Copyright

Version: B00

No: 046-001618-01

Revision Date: 09/2024

Product Name: Specialized Fetal & Maternal Monitor

Product Model: C10/C11

Software Version: V2

Date of Manufacture: Refer to the Nameplate

Service life: 10 years

Company name: Shenzhen Comen Medical Instruments Co., Ltd.

Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China.

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Statement

Warranty

Comen will be responsible for the safety, reliability and performance of the product within the limited warranty period, if all of the following conditions are satisfied:

- The product is used in accordance with this Manual.
- The product is installed, maintained or upgraded by approved or authorized personnel by Comen.
- The storage and operating environments for the product shall comply with the recommended information and product specifications contained in this manual
- The serial number label or manufacturing mark of the product is clearly legible.
- The damage is not caused by human factors.

Comen provides services free of charge for all products based on Comen's Warranty Service conditions. Comen may charge service fees for any service not within the product's warranty. The user shall bear any or all transportation costs (including custom duties) incurred during transportation of the products back to Comen.

Return Procedure

If you need to return the product to Comen, please follow the procedure below:

Request for product return: Contact Comen's after-sales service department and inform them of the product serial number marked on the product's nameplate. If the product serial number is not clear and legible, product return will not be accepted. Please indicate the product serial number, manufacturing date, and a brief description of the reasons for returning.

After-sales Service Department

Name: Shenzhen Comen Medical Instruments Co., Ltd.

Address:

Floor 5 of Building 2 FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

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Preface

This user manual provides details on the performance, operations and safety instructions about the product. Please read carefully and understand the content of this manual so as to ensure the safety of the patients and operator.

This manual introduces the product of the most complete configurations. Some configurations or functions may not be available on the product you have purchased. If you have any questions, please contact us.

Please keep this manual near the device for easy and prompt access when needed.

Intended Users

This Manual is suitable for professional clinical personnel or those who are expected to have knowledge and work experience in medical procedures, practices, and terminology necessary to monitor patients.

Illustrations

All illustrations provided herein are for reference only. The menus, options, values and functions shown in the illustrations may be not exactly identical to those shown on the product.

Conventions

- →: This symbol is used to indicate operating steps.
- [**Character**]: This is used to represent character strings in the software.
- ***Bold and italic***: This is used to represent chapters quoted.
- **[Maintenance]** Password: 5188

Contents

Chapter 1 Safety

1.1 Safety Information

⚠ Warning

- Alerts you to situations that may result in serious consequences or adverse events or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of the user or patient.

⚠ Caution

- Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage, or cause more serious injury in the future.

⚠ Note

- It emphasizes primary warnings or provides descriptions or explanations so that this product can be used in a better way.

⚠ Warning

- This monitor is used for monitoring the clinical patients, and it is only for use by trained and qualified doctors and nurses.
- Before using this device, please read and understand the entire User Manual. Any attempt to use this device (and all other medical devices) without full understanding of the operating instructions may cause injury to the patient or user.
- This device is intended to be operated only by trained users, whose training records should be archived. No unauthorized or untrained persons are allowed to operate this device.
- Please keep this User Manual near to the device for easy reference.
- Attention should be paid to all warnings and prompts on the surface of the device so as to ensure the safety of the operator and the normal operation of the device.
- This device has not been sterilized before delivery. Be sure to clean and sterilize before using for the first time.
- No modification of this equipment is allowed.

- Do not maintain or repair when the monitor is in a normal use.
- Check whether this instrument and its accessories can work normally and safely prior to use.
- Alarm volume and high/low alarm limits should be set depending on the patient. When a patient is monitored, do not exclusively rely on the audible alarm system. If the alarm volume is set too low or is completely turned off, the alarm will not be heard, and the patient may be put in danger. Paying close attention to the patient's actual clinical conditions is the most reliable monitoring method.
- The monitor can only be connected to a power outlet with protective ground. If the power socket is not connected to a ground conductor, use the battery to supply power to the monitor instead of using the power outlet.
- Do not open the housing of this instrument to avoid potential electric shock. The monitor must be maintained and upgraded by service technicians trained and authorized by Comen.
- Observe the local laws and regulations or the waste disposal rules of the hospital when disposing of packaging materials. Keep the packaging materials out of the reach of children.
- Do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Carefully place the monitor power cord and accessories cables to avoid entanglement, potential strangulation, and electrical interference to the patient.
- Do not use a mobile phone near the monitor because the mobile phone will generate high-intensity electromagnetic radiation and affect the performance of the monitor.
- Any equipment connected to the monitor shall form an equipotential circuit (effective connection of protective ground).
- When the monitor is used in conjunction with electrosurgery unit, the user shall ensure the patients' safety.
- The physiological waveform and parameter, alarm message and other information displayed by the monitor are only for reference by physicians, and not directly used as a basis for clinical treatment.
- Electromagnetic fields can affect the performance of the monitor. Therefore, equipment used near the monitor should conform to the applicable EMC requirements. For example, mobile phones and X-ray machines are potential sources of interference, since they transmit high-intensity electromagnetic radiation.
- When connecting the electrodes or patient cable, ensure that the patient does not come into contact with any other conductive parts or the ground. Confirm that all ECG electrodes (including the neutral electrode) are attached to the patient's body.
- This is not a treatment device.
- Do not place the power plug used to disconnect the device from supply mains in a position not easily accessible by the operator.
- The installation and replacement of the fuse should be performed by trained and qualified service

personnel.

- The use of this monitor is restricted to one patient at a time.
- When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided conductive connection to the HF equipment to protect against burns to the patient.
- The ultrasound transducer chip is ceramic and should not be dropped or scratched.
- Do not operate the monitor under MRI examination.

⚠ Caution

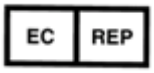
- To avoid damage to the monitor, and ensure the patient's safety, only use accessories specified in this manual.
- Handle the monitor carefully to avoid damage caused by dropping, collision, strong oscillation or other external mechanical forces.
- Before powering on the monitor verify that the supply voltage and frequency conform to the requirements specified on the monitor nameplate or in this manual.
- Dispose of the expired in accordance with the local laws and hospital's regulations.

⚠ Note

- Place the monitor at a position where observation, operation and maintenance are convenient and not obstructed.
- This user manual is based on the maximum configuration, and therefore some contents may not be applicable to your monitor.
- Please place this user manual near the device for easy and timely reference.
- This device is not intended for home use.
- The analysis report is for reference only and the doctor should sign to ensure the correctness.

1.2 Symbols

(1) Product Symbols

Symbol	Description	Symbol	Description
	Operator's manual		Refer to operation manual / booklet
	Defibrillation-proof type BF applied part	IP67	IP degree of transducers
CE 1639	**Conformité Européenne** Complies with Regulation (EU) 2017/745		European community representative
	Caution		USB interface
	ON/OFF button		Network (connect with Comen central monitor)
	AC power indicator		Print/Stop key
	Alarm reset key		Defibrillation-proof type CF applied part
	Equipotentiality		Battery working status
	Freeze/Unfreeze key		TOCO zero key
	Rechargeable battery		Rotary knob
	Main menu	SN	Serial number
IPX0	IP degree of the monitor		

(2) Package Symbols

Symbol	Description	Symbol	Description
	This way up		Stacking limits
	Fragile, Handle with care		Keep dry
	Temperature limits		Humidity limitation
	Atmospheric pressure limitation		

Chapter 2 Overview

The monitor is mainly used to monitor the fetal, maternal uterine activity. It can generate alarms from the fetal parameters, and display, store and record the corresponding patient data and related waveforms. The monitor is equipped with a 5.7-inch screen. And the monitor supports two operating modes: button and rotary knob.

2.1 Intended Use

This monitor is intended to monitor the heart rate and movement of the fetus and the uterine contraction pressure of the mother.

2.2 Components

The monitor is composed of the main unit (including battery, display screen, recorder and enclosure) and functional accessories (including FHR transducer, TOCO transducer, and FM marker).

2.3 Contraindications

None

2.4 Appearance Introduction

2.4.1 Front View

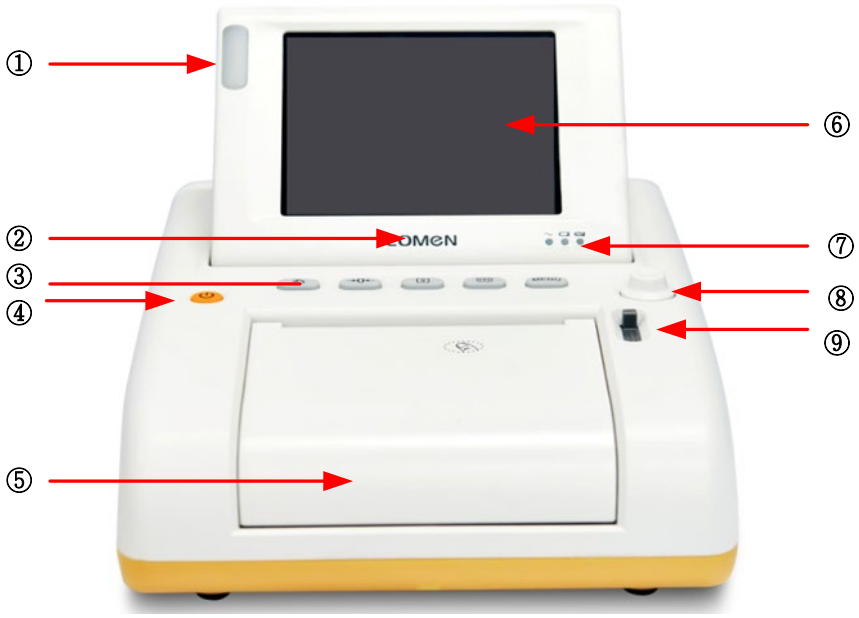


Figure 2-1 C10/C11 Front view

①	Alarm indicator: When an alarm occurs, different lights flash according to different alarm levels.		
②	Trademark identification: COMEN		
③		Alarm reset button	Press to reset the alarm system.
		Freeze/Unfreeze button	Press to freeze or release all waveforms on the screen.
		Print/Stop key	Press to start printing or stop printing
		TOCO zero key	Press to perform TOCO zeroing.
		Menu button	Press to pop up the main menu or exit the main menu.
④		ON/OFF button	Press this button to turn the instrument on or off.

⑤	Recorder		
⑥	Display		
⑦		AC indicator	On: The monitor is connected to an AC power supply
			Off: The monitor is not connected to an AC power supply.
		Battery working status indicator	On： Battery powered
			Off： Not using battery power
		Rechargeable battery (The device has a built-in rechargeable battery)	
⑧	Rotary knob: rotate clockwise or counterclockwise to move the cursor, or press the knob to perform an operation.		
⑨	Paper compartment Lock: To Open and lock the paper compartment door		

2.4.2 Right View

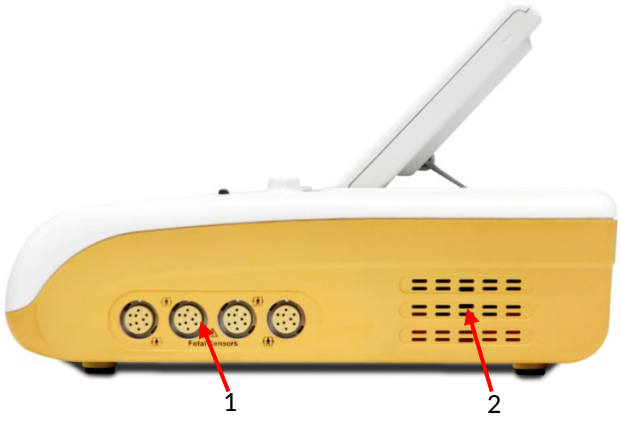


Figure 2-2 C10/C11 Right view

1	Interfaces: including four sockets with the same definition, used as Fetal Heart Rate (FHR) socket 1, FHR socket 2, socket of fetal movement marker sensor and TOCO socket. The FHR sensor, fetal movement marker sensor or TOCO sensor can be inserted into any of these sockets and the monitor recognizes it automatically. After a patient is connected, the

	waveforms and values appear in 5-30s. **Note: twins are optional.**
2	Loudspeaker: loudspeaker for fetal heartbeat. **Note: there are a cooling fan and an alarm loudspeaker on the left of the monitor**

2.4.3 Rear View

⚠ Note

- **When tilting the display, first pull the display forward until the end and the display will be fixed, then push the display to your desired position.**
- **When folding the display, pull the display forward until the end and the display will be fixed.**

⚠Warning

- **The fuse must be installed by the designated operator.**
- **Only the analog or digital equipment complying with the specified IEC standards (like IEC 60950 for data processing equipment, IEC 60601-1 for medical equipment, etc.) are allowed to be connected to the monitor. The configuration of these equipment should comply with the valid version of IEC 60601-1-1 standards. The person who connects external equipment to the signal I/O ports should configure the medical system and ensure the medical system complies with IEC 60601-1-1 standards. If you have any question, please contact the supplier.**
- **Do not touch the I/O port and the patient at the same time during normal use, otherwise the patient may be injured.**
- **If more than one external equipment are connected to the monitor at one time through the patient cable socket, network connector or other signal interfaces, the total leakage current should not exceed the allowance.**

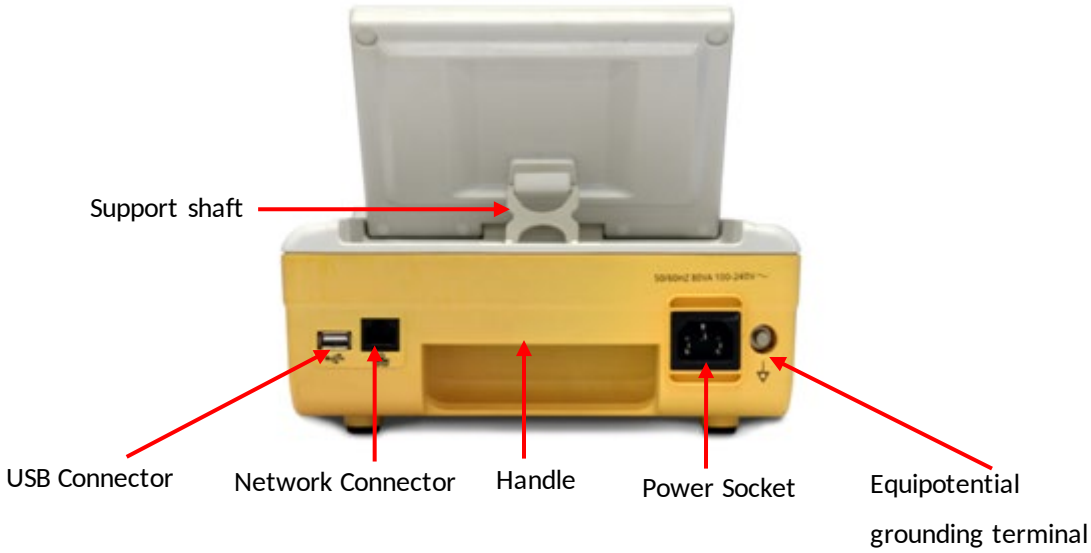


Figure 2-3 C10/C11 Rear view

1	Supporting shaft: to support the display. The tilting and folding of the display is realized by a one-way gear system. The display can only stay at 6 fixed positions of the bottom gear, and when the display is tilted to one of these positions, you hear a "click". When folding the display, tilt forward the display to the end and then fold it back.
2	USB port: for USB disks which can be used to copy patient file from/to the monitor and copy update package from a computer to the monitor to update its software. For more details, please refer to ***Chapter 6.5 Document Manage***.
3	Network port: for connection to the network.
4	Handle: you can hold the handle to move the monitor.
5	Power socket: to connect with the power supply.

Fuse socket: fuse specification: PSL300 3A/16V/Straight

2.5 On-screen Display

The color screen can display the patient parameters, waveform, alarm message, system time, network connection status, bed number, battery status and other messages simultaneously

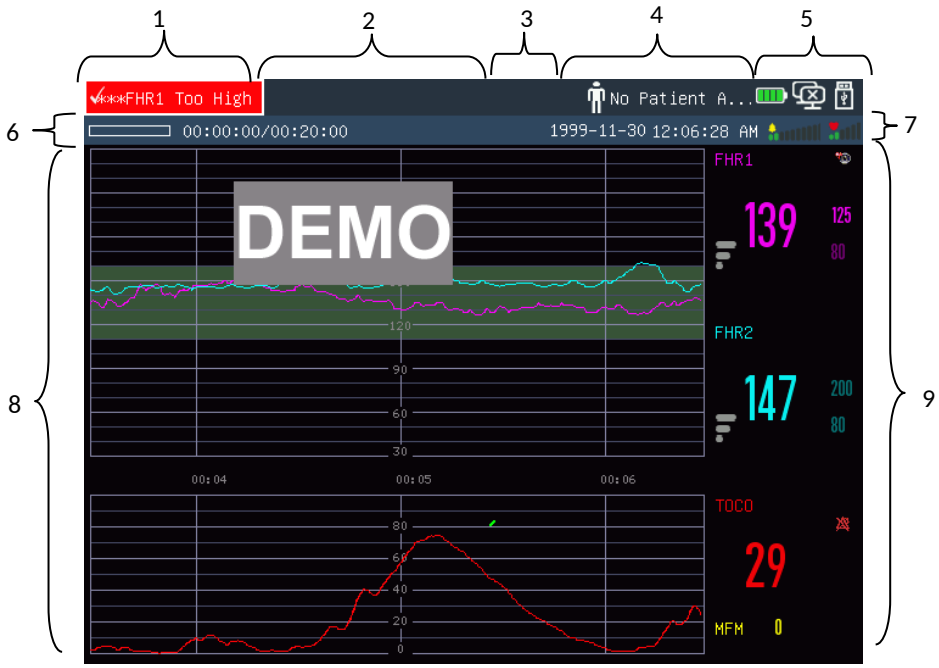


Fig. 2-4 Main interface

1. Physiological alarm message
   - Display physiological alarm message. When there are multiple messages, they will be displayed circularly.
   - Click here to directly access [View Physiology Alarm] window.
2. Technical alarm message area

   Display technical alarm message and status message. When there are multiple messages, they will be displayed circularly.
3. Icons area
   - Display the mute and printing sign. If the print paper is moving, the printer is working.
   - Alarm status icon: The corresponding icon appears when the alarm is reset, paused and sound is turned off.
4. Patient management
   - Display patient type (Adu, Ped and Neo) and patient name.
   - If no patient is admitted, the prompt message “No Patient Admitted” will be displayed here. If a patient has been admitted, the patient name will be displayed here.
   - Click here and choose [Patient Info] to view the patient information.
5. Monitor Setup
   - Show the network connection status between monitor and central monitoring system. indicates that the network between the monitor and central monitoring system has not been connected successfully; indicates that the network between the monitor and central

monitoring system has been connected successfully;

-  indicates the battery charge level.
-  indicates SD card status.
-  indicates the monitor has connected with USB connecting line.
- Click here to enter [Monitor Setup] menu.

6. Printing progress bar
7. System Information
   - System Time: Display the current system time.
   - Alarm Volume: Display the current alarm volume
   - FHR Volume: Display the current FHR volume
8. Waveform area
   - Display the measurement waveforms with the waveform name at the left top corner.
   - Click the waveform area and the corresponding setup menu will be displayed.
9. Parameter area
   - Display the measured value and the set alarm limit of each measurement parameter.
   - The color of a certain parameter is the same as that of its waveform.
   - Click each parameter area and the corresponding setup menu will be displayed.

Chapter 3 Installation

⚠ Note

- **In order to ensure the normal operation of the monitor, please read this chapter and *Chapter 1 Safety* before use, and install the device as instructed herein.**

3.1 Unpack and Check

Carefully take the device and its accessories out of the packing box; keep the packaging materials safe for use in future transportation or storage. Check the accessories according to the Packing List. Check to see if there is any mechanical damage. Check all exposed lead wires and the parts and accessories with plugs. In case of any problem, contact our Sales Department or agency immediately.

3.2 Connect the AC Power Cord

Before connecting the power cord, confirm that the AC power supply meets the following specifications: 100-240V~, 50Hz/60Hz.

Use the power cord provided along with the monitor, and connect the power plug to the grounded three-phase socket.

⚠ Note

- **To ensure the safe operation, please only use the accessories (like FHR transducer) and consumable materials provided or designated by Comen.**
- **Please connect Comen equipment to the monitor only. If you connect any other electrical equipment or device to the monitor, there could be safety problems caused by superimposed leakage current.**
- **Plug the power cord to the dedicated hospital socket.**
- **Please charge the battery after the transport or storage of the monitor. Otherwise, if you turn on the monitor without connecting it to the AC power supply, the battery power may not support its normal operation. The battery will be charged when the AC power supply is connected, whether you turn on the monitor or not.**

Please connect equipotential grounding wire if necessary, referring to ***Chapter 4.4 Equipotential Grounding***.

3.3 Turn on the Monitor

Press the ON/OFF button to turn on the monitor. The alarm indicator is illuminated in red, cyan and yellow, and the company logo is displayed on the screen. If a self-test is successfully performed in 1s to 20s, the main screen will be shown with a “Dee” sound.

⚠ Note

- **The system sounds an alarm when a major error is detected during the self-test.**
- **Check all monitoring functions to ensure that the monitor is operating correctly.**
- **To extend the service life of the monitor, after shut-down, wait for at least 1 minute before restarting the monitor.**

⚠ Warning

- **If there is any evidence of failure or any error messages are displayed, do not use this monitor. Contact a service technician of Comen or a biomedical engineer in your hospital.**

3.4 Connection of Sensors

Connect the required sensor to the monitor and the monitoring part of patient. For the correct connection methods and related requirements, please refer to relevant chapters.

Chapter 4 Patient Safety

4.1 Safety Instructions

The monitor is designed in accordance with international safety standards for medical electrical equipment. It is provided with defibrillation-proof and electrosurgical protection with a floating ground input.

4.2 Environmental Requirements

The following guidance should be followed to ensure the safety of electrical installations.

The monitor should be used in an environment that can reasonably avoid vibration, dust, corrosive or explosive gases, extreme temperature and humidity, etc.

When the monitor is installed in an enclosed space, make sure the space is well ventilated. Leave at least 2 inches (5cm) free space around the monitor for air circulation. Also, leave sufficient space around it for easy operation and maintenance.

The monitor should be operated in the ambient temperature of 5°C - 40°C to meet the requirements. Hostile ambient temperature may affect the precision and accuracy of the instrument, and cause damage to the components and circuits.

4.3 Power Supply Requirements

Power supply specification: 100-240V~, 50/60Hz.

4.4 Protective Grounding

To protect both the patient and the operator, the housing of the monitor must be grounded. The monitor is equipped with a detachable 3-wire power cord, which shall be inserted into a grounded power outlet to ensure that monitor is grounded. If a grounded power outlet is not available, contact the maintenance department in your hospital.

⚠ Warning

- **Do not connect the 3-wire power cord to a 2-wire power outlet.**

Connect the ground wire to the equipotential connector of the monitor. If you have any doubts about whether equipment used may cause any electrical risks, such as risks caused by the accumulation of leakage current, consult an expert in this field to ensure the safety of all equipment.

4.5 Equipotential Grounding

The monitor must be connected to a power outlet with protective grounding. For cardiac or cerebral examinations, the monitor must be connected to a standalone equipotential grounding system. Connect one end of the equipotential conductor (potential equalization conductor) to the equipotential connector on the rear panel of the monitor and the other end to a connector of the equipotential grounding system. In the event the protective grounding system is damaged, the equipotential grounding system serves as the safety function of the protective grounding wire.

Cardiac (or cerebral) examination can only be performed in a room installed with a protective grounding system. Before each use, ensure the monitor is in a normal operating status. Cables connecting the patient to the monitor must not be contaminated by electrolyte.

⚠ Warning

- **Battery power should be used to power the monitor against unstable protective grounding system.**

⚠ Note

- **If the use of the equipment is affected by equipotential grounding, please contact our After-sales Department or agency.**

4.6 Condensation

Ensure that the monitor is free from condensation during operation. When the monitor is moved from one room to another condensation may form due to exposure to damp air and temperature differences. If condensation is present, do not use the monitor until it is dry.

Note: Condensation means gas or liquid condenses when it cools. For example, water vapor is changed into water when it cools, and the water is changed into ice when it cools. The lower the temperature, the faster the condensation goes.

⚠ Warning

- **In order to avoid fire or explosion, never use this monitor in an environment with inflammables such as anesthetics.**
- **DO NOT use the monitor during MRI inspection; or the induced current will cause burns.**

Chapter 5 Basic Operations

5.1 Entering the Main Menu

Press the key on the front panel to enter the [Main Menu] window, where you can set up system menus easily. See the figure below:

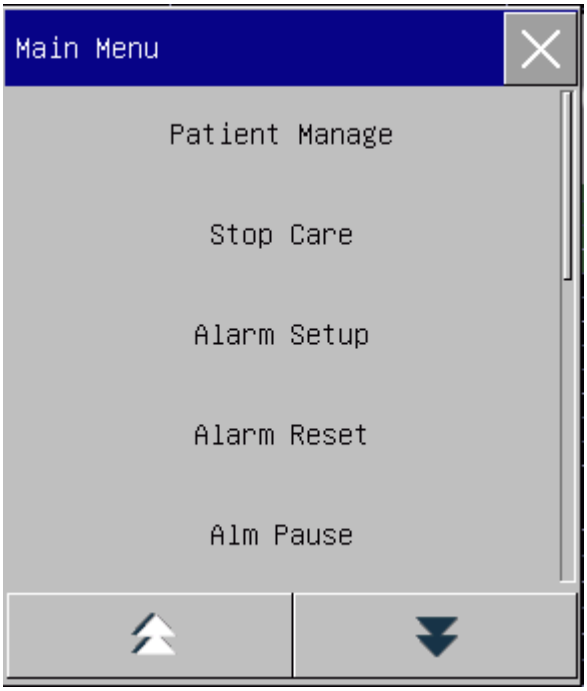


Figure 5-1 Main Menu

button: Press this button to exit the current menu.

> **Note**
>
> - **The system settings are saved once you set them up and remain valid until you modify them or restore factory settings. In case of power failure, the monitor stores all the settings and patient data and recover them upon power restoration.**

5.2 Entering the User Maintenance

Access [Main Menu] → [Maintain], enter the correct password in the [Password] dialogue, then click enter key to enter the [Maintain] menu.

5.3 General Settings

5.3.1 Setting System Time

1. Access [Main Menu] → [Maintain] → [Time Setup].
2. Set the system time according to your local time.
3. Return to [Time Setup] and click [Enter] in the top bar.

5.3.2 Changing System Language

1. Access [Main Menu] →[Maintain] and enter the password 5188;
2. Click [Language] to select the required system language.

5.3.3 Adjusting Alarm Volume

For specific methods of adjusting alarm volume, please refer to ***Chapter 8.4 Adjusting the Alarm Volume***.

5.3.4 Adjusting Fetal Volume

1. Access [Main Menu] → [Volume Setup] → [Fetal Volume];
2. Select the Fetal volume in the pop-up list box;
3. Click to decrease or increase the FHR volume. Available volume levels are 0 to 6. 0 means off and 6 is the maximum volume.
4. Click to save the settings.

When the FHR volume is 0, the FHR volume icon turns to , indicating the FHR volume is 0. When the FHR volume is set to 1, the FHR volume icon turns to , and so on.

5.3.5 Adjusting Key Volume

1. Access [Main Menu] → [Volume Setup] → [Key Vol];
2. Select the key volume in the pop-up list box;
3. Click to decrease or increase the key volume. Available volume levels are 0 to 10. 0 means off and 10 is the maximum volume.
4. Click to save the settings.

5.4 Viewing Monitor Info

The software version is used for maintenance or tracing of the monitor.

Enter [Main Menu] → [Monitor Info] (Monitor Information) to view the monitor's software version.

5.5 Demo

To enable Demo function:

1. Access [Main Menu] →[Maintain] and enter the password;
2. Click [Demo].

During the working state of the demo function, the [Demo] button changes to [Exit Demo]. Follow the same path and click [Exit Demo] to exit the demo state.

⚠ Warning

- **Demo waveforms are used to simulate the monitoring process. Demo mode can only be used to demonstrate the device performance and assist in training course. In actual clinical use, it is forbidden to use the Demo mode, because medical workers may mistake the demo data for waveforms and parameters of the patient, which puts the patient in danger. Therefore, the Demo menu is password-protected.**

5.6 Network Settings

This monitor can be connected to the central monitoring system via both wired network and wireless network. The specific methods are as follows:

1. Click the network connection status icon  to enter [Monitor Setup] → [Network Setup];
2. Click [Net Bed] to enter the network bed number of this monitor on central monitoring system. Valid range is 1 to 254;
3. Click [IP Address] to enter the IP address of this monitor, for example, 200.200.200.X. The valid range of X is 1 - 254. If the entered value is out of this range, the valid range will be displayed.
4. Click [MAC] to enter the MAC address of this monitor;
5. Click [Subnet Mask] to enter the subnet mask of this monitor;
6. Click [Service IP] to enter the IP address of the central monitoring system. The server IP and IP address of the monitor must be in the same network segment.
7. Click [Server Port], enter the server port of this monitor.

How to recognize whether the network has been connected successfully:

Icon indicates the network between this monitor and central monitoring system has not been connected successfully;

Icon indicates the network between this monitor and central monitoring system has been connected successfully.

⚠ Note

- **The network bed number must be unique and cannot be the same as that of any other monitor connected to the central monitoring system, or it will cause signal deadlock because of the preemption of the central monitoring system channel.**
- **If the monitor system halted due to network bed number repetition, remove the network cable, turn off the monitor and restart. Reset the networks and then reconnect the network.**

5.7 Freezing Waveform

How to freeze waveforms on the screen:

1. Press the key on the front panel in the unfreezing status.
2. All waveforms are frozen, which will not roll or refresh. The parameter data will refresh normally.\

How to view frozen waveforms:

The users can freeze the waveforms on the screen during patient monitoring and view the waveforms in detail. Up to 60h frozen fetal waveform can be reviewed on this monitor. The specific operations are as follows:

1. Under the frozen status, rotate the knob to view the frozen waveform of the previous or next page;
2. Press the key on the front panel again to exit the frozen status.

How to record the frozen waveforms:

User can print the frozen waveform by the recorder, please refer to *Chapter 10.2.2 Freezing Print* for more details.

Chapter 6 Patient Management

You can enter the [Patient Management] menu in two ways:

- Enter the main menu and select [Patient Manage]
- Click patient info area on the upper menu bar.

6.1 Admit a Patient

Once a patient is connected to the monitor, even if no patient is admitted, the monitor can also display and store the physiological data of the patient. But it is of great importance to correctly admit the patient.

To admit a hospitalized patient:

1) Enter [Patient Manage] → [Admit].
2) If another patient has been admitted on the monitor, the prompt message [Discharge current patient? Admit new patient?] will be shown. Select [Yes] to discharge the existing patient. If no patient has been admitted, the prompt message [Apply the monitoring data to the patient to be admitted?] will be shown.
   - [Yes]: Apply the data to the new patient.
   - [No]: Clear the stored data on the monitor.
3) Set patient information in the [Patient Info] menu. You can use EN or Handwriting input methods to input information.

⚠ Warning

- **Ensure the alarm limits are suitable for the patient before monitoring.**

⚠ Note

- **Wrong patient information could result in printout and affects automatic scoring for the patient. Therefore, discharge the last patient before admitting a new patient in order to avoid confusion.**

6.2 Quick Admit

The Quick Admit mode can be used in emergent situation when there is not enough time to fill in patient info. You must complete the patient info later.

1) Enter [Patient Manage] → [Quick Admit].
2) If another patient has been admitted on the monitor, the prompt message [Discharge current patient? Admit new patient?] will be shown. Select [Yes] to discharge the existing patient. If no patient has been

admitted, the prompt message [Apply the monitoring data to the patient to be admitted?] will be shown.

- ◆ [Yes]: Apply the monitor data to the new patient.
- ◆ [No]: Clear the stored data on the monitor.

3) Enter the [Patient Info] window, set up [Pat Type] and [Pacer], and then close the window.

6.3 Patient Information

When the user adopts the [Quick Admit] mode, only [Pat Type] (Patient Type) and [Pacer] (Pacemaker) in [Patient Info] (Patient Information) are set, and other information of the patient needs to be completed later.

1) Enter [Patient Manage] → [Patient Info].
2) According to the actual situation, input the patient's information in the menu of [Patient Info].

6.4 Discharge

To discharge a patient from the monitor:

1) Enter [Patient Manage] → [Discharge].
2) The system will give the prompt message [Discharge?].
   - ◆ [Yes]: Discharge the current patient. The patient data monitored will be archived automatically if the monitor is mounted with a SD card. You can review the archived patient data in [Document Manage].
   - ◆ [No]: Cancel the discharge operation.

6.5 Document Manage

You can inquire, review, delete and export archived patient files in [Document Manage]. [Document Manage] supports users to automatically match or manually search existing patient files. You can view, delete and export the patient files of the search results.

[Search]: Enter the patient name in the field at the lower left corner of the [Document Manage] window and click [Search] to search for the patient's file.

[View]: Select the patient info bar you want to review. Click [View] to open [Review] menu, in which you can view [Patient Info], [Trend Review], [NIBP Review], [Alarm Event Review], [Wave Review]and [Patient Event Review].

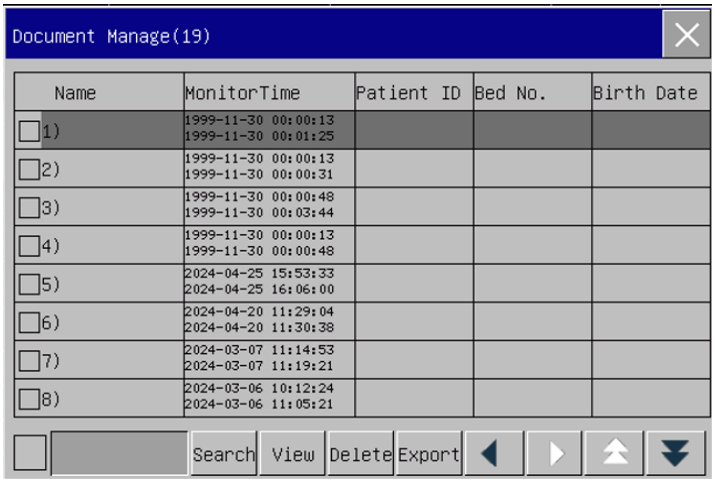
[Delete]: Delete the selected patient file.

[Export]: Export the selected patient file to a USB flash drive or FTP server.

If there are multiple patient files found, click the keys to select the one you want to view; click the keys to show more information of the patient.

To manage patient file, do the followings:

1. Enter [Main Menu] → [Document Manage].
2. Enter a patient name in the input field at the lower left corner of the window.
3. Click [Search] the show the patient files found.
4. You can [View], [Delete] and [Export] the selected patient file.
5. If you check the box at the lower left corner, all patient files are selected. At this time, you can click [Delete] to delete all patient files.
6. You can export patient files by following these steps:
   - If a single patient file is selected, select [Export] to open the [Data Export] menu.
     1) Set the [Start Time] and [End Time].
     2) Select [File Format]: options are .bin, .txt or .xls.
     3) Select [Data Export] to export to a USB flash drive.
     4) When it is finished, the prompt message [Data export succeeded, please restart.] is shown.
   - If multiple patient files are selected, operations steps are the same with those for single patient file except that [Start Time] and [End Time] cannot be set.



Warning

- **For patient alarm messages, physiological and technical alarms are saved in the patient file.**
- **In the event of a power interruption, alarm events are still saved in the patient file.**
- **When exporting data to a USB drive, do not remove the USB drive until the export process is completed in order to prevent data corruption.**

7.1 User Screen Styles

This monitor provides 2 types of user interface: Fetal Screen and Big Font. The information displayed on the screen is different in these two types.

Enter [Main Menu] → [Screens] to select Fetal Screen or Big Font.

7.1.1 Fetal Screen

FHR value, FHR trace, TOCO and its waveform, manual/auto fetal movement (FM) marks and FM waveform are displayed on this interface.

On the pop-up [Screens] window, select [Fetal] (Fetal Screen) and it is shown as below:

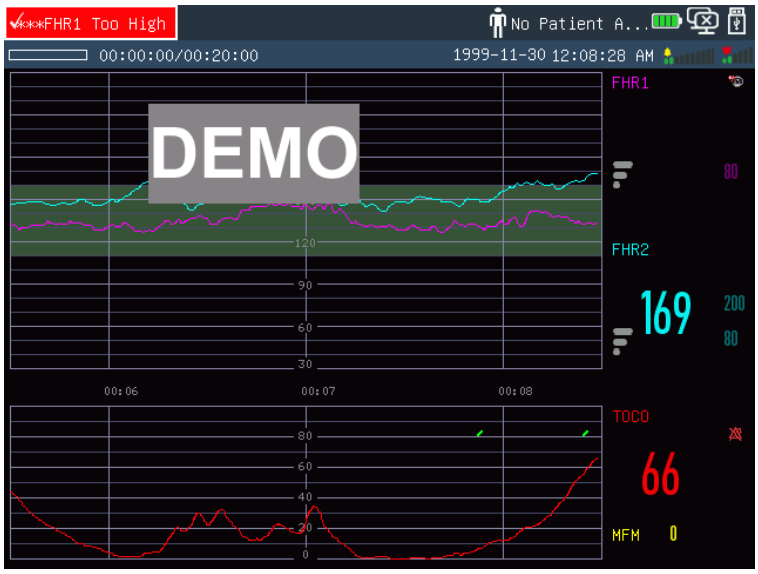


Fig. 7-1 Fetal Screen

7.1.2 Big Font

In Big Font interface, parameters are shown in large font, so that the text can be read at a certain distance from the monitor. Four parameters are displayed in this interface.

To open Big Font interface:

On the pop-up [Screens] window, select [Big Font] and it is shown as below:

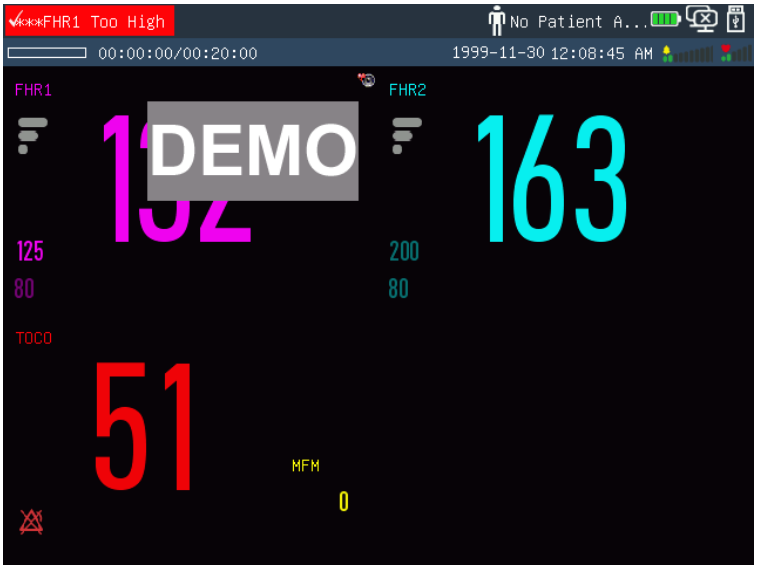


Fig. 7-2 Big Font screen

7.2 Tailoring Your Screens

You can tailor your monitor's screen by setting, such as:

- Wave sweep speed.
- Color of parameters and waveforms displayed.

You can set up the visual style for all parameters using the method described in this section.

7.2.1 Changing the Waveform Sweep Speed

Select the FHR waveform, and in the pop-up [FHR setup] window, select [Sweep] to set sweeping speed of waveforms (options: 1 cm/min, 2 cm/min, and 3 cm/min).

7.2.2 Setting the Module Color

1. Access [Maintain] → [Module Color]
2. In the pop-up [Module Color] window, select required parameter to set a color waveform (options: green, cyan, red, orange, yellow, white, blue, and purple).

Chapter 8 Alarms

8.1 Alarm Type

Alarms generated by the monitor are classified into physiological and technical alarms.

(1) Physiological alarm

A physiological alarm is generated when a certain physiological parameter of the patient is beyond the high/low alarm limit or the patient has physiological disorder. Physiological alarm messages are displayed in the physiological alarm area in the upper part of the screen.

(2) Technical alarm

A technical alarm, also known as a system error message, is triggered when a system function cannot work normally or the monitoring result is unreasonable due to improper operation or system failure. Technical alarm messages are displayed in the technical alarm area in the upper part of the screen.

NOTE: In addition to physiological and technical alarms, the monitor also shows messages about system status. Generally, these messages are not related to vital signs of the patient.

⚠ Warning

- **Use of different configuration on different monitors in one area (e.g., ICU or OR) may result in danger to the patient.**

8.2 Alarm Level

Physiological and technical alarms are classified into high, medium and low-level alarms by severity.

	Physiological alarm	Technical alarm
High-level alarm	The patient is in life-threatening, imminent danger (for example, FHR exceeding the high-level limit set before), and emergency treatment should be carried out.	Serious device failures or mis-operations (for example, low battery) may result in failure to monitor the critical conditions of the patient, which threatens their life.
Medium-level alarm	Abnormality is detected in the patient's vital signs; treatment measures should be taken promptly.	Some device failures or mis-operation may not endanger the patient's safety, but will affect

		normal monitoring of vital physiological parameters.
Low-level alarm	Abnormality is detected in the patient's vital signs; treatment may be necessary.	Some device failures or mis-operation may result in certain malfunctions, but will not endanger the patient's safety.

The levels of all technical alarms and certain physiological alarms have been set before delivery of the monitor and cannot be changed by the user. The levels of other physiological alarms can be modified.

8.3 Alarm Mode

When an alarm is generated, the monitor will use the following alarm modes to alert the user:

- Light Alarm
- Audible Alarm
- Alarm Message
- Flashing Parameter

For light alarms, audible alarms and alarm messages, the alarm levels are differentiated as described below.

8.3.1 Light Alarm

Alarm indicator of the monitor indicates alarm levels with different light colors and blinking frequencies.

Physiological Alarm:

- High-level: Red, flashing twice every second.
- Medium-level: Yellow, flashing once every two seconds.
- Low-level: Yellow, remaining on

Technical Alarm:

- High-level: Red, flashing twice every second.
- Medium-level: Yellow, flashing once every two seconds.
- Low-level: Yellow, remaining on

When physiological alarm and technical alarm are triggered simultaneously, the one with higher level is indicated. The alarm indicator remains yellow when there is only low-level alarm (physiological or technical).

8.3.2 Audible Alarm

The monitor indicates alarm levels with audio alarm with different intervals.

High-level: beep-beep-beep--beep-beep----beep-beep-beep--beep-beep.

Medium-level: beep-beep-beep.

Low-level: beep.

⚠ Warning

- **Both the bedside monitor and the CMS are provided with audible alarm function.**
- **When this monitor is connected to the CMS, you can use the same alarm levels and alarm limits for the monitor and CMS. But if you enable alarm delay on the bedside monitor, it will not give alarm when the CMS has given an alarm.**
- **When multiple alarms of different levels are generated simultaneously, the monitor activates the warning sound and light for the highest-level alarm.**

8.3.3 Alarm Message

⚠ Note

- **The alarm log is not maintained when the alarm system is powered down.**
- **After the monitor is powered off or shut down, the stored logs do not change.**

Alarm messages are shown in the physiological alarm area or technical alarm area on the screen. Different background colors are used to indicate the alarm levels:

- High-level: Red (physiological alarm), blue (technical alarm)
- Medium-level: Yellow
- Low-level: Yellow

Different marks are added in front of alarm messages to indicate the alarm levels:

- High-level: ***
- Medium-level: **
- Low-level: *

8.4 Alarm Parameter Flash

When a parameter reaches the alarm limit, the parameter and its upper and lower limits will flash once every second, indicating the measured result is beyond the upper or lower limit.

8.5 Alarm Volume

8.5.1 Minimum Alarm Volume

The minimum alarm volume is set to avoid the situation that the alarm cannot be heard due to the alarm volume being set too low. It decides the minimum alarm volume which can be set by users.

How to adjust the minimum alarm volume:

1 Access [Main Menu] → [Maintain] and enter the password.

2 Select [Alarm Setup];

3 Select [Min Alm. Volume] to adjust the minimum alarm volume from 0 to 10.

4 Click  to save the setting.

8.5.2 Adjusting Alarm Volume

There are 2 ways to set the alarm volume:

1. Enter [Main Menu]→ [Volume Setup]→[Alm Vol] to set the alarm volume (range: X-10, where X is the minimum alarm volume).

2. Or enter [Main Menu] → [Volume Setup] → [Alm Vol] to adjust alarm volume → Click  to save the setting, the range is the same as the above.

When the alarm volume is set to 0, the icon  will appear on the screen indicating the alarm volume is 0 and the system information area will appear  . When the alarm volume is set to 1, the icon will become  , and so on.

The alarm signal sound pressure level from level 0 to level 10 of this monitor is between 45 dB to 85dB.

⚠ Warning

- **When the alarm volume of the system is set to 0, the monitor cannot make any alarm sound even if a new alarm is generated. Therefore, the operator should use this function with caution.**
- **Set an appropriate alarm volume. It hinders the operators from distinguishing an alarm when the alarm volume is set to be lower than the ambient noise.**

8.5.3 Setting the Reminder Sound

When alarms are turned off, the monitor will give a periodic reminder signal: Ting---Ting---Ting---.
To set up alarm reminders:

1 Access [Main Menu] →[Maintain];

2 Select [Alarm Setup] → [Alarm Reminder];

3 Switch [Alarm Reminder] on

4 Select [Reminder Volume] to adjust the alarm volume from 0 to 10. 0 means off and there is no reminder tone when alarms are switched off. 10 means the maximum reminder tone.

5 Select [Reminder Interval] to adjust the reminder interval. Available options include [1 min], [2 min], [3 min].

⚠ Note

- **After switching [Alarm Reminder] on, the [Reminder Interval] and [Reminder Volume] can be set.**

8.5.4 Setting the Alarm Sound

The monitor provides 7 alarm sounds.

How to set reminder tone:

1 Access [Main Menu], select [Maintain] and enter the password.

2 Select [Alarm Setup];

3 Select [Alarm Sound] to adjust the reminder sound from 1 to 7.

8.6 Setting Parameter Alarm

8.6.1 Setting the Alarm limit

⚠ Warning

- When setting alarm limits to extreme values, the alarm system may be useless.
- Before monitoring, please ensure that the current alarm limit is only applicable for the current patient.
- When setting high and low alarm limits, make sure the patient type is correct (Adu, Ped or Neo).
- If you have set the high and low alarm limits manually, the monitor will display these high and low alarm limits instead of the default alarm limits of the system.
- If power-off accidentally occurs, the equipment retains the latest setting for 120s. After120s, the monitor sets the configurations according to [Startup Configuration] when restarts.

⚠ Note

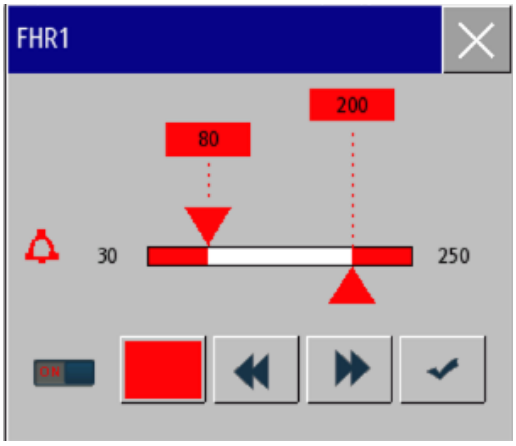
- When applying factory default configurations, alarm limits of the parameters will also change. See "Default Configurations" for details.

Colors of Alarm Limits

- Red represents high-level alarms
- Yellow represents medium-level alarms

The procedures to set alarm limit of parameters are generally the same.

1) Select the RESP parameter area; enter the Setup menu → [Alarm Limit Setup].
2) Select the parameter needed to set the alarm limit and enter the corresponding the setting window. Take RESP alarm limit setup as an example:



3) Select the check box  at the lower left corner of the Setup window for the corresponding parameter to switch the alarm level.
4) Switch the alarm ON/OFF icon  to [ON].
5) Select the triangle icon  , and rotate the knob to change the range of alarm limit, press the knob again.
6) Select the confirm key  to save the settings.

When some parameter alarm function is switched off, the system will prompt  in the corresponding parameter area to show the alarm is switched off.

8.6.2 Setting the Auto Alarm Limit

The monitor can automatically set the Alarm Limits for the currently measured parameters according to the patient type.

Before applying these alarm limits, make sure they are appropriate for the patient. If inappropriate, you need to manually set the alarm limits.

Follow the steps to set auto alarm limit:

Enter [Main Menu] → [Alarm Setup] → [Alarm Limit Setup], enter your password→ [Auto Alarm Limit] → [Yes].

⚠ Warning

- **When setting alarm limits to extreme values, the alarm system may be useless.**

⚠ Note

- **The monitor will always save the alarm settings in case of power interruption and the alarm settings are restored automatically after power interruption.**

8.7 Setting Alarm Delay

The system provides five options for parameter alarm delay: [Not Allowed], [5s], [10s], [15s] and [20s]. If [Not Allowed] is selected, when the measured parameter is beyond the alarm limit, the monitor gives alarm immediately. If [5s]/[10s]/[15s]/[20s] alarm delay is selected, the monitor gives alarm when the measured parameter value has been consistently beyond the alarm limit for 5s, 10s, 15s, 20s, respectively.

Follow the steps to set alarm delay time:

1) Enter [Maintain] → [Alarm Setup] → [Alarm Delay].
2) Set the appropriate delay time.

8.8 Alarm Pause

You can press the key on the control panel to quickly enter the alarm pause state:

- Alarm sound, alarm light and alarm message are disabled for physiological alarms, and no physiological alarms will be triggered.
- The physiological alarm message area shows the prompt message "Alm Pause XXXs".
- The icon area will prompt .
- Alarm sound and alarm light are disabled for technical alarms; if a new technical alarm is triggered, only text prompt will be given.

8.8.1 Setting Alarm Pause

1) Enter [Maintain] → [Alarm Setup] → [Alm Pause Time].
2) Set the appropriate pause time: [1min], [2min], [3min], [5min], [10min], [15min].

8.9 Alarm Off

The Alarm OFF function is effective just for physiological alarms. When the function is activated:

- The Alarm OFF sign will be shown on the right side below the corresponding parameter in the parameter area.
- For physiological alarms, sound, light and text prompts will be disabled, and no new physiological alarms will be triggered.
- The parameter triggering the physiological alarm will stop flash.

Operation steps:

a) Click the parameter value area to open the Setup menu, and then select [Alarm Limit Setup]. You can also select the [Alarm Setup] shortcut key to directly enter [Alarm Limit Setup].
b) Or choose any parameter or waveform on the screen to enter [Alarm Limit Setup].
c) Select [All Alarm Off] to disable alarms against all parameters. If the alarm ON/OFF icon ON of a parameter is switched to "OFF", alarms for that parameter will be disabled.

To exit the alarm OFF state of all parameters, select [All Alarm On]; to exit the alarm OFF state of one

parameter, switch the alarm ON/OFF icon  of that parameter to "ON".

⚠ Warning

- **If the alarm function is set to [OFF], the monitor cannot trigger alarm when there is an alarm condition. Therefore, the operator should use this function with caution.**

8.10 Alarm Reset

You can reset the current alarm with the [Alarm Reset] soft key:

- Cease the audio alarm indication of all physiological alarms and technical alarms.
- If a new alarm occurs, resetting will be interrupted, and the alarm indications are generated immediately.
- For the technical alarms of lead off and sensor off, background color is cleared and alarm light is switched off. Other physiological and technical alarms background color and alarm light cannot be cleared.
- The sign√ appears in front of the alarm message, indicating that the alarm is acknowledged.

8.11 Alarm Preset

This monitor has an alarm preset: the factory adult/pediatric/neonate default settings. Refer to ***Appendix V*** for the factory alarm default settings.

How to use factory adult/pediatric/neonate default settings:

1. Access [Main Menu] → [Load Config];
2. Select [Default Adu Config], the alarm limit will restore to the factory default settings.

The users should notice the following items when using this monitor:

Once the alarm settings have been modified, the monitor will always save the modified alarm settings. When changing the patient type, the monitor will restore to the alarm settings of that patient type set previously. Therefore, the users should check whether the alarm settings are suitable for the patient to be monitored prior to monitoring.

⚠ Warning

- **A hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.**

8.12 Alarm System Test

You can know whether the alarm system works normally by the state of the sound-light alarm. For example:

(1) Click FHR1 parameter area to enter [FHR Setup] menu;

(2) Select [Alarm Limit Setup] and switch the alarm on.

(3) Set the [FHR1] upper limit as 120 and lower limit as 80.

(4) When the measured value is beyond the high/low alarm limit, confirm whether the changes in sound, light, message and parameter flashing on the monitor conform to the descriptions in *Chapter 8.3 Alarm Mode*.

Chapter 9 Battery

9.1 Overview

The monitor is equipped with a built-in rechargeable battery. When AC power supply is connected, the battery is charged automatically until it is full whether the equipment is turned on or not. In the event of unexpected power failure, the system automatically uses the battery to supply power for the running of the equipment. When AC power supply is cut off, the battery indicator blinks, indicating that the battery is being used and equipment operation is not affected.

The Battery icon shown on the screen indicates the battery status.

 indicates battery level is full.

 indicates battery level is medium.

 indicates battery level is low and charging should be considered.

 indicates battery level is too low and should be charged immediately.

 indicates absence or damage of the battery.

 indicates battery is charging.

Note

- **If the battery is not to be used for a long period of time, please remove the battery and store it properly according to the manufacturer's instructions.**
- **If the monitor is provided with a built-in battery, the battery must be charged after each use to ensure sufficient charge.**

Warning

- **Battery electrolyte is hazardous. In case that battery electrolyte comes into contact with your skin or enters your eyes, wash it with clean water immediately and seek for medical help.**
- **Keep the battery out of the reach of children.**

9.2 Low Battery Alarm

The monitor will automatically shut down in case of two low battery. When the battery icon turns to  , indicating the battery power is less than 10%, the monitor will trigger a technical alarm with alarm message of [Low Battery]. At this moment, the monitor should be immediately connected to AC supply to charge the battery, or the monitor will auto shut down before the battery is fully used up.

9.3 Installing Battery

Procedure of changing or installing the battery:

(1) Turn off the monitor, and disconnect the power cord and other connection lines.

(2) Place the monitor with the back up.

(3) Unscrew the battery cover.

(4) Take out the used battery and put the new one into the battery holder making sure the positive and negative poles match what is indicated on its shell.

(5) Replace the battery and screw it on, and turn the monitor upright.

9.4 Optimization and Check of Battery Performance

(1) Optimization of battery performance

When the battery is used for the first time at least two complete cycles of optimization of the battery should be carried out. A complete optimization cycle should be: uninterrupted charging battery until the power is full, followed by use until the battery is fully discharged and monitor is automatically shut off.

This will ensure the battery is in optimization process:

(a) Disconnect the monitor from the patient and suspend all monitoring and measuring procedures.

(b) The optimized battery should be kept in the battery compartment of the unit.

(c) When charging the battery, at least six hours of charging should be ensured until it is fully charged.

(d) When you disconnect the AC power supply, the monitor is powered with the battery until the battery runs out and the monitor automatically shuts off.

(e) This completes the battery optimization process.

(2) Check of Battery Performance

The service life of battery is changeable along with its storage, working environment charge cycles and service time. Even though battery is out of service its performance will gradually deteriorate.

Procedure for checking the battery is as follows:

(a) Confirm whether the battery is damage or not. When the battery shows the symbol "  ", it indicates

the battery is damaged or no battery.

(b) Check whether the battery can be normally charged when the battery is connected to alternating current;

(c) Disconnect the monitor from the patient and suspend all monitoring and measuring procedures.

(d) When charging the battery, at least six hours of charging should be ensured until it is fully charged.

(e) Disconnect the AC power supply, power on the monitor with the battery until it is fully discharged and the monitor shuts off automatically Record the start and stop time.

(f) The duration of battery discharge will reflect the battery performance.

(g) Once the discharge duration is down to 50% of the original time, it requires changing the battery.

Note

- **In order to extend the service life of the battery, it is recommended to charge it every three months after a long dormant period to prevent overdischarge.**
- **Battery power supply loss depends on the configuration and operation of the monitor; for example, the unit will have a big loss of battery power if it is used to measure NIBP parameter often.**

9.5 Battery Recycling

If the battery shows apparent damage or is at an energy exhaustion condition, it should be exchanged immediately, and the used battery should be recovered and properly disposed of in accordance with relevant laws or rules and regulations for hospitals.

Warning

- **Do not remove the battery or make it short-circuiting or put it into fire; otherwise, it would cause battery on fire, explosion, harmful gas leakage or other dangers.**

Chapter 10 Printing

10.1 Loading Recording Paper

⚠ Warning

- You must use required folded thermal recording paper, otherwise it may lead to inability to record, record quality degradation or damage to the thermal head.
- Do not use hands or other rough material to touch the thermal head, or it will result in damage to the recorder.

⚠ Note

- Please do not pull the recording paper when it is out from the recorder at a constant speed, or the recorder could be damaged.
- Do not use the recorder without recording paper inside.
- Do not contact the thermal print head. Do not keep the recorder door open except for paper change or troubleshooting.
- The recorder doesn't stop printing until all the recorded waveforms and data are output. Do not press the print key when it is printing, or the printing will be stopped.
- Do not keep the recorder door open except for paper change or troubleshooting.

*Paper jam

If the recorder makes any abnormal sound during operation or the record paper outputs abnormally, check to see if any paper is jammed.

Fig 11-1 Loading record paper

1) Unlock the paper compartment with your right hand and open the compartment door outwards;

2) Put new record paper into paper slot with the grid side facing up and top of the paper (210) toward the left of the monitor;

3) Pull the paper through top of the paper roller until it reaches out of the opening, and put the paper upright;

4) Press down the door. Make sure the door is properly locked.

10.2 Printing

The monitor supports three print methods: real-time print, freeze print and review print. Fetal waveforms can be printed as well. The monitor prints different contents in different interface. See the table below:

	Printed content	
	Real-time print	Freeze print
Fetal Screen	Fetal waveforms	Fetal waveforms
Big Font	Fetal waveforms	N/A

■ Start recording manually:

- ◆ To start real-time recording, select on the front panel of the monitor.
- ◆ To start recordings related to specific functions, select the corresponding record button in the current menu or window.

- Stop recording manually:
  - Select on the front panel of the monitor or the corresponding record button in the current menu.
- The recorder stops recording automatically in the following situations:
  - The recording task is fulfilled
  - The recorder is out of paper
  - The recorder is not operating properly.

10.2.1 Real-Time Printing

Real-time printing means the printing triggered during real-time monitoring, the specific steps are as follows:

1. Press the print key on the front panel.
2. Enter a prompt window: choose [Yes] or [No].

- [Yes]: Start real-time recording and print real-time recording data.
- [No]: Cancel the real-time record.

The print time is decided by the [Print time] of [Record Setup], defaulted by 20min.

10.2.2 Freeze Printing

Freeze print is print by pressing the print key on the front panel under freezing status.

To print frozen fetal waveforms:

1. Press the print key on the front panel under freezing status to enter [Preview] window;
2. Confirm waveforms and scores and press print key, and the monitor starts printing frozen waveforms from the left of current interface according to the time set on [Print time] of [Record Setup];
3. If [Print Score Form] [On] is selected, the monitor also prints scores after printing the frozen waveforms.

10.2.3 Review Printing

10.2.3.1 Segmental Grade Printing

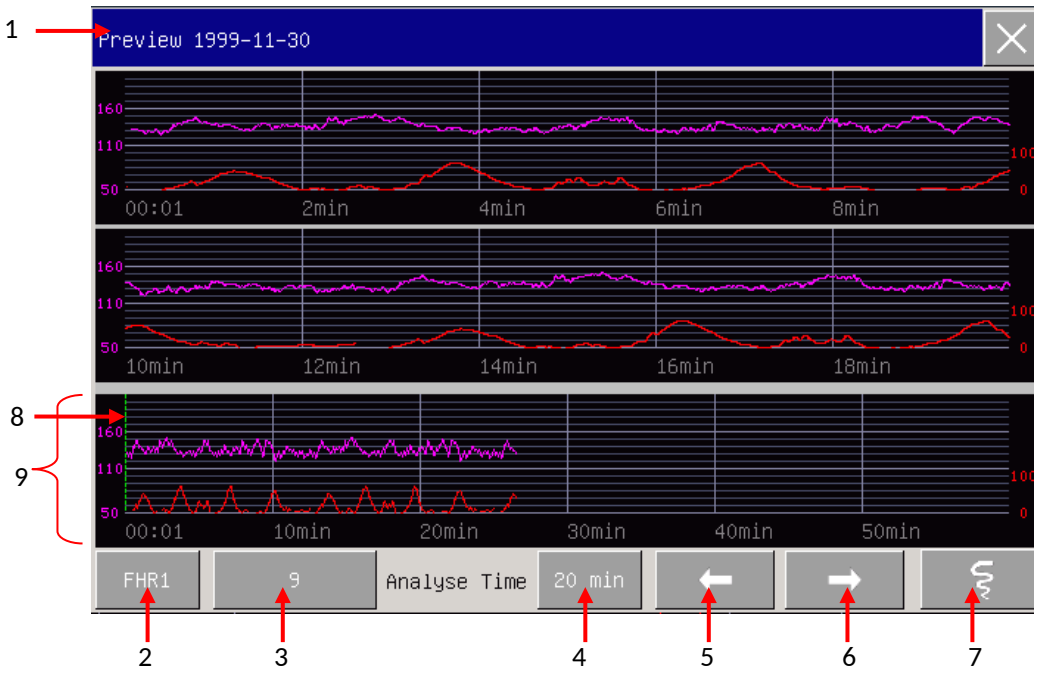
Segmental grade printing refers to fetal waveform printing under the general monitoring mode. Frozen fetal waveform and load fetal cases also support segmental grade printing. The operation steps are as follows:

1. Access [Main Menu] → [Document Manage] → Select a case→[View] → [Fetal Review], press to enter preview interface, then click the score in the bottom of the preview interface to enter [Patient Info & Advanced Fischer Score] window;

2. Confirm the patient information and score results and click [Enter]. The monitor starts to print the fetal waveform according to the speed set in [Real Speed] and the time set in [Real Time].

3. To stop printing during printing process, just press the print key on the front panel or click the [Record] on-screen key. If [Print Score Form] is set to [ON], the monitor will output the score report immediately and then stop printing; if [Print Score Form] is set to [OFF], the monitor will stop printing immediately.

Segmental grade printing supports internal and external printer at the same time. The steps of printing fetal report for external printer are the same as the internal printer. The preview of fetal report is as follows:



1. System date
2. Grade object, click to switch [FHR1], [FHR2] or [FHR1&2].
3. Select the waveform grade, click here to view the grade standard and the score of a specific item in the pop-up window
4. Analyse Time. Click here to select analyse time.
5. Click to page forward.
6. Click to turn page back.
7. Click to record.
8. Waveform selection cursor. Drag it to select the waveform to print, the analysis time after the cursor waveform will be used to score and print.
9. In the uncompressed waveform area, the selected waveform will be displayed at the normal waveform amplitude.

10.2.3.2 Alarm printing

Alarm printing only supports external printer, the steps are as follows:

1. Connect the external printer.

2. Access [Main Menu]→[Printer Setup (USB)]→[Print Report];

3. Click [Alarm Event Review Report] to print.

10.2.4 Print Setup

Enter [Main Menu] → [Record Setup]

[Record Setup] mainly includes:

- [Print time]: 10min, 15min, 20min, 25min, 30min, 40min, 50min, 60min, 70min, 80min, and undefined.
- [Score Channel]: FHR1, FHR2 and FHR1&2.
- [Head Direction]: Horizontal and Vertical.
- Access [Maintenance] → [Paper Type], the paper type can be set to 30~240, 50~210

Click FHR parameter to set recording setup:

- [Grade Criterion]: [KREBS], [Fischer], [Advanced Fischer], [NST] and [OXFORD].
- [Print Score Form]: On, Off
- [Auto Grade]: On, Off
- [Fetal Printer Type]: [Recorder] and [External Printer]
  - [Recorder] means using the 150mm recorder equipped with the monitor to print and the print paper is the recording paper.
  - [External Printer] means using the external USB printer to print and the print paper is A4 paper, which supports Lenovo LJ2650DN and Hewlett-Packard HP2055d. This item is only available when connecting the external USB printer to the monitor.

◆[Fetal External Printer Setup]: it can set [Interval] and [Detailed patient information option].

- [Interval]: 1 cm/min, 2 cm/min, 3 cm/min and Self-adaption
- [Detailed patient information option]: set the patient information that needs to be printed

If the device is connected with the external printer, user can enter [Main Menu]→[Print Setup (USB)] to choose the report needed printing. For example, the user can click [Fetal Report] to set printing setup.

10.3 Score Criterion

The monitor supports five kinds of score criteria: KREBS, Fischer, Advance Fischer NST and OXFORD. The following tables are instructions of the five criteria.

NST score criterion is as follows:

NST Score / Item	0 score	1 score	2 score	Value	Score
Baseline FHR (bpm)	<100, >180	100~109,161~180	110~160		
Var .Range (bpm)	<5	5~9,>30	10~30		
FHR Rise Time with FM (s)	<10 s	10~14 s	>14 s		
FHR Rise Amp. with FM (bpm)	<10	10~14	>14		
FM	0	1~2	>2		

KREBS score criterion is as follows:

KREBS Score / Item	0 score	1 score	2 score	Value	Score
Baseline FHR (bpm)	<100,>180	100~109,161~180	110~160		
Var .Range (bpm)	<5	5~9,>25	10~25		
Var. Freq. (cpm)	<3	3~6	>6		
Acc	0	1~4	>4		
Dec	>2	1~2	0		
FM	0	1～4	>4		

Advanced Fischer score criterion is as follows:

Advanced Fischer Score / Item	0 score	1 score	2 score	Value	Score
Baseline FHR (bpm)	<100,>180	100~109,161~180	110~160		
Var .Range (bpm)	<5	5~9,>30	10~30		
Var. Freq. (cpm)	<2	2~6	>6		
Acc	0	1~4	>4		
Dec	LD or SVD	MVD	None		

Fischer score criterion is as follows:

Fischer Score / Item	0 score	1 score	2 score	Value	Score
Baseline FHR (bpm)	<100,>180	100~109,161~180	110~160		
Var .Range (bpm)	<5	5~9,>25	10~25		
Var. Freq. (cpm)	<2	2~5	>5		
Acc	None	PA	NPA		
Dec	LD or SVD	MVD	None		

OXFORD grade criterion is as follows:

Items	Result	Items	Result
Signal loss rate		Basal fetal heart rate (bpm)	
Number of TOCO		Decelerate>20 losses	
FM per hour		Long-term Variability (min)	
Accelerate>10bpm & 15s		Low Variability (min)	
Accelerate>15bpm & 15s		Short-term Variability (ms)	

Note

- **Diagnosis results output by doctors are only selectable software functions of the monitor, which can only be reference to doctors' clinical diagnosis. Doctors should make diagnosis based on the actual waveforms and then sign to confirm. Doctors are responsible for the conclusion of the output reports.**

Chapter 11 Cleaning and Disinfection

Only materials and methods listed in this chapter that are accepted by the Company can be used for cleaning or disinfection of the device. For any damage arising from use of unaccepted materials or methods, the Company will not provide any warranty.

The Company will not assume any liability for the effectiveness of listed chemicals or methods when they are used as infection control means. For infection control methods, please consult the Infection Prevention Department or an epidemiologist in your hospital. Besides, please refer to local policies that apply to your hospital and country.

11.1 Overview

Please keep the device and its accessories dustless. After cleaning, please check the device carefully. If there is any evidence of ageing or damage, please stop using it immediately. If it is necessary to send back the device to Comen for repair, first clean it. Please observe the following precautions:

- Please dilute detergent and disinfectant as specified by the manufacturer, or use a concentration as low as possible.
- Never allow any liquid to flow into the housing.
- Never pour any liquid onto any part or accessory of the device.
- Never soak the device in any liquid.
- Do not use any frictional material, bleaching powder or strong solvent (e.g., acetone or detergent containing acetone).

11.2 Cleaning and Disinfection of the Monitor and Accessories

To avoid cross infection, please clean the monitor and accessories after each use. Please understand the relevant regulations about equipment cleaning in your hospital before cleaning.

Steps of cleaning:

1. Turn off the monitor,
2. Disconnect the power cord and accessory cable from the monitor;
3. Clean the display screen and the enclosure of the monitor and plug-in modules with a soft cloth moistened (not wet) with cleaning agents;
4. Clean the accessory cable and sensor with a soft cloth moistened (not wet) with cleaning agents;

5. After cleaning, wipe off the cleaning agent with a dry soft cloth;
6. Allow the monitor, accessory cable and sensor to air dry.
7. To avoid damage to the monitor and accessories, disinfection is recommended only when regulated as necessary in the Hospital Maintenance Schedule. Please wash the monitor and accessories first before disinfection.

The recommended cleaning agents and disinfectants for the monitor and accessories are listed in the following table:

Components	Selectable Cleaning Agents	Selectable Disinfectants
Monitor enclosure	Isopropyl alcohol (70%), Hydrogen peroxide	Isopropyl alcohol (70%), Glutaraldehyde solution (2%), Sodium hypochlorite
Power cord	Isopropyl alcohol (70%), Hydrogen peroxide	Isopropyl alcohol (70%), Glutaraldehyde solution (2%), Sodium hypochlorite
TOCO transducer	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol (70%), Glutaraldehyde solution (2%), Sodium hypochlorite
FHR transducer	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol (70%), Glutaraldehyde solution (2%), Sodium hypochlorite
FM marker	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol (70%), Glutaraldehyde solution (2%), Sodium hypochlorite

⚠ Warning

- **Do not use the cleaning agents and disinfectants other than those recommended in this user manual, because permanent damage to the monitor or accessories may occur, or safety hazards may be caused.**
- **Do not use the following detergents unless otherwise stated:**
  1. **Detergents containing acetone**
  2. **Detergents containing trichloroethylene**
  3. **Detergents containing cresol soap (Lysol water)**

4. Detergents containing phenolic compound base
5. Alkaline detergents
6. Acid detergents

- Do not use the following disinfectants unless otherwise stated:
  1. Disinfectant containing chlorine dioxide
  2. Disinfectant containing trichloroisocyanuric acid
  3. Disinfectant containing peracetic acid
  4. Disinfectant containing benzalkonium bromide or benzalkonium chloride
  5. Disinfectant containing chlorhexidine gluconate or chlorhexidine acetate
  6. Disinfectant containing quaternary ammonium salt
  7. Disinfectant containing potassium persulfate
  8. Disinfectant containing potassium permanganate
  9. Iodophor or tincture of iodine
  10. Ozone disinfection
  11. Disinfection with high pressure steam
  12. High temperature sterilization
- Before cleaning the monitor, make sure that it is switched off and disconnected from AC power.
- Never use acetone on any part of the monitor.
- Never pour or spray liquid on the monitor.
- Use a cloth to wipe off any cleaning agent remaining on the monitor or accessories.
- Do not mix the cleaning agents, or dangerous gas will be produced.
- Do not clean or disinfect the disposable accessories. Do not reuse the disposable accessories to avoid cross infection.
- To protect environment, the disposable accessories must be disposed of properly according to local regulations and requirements.
- After cleaning, inspect the sensor cable for damage or aging. If any damage or aging is found, please replace the sensor cable.
- Do not sterilize the monitor and accessories by autoclave.
- Do not use ETO gas to disinfect the monitor or accessories.
- Do not immerse the sensor or connector into any cleaning agent or disinfectant.

⚠ Caution

- If you accidently pour liquid onto the monitor or accessories, please contact the customer service immediately.

11.3 Cleaning the probe strap

The probe strap should be cleaned with soapy water with temperature lower than +60°C.

Chapter 12 Maintenance

12.1 Maintenance Check

The overall check of the monitor, including a safety check, should be performed only by qualified personnel before first use, every 6 to 12 months, and each time after repair.

Before using the monitor, do the following:

(a) Check if the work environment and power supply meet the requirements.

(b) Check if there is any mechanical damage.

(c) Check if the cables are worn and ensure insulation is in good condition.

(d) Check all the functions of the monitor to make sure that the monitor is in good condition.

(e) Check if the accessories used are specified by the manufacturer.

(f) Check the battery.

(g) If the monitor is equipped with a recorder, please check if the recorder is normal and recording paper meets the specified specification.

(h) Check if the wiring resistance and leakage current meet the requirements.

If you find any damage on the monitor, stop using the monitor on patient,and contact the biomedical engineer of the hospital or our customer service immediately.

All the safety and maintenance checks that need to dismantle the monitor should be performed by a qualified customer service technician. Non-professional operation can cause the monitor damage or cause a security risk, and human health may be endangered.

The circuit diagrams of the monitor can be provided by Comen as per customer demands. Qualified technicians can use it to help the user repair some apparatus that Comen classifies as “can be maintained by the user”.

⚠ Warning

- **If the hospital or agency that is responsible for using the monitor does not follow a satisfactory maintenance schedule, the monitor may become damaged, and human health may be endangered.**
- **Before using the monitor, check the monitor, probes, and cables for damage that may affect patient safety or performance, especially if the probe and cable are cracked.**
- **Be sure to check the cable and plug of the transducer assembly before use. Do not use damaged cable and plug.**
- **In order to avoid polluting the environment or other equipment, it is necessary to properly disinfect and decontaminate the monitor after reaching the service life, and then handle the monitor according to the local regulations for handling equipment containing electrical and electronic parts.**

- **After the equipment and accessories reach a certain service life, problems such as inaccurate measurement may occur, so it is necessary to check the equipment and accessories regularly.**
- **The monitor or accessories that are not serviced or maintained while in use with the patient.**

12.2 Maintenance Schedule

The following safety and maintenance check can be conducted by professional persons approved by Comen. You can contact the customer service technicians if you need the following maintenance. Before the inspection or maintenance, the facilities should be cleaned and disinfected.

Check and maintenance items	Frequency
Safety check according to IEC 60601-1 requirements	At least once a year. Or after monitor falling, power replacement, or as required.
The performance of all measuring functions	At least once a year or when you doubt the measured value.
Battery	See the section on battery for reference

12.3 Testing FHR probe

After starting the monitor, please connect the FHR transducer.

(1) Hold the sensor surface with one hand, pay attention to put the palm as close as possible to the sensor surface, and the other hand taps the back of the hand holding the sensor surface at a certain frequency.

(2) Check whether the screen displays a frequency value of this tap.

Please check all FHR transducers mentioned above. If there is any error, please contact our After-sales engineers.

12.4 Testing TOCO Transducers

(1) After starting the monitor, please connect the TOCO transducer.

(2) Apply appropriate pressure to the middle of the sensor surface.

(3) Check whether the screen displays the press change.

Please check all TOCO transducers mentioned above. If there is any error, please contact our After-sales engineers.

Chapter 13 Fetus Monitoring

There are two basic types of fetus monitors: antepartum monitor for pre-delivery use and intrapartum monitor for in-delivery use. The antepartum monitor does not have the internal monitoring ability and thus cannot monitor the fetal heart rate (FHR) directly through the fetus scalp electrode or monitor the internal uterine pressure (IUP) of the mother through the internal pressure pipe. It monitors the FHR by connecting the ultrasound transducer to the mother's abdomen and monitors the uterine pressure by connecting the TOCO Transducer to the bottom of the mother's uterus.

Monitor provides Non-Stress testing for pregnant women from the 24th week of gestation. It can externally monitor the FHR, FM and TOCO.

⚠ Note

- **Before operating the monitor, please be sure to use foetoscope, stethoscope and other methods to confirm whether the fetus is alive.**
- **Before monitoring each time, please check Alarm Setup to make sure whether it is suitable for the current pregnant woman, if not, please adjust.**
- **Before monitoring, please check the skin condition where the probe is placed and avoid damaged and allergic skin.**
- **When conducting a long-time monitor, please pay attention to change the probe site every half hour at least. If the skin condition changes, move the probe site immediately.**
- **Fetal heart monitoring should not be performed unless a clear fetal heart sound signal is detected.**
- **If the FHR suddenly drops below 10bpm or exceeds 10 bpm, or if the rhythm of the FHR suddenly slow down, check that the FHR probe captures the mother's heart rate, rather than FHR. If the situation occurs, you need to adjust the probe site to ensure that the probe can obtain a clear fetal heart sound.**
- **If fetal movement deviates from the ultrasound probe due to frequent fetal movement, re-position the fetal heart probe to ensure that the probe can obtain clear fetal heart sounds.**

13.1 Fetal Monitor

13.1.1 Fetal Monitoring Principle

Below are the ultrasound Doppler FHR monitoring principles:

The Doppler FHR monitoring is supported by the Doppler Effect. The ultrasound wave will be reflected when meeting any obstacle in the propagation process. If the obstacle is still, the reflection frequency will be

identical with the transmitting frequency. If the obstacle moves, the reflection frequency will change: become higher (or lower) when the obstacle faces the sound source with the front (or back). The faster the obstacle moves, the greater change the reflection frequency will experience. That is the Doppler Effect. In clinical application, the ultrasound transducer is used to transmit the ultrasound wave into the human body. When the ultrasound wave meets any locomotive organ (like heart), the echo signals will be changed and processed to collect the heart rate information which indicates the heart activities.

It is the best time to do the Doppler FHR monitoring when the fetus faces the mother's abdomen with the back. If the fetus faces the mother's abdomen with the front, his/her arms and legs will impact the echo signals. When the fetus turns, his/her heart will deviate from the irradiation area of the transducer to cause weaker echo signals and reduced Doppler Effect.

13.1.2 Terms about Monitor

Continuous wave mode: ultrasound transducer and receiver work simultaneously in a continuous fashion. This mode features simple circuit and large speed variation, with the disadvantages of inability to determine the distance, vulnerability to external noises, large transmitting power and small sensor coverage.

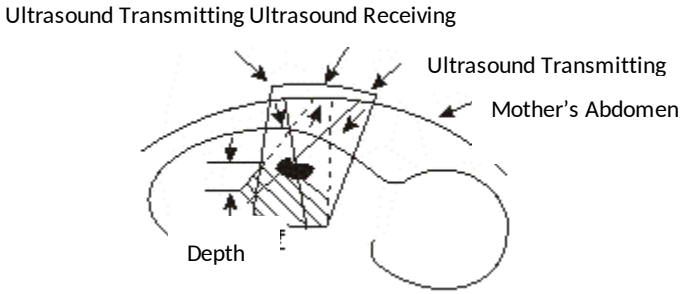


Figure 13-1 Continuous Wave Transmitting/Receiving

Pulse wave mode: this work mode has a small transmit power and a large sensor coverage. It can selectively receive a certain range of ultrasound thus block other noises. The disadvantage is complicated circuit design. Generally, 1 MHz frequency is used for fetal monitoring. Higher frequency means lower penetrability but higher resolution of organism structure, and vice versa. The international safety standard of ultrasound transmitting power is 10MW/cm^2. Higher power could have harmful effect on the fetus.

13.2 FHR Monitoring

13.2.1 Confirming Fetal Life

Fetal monitoring with ultrasound cannot differentiate a fetal heart rate signal source from a maternal heart rate source in all situations. These are some of the signal sources that might be taken as FHR signal source by mistake:

- High maternal heart rate signal.
- Maternal aorta or other large vessels signals.
- Electrical impulse from the maternal heart transmitted through a recently deceased fetus.

These are some of the signal sources that might be taken as fetal movement by mistake:

- FHR probe movement;
-Movement of the dead fetus during or after palpation;
- Movement of the deceased fetus during or following maternal movement.

So you need to confirm fetal life by other means before starting to use the fetal monitor, such as using a fetoscope, stethoscope, Pinard stethoscope or obstetric ultrasonography.

13.2.2 FHR measurement steps

(1) Let the patient lie on her back with the belt placed under her back, lay the patient on the bed and then use the stethoscope to find the position of the fetal heart.

(2) Apply a certain amount of ultrasound gel to the contact surface of the transducer to ensure the largest FHR monitoring area. Before applying the transducer to the pregnant woman, please apply coupling medium to the middle 2/3 part of the contact surface. The ultrasound gel will be pressed to cover the whole contact surface (shaded part as showed below) after the transducer is fixed to the pregnant woman's abdomen.

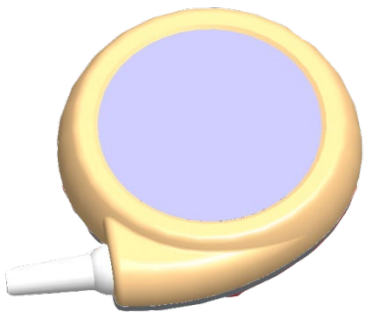


Figure 13-2 FHR Transducer

(3) Connect the ultrasound transducer to the abdomen of the pregnant woman and then adjust its position until you find loud fetal heart signal.

(4) Fix the ultrasound transducer with the belt. Fasten the sensor belt with appropriate tightness.

(5) Make sure you can hear the fetal heart beats in the monitoring process. **Do not adjust FHR volume to zero**. The FHR curve is not reliable without strong fetal heart signals.

(6) If there is any strong fetal movement or uterine contraction or the pregnant woman moves her body, the fetal heart position may change a lot. Please check whether you can hear clear fetal heart beats from time to time. If not, please adjust the position of the ultrasound transducer to find strong fetal heart signals again.

13.2.3 Cross-Channel Verification

The fetus is not necessarily alive even if the fetal heart rate is detected, because the ultrasound transducer may collect signals from other sources, like the mother's heart, aorta, or large vessel pulsation.

During fetus monitoring, if the monitored heart rates (from a fetal or mother) coincide at any time, the same heart rate is probably being monitored by more than one transducer. The cross-channel verification feature is helpful to detect whether the same heart rate is being monitored by more than one transducer.

How to activate the cross-channel verification feature:

1. Select FHR waveform, in the pop-up [FHR Setup] menu, select [Cross Duration] and adjust the duration for cross-channel verification. Available duration includes [Close], [30 S], [60 S], [90 S] and [120 S]. The default is [60s]. [Close] means the monitor will not give alarms even though the monitored heart rates coincide; [30 S] means when the monitored FHR1 and FHR 2, or the monitored fetal heart rate and maternal heart rate coincide for more than 30 seconds, the monitor will give a high level technical alarm.
2. Select [Cross Error] and select the allowable error for cross-channel verification. Available options include [0bpm], [1bpm], [2bpm], [3bpm], [4bpm] and [5bpm]. [0bpm] means once the monitored FHR1 and FHR 2, or the monitored fetal heart rate and maternal heart rate coincide for more than the time set in [Cross Duration], the monitor will give a high level technical alarm; [1bpm] means when the difference between the monitored FHR1 and FHR 2, or the monitored fetal heart rate and maternal heart rate is less than or equal to 1bpm and lasts for more than the time set in [Cross Duration], the monitor will a high level technical alarm.
3. The technical alarm message is [Adjust Sensor Position] (Adjust the positions of ultrasound transducers) and the FHR1 and FHR2 parameter area will display "_?_" at the same time.

13.2.4 Trace Separation

The trace separation function is to help you interpret traces with similar baselines.

- **Enable Trace Separation**

  Select FHR waveform, in the pop-up [FHR Setup] menu, select [FHR Separation of Trace] and select [+20bpm] or [-20bpm]. [+20bpm] or [-20bpm] means the FHR2 trace is displayed and recorded 20bpm higher or lower than it really is respectively. The FHR2 trace recorded on the recording paper is thinner with light color.

  Take +20bpm offset as an example, see the figure below:

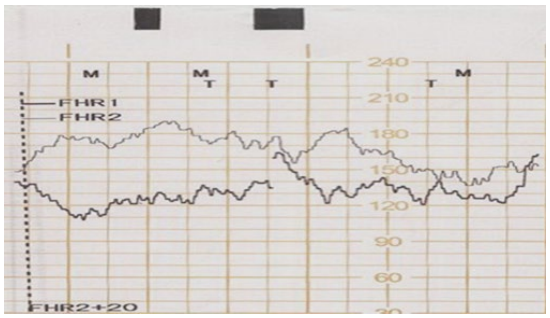


Figure 13-3 Trace separation enabled

Note：The FHR2 trace on the recording paper has an offset, but the FHR2 value on the screen remains unchanged.

- **Disable Trace Separation**

  Select FHR waveform, in the pop-up [FHR Setup] menu, select [FHR Separation of Trace] and select [+0bpm].

  The FHR2 trace recorded on the recording paper is thinner with light color, and the FHR2 trace is the true one, see the figure below:

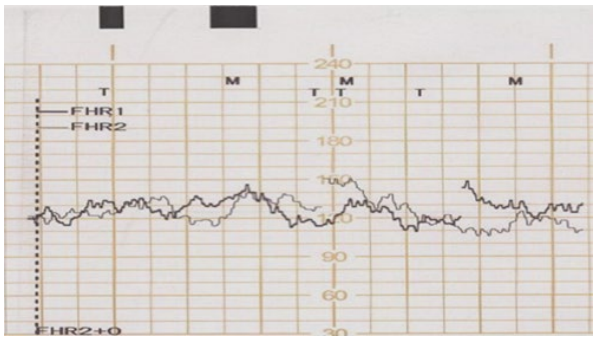


Figure 13-4 Trace separation disabled

13.2.5 FHR Settings

13.2.5.1 Setting the FHR Sound Channel

FHR sound channel means which channel the FHR sound comes from. The available options include [FHR 1] and [FHR2]. When there is only one FHR transducer connected, the FHR sound channel will be locked as [FHR1] and when there are two FHR transducers connected, the users can select the FHR sound channel as needs.

How to set the FHR sound channel:

Select FHR1 or FHR2 parameter area, select [FHR Setup] → [FHR channel] and choose appropriate FHR sound channel.

13.2.6 Confirming that the Fetus is the Signal Source

Because there are possibilities that maternal heart rate signal is mistaken for FHR signal, so it is highly recommended to confirm that the fetus is the signal source continuously.

- Check the mother's pulse by other methods at the same time to see if it is consistent with the changes in fetal heart rate.

If the maternal heart signal is misidentified as the fetal heart signal, repositioning of the transducer is needed.

⚠ Note

- **Do not mistake the high maternal heart rate. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during examination.**
- **The best quality records only be obtained if the probe is placed in the optimum position. Position with strong placental sounds or umbilical blood flow sound should be avoided.**
- **During long-time monitoring, pay attention to prevent the occurrence of low blood pressure in pregnant women, it is best to let pregnant women take a lateral lying position or sitting position for monitoring can make it more comfortable.**
- **When applied to the patient, the ultrasound transducer may warm slightly (less than 2°C compared to ambient temperature)**
- **When NOT applied, the ultrasound transducer can reach 43°C under 40°C ambient temperature.**
- **Unexpected intermittent FHR readings may be measured when the ultrasound probe is connected to a monitor but not worn on the patient.**

13.3 TOCO Monitoring

Uterine contraction pressure is a criteria of labor intensity. It is clinically proven that contraction status has a direct influence on fetal heart activity and labor. For example, it can cause increased or decreased FHR. The curves recorded by the monitor provide important information such as uterine contraction level, frequency, duration, pattern, all of which, combined with FHR monitoring, help medical personnel to make diagnosis on FHR changes.

External pressure monitoring collects information of contraction status from maternal abdomen. When contraction happens, the abdomen tension presses on the pressure sensor above. The sensor transfers the pressure into electrical signals which are processed by devices and eventually displayed on screen or printed out.

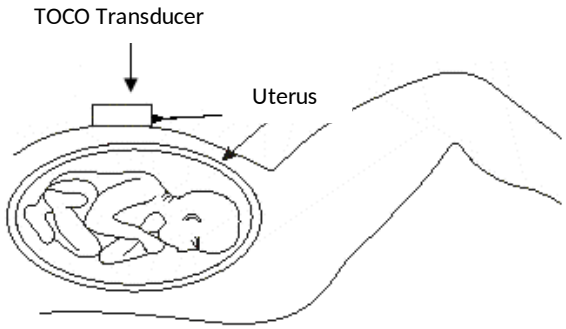


Figure 13-5 TOCO Measuring

13.3.1 Connect the TOCO Transducer

(1) Make the belt pass through the back of the TOCO transducer (See below), place the TOCO transducer at the bottom of the patient's uterus, and then tie the belt to the proper position with proper tension.

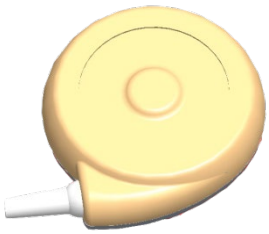


Figure 13-6 TOCO Transducer

(2) Perform TOCO zeroing with one of the following four methods:

- Select TOCO waveform area or parameter area, Enter[TOCO Setup] menu and select [TOCO Base].
- Or press the TOCO zero key →0← on the front panel.

(3) When the TOCO transducer is placed on the pregnant woman, please observe the TOCO value on the screen.

⚠ Note

- **Before measurement, press the TOCO zero key manually.**
- **Do not apply conductive gel to TOCO transducer or probe contact area.**

13.3.2 Setting the TOCO Zero Value

TOCO Base is zero the value of uterus shrink pressure. If you set [TOCO Base] to 0, the minimum TOCO value will be 0 after zeroing. This operation will also zero the trace on the screen.

(1) Select the TOCO waveform area or parameter area and the [TOCO Setup] menu will be displayed;

(2) Select [TOCO Base] and select the TOCO zero value from 0, 5, 10, 15 and 20.

In the absence of contractions, the key →0← returns to zero (adjusting the TOCO baseline). After the contraction returns to zero, the TOCO reading displayed on the monitor should be between 30% and 90%. If the reading is not in this range, it may be because the abdominal band is too tight or too loose. If the abdominal band is too tight, the contraction peak in the TOCO value range may appear less than 100 units flat; If the belly band is too loose, the probe may slip, causing an abnormal reading. Adjust it according to the actual situation.

13.4 Counting Fetal Movements

13.4.1 Counting Fetal Movement Manually

Let the pregnant woman hold the marker and press it each time the fetus makes a movement.

Fig 13-7 Manual Fetal Movement Marker

The marked fetal movements displayed on screen and printed on paper are indicated respectively with icon“ ” in green and the letter “M”.

⚠ Note

- **If fetal movements are counted manually, remind the pregnant woman that movements lasting for 5 seconds are counted as only one movement and that she should press the marker only once. If the marker is pressed for multiple times in 5 seconds, they are counted as one.**

13.4.2 Counting Fetal Movement Automatically

The auto fetal movement is detected by Doppler heart rate signals. But the difference between FHR signal and auto FM is auto fetal movement signals have larger extent and lower frequency. The larger extent is because of the bigger scope of moving areas (e.g., the fetal arms or legs); lower frequency is because of the lower velocity of the fetal movements compared with those of the fetal heart. The movement can be detected and displayed in AFM on the monitor.

Place the marker at somewhere with the least interference and impact. The device automatically counts fetal movements according to clinical conditions.

The yellow icon "  " displayed on screen represents automatic marks of fetal movement (AFM). AFM color is the same as automatic fetal movement wave. To change the wave color, select TOCO wave to enter [TOCO Setup] menu, then select [AFM color] to adjust. If AFM is printed out, it is represented by the letter "T".

13.4.3 Setting up FM Counting Mode

There are two kinds of FM counting mode supported by the monitor, [Auto] and [Manual].

- [Manual] means the pregnant woman holds the FM marker and counts the FM manually when she feels the fetal movement.
- [Auto] means that the FM marker automatically makes the judgment of fetal movement calculation according to the clinical situation. At the same time, when the pregnant woman feels the fetus is moving, the pregnant woman can manually press the fetal movement marking device for fetal movement counting

How to set the FM counting mode:

Select FHR1 or FHR2 waveform area, in the pop-up [FHR wave] menu, select [Fetal Move] → [Manual] or [Auto].

13.5 Fetus-awakening Acoustic Stimulator

The fetus-awakening acoustic stimulator is designed to awaken the fetus during ultrasound examination.

There are three working modes:

1. Fast mode

Vibration time: 0.2s, vibration period: 1.4s (frequency 0.714Hz)

2. Slow mode

Vibration time: 0.8s, vibration period: 2s (frequency 0.5Hz)

3. Manual mode

Fast mode or Slow mode vibrates for 3 periods, then stops

13.5.1 Appearance Introduction

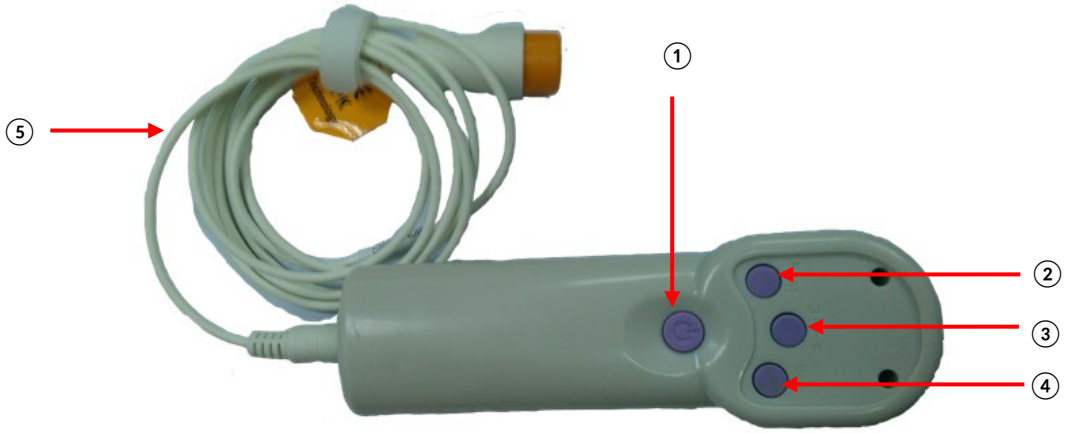


Figure13-8 Front View

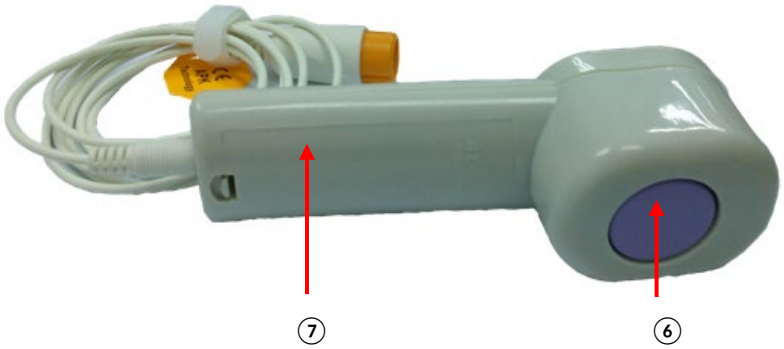


Figure13-9 Side View

① Power switch
② Fast: press to increase the vibration speed.
③ Speed level: level 3 to level ∞. Level 3 is the minimum level.
④ Slow: press to decrease the vibration speed.
⑤ Cable: to connect the monitor.
⑥ Vibration part.
⑦ Battery: the fetus-awakening acoustic stimulator is powered by two AA batteries.

⚠ Note

- The fetus-awakening acoustic stimulator cannot contact with the pregnant women's skin directly.
- When using the acoustic stimulator, its vibration part should be coated with one layer of disposable medical gauze and stuck firmly with medical proof fabric. Replace gauze for each patient to avoid cross infection.

Appendix I Product Configuration

Function Parameter	Model	
	C10	C11
FHR1	√	√
FHR2		√
TOCO	√	√
FM	√	√
Recorder	√	√
Rotary knob	√	√

Note

① "√" indicates that the device is equipped with the function.

② Blank indicates that the device does not have this function.

③ The structure, safety and effectiveness of the same functional module of each type of monitor are completely same.

Appendix II Accessories

Here we recommend the following accessories for the Monitor.

⚠ Warning

- **Use the accessories of designated types only, or the Monitor may be damaged.**
- **To prevent reduced performance and cross infections, please do no reuse any disposable accessory.**

No.	Part No.	Model	Name
1	040-000616	CM-FSUS1	FHR probe, waterproof (twins)
2	040-000617	CM-FSUS2	
3	040-000618	CM-FST	FHR probe, waterproof
4	040-000619	CM-FSM	Fetal Movement Marker, waterproof
5	040-000226	HX-1	Fetus awakening acoustic stimulator

Others:

No.	Part No.	Name	Remarks
1	009-000074	Power cable	/
2	040-000008	Ground wire	/
3	040-000117	Probe strap	/
4	040-000050	Paper	/

Appendix III Replacement Plan for Accessories

Name	Service life
TOCO probe, waterproof	Two years
FHR probe, waterproof	Two years
FM Mark, waterproof	Two years
Wake probe	Two years

Appendix IV Product Specifications

1. Monitor Type

Classified by	Type
Electric shock protection classification	Externally powered Class-I equipment or internally powered;
	BF applied parts: TOCO, FHR, FM
Safety standards	IEC 60601-1, IEC 60601-1-8, IEC 60601-1-2 IEC60601-2-37. IEC60601-1-6 IEC60601-1-9
IP grade	IPX0
Safety level if there is any mixture of flammable anesthetic gas and air or oxygen/nitrous oxide (not applicable)	The monitor is not allowed to be used if there is any mixture of flammable anesthetic gas and air, or mixture of flammable anesthetic gas and oxygen or nitrous oxide.
Work mode	Continuous operation equipment

2. Monitor Specifications

(1) Dimension and Weight

Item	Specification
Dimension and weight	287mm ×232mm ×90mm
	2.1Kg（not including accessories）
Fuse specification	PSL300 3A/16V/Straight

(2) Environmental Specifications

⚠ Note

- **Please use the device in the specified environment, otherwise the technical specifications stated in this manual will not be guaranteed and may result in equipment damage or other consequences.**

Item	Specification	
Working conditions	Work environment	5℃～40℃
	RH	≤83%, non-condensing
	Barometric pressure	700hPa ～1060hPa
Power supply requirement	AC input voltage	100-240V～
	AC input frequency	50Hz/60Hz
	Input power	80VA
Transport requirement	Protect the device against violent impact, vibration, rain and snow during transportation.	
Storage	After packaging, the monitor should be kept in temperature: -20℃～55℃, RH≤96%, Non-condensing, atmospheric pressure: 500hPa ～1060hPa.Keep in a well-ventilated environment free of corrosive gas.	

(3) Display

Item	Specification
Display	5.7-inch

(4) Battery

Item	Specification
Battery specification	11.1V⎓ 2200mAh, with +5%, -10% relative error
Charge time	Power off status: a minimum of 5 hours to 90%, and 6 hours to 100%.
Operating time	At least 2 hours for a new and fully charged battery

(5) Fetus Monitoring

Item	Specification
Work mode	Pulse wave
The frequency of ultrasound	1MHz, ±1%
Mechanical Index（*MI*）	<1
Soft-Tissue Thermal Index（*TIS*）	<1
Bone Thermal Index（*TIB*）	<1
P_-(peak negative acoustic pressure)	<1MPa

I_{ob}（Intensity of output beam）	<5mW/cm^2
I_{spta} (spatial peak - temporal average intensity)	<100mW/cm^2
FHR measuring range	30bpm～250bpm
FHR measuring accuracy	±1bpm
FHR 1/2 alarm preset limit	a. The monitor can produce a continuous sound alarm signal, the fetal heart rate exceeds the limit to the start of the alarm time is not more than 30s b. Alarm range: 31bpm~249bpm
FHR alarm error	≤±1bpm
TOCO measuring range	0～100
Uterine pressure measurement nonlinear error	≤±5%
Uterine pressure measurement setting range	The upper limit should not be narrow to (lower limit +1 units) ~ 100 units, the lower limit should not be narrow to 0 units ~ (upper limit - 1 units)
Waterproof Fetal Movement Marker, FHR probe and TOCO probe	IP67

Acoustic output reporting table

Index lable		*MI*	*TIS*			*TIB*	*TIC*
			Scan	Non-scan		Non-scan	
				$A_{aprt\leq 1cm^2}$	$A_{aprt>1cm^2}$		
Maximum index value		0.02	-	-	0.002	0.03	(a)
Associated acoustic parameters	p_{ra}	0.017					
	P		-	-		4	#
	Min [$P_a(z_s)$,$I_{ta,a}(z_s)$]				0.46		

	z_s				2.0		
	z_{bp}				1.8		
	z_b					2.0	
	Z at max $I_{pi,a}$	2.0					
	$d_{eq}(Z_b)$					1.2	
	f_{awf}	1.0	-	-	1.0	1.0	#
	Dim of A_{aprt} X		-	-	ϕ1.2	ϕ1.2	#
	Dim of A_{aprt} Y		-	-	ϕ1.2	ϕ1.2	#
Other information	t_d	903.9					
	prr	1250					
	p_r at max I_{pi}	0.018					
	d_{eq} at max I_{pi}					1.2	
	$I_{pa,a}$ at max *MI*	0.00					
Operating control conditions	Control 1	-	-	-	-	-	-
	Control 2	-	-	-	-	-	-
	Control 3	-	-	-	-	-	-

NOTE 1 Data should only be entered in one of the columns related to TIS

NOTE 2 Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses

NOTE 3 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.

NOTE 4 If the requirements of 201.12.4.2b) are met, it is not required to enter any data in the column related to MI.

NOTE 5 Focal Length is a NOMINAL value

Appendix V Alarm Message

1. Physical Alarm Message

Alarm Message	Adjustable Level	Cause	Solution
FHR1 Too High	High, medial, low	Measured value of the parameter is higher than the upper limit or lower than the lower limit of alarm.	Check if alarm limit is reasonable and if patient is in good condition.
FHR1 Too Low	High, medial, low		
FHR2 Too High	High, medial, low		
FHR2 Too Low	High, medial, low		
TOCO Too High	High, medial, low		
TOCO Too Low	High, medial, low		

2. Technical Alarm Message

All technical alarm events are classified to a certain alarm level. Users can not adjust the alarm level.

Alarm Message	Alarm Level	Cause	Solution
No Recorder Paper	High	Printer runs out of paper	Install printing paper.
Recorder Door Open	High	Paper tray is not closed.	Close paper tray.
Stop Care	High	Timed monitoring (TM) is manually stopped.	Resume TM.
Low Battery!	Medial	Low battery.	Charge battery instantly.
TOCO Sensor Off	Low	TOCO probe is not connected.	Check connection of TOCO probe.
FHR1 Sensor Off	Low	FHR1 sensor is not connected.	Check connection of FHR1 sensor.
FHR2 Sensor Off	Low	FHR2 sensor is not connected.	Check connection of FHR2 sensor.
FHR1 Sensor Low Battery	High	Wireless FHR1 sensor battery is low.	Change the wireless FHR1 sensor battery.
FHR2 Sensor Low Battery	High	Wireless FHR2 sensor battery is low.	Change the wireless FHR2 sensor battery.
TOCO Sensor Low Battery	High	Wireless TOCO sensor battery is low.	Change the wireless TOCO sensor battery.

Appendix VI Default Settings

System default configuration

Item	Default Factory Adult Configuration	Note
Alarm Volume	2	
Minimum Alm Volume	2	
FHR Volume	2	
Key Volume	1	
Alarm Records Print	Off	
Alarm Delay Time	Not Allowed	
Alarm Pause Time	2min	
Language	English	
Auto Grade	On	
Paper Type	30-240 (COMEN)	
Select Printer	Built-in printer	
Score Select	FHR1	
Score Criterion	Advanced FISCHER	
Print time	20 minutes	

FHR1 default configuration

Item	Default Factory Adult Configuration	Note
Module Color	Yellow	
Fetal Movement Count	Auto/Manual	
Fetal Sound Channel	FHR1	FHR1 is the available channel if only one sensor is connected.
Trace Separation	0bpm	
Sweep	3cm/minute	
Cross Duration	60s	
Cross Error	5bpm	

FHR2 default configuration

Item	Default Factory Adult Configuration	Note
FHR1 display color	Purple	
FHR2 display color	Blue	
Fetal Movement Count	Manual	
Fetal Sound Channel	FHR1	The FHR sound channel will be locked if there is only on FHR transducer connected
FHR2 Trace Separation	0bpm	
Sweep	3cm/minute	
Cross Duration	60s	
Cross Error	5bpm	

TOCO default configuration

Item	Default Factory Adult Configuration	Note
Module Color	Red	
TOCO Base	10	
MFM Color	Yellow	

TOCO default configuration

Item			Default Factory Configuration
FHR1/FHR2	Alarm Level		High
	Alarm (on/off)		On
	FHR1/FHR2 Alarm Setup	Upper limit	200
		Lower limit	80
TOCO	Alarm Level		High
	Alarm (on/off)		On
	TOCO Alarm Setup	Upper limit	90
		Lower limit	0

Appendix VII EMC

Note

- The monitor C10/C11 complies with the applicable EMC requirements in IEC60601-1-2.
- Please follow the EMC instructions in the User's Manual to install and use the Monitor.
- Portable and mobile RF communication equipment may affect the performance of the monitor C10/C11. To protect the Monitor against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.
- Refer to the attached guide and manufacturer's statement.

Warning

- This device is intended for use in professional healthcare facility environment only. If it is used in a special environment, such as a magnetic resonance imaging environment, or near active HF surgical equipment, the equipment may be disrupted by the operation of nearby equipment.
- If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the monitor or shielding the location. During this time, the user should stop using the monitor and contact the service personnel.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the C10/C11 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the C10/C11, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Class-A equipment is intended to work in industrial environments. Considering this product's conduction disturbance and radiation disturbance, it may be difficult to ensure its EMC in non-industrial environments.

Cable information:

No.	Name	Cable length (m)	Shielded	Remarks
1	Power cord	3.0m	No	/
2	Ground wire	3.0m	No	/
3	TOCO probe cord	2.2m	Yes	/
4	Main FHR probe cord, waterproof	2.2m	Yes	/
5	Secondary FHR probe cord, waterproof	2.2m	Yes	/
6	FM cord, waterproof	2.2m	Yes	/
7	Fetal awakening stimulator cable	2.0m	Yes	/

Essential performance:

1. FM measurement accuracy

2. FHR measurement accuracy

3. TOCO measurement accuracy

4. Fetal awakening function

Guidance and manufacturer's declaration – electromagnetic emissions		
The C10/C11 is intended for use in the electromagnetic environment specified below. The customer or the user of the C10/C11 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The C10/C11 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guide and Manufacturer's Statement – Electromagnetic Immunity			
The monitor is intended to work in the following electromagnetic environment. Please use it in such electromagnetic environment.			
Immunity Test	**IEC 60601-1-2**	**Coincidence Level**	**Electromagnetic Environment – Guide**
ESD **IEC 61000-4-2**	Contact discharge: ±8kV Air discharge: ±15kV	Contact discharge: ±8kV Air discharge: ±15kV	Floors should be wood, concrete or ceramic tie. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
EFT **IEC 61000-4-4**	To power cord: ±2kV To input/output wire: ±1kV	To power cord: ±2kV To input/output wire: ±1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge **IEC 61000-4-5**	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage sag, short interruption and voltage change on mains input wire **IEC 61000-4-11**	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the C10/C11 requires continued operation during power mains interruptions, it is recommended that the C10/C11 be powered from an uninterruptible power supply or a battery.
PFMF (50/60Hz) **IEC 61000-4-8**	30 A/m	30 A/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.			

<table>
<tr><th colspan="4">Guide and Manufacturer's Statement – Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601-1-2 Test Level</th><th>Coincidence Level</th><th>Electromagnetic Environment – Guide</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V
0.15 MHz to 80 MHz
80%AM at 1kHz

6 V in ISM and between 0.15 MHz and 80 MHz
80%AM at 1kHz</td><td>3 V
0.15 MHz to 80 MHz
80%AM at 1kHz

6 V in ISM and between 0.15 MHz and 80 MHz
80%AM at 1kHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the monitor, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$d = 1.2\sqrt{P}$ 150 KHz to 80 MHz
$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 80 MHz to 2.7 GHz
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).

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.

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3V/m
80 MHz to 2.7 GHz
80%AM at 1kHz</td><td>3V/m
80%AM at 1kHz</td></tr>
</table>

NOTE 1 At 80 MHz and 800 MHz, 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.

Field strengths from fixed RF 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 C10/C11 is used exceeds the applicable RF compliance level above, CB11 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating C10/C11.

Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and C10/C11

C10/C11 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of C10/C11 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and C10/C11, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150kHz~80MHz $d = 1.2\sqrt{P}$	80MHz~800MHz $d = 1.2\sqrt{P}$	800MHz~2.7GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer

NOTE 1 At 80 MHz and 800 MHz, the 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.

Immunity to proximity fields from RF wireless communications equipment						
C10/C11 is intended for use in an electromagnetic environment in which RF wireless communications equipment are controlled.						
Immunity test	IEC60601 test level				Compliance level	Electromagnetic environment - guidance
	Test frequency	Modulation	Maximum power	Immunity level		
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m	
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m	
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m	
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m	
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m	
Note * - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.						

Appendix VIII Limitations of Ultrasound Monitoring

Principle

When the ultrasound waves strike an object, they bounce back and create an echo. If the object moves toward the sound source, the frequency of the echo increases. If the object moves away from the sound source, the frequency of the echo decreases. This is called “Doppler Effect”. In the 1960s, the ultrasonic technology was first applied to medical diagnostic imaging.

The ultrasound process requires the transducer to be placed on the skin of the patient near the region of interest, and the transducer combines the ultrasonic emission and reception functions: it emits high-frequency sound wave that cannot be heard by the human ear. The movement of the organ tissue causes the reflected wave to produce a Doppler effect, and by measuring the reflected wave, the motion of the organ tissue can be measured and depicted.

During fetal monitoring, the sound waves emitted by the ultrasonic transducer penetrate the mother's abdomen and are reflected back by the fetal heart. Then the transducer receives the echoes and transfers them to the monitor, which turns the signal into fetal heart beating sound and fetal heart rate trace.

Due to the limitations of the ultrasonic testing technology itself, some abnormal conditions such as artifacts, audio and display inconsistency occur when using fetal ultrasound for fetal heart rate detection. Fortunately, this anomaly does not occur often. Still, knowing how to identify these anomalies and what you should do can give you better fetal monitoring.

Artifacts in fetal heart monitoring.

1. The generation of artifacts

The probe detects sound waves reflected from the fetal heart, but the sound waves reflected from the mother's blood vessels may also be received and processed, resulting in artifacts.

If these artifacts are not properly discerned, it is very likely that the medical staff will perform some unnecessary interventions or fail to detect fetal distress without the necessary intervention.

The most common artifacts are doubling or halving.

2. Doubling

When the fetal heart rate drops to 120 bpm or lower, the diastolic and contraction intervals of the heart become so long that it is possible for the monitor to interpret the two heart movements of one heartbeat as two separate heart beats. This produces a heart rate curve that doubles to the actual heartbeat. This phenomenon generally occurs during periods of severe deceleration and bradycardia, as the heart rate curve suddenly switches to double and actual heart rate values.

3. Halve

When the fetal heart rate rises to 180 bpm or changes, the diastolic and contraction intervals of the heart become so short that it is possible for the monitor to interpret the two separate heartbeats as two heart

movements of one heartbeat. This produces a heart rate curve that is half the actual heart rate. This phenomenon usually occurs during tachycardia, and the heart rate curve suddenly switches to half of the actual heart rate value, which the physician may consider to be a "deceleration."

However, when the doubling or halving occurs, the fetal heart sound emitted by the monitor is still reliable. Therefore, when a sudden change in the baseline value occurs, the result of the auscultation should prevail.

4. Erratic Traces / Drop out

When the fetal heart portion moves beyond the probe's ultrasonic coverage, the probe receives a mixed or weak signal, so the monitor displays an erratic curve. When the fetal heart is completely removed from the ultrasonic coverage, continuous and periodic signals are received, causing the curve to disappear.

Curved erratic and short-term curves disappear very often, especially when the fetus and/or mother is exercising. However, if this condition persists for a long time, indicating that the probe is not aligned with the fetal heart, the probe position should be adjusted.

Audio output and screen display.

In most cases, the monitor's audio output (fetal heart sound) and screen display (fetal heart rate curve and value) correspond. But occasionally there are inconsistencies between the two.

When the fetal heart portion is moved outside the ultrasound coverage, the probe receives a weaker fetal heart rate signal and a stronger other signal (usually the mother's heart rate signal). After these mixed signals are transmitted to the monitor, the monitor filters out the lower frequency mother signal and outputs a high frequency fetal heart rate signal (ie, fetal heart rate). On the other hand, the monitor's autocorrelation algorithm calculates a strong mother's signal, which shows the mother's heart rate.

This situation does not happen often. If it does, it can be eliminated by adjusting the probe position.

We hope this information is useful to you. If you have any questions during the fetal monitoring process, our sales consultants and perinatal experts will be available to answer your questions.

Appendix IX Abbreviation List

EMC	Electromagnetic Compatibility
ESD	Electro-static Discharge
RF	Radio Frequency
MRI	Magnetic Resonance Imaging
HF	High Frequency
ICU	Intensive Care Unit
NICU	Neonatal Intensive Care Unit
CCU	Cardiac (Coronary) Care Unit
OR	Operating Room
CMS	Central Monitoring System
ID	Identification
IP	Internet Protocol
LCD	Liquid Crystal Display
LED	Light Emitting Diode
Adu	Adult
Alm.	Alarm
HR	Heart Rate
SN	Serial Number
USB	Universal Serial Bus
CE	ConformitÉ EuropÉEnne Complies with Medical Device Regulation (EU) 2017/745
AC	Alternating Current
DC	Direct current
TOCO	Tocodynamometer
FHR	Fetal Heart Rate
FM	Fatal Movement
US	Ultrasound [Transducer]
WIFI	Wireless Fidelity
SD	Secure Digital Memory Card
IUP	Internal Uterine Pressure
ESU	Electrosurgical Unit
IEC	International Electrotechnical Commission

IEEE	Institute of Electrical and Electronic Engineers
UL	Underwriters Laboratories
DFU	Direction for Use
NST	Non-stress Test
MI	Mechanical Index
TIS	Soft-tissue Thermal Index
TIC	Cranial-bone Thermal Index
TIB	Bone Thermal Index