the printing part is under abnormal status. After setting monitoring time (monitoring time can be set in system setting interface). If it is not 0, it indicates the monitoring time has been set. From starting monitoring to the end of monitoring time, the system alarms, it shows time is up.

Current status: Shows current display status, monitoring mode or demonstration mode. When frozen, it shows in frozen.

Power status mark: Refers to external power; Refers to internal power.

Network connecting symbol: Refers to the network has been connected, if no

connection, displays  .When  the 3 dots in the symbol flashing refers to start Central Monitoring from the terminal(only in RS485 mode).

Fetal heart alarming sign:  Refers to the alarming is turn on,  Refers to the alarming is turn off.

Printing mark:  Refers to the printer is printing,  Refers to the printer is under non-printing status.

Fetal heart rate curve and uterine contraction pressure marking area:

Fetal awakening icon  : Indicates the monitor has inspected that the fetal awakening function has been started at some time.

Clinical events recording icon : Indicates the monitor has inspected that the clinical events has been recorded at some time.

Cylindrical icon  : Indicates the monitor has inspected that the fetal movement pen has been pressed by the pregnant women at some time.

Pressure resetting icon  : Indicates that the system has inspected that the pressure has been reset at some time.

Right side of display numerical value display area:

Volume: Speaker volume display, there are 8 options from 0 to 7 and the corresponding system volume is

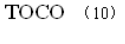
 from mute to the loudest. When scan displays, the volume can be adjusted by the marks up and
down on the panel.

Signal strength: (used only in three-parameter type) Use the dots of different color to show the signal

Fetal heart: Fetal heart rate display (the number of heart beats per minute). When there is no signal

 or the signal is not good, it shows '---' and freezing replaying, the numerical value does not make sense.

Uterine contraction: Uterine contraction pressure value display (relative value 0~100). When



freezing,  the numerical value does not make sense.

Fetal movement: Press the fetal movement mark once, then the number of fetal movement will add

 up. When repeatedly press within 5 seconds, mark only once. When frozen, the

numerical value does not make sense.

NIBP, SpO_2 and MHr: these are the maternal parameters display items. If no value, they will display "---".

3.3 Encoding Board Functions Description

When the curve scans display, rotate the encoding board, the frame of status indicating area or numerical value display area will be blue. Press the encoding board to enter main menu interface or fetus and pregnant women parameter interface. Then rotate the encoding board again and choose corresponding setting. Red item indicates current selected item or setting result.

When frozen, press the volume increase/decrease key to choose a pregnant woman. The monitoring information during different time can be adjusted by the encoding board.

3.4 Fetus and Pregnant Women Parameter Interface Illustration

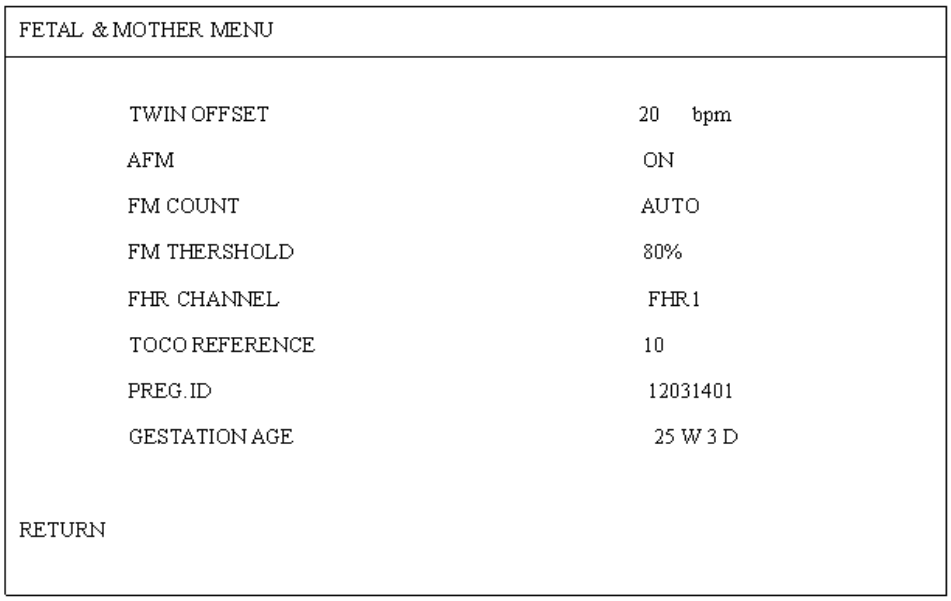


Figure 3-4-1 Fetus and pregnant women parameter interface

Curve separation: When two fetuses are working at the same time, the display position should go down several unit points to prevent the curves of fetal two and fetal one will not be overlapping. The unit points are the numerical value of curve separation. There are two items 20 and 0. 0 represents no separation.

Fetal movement intensity curve: Can choose "on" or "off".

Fetal movement counting mode: Select fetal movement counting mode. There are two options "automatic" and "manual".

Fetal movement threshold: When the fetal movement counting is automatic, there is fetal movement value. And the value can be selected from 10% to 80%.

Fetal pulse channel: Select "fetal heart one" or "fetal heart two" as the fetal pulse channel.

Uterine contraction resetting value: Select uterine contraction resetting value. There are five options including 0, 5, 10, 15 and 20 for choosing.

Pregnant woman serial number: It is current monitoring pregnant woman serial number. If there is no

setting, the system will automatically generate a pregnant woman serial number according to date and time.

Gestational age: The gestational age is how many weeks and how many days. Record this item on printing paper.

Back: Back to scan status.

3.5 Main Menu Interface Illustration

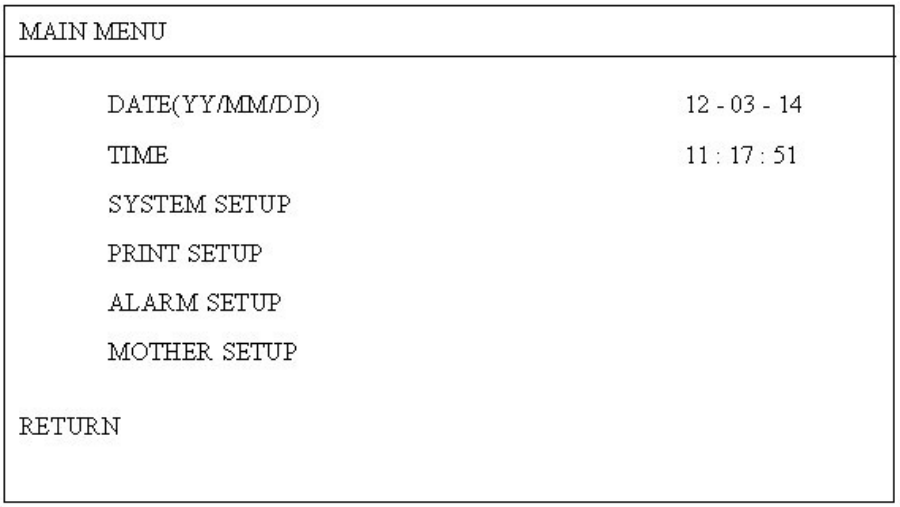


Figure 3-5-1 Main menu interface

Date: It is real-time date of the system.

Time: It is real-time time of the system.

System setting: System setting includes monitoring time, display mode, interface selection, language selection, networking mode, bed number, turning off the instrument and default factory setting.

Printing setting: Printing setting includes setting printing speed, printing denseness, uterine contraction 0 position, uterine contraction 100 position, fetal heart 90 position and fetal heart 210 position.

Alarming setting: Alarming setting includes setting fetal heart upper limit, fetal heart lower limit, fetal heart delay, alarming switch and printing alarming switch.

Color setting: Color setting includes setting the display color of fetal heart one, fetal heart two, uterine contraction and fetal movement.

Maternal parameter: Maternal parameter setting includes setting ECG channel type, ECG leading type, ECG waveform gain, blood pressure measurement interval, blood pressure unit and temperature unit. (Three-parameter type does not have the setting item of “maternal parameter”)

Back: Back to scan status.

3.5.1 System Setting

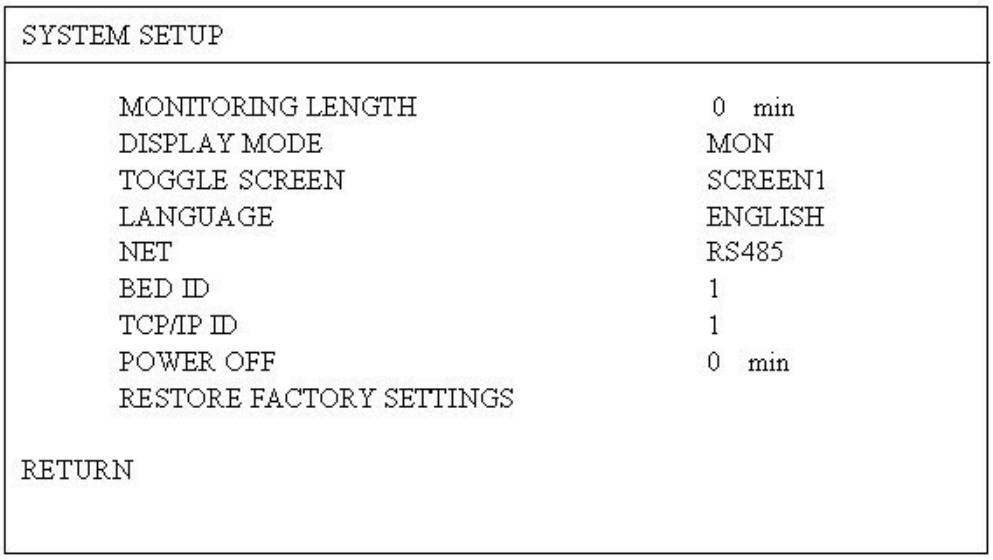


Figure 3-5-2 System parameter interface (Note: Nine-parameter type does not have the setting item of “interface selection”)

Monitoring time: Setting the monitoring time, it will alarm when the time is end. The alarming aims to remind the operator that the scheduled monitoring time is end. And the lower area of the screen will show three red words “Time is up”. 0 indicates the monitoring has not been set and it is under monitoring.

Display mode: There are two statuses monitoring and demonstration to choose.

Interface selection: The instrument provides two interfaces including interface one: waveform and subtitle display and interface two: large subtitle display. (Nine-parameter type does not have this setting item).

Language selection: It is convenient to operate for people from different countries. There are two language Chinese and English people can choose.

Networking mode: Choose the networking mode RS485 or TCP/IP.

Bed number: When it is under network monitoring, the instrument can choose any one bed among 1-32 to monitor.

TCP/IP ID: This setting must be set by the manufacturer or under manufacturer's control .

Turning off the instrument: It is automatic turning off function. When the duration of no signal is beyond the value, the system will turn off automatically. 0 indicates the function is invalid.

Default factory setting: Clear all setting of the instrument to back to the default factory setting.

Back: Back to main menu interface.

3.5.2 Printing Setting

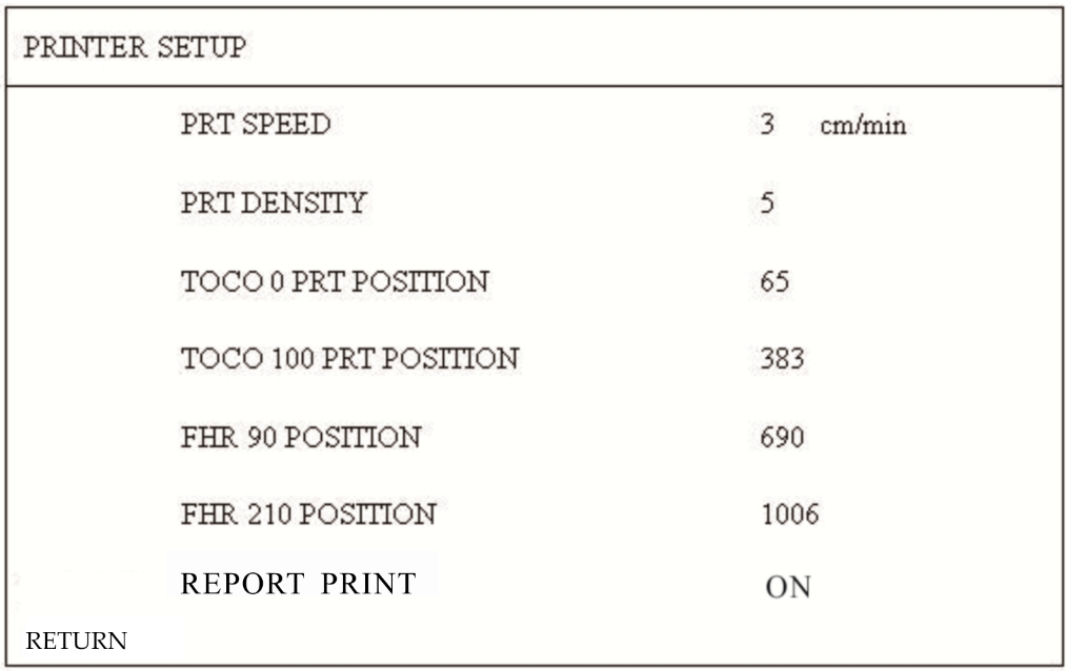


Figure 3-5-3 Printing Interface

Printing speed: Adjust printing speed. There are three options: 1.1cm/min, 2cm/min and 3cm/min. 2.The printing speed would stay at 3cm/min in the frozen state. 3.Paper moving speed is in line with printing speed, with tolerance no more than 2cm every 30 minutes.

Printing denseness: Adjust the denseness of printing curve to adapt to different thermal printing paper.

Uterine contraction 0 position: Ensure the uterine contraction curve can be printed by 110mm printing paper of different specifications.

Uterine contraction 100 position: Ensure the uterine contraction curve can be printed by 110mm printing paper of different specifications.

Fetal heart 90 position: Ensure the fetal heart rate curve can be printed by 110mm printing paper of different specifications.

Fetal heart 210 position: Ensure the fetal heart rate curve can be printed by 110mm printing paper of different specifications.(The system is designed to use printing paper with the width of 152mm of different specifications).

Report score: Open or close report score. Default setting is OFF. While this setting is ON, when you stop printing, the report score will be printed at print paper.

Grading:FHR data won't be graded when detection lasts less than 10 min.FHR data detected between 10 min. and 40 minutes would all be graded. In case detection duration exceeds 40 min., only the FHR data detected in the most recent 40 min. would be graded.

Back: Back to main menu interface.

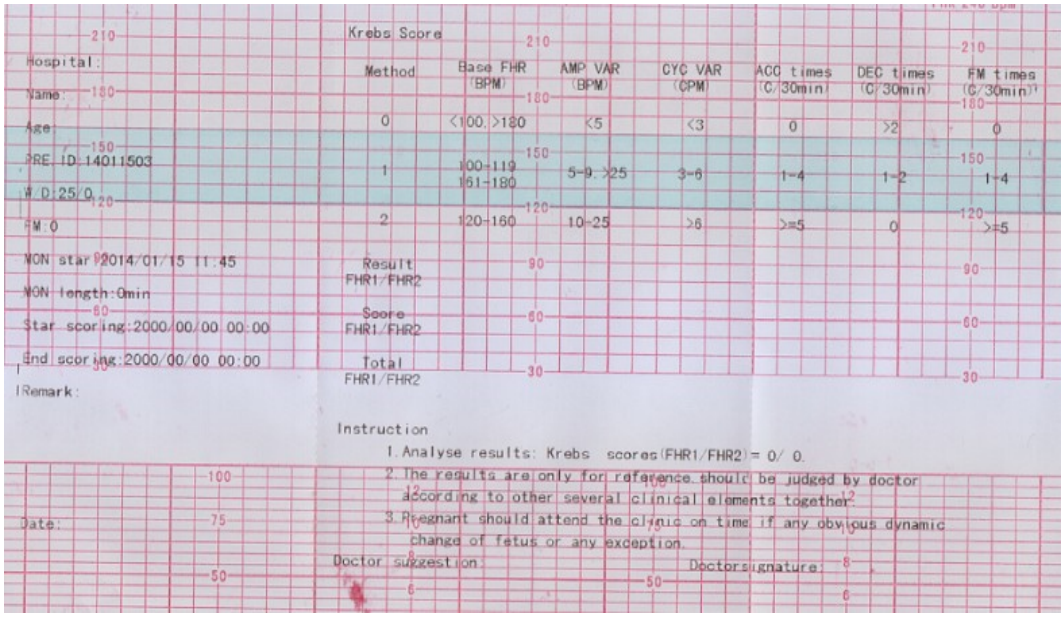


Figure 3-5-4: Patient information and Report Score

3.5.3 Alarming setting

ALARM SETUP		
ALM HI_LIMIT	160	bpm
ALM LO_LIMIT	120	bpm
ALM MUTE	15	sec
ALM ENABLE	OFF	
PRT_ALM ENABLE	OFF	
RETURN		

Figure 3-5-5 Three-parameter Type Alarming Setting Interface

Fetal heart upper limit: There are four options including 160, 170, 180 and 190bpm for fetal heart rate alarming upper limit.

Fetal heart lower limit: There are four options including 90, 100, 110 and 120bpm for fetal heart rate alarming lower limit.

Fetal heart delay: There are two options including 15 and 30 seconds during the interval the fetal heart rate beyond the limit to the alarming occurs for trigger time. When the alarming setting item is “on”, it means the trigger time is up, namely, the alarming occurs.

Alarming switch: Whether the fetal heart rate parameter out of limit alarming is permitted.

Printing alarming switch: Whether alarming is allowed when there is no printing paper.

Back: Back to main menu interface.

ALARM SETUP			
	ALM ENANLE	ALM HI_LIMIT	ALM LO_LIMIT
FHR	OFF	160	120
SPO2	OFF	99	94
MHR	OFF	110	55
SYS	OFF	150	95
DIA	OFF	85	60
MEAN	OFF	100	70
RESP	OFF	28	9
TEMP	OFF	389	361
PRT_ALM ENABLE	OFF		
RETURN			

Figure 3-5-6 Nine-parameter Type Alarming Setting Interface

The nine-parameter type alarming setting interface is a little different with that of three-parameter type. However, the setting method is similar. It is omitted here.

3.5.4 Maternal Parameter

MOTHER SETUP	
LEAD CHOOSE	PATH 1
MAIN LEAD	III
ECG GAIN	4X
NIBP INTERVAR	0 min
NIBP UNIT	mmHg
TEMP UNIT	° C
RETURN	

Figure 3-5-7 Nine-parameter Type Maternal Parameter Setting Interface

ECG channel type: Nine-parameter type provides two ECG channel types including channel one and channel two.

ECG leading type: The instrument has three ECG leading types.

ECG waveform gain: There are five options including 0.25X, 0.5X, 1X, 2X and 4X for ECG waveform gain.

Blood pressure measurement interval: It means the interval of blood pressure inflation.

Blood pressure unit: There are two measurement units including mmHg and Kpa for blood pressure.

Temperature unit: There are two units including °C and °F for temperature.

Back: Back to main menu interface.

3. 6 Front Panel Keys Illustration

The keys on lower part of display from left to right in sequence are as following:

3.6.1 Power switch key.

1) Turn on: Slightly press for one second, when the buzzer's "beep" sound occurs, then the instrument is turn on.

2) Turn off: Long press for 2 seconds to turn off the instrument.

3) Update pregnant women records: When the instrument is working, slightly press once, then the pregnant women serial number will increase 1 and starts new monitoring.

3.6.2 Volume increase key.

1) Increase volume: Slightly press once, the fetal heart volume will increase 1; until to the loudest volume "7" (see the number on the back of the volume icon), the volume will not increase.

2) Switch interface: Long press for 2 seconds, the scan interface will switch into large letters interface. Long press for 2 seconds again will back to scan interface (only available in three-parameter type).

3) Under frozen status, backward to look at the monitoring records until to see the earliest record it can store. Each press, the pregnant woman number and monitoring information will be different. The date and time on LCD are the original time of the pregnant woman.

3.6.3 Volume decrease key.

1) Increase volume: Slightly press once, the fetal heart volume will decrease 1; until to the mute volume "0" (see the number on the back of the volume icon), the volume will not decrease.

2) Under frozen status, forward to look at the monitoring records until to see the latest record. Each press, the pregnant woman number and monitoring information will be different. The date and time on LCD are the original time of the pregnant woman.

3.6.4 Pressure resetting key.

1) When real-time scan, press the key once. The pressure display value will be reset as the setting value and there will be the up part of the pressure curve.

2) In the settings interface, press the key will return to the real time scanning display interface.

3.6.5 Freezing key. Press the key once, the system will enter into frozen status. The display status will show "be frozen" . Press once again, the frozen status will be cleared. And the real-time scan display status will recover.

Under frozen status, cannot enter into the system menu directly. Only when the frozen status is canceled, the system menu can be entered into.

3.6.6 Printer selection key. When scan displays, press the key once and enter into real-time printing status. Under frozen status, the current displayed pregnant woman records can be printed. Press the key once again, the printing is canceled. When the printer is working, the lower part of the screen dynamically display the icon “in printing” .

3.6.7 Blood pressure measurement beginning key: Press the key once, the measurement starts. Press the key once again, the measurement stops.

3.6.8 Awakening key: Press the key once, the awakening starts once.

3.6.9 Mark key

1) Mark: Press the key once, the icon will be recorded once. It is used for helping doctors to record abnormal events during monitoring.

2) Issuing central monitoring automatic operation signal: Press the key for 2 seconds, the lower part of the interface will occur the flashing icon . It indicates the central monitoring system monitoring signal has been issued. If the connection of the equipment is normal and the central monitoring software is working, then the corresponding sub-interface of the central monitoring system will automatically enter into monitoring status.

3.6.10 Encoding board.

3.7 Side Port Illustration

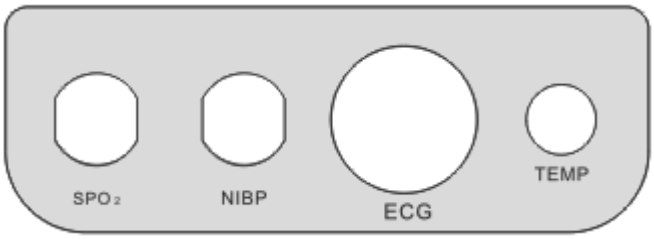


Figure 3-7-1 Left Side Panel

SpO_2: Pregnant women oxygen saturation probe input

NIBP: Pregnant women non-invasive blood pressure cuff access

ECG: ECG probe plug

TEMP: Pregnant women body temperature probe input

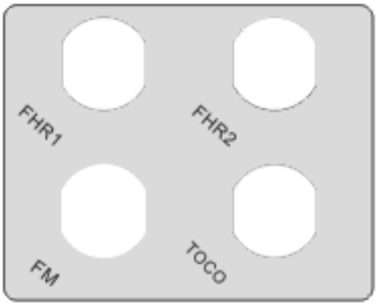


Figure 3-7-2 Right Side Panel

FHR1: Ultrasonic fetal heart probe input

FHR2: When monitor double fetuses, the second fetal heart probe input

FM: Manual fetal movement input

TOCO: uterine contraction input

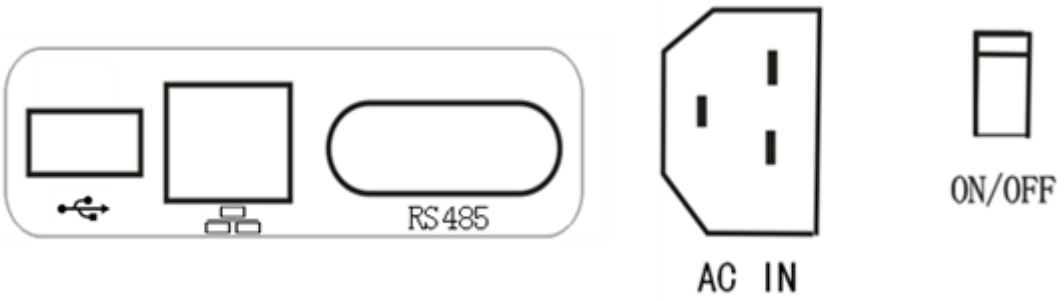


Figure 3-7-3 Back Panel

USB: Preserve to expand.

RJ45: TCP/IP network port

RS485: Central monitoring network port

AC IN: AC power switch socket

ON/OFF: Power switch

Note: RJ45 and RS485 cannot used at the same time. Set network mode in system setting item.

4. Monitor Setting

In this part, you will be told how to

- Disassemble and reassemble
- Connect power
- Place printing paper
- Set instrument parameter

4.1 Disassembly and Reassembly

4.1.1 Carefully take out the motherboard and accessories from the package

4.1.2 Check whether there is loss or damage of the things in the package according to following table

- One ultrasonic fetal monitor's motherboard
- One ultrasonic probe
- One uterine contraction pressure probe
- One fetal movement pen
- Two probe bandages
- One power cable
- Two books of recording paper
- One 250ml coupling agent
- Usual manual

- Certificate

4.2 Connect Power

The ultrasonic fetal monitor uses power supply : a.c.100V-240V, 50/60Hz or 16.8v Li-ION battery.

4.2.1 Plug the power output cable into the back power socket of the instrument.

4.2.2 Plug the other end of power cable into power socket.

4.2.3 Slightly press the power key for one second, when the buzzer's "beep" sound occurs, the instrument will normally display status after several seconds.

4.3 Place Printing Paper

The placement of the printing paper is very convenient. There are only the following two procedures.

4.3.1 Open printer panel, unfold the top-page printing paper from outside (close to instrument) to inside. You can see thermal grid surface, on the surface, the fetal heart rate grid is on the left and uterine contraction grid is on the right (if the top-page printing paper is unfolded from inside to outside, you can also see thermal grid surface, however, the fetal heart rate grid is on the right and uterine contraction grid is on the left. It is wrong to do like this.) and then place the pace into paper box.

4.3.2 Pull the paper to ensure the two sides of the paper are basically parallel with the brims of the printing door. Then slightly close the printing door.

The system is designed to use printing paper with the width of 152mm of different specifications.

4.4 Set Instrument Parameter

Setting operation:

When curve scan displays, rotate the encoding board, the frame of status indicating area or numerical value display area will be blue. Press the encoding board to enter main menu interface or fetus and pregnant women parameter interface. Then rotate the encoding board again and choose corresponding setting. Red item indicates current selected item or setting result. Press the encoding board again to enter the adjusting status. Rotate right or left of the encoding to set parameter. After setting, rotate to back item. Press encoding board and exit setting status to back to items selection status.

Back operation

In items selection status, choose back item and press encoding board. Then it backs to scan display status or main menu interface.

For instance:

1. Setting time and date

In main menu interface, rotate encoding board to choose the date or time you want to change. Press encoding board once again to enter into adjusting status. Rotate encoding board to adjust corresponding size. After setting, enter into selection status, rotate encoding board. Choose back item and press encoding board again to back.

2. Setting monitoring time

In main menu interface, rotate encoding board to choose system setting item. Press encoding board

once again to enter into system setting interface. Rotate encoding board to choose monitoring time item. Press encoding board once again to enter into setting status. Rotate encoding board to set monitoring time. 0 indicates no setting. After setting, enter into selection status, rotate encoding board. Choose back item and press encoding board again to back.
Under menu status, the system can still real-time calculate fetal heart rate and uterine contraction pressure. If it is in real-time printing status, the real-time printing is still available.

5. Operation Guide

5.1 Preparation

Plug the ultrasonic probe, uterine contraction probe, fetal movement marker, oxygen probe and blood pressure cuff. Press the power key for several seconds, after turning on, the display is in scan display status.

5.2Fetal Heart Rate (FHR) Monitoring

5.2.1 Pregnant women should act a posture easily monitored, usually the semi-supine posture is ok.

5.2.2 Go through the strap from the waist. (the fetal heart rate and uterine contraction monitoring need two straps)

5.2.3 Coat proper amount of coupling agent on the surface of ultrasonic probe. Place the probe on the pregnant woman's abdomen. The coupling agent should make the probe and abdomen of the pregnant woman contact well. When the probe is on the back of fetal left shoulder, the ultrasonic signal is best. After placing the probe well then slowly adjust the position of probe to find the best position. At that time, the fetal heartbeat heard from the speaker is loudest and the fetal heart rate will be shown on the screen continuously.
5.2.4 After finding the best position, the probe should be fixed and the bandage is also should be fixed well. If the probe is deviated, it is need to readjust the position of probe to receive best signal.
5.2.5 During the process of monitoring, the volume of the speaker should not be turned off. When the fetal heart rate signal is very weak, the volume of fetal heart can hardly heard in the speaker. At that time, it should be paid special attention that the numerical value of fetal heart showing on the screen maybe has no meaning.
5.2.6 After fixing the ultrasonic probe well, press volume increase key and volume decrease key to adjust to proper volume.

5.3Uterine Contraction (TOCO) Monitoring

5.3.1 Go through the back of pressure probe by using bandage and place the probe on the bottom of the uterine of pregnant woman. Fix the bandage well and adjust the position well. The tightness of the bandage should be proper.

5.3.2 Press uterine contraction resetting key (0), then the position of uterine contraction on the screen will show the uterine contraction pressure resetting value.

6. Maintenance of Ultrasonic Fetal Monitor

6.1 Moving

Through the design of the ultrasonic fetal monitor is firm and fit for the clinical application, during operating, you should be careful and pay attention to maintenance. Especially do not drop or collide the ceramic chip of the ultrasonic probe.

6.2 Maintenance

Except for cleaning, the ultrasonic fetal monitor does not need any additional maintenance. Keep the cleanness of the surface. Make sure there is no dust on the surface. Use a dry and soft cloth to clean the surface of the instrument (includes LCD). If necessary, only the soap or a soft cloth soaked in water is allowed to clean the shell of the instrument. Wipe the redundant coupling agent on the probe by a soft cloth. Only use the soap and water to clean the probe.

Be careful: Please do not use strong solvent such as acetone.

Be careful: Do not use abrasive material (such as steel wool or silver polishing agent)

Be careful: Do not let any liquid flow into the shell and let any part of the instrument in the liquid.

Be careful: Do not pour the liquid into the instrument when cleaning.

Be careful: Do not leave any cleaning fluid on the surface of the instrument.

Be careful: Wipe the surface of the probe by 70% alcohol or isopropyl alcohol and use a dry and clean cloth to clean the probe.

6.3 Disinfection

Clean the surface of the equipments and probe according to the methods mentioned above and then wipe the surface of the probe by 70% alcohol or isopropyl alcohol. Use a dry and soft cloth to wipe the liquid material remained on the probe.

Be careful：**：** Please do not disinfect the equipments or probe by low-temperature steam or other method.

6.4 Coupling Agent

The attached water-based coupling agent is recommended. **Absolutely prohibit the use of oil-based coupling agent.** If the probe is broken caused by the use of oil-based coupling agent. The maintenance of the instrument will be terminated.

6.5 Clean Printing Head

The normal working time of the thermal printing head is over 20 years. This is only the promise in the electrical aspect. The printing effect is greatly affected by the printing paper and the cleanness of the operating environment. When printing is not clear or there can't print in partial area, the first thing you

should do is to clean the printing head. The following are the methods and procedures:

6.5.1 Cut off the power of the monitor.

6.5.2 Open the panel of the printer.

6.5.3 Put the cotton swab dripped with ethanol containing no water into thermal components part of the printing head (the tiny black partial visible thermal area of the printing head) and slightly wipe left and right especially the dim printing area. After wiping, start the instrument and ensure it is ok.

6.5.4 If the faults are still there, conduct the third procedure repeatedly until the effect is good.

7. Troubleshooting

The prenatal boasts good quality and high reliability. If there are something wrong, please find and solve the problem according the following table.

Faults	**Probable causes**	**Approaches**
No displaying after start	Power cord is not plugged well Power failure or poor power plug or socket. The power switch is not open	Inspect the power and power cord
When start the instrument, the LCD interface is normal but can't move the cursor.	Poor or broken connect between fetal monitoring module and motherboard	Connect again or replace the module
Fetal heart rate is abnormal	Poor connect of probe and connector The probe position is wrong and the probe does not find fetal heart. No coupling agent or the coupling agent is too little. Fetus/Pregnant women's movement The probe is broken.	Connect again Readjust the probe position Add coupling agent When there is signal again, readjust the probe position. Replace the probe.
Uterine contraction is abnormal	Poor connect of probe and instrument The probe position is wrong. The pressure has not been reset. Pregnant women have no uterine contraction	Connect again Readjust the probe position Reset the pressure Wait for uterine contraction
When press the pressure probe, there is no change or little change of the uterine contraction numerical value.	Drift of pressure probe internal circuit or the pressure probe is broken	Adjust the potentiometer in the side holes of pressure probe by straight screwdriver fixing watches to make the probe can read normal numerical value when pressing. Replace the pressure probe.
Press fetal movement pen, there is no display and printing icon.	Poor contact of scaler button switch	Inspected and determined by universal meter
The speaker is mute.	The volume is too low.	Turn up the volume.
The paper is running but no printing curve. Fetal heart curve is printed in uterine contraction area and uterine contraction	The placement of thermal printing paper is adverse. The left and right sides of thermal surface are adverse.	Inspect whether thermal surface is upward and place paper again Take out the thermal paper

curve is printed in fetal heart area.		and place again.
The printing is not clear or there can't print in partial area.	The printing denseness is set too light Poor printing paper has been used or the printing paper is subject to deterioration The printing thermal head is dirty.	Adjust printing denseness Replace printing paper Clean printing head in sequence.
The paper feed is deviated and there is error of the printing curve position.	The paper is not placed well The printing paper of different brands has been used	Adjust the direction and position of printing paper In the printing control menu, adjust the printing position according to indication

8. Warranty and Maintenance

Our company treats every custom as equal one. And all of our products enjoy one-year free maintenance and we offer a lifelong maintenance to our products.

As for its after-sale service, maintenance or other relevant problems or other problems about other products of our company, please contact us.

In case that you want to retreat the product, please disinfect it according local disinfection procedures and provide corresponding documents describing the current state of this product. Please attach the document to the internal package of the product.

Notice: Our company is not responsible for the errors contained within the manual and the occasional or indirect damages caused by the provision, actual performance or the using of the manual.

The contents contained in the manual can be changed without notice.

Warning: The intended use of the instrument is for clinical application not for treatment. If the results of fetal heart rate are not credible, please adopting other methods immediately such as using the stethoscope to verify the results.

Notes of this manual:

Warning: You should get to know information about how to avoid the harms the patients and medical staff may suffer.

Be careful: You should get to know information about how to prevent the harms the equipment may suffer.

Note: The important information you should get to know.

IPX1: Anti-drop closed equipment.

: See attached documents.

Product is manufactured by:

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Tel:+86-755-26696279 Fax:+86-755-26852025
Web site: http://www.jumper-medical.com

Authorized European Representative:

Wellkang Ltd
Suite B, 29 Harley Street, London W1G 9QR,UK

Customer Service:
To receive customer support:
+ 86 755 26692303

+ 86 755 26852025 (Fax)

Email:info@jumper-medical.com

9. Technical Parameter

Name of product: Fetal /Maternal monitor

Fetal Heart Rate:

Transducer: Multi-crystals, pulsed doppler , high sensitively

Strength: <5mW/cm^2

Working frequency: 1.0MHz

Signal processing: Special DSP system and modern recognization.

Measurement range: 60bpm ~210bpm

Alarm Range:

High limit: 160bpm,170bpm,180bpm,190bpm

Low limit: 90bpm,100bpm,110bpm,120bpm

Maximum audio output power : 1.5 Watt

Toco:

Measurement range: 0 units ~100 units

Maternal SpO_2 measure:

Measure scope : 70%～99%。

Measure accuracy: ±3%

Pregnant HR Measure:

Measure scope: 30bpm～240bpm

Measure accuracy: ±2bpm

NIBP measure:

a) NIBP-SYS 6.7KPa～32.0KPa (50mmHg～240mmHg)

b) NIBP-DIA 3.4KPa～26.6KPa (25mmHg～200mmHg)

c) NIBP-MEAN 2.0KPa～24.0KPa (15mmHg～180mmHg)

NIBP Accuracy: ±1.1KPa（±8mmHg）or ±5% of the results, take the bigger one.

Maximum Mean error ±5mmHg

Maximum Standard deviation 8mmHg

Pulse Rate Accuracy: Maximum Mean error ±2bpm

Measure accuracy: ±2bpm or ±5％ of the results, take the bigger one.

Measure mode: Manual

Display:

The LCD displays FHR, TOCO, FM , maternal parameters , time, date, volume and so on, It can store and play back the data.

Power: a.c.100V - 240V, 50/60Hz or 16.8v Li - ION battery

Power Consumption: < 20W

Dimension: 355mm (length) ×340mm (width) ×106mm (height)

Net weight: Three-parameter type: 4Kg; nine-parameter type: 4.3Kg. (Both does not contain accessories

such as probe)

Environment

Working environment: Temperature: +5℃ ～ +40℃

Humidity: < 85％

Atmospheric pressure: 86KPa ～ 106KPa

Transport and storage temperature: Temperature: -10℃ ～ +55℃

Humidity: < 93％

Atmospheric pressure: 86KPa ～ 106KPa

Transducer Acoustic Output:

Under the requirements laid down in IEC 1157, 1992, the peak negative acoustic pressure does not exceed 1Mpa. The output beam intensity does not exceed 20mW/cm^2 and the spatial-peak temporal-average intensity does not exceed 100mW/cm^2

GEL:

Viscous aqueous non-sensitizing , hypo-allergenic and non-irritating to skin. Indefinite shelf life, Bacteriostat (not sterile)..

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