Fetal/Maternal Monitor

User Manual

Version: V1.1
Date: 04.2020
No.: 1.263.0250-11

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.

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.

Storage and transportation

Storage: The packaged instrument should be stored at an ambient temperature of -10°C ~ +55°C, relative humidity less than 93%, no corrosive gases and ventilation good indoors.

Transportation: Shock, vibration and humidity should be prevented during transportation.

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Chapter 1 Preface

- Introduction
- Safety Guide
- Recommended clinical application

1.1 Introduction

This Manual will describe the performance indicators, use and maintenance 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 it in conformity with safety standards.

This User's Manual is attached with the device. It should be placed near the Monitor for easy reference.

1.2 Safety Guide

L8ME is BF applied device. It is portable fetal monitor.

 indicates BF applied parts;

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.
- Do not use the device in the presence of flammable gases such as anesthetic agents, or it may cause an explosion.
- Don't throw the battery into fire, or it may cause an explosion.
- Don't touch the signal input or signal output connectors and patient at the same time
- The device can be used on one patient at one time.
- To keep mother safe, please do not use other electronic device which connect with mother, such as Pace

Maker or other electronic stimulator.

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

Caution

- ❖ This device must be maintained by qualified engineers.
- ❖ This device is designed to work continuously, water drop proof type, pay attention to avoid to be splashed.
- ❖ Keep this device clean and avoid vibrating.
- ❖ No high temperature disinfection, electron beam or γ-ray sterilization.
- ❖ Electromagnetic interference – ensure the operating environment of the device away from strong interference, such as wireless transmitters, mobile phones or other interference.
- ❖ Before using the device, please check if there is any damage of equipment that may affect the patient's safe or the device performance. The recommended check period is every one month or shorter. If an obvious damage is found, it should be solved before use.
- ❖ 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.
- ❖ After the effective life of this device, Please send it back to the manufacturer according to local rules for recycling.
- ❖ Disposal the battery properly according to local rules after the capability of battery run out.
- ❖ If this device is not in use for a long period of time, remove the battery in time.
- ❖ The battery should be stored in a cool and dry environment.
- ❖ When store battery, please don't mix it with metal objects to avoid short-circuit accident.
- ❖ 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.
- ❖ Don't use this device immediately when it is transferred from a cold environment to a warm and moisture place.
- ❖ To ensure electric installation safety, the environment shall be reasonably dust free, without corrosive or combustible gas, or extreme temperature or humidity.
- ❖ Please stop operating if this device is splashed or has water drops.
- ❖ Although the device 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 probes which should not be dropped or knocked.
- ❖ The use of water based gel supplied by certificated suppliers is strongly recommended. Oil based gels can damage the probe and must not be used. The use of oil based gels will invalidate your warranty.
- ❖ Excess gel should always be wiped off after use. The probe faceplate, probe body and main unit can be cleaned with a damp cloth impregnated with a mild disinfectant or detergent.
- ❖ A soft cloth dampened with sodium hypochlorite 1000ppm may be used for cleaning and disinfection.
- ❖ The main unit, probes and other accessories can't be disinfected by steam.
- ❖ TOCO probe is non-waterproof type, don't use Gel and avoid any liquids into it.
- ❖ The power wire should be inserted into the socket with three pins, the ground wire mustn't be removed. Don't use the socket with bad connection.
- ❖ After use, do not wire the probe cable together with the probes to avoid damage.
- ❖ Do not turn off the volume during monitoring, it is very important to monitor fetal heart sound.

- ❖ 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.
- ❖ Bluetooth maximum communication distance is 5meters. Distance between Bluetooth probe and main device should be within 5 meters, otherwise there may be signal loss and unstable sound.

1.3 It is needed to confirm fetal alive 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 probe is used:
  - ➢ you can pick up signals from 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 probe.
- ➢ Ultrasonic probe 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

It is intended to be used to monitor Fetus Heart Rate, Fetal Movement, mother TOCO.

Contraditions: Do not use during Defibrillation, Electrosurgery, or Magnatic Resonance Imaging(MRI).

Chapter 2 Installation

- Unpacking and checking
- Power supply
- Starting up
- Connecting the probe
- Checking the Printer

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.

- Main unit
- Power cord and power adapter
- ultrasonic probe U/S, uterine contraction probe TOCO and an event marker
- Second ultrasonic probe (optional)
- Belt
- Printing paper
- Certificate
- Warranty Card
- User 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.

Note: If device get moist accidentally, please put in a well-ventilated environment for 24hours.

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 power cord along with goods. Plug the power cord into the power socket and the other end into power outlet which has grounding wire.

Device keeps running after 30 seconds power-off.

[Note]Connect the power cord to the dedicated outlet in the hospital.

Quarterly checkup of the power adapter and power cord is needed. If any failure, please replace them. If grounding does not work, please use battery.

Turn the power switch to "-".

Caution: AC power cable need regular checkup, usually every 3 months. Please replace it if there is any problem.

Caustion: AC power need to connect with good power inlet with grounding connection. If there is grounding

problem in the power inlet, please use battery power.

2.2.2 Battery Power

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 assumption. When the battery is running low, the battery symbol in the upper right corner of the screen will flash, reminding the user to charge as soon as possible.

It will take about 2.5hours from exhausted status to 90% of power.

Warning:

Please disconnect with AC power if not using of the device for a long time.

Even if the device 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.

Battery lifetime will get shorten after long time using. If battery working time is less than 1hour after fully charging, please replace it.

2.2.3 Battery Installation

Firstly, user must take off AC power from the device, then put rear panel upward, use screwdriver to open battery cover, install battery correctly and connect the cable. Then fix the battery cover.

Warning: Battery positive end and negative end need to be correctly installed. Otherwise it will burn component or cause battery explosion.

2.3 Starting Up

2.3.1 Switch on

Press and hold the Power button for about 2 seconds to enter the starting up state, and the alarm LED turns green. After 40 seconds of self tests, it goes to the main screen and ready for operating.

[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 service engineer of the company.

2.3.2 Switch off

Press and hold the Power button for about 2 seconds until it prompts: "Switch off", Click "Yes" to switch off the machine; Click "No" to cancel switch off.

2.4 Connecting the Probe

Connect the needed probe to the Monitor and correct place on patient.

[Note]For the correct connection of probes and related requirements, see Chapter 5.

2.5 Checking the Printer

Check if paper runs out after pressing "Printing button."If no paper out, please check Chapter 10.

Chapter3. Monitor Overview

- Monitor Overview
- Front View
- Operation and Functions of Keys
- External Interfaces

3.1 Monitor Overview

This device composes of main device, wireless probes.

Functions:

- ❖ Monitor and display FHR, TOCO, and FM.
- ❖ Generate FHR sound, sound level is adjustable, FHR1 and FHR2 sound channel is selectable.
- ❖ Visual and audible alarming function
- ❖ 3 level alarming, user selectable
- ❖ Alarm silence and mute function
- ❖ Thermal paper printout, with monitoring data and graph printout

3.2 Front View

The front panel of the Monitor is shown in Fig. 3-1.

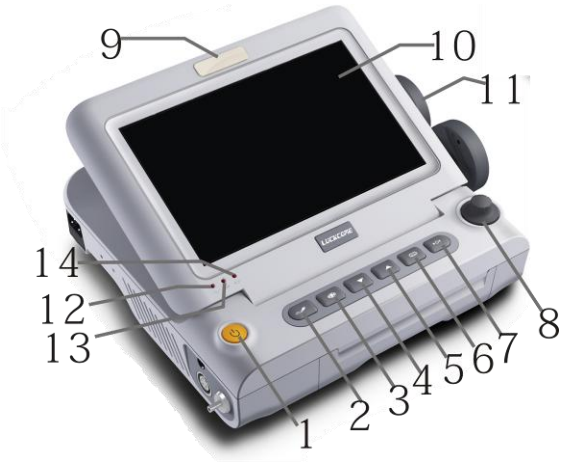


Fig 3-1 Front View

①Power button ②Blood pressure measuring button ③Freeze button ④Volume- button ⑤ Volume+ button ⑥Print button ⑦UC Reset button ⑧Rotate knob ⑨Alarm indicator ⑩Display ⑪Probe holder ⑫ AC indicator ⑬Charging indicator ⑭Battery status indicator

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.

2. Blood pressure measuring button: No use

3. Freeze button: Press this button once to freeze the system, and the main interface displays “Freeze”; 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 the setup surface, switch cursor to the left.

5. VOL+ button

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

In the setup surface, switch cursor to the right.

6. Print button

Before monitoring, press it, mother information interface prompt.

After monitoring finished, press it, activate record printout, click analysis and scoring, and realize scoring printout.

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. Rotate knob

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

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: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, it shows that the Monitor is connected to the external AC power.

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

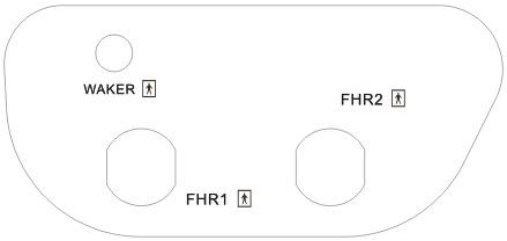


Fig 3-2. Right panel

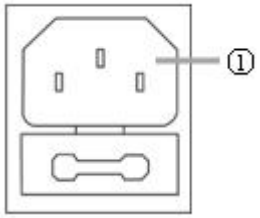


Fig 3-3. Left panel

Fig 3-4. Rear panel

Port Introduction

FHR1： Wireless FHR1 probe

FHR2： Wireless FHR2 probe

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

①：AC adapter input socket

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

NET： network port of central nurse station

RS232：retained

Chapter 4 Monitor Display Interface

- Overview
- Main Interface
- Setup Interface

4.1 Overview

Interface and functions are as below:

Function / Interface	(FHR)	(TOCO）	（FM）
3 Parameters	√	√	√
Big font	√	√	√

4.2 Main Interface

The display of the Fetal/Maternal Monitor is a 10.2-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 Fig 4-2.

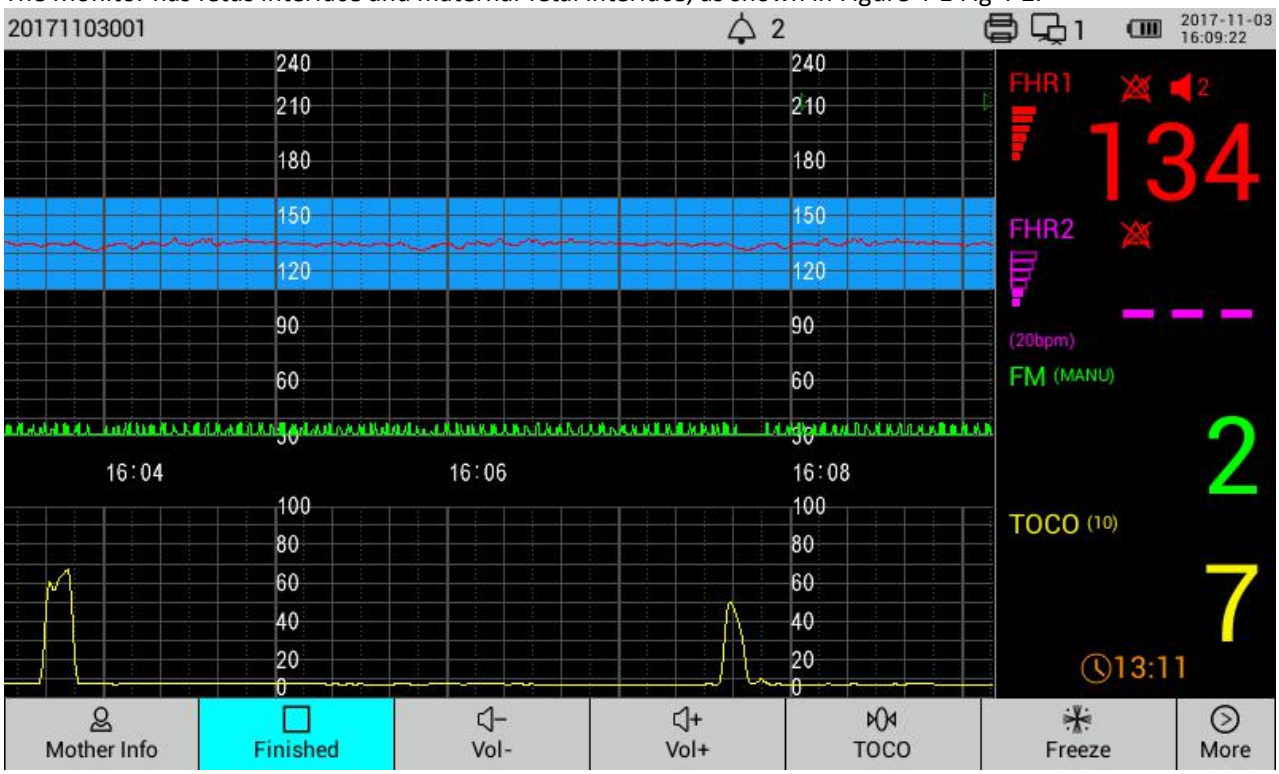


Fig 4-1 3 Parameter Interface

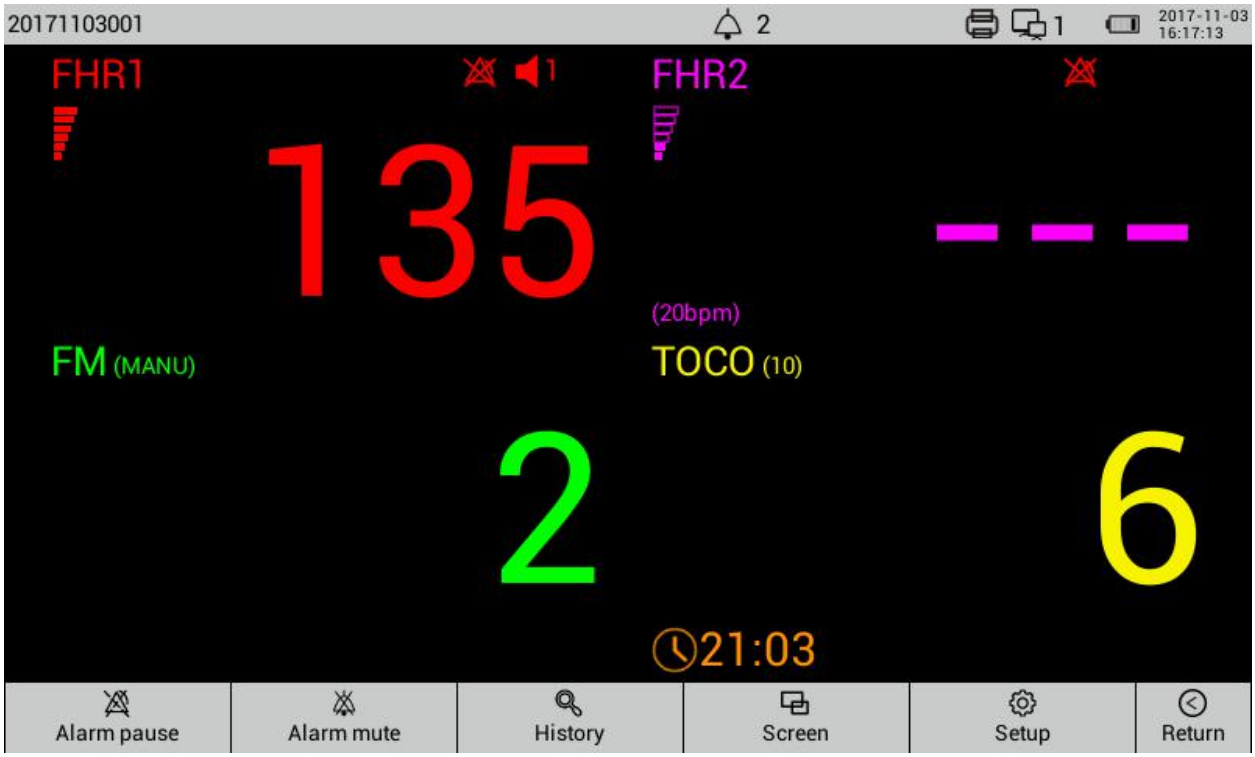


Fig.4-2 Big-font Interface

The monitoring interface has four sections:

①Wave area ②Numeric area ③Information area ④ Function button area

①Wave area

Three parameters interface: Waveforms from top to bottom are: FHR waveform (shown as two FHR waveforms for twins, the interval between two waveforms is determined by the twin separation value set by the system), uterine contraction pressure waveform, and fetal movement waveform (the user can choose to display or close the waveform as required);

② Numeric area

1） FHR1/FHR2 :Hear beat per minute (Unit: times/min, bpm)

Alarm off indicator: **Cross** appeared after choose alarm off.

3 Speaker volume indicator: Level 0– Level 7, sound goes up from Level 0 to Level 7.

(20bpm) FHR 1 and FHR 2 offset. FHR 2 moves 20bpm down.

FHR signal strength indicator bar: bad, normal， good

2） Fetal Movement: Manual/Auto

Manual: Press FM marker to count FM times

Auto: Fetal monitor will auto count FM times by built-in algorithm.

3） TOCO (0-100): It is meaningless if waveform freeze.

(10) TOTO zeroing value, adjustable.

4） Monitored Time Length

User can setup parameters in Setup interface.

③ Information Area

It lies at top of display screen. From left to right, it display Mother Information, Alarm Information, Alarm sound icon, Alarm pause icon, Bluetooth Icon, Printing Icon, Network icon, Power icon, Date/Time.

Mother Info: Display mother ID and name. After power on, device will automatically generate mother ID based on Date and Time.

Alarm Info: Technical Alarm/Physiological Alarm. Left side display Technical Alarm; right side display Physiological alarm.

Alarm sound: 1 indicate sound volume is Level 1; 1 **Alarm silence**. During Alarm Silence, if new alarm event occur, it will activate alarming. Alarm silence is ended.

Alarm Pause: Click Alarm pause to activate Alarm Pause countdown 02:00: 2 minutes.

During alarm pause, if there is technical alarm, device will trigger alarm; alarm pause is ended.

During alarm pause, if there is physiological alarm, no alarm is triggered.

Bluetooth Icon: If probe type is "Bluetooth", Bluetooth function will auto turn on.

Bluetooth On; Bluetooth searching; Bluetooth connected; Bluetooth disconnected.

Printer: If printer works, display ; if printer does not work, display

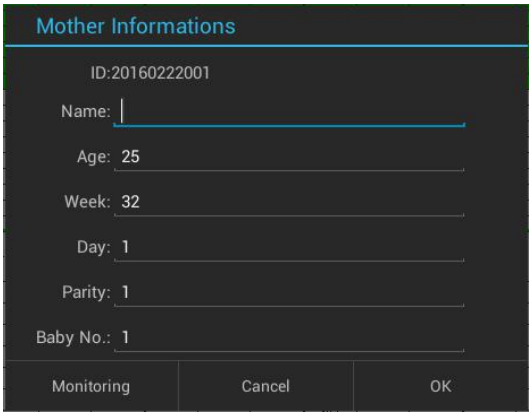
Network: ---WiFi connection; ---Disconnected; ---Wired connection; not connect with Central station; ---Connect with CMS; The Number after this icon is Bed No. Go to "Setup-System "to set up Bed No.

Power: If connected with AC power, display; If bars keep rolling, indicate power charging; If fully charged, display, Device will automatically use AC power upon connected with external power supply.

Date/Time: Present Date and Time.

④ Button area (Touch operation)

【Mother Info】: Press this button to enter the Mother Information interface. In this interface, you can type in or modify the information.



After input mother information, press 【Monitoring】 to start monitoring; Click 【Finished】 to close this interface without saving present setup. Click “OK ” to close this interface and saving setup.

【Monitoring】: Click this button, mother info input interface will prompt; after input mother information, press this button to start monitoring, and the button will change into【Finished】; Click【Finished】to stop monitoring.

【Vol -】: Click this button, the volume of the fetal heart decreases.

【Vol +】: Click this button, the volume of the fetal heart increases

【Toco】: Press this button to preset TOCO calibration value.

【Freeze】: Press this button once to freeze the system, and the main interface displays “Freeze”; press it again to real-time scanning state.

【More】:: Press this button to find hidden functions.

【Alarm pause】: Click this button, enter Alarm pause state, the duration is 2min.

【Alarm mute】: Click this button to enter the alarm mute state.

【History】: Go to Record List

【Screen】: Click to change Interface

【Setup】: Press this button to enter the Setup interface.

【Return】: Press this button to go back to the previous menu.

4.3 Setup Interface

4.3.1 Main menu:

Non-monitoring mode, Press ”More”---“Setup”, and enter the Setup interface.

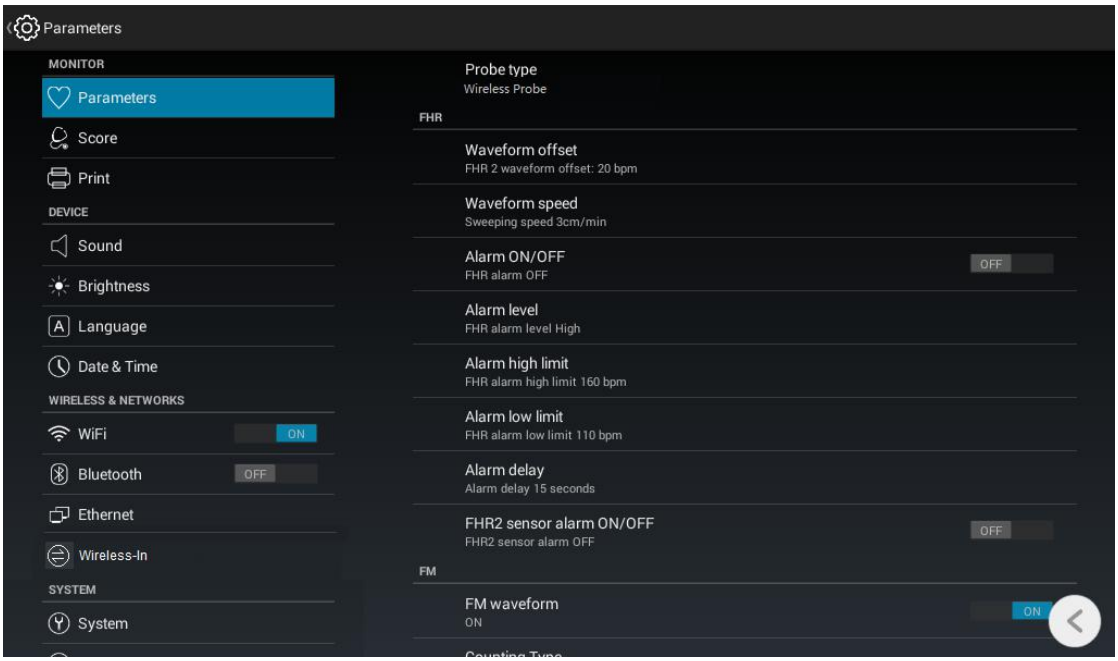


Fig 4-3 Setup Interface

4.3.2 Setup

Parameters—Set up probe type, FHR, TOCO, Fetal Movement

Score--Fischer and Krebs

Print-- Set the printing parameters.

Volume-- Volume Level

Brightness--Set the brightness of the screen.

Language--Choose language

Date and time--- Set the system date and time. After setup, need to power off/on machine to save it.

WiFi--WiFi On/Off

Bluetooth--Bluetooth On/Off. Choose wireless probe, Bluetooth auto On; choose wired probe, Bluetooth auto Off;

Ethernet—Wired network On/Off

System--Setup parameters, FHR Range, Mode, Bed Number, Central Station IP, Background color, Hospital Name, and so on.

About-- Model No., Software version, resolution.

4.3.3. Setup Interface operation

Two ways:

4.3.3.1 One way: Using touch function, touch it to start setup

4.3.3.2 Rotate Knob + Volume up/ Volume down. For example:

FHR upper limit setup:

1) Rotate the knob to left side “Parameter”, press the knob, corresponding setup items will display at right side;
2) Press Volume up, cursor move to right side;
3) Rotate the knob, cursor move to ”FHR-upper limit”, press Rotate Knob, return to Setup Interface. Finish setup.
4) Rotate the knob, cursor move to setup to be chosen, press Rotate Knob and confirm, return to Setup interface, finish setup.

Chapter 5 Wireless Probes Introduction

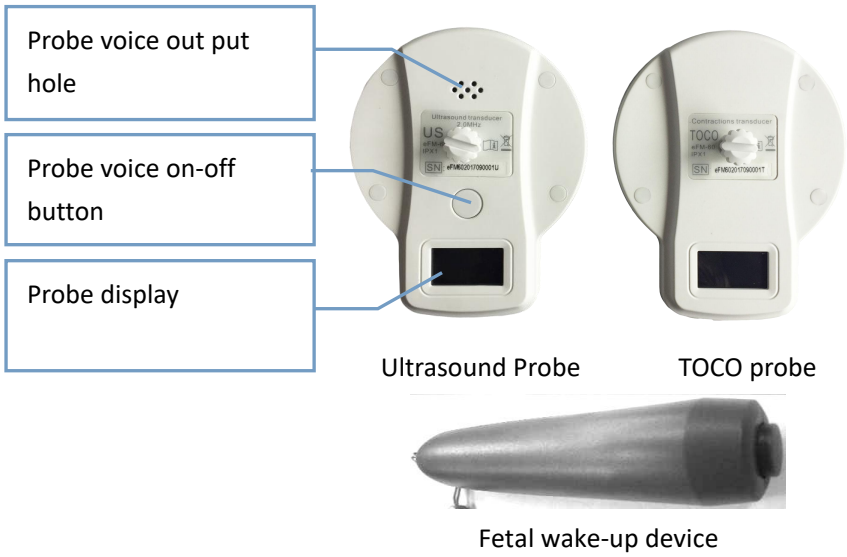
Appearance

Probe display

Probe paring and impairing

Battery Installation and replacement

5.1 Appearance

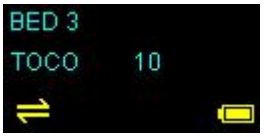


Ultrasound Probe TOCO probe

Fetal wake-up device

5.2 Probe Display

FHR1 Connected



TOCO connnected

BED 3：ID No. It can be changed in setup of main device. After new setup, user needs to repairing the probes.

US1/US2/TOCO: US1- Ultrasound Probe 1(FHR1), US2- Ultrasound Probe 2(FHR2)， TOCO- TOCO probe

：Probe battery status. ：Charging.

：Turn off probe voice ：Turn on probe voice

：Means good connection between probe and main device; if not well disconnection, shows .

5.3 Probe pairing and impairing

5.3.1 Probe pairing steps:

1）How to pair US1/US2/TOCO probe:

i） Place the probe on the socket;

ii） Setup→Internal wireless→Click US1 pairing/US2 pairing/TOCO pairing;

iii） Log out setup then paired ok

2） How to pair event marker

i) Setup→Internal wireless；

ii) Press marker button manually(do not release), click FM pairing, then release marker button;

iii) Log out setup and re-start the machine, then paired ok

Note: US,TOCO probes can not be paired if they are already connected

The probes can not be re-paired if the fetal monitor has connected with other wireless probes

Note： 1）After successfully paired, probe will indicate type of probe, setup ok, bed No., and it will 'di' when you press the button.

2） The wireless ID can't be repeated in the same room to avoid wireless probes mixture

3） To avoid any influence WLAN has on the fetal monitor, 84-99 working channel is recommended; Recommended working channel like below:

Sheet 1 Wireless ID and related channel

Wireless ID	1	2	3	4
Channel2	93	97	87	91

Wireless ID	5	6	7	8
Channel2	85	89	95	99

Wireless ID	9	10	11	12
Channel2	84	88	92	96

Wireless ID	13	14	15	16
Channel2	94	98	86	90

Wireless ID	17	18	19	20
Channel2	93	97	87	91

Wireless ID	21	22	23	24
Channel2	85	89	95	99

Wireless ID	25	26	27	28
Channel2	84	88	92	96

Wireless ID	29	30	31	32
Channel2	94	98	86	90

【Note】Any of Wireless ID or Channel2 is re-set, it shall be re-paired with probe

5.3.2Method to unpair probes

1）Unpair US1/US2/TOCO probe

i）Take the probe away from the socket;

ii）Change ID: Setup->Internal wireless->wireless ID;

iii）Click any of US1 pairing/US2 pairing/TOCO pairing;

iiii） Log out setup, if the probe connection symbol shows disconnection, it means successfully unpaired.

2）Unpair event marker

i）Change ID: Setup->Internal wireless->wireless ID;

ii）Click FM pairing;

iii） Log out setup, press event marker button, if main unit is no response, it means successfully unpaired.

5.4 Battery charging, capacity and replacement

● Charging

Return the probes to socket for charging.

● Power indication

An icon of battery power will display on the screen after powering on, different icons indicate the various conditions of battery capacity, see the meaning below:

 : The battery level is full;

 : The battery level is low and requires charging;

 : The battery is run out and requires charging immediately.

【Note】: In battery mode, the device will shut down automatically when the battery power is closed to exhaust.

【 Note 】 Battery can be only replaced by the professional maintenance staff, please do not disassembly by users to prevent any negative effects on probes.

Chapter 6 FHR Monitoring

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

6.1 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 1.3 Confirming 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 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 manual palpation of fetal movement (especially if the applied pressure is too large).

△ Movement of the ultrasonic sensor.

6.2 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.

6.3 FHR Setting

6.3.1Setup-Paramter-FHR

Waveform Offset (for twins): If monitoring twins, to avoid FHR2 wave form overlap 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.

Waveform speed: Adjust wave form sweeping speed; available options are 1cm/min,2cm/min,3cm/min.

Alarm ON/OFF: On- FHR out of range alarms; Off- FHR out of range, no alarm.

Alarm Level: high, medium and low.

Alarm high limit: High limit of FHR alarm; options are 160, 170, 180, and 190 bpm.

Alarm low limit: Low limit of FHR alarm; options are 90, 100, 110, and 120 bpm.

Alarm Delay: Trigger time; the time interval from FHR out--of--limit to alarm started; options are 15 seconds and 30 seconds; Setup as On, an alarm sound generated when the trigger time is due.

FHR2 sensor alarm ON/OFF: On- Generate alarm if FHR2 probe disconnected; Off- Do not generate alarm if FHR2 probe disconnected. (It is only effective when the probe type is wired.)

6.3.2 Setup-Sound

FHR sound channel: FHR galloping sound channel, FHR 1/FHR2 alternative

FHR1 sound level: The volume outputted is from FHR1, 0-7 available

FHR2 sound level: The volume outputted is from FHR2, 0-7 available

Alarm sound level: The volume outputted is from alarm voice, 1-3 available

[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 clinicians can detect abnormal FHR on time.

6.4 FHR Monitoring

FHR measurement: 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.

6.4.1 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.

6.4.2 Single Fetus Monitoring

Monitor one fetus. Identify the fetal heart position and tie the ultrasonic probe according to 6.4.1 FHR Signal Acquisition Methods and Steps.

In the monitoring process, the Monitor will display the FHR value and corresponding curve. If the FHR is greater than the upper alarm limit or lower than the lower alarm limit, the indicator on the front panel of the Monitor will change the color and flash according to the alarm levels. If the time of FHR out--of--limit exceeds the preset alarm delay, the system will alarm if the alarm is enabled, the top of the screen has prompt; if the alarm is disabled, alarm prompt and alarm icon will not appear.

6.4.3 Twins Monitoring

Monitor twins. Identify the fetal heart position and tie the master and secondary ultrasonic probes according to 6.4.1 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).

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

In the monitoring process, the Monitor will display two FHR values and corresponding curves. To monitor single fetus with twins monitor, please select FHR1 as the fetal tone channel, otherwise you can’t hear the fetal heart tone.

6.5 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.

6.6 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.

6.6.1 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:

Alcohol--ethanol 70%

6.6.2 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%

Caution:

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

Chapter 7 Uterine Contraction Pressure Monitoring

- Introduction
- TOCO Settings
- TOCO Monitoring

UC Reset mark: 

7.1 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.

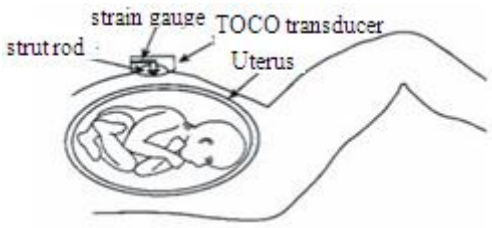


Fig. 7--1 Uterine Contraction Pressure Monitoring Diagram

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.

7.2 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.

7.3 TOCO Monitoring

1. Connect the probe

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

Warning:

Do not monitor patients underwater.

2. 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.

3. 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.

Chapter 8 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: 

8.1 Introduction

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.

8.2 Fetal Movement Monitoring

This Monitor features automatic and manual fetal movement monitoring.

Fetal movement intensity curve: 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.

Fetal movement counting mode: “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.

Fetal movement counting 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.

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]:

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.

8.3 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.

8.3.1 Fetal Wake-up Device

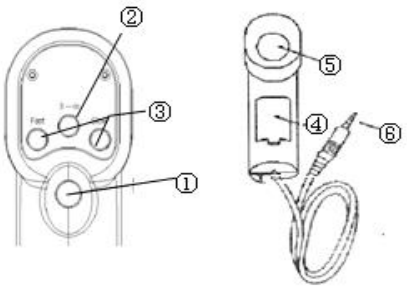


Fig.8-1 Wake-up Device and Connecting Cable

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.

8.3.2 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. 8-2)

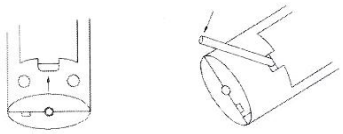


Fig. 8-2 Removing the Battery Cover

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. 8--3.

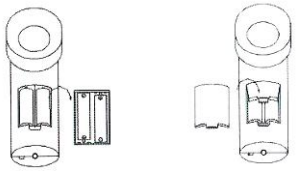
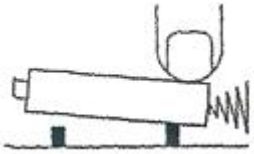


Fig. 8-3 Loading the Batteries

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.

8.3.3 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.

Chapter 9 Records review and Score

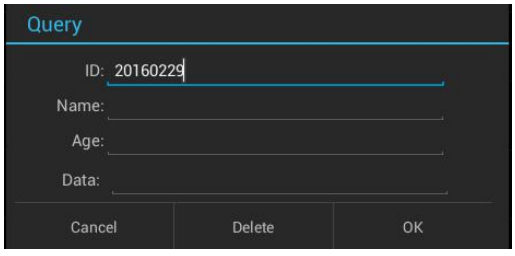
- Records list
- Data review
- Score
- Warn
- Record export
- Record delete

9.1 Records list

Press ‘More’->‘History’ to Record Interface. See Fig. 9-1.

Fig. 9-1 Records list

Press  go to Query interface,user can input Mother ID/name/age/date to search.



【Cancel】Can not check record
【Delete】 Empty check request
【OK】 Confirm checkup and close dia-box.

9.2 Data review

Check the data of a record. See Fig. 9-2.

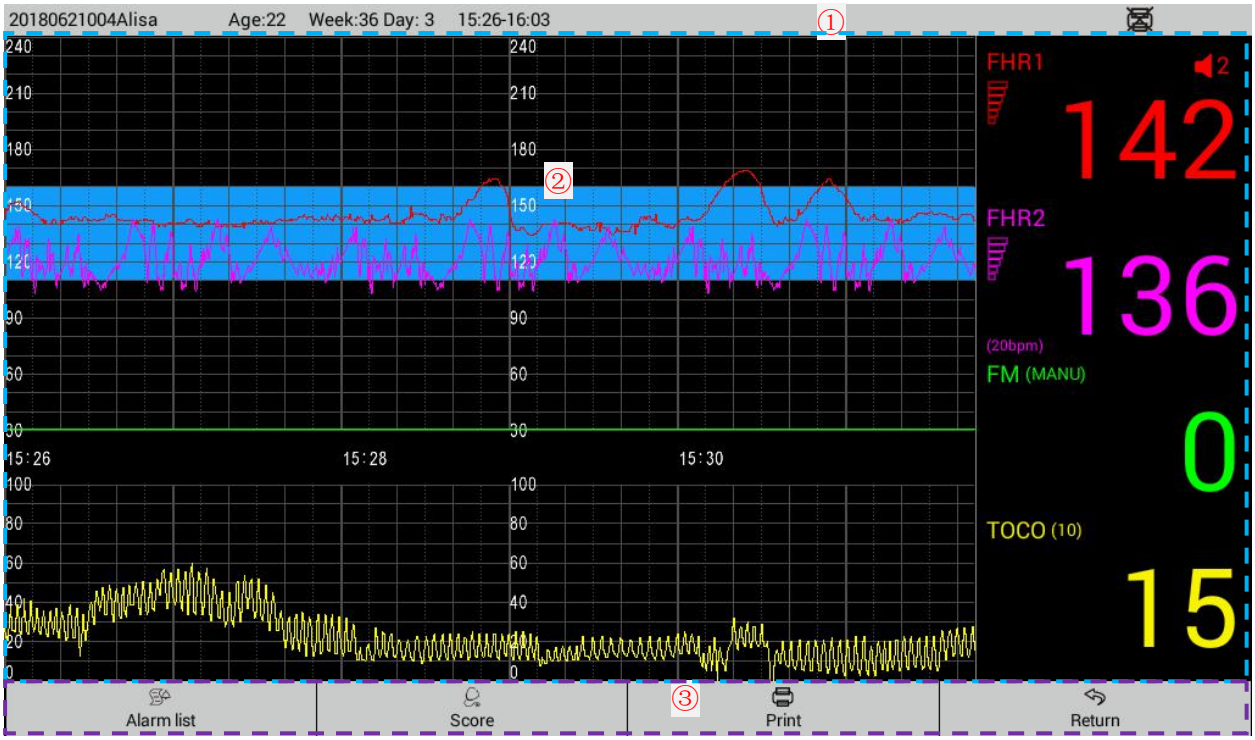


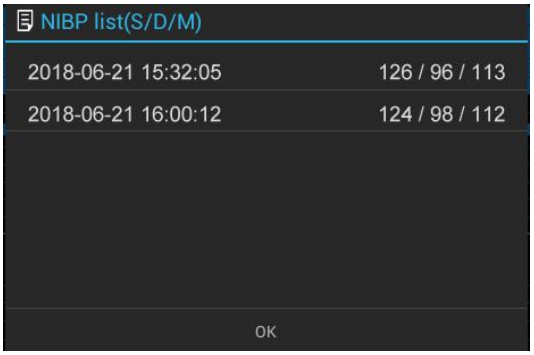
Fig 9-2 Data review

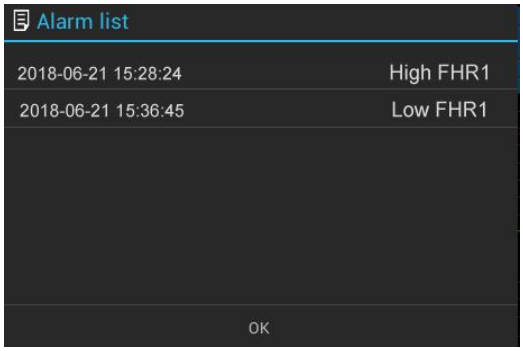
①Monitoring information

ID/name/age/gestational weeks and days/monitoring start time and finish time/the printer state.

② Waveform area: From top to Bottom, FHR wave, FM wave, TOCO wave. User can rotate the knob to left/right to check the waveform.

③ Button





NIBP list: the corresponding NIBP record

Alarm list: the corresponding alarm information of the record

Score: enter the scoring interface. If monitoring duration is less than 10min, no scoring.

Print: start/stop printing

Return: return to the records list interface

9.3 Score

9.3.1 Score Interface

At the Data review interface, click 

to enter the Score interface. (see Fig 9-3)

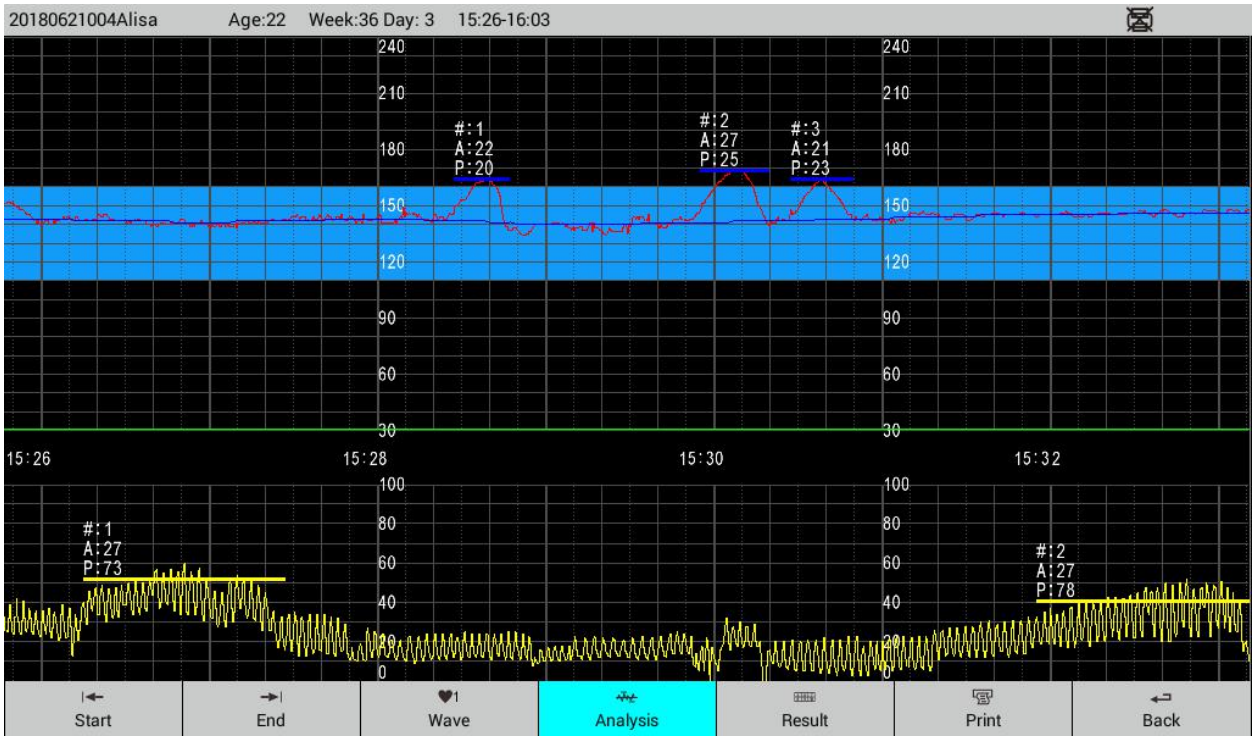


Fig 9-3 Score Interface

The duration between two vertical lines is 1minute.

Scoring: Minimal time duration is 10-minute and the maximal time duration is 120-minute.

Each time, user can only choose one FHR for scoring.

9.3.2 Operation

(1) Start: Click it, cursor turns to red; click waveform area, move the cursor to a starting point for score. Click again to exit.

(2) End: Clict it, cursor stops to a stop point for score.

Start point and Stop point: minimum gap is 10min; if less than 10min, alarm prompt: Data length is less than 10min. Please re-select.

(3) Wave: Choose FHR1 score or FHR2 score.

(4) Analysis: Analyze the selected data, and display results near to the selected waveform.

Click the icon, and the analysis result will be displayed. Click again, and the analysis result will be cleared.

Blue hyphen: FHR acceleration

Red hyphen: FHR Deceleration

Yell hyphen: FHR Deceleration

Number after #: The serial NO. of accelerate and decelerate events

A: Amplitude P: Time durance

Blue line: FHR baseline

(5) Result: display score result.

Click the icon, and the score result table will be displayed. Click again, table will be cleared. Click 【Print】 to print out waveform , analysis and score result.

(6) Print: When the printer is connected, click the icon to print; when the printer is disconnected, 'No Printer' will show up when you click the icon.

Click "Analysis"	√	√	×	×
Click "Result"	×	√	√	×
Printing content	FHR graph, Analysis , Score result			FHR graph, Blank Score

Note: √ means proceed this operating; × do not proceed this operating.

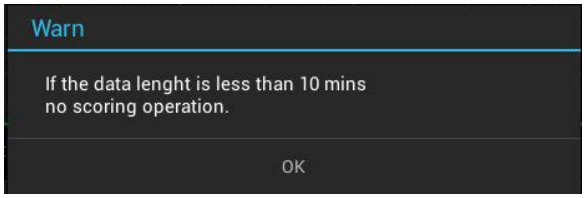
(7) Back: Click the icon to return to the records list interface.

[Note]

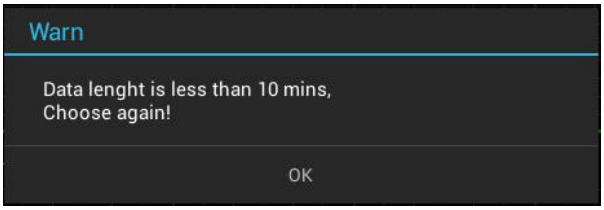
Before entering the scoring mode, select score criteria，ACOG、Fischer、Krebs.

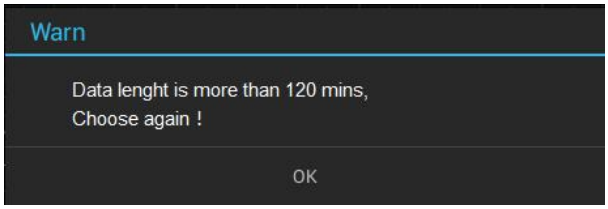
9.4 Warn

If the monitoring data is lessen than 10 minutes, following dialogue prompt:



Normal score data should be 10-120min. If the time length between two scales is less than 10 minutes or longer than 120 minutes. The display shows prompt box:





Click ‘OK’ to shutdown the dialogue box. Go on monitoring.

9.5 Record export

User can export monitored data into USB disk.

1)Click “History”, go to record list

2) Press one record without release, go to record export interface

3) Click records, chosen record will be exported to USB disk.

Unchosen ☐; Chose ☑

4) Click “Confirm” or “PDF”, if device detect USB disk, it will start export and export processing bar prompt.
[OK]: Export data format is .fhr, need special software to review export data.
[PDF]: Export data form is .PDF, user can review and print it directly.

If not detecting of USB disk, “Failed to detect any external storage card” will prompt.

5) After export, auto back to record list.

9.6 Record delete

[Warn] Records cannot be recovered after deletion, please use this operation with caution.

1) Setup->System->Delete record-> input password “62596535”
2) Record delete-> Choose record Unchosen ☐; Chose ☑
3) Click “Delete”, Click “Confirm”, start delete record.

Chapter 10 Printing

- Installing Printing Paper
- Print Settings
- Print
- Cleaning the Printing Head

10.1 Installing Printing Paper

The printer is retractable one as below pictures. It is 152mm size thermal printer paper, installation steps as below

Picture 10-1 Slot of Printer

（a） (b) (c)

Picture 10-2 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.

[Note]

If the printer compartment door is open or if the printer has no paper, the instrument will sound an alarm and prompt in the message area.

10.2 Print Settings

Setup→Print

Print Alarm: On: running out of paper or printer door is not closed, trigger alarming;

Off: no alarming for above-mentioned situation:

Print Speed: 1cm/min, 2cm/min, or 3cm/min selectable

Print Density: Thicknesss of waveform curve (1,2,3,4,5,6,7,8)is adjustable.

Real-time printing: Turn on--it supports real-time printing during monitoring process;Turn off--it doesn't support real-time printing during monitoring process. For details, please refer to 10.3.

Printing baseline:

On: Activate and print out baseline;

Off: Not printout baseline or stop printing baseline.

Please follow below instruction to fit different scale of 152mm thermal paper,

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

Printing baseline, “On”, 4 straight lines will show on the paper, they falls on FHR 210/ FHR90/TOCO100/TOCO 0. If some lines have position deviation, click this item for adjustment; or press, move cursor to right side rotate knob to the deviated items, make minor adjustment. After finish baseline adjustment, choose “Off” to stop baseline printing.

Setup→Score：

Automatic printing score：Turn on--When the effective data is over 10 min, it will print scores and results sheet; if less then 10 min, it won’t print; Turn off--it won’t print results.

10.3 Print

10.3.1 Printing and monitoring

<table>
<tr><th>Premise</th><th colspan="2">Operation</th><th colspan="2">Phenomenon</th></tr>
<tr><td rowspan="3">Turn off ‘real-time monitoring’ button</td><td colspan="2">Monitoring doesn’t start, press print button</td><td colspan="2">No response</td></tr>
<tr><td rowspan="2">Monitoring starts</td><td>Press print button</td><td colspan="2">Monitoring ends and print monitored data automatically</td></tr>
<tr><td>Press stop monitoring button</td><td colspan="2">Monitoring ends but won’t print data</td></tr>
<tr><td rowspan="4">Turn on ‘real-time monitoring’ button</td><td colspan="2" rowspan="2">Monitoring doesn’t start, press print button</td><td rowspan="2">monitoring starts and print</td><td>Press print button again → monitoring ends and stop printing</td></tr>
<tr><td>Press stop monitoring button again → monitoring ends and stop printing</td></tr>
<tr><td colspan="2" rowspan="2">Monitoring starts and press print button</td><td rowspan="2">start printing</td><td>Press print button again→printing stops and re-start monitoring</td></tr>
<tr><td>Press stop monitoring button →monitoring ends and stop printing</td></tr>
</table>

【**Note**】In the process of real-time printing

1） when probe signal misses, printing will pause

2） When probe signal is back to normal, it will upload the missing data and print it out quickly, then real-time printing continues

10.3.2 Clearing Paper Jam

If the sound of recorder and output of the thermal paper are abnormal, open the printer door to 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.

10.4 Cleaning the Printing Head

Non-failure working time of the thermal printer head can reach over 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 printer head as below:

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.

Chapter 11 Alarm

- Alarm Category
- Alarm Level
- Alarm Indication
- Alarm pause and alarm Scilent(mute)/reset
- Alarm Verification

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 LED indicator flashing and text prompt.

11.1 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.

11.1.1 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

11.1.2 Technical Alarms

The technical alarms of this Monitor include:

Cuff leaks air, pressure measurement timeout, "FHR Overlap", "Low battery", "Probe off", short of printing paper, printer door is not closed, network disconnected;

[Note]

FHR overlap ： If FHR 1 and FHR2 numeric gap <= 5bpm, duration is >= 10seconds, device will indicate FHR overlap alarm.

Alarm level: low level;

Text prompt: FHR overlap, black words with yellow background;

Alarm sound: beep, beep

11.2 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.

11.3 Alarm Indication

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

11.3.1Audible 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' Time interval is 10sec.

Intermediate level audible alarm is 'beep, beep, beep' Time interval is 20sec.

Low level audible alarm is 'beep, beep' Time interval is 30sec.

Note

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

11.3.2 Warning LED indicators Flashing Alarm

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

Alarm indicator: Flashing red ---High level alarm Flash frequency 2Hz

Flashing yellow --- Intermediate level alarm Flash frequency 0.5Hz

Constant yellow --- Low level alarm Keep on flashing

[Note]

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

11.3.3 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, FHR coincided, and low battery/Sensor off.

Alarm text: Red background, black text flash- High level alarm, flash frequency 0.8Hz

Yellow background, black text flash- Middle level alarm, flash frequency 0.8Hz

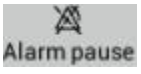
Yellow background, black text no flash- Low level alarm, flash frequency 0.8Hz

[Note]

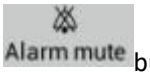
Text alarm messages will be prefixed with star symbols:

High level alarm------*** Intermediate level alarm------** Low level alarm------*

11.4 Alarm pause and alarm Scilent(mute)/reset

Press 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 LED flashing alarm and text alarm are not affected.

		Default alarm level（high/ middle/ low）	Alarm pause		Alarm mute	
			alarm pause	During the alarm pause, new alarms occur	Alarm mute	During the alarm mute, new alarms occur,
Physiological alarms	Audible Alarm	Yes	No	No	No	Yes
	Visual Alarm	Yes	No	No	Yes	Yes
	Text Alarm	Yes	No	No	Yes	Yes

Alarm

Technical alarms	Audible Alarm	Yes	No	Yes	No	Yes
	Visual Alarm	Yes	Yes	Yes	Yes	Yes
	Text Alarm	Yes	Yes	Yes	Yes	Yes

[Note]

1. During the alarm pause, if new technical alarms occur, the alarm will turn to normal state.
2. Normal state: no alarm pause or alarm mute/reset.
3. During the alarm mute, if new alarms occur, the mute will stop and the alarm will turn to normal state.
4. If power failure last less than 30seconds, alarm setup keep unchanged; if over 30 seconds, alarm setup will go back to default.

11.5 Alarm Verification

Power on the device, connect with probe.

Go to Setup-Parameter-FHR-Alarm on/off, choose On Alarm level, choose High

Alarm high limit: 160bpm Alarm delay-15

Gently pat the FHR probe to generate FHR beat, pat quickly to generate FHR reading over 160bpm and last over 15sec. If alarm indicator turn to red and “FHR 1 High” prompt and “‘beep, beep, beep -- beep, beep” sound output, it indicate alarm function works; if not, alarm does not work.

Table 11-1 Default Alarm Limits of Parameters

Type	Default Alarm Levels	Lower Range	High Range	Default Alarm Limit Range	Step
FHR	High	90-120	160-190	120-160	10

Chapter 12. Networking

- WiFi setup
- Etherenet setup
- System setup

Fetal monitor can communicate with central station by WIFI or Ethernet.

Networking icon:

 **wifi connection;**  network disconnected ;  Ethernet connected, CMS disconnected;

 CMS connected.

12.1 wifi Setup

Setup→wifi→On

Wifi name listed on right side, choose WIFI needed, click it for connection; after connected, WIFI icon  **shows on monitoring interface.**

12.2 Ethernet setup

Setup→Ethernet→On

Ethernet card shows on right side, click it and set as per real situation.

12.3 System Setup

Setup→System→Central station IP

Input Central station IP address manually.

Appendix 1: Troubleshooting

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.
During power on, LCD display normal, but no cursor moving	Connection between FHR module and mainboard is not good or damaged.	Reconnect the cable or replace FHR module.
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.

Appendix 2: Specifications

Product name: Fetal/Maternal Monitor

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

Power consumption: ≤ 75VA

Battery: Main device: 14.8V, 2200mAh Li-Ion battery; probes: 4.2V, 1000mAh Li-Ion 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.

Storage: 3000hours

Charging time: Main device 3 hours; probes: 4 hours

Working time: Main device: 2.5 hours; probes: 8 hours

Radio frequency information

Working frequency: 2.400GHz~2.4835GHz

Maximum transmit power:

WIFI:16dbm;BT:5dbm

Receiving sensitivity:

WIFI:802.11b -84dbm@11Mbps

BT:-89dBm@1Mbps，-90dBm@2Mbps，-83dBm@3Mbps

Fetal Heart Rate:

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

Strength: <5mW/cm^2

Working frequency: 1.0MHz (FHR1); 1.5MHz (FHR1);

Measurement range: 50~240 bpm， Tolerance is not greater than ±2bpm

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, Tolerance is not greater than ±10%

Display:

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

Resolution: 800x480

Dimension: 295 x 293x 91.5 (mm) (L X W X H)

Net weight: 3.5kg

Working environment: Temperature: +5℃ ～ +40℃; Humidity: ≤ 80%

Atmospheric pressure: 86kPa ～ 106kPa

Probe acoustic output: Negative peak sound pressure < 1 MPa,

Beam intensity < 20mW/cm^2

Spatial peak instantaneous average intensity density < 100mW/cm^2.

Appendix 3 Accessories

	Name	No.
	Wireless US1 probe	9.570.0156-10
	Wireless US2 probe	9.570.0158-10
	Wireless TOCO probe	9.570.0157-10
	Fetal wake-up device	1.117.0002-10
	Fuse	120-000003-000
	Power cord	1.121.0170-10
	Belt	1.371.0007-10
	Thermal Paper	1.370.0006-10

Appendix 4: Symbols

Symbol	Note	Symbol	Note
FHR1	Three-to -one socket	FHR2	FHR2 socket
	BF applied part, against Defibrillator		BF-applied part, not against Defibrillator.
	Refer to attached documents.		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		Battery indicator
	TOCO reset key	IPX1	Protective grade, against water splash.
	Power indicator		In compliance WEEE Dispose standard.
	Charge indicator		In reference to User Manual
	Equalqpotential		CF-applied part, against Defibrillator.

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 CISPR11	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 CISPR11	Class B	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 IEC 616000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

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	IEC60601 test level	Compliance Level	Electromagnetic environment-Guidance
Electrostatic discharge(ESD) IEC 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 IEC 61000-4-4	±2KV for power supply lines ±1KV for input/output lines	N/A	
Surge IEC 61000-4-5	±1KV differential mode ±2KV common mode	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT 1 (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles	N/A	

	70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec		
Power frequency(50/60Hz) magnetic field IEC 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.

Table3 Guidance and manufacture's declaration - electromagnetic immunity - for ME 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	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF IEC61000-4-6	3Vrms 150k to 80MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the models MT1PC1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=[\frac{3.5}{E_1}]\sqrt{P}$ 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 IEC61000-4-3	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 Fetal/Maternal Monitor 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)	
	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	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
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 101 Acoustic Output Reporting Table

Model No.: L8ME, US1 probe Frequency:1.0MHz, pulse wave,

Index Name			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1$ cm^2	$A_{aprt} > 1$ cm^2		
Max. Index			0.03	-	-	0.005	0.027	
Associated acoustic parameter	$p_{r.a}$		0.032					
	P			-	-		2	
	Min of $[P_\alpha(z_s). I_{ta,\alpha}(z_s)]$					1.05		
	z_s					2.0		
	z_{bp}					1.8		
	z_b						2.0	
	z at max.$I_{pi.\alpha}$		2.0					
	$d_{eq}(z_b)$						1.2	
	f_{awf}		0.999	-	-	0.999	0.999	#
	Dim of A_{aprt}	X		-	-	Φ1.2	Φ1.2	#
		Y		-	-	Φ1.2	Φ1.2	#
Other Information	t_d		148.71					
	prr		2632					
	p_r (Max Ipi)		0.035					
	d_{eq}(Max . Ipi)						1.2	
	$I_{pa.3}$(Max MI)		0.01					
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 51.2aa) and 51.2dd) are met, it is not required to enter any data in the column related to MI and TI.

US2 probe Frequency:1.5MHz, pulse wave

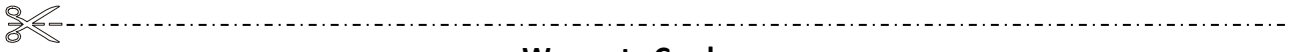
Index Name			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
Max. Index			0.03	-	-	0.003	0.01	
Associated acoustic parameter	$p_{r.a}$		0.034					
	P			-	-		2	
	Min of $[P_\alpha(z_s). I_{ta,\alpha}(z_s)]$					0.47		
	z_s					1.9		
	z_{bp}					1.8		
	z_b						1.9	
	z at max.$I_{pi.\alpha}$		1.9					
	$d_{eq}(z_b)$						1.1	
	f_{awf}		1.499	-	-	1.499	1.499	-
	Dim of A_{aprt}	X		-	-	Φ1.2	Φ1.2	-
		Y		-	-	Φ1.2	Φ1.2	-
Other Information	t_d		158.02					
	prr		4000					
	p_r (Max Ipi)		0.037					
	d_{eq}(Max . Ipi)						1.1	
	$I_{pa.3}$(Max MI)		0.00					
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.

Note4: If the requirements of 51.2aa) and 51.2dd) are met, it is not required to enter any data in the column related to MI and TI.

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