Fetal/Maternal Monitor

AFM-800P

User's Manual

ARI Medical Technology Co., Ltd.

About User Manual

This is only available for this fetal monitor. We will not undertake any results and blames caused by using for other purposes

No part can be photocopied, copied, and translated it into other languages without the prior written consent.

The data of this manual can be changed without notice.

Due to technical update or special requirements of users, without affecting the performance index of monitor, some parts may be different with the standard configuration as this manual said, please note.

Note: you should know this important information.

Warn: User should know that how to avoid damage on patient and clinicians.

Caution: User should know that how to avoid damage on devices.

Note: User should know some important information.

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□ Introduction

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1.1 Introduction

Welcome to use the Fetal/ Maternal Monitor (referred to as the Monitor)!

This Manual will describe the performance indicators, use and maintenance method of the Fetal/ Maternal Monitor in details, and is intended for the personnel that are familiar with the parameters and have experience in the use of the Monitor.

Before using this Monitor, please read the User's Manual carefully in order to use the monitor properly, make the device reach its performance indicators and use under the required safety standards.

This User's Manual is provided together with the Monitor, and should be placed near the Monitor for easy reference.

1.2 Safety Guide

BF & CF hybrid-typed mobile device.

 indicates BF application;  indicates anti-vibration BF application;  indicates CF anti-vibration application.

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

The waterproof rating of the ultrasonic probe is IPX1.

Before use it, please check its lifetime. Its lifetime is 5 years and manufacturing date is labeled at the bottom side of device.

Instructions for Operation Safety

To avoid potential injury, be sure to abide by the following safety instructions while operating the Monitor.

Warning: Do not rely solely on the alarm system of the Monitor when monitoring the patient. If the alarm limit is set too low or alarm sound is turned off, it may hurt the patient. The most reliable method is that the health care professionals closely monitor and properly use the Monitor. The alarm functions of the Monitor must be periodically verified. When several devices are simultaneously used on the same patient, the leakage current may be superposed. Before interconnection, it is recommended that ask qualified professional to test the leakage current to ensure that the leakage current is in the safe range, that is, won't cause any harm to the patient, the operator and the surrounding environment. If you still have questions, please consult the manufacturer for the correct use. Before using this Monitor, the operator must verify that the Monitor is in proper working condition and operating environment. Regularly check if the reusable accessories and the sensors are damaged, if the cables are connected reliably, replace if necessary, and dispose the damaged accessories properly as medical waste.

Warning: Do not use the instrument in the presence of flammable gases such as anesthetic agents, or it may cause an explosion.

Warning: Don't throw the battery into fire, or it may cause an explosion.

Warning: Don't touch the signal input or signal output connectors and patient at the same time

Warning: To keep mother safe, please do not use other electronic device which connect with mother, such as Pace Maker or other electronic stimulator.

Warning: This device is against Defibrillator. If Defibrillation is applied to mother, please take special measurement.

Caution: This instrument must be maintained by qualified engineers.

Caution: This instrument is designed to work continuously, water drop proof type, pay attention to avoid to be splashed.

Caution: Keep this instrument clean and avoid vibrating.

Caution: No high temperature disinfection, electron beam or γ-ray sterilization.

Caution: Electromagnetic interference – ensure the operating environment of the instrument away from strong interference, such as wireless transmitters, mobile phones or other interference.

Caution: Before using the instrument, please check if there is any damage of equipment that may affect the patient's safe or the instrument performance. The recommended check period is every one month or shorter. If an obvious damage is found, it should be solved before use.

Caution: The following safety check is done by the authorized person, normally one time per two years or according to test regulation by the public organization.

- ✧ Check whether there are damages in the mechanical and functions.
- ✧ Check whether the relative safety label is easy to identify.
- ✧ Check whether the function is the same as described in the user manual.

Caution: After the effective life of this instrument, Please send it back to the manufacturer according to local rules for recycling.

Caution: Disposal the battery properly according to local rules after the capability of battery run out.

Caution: If this instrument is not in use for a long period of time, remove the battery in time.

Caution: The battery should be stored in a cool and dry environment.

Caution: When store battery, please don't mix it with metal objects to avoid short-circuit accident.

Caution: We recommend that exposure to ultrasound should be kept As Low As Reasonably Achievable. This is considered to be good practice and should be observed at all times.

Caution: Don't use this instrument immediately when it is transferred from a cold environment to a warm and moisture place.

Caution: To ensure electric installation safety, the environment shall be reasonably dust free, without corrosive or combustible gas, or extreme temperature or humidity.

Caution: Please stop operating if this instrument is splashed or has water drops.

Caution: Although the instrument is robust and designed to withstand the clinical use, the unit does contain delicate components and should be treated with care. This applies especially to the transducers which should not be dropped or knocked.

Caution: The use of water based gel supplied by certificated suppliers is strongly recommended. Oil based gels can damage the transducer and must not be used. The use of oil based gels will invalidate your warranty.

Caution: Excess gel should always be wiped off after use. The transducer faceplate, transducer body and main unit can be cleaned with a damp cloth impregnated with a mild disinfectant or detergent.

Caution: A soft cloth dampened with sodium hypochlorite 1000ppm may be used for cleaning and disinfection.

Caution: The main unit, transducers and other accessories can’t be disinfected by steam.

Caution: TOCO transducer is non-waterproof type, don’t use Gel and avoid any liquids into it.

Caution: The power wire should be inserted into the socket with three wires, the ground wire mustn’t be removed. Don’t use the socket with bad connection.

Caution: After use, do not wire the transducer cable together with the transducers to avoid damage.

Caution: Do not turn off the volume during monitoring, it is very important to monitor fetal heart sound.

Caution: The accuracy of FHR is decided by machine itself and cannot be adjusted. If you are suspicious of accuracy of the result, you can verify it through other devices like a stethoscope, or you can contact local distributors or manufacturers for help.

1.3 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.

1.4 Intended Use

The Fetus Monitor applies to external monitoring.

- Antenatal monitoring in the hospitals
- Antenatal monitoring within the family or community
- Examination before hospitalization

2. Monitor Installation

□ Unpacking and checking
□ Power supply
□ Starting up
□ Connecting the probe
□ Checking the printer
[Note]
To ensure normal working of the Monitor, please read this chapter and 1.2 Safety Guide before using, and install as required.

2.1 Unpacking and Checking

Unpack and take out the Monitor and accessories carefully, and keep the packing materials for future transport or storage. Please check the Monitor, accessories and provided documents according to the Packing List.

- Master unit
- Power cord
- Three-in-one probe (ultrasonic probe U/S, uterine contraction probe TOCO and an event marker for pregnant woman)
- Second ultrasonic probe (optional)
- Oximeter probe (SpO_2) for pregnant women, air cell, ECG lead and body temperature probe (optional) for noninvasive blood pressure measurement of pregnant women
- Printing paper
- Coupling agent (optional)
- Certificate
- Warranty Card
- User's Manual
- Packing List

※ Check for any mechanical damage.

※ Check all exposed wires and connect the accessories.

For installation, keep at least 2 inches (5 cm) space around the Monitor to ensure air circulation. The environment for the Monitor should avoid vibration, dust, corrosive or explosive gases, extreme temperature and moisture. If you have any questions, please contact our Sales Department or the dealer.

2.2 Power Supply

2.2.1 AC Power

To connect the AC power cord:

※Make sure the AC power supply meets the following specifications: AC 100~240V, 50/60Hz

※ Use the provided power cord. Plug the power cord into the power connector of the Monitor, and plug the

other end into a grounded three-wire power outlet.

[Note]

Connect the power cord to the dedicated outlet in the hospital.

※ Turn the power switch to "-".

2.2.2 Battery Powered

Built-in battery is powered by 4 18650 / 2200mAh / 14.8V lithium battery components.

When the AC power is cut off, the Monitor will be powered by the built-in batteries. Before using, please charge the batteries. When the Monitor is connected to AC power, the charging starts automatically, and doesn't require additional charger. To ensure the batteries are fully charged, we recommend that the users connect this Monitor to an AC power source even when the Monitor isn't used.

The new fully charged batteries can maintain monitor work, while NIBP measurements and using the printer will accelerate the power dissipation. When the batteries are running low, the battery symbol in the lower left corner of the screen will flash, prompting the user to charge as soon as possible.

Warning:

Even if the instrument is not working, the batteries will gradually discharge. If the Monitor will be stored for long-term, please keep the Monitor fully charged. Check the battery status at least once a month and recharge.

2.3 Starting Up

Press and hold the Power button for about 2 seconds to enter the starting up state, and the alarm lamp is lit in green. After three seconds, the system self-tests successfully and enters the main screen, and then the user can start operation.

[Note]

If fatal error is found during self-test, the system will alarm.

[Note]

Check all available monitoring functions to ensure that the Monitor functions properly.

Warning:

If the monitor function has any signs of damage or an error message, do not use this Monitor, and contact the biomedical engineer of the hospital or the maintenance engineer of the company.

2.4 Connecting the Probe

Connect the desired probe to the Monitor and the monitoring position of the patient.

[Note]

For the correct connection of probes and related requirements, see Chapter 5-11.

2.5 Checking the Printer

Check if the paper outlet in the front side of the Monitor has printer paper. If not, see Chapter 13 Printing.

2.6 Turning off the Monitor

2.6.1 Automatic Power off

Select "Turn off the Monitor" in the System Settings interface to set the time of automatic power off: 0 indicates that the function is invalid. Other values indicate that if the time without signal exceeds the values,

the system will automatically shut down. The time of automatic power off can be set up to 240min.

When the set time of automatic power off is up, the interface prompts: turn off automatically.

2.6.2 Manual Power off

Press and hold the Power button for 2 seconds, the screen displays “Power off”, and then turns off the Monitor.

3. Monitor Overview

□ Monitor Overview

□ Front View

□ Operation and Functions of Keys

□ External Interfaces

3.1 Monitor Overview

Environmental Requirements

Temperature

Operating: +5℃ ~ +40℃

Transport and storage: -10℃ ~ +55℃

Humidity

Operating: 30%~75%

Atmospheric pressure: 86kPa ~ 106kPa

Transport and storage: < 93%

Atmospheric pressure: 86kPa ~ 106kPa

Power Requirements

input:100-240V~,50/60Hz 1.0A

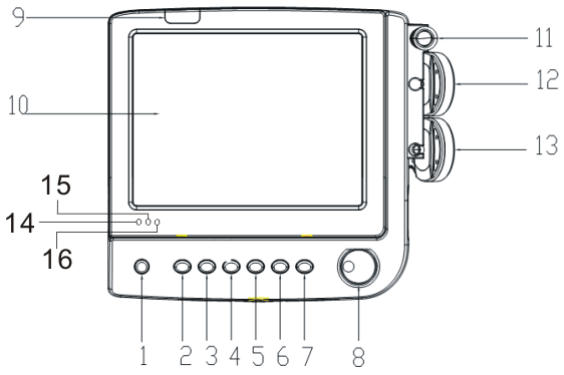
Battery: 14.8V lithium battery

Do not use beyond the specified environmental requirements and power requirements, otherwise the Monitor may not work properly.

This Monitor applies to the bedside monitoring of fetus, pregnant women and patients on ECG, noninvasive blood pressure (NIBP), oxygen saturation (SPO2), respiration (RESP), body temperature (TEMP) and other major life parameters. It integrates the parameter measurement, display and record output, compact, lightweight and easy to use. Its high-resolution display interface can clearly show the waveforms and all monitoring parameters.

3.2 Front View

The front panel of the Monitor is shown in Fig. 3-1. It has a friendly interface, and all the operations are available through the buttons and encoder disk on the front panel (①~⑧ shown in Fig. 3-1). For more information, see 3.3 Operation and Functions of Keys.



Picture 3-1 Front view

①Power ②NIBP start/stop ③Freeze ④Volume-Down ⑤Volume-Up
⑥Printing ⑦TOCO Reset ⑧Encoder ⑨Indicator Lamp ⑩TFT LCD
⑪⑫⑬: Transducer Holder

⑭AC indicator lamp ⑮Charging indicator lamp

⑯indicator lamp when support by battery

3.3 Operation and Functions of Keys

1. Power button

Press and hold this button for about 2 seconds to turn on the Monitor, and press and hold it again for 2 seconds to turn off the Monitor.

In monitoring state, press this button once to refresh the display interface and generate a number for the pregnant women, and the fetal movement counting is reset.

2. Blood pressure measuring button

Press this button to activate the blood pressure measurement, and press this key blood while measuring the blood pressure to stop the measurement.

3. Freeze button

Press this button once to freeze the system, and the main interface displays “Frozen”; press it again to unfreeze and restore real-time scanning state.

4. VOL- button

In monitoring state, press this button in the main interface to turn down the speaker volume.

In freezing state, press this button to play the stored records reversely.

5. VOL+ button

In monitoring state, press this button in the main interface to turn up the speaker volume.

In freezing state, press this button to play the stored records forwardly.

6. Print button

After installing the printing paper, press this button to enter the real-time printing status, and press it again to stop printing.

In freezing state, you can print the currently displayed monitoring records and press it again to stop printing.

7. UC Reset button

Press this button once and the displayed pressure is reset to the set value.

During menu setting, press this button again to return to the monitoring screen.

8. Encoder disk

In monitoring state, rotate the encoder disk, press the encoder disk to confirm when the selected area displays a blue frame, and then enter the appropriate settings.

In freezing state, rotate the encoder disk to turn pages of monitoring records.

9. Indicator

Under normal conditions, the indicator is green; in monitoring state, it flashes with the fetal heart rate; when the heart rate is within the safe range, the indicator is green; when the heart rate exceeds the limit and alarms, the indicator color depends on the alarm level.

10. Display

A 10.2-inch TFT display shows waveforms, menus, alarms and physiological measurement parameters.

11. Probe holder: used to hold the probe.
12. AC Indicator

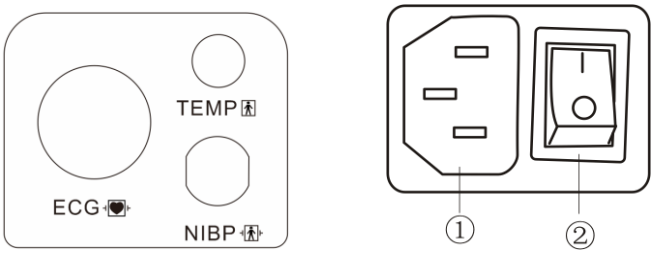
    When this indicator is green, the Monitor is connected to the.
13. Charging Indicator

    When external power supply is connected, this indicator is orange, indicating that the batteries are being charged; after charging is completed, the indicator goes out.
14. Battery status indicator

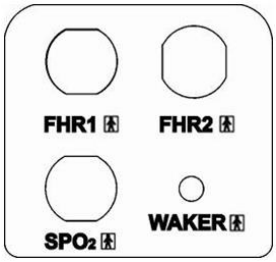
    When this indicator is green, the Monitor is powered by internal batteries.

3.4 External Interface

In order to facilitate the operation, different interfaces are located in different parts of the Monitor.



Picture 3-2. Left panel



Picture 3-3. Right panel

Picture 3-4 Back panel

Port Introduction

ECG: ECG probe port

TEMP: maternal temperature probe port

NIBP: maternal NIBP cuff input port，symbol indicates signal input is insulation and anti-vibration

①：AC adapter input socket

②：Power switch. Turn on or off the power. I：turn on; O：turn off.

FHR1: port of 3 in 1 transducer

FHR2: the second ultrasound transducer port when doing twin monitoring.

SpO2: port of maternal SpO2 transducer.

WAKER: Fetal acoustic stimulator (FAS) port (option)

NET: network port of central nurse station

USB: retained.

RS232: retained.

4. Monitor Display Interface

□ Overview

□ Description of Main Interface

□ Description of Menu Settings Interface

4.1 Overview

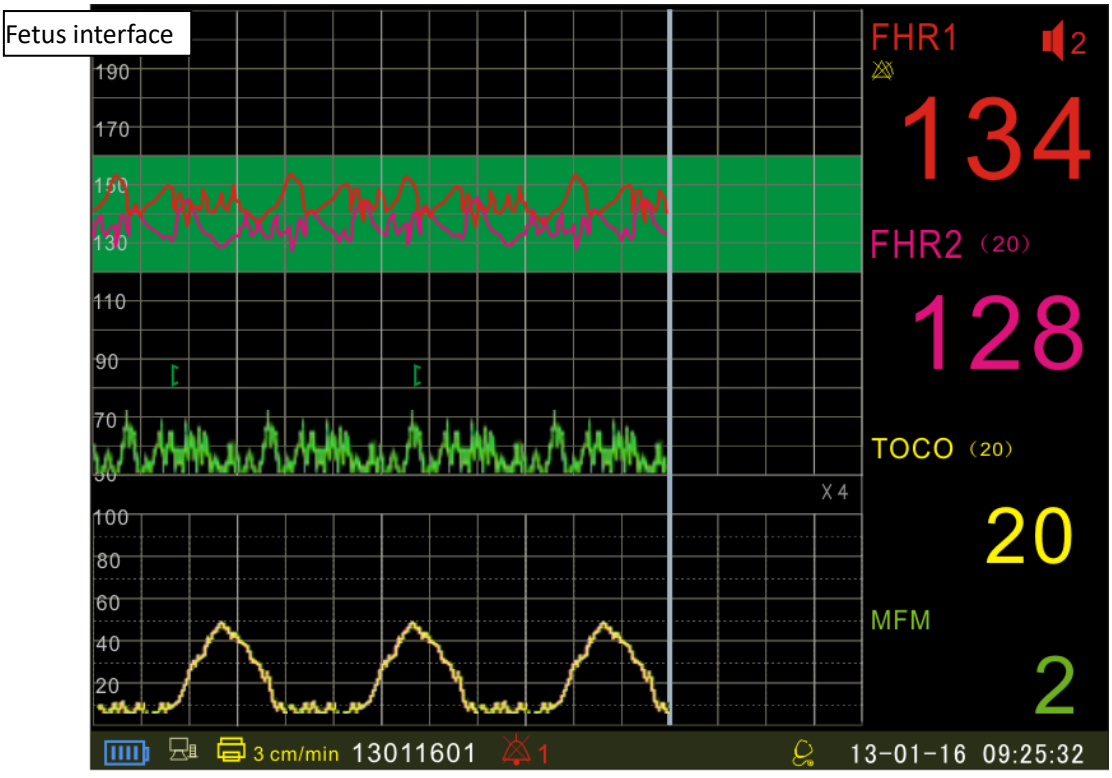
The Fetal/ Maternal Monitor has models: three parameters and nine parameters, the monitoring functions of which are:

Function / Model	Three parameters	Nine parameters
Interface	Fetus interface	Fetus interface, six parameters interface, maternal-fetal interface
Fetal heart rate (FHR)	Waveform/numeric value	Numeric value
Uterine contraction pressure (TOCO)	Waveform/numeric value	Numeric value
Fetal movement (AFM/MFM)	Waveform (optional) /numeric value	Numeric value
Pulse rate (MHR)	None	Numeric value
Blood oxygen (SPO2)	None	Waveform/numeric value
Blood pressure (NIBP)	None	Numeric value
Electrocardiogram (ECG)	None	Waveform
Respiration (RESP)	None	Waveform/numeric value
Body temperature (TEMP)	None	Numeric value

4.2 Description of Main Interface

The display of the Fetal/ Maternal Monitor is a 12.1-inch TFT screen, which can display the information about pregnant women, parameter waveform and values, monitoring status, alarm information, and other tips.

The Monitor has fetus interface and maternal-fetal interface, as shown in Figure 4-1:



Maternal-fetal interface

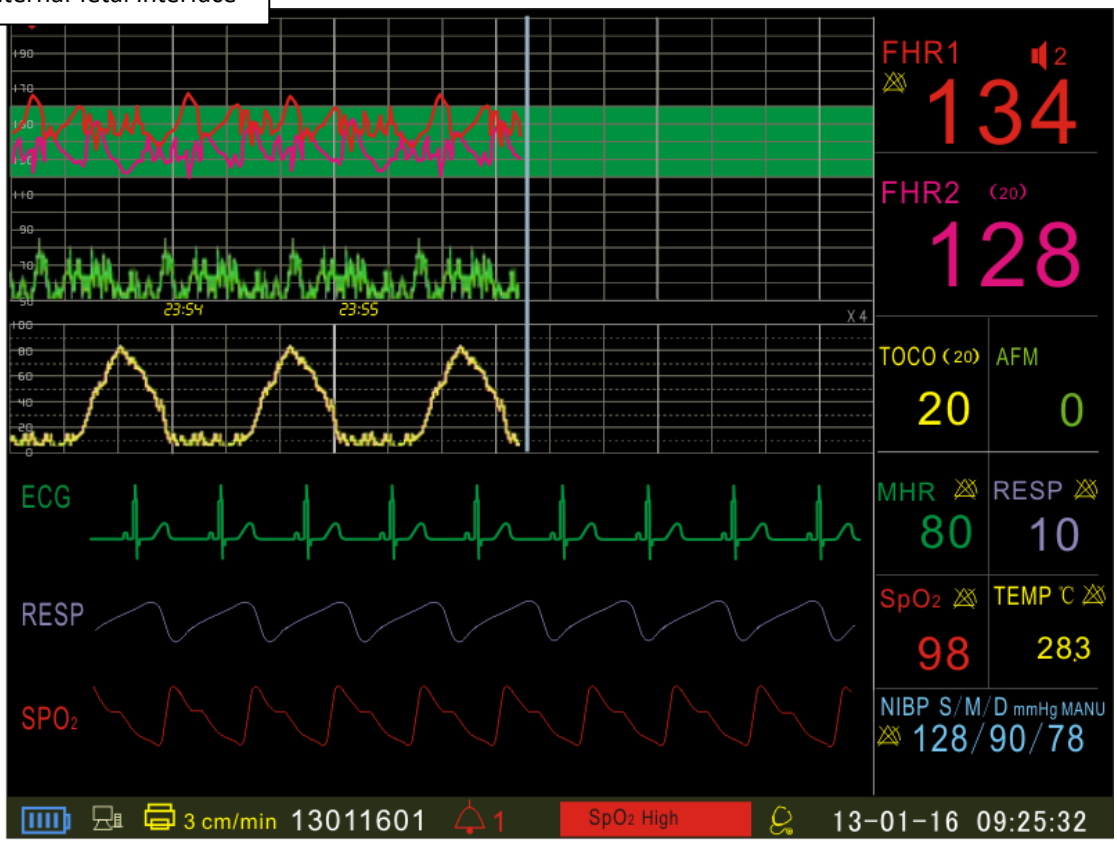
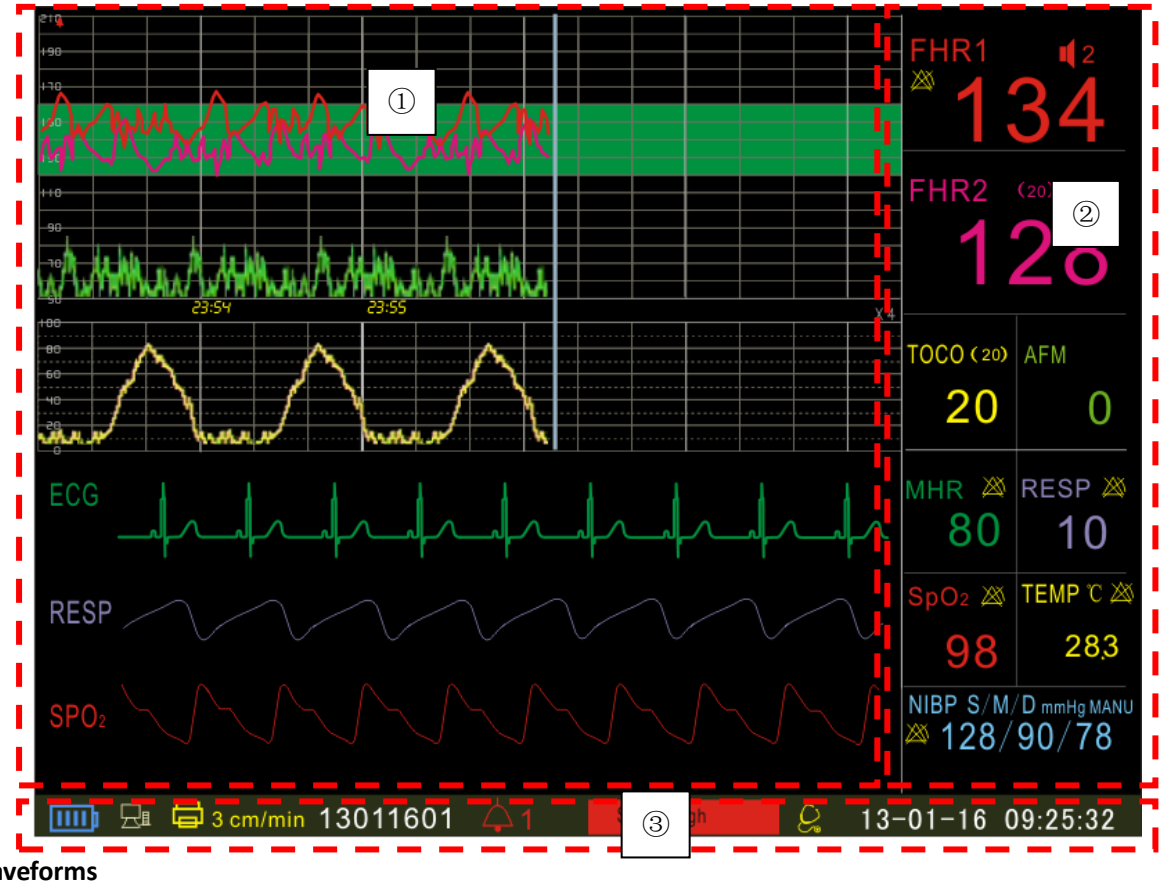


Fig. 4-1 Monitoring Interface Display

The monitoring interface has three sections: ① Waveforms; ② Parameters; ③ Information (as shown in Fig. 4-2)



① Waveforms

The fetus interface: Waveforms from top to bottom are: FHR waveform (shown as two FHR waveforms for twins,

the interval between the two waveforms is determined by the twin separation value set by the system), and fetal movement waveform (the user can choose to display or close the waveform as required), uterine contraction pressure waveform;

Maternal-fetal interface: the waveforms from top to bottom are: ECG waveform, respiration waveform, and blood oxygen waveform.

② Parameters

The parameters section is in the right of the screen：

1) Fetal heart rate (FHR)

Fetal heart beats per minute (Unit: bpm)

Alarm off; only displayed when the alarm is turned off.

Speaker volume indication in eight levels (0-7); when the system displays, you can adjust the volume through the Up/Down button on the panel.

(20) Separation values of FHR1 curve and FHR2 curve.

FHR signal quality indicator. Red - poor signal/no signal; Yellow - signal in general; Green - good signal.

2) Uterine contraction (TOCO)

Uterine contraction value display (relative value from 0 to 100). This value has no meaning in frozen state.

(20) Uterine contraction baseline value, adjustable

3) Fetal movement (FM)

AFM: Automatic fetal movement counting, MFM: Manual fetal movement counting

4) Oxygen saturation (SPO2)

Oxygen saturation SPO2 (unit: %)

5) Pulse rate/heart rate (PR): unit: pulse/min.

6) Respiration (RESP)

Respiration rate (Unit: times / min)

7) Non-invasive Blood pressure (NIBP)

Systolic / mean / diastolic pressure (S / M / D, Unit: mmHg or kPa)

8) Body temperature (TEMP): unit ℃ or ℉

Users can set up the monitoring parameters in detail, and the main screen displays the corresponding menu in specific settings. The specific method will be described in the parameter monitoring chapter in detail.

③ Information

The information section is in the bottom of the screen, displaying the current status of pregnant woman and the Monitor. From left to right: power mark, networking mark, printing mark, printing speed, pregnant woman ID, alarm volume mark, alarm information, date / time.

Power mark: When external power supply is connected, the icon scrolls, indicating that it is charging; after fully charged, the icon changes to , which means that you are using an external power supply and the batteries are fully charged; when using the internal batteries, the icon is , indicating the battery status.

Networking mark: When connected to central station, the icon is ; when disconnected, the icon is .

Printing mark: When printing starts, the icon is blinking; when printing stops, the icon is .

Printing speed: the current printing speed: 1cm/min, 2cm/min or 3 cm / min.

Pregnant woman ID: after started every time, the system automatically generates a serial number according to the date and time. The serial number can be changed in the monitoring process, and the

changed ID is valid only for later data.

Alarm volume mark: 1 indicates the current alarm volume, which can be set in the menu. Press this mark to enter the alarm mute state 1 until a new alarm event occurs; press and hold the mark to enter the alarm pause state 02:00, and the duration is 2min. In alarm pause period, it won't alarm even if alarm event occurs.

Alarm information: When an alarm occurs, this position indicates the reason of the alarm; if the parameter limit alarm is set to ON, the option displays the parameter alarm information when alarm occurs. When the paper runs out, the door is not closed or printer malfunctions, the system will alarm and display Print Alarm Info, indicating that the printer is in a non-normal state.

Rating button : Click this button to enter rating screen.

Date / Time: Monitoring date and time; in freezing state, it displays the starting date and time of monitoring records.

4.3 Description of Menu Settings Interface

4.3.1 Main menu:

Click for touch operation = Turning the code-wheel+ Pressing the code-wheel

Enter the main menu in the following steps:

Rotate the encoder disk, select the **parameter section** in the right of the screen and press the encoder disk to enter the Main menu interface.

The operation in this interface is simple and easy: Rotate the encoder disk, press the encoder disk to confirm when an item turns blue to enter the Settings interface, or touch a certain item to access the setting interface of this item.

The detailed parameters of the interface are as below:

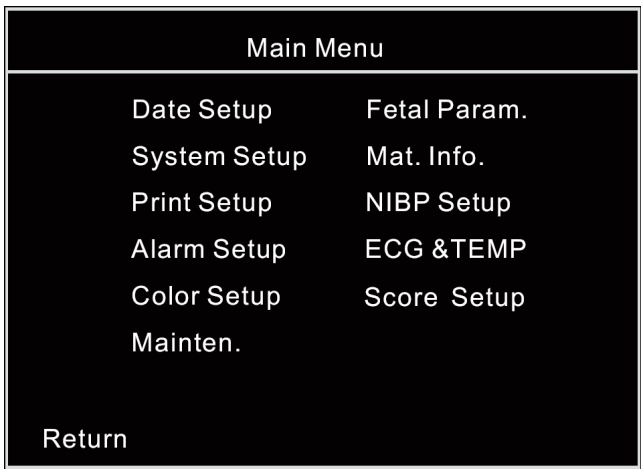


Fig. 4-3 10.2-inch Main Menu Settings Interface

Date Setup: Set the system date and time.

System Setup: Set the system parameters.

Print Setup: Set the printing parameters.

Alarm Setup: Set the parameter alarm information.

Color Setup: Set the parameter color.

Mainten.: Set the maintenance info.

Fetal Param: Set the fetus parameters.

Mat. Info: Set the relevant information of pregnant woman

NIBP Setup: Set the blood pressure parameter

ECG&TEMP: Set the ECG and body temperature parameters

Score Setup: Set the rating information.

The operation in each setting interface is as follows:

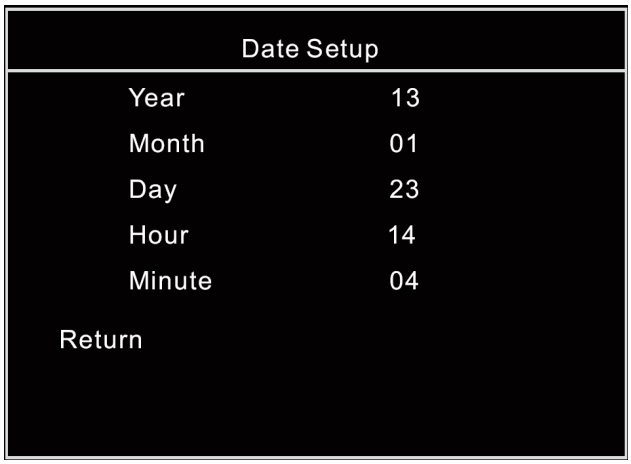
Rotate the encoder disk, when an item turns blue, press the encoder disk to confirm and pop up the

adjustable parameters, then rotate the encoder disk to select, press the encoder disk to confirm, finally rotate the encoder disk to X, and press the encoder disk to exit the setting.

or

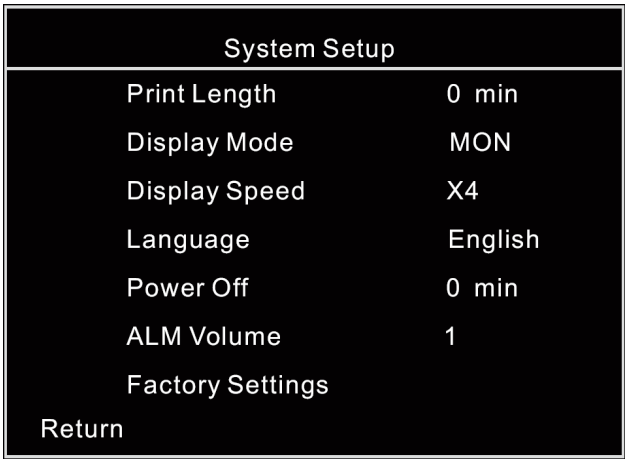
Touch a certain item to pop up the adjustable parameters of this item. Then touch the required parameter. Finally touch 【X】to exit this item.

4.3.2 Date



Set the system date and time (24-hour).

4.3.3 System



Print Length: Set the printing duration (up to 60min); when the print time is up, printing stops. 0 indicates that the function is invalid.

Display Mode: Select “Monitoring” or “Demonstration”. In demo mode, the curve interface displays “DEMO”.

Display Speed: Adjust curve display speed; available options are X1, X2, X4, and X8.

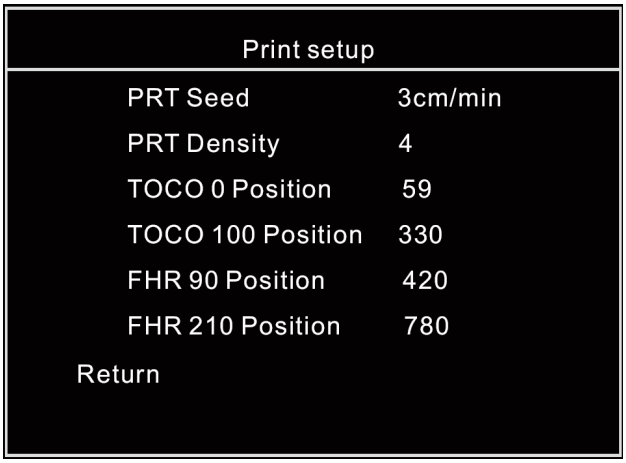
Language: Switch languages.

Power Off; 0 indicates that the function is disabled; other values indicate that if the time without signal exceeds the values, the system will automatically turn off. The time of automatic power off can be set up to 240min.

ALM Volume: Set the alarm volume; available options are 0, 1, 2, and 3.

Factory Settings: Press this option to restore the system to its default values.

4.3.4 Print



PRT Speed: Adjust the printing speed; available options are 1cm/min, 2cm/min, and 3cm/min.

PRT Density: Adjust the printing density of curves to accommodate different thermal paper; available options are 1, 2, 3, 4, and 5.

The following four operations are to ensure that you can print with 152mm printing paper of different specifications:

TOCO 0 Position: Adjust the printing position of TOCO 0

TOCO 100 Position: Adjust the printing position of TOCO 100

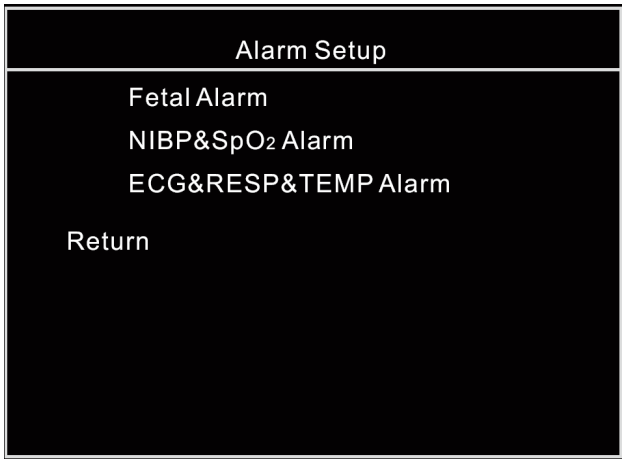
FHR 90 Position: Adjust the printing position of FHR 90

FHR 210 Position: Adjust the printing position of FHR 210

The adjustment method is as follows:

In the printing setting interface, rotate the encoder disk to select one of the items, press the encoder disk to confirm and enter the sub-menu, and the printer starts printing four lines on the printing paper, which are UC 0, UC 100, FHR 90 and FHR 200 respectively. If a position has deviation, adjust in the sub-menu to make the positions coincide. After adjusted, click X in the top of the sub-menu to close the submenu and stop printing. This system can print with 152mm printing paper of different specifications.

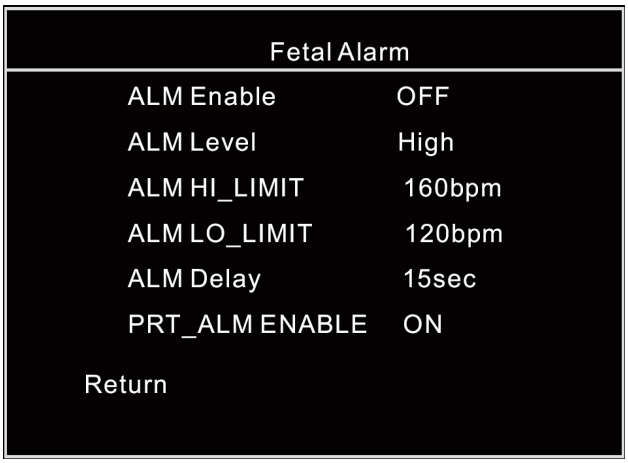
4.3.5 Alarm Setup



Fetal Alarm: Enter the fetus parameter alarm setting interface.

NIBP&SpO_2 Alarm: Enter the setting interface of blood pressure and oxygen parameter alarm.

ECG&RESP&TEMP Alarm: Enter the setting interface of heart rate, respiration, and body temperature parameter alarm.



Alarm Enable: Whether enable fetal parameter out-of-limit alarm; ON --- Enable; OFF --- Disable.

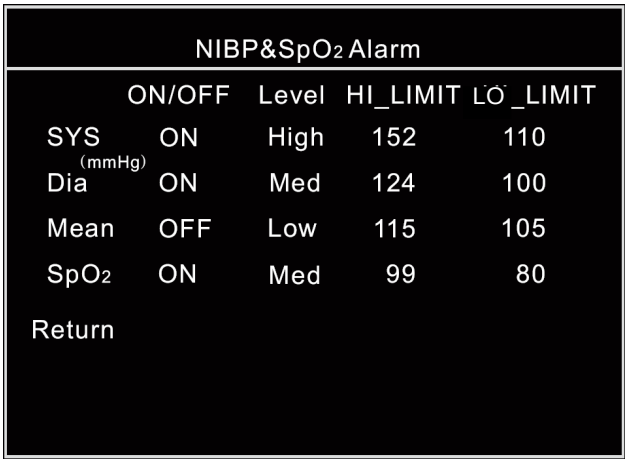
Alarm Level: Alarm priority: high, medium and low.

ALM HI_LIMIT: High limit of FHR alarm; available options are 160, 170, 180, and 190 bpm.

ALM LO_LIMIT: Lower limit of FHR alarm; available options are 90, 100, 110, and 120 bpm.

Alarm Delay: Trigger time; the time interval from the discovery of FHR out-of-limit to alarm started; available options are 15 seconds and 30 seconds; when the alarm is set to ON, an alarm sound is produced when the trigger time is up.

PRT_ALM ENABLE: Whether enable printing fault alarm; ON --- Enable; OFF --- Disable.

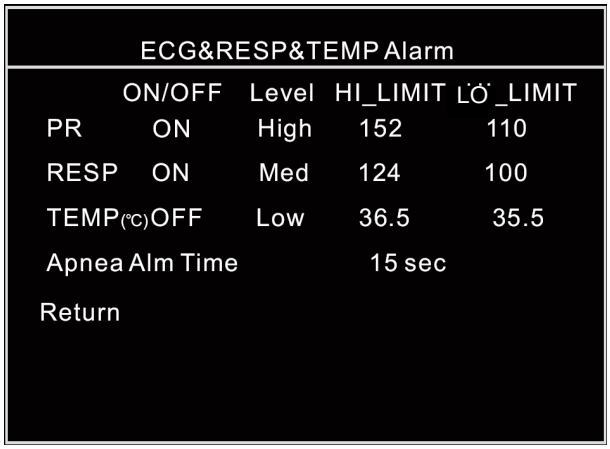


ON / OFF: Whether enable parameter out-of-limit alarm; ON --- Enable; OFF --- Disable.

Level: Alarm priority: high, medium and low.

HI_LIMIT: High limit of parameter alarm. The high limit of systolic, diastolic and mean pressure is 35~250mmHg, and the step is 5; the high limit of blood oxygen range is 86~100 and the step is 1.

LO_HIMIT: Lower limit of parameter alarm. The lower limit of systolic, diastolic and mean pressure is 30~245mmHg, and the step is 5; the lower limit of blood oxygen range is 85~ 99 and the step is 1.



ON / OFF: Whether enable parameter out-of-limit alarm; ON --- Enable; OFF --- Disable.

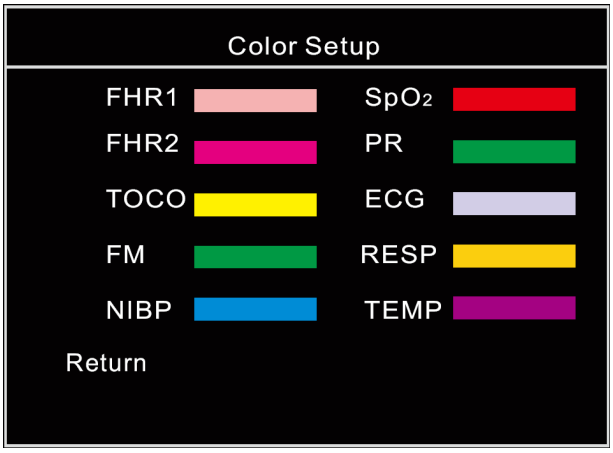
Level: Alarm priority: high, medium and low.

HI_LIMIT: High limit of parameter alarm. The high limit of heart rate is 35~240 beats / min, and the step is 5; the high limit of respiration range is 7~60 times/min, and the step is 1; the high limit of respiration range is 30.5~50.0°C, and the step is 0.5.

LO_LIMIT: Lower limit of parameter alarm. The lower limit of heart rate is 30~235 beats / min, and the step is 5; the lower limit of respiration range is 6~59 times/min, and the step is 1; the high limit of respiration range is 30.5~50.0°C, and the step is 0.5.

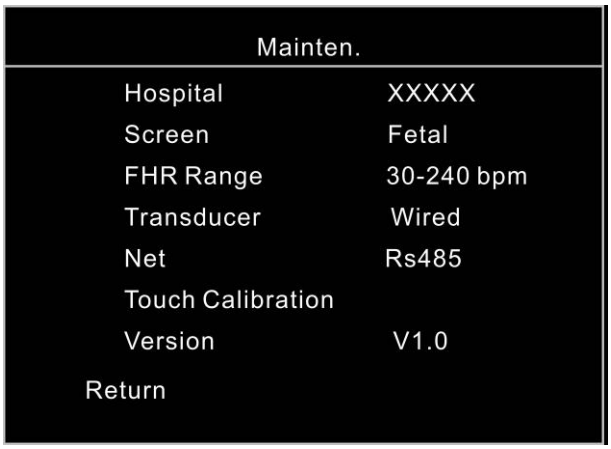
Suffocation Alarm Time: The suffocation alarm delay, ranging from 10 to 60 seconds, in steps of 5.

4.3.6 Color



Set the colors of physiological parameters in the interface.

4.3.7 Maintenance



Hospital: Can be edited by entering the name of the hospital, which can be saved after turning off. You can enter up to 20 characters.

Screen: The monitoring interface displaying form, including fetus interface and maternal-fetal interface.

FHR Range: The display range of fetal heart curve: 50-210 bpm/30-240 bpm.

Transducer: The type of connected probe: wired and wireless.

Net: With the central station networked communications, TCP/IP, RS485 is optional.

Touch Calibration: Into the touch calibration mode.

Version: Software version number; not adjustable.

4.3.8 Fetal Param

Twin Offset: In twins state, to avoid FHR2 curve coinciding with FHR1 curve, lower the position of FHR2 curve for several unit points, which are the curve separating values; available options are 0, 20, 30; 0 indicates no separation. Unit: bpm.

FM Trace: Display or close fetal movement curve on the interface. Fetal movement curve is a uterine contraction curve shown in TOCO area, indicating the dynamic information of fetal movement; select “ON” to display the fetal curve, or select “OFF” to hide.

FM Count: “Manual” and “Auto” are available; select “Auto”, and the display shows “Automatic fetal movement” on the right of the fetal movement area; select “Manual”, and the display shows “Manual fetal movement” on the right of the fetal movement area. About the “Automatic fetal movement” and “Manual fetal movement”, refer to the description of fetal movement in Chapter 7.

FM Threshold: Threshold of automatic fetal movement, adjustable from 10% to 80%; fetal movement threshold indicates the percentage of fetal movement intensity; if 10% is selected, a minor fetal change is counted as a fetal movement; if 80% is selected, only strong fetal movement will be counted; it is recommended to set to 40%~60%. If the ‘fetal movement counting’ is set to ‘Auto’, i.e. automatic fetal movement, the setting is effective.

FHR Channel: Select the channel of fetal heart tones.

TOCO Reset: Select the uterine contraction reset value; available options are 0, 05, 10, 15, and 20.

4.3.9 Pregnant Woman Info

ID: ID of the pregnant women under monitoring; if it isn't set, the system will automatically generate an ID according to the date and time.

Name: Select this option to enter the name input interface, which only accepts numbers and English letters. Enter the name, which won't be saved after turning off.

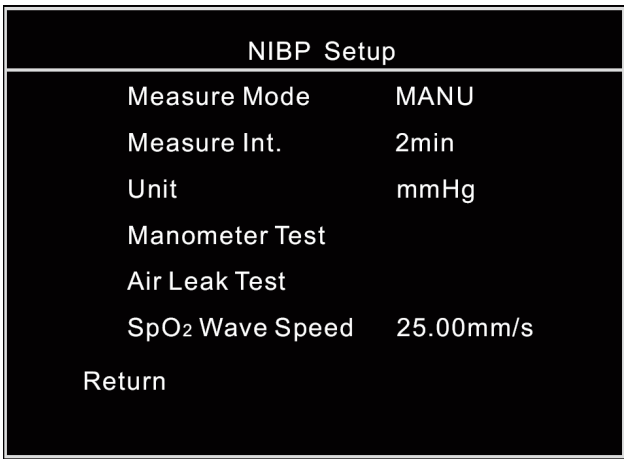
Gest. Week: The weeks of gestation, which are from 25~44.

Gest. Day: The number of days after removing the number of gestational weeks: 0 ~ 6.

Parity: The times of pregnancy.

Bed ID: Set the bed when networked with the central station. Networking option R485 corresponds to 1-4; networking option TCP / IP corresponds to 1-32.

4.3.10 Blood Pressure



Measure Mode: Blood pressure measurement mode: "Auto" and "Manual" are available.
The selected measurement mode can be displayed in blood pressure value section in the monitoring interface.

Measure Int.: 03, 05, 10, 20, 30, 60, 90, 120, and 240; unit: min; only when the measurement mode is "Auto", the measurement interval value is effective.

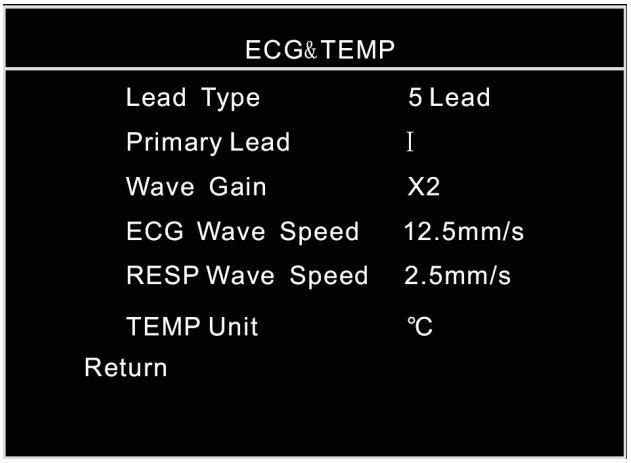
Unit: Blood pressure units, kPa or mmHg.

Manometer Test: Click this option to return to the monitoring interface, and the blood pressure value display area prompts: Hydrostatic testing.

Air Leak Test: Click this option to return to the monitoring interface, and the blood pressure value display area prompts: Air leakage testing; the prompt disappears when the test completes. If air leaks, it will prompt "Air leaks" after testing. During the test, press the 'Blood pressure measurement button' to cancel the test.

SpO_2 Wave Speed: The interface displays the speed of blood oxygen waveform: 6.25mm/s, 12.5mm/s, and 25mm/s are available.

4.3.11 ECG & Temperature



Lead Type: Three-lead and five-lead are available.

Primary Lead: If three-lead is selected, I, II and III are available; if five-lead is selected I, II, III, AVR, AVL, AVF and V are available.

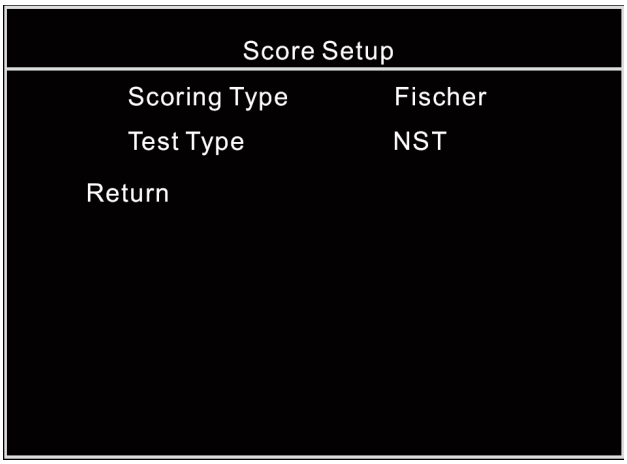
Wave Gain: Used to adjust the amplitude of ECG waveform; 0.25X, 0.5X, 1X, 2X, and 4X are available.

ECG Wave Speed: The interface displays ECG waveform speed; 6.25mm/s, 12.5mm/s, and 25mm/s are available.

RESP Wave Speed: The interface displays the speed of respiration waveform; available options are 6.25mm/s, 12.5mm/s, and 25mm/s.

TEMP Unit: °C (Celsius) and °F (Fahrenheit).

4.3.12 Rating



Rating Criterion: The reference of rating; available options are Fischer and Krebs.

Type of Experiment: NST, CS-NST, OCT and CST are available.

4.4 Backing Operation:

In the menu screen, select 'Back' to return to previous menus step by step, or press the UC Reset button to return to the monitoring interface directly.

In the menu state, the system can still calculate the real time fetal heart rate and uterine contraction pressure; if the system is in real-time printing state, you can still print it in real time.

5. FHR Monitoring

□ Misidentifying MHR as FHR
□ Introduction
□ FHR Setting
□ FHR Monitoring
□ Common Symptoms of Fetal Monitoring
□ Cleaning and Maintenance

5.1 Misidentifying MHR as FHR

It does not always mean that the fetus is still alive when the Monitor detects FHR. Before monitoring, confirm that the fetus is still alive, and then confirm that the fetus is the source of recorded heart rate (see 1.3Confirming the Fetus is Still Alive before Monitoring).

The following examples indicate how MHR is misidentified as FHR.

- **When using an ultrasonic transducer:**

△ The maternal signal source may be picked up, such as the beats of mother's heart, aorta or other large vessels.

△ When MHR is higher than normal value (especially above 100bpm), misidentification may occur.

- **When fetal movement curve (FM) is enabled:**

Keep in mind that the only the FM mark on the fetal trace does not always indicate that the fetus is still alive. For example, the FM mark still appears when the fetus is dead under the following conditions:

△ Dead fetus moves during or after the mother moves.

△ Dead fetus moves during and after artificial palpation of fetal movement (especially if the applied pressure is too large).

△ Movement of the ultrasonic sensor.

5.2 Introduction

FHR monitoring is achieved basing on the Doppler Effect. We know that a certain frequency of ultrasonic will be reflected when encountering obstacles in the transmission. If the object is stationary, the reflected wave and the transmitted wave have the same frequency. Once the object moves, the reflecting frequency will change. The reflecting frequency of the object facing the sound source becomes higher, and the reflecting frequency of the object back to the sound source becomes lower. The faster the object moves, the greater the frequency changes. This effect is called the Doppler Effect. Clinically, the ultrasonic sensor is used to emit ultrasonic waves to human body, the echo signal changes when encountering organs in motion, such as the heart, and the heart rate is derived by processing the echo signal.

Clinically, the best position for heart rate monitoring with Doppler is the fetus with its back toward the mother’s abdomen. If the fetus is facing the abdomen, the hands and the feet will affect the echo, the fetal turn makes the heart deviate from the irradiation area of the probe, the echo signal will decay, and some of the Doppler components disappear.

Fetal heart probe position

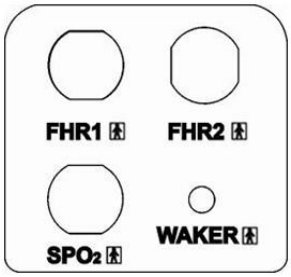


Fig. 5-1 Right Panel

The fetal heart probe is connected to the FHR1 three-in-one probe socket and FHR2 secondary probe socket in Fig. 5-1.

[Warning] Please use the accessories produced or recommended by the manufacturer.

5.3 FHR Setting

FHR settings include: Curve separation (for twins), upper alarm limit, lower alarm limit, alarm switch, alarm levels, alarm volume, fetal tone channel (for twins), etc.

[Note]

The high limit of FHR alarm is usually set to 160bpm, and the lower limit is set to 110bpm.

Please set the alarm switch to ON, so that the FHR abnormalities can be detected timely.

5.4 FHR Monitoring

FHR measurement is to obtain the fetal heart rate by the mother's abdominal wall: place the ultrasonic probe on the abdomen of pregnant woman, the sensor will emit low-energy ultrasonic signals to fetal heart and receive the echo signals from the fetal heart.

5.4.1 FHR Signal Acquisition Methods and Steps:

1) Find the position of strongest fetal heart with a stethoscope, or touch the fetal position and find the optimal fetal position;

2) Coat coupling agent evenly on the acoustic surface of the ultrasonic probe;

3) Place the ultrasonic probe on the maternal fetal side, move slowly and listen to the fetal heart signal until you find the clearest fetal heart signal;

4) Secure the ultrasonic probe with a bandage, and then adjust to make the signal is clear and the instrument can accurately count; if the fetus is in head position, the best position is usually in the left or right below the navel; if the fetus is in breech position, the best position may be above the womb;

5) Check if the FHR value displayed by the Monitor appears.

In the monitoring process, the Monitor always keeps the volume with fetal heart beat clearly audible. Do not completely turn off the Monitor's sound;

6) When there is strong fetal movement, uterine contraction or body movement of pregnant woman, the position of fetal heart may change greatly, and can’t hear clear fetal heart beats. In this case, adjust the position of the ultrasonic probe to regain excellent fetal heart signals.

[Note]

The monitoring records of the best quality can be obtained only when the probe is placed in the best position.

[Warning]

Do not turn off the speaker volume during monitoring. When the FHR signal is very weak (fetal heart abnormal or fetal heart drifts to edges of probe detection zone) or there is no FHR signal (fetal heart drifts out

of the probe detection zone or stillbirth), and hear rhythmic fetal heart tones are barely heard through the speaker, pay particular attention in this case. The FHR figure shown on the screen is meaningless.

5.4.2 Single Fetus Monitoring

Monitor one fetus. Identify the fetal heart position and tie the ultrasonic probe according to **5.4.1 FHR Signal Acquisition Methods and Steps**.

During monitoring, there is FHR numeric and waveform display; when FHR is out of preset limit, alarming LED indicator will turn to red flash (alarming level is set as High) or orange flash (alarming level is set as middle/low); If alarm is set ON, if FHR is our of limit for some time which is longer than preset alarming delay time; the audibal alarm will be activated; Alarming message prompt at the bottome of the screen. If alarm is set OFF, no audible alarm and alarm message prompt.

5.4.3 Twins Monitoring

Monitor twins. Identify the fetal heart position and tie the master and secondary ultrasonic probes according to **5.4.1 FHR Signal Acquisition Methods and Steps**. In order to observe two FHR curves clearly, it is recommended to set the separation value of twins curve (i.e. a value other than 0).

Curve separation: In twins state, to avoid FHR2 curve coinciding with FHR1 curve, lower the position of FHR2 curve for several unit points, which are the curve separating values; available options are 0, 20, 30; 0 indicates no separation. If 20 are selected, FHR2 curve is 20BPM lower than the real curve; the FHR2 value displayed in the parameter area in the right is true value and isn't affected by the curve separation setting.

Identify the sound output from the master probe (FHR1) or the secondary probe (FHR2) by setting fetal heart tone channel.

During monitoring, there is FHR numeric and waveform display; when FHR is out of preset limit, alarming LED indicator will turn to red flash (alarming level is set as High) or orange flash (alarming level is set as middle/low); If alarm is set ON, if FHR is our of limit for some time which is longer than preset alarming delay time; the audibal alarm will be activated; Alarming message prompt at the bottome of the screen. If alarm is set OFF, no audible alarm and alarm message prompt.

To monitor single fetus with twins monitor, please select FHR1 as the fetal tone channel, otherwise you can't hear the fetal heart tone.

5.5 Common Symptoms of Fetal Monitoring

The normal range of FHR baseline is 110~160 beats / minute (BPM), and baseline changes are those changes over 15 minutes.

(1) Fetal tachycardia:

The heart rate baseline exceeds 160BPM, and factors in relation to or resulting in tachycardia include: fetal hypoxia, maternal fever, maternal hyperthyroidism, anemia in the fetus, amnionitis; fetal tachycardia is usually accompanied by heart rate variability disappearing.

(2) Fetal bradycardia:

The heart rate baseline is lower than 110BPM.

(3) Heart rate variability:

Heart rate variability is an important feature to estimate fetal status at any given time. It reflects the integrity of the neural regulation system and cardiovascular systems of the fetal heart, including short-term and long-term variability.

Short-term variability is the irregularity between heartbeats, and is caused by the error of normal cardiac electrical activity cycle.

Long-term variability is the fluctuations of heart rate curve.

Acceleration is the periodic heart rate changes above FHR baseline, and relates to fetal movement and

uterine contractions.

Deceleration is the periodic heart rate changes below FHR baseline. Unlike the baseline change, the duration of deceleration is relatively short, usually less than 10 minutes. According to the shape and the relation with uterine contraction cycle, it can be divided into the following three types:

① Early deceleration: The obvious feature is that FHR begins to decline before uterine contractions and returns to the baseline after uterine contractions. It is generally related to the pressure on fetal brain.

② Late deceleration: The obvious feature is that FHR begins to decline when uterine contraction begins, and returns to the baseline after uterine contractions. It is generally caused by fetal hypoxia.

③ Variable deceleration: The shape, start time and duration of FHR curve are not the same. It is the most common during childbirth, and is usually caused by umbilical cord compression.

5.6 Cleaning and Maintenance

Caution:

If possible, always comply with the specific instructions supplied with the probe. These data may be newer than the information provided in this Manual. The information provided in this chapter is intended to be general cleaning guidelines when you can't get the special cleaning methods of certain products.

If there is any deterioration or damage, please replace the cable. In this case, do not use this cable for patient monitoring.

5.6.1 Cleaning the Probe Cable

In order to maintain cable dust-free, clean it with a piece of lint-free cloth soaked in warm soapy water (≤ 40°C/104°F), diluted non-corrosive detergent or one of the following approved cleaning agents.

Recommended cleaning agents and trademarks:

Soap: mild soap

Tensides dishwasher detergents: Alconox

Ammonia: diluted ammonia <3%, window cleaner

Ethanol: 70% ethanol, 70% isopropanol, 70% window cleaner

5.6.2 Cable Sterilization

In order to avoid causing long-term damage to the cable, we recommend sterilizing the cable only when it is deemed necessary according to the hospital procedure. We recommend cleaning first.

Recommended sterilization materials:

Alcohol-ethanol 70%, isopropyl alcohol 70%

Oxoethyl Clidex

5.6.3 Processing the Cable to Prevent Cross-contamination

In order to avoid causing long-term damage to the cable, we recommend sterilizing the cable only when it is deemed necessary according to the hospital procedure. We recommend cleaning first.

Caution:

Do not sterilize the cable with a pressure cooker or bleach containing sodium hypochlorite.

6. Uterine Contraction Pressure Monitoring

□ Introduction

□ UC Settings

□ UC Pressure Monitoring

UC Reset mark: 

6.1 Introduction

Uterine contraction pressure monitoring is to measure uterine activities by placing a TOCO transducer on the abdomen of pregnant woman.

Measure and record the relative pressure changes, as shown below.

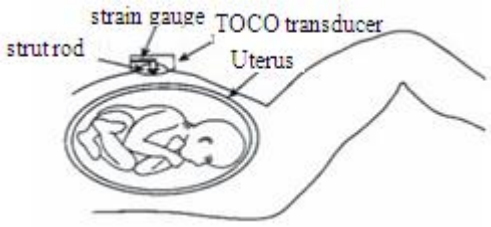


Fig. 6-1 Uterine Contraction Pressure Monitoring Diagram

UC pressure monitoring is to monitor the uterine contractions. UC pressure is the indicator of childbirth strength. Clinically, the uterine contraction has directly affected the fetal heart rate activities and childbirth. The curves recorded by pressure monitoring can provide a lot of information, such as the intensity, frequency and duration of uterine contraction, regularity and shape; the uterine contraction may cause FHR increased or reduced. At present, the FHR monitoring is accompanied by UC pressure monitoring, and the medical personnel can combine UC situation and FHR changes for diagnosis.

External pressure monitoring is to obtain UC pressure from the maternal abdomen. When a contraction occurs, the compression of the abdominal wall tension is applied on the pressure sensor, which will convert the pressure into electric signals. The resulting pressure signals are amplified and processed through the instrument, and finally output or printed.

6.2 TOCO Settings

Setting options for TOCO pressure monitoring:

TOCO Reset: Select the TOCO Reset value from 0, 5, 10, 15, and 20.

Display the contraction strength basing on selected value.

6.3 TOCO Monitoring

1. Prepare the Monitor

2. Connect the probe

Place the TOCO probe on mother’s abdomen and fix with strap.

Warning:

Do not monitor patients underwater.

3. Collecting TOCO Data

The strap should have moderate elasticity. If it is too tight, the peak of uterine contraction may be flat topped and lower than 100 on the pressure gauge. If it is too loose, the probe may slip, causing abnormal readings. Adjust the strap pressure as required.

[Note]**:**

Do not use ultrasonic coupling agent on the UC probe or probe contact area.

4. Monitor Adjustment

Press the UC Reset button on the front panel to adjust the pressure to the reset value. Press the UC Reset button once, the main interface will show a UC reset mark, and only one press is valid if the UC Reset button is pressed repeatedly within 5 seconds.

[Note]:

Pressure adjustment must be carried out between two uterine contractions.

7. Fetal Movement Monitoring and Fetus Wake-up

□ Introduction

□ Fetal Movement Monitoring

□ Fetal Wake-up

Automatic fetal movement mark:  ; manual fetal movement mark:  ; wake-up device mark: 

7.1Introduction

The activities of the fetus in the uterus is called fetal movement, which are shown as fetal limb movement, swing, fetal head and body rotating, turning and rolling. Fetal movement is the movement signals sent by fetus to its mother, and an objective sign of fetal life. Presence or absence of fetal movement is directly related to fetal safety, and the state of fetal movement is also an important indicator used by obstetricians to observe the fetus. Therefore, both pregnant women and obstetrician must know the fetal movement timely.

Fetal movement monitoring includes automatic and manual monitoring. Automatic fetal movement monitoring is to convert the fetal movement signal into electrical signals through the sensor, amplify and process through the instrument, and then automatically record the fetal movement information obtained by the instrument. Manual fetal movement monitoring is that the pregnant woman uses the relevant accessories to mark fetal movement information according to the fetal movement during monitoring.

7.2 Fetal Movement Monitoring

This Monitor features automatic and manual fetal movement monitoring.

Setting options for fetal movement monitoring

Fetal movement intensity curve

Fetal movement counting mode

Fetal movement counting threshold

See 4.3.8 Fetus Settings for specific parameter settings.

If the fetal movement counting is 'Auto', the Monitor will determine if fetal movement occurs according to the fetal movement threshold; if yes, it marks once  , and the number of fetal movement increases by one.

If the fetal movement counting is 'Manual', the pregnant woman shall hold the fetal movement event marker, press the button in the top of the fetal movement event marker when feeling fetal movement; the interface displays the mark  , and the number of fetal movement increases by one.

[Note]:

Fetal movement waveform and uterine contraction are displayed on the same channel.

The measurement results of automatic fetal movement monitoring may be related to the following factors: fetal movement, maternal body movement, and other external interference. Therefore, please reduce the external interference (touching pregnant woman, move monitoring bed, etc.) in monitoring, and the pregnant woman should keep quiet, so that accurate results of automatic fetal movement monitoring can be obtained.

7.3 Fetus Wake-up

Fetus wake-up is to use the fetus wake-up device to give the fetus a certain amount of stimulation and wake up the sleeping fetus. Fetus wake-up mainly applies non-stress test (NST), which can avoid misjudgment of NST results by obstetrician. NST is to observe and record fetal heart rate and uterine contraction curve without uterine contraction or other external stress; it is an ideal method to determine the function of fetal placenta.

7.3.1 Fetal Wake-up Device

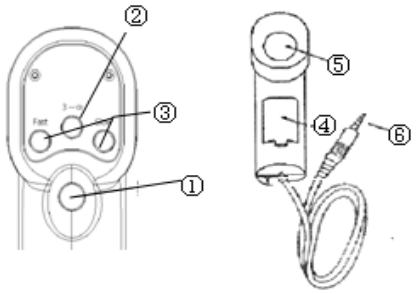


Fig. 7-1 Wake-up Device and Connecting Cable

① Power switch

Press this switch and the instrument begins operation; press it again to stop operation.

There are two modes of operation: continuous mode that operates when the switch is pressed and three-time mode that operates three times and stops in any condition.

② Mode selector switch

Continuous mode and 3-sec mode are optional.

③ FAST, SLOW knob

Adjust vibration rhythm during operation (intermittent repetition period).

④ Battery holder

Use two alkaline batteries.

⑤ Vibrating head

Vibrating surface

⑥ Marker socket

Connect to the fetal monitor, and a message appears automatically when the vibration sound pulse occurs.

7.3.2 Preparation for Operation

(1) Turn on the fetus wake-up device, and check if the device works properly. Do not use if there is any problem;

Before using, load the batteries and close the battery compartment cover in the steps as follows:

- Remove the battery compartment cover

Insert a coin, tweezers or similar flat object in the position indicated by the arrow in the lower left to remove the battery compartment cover, and press down the battery compartment in the arrow direction (Fig. 7-2)

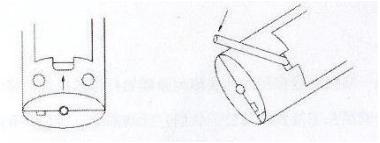


Fig. 7-2 Removing the Battery Cover

- Load the batteries

Load two alkaline batteries into the battery compartment according to the polarity indication on the battery compartment (battery anode and cathode matching the anode and cathode on the battery compartment) and close the battery cover, as shown in Fig. 7-3.

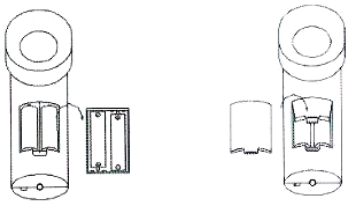


Fig. 7-3 Loading the Batteries

➢ Remove the batteries

Press down the cathode Θ of the batteries with a finger to remove the batteries.

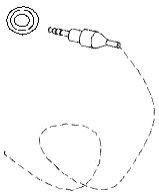
Caution: If the instrument won't be used for a long time, take out the batteries.

[Note]

① Do not mix old and new batteries or different types of batteries together;

② Do not disassemble the batteries to avoid battery leakage or rupture

(2) Connect the fetus wake-up device to the interface in the rear of the fetal monitor. Connection example is shown below:



(3) Press the Mode button to switch the wake-up device between three-time mode (stop automatically after vibrating three times) and continuous mode.

7.3.3 Waking up the Fetus

Place the vibrating head of the instrument on the mother's abdomen, press the vibration switch, and release to stop vibrating. Under normal circumstances, the vibration can awaken the fetus. When the fetus wake-up device is started, the main interface will show a mark of fetus wake-up device.

8. NIBP Monitoring

□ Introduction
□ NIBP Measurement
□ Cleaning and Maintenance

8.1 Introduction

Blood pressure is the force that the heart pinches off the blood and the pressure on vessel wall when blood flows. It is an important physiological parameter reflecting the function of human circulatory system, and has very important significance to blood pressure monitoring in clinical practice.
Blood pressure can be measured after converted to electrical signals by blood pressure transducer. The measurement methods include direct and indirect. Direct measurement is accurate, and can track the instantaneous change in arterial blood pressure, but it is invasive because the catheter must be put into the blood vessel percutaneously, and are generally used for critically ill patients or patients require surgery. Indirect method is simple and noninvasive, causes small perturbations to human body, and is widely used in clinical measurements. Indirect methods include auscultation, ultrasonic, oscillation and double-cuff. Our products use the oscillation method, which is used by most foreign non-invasive blood pressure monitors.

Oscillometric method is also known as vibrometer method or oscilloscope method. Oscillometric method still uses inflatable cuff to block arterial blood flow. Due to the pulsation of arterial blood flow, air pressure batteries generated by arterial blood flow can be detected in the cuff. First, the cuff is inflated to 20mmHg higher than the systolic blood pressure, then the cuff slowly deflates; when the pressure in the cuff is higher than systolic blood pressure, the arteries are blocked; due to proximal blood pulsation, oscillatory wave with smaller amplitude occurs. When the pressure in the cuff is equal to systolic pressure, the amplitude of the oscillatory wave increases; with continuous decrease of the pressure in the cuff, the amplitude of the oscillatory wave increases; when the pressure in the cuff reaches a certain value, the amplitude reaches the maximum, and the pressure in the cuff is mean arterial pressure. The oscillometric method is to identify arterial mean pressure based on the variation of amplitude of oscillatory wave under different cuff pressure, and then obtain the arterial systolic and diastolic blood pressure with the mean pressure.

8.2 NIBP Measurement

Noninvasive Blood Pressure (NIBP) measurement uses oscillometric method
Measurement mode: manual and auto. Each mode shows systolic, mean and diastolic pressures.
“Manual” mode only measures once.
“Auto” mode measures repeatedly. Time interval can be set to 3, 5, 10, 20, 30, 60, 90, 120, and 240min.
[Note]
1) Non-invasive blood pressure measurement isn’t allowed for the patients with sickle cell disease and skin damage or any expected damage.
2) For patients with severe coagulation disorder, determine if the automatic blood pressure measurement should be taken according to the clinical evaluation, because the friction between the body and the cuff may produce hematoma.
[Warning]
Do not install cuff on a limb with intravenous infusion or catheter. During inflating the cuff, if the infusion is

slowed or blocked, it may cause injury around the catheter.

The inflatable tube connecting blood pressure cuff and the Monitor should smooth.

8.2.1 Measuring Method:

1. Insert the inflatable tube into the blood pressure cuff port of the Monitor, and turn on the instrument.

2. In accordance with the following method, tie blood pressure cuff on the arm or the thigh of the patient (Fig. 8-1).

※ Confirm the cuff is completely deflated.

※ Use the cuff of appropriate size for patients to ensure that the symbol ϕ is located just above the appropriate artery. Make sure that the cuff around limbs is not too tight, or else it may cause distal discoloration or ischemia.

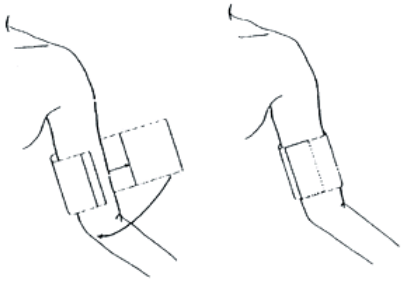


Fig. 8-1 Using Cuff

[Note]

Cuff width should be 40% of limb circumference (50% of newborns), or 2/3 of the upper arm length. The length of the inflated part of the cuff should be sufficient for 50 to 80% around the limb, because the wrong size cuff will produce erroneous readings. If there is any problem with the cuff size, use a bigger cuff to reduce errors.

When measuring in the newborn mode, the maximum possible pressure in the cuff is 147mmHg, the maximum pressure in normal use is 140mmHg, and the initial inflation pressure is 70mmHg.

3. Connect the cuff and inflation tube. The body part for pressure measurement should be in the same horizontal position with the patient's heart. If it is impossible, correct the measurement results in the following method:

※ If the cuff is above the heart level position, the gap per centimeter should be the displayed value plus 0.75mmHg (0.10kPa).

※ If the cuff is below the heart level position, the gap per centimeter should be the displayed value less 0.75mmHg (0.10kPa).

4. Select the measurement mode: if ‘Auto’ is selected, the time interval should be selected; see the following “Operation Tips” for specific methods.

5. Press the blood pressure measurement button on the front panel to inflate and measure the pressure.

8.2.2 Operation Tips

1. Automatic measurement

Set the “measuring mode” to “Auto”, and the user can select ‘measurement interval’ value for automatic measurement.

2. Stop the automatic measurement

During the automatic measurement, press the blood pressure measurement button to stop the measurement.

3. Manual measurement

Set the “measuring mode” to ‘Manual’, and then press the blood pressure measurement button on the front panel to start a manual measurement.

4. Conduct a manual measurement in the automatic measuring process

In the idle time of automatic measurement, press the blood pressure measurement button to start a manual measurement. During the measurement, press the blood pressure measurement button to stop the manual measurement and continue the automatic measurement.

[Warning]:

The noninvasive measurement time of automatic mode is too long, and the limbs frictionized with cuff may be accompanied by purpura, ischemia, and nerve damage. During patient monitoring, the distal color, warmth and sensitivity should be checked. Once there are any abnormalities, put the cuff in another place or stop blood pressure measurement immediately.

8.3 Cleaning and Maintenance

[Warning]

※ Do not squeeze the hose on the cuff.

※ Do not allow water or cleaning fluid flowing into the connector socket of the Monitor to prevent damage to the instrument.

※ When cleaning the Monitor, only wipe the outer of the coupling socket, and do not wipe its interior.

The cuff can be reused, sterilized by conventional hot air oven, disinfected by gas or radiation sterilization method, or immersed in decontamination solution for sterilization. But keep in mind that the rubber bag should be removed to use this method. Cuff can’t be dry-cleaned. It can be machine washed or hand washed, and hand wash can extend the useful life. Before cleaning, remove the rubber bag. When the cuff is dry, reload the rubber bag, as shown in Fig. 8-2 and Fig. 8-3.

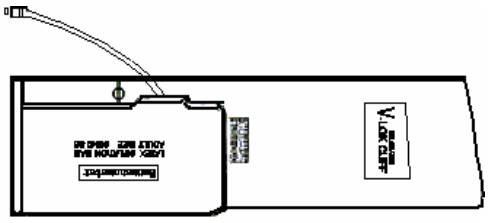


Fig. 8-2 Replacing Rubber Bags in the Cuff

Fig. 8-3 Replacing Rubber Bags in the Cuff

9. SPO2 Monitoring

□ Introduction
□ Blood Oxygen Monitoring
□ Precautions
□ Factors Affecting the Reading
□ Cleaning and Maintenance
□ Troubleshooting

9.1 Introduction

SpO2 parameter measures arterial oxygen saturation, which is the percentage of oxygenated hemoglobin in the sum of oxygenated hemoglobin and deoxygenated hemoglobin.

Oxygen monitoring uses optical technology, which can measure the arterial blood oxygen saturation continuously without taking blood. The conventional oxygen probe of the Monitor is a finger probe, which is put on the finger for use. The upper wall of the probe fixes two juxtaposed light emitting diodes (LED), which emit 660nm wavelength red light and 890nm wavelength infrared light. The lower wall has a photodetector, which convert the red light and the infrared light transmitted through the finger artery into electric signals. The pulse of optical signals is same to the heart beat, so that the repetition period of the signal is detected, and the pulse rate is determined.

Caution:

Deal with sensors and cables carefully. The sensors have sensitive electronic components inside, which will be damaged due to rough treatment. Protect the cables from contact with sharp objects. The wear due to patient movement and normal sensor cleaning means that SpO2 sensor life is limited.

Our guarantee does not apply to damage caused by incorrect use.

Warning:

During MRI, applying SpO2 sensor can cause severe burns. To minimize this risk, ensure that the location of the cable will not form induction loops. If the sensor can’t work correctly, take it away from the patient immediately.

Do not attach SpO2 sensor in the ambient temperature over 37°C, as long attachment will cause severe burns.

Caution:

Injected dyes such as methylene blue, or intravascular staining hemoglobin, such as methemoglobin, may result in inaccurate measurements.

Known possible sources of interference include strong ambient light and patient movement.

9.2 Blood Oxygen Monitoring

9.2.1 Blood Oxygen Probe

Adult finger probe, reusable

Insert the patient's finger into the probe, and ensure that the probe completely encases the finger.

9.2.2 Monitoring Steps:

1) Turn on the Monitor;

2) Attach the sensor to the finger of the patient in the appropriate place;

3) Plug one end of the sensor cable into SpO2 hole of SpO2 module.

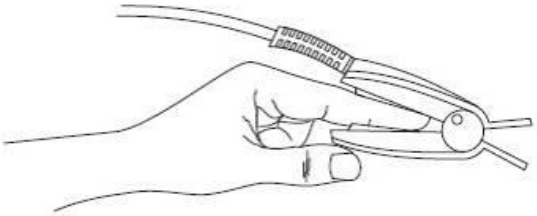


Fig. 9-1 Placement of Oximetry Finger Cot

Warning:

Do not put the probe on the limbs with arterial duct or intravenous injection tube.

Make sure that the light emitter and the light detector are opposite to each other, and all of the light emitted passes through the patient's tissue.

[Note]

Confirm that pulsating blood flow exists at the attaching position.

Confirm that the attaching position has no vibration or excessive movement.

Confirm that the skin at the attaching position is neither too thick nor too thin.

Applying the probe in strong light may lead to inaccurate measurement results; please cover the attaching position with opaque material.

Keep the power cable away from the probe cable.

Warning:

Continuous monitoring for too long may cause skin redness, blistering or pressure necrosis. Therefore, regularly check the attaching position of the probe, and change the placement of the probe if the skin quality declines; for special status of particular patient, more frequent inspections may be required.

9.3 Precautions

Warning:

Check the attaching position every 2 to 3 hours to ensure the skin quality and the correct position of optical measurement. If skin quality changes, move the probe to another position. Avoid affecting the accuracy of measurement caused by movement and other factors.

[Note]

Clean the surface of the oxygen probe with 70% ethanol solution before and after each use, but do not completely immerse the probe in the solution.

If the package or the oxygen sensor probe is damaged, do not use.

Do not sterilize the blood oxygen probe by radiation, steam or ethylene oxide.

Be careful when connecting cables to avoid entangled in the patient.

If the test position and the probe can't be accurately located, the oxygen readings may be inaccurate, and repositioning is required.

9.4 Factors Affecting the Reading

1) Nail polish, especially the purple and blue; the reading will be reduced by the same absorption; it is recommended washing the nail polish before measuring.

2) Fake nails prevent the detection from penetrating the tissue, thus affecting the measurement of oxygen values.

3) Blood oxygen value of the patient is too low.
4) Excessive smokers have high instantaneous CO level, resulting in higher blood oxygen readings.
5) Injected dye or intravascular dyeing hemoglobin.
6) Known potential sources of interference: strong ambient light, patient movement.
7) Sensor is placed incorrectly or an improper sensor is used.
8) Poor perfusion of the measured position.
9) When the Hb-CO, Met-Hb or chemical agent is present, blood oxygen value may be high.
10) Vein has rhythmic vibration.
11) Severe disorders in haemochrome function (such as hemoglobin and ferritin).

9.5 Cleaning and Maintenance

Warning:

Before cleaning the monitor and the probe, make sure the power has been off or the power cord is unplugged.

Caution:

Do not disinfect the sensor in autoclave.

9.5.1 Cleaning the Probe

1) Clean the sensor appearance with mild detergent solution, salt solution (1%) or one of the following solvents:
Microzid (pure), Mucocit (4%), Incidin (10%), Cidex (pure), Sporicidin (1:16), Mucaso (3%), Buraton (pure), alcohol (pure), Alconox (1:84), Cetylcide (1:63)
2) Scrub the sensor's appearance with dry cloth, and let it dry.
3) Wipe the emitting and receiving parts of the sensor with soft cloth moistened with detergent or medical alcohol, then wipe with dry cloth.
4) Check the sensor and cable, and do not use if there is any sign of deterioration or damage.

9.5.2 Cleaning the Cable

Clean the cable in the following method:
1) Please wipe the outer surface of the cable with antibacterial soap water or alcohol; be careful to avoid liquids entering the cable connections.
2) Wipe with clean dry cloth.

Warning:

Do not soak the probe in any liquid or let any liquid enter into electrical connections.

9.6 Troubleshooting

9.6.1 No blood oxygen values

Failure:
In the monitoring process, there are no blood oxygen waveforms and values.
Inspection method:
Check if the finger probe flashes red, if the arm of examinee is oppressed, and if the temperature in the monitoring room is too low.
Solution:
If the finger probe doesn’t flash red light, the wire interface contact may be poor; please check the extension cord and socket interface. In cold areas, do not expose the patient's arm to avoid affecting the

testing effect. Do not measure the blood pressure and the blood oxygen on the same arm, in order to avoid affecting the measurement.

If the blood oxygen channel waveform isn't displayed, the blood oxygen module and master unit have communication problem; please turn off the unit and turn it on again; if there is still such prompt, please contact the biomedical engineer of the hospital or your supplier.

9.6.2 Intermittent blood oxygen values

Failure:

The blood oxygen values appear intermittently when measuring the body oxygen saturation.

Inspection method:

1) During long-term monitoring and surgery, the patient has severe vibration or movement, resulting in intermittent blood oxygen values.

2) Check the blood oxygen extension cord.

Solution:

Keep the patient stable; once the blood oxygen value is missing due to hand movements, it is considered normal. If the blood oxygen extension cord is damaged, replace it.

10. ECG/Respiration Monitoring

□ ECG Monitoring Definition
□ Precautions
□ Monitoring Steps
□ Respiration Monitoring
□ Maintenance and Cleaning

10.1 ECG Monitoring Definition

ECG monitoring generates continuous waveform of patient's cardiac electrical activities to accurately assess the physiological state of the patient. In order to obtain the correct measurements, appropriately prepare patient's skin, accurately place the electrodes and properly connect ECG cables. During normal display, a line of ECG waveform can be displayed.

※ Patient cable consists of two parts:

Main cable connecting to the Monitor;
Lead connecting to the patient.

※The instrument is configured with five-lead wire.

10.2 Precautions

Warning

When you connect the electrodes or patient cable, assure that it is not connected to any other conductive parts or the ground. In particular, make sure that all the ECG electrodes, including the neutral electrodes, are attached to the patient in order to prevent them from contact with the conductive member or ground.
[Note]
Do not use equipment with electric radiation near ECG / respiration measurement.

10.3 Monitoring Steps

10.3.1 Preparation

1) Prepare patient skin before placing the electrodes.

※Skin is a poor conductor; to get a good contact between electrodes and the skin, it is very important to prepare the patient's skin.

※ If necessary, shave body hair at the position that the electrode is placed.

※ Wash the skin thoroughly with soap and water. (Do not use ether and pure alcohol, as this will increase the skin's impedance).

※ Dry rub the skin to increase capillary blood flow to tissues and removes skin debris and grease.

2) Prior to the placement of the electrodes, install the spring clip or snap.
3) Place the electrodes on the patient's body; if the used electrodes are free of conductive paste, apply the

conductive paste before placing.

4) Connect the electrode leads to the patient cable.

5) Connect the power of the Monitor.

Warning

Attach the electrodes carefully and ensure good contact.

Warning

Check if the ECG electrode patches irritate the skin every day. If there are signs of allergy, replace the electrodes or change position every 24 hours.

[Note]

To protect the environment, the used electrodes must be recycled or properly disposed of.

Warning

Before monitoring starts, check if the leads are normal.

10.3.2 Installing ECG Leads

See Fig. 10-1 for the position of ECG monitoring electrodes.

Upper Right (RA): First intercostal of the midclavicular line in the right edge of the sternum.

Lower Right (RL): At the level of the xiphoid on right midclavicular line.

Center (C): Fourth intercostal in the left edge of the sternum.

Upper Left (LA): First intercostal of the midclavicular line in the left edge of the sternum.

Lower Left (LL): At the level of the xiphoid on left midclavicular line.

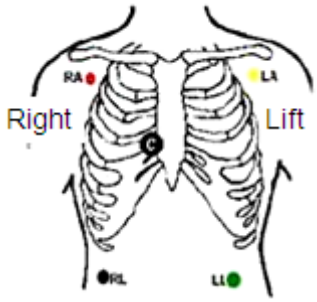


Fig. 10-1 Conductive Electrodes Placement

[Note]

To ensure patient safety, all leads must be connected to the patient.

Warning

In the use of electrical surgical (ES) equipment, never place the electrodes on the grounding plate near the electrical surgical equipment, otherwise the ECG signal will have a lot of interference.

10.3.3 ECG Parameter Settings

ECG parameter settings include:

Lead type, main lead, waveform gain and ECG waveform speed; see 4.3.11 ECG Body Temperature for specific parameters.

10.4 Respiration Monitoring

10.4.1 How is respiration measured?

The Monitor measures respiration with the thoracic impedance of the two electrodes. The changes in impedance between the two electrodes (due to activity of the thorax) produce a respiratory wave on the screen.

10.4.2 Respiration Monitoring Settings

Respiration monitoring doesn't require additional electrode, but the electrode placement is very important. Due to the clinical condition of some patients, the lateral expansion of the thorax results in negative intrathoracic pressure. In this case, it is best to place the two respiration electrode in the largest region when the right axillary line and left thoracic breathe to obtain the best respiratory wave.

[Note]

Respiration monitoring doesn't apply to the patients with large range of activities, as this may lead to false alarms.

Respiration monitoring examination:

1) Prepare patient skin before placing the electrodes.

2) Install spring clip or snap to the electrodes, and place the electrodes onto the patient according to the method described in 10.3.2.

3) Connect the power of the monitoring system.

[Note]

Place the green electrode and red electrode diagonally for optimum respiratory wave. Avoid liver and ventricle in the connection line of the electrodes, so as to avoid artifact caused by heart overwriting or pulsating blood flow, which is particularly important for newborns.

10.5 Maintenance and Cleaning

Warning

Turn off the Monitor and cut off the AC power before cleaning the Monitor or probe.

If the ECG cable is damaged or aging, replace a new cable.

Cleaning

The Monitor and probe surface can be cleaned with medical alcohol and dried naturally, or with a clean, dry cloth.

Sterilization

In order to avoid long-term damage to the product, we recommend sterilizing the product only when it is deemed necessary according to hospital procedure. We also recommend cleaning the product before sterilizing.

Bactericidal materials recommended for the Monitor:

Ethanol based: 70% alcohol, 70% isopropyl.

Disinfection

In order to avoid long-term damage to the product, we recommend disinfecting the product only when it is deemed necessary according to hospital procedure. We also recommend cleaning the product before disinfecting.

11. Body Temperature Monitoring

□ Temperature Monitoring

□ Maintenance and Cleaning

11.1 Temperature Monitoring

This Monitor only has one body temperature measurement channel, which allows measuring the body temperature with the body temperature probe.

Body temperature measurement settings

If you are using disposable body temperature probe, insert the body temperature cable into the interface, and then connect the probe and the cable. For reusable body temperature probes, you can insert it directly into the interface.

Attach the body temperature probe to the patient firmly.

The temperature units include Celsius and Fahrenheit; to switch the temperature unit, adjust in ECG & Body Temperature Settings menu.

Warning

Check if the probe cable is normal before monitoring.

Warning

Hold the temperature probe and cable carefully, and roll into a loose ring when the probe and cable are not used. If the cable is pulled too tight, it will lead to mechanical damage.

Warning

Calibrate the body temperature measuring instrument every two year (or according to hospital procedures). When calibration is required, please contact the manufacturer.

11.2 Maintenance and Cleaning

Warning

Before cleaning the Monitor or connected probe, turn off the unit and disconnect the AC power.

Reusable body temperature probe

1) The heating of body temperature probe must not exceed 100°C. It is tolerant to 80°C ~ 100°C temperatures for short time only.

2) Do not disinfect the probe with steam.

3) Only disinfect with detergent containing alcohol.

4) When use rectal probe, cover with protective colloid.

5) When cleaning the probe, hold the head end with one hand, and scrub the probe with moistened lint-free cloth downwards toward the connector with the other hand.

12. Alarm

□ Alarm Category
□ Alarm Level
□ Alarm Indication

Alarm is a means of prompt when the patient monitoring data and the state of the Monitor have abnormalities. The alarm category includes physiological and technical. Alarm indication means include audible alarm, warning lamp flashing and text prompt.

12.1 Alarm Category

Monitor alarms mainly refers to the physiological alarms and technical alarms. Physiological alarms are generated when the physiology of the patient is abnormal. Technical alarms are generated when the Monitor or the application part can't monitor the patient properly.

12.1.1 Physiological Alarms

Physiological parameter alarm requires the following three conditions:

1) Alarm switch is ON;

2) The parameter value is out-of-limit and the duration exceeds the set alarm delay;

3) Alarm occurs in the non-suspension period of alarm.

The physiological alarms of this Monitor include:

FHR1 high / low
FHR2 high / low
Systolic pressure high / low
Diastolic pressure high / low
Mean pressure high / low
Blood oxygen value high / low
Pulse rate value high / low
Respiration value high / low
Body temperature value high / low

12.1.2 Technical Alarms

The technical alarms of this Monitor include:

- Printing abnormal alarms of the system include
  Print compartment is not closed
  Lack printing paper
- The abnormal state alarm of the system include
  Cuff leaks air, pressure measurement timeout
- Prompt messages used by the Monitor, including "FHR coincided", "low battery", etc.

12.2 Alarm Level

Both technical alarm and physiological alarm have corresponding alarm levels, and need different medical treatment.

The physiological alarm levels of the Monitor are set to high, medium, and low, and the technical alarm level is always low.

12.3 Alarm Indication

When the Monitor alarms, there are three ways of alarm indication, audible alarm, warning lamp flashing alarm, and text alarm.

12.3.1 Audible Alarm

Audible alarm is that the Monitor automatically sends alarm sound when the alarm occurs. According to the alarm levels, audible alarms are divided into three types.

- High level audible alarm is 'beep, beep, beep - beep, beep'
- Intermediate level audible alarm is 'beep, beep, beep'
- Low level audible alarm is 'beep, beep'

Note

When different levels of alarms occur simultaneously, the alarm sound is the highest level audible alarm.

Press and hold the button to pause alarm. Press the button to enable alarm mute / reset function.

Alarm mute / reset function is achieved by controlling the alarm sound; while the warning lamp flashing alarm and text alarm are not controlled.

12.3.2 Warning Lamps Flashing Alarm

Warning lamp flashing alarm is that the alarm indicator of the Monitor changes automatically when alarm occurs.

Alarm indicator: Flashing red ---- High level alarm

Flashing yellow ---- Intermediate level alarm

Constant yellow ---- Low level alarm

Note

When different levels of alarms occur simultaneously, the alarm indicator is the highest level alarm indication.

12.3.3 Text Alarm

When the Monitor has abnormal condition alarm, the bottom of the screen displays the text prompt.

Text alarms include:

- FHR1 high / low, FHR2 high / low, systolic pressure high / low, diastolic pressure high / low, mean pressure high / low, blood oxygen value high / low, pulse rate value high / low, respiration value high / low, body temperature value high / low
- Printer compartment is not closed, lack printing paper, FHR coincided, and low battery.
-

Table 12-1 Default Alarm Limits of Parameters

Type	Default Alarm Levels	Lower Range	High Range	Default Alarm Limit Range	Step
FHR	Med	90-120	160-190	120-160	10
Blood Oxygen	Med	85-99	86-100	90-100	1
Pulse Rate	Med	30-235	35-240	50-120	5
Noninvasive Blood Pressure (mmHg)					
Systolic Pressure	Med	30-245	35-250	90~160	5
Diastolic Pressure	Med	30-245	35-250	50-90	5

Mean Pressure	Med	30-245	35-250	60-110	5
Respiration	Med	6-59	7-60	8~30	1
Temperature (°C)	Med	30.0-49.5	30.5-50.0	36.0~39.0	0.5

13. Printing

□ Installing Printing Paper

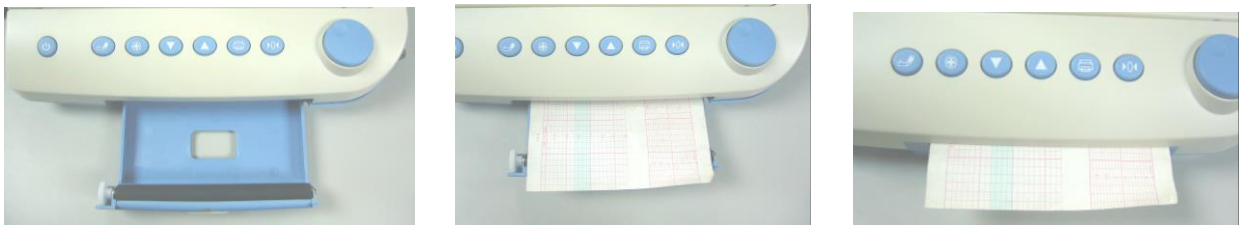
□ Print Settings

□ Print

□ Cleaning the Printing Head

13.1 Installing Printing Paper

Picture 13-1 Slot of Printer



（a） (b) (c)

Picture 13-2 Install the printer paper

Steps to install printer paper:

1. Open the printer slot, spread the uppermost page of printer paper from outside (close to the machine) to inside (close to the user) as picture 13-2(a), then you will see the thermosensitive grid on it, grid of FHR is on the left, grid of TOCO is on the right, (if opposite order, spread from inside to outside, the place of FHR and TOCO will be opposite, and it is wrong operation), and then put the pack of paper inside as picture 13-2(b).

2. Pull out a small length of printer paper, make sure both sides of it are kept in line with the printer two slots as picture 13-2(c).

3. Close the printer door lightly.

CAUTION】

If the printer mechanism is not closed well or no printer paper inside, the monitor will alarm, and will have the following tips in the information area.

Panel Open: Printer panel not closed or not closed completely.

NO PAPER: out of paper

13.2 Print Settings

Rotate the encoder disk, and press the encoder disk to enter the System Parameters interface for print settings:

Print Speed: Adjust the print speed to 1cm/min, 2cm/min, or 3cm/min

Print Density: Adjust the density of print curves to 1, 2, 3, 4, or 5.

The following four operations are to ensure that you can use different sizes of 152mm paper for printing:

Adjust the printing position of TOCO 0

Adjust the printing position of TOCO 100

Adjust the printing position of FHR 90

Adjust the printing position of FHR 210

The adjustment method is as follows:

In System Parameters interface, rotate the encoder disk to select any one of the above four options, press the encoder disk to enter the adjustable state, and the printer starts printing four lines on the printing paper, which are TOCO 0, TOCO 100, FHR 90 and FHR 210 respectively. If any position has deviation, rotate the encoder disk to adjust when the option is in adjustable state so that the position coincides. After adjusted, press the encoder disk to stop printing.

13.3 Print

To print, press the Print button once. When the printer is working, the bottom of the screen dynamically displays the Printing icon, indicating that the printing has started. Press the Print key again to stop printing. In frozen state, all the displayed data of the pregnant woman can be printed.

Clearing jams

If the sound of recorder running and output of the recording paper are abnormal, open the door of the recorder and check paper jams. To clear the jam:

1. Open the printer compartment door;
2. Take out the jammed paper in the printer;
3. Pull out the printing paper for a small fraction, and ensure that both sides of the paper and both sides of the compartment door are substantially parallel;
4. Gently close the printer compartment door.

13.4 Cleaning the Printing Head

The time between failures of thermal print head of this Monitor is more than 20 years. This is only the electrical guarantee. The printing paper and operating environment cleanliness have great influence on the printing. If the print is not clear or some areas can’t be printed, clean the print head in the methods and steps as follows:

1. Turn off the Monitor.
2. Open the printer panel.
3. Insert a cotton swab dipped in anhydrous ethanol onto the thermosensitive element of the print head (visible thin black thermal tape on the print head), move around and wipe gently, especially in the area of unclear printing, and turn on the instrument after a few minutes.
4. If the problem is not completely eliminated, repeat step 3.

14. Rating

□ Description

□ Operation

□ Alarm

14.1 Description

Turn the code-wheel in the monitoring mode, select "", and press the code-wheel to confirm to access the rating mode.

Or

Just touch to access the rating mode.

Red border—The option is chosen.

Green border—The option is adjustable.

The duration between two neighboring time marks is 2 minutes.

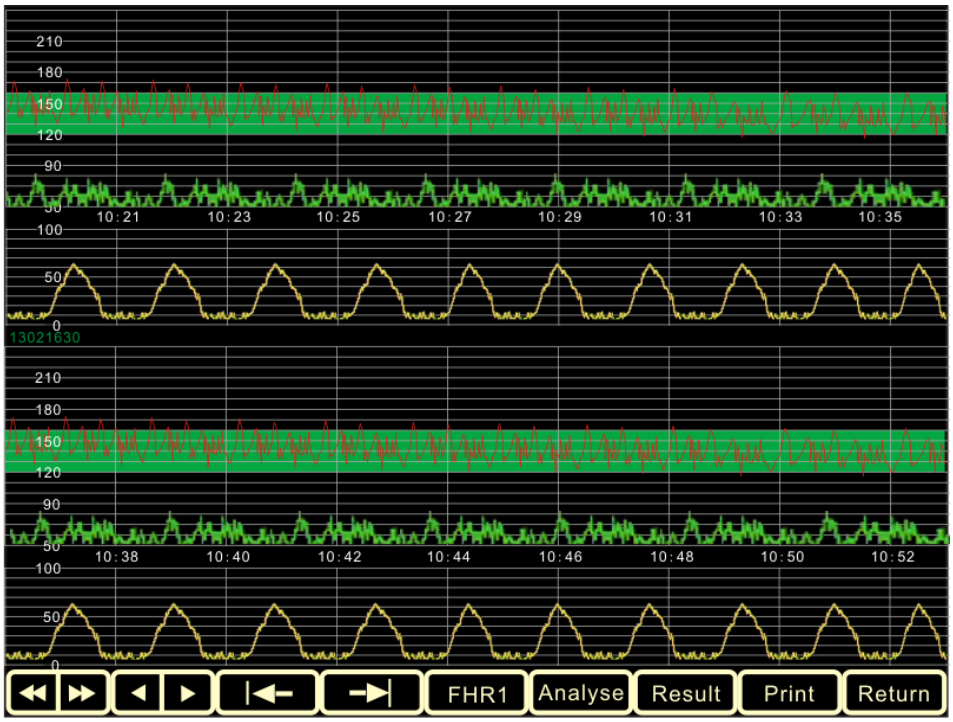
The minimal time duration to be rated and analyzed is 10 minutes and the maximal time duration is 34 minutes.

The selection of channels for rating fetal hearts

Data of only one fetal heart can be rated at a time. When pregnant woman numbers are changed, the selection of fetal hearts will restore to its default value.

The principle follows:

Select FHR with data by default; if both FHR1 and FHR2 have or do not have data, the default is FHR1



14.2 Operation

(1)  : Select record; view the monitoring records of different pregnant woman IDs.

Method of operation: Rotate the encoder disk to select the icon, press the encoder disk to confirm, and then select the records. Rotate the encoder disk counterclockwise to switch to previous ID, rotate the encoder disk clockwise to switch to next ID, and finally press the encoder disk to confirm; the operation is completed;

Method of touching operation: Click  , and you will turn forward to a pregnant woman number. Click  , and you will turn backward to a pregnant woman number.

(2)  : Select area; select the monitoring records of the same ID so that the rating area is shown on the display.

Method of operation: Rotate the encoder disk to select the icon, press the encoder disk to confirm, and then adjust the waveform; rotate the encoder disk counterclockwise to switch to previous five minutes of data, rotate the encoder disk clockwise to switch to next five minutes of data, and finally press the encoder disk to confirm; the operation is completed;

Method of touching operation: Click  , and you will turn 5-minute data forward. Click  , and you will turn 5-minute data backward.

(3)  : Select the starting point, and adjust the starting point of the data to be rated.

Method of operation: Rotate the encoder disk to select the icon, press the encoder disk to confirm, and then the starting scale of the rating data changes from blue to red; move the encoder disk in different directions to move the starting scale of rating data, select the appropriate position, press the encoder disk to confirm, the scale becomes blue and the icon turns red; the operation is completed;

Method of touching operation: Click  , and now the starting scale of data to be rated turns from blue to red. Click the waveform area, and move the scale to the position you click. Click  again to quit the operation.

(4)  : End point selection, to adjust the end point of data to be rated. The operation method is the same as (3). While operations of (3) and (4) are being performed, all the other buttons are non-operable.

(5)  : Select FHR waveform.

Method of operating the code-wheel: Turn the code-wheel, choose the icon, press the code-wheel to confirm, and it will change over to FHR2. Confirm again, and it will

change over to FHR1.

Method of touching operation: Click the icon, and it will change over to FHR2. Click again, and it will change over to FHR1.

(6) Analyse: Analyze the selected data, and mark the results on the corresponding position of the waveform.

Method of operating the code-wheel: Turn the code-wheel, choose the icon, press the code-wheel to confirm, and the analysis result will be displayed. The icon changes over to Cancel. Click again, and the analysis result will be cleared. The icon changes over to Analyse.

Method of touching operation: Click the icon, and the analysis result will be displayed. The icon changes over to Cancel. Click again, and the analysis result will be cleared. The icon changes over to Analyse.

(7) Result: Click the icon, and the rating result will be displayed in a tabular form. Meanwhile, the icon will change over to Cancel. Click again, and the form of rating result will be cleared.

Method of operating the code-wheel: Turn the code-wheel, choose the icon, press the code-wheel to confirm, and the rating result will be displayed in a tabular form. Meanwhile, the icon will change over to Cancel. Press the code-wheel to confirm again, and the icon will change over to Result and the rating result will be cleared.

Method of touching operation: Click the icon, and the rating result will be displayed in a tabular form. Meanwhile, the icon will change over to Cancel. Click again, and the icon will change over to Result and the rating result will be cleared.

(8) Print: Click on this icon to print out the currently selected waveform and rating results table; if “Analyze” or “Rating Results” operation has been carried out, the printed waveform will have analysis remark, and the rating results table has the rating points; if no operation is performed, rating result will not appear, and the rating table is blank;

(9) Return: Click on this icon to exit the rating mode and return to the monitoring mode.

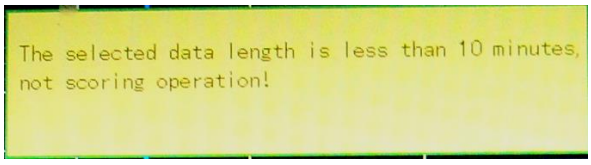
[Note]

- The operations of icons (1) - (5) are to select waveform, which are primary operations; other operations can be performed after these operations;
- The operations of icons (6) and (7) are the scoring process and result display, which are

secondary operations. If one or more operations are performed, but aren't canceled, only option (6), (7) and (8) are available;

- Operation (8) (Print) is effective in both primary operation and secondary operation; The difference is that primary operation can't print the results, while secondary operation can print the results;
- Operation (9) returns to monitoring mode, and is primary operation;
- Before entering the scoring mode, select the scoring criteria (FISCHER and KREBS) in the System Settings.

14.3 Alarm



If the monitoring data length of currently selected pregnant woman ID is less than 10 minutes, the display shows prompt box, and only two operations are available, i.e. scrolling pregnant woman ID, exiting rating and returning to monitoring mode;

If the current data length is longer than 10 minutes, other operations can be performed. If the time length between two scales is less than 10 minutes when adjusting the rating data starting scale and ending scale, the system will prompt data too short, and the rating data can't be shortened any more.

Appendix 1: Troubleshooting

The Monitor has high quality and reliability. If there is any problem, please check and eliminate the problem according to the table below.

Failure	Possible Reason	Solution
No display when unit switched on.	Power cable poorly connected. Power failure, power plug or socket badly connected.	Check adapter and power cable.
Abnormal FHR value	Transducer poorly connected with instrument. Fetal heart not found, the place of transducer is incorrect. No gel or little gel. Fetal/maternal activity. The transducer is broken.	Re-connect. Re-adjust the ultrasound transducer. Add gel. Re-adjust the ultrasound transducer when signal recovered. Replace the ultrasound transducer.
Abnormal TOCO value	Transducer poorly connected with instrument. The place of transducer place is incorrect. No pressure reset No contraction	Re-connect the ultrasound transducer. Re-adjust the ultrasound transducer. Reset the TOCO value. Waiting the contractions appears.
Press the TOCO transducer, the TOCO value does not change or changes a little only.	The initial output value should be re-adjusted. TOCO transducer broken	Re-adjust the inner potentiometer inside the transducer. Replace the TOCO transducer.
Press the marker, no icon is displayed and printed	Bad marker.	Check with a multimeter and confirm.
No sound from speaker	Volume is too low	Increase the volume
Printer is working, but no FHR curve, TOCO curve on paper, or the FHR curve and TOCO curve is not in right area.	The paper is inversely installed. Or right side and left side is inversed.	Re-load the paper with the thermal side facing the printer head.
Print unclearly or some parts can't be printed out	Light printing deepness Unqualified paper Dirty printer head.	Adjust the printer deepness. Replace the paper. Clean the printer head.
Paper goes with alias Printing data position error	Paper is not loaded at its place. Using other brand printer paper Printing position is not calibrated.	Reload the paper. Replace with qualified paper. Re-adjust the printing data position according to this manual.
Rating table isn't printed	Rating switch is off	Enter Maintenance setting, and turn the rating switch to ON

Appendix 2: Specifications

Product name: Fetal/ Maternal Monitor

Power supply: AC 100-240V, 50/60Hz

Power consumption: ≤80 VA

Battery: 14.8V lithium battery

Charging mode: Connect the Monitor to AC power and battery charging is started automatically

Discharge protection: In battery-powered mode, the Monitor will automatically turn off when the battery nearly runs out.

Fetal Heart Rate:

Transducer: Multi-crystals, Wide beam, pulsed doppler, high sensitivity.

Strength: <5mW/cm^2

Working frequency: 1.0MHz

Signal processing: special digital signal.

Measurement range: 50~210 bpm/ 30-240bpm

Alarm Range:

High limit: 160,170,180,190 bpm

Lower limit: 90,100,110,120 bpm

Maximum audio output: 1.5 W

TOCO:

Measurement range: 0~100 units

Maternal SpO2 measurement:

Measurement scope : 70%～99%。

Measurement accuracy: ±3%

Pregnant HR Measurement:

Measurement scope: 30bpm～240bpm

Measurement accuracy: ±2 bpm

Non-invasive blood pressure measurement

Measuring Range

a) Systolic pressure: 6.7~32.0kPa (50~240mmHg)

b) Mean pressure: 3.4~26.6kPa (25~200mmHg)

c) Diastolic pressure: 2.0~24.0ka (15~180mmHg)

Accuracy: ±1.1kPa (±8mmHg) or reading ± 5%, whichever has the greater absolute value;

Pulse rate measuring range: 40bpm ~ 240bpm.

Pulse rate accuracy: ± 2 bpm or reading ± 5%, whichever has the greater absolute value.

Measurement mode: manual / automatic NIBP measurement;

Body Temperature

Range: 0~50°C

Resolution: 0.1°C

Accuracy: ±0.1°C (excluding sensor error)

Display:

The LCD displays FHR, TOCO, FM, maternal parameters, time, date, volume and so on, it support freeze and review monitor data.

Resolution: 800x600

Dimension: 350 x 320 x 85 (mm) (L X W X H)

Net weight: 3.5kg

Environment

Working environment: Temperature: +5℃ ～ +40℃; Humidity: 30%~75%

Atmospheric pressure: 86kPa ～ 106kPa

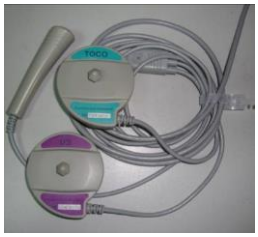
Transport and storage temperature: Temperature: -10℃ ～ +55℃; Humidity: < 93％

Atmospheric pressure: 86kPa ～ 106kPa

Probe acoustic output: In accordance with the provisions of 1992 IEC1157, negative peak sound pressure shouldn't exceed 1 MPa, and the beam intensity shouldn't exceed 20mW/cm^2. Spatial peak instantaneous average intensity density shouldn't exceed 100mW/cm^2. The sound intensity of this model does not exceed 5mW/cm^2. Sound output meets the conditions exempted from publication.

Coupling agent (GEL): Viscous water-based compound, no skin irritation or allergy, chemically stable, bacteriostatic.

Appendix 3: Accessories

	Three-in-one probe FHR probe Uterine contraction pressure probe Fetal movement mark button
	FHR secondary probe: for twins
	Fetal wake-up device
	Blood oxygen finger cot
	NIBP cuff
	ECG cable
	Insurance tube
	Power cord
	Thermal printing paper
	Belt

Appendix 4: Symbols

Symbol	Note	Symbol	Note
FHR1	Three-to -one socket	FHR2	FHR2 socket
WARER	Fetus waker socket		BF-applied part, not against Defibrillator.
	CF-applied part, against Defibrillator.		Volume up key
	It indicates that this device is BF applied devices, is against Defibrillation function.		Volume down key
	on-off key		Print key
	Freeze key		TOCO reset key
	Battery indicator	IPX1	Protective grade, against water splash.
	Power indicator		In compliance WEEE Dispose standard.
	Charge indicator		In reference to User Manual
	Equalqpotential		Refer to attached documents.

Appendix 5: Guidance and Manufacturer's EMC Declaration

Table1 Guidance and manufacture's declaration - electromagnetic emission - for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emission		
The Fetal/Maternal Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal/Maternal Monitor should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment Guidance
RF emissions EN 55011	Group 1	The Fetal/Maternal Monitor 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 EN 55011	Class A	The Fetal/Maternal Monitor 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 EN 616000-3-2	Class A	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Table2 Guidance and manufacture's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The Fetal/Maternal Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal/Maternal Monitor should assure that it is used in such an environment.			
Immunity Test	EN 60601 test level	Compliance Level	Electromagnetic environment-Guidance
Electrostatic discharge (ESD) EN 61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient/burst EN 61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±2KV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1KV differential mode ±2KV common mode	±1KV differential mode ±2KV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% UT (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles	<5% UT (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Fetal/ Maternal Monitor requires continued operation during power mains interruptions, it is recommended that the Fetal/Maternal Monitor be

	70% UT (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	powered from an uninterruptible power supply or a battery.
Power frequency(50/60Hz) magnetic field EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table3 Guidance and manufacture's declaration - electromagnetic immunity - for EQUIPMENT AND SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
The Fetal/Maternal Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Fetal/Maternal Monitor should assure that it is used in such an environment.			
Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF EN 61000-4-6	3Vrms 150k to 80MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Fetal/Maternal Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80MHz to 800MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800MHz 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 meters (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF EN 61000-4-3	3V/m 80M~2.5GHz	3V/m	
NOTE 1 At 80 MHz and 800MHz, 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.
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Fetal/Maternal Monitor are used exceeds the applicable RF compliance level above, the Fetal/Maternal Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Fetal/Maternal Monitor. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table4 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 Fetal/Maternal Monitor			
The Fetal/Maternal Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Fetal/Maternal Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter(m)		
	150kHz to 80MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	80MHz to 800MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800MHz to 2.5GHz $d=[\frac{7}{E_1}]\sqrt{P}$
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	
100	12	12	
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix 6: Table 201.103 Acoustic Output Reporting Table

Transducer mode: PW Doppler

Frequency:1.0MHz

Index Name			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
Max. Index			0.04	-	-	0.015	0.18	（a）
Associated acoustic parameter	$p_{r.a}$		0.036					
	P			-	-		30	#
	Min of $[P_\alpha(z_s). I_{ta,\alpha}(z_s)]$					3.06		
	z_s					1.6		
	z_{bp}					1.8		
	z_b						1.6	
	z at max.$I_{pi.\alpha}$		1.6					
	$d_{eq}(z_b)$)						3.6	
	f_{awf}		1.0	-	-	1.0	1.0	#
	Dim of A_{aprt}	X		-	-	Φ1.2	Φ1.2	#
		Y		-	-	Φ1.2	Φ1.2	#
Other Information	t_d		108.73					
	prr		1250					
	p_r (Max Ipi)		0.038					
	d_{eq}(Max . Ipi)						3.6	
	$I_{pa.3}$(Max MI)		0.02					
	Focal Length	FLx			-	3.14		
		FLy			-	3.28		
Operating Control Conditions	-		-					
	-		-					
	-		-					

Note1: Data should only be entered in one of the columns related to TIS.

Note2: Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note3: If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the columns related to TIS, TIB or TIC.

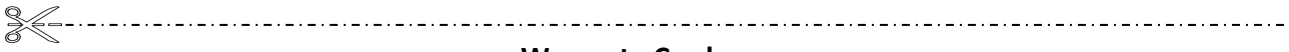
Note4: If the requirements of 201.12.4.2a) are met, it is not required to enter any data in the column related to MI.

Note5: Focal Length is a NOMIMAL value

(a) Intend use does not include cephalic so TIC is not computed

No data reported

To protect your rights of repair service, please take a few minutes to fill out the Warranty Card as follows:



Warranty Card

Product Name		
Product Type		
No.		
Date of Purchase		
Warranty Period		
Client Information	**Name**	
	Telephone	
	Fax	
	Address	
Sources of information	☐ **Internet** ☐ **Exhibition** ☐ **Magazine** ☐ **Recommended by salesman** ☐**Other**_____	
Assessment