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Shenzhen Comen Medical Instruments Co.,Ltd.
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Product Name: Fetal & Maternal Monitor
Product Model: STAR5000D/STAR5000E

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After-sales Service Contact

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Preface

This manual provides details on the performance, operations and safety instructions of STRA5000E Fetal& Maternal Monitor (hereinafter referred to as the “monitor”). It is the best starting point for new users of the monitor.

Intended Readers

This user manual is only intended for trained professionals who are expected to have working knowledge of medical procedures, practices and terminology as required for monitoring patients.

Illustrations

All illustrations provided herein are for reference only. The menus, options, functions and parameters shown in the illustrations may be not exactly identical to what you see on the monitor.

Conventions:

- : Indicates operating sequences.
- [Character]: Indicates user interface text.

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Chapter 1. Safety

1.1 Safety Information

WARNING

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

- Emphasizes important precautions and provides instructions or explanations for better use of the product.

WARNING

- This monitor is intended for monitoring of clinical patients, and can be used only by trained, qualified doctors and nurses.
- Prior to use, the user must check the monitor and its accessories to ensure their normal and safe operation.
- Alarm volume and upper/lower 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 into danger. The most reliable monitoring method is to pay close attention to the patient's actual clinical conditions.
- This monitor can only be connected to a power socket with protective earth. If the power socket is not connected to an earth conductor, use the rechargeable battery to supply power to the monitor instead of using this socket.
- DO NOT open the housing of the monitor to avoid the potential risk of electric shock. The monitor must be maintained and upgraded by service personnel 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.
- In order to avoid fire or explosion, never use this monitor in an environment with

inflammables such as anesthetics.

- Please carefully place the power cord and the cables of various accessories to avoid entanglement and potential strangulation and to keep the patient free from electrical interference.
- DO NOT use mobile phones near the monitor, which produces excessive radiation and interfere the monitor's operation.
- During defibrillation, the operator should not come into contact with the patient, the monitor or the supporting table.
- The equipment connected with this monitor shall form an equipotential body (effective connection of protective earth).
- This monitor is designed against electrosurgical interference. But when it is used in conjunction with electrosurgical units, make sure the patient is safe.
- The physiological waveforms and parameters, alarm messages and other information displayed by the monitor are only for reference by the doctor, which shall not be directly used as a basis for clinical treatment.
- Electromagnetic field can affect the performance of the monitor. Therefore, other devices used near the monitor should conform to the applicable EMC requirements. For example, mobile phones, X-ray machines and MRI devices are all potential sources of interference since they all 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.
- This monitor is not a therapeutic device.
- The fuses shall be installed or changed only by trained professionals.
- This monitor can be used for only one patient at a time.
- When this monitor is working together with high-frequency surgery devices, avoid any conductive contact between the former's sensors or cables and the latter to prevent burning the patient.
- During normal use, the operator is expected to be 1m away from the monitor.

⚠ CAUTION

- To avoid damage to the monitor and ensure the patient's safety, use accessories specified in this manual.
- Handle the monitor carefully to avoid damage caused by drop, collision, strong oscillation or other external mechanical forces.
- Before powering on the monitor, confirm that the supply voltage and frequency conform to the requirements specified on the monitor nameplate or in this manual.
- At the end of their service life, the monitor and its accessories must be disposed of in accordance with the local laws and regulations or the rules of the hospital.

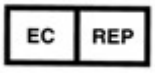
⚠ NOTE

- Place the monitor at a position where observation, operation and maintenance is convenient.
- This user manual is based on the maximum configuration; therefore, some contents may not be applicable to your monitor.

- Keep this manual handy for easy and timely reference.
- This monitor is not intended for home use.
- The service life of this monitor is 5 years.
- The computer-analyzed result is for your reference only and must be signed and confirmed by the doctor.

1.2 Symbols

Symbols Used by the Monitor

Symbol	Description	Symbol	Description
	Caution		Refer to instruction manual/booklet
	Defibrillation proof type BF applied part		Conformité Européenne Complies with medical device directive 93/42/EEC
	Power on/off key		Environment-friendly use period for electric product
	AC indicator		USB port
	Alarm reset key		Network port (connected to Comen central monitoring system)
	Equipotential terminal		Record/Stop key
	Freeze/Unfreeze key		Battery indicator
	Battery charging indicator		Main menu key
IPX0	Waterproof rating of complete machine		TOCO reset key
	Knob/OK key		European community representative

	Separate collection for electric and electronic equipment		

□ Symbols on Package

Symbol	Description	Symbol	Description
	This Side Up		Stacking Layer Limit
	Fragile		Keep dry

Chapter 2. Overview

This monitor is designed to monitor activities of fetus and maternal uterine, display, record and store patient data and waveforms, and raise alarms when the fetal/maternal parameters are abnormal. It features a 5.6 inches display and can be operated with both keys and control 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 Composition

This monitor is mainly composed of a main unit and functional accessories (a FHR sensor, a TOCO sensor and a fetal movement key).

2.3 Contraindications

N/A

2.4 Appearance

2.4.1 Front View

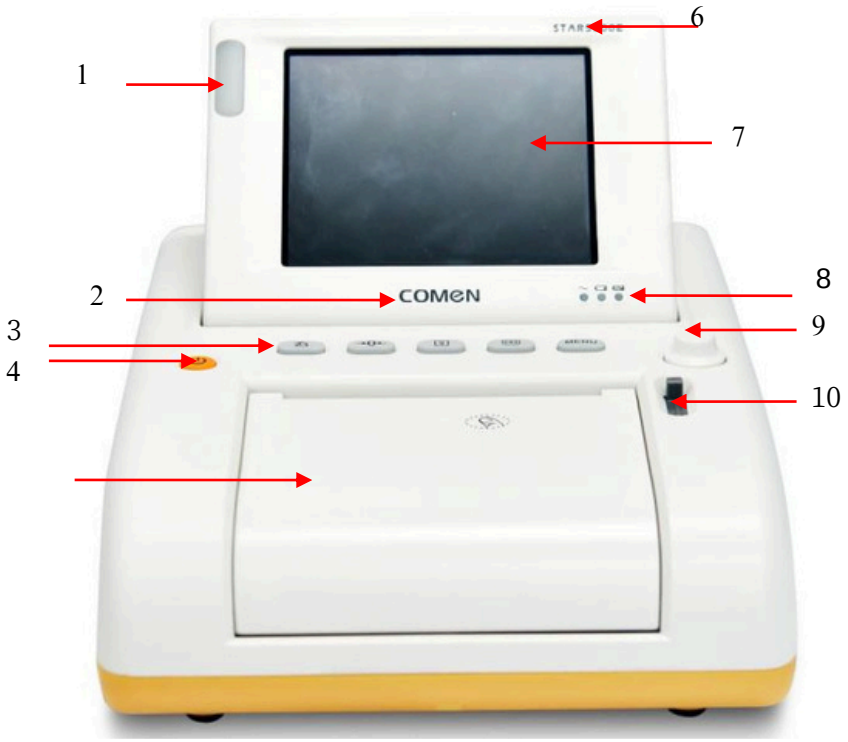


Fig. 2-1 Front View

1：Alarm indicator: emitting light of different colors according to different alarm levels.

2: Logo: COMEN.

3：Keys: alarm reset key, TOCO reset key, record/stop key, freeze/unfreeze key and multi-function key. All operations can be performed with keys and knob as follows:

	Alarm reset key
	Freeze/unfreeze key: during normal use, press this key to freeze all waveforms on the screen; press it again to unfreeze them. After freezing, all waveforms stored within the last 60 hours can be reviewed by turning the knob. Record/stop key: press this key to start a real-time recording. The recording time can be set at “Print Time” under “Print Setup”. Press this key again stop recording. The time interval between two presses shall be longer than 2s. TOCO Reset key: press this key to reset the uterine contraction pressure to a basic value set at “TOCO Base” under “Parameter Setup” (options: 0, 5, 10, 15, 20).

	Main menu key: press this key to enter or exit the main menu.
	Power on/off key: press this key to switch on/off the monitor.
	The knob can be rotated clockwise or counterclockwise or pressed down to select menu items or change values.

4: Power on/off key: press this key to switch on/off the monitor.

5：Paper compartment: printing paper is put here.

6：Monitor model: STAR5000D/STAR5000E

7: Screen: 5.6-inch tiltable and foldable screen to display waveforms, menus, alarms and various parameters and data.

8：AC indicator (lit when the monitor is powered by AC supply), battery indicator (lit when the monitor is powered by the battery) and battery charging indicator (lit when the battery is being charged) from left to right.

9：Knob: turn this knob to select menu items or change values.

10：Paper compartment lock: lock/unlock the compartment door.

2.4.2 Right View

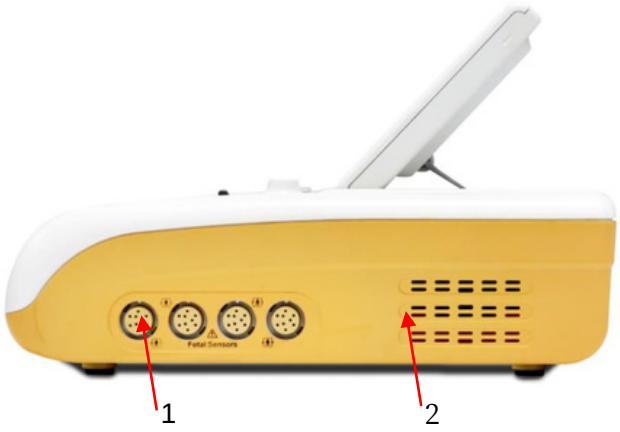


Fig. 2-2 Right View

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” is 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

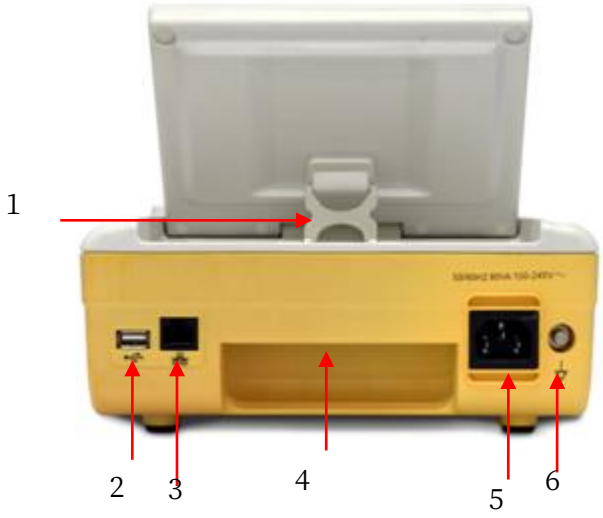


Fig. 2-3 Rear view

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.

⚠ NOTES

- 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.

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 (see 6.3.3 Import/export patient file with USB disk and 6.3.4 Updating software with USB disk respectively).

3： Network port: for connection to the network.

⚠ WARNING

- The network port can only be connected to the central monitoring system of Comen.

4 Handle: you can hold the handle to move the monitor.

: Power socket: to connect with the power supply.

5 Fuse-holder: for fuse of T1.6AL 250V Ø5×20.

:

WARNING

- The fuse shall be installed by assigned operators.

6: Equipotential terminal: to connect with equipotential connector.

WARNING

- Every analog/digital accessory connected to this monitor shall pass the EC certification (such as IEC 60950 for information technology equipment and IEC 60601-1 for medical electrical equipment). All configurations shall comply with the effective version of IEC 60601-1. Personnel who connect the accessories with the I/O port of the monitor shall ensure the system's compliance to IEC 60601-1. In case of any doubt, contact the supplier. When several
- accessories are connected with the monitor via patient cable port, network port, etc., the total leakage current shall not exceed the upper limit.

2.5 OSD (On-screen Display)

This monitor uses a color screen to display:

- physiological parameters,
- waveforms,
- alarm message,
- clock,
- network connection status,
- bed number,
- battery level and
- other prompts.

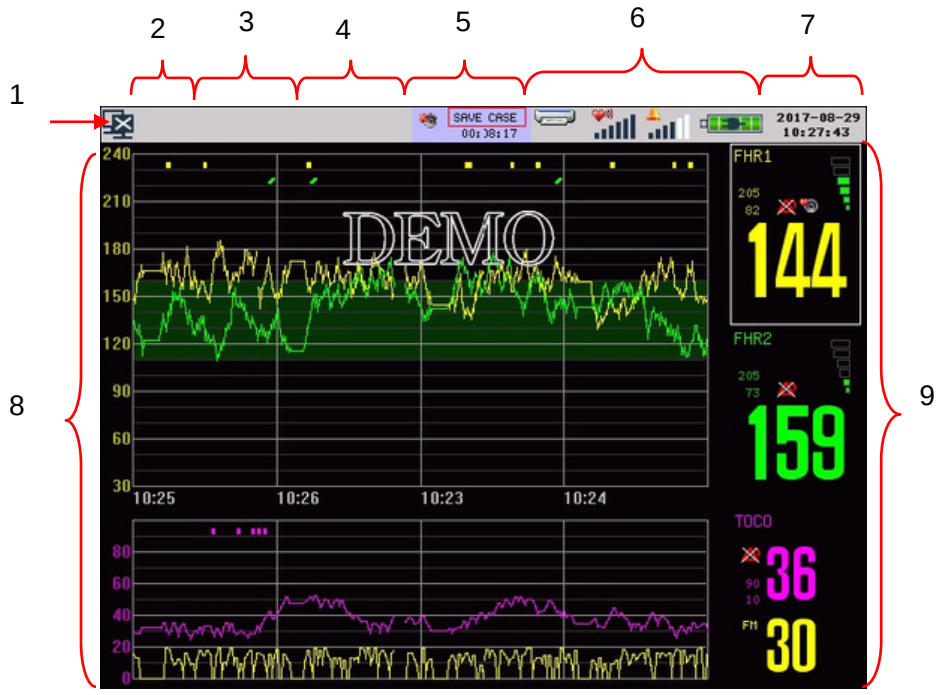


Fig. 2-7 Main interface

1. Connection status icon

   - Show the connection status to the central monitoring system (CMS);
   - indicates that the monitor is not connected with the CMS;
   - indicates that the monitor is connected with the CMS;
   - Click this icon to enter [Network Setup] menu and set up the network.

2. Patient info area

   - When no patient is admitted, "No Patient Admitted" is displayed;
   - When a patient is admitted, his/her name and bed number is displayed (if the information cannot be shown completely on this area, it will be scrolled);
     Click on this area to enter [Patient Management] menu and set detailed info about the patient.

3. Technical alarm message area

   Display technical alarm messages and prompts. When there are multiple messages, each will be displayed in turn.

4. Physiological alarm message area

   - Display physiological alarm messages. When there are multiple messages, each will be displayed in turn.
   - Click on this area to enter [Alarm Event Review] window and view alarm history.

5. Timed monitoring message area

   Display relevant messages on timed monitoring. Click on this area to enter [Timed Monitor] menu and set up timed monitoring.

6. Icon area

   - Printer icon: indicate the printing status. The moving printing paper on this icon indicates that the monitor is printing. Click this icon to enter [Print Setup] menu and set up printing options.
   - FHR volume icon: click this icon to set the FHR volume;
   - Alarm volume: click this icon to set the alarm volume;
   - Battery icon: show the battery level. Click this icon to call up [Power Manage] window, in which you can manage the battery.
   -

7. System time

   Display the current system time of the monitor. Click this icon to enter the [Time Setup] menu and reset the system clock according to your local time zone.

8. Waveform area

   Display waveforms of physiological parameters. The name of each waveform is shown on the upper left hand corner of the waveform.

9. Parameter area

   Display the corresponding measured values of each parameter module. Color of each parameter is the same with that of the waveform.

Chapter 3. Installation

NOTE

- To ensure normal operation of the monitor, read this chapter and “Safety Information” and “Patient Safety” carefully before the installation of the monitor.

3.1 Unpacking and Inspection

Carefully take the monitor and its accessories out of the packing box and check each of the following points. For any problem or inconsistency, contact sales or your distributor at once.

1.Check whether all accessories are provided according to the Packing List. In case of any missing accessory, contact Comen or your distributor at once.

2.Check for damage.

3.Check all exposed lead wires and connectors.

Keep the packaging materials properly for future use.

3.2 Connection of AC Power Cord

Make sure the AC power supply conforms to the following specification: 100-240V~, 50/60Hz.
Connect one end of the power cord supplied with the monitor to the power socket on the monitor, and insert the other end to a grounded three-pin socket.

NOTES

- To ensure safe operation, only use accessories (such as FHR sensors) and all kinds of consumables (such as couplant) supplied or accepted by Comen.
- The safety and normal operation of the monitor is ensured only when the accessories connected are supplied by Comen; otherwise there may be danger caused by leakage currents.
- Use a medical grade power supply.
- When a battery is provided, the battery must be charged after transportation or storage. If the battery is low, startup of the monitor may fail without connecting an AC power supply. Once connected to an AC power supply, the battery will be charged until it is fully charged.

Connect the equipotential conductor when necessary. See the content about equipotential grounding in the Chapter “Patient Safety”.

3.3 Startup

After the power switch is turned on, the alarm indicator turns red and then yellow. Then the Comen logo appears. After 10-20s, the self-test process is complete and, with a “beep” sound, the main interface appears.

NOTES

- The system gives an alarm when a critical error is detected in the self-test.
- Check all monitoring functions to ensure that the monitor can function normally.
- Wait for at least 1 minute before restart after you shut down the monitor.

WARNING

- If any evidence of failure or any error message is found, DO NOT use this monitor. Contact a service engineer of Comen or a technician in your hospital.

3.4 Connection of Sensors

Connect the sensors to the monitor and the patient according to the detailed description in the relevant chapters.

Chapter 4. Patient Safety

4.1 Safety Instructions

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

4.2 Environmental Requirements

Observe the following instructions to ensure absolute safety of electrical installation. 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 within the ambient temperature of 5°C-40°C. Hostile ambient temperature may affect the precision and accuracy of the monitor, 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 supplied with a detachable 3-prong power cord, which shall be inserted into a grounded power outlet to connect the monitor to the earth. If grounded power outlet is not available, contact the electrician in your hospital.

⚠ WARNING

- It is forbidden to connect the 3-prong power cord to a 2-prong power outlet.

Connect the earth (ground) wire to the equipotential connector of the monitor. If you have doubt about whether devices used together involves any electrical risks, such as risk caused by accumulation of leakage current, consult an expert in this field to protect the safety of all devices from damage caused by the combination of them.

4.5Equipotential Grounding

The monitor must be connected to a power supply with protective grounding. For cardiac or cerebral examination, the monitor must be separately connected to an 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 connect the other end to a connector of the equipotential grounding system. In the event that the protective grounding system is damaged, the equipotential grounding system can provide protection to the monitor.

Cardiac (or cerebral) examination can only be performed in a room installed with a protective grounding system. Before each use, check whether the monitor is in normal working status. Cables connecting the patient to the monitor cannot be tainted with electrolyte.

⚠ WARNING

- If the protective grounding system is not stable, use the built-in battery to supply power to the monitor.

4.6Condensation

Ensure that the monitor is free from condensation during operation. When the monitor is moved from one room to another, condensation may be formed due to exposure to damp air and temperature difference. In this case, do not use the monitor until it gets dry.

⚠ 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.

5.1 Main Menu

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

Fig. 5-1 Main 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 General Setup

5.2.1 Time Setup

There are two ways to set the system time:

1. Turn the knob to highlight the system time area, and set system time according to your local time zone in the pop-up [Date time Setup] menu;
2. Enter [Main Menu] → [Monitor Setup] → [Time Setup] to set system time.

5.2.2 Language Setup

1. Enter [Main Menu] → [Maintain] and input the maintenance password;
2. Click [Language] to select desired language.

5.2.3 Alarm Volume Setup

See 8.5 Alarm Volume.

5.2.4 FHR Volume Setup

There are two ways to set the FHR volume:

1. Enter [Main Menu] → [Option Setup] → [FHR Vol] (FHR volume) to set up FHR volume;
2. Click  and select FHR volume in the pop-up list (options: 0, 1, 2, 3, 4, 5, 6). When it is set to 0, the FHR volume icon changes to  .

5.2.5 Key Volume Setup

1. Enter [Main Menu] → [Option Setup];
2. Select [Key Vol] (Key Volume) to adjust it (options: 0, 1, 2, 3, 4, 5, 6).

5.3 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.

5.4 Demo

Enter [Main Menu] → [Demo] and input the password to put the monitor into demonstration mode.

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.

5.5 Network Setup

The monitor can be connected with CMS of Comen by setting the network as follow:

1. Click to enter [Network Setup] menu;
2. Click [Net Bed] and input a net bed for the monitor in the system (valid range: 1-64);
3. Click [IP Address] and input the IP address of the monitor, such as 223.200.200.X (valid range of X is 1-254, which is prompted if the X you input falls outside of the range).
4. Click [MAC] and input the MAC address of the monitor;
5. Click [Subnet Mask] and input the subnet mask of the monitor;
6. Click [Service IP] and input the IP address of the CMS, which shall be within the same network segment with the monitor.

Connection status icons and indicate failed and successful connection with the CMS respectively.

NOTES

- Network bed number must be unique in one CMS. If two devices using the same bed number are connected to the CMS, system crash will be caused.
- If the monitor is affected by bed number conflict, unplug the network cable, turn off the monitor and then restart it. Then you can reset the network bed number and reconnect the network cable.

5.6 Waveform Freeze

To freezing waveforms:

1. Press the freeze key on the front panel;
2. All the waveforms are frozen (no longer updated or scrolled), while the data on the parameter area are updated as usual.

To review frozen waveforms:

You can review frozen waveforms to observe details of the patient's waveforms. Maternal waveforms within 240s (s: second) and fetal waveforms within 60h (h: hour) can be reviewed in frozen way on the monitor. Turn the knob to flip page when reviewing frozen waveforms.

Press the freeze key  again to unfreeze the waveforms.

To record frozen waveforms:

Frozen waveforms can be recorded and output via a printer. See 10.2.2 Freeze print.

Chapter 6. Patient Management

6.1 Admission

When a patient is connected to the monitor, the monitor displays and saves the patient's physiological data even if the patient is not admitted. But correct patient admission is important for patient monitoring.

To admit a patient:

1. Click on the patient info area to enter [Patient Management] menu;
2. Click [Discharge] to discharge the existing patient (if any) first;
3. Input patient info. The monitor supports alphanumeric characters;
4. Click [Admit] and a prompt saying "Clear previous patient's history data! Continue?" pops up. Select [Yes] to admit the patient (then the [Admit] option becomes [Discharge]), or select [No] to exit.

⚠ 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 Discharge

To discharge a patient:

(a) Click on the patient info area to enter [Patient Management] menu;

(b) Click [Discharge] to discharge the current patient;

(c) The option [Discharge] becomes [Admit], and a prompt of [No Patient Admitted] is shown on the patient info area.

6.3 Case Management

6.3.1 Saving Case

This function is to save the cases for future reference. The cases can be saved automatically during monitoring.

To save the cases automatically:

1. Enter [Main Menu] → [Case Setup];
2. Click [Case Save] and select [On] (if you select [Off], the cases will not be saved);
3. Click [Least Time] to select the shortest time period of monitoring before saving a case automatically (options: 5 min, 10 min, 15 min, 20 min). For instance, if you select 5 min (min: minute), the case is not saved when the patient is monitored for less than 5 min;
4. The cases saved can be reviewed at the [Case List] window.

6.3.2 Reviewing Case

To review, delete or load cases at the [Case List]:

1. Enter [Main Menu] → [Case Setup] → [Case List];
2. All the cases are shown at the pop-up [Case List(SD)] window ("SD" indicates that cases are stored on the SD card);
3. Click  or  to view cases on different pages;
4. Click [Delete All] to delete all the cases in the current window;
5. Click one case to view details in the pop-up [Case Review] window; click [Delete] to delete this case; click [Load] to call up [Case Review] window, in which you can review or print the detailed info of this case.

6.3.3 Importing/exporting cases with USB disk

To import/export cases with a USB disk:

1. Insert a USB disk into a PC, right click its drive letter in My Computer and select "format" (select FAT or FAT32 as its file system). Remove the USB disk after formatting is completed;
2. Insert the USB disk into the USB port at the back of the monitor;
3. Enter [Main Menu]→ [Case Setup] → [Case List];

4. Two options [Remove USB] and [USB Copy] appear on the case list interface, which indicates that the monitor has recognized the USB disk;
5. Exporting cases: select [USB Copy], and on the pop-up dialog box, select [Copy All Cases to USB] to export all cases from the monitor to the USB disk; or select a desired case and click [Copy to USB] to export such case to the USB disk;
6. Importing cases: select [USB Copy] → [Enter USB Case List] → [USB Copy], and on the pop-up dialog box, select [Restore All Cases to System] to import all cases form the USB disk to the monitor; or select a desired case and click [Restore to SYS] (Restore to System) to import such case to the monitor;
7. You can [load] or [delete] cases saved on the USB disk using the same method as you load or delete cases on the monitor. When a USB case is opened, the window name [Case List (USB)] indicates that the current case is from USB disk.
8. Click [Remove USB] to stop importing/exporting cases.
9. Remove the USB disk and insert it into the PC again to transfer the exported cases to the computer memory.

6.3.4 Updating Software with USB Disk

The software of the monitor can be updated with a USB disk as follow:

1. Insert a USB disk into a PC, right click its drive letter and select “format” (select FAT or FAT32 as its file system).
2. Create a folder named “COMENSOFT” and copy the upgrade file into it;
3. Insert the USB disk into the USB port at the back of the monitor;
4. Press the power on/off key of the monitor. After startup, select [Factory Maintenance] → [System Upgrade] and input the password to start updating the software. When a prompt “System update succeeded, please restart!” appears on the display, restart the monitor to finish the software update.

⚠ NOTE

- Updating software with USB disk shall be carried out by the manufacturer.

7.1 User Interface 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, uterine contraction pressure 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) as shown below:

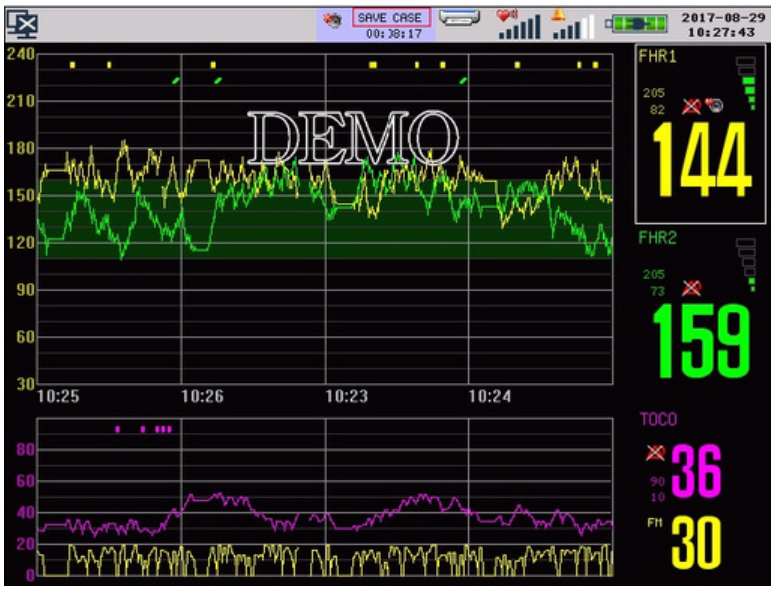


Fig. 7-1 Fetal Screen

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] as shown below:

Fig. 7-2 Big Font screen

7.2 Interface Style

You can set the interface style as needed, 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 Wave Sweeping Speed

Click 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, 3 cm/min).

7.2.2 Waveform Color

Click the FHR waveform, and in the pop-up [FHR setup] window, select [FHR1 Disp Color] to set a color for FHR1 waveform (options: green, cyan, red, yellow, white, blue, 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.

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	Some device failures or

	patient's vital signs; treatment may be necessary.	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
- Sound Alarm
- Alarm Message
- Blinking Parameter

For light alarms, sound 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, blinking twice every second.
- Medium-level: Yellow, blinking once every two seconds.
- Low-level: Yellow, remaining on

Technical Alarm:

- High-level: Red, blinking twice every second.
- Medium-level: Yellow, blinking 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 Sound Alarm

The monitor indicates alarm levels with alarm sounds 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 sound 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

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 Blink

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

8.5 Alarm Volume

8.5.1 Minimum Alarm Volume

A minimum alarm volume can be set up to prevent the alarm volume from being set too low.

To set the minimum alarm volume:

1. Enter [Main Menu] → [Maintain] (Maintenance) and input the password;
2. Enter [Alarm Setup] → [Min. Alm Volume] to set the minimum alarm volume (range: 0-5).

8.5.2 Setting Alarm Volume

There are 2 ways to set the alarm volume:

1. Enter [Main Menu] → [Option Setup] → [Alm Vol] (Alarm Volume) to set the alarm volume (range: X-6, where X is the minimum alarm volume).
2. Click the alarm volume icon  to set the alarm volume (range: X-6, where X is the minimum alarm volume).

The icon  indicates that the alarm volume is set to 0.

The alarm sound pressure level (SPL) of the monitor is 45-85 dB.

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 Alarm Reminder

When the alarm system is turned OFF, the monitor sounds periodic prompt tone to remind the operators that the alarm system is turned off.

To set up alarm reminders:

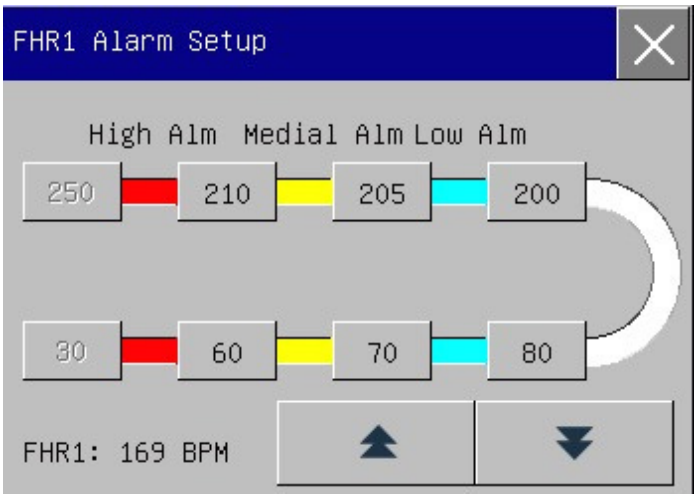
1. Enter [Main Menu] → [Maintain] and input the password;
2. Enter [Alarm Setup];
3. Click [Reminder Volume] to set the reminder volume (range: 0-6);
4. Click [Reminder Interval] to set the interval between two reminder tones (options: Off, 6 seconds, 15 seconds, 30 seconds, 60 seconds, 300 seconds, 600 seconds).

8.6 Alarm Setup

8.6.1 Alarm Limit

This monitor supports intelligent alarm for certain patient parameters. You can simultaneously set up alarm limits for high, medium and low-level alarms for these parameters. When a measured parameter value is beyond the normal range, the monitor determines the alarm level and generates alarm accordingly. Intelligent alarms are supported for FHR1, FHR2 and TOCO. For some other parameters, only one alarm level can be set up. You need to set up the alarm limits according to the alarm level. When the measured parameter value is beyond the normal range, the monitor generates an alarm of the corresponding level. You can set up the alarm limits for all alarm levels with the same method. Here FHR1 is taken as an example:

1. Click the FHR1 parameter area;
2. Select [FHR1 Alarm Setup] in the pop-up [FHR1 Setup] window to enter the FHR1 alarm setup menu as follow:



- [High Alarm]: a high alarm is triggered when the measured value is greater than the upper limit or less than the lower limit of high alarm;
- [Medial Alarm]: a medial alarm is triggered when the measured value is greater than the upper limit of medial alarm but less than the upper limit of high alarm, or less than the lower limit of the medial alarm but greater than the lower limit of high alarm;
- [Low Alarm]: a low alarm is triggered when the measured value is greater than the upper limit of low alarm but less than the upper limit of medial alarm, or less than the lower limit of the low alarm but greater than the lower limit of medial alarm.

3. Click the upper or lower limit of an alarm level, and adjust it by clicking and keys. Red,

yellow, blue and white area indicates high alarm, medial alarm, low alarm and normal range respectively.

WARNING

- Setting the alarm limits to the maximum values allowed by the system will void the alarm system.

NOTE

- In case of power failure, the monitor stores all the alarm settings and recovers them upon power restoration.

8.6.2 Alarm Record

If a parameter's alarm function and alarm recording function is turned ON, you can turn on the monitor's Alarm Records function so that the monitor automatically prints out the alarm events when the measured parameter value falls out of the alarm limits. Basically, you can turn on Alarm Records function for all parameters with the same operation. Here FHR1 is taken as an example:

1. Enter [Main Menu]→ [Monitor Setup] → [Alarm Setup] → [Alarm Records] (Alarm Records Print), and select [On];
2. Click FHR1 parameter area;
3. Select [Alarm Record] in the pop-up [FHR1 Setup] window to turn on/off alarm recording function.

When the measured FHR1 value falls out of the alarm limits, the monitor prints out its waveform during a time period of 8 seconds (from 4 seconds before the alarm to 4 seconds after the alarm).

8.6.3 Alarm Delay

The system provides five options to delay parameter alarm: [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 has been beyond the alarm limit for 5s, 10s, 15, 20s, respectively.

Set alarm delay as follow:

1. Enter [Main Menu]→ [Maintain] and input the password;
2. Enter [Alarm Setup];
3. Click [Alarm Delay Time] and select an appropriate delay time on the pop-up menu.

8.7 Alarm OFF

8.7.1 Turning off Alarm for a Single Parameter

You can turn off alarms for all parameters with the same operation. Here FHR1 is taken as an example:

1. Click FHR1 parameter area;
2. Select [Alm] (Alarm)in the pop-up [FHR1 Setup] window;
3. Select [Off].

After the alarm for a parameter is turned off, the icon  is shown at the corresponding parameter area.

8.7.2 Turning off Alarm System

The operation to turn off the overall alarm system is password-protected and can only performed by authorized personnel.

To turn off the alarm system:

1. Enter [Main Menu]→ [Maintain] and input the password;
2. Enter [Alarm Setup];
3. Click [Alarm Off] → [On] to turn off the alarm system.

The administrator of the monitor can also authorize other operators to turn off the alarm system as follow:

1. Enter [Main Menu]→ [Maintain] and input the password;
2. Enter [Alarm Setup];
3. Click [Alm Off Authorize] (Alarm Off Authorize)→ [On] to authorize other operators to turn off the alarm system. Now the authorized operators can enter [Main Menu]→ [Monitor Setup] → [Alarm Setup] → [Alarm Off] → [On] to turn off the alarm system.

If other operators are not allowed to turn off the alarm system, click [Alm Off Authorize] → [Off].

When the alarm system is turned off,

1. Light and sound alarms for existing physiological alarms are off;
2. Upper and lower limit of the existing physiological alarms stop blinking;
3. Alarm messages are not shown;
4. “Alarm Off” with a red background is shown on the physiological alarm area;
5. Sound alarms for technical alarms are off while light and text indication remain on.

In this case, the monitor sounds periodic prompt tone to remind the operators that alarm function is disabled.

To turn on the alarm system again:

1. Enter [Main Menu]→ [Monitor Setup] → [Alarm Setup];

2. Click [Alarm Off]□□[Off] to turn on the alarm system.

WARNING

- The monitor doesn't generate an alarm when the alarm is turned off or reset, so operators shall pay close attention to patients' actual situation.

8.8 Alarm Reset

Alarm reset is to clear alarm signals when there is no ongoing alarm currently and to activate the alarm system to receive new alarms. Click [Alarm Reset] to:

- Clear locked alarm signals for which there is no ongoing alarm conditions;
- Stop all ongoing alarm sounds;
- Clear alarm signals for which there is no ongoing alarm conditions, and activate the alarm system to receive new alarms;
- Clear light and sound alarms for technical alarms of lead-off and sensor-off. The alarm messages turn to prompt messages.

8.9 Default Alarm Settings

The monitor supports two kinds of default alarm settings: default factory adult configuration and default user adult configuration. Refer to Appendix IV.

Specification of default factory adult configuration cannot be changed, but users can change its values and save it as a default user adult configuration.

To save default user adult configuration:

1. Change the alarm settings such as alarm limits and alarm levels;
2. Enter [Main Menu]□□[Maintain] and input the password;
3. Click [SAVE CURRENT AS USER CONFIG] to save the current configuration as default user adult configuration.

How to use default factory adult configuration:

1. Enter [Main Menu]□□[Monitor Setup] □□[Restore Default Configuration];
2. Click [Adopt Default Factory Adu Config] to restore the alarm configurations to default factory adult configuration.

How to use default user adult configuration:

1. Enter [Main Menu]□□[Monitor Setup] □□[Restore Default Configuration];

2. Click [Default User Adu Config] to restore the alarm configurations to default user adult configuration.

Notes:

1. The monitor saves changes to alarm settings automatically;
2. You can enter setup menu of a parameter and click [Default Config] (Default Configuration) to restore the default alarm settings for this parameter.

WARNING

- If devices of similar usage are used together (such as in ICU or cardiac surgery room), the same alarm configuration shall be used; otherwise it could be a potential danger.

8.10 Alarm System Inspection

You can check if the alarm system is normal through light and sound alarms. For example:

1. Click FHR1 parameter area to enter [FHR1 Setup] menu; Click [Alarm] ⌧⌧ [On]; Click [FHR1
2. Alarm Setup] and set its upper and lower limit as 120 and 80 respectively;
3. When the measured value exceeds the upper/lower alarm limit, check the light and sound alarms
4. and
parameter blinking to estimate whether the alarm system is working normally. For details, see the section “Sound Alarm” “Light Alarm” “Alarm Message” and “Alarm Parameter Blink” in this chapter.

Chapter 9. Battery

9.1 Overview

The monitor is equipped with a built-in rechargeable battery. When an AC power supply is connected, the battery is charged automatically until it is fully charged. In the event of unexpected power outage, the system automatically uses the battery to supply power, thus to avoid interruption of device operation. After grid power supply is cut off, the battery indicator turns on.

 indicates battery level is full.

 indicates battery level is nearly 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.

⚠NOTES

- If the battery is to be left unused for a long period of time, remove the battery and store it properly according to the manufacturer's instructions.
- If the device is provided with a built-in battery, the battery must be charged after each use to ensure sufficient battery power.

⚠WARNING

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

9.2 Low Battery Alarm

When the battery is used to supply power, the monitor turns off by itself when the battery level is low. When

the icon indicating that battery level is too low is shown, a high-level technical alarm is triggered and [Low power! Please charge the battery] is shown on technical alarm message area. The monitor should be connected to AC power supply timely, or it will be turned off automatically before the battery runs out.

9.3 Power Management

Power management helps save energy and extend battery life.

Click the battery icon to enter [Power Manage] menu. Here you can see:

- [Timer]: set a time interval (range: 1-30 minute(s)) after which [Timer Trigger] instruction is triggered if no operation is performed.
- [Timer Trigger]: choose an instruction (options: [No], [Standby], [Shutdown]) that will be performed if no operation is performed during the period set in [Timer]. If [Timer Trigger] is set to [No], it is disabled.
- [Recover Trigger]: set operations that can be performed to restore the monitor to monitoring interface after the instruction in [Timer Trigger] is triggered (option: [Key]).

9.4 Battery Installation

Steps for replacement or installation of the battery:

1) Power off the monitor. Disconnect the power cord and other connecting cables.
2) Place the monitor with its back facing upward.
3) Remove the screws with a screwdriver.
4) Take out the old battery, install the new battery into the battery compartment, tighten the screws, and place the monitor upright.

WARNING

- Only use battery designated by the manufacturer.
- Do not remove the battery when the monitor is operating.
- Replacement and installation of the battery shall be performed by trained personnel.

9.5 Battery Performance Optimization and Inspection

1) Battery Performance Optimization

Before the first use, ensure that the battery has undergone at least two complete optimization cycles. A complete optimization period means uninterrupted charging until the battery is fully charged, and then discharging it until the monitor shuts down automatically.

In this process, pay attention to:

(a) Completely disconnect the monitor from the patient and stop all monitoring and measurement;

(b) Install the battery in the battery compartment in the monitor;

(c) Charge the battery uninterruptedly for at least 6 hours until it is fully charged;

(d) Disconnect the AC power supply, and use the battery to power the monitor until the monitor shuts down automatically;

(e) Battery performance optimization is done.

2) Battery Performance Inspection

The battery life varies with the storage and operation environments, discharging frequency and use time. The battery performance degrades gradually even if the battery is not used.

Here are the steps for checking the battery:

(a) Determine whether the battery is damaged. If the battery is already installed in the battery compartment, when the battery icon shows  , it indicates the battery is damaged.

(b) Check whether the battery can be charged normally when connected to AC power supply.

(c) Completely disconnect the monitor from the patient and stop all monitoring and measurement.

(d) Charge the battery uninterruptedly for at least 6 hours until it is fully charged.

(e) Disconnect AC power supply, and use the battery to power the monitor until the monitor shuts down automatically. Take note of the start time and end time of discharging to calculate the battery life.

(f) The discharging time indicates the battery performance.

(g) When the battery life drops by 50% or more, replace the battery.

⚠NOTES

- In order to prolong the service life of the rechargeable battery, if the battery will be stored for a long period of time, it is suggested that the battery is charged every three months to prevent excessive discharging.
- The discharging time of battery depends on the configuration and operation of the monitor. For example, frequent NIBP measurement reduces the battery life.

9.6 Battery Recycling

If the battery is obviously damaged or reaches the end of its service life, it should be replaced. Waste batteries should be properly recycled in accordance with applicable laws and regulations or the rules of the hospital.

⚠WARNING

- Do not disassemble or short-circuit the battery or place it in fire; otherwise fire, explosion, leakage of hazardous gas, or other hazards may be caused.

Chapter 10. Print

10.1 Loading Record Paper

Changing record paper:

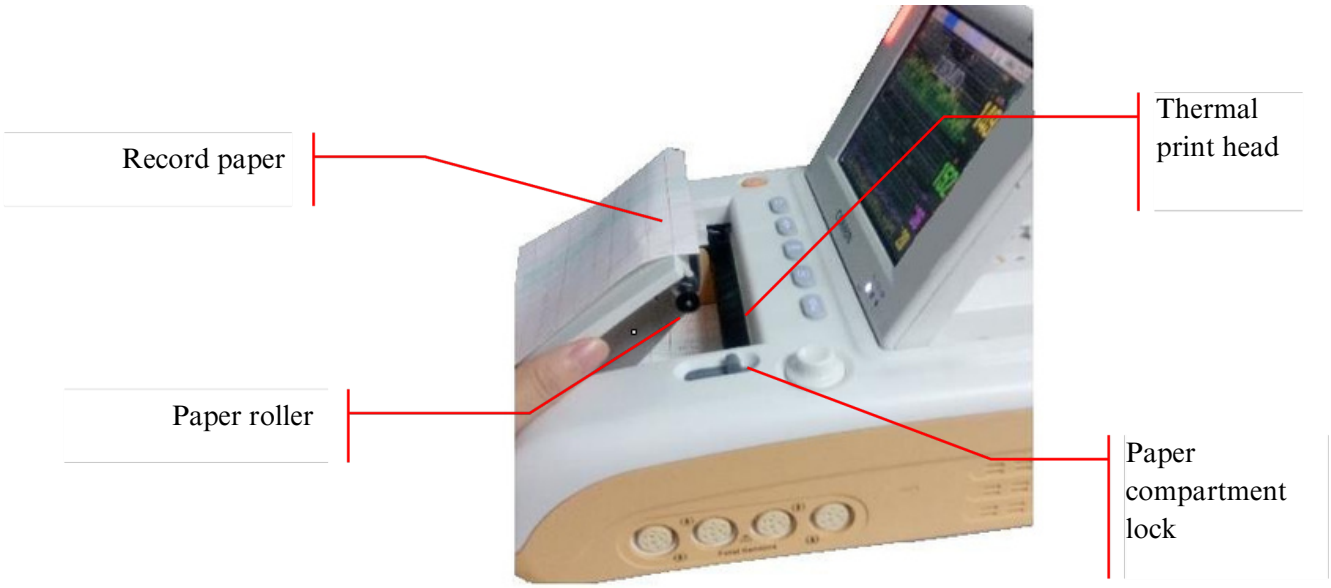


Fig. 10-1 Loading record paper

(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.

⚠NOTES

- 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.
- The record paper is delivered at constant speed in printing. DO NOT pull it out forcibly to prevent damages to the recorder.
- DO NOT use the recorder without loading record paper.
- Do not contact the thermal print head. Do not keep the recorder door open except for paper change or troubleshooting.

⚠WARNING

- Use foldable thermal record paper supported by the recorder, or failure to record, poor record quality or thermal print head damage could be caused.
- DO NOT touch the thermal print head, or damages to the recorder could be caused.

*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.

10.2 Print

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	Fetal waveforms
Big Font	waveforms	N/A

10.2.1 Real-Time Print

Fetal waveforms

To start real-time printing, press the Print key on the front panel under real-time monitoring status.

To print real-time fetal waveforms:

1. Press the print key on the front panel under real-time monitoring status to enter [Patient Info & Fischer Score] window;
2. Confirm waveforms and scores and press the Print key. The monitor starts printing according to the speed set on [Real Speed] (Real Print Speed) and the time set on [Real Time] (Real Print Time);
3. You can press the Print key on the front panel to stop printing manually. If [Print Report] [On] is selected, the monitor prints scores and stops printing; If [Print Report] [Off] is selected, the monitor stops printing immediately.

10.2.2 Freeze Print

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 [Real Time] (Real Print Time);
3. If [Print Report]→ [On] is selected, the monitor also prints scores after printing the frozen waveforms.

10.2.3 Review Print

Review print is print by pressing the print key on the front panel after the monitor loaded a case and enters case review interface.

Steps for review print:

1. Enter [Case List] and click one of the cases and enter [Case Review] window;
2. Click [Load] to enter review interface of this case;
3. Press the print key on the front panel to enter [Preview] window;
4. Confirm patient info and rating results and press the print key, and the monitor starts printing frozen waveforms from the left of current interface according to the time set on [Review Time] (Review Print Time);

10.2.4 Print Setup

To enter print setup menu:

1. Enter [Main Menu] → [Monitor Setup] → [Print Setup];
2. Or click print icon  on icon area.

Adjustable items vary as per different interfaces. Grey background indicates that the item cannot be adjusted on current interface.

- Click [Auto Score] and select [On] or [Off] to turn on/off auto score of the monitor. Click [Print Report] and select [On] or [Off] to choose to print scores or not after printing fetal waveforms.
- Click [Paper Type] to select appropriate type of paper (options: 30-240 (COMEN), 50-210, other).
- Thermal recorder resolution: 8 dots/mm.
- Click [Printer Type] to select type of the printer (options: [Inlay Printer], [External Printer], [Print to Picture]).
  - Select [Inlay Printer] to use a 150mm recorder included with the monitor, using fetal record paper;
  - Select [External Printer] to use an external USB printer using A4 paper. This option is selectable when the monitor is connected with an external USB printer;
  - Select [Print to Picture] to save waveforms as A4 sized pictures on a USB disk and to view them on other devices such as a computer. This option is selectable when a USB disk is connected to the monitor.

When external USB printer or USB disk is connected, the monitor recognizes it automatically, and “Connect the external printer”/ “Connect the USB storage device” is shown for 5 seconds on the interface. When an external USB printer is connected, the printer type will be changed to [External Printer] automatically.

- Click [Score Select] to show the scores on the case report. Click [Score Criterion] to select scoring criterion you use (options: [KREBS], [Fischer], [Advanced Fischer], [NST]).
- Click [Real Speed] to set print speed of real-time fetal waveforms (options: [1 cm/min], [2 cm/min], [3 cm/min]).
- Click [Real Time] to set print time of real-time fetal waveforms (options: 5,10, 15,20, 25,30,Infinite).
- Click [Review Time] to set time of review print of loaded cases (options: 5min,10 min, 15min,20 min,25min, 30 min, 35min,40 min, 50 min, 60 min, 90 min, 120 min, 150 min, 180 min, 210 min, 240 min, 480 min). If you select 10 min, the monitor prints waveforms within 10 min from the left of current frozen screen, and so on for other options.

The print icon changes to  when case is printing.

10.3 Score Criteria

The monitor supports four Scoring Criteria: KREBS, Fischer, Advanced Fischer and NST, as illustrated in the following tables.

NST Criterion:

Item	0	1	2	Result	Score
FHR baseline (bpm)	＜100, ＞180	100～109, 161～180	110～160		
FHR rising time in fetal movement (s)	0～9	10～14	＞14		
FHR rising amplitude in fetal movement (bpm)	0～9	10～14	＞14		
Variation range (bpm)	0～4	5～9,＞30	10～30		
Fetal movement (bpm)	None	1～2	＞2		

KREBS Criterion:

Item	0	1	2	Result	Score

FHR baseline (bpm)	＜ 100, ＞ 180 0～	100 ～ 109,161 ～ 180 5	110～160		
Variation range (bpm)	4 0～2	3 ～9, ＞25	10～25		
Variation frequency (cpm)		～6	＞6		
Acceleration (time/20 min)	None	1～4	＞4		
Deceleration (time/20 min)	＞2	1～2	None		
Fetal movement (bpm)	None	1～4	＞4		

Advanced Fischer Criterion:

Item	0	1	2	Result	Score
FHR baseline (bpm)	＜100,＞180	100 ～ 109,161 ～ 180	110～160		
Variation range (bpm)	0～4	5～9,＞30	10～30		
Variation frequency (cpm)	0～1	2～6	＞6		
Acceleration (time/20 min)	None	1～4	＞4		
Deceleration (time/20 min)	Late deceleration or severe variation	Mild variation	None		

Fischer Criterion:

Item	0	1	2	Result	Score
FHR baseline (bpm)	＜100,＞180	100～109,161 ～ 180	110～160		
Variation range (bpm)	0～4	5～9,＞25	10～25		
Variation frequency (cpm)	0～1	2～5	＞5		
Acceleration (time/20 min)	None	Periodical acceleration	Aperiodic acceleration		

Deceleration (time/20 min)	Late deceleration or severe variation	Mild variation	None		

NOTE

- Diagnosis output is an optional software function, and the results are for clinic reference only. Clinician shall be responsible for the diagnosis made in accordance with actual waveforms.

Chapter 11. Cleaning and Disinfection

Only materials and methods listed in this chapter that are accepted by Comen can be used for cleaning or disinfection of the device. For any damage arising from use of unaccepted materials or methods, Comen will not provide any warranty. Comen 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, consult the Infection Prevention Department or an epidemiologist in your hospital. Besides, you shall also refer to local policies that are applicable to your hospital.

11.1 Overview

Keep the device and its accessories clean. After each cleaning, check the device to make sure there is no deterioration or damage. If there is any evidence of abnormality, stop using it. If it is necessary to return the device to Comen for repair, clean it before transportation. Observe the following precautions:

- Dilute detergent and disinfectant as specified by the manufacturer, or use a concentration as low as possible.
- Do not allow any liquid to flow into the housing.
- Do not pour any liquid onto any part or accessory of the device.
- Do not soak the device in any liquid.
- Do not use any abrasive or corrosive material, bleaching powder or strong solvent (for example: acetone or detergent containing acetone).

11.2 Cleaning and Disinfection of Monitor

To avoid cross-infection, clean the monitor and accessories after each use. Prior to cleaning, you shall refer to and understand the rules of your hospital on device cleaning.

Cleaning steps:

1) Power the device off, and unplug the power cord.
2) Pull of the cables connected to the monitor.
3) Use a soft cloth damped with detergent solution to wipe the monitor housing and the display screen.
4) Use a soft cloth damped with detergent solution to wipe the accessory cable and sensors.
5) If necessary, you can use a soft, dry cloth to remove residual detergent.
6) Put the monitor and accessories in a cool, well-ventilated environment to air-dry it.

7) The disinfection operations can harm the monitor to a certain extent. It is suggested that the device can be disinfected only when it is considered necessary in the maintenance plan of your hospital. Before disinfection, clean the device first.

Optional detergents:

Part for Cleaning/Disinfection	Eligible Detergent	Eligible Disinfectant
Housing	Isopropanol (70%), Alcohol-free hand soap, sodium hypochlorite (bleaching powder containing chlorine, 3% aqueous solution), hydrogen peroxide	Isopropanol (70%), glutaraldehyde solution (2%),sodium hypochlorite disinfectant
Power cord	Isopropanol (70%), Alcohol-free hand soap, sodium hypochlorite (bleaching powder containing chlorine, 3% aqueous solution), hydrogen peroxide	Isopropanol (70%), glutaraldehyde solution (2%),sodium hypochlorite disinfectant
TOCO sensors	Alcohol-free hand soap, sodium hypochlorite (bleaching powder containing chlorine, 3% aqueous solution), hydrogen peroxide	Isopropanol (70%), glutaraldehyde solution (2%),sodium hypochlorite disinfectant
FHR sensors	Alcohol-free hand soap, sodium hypochlorite (bleaching powder containing chlorine, 3% aqueous solution), hydrogen peroxide	Isopropanol (70%), glutaraldehyde solution (2%),sodium hypochlorite disinfectant
Marker	Alcohol-free hand soap, sodium hypochlorite (bleaching powder containing chlorine, 3% aqueous solution), hydrogen peroxide	Isopropanol (70%), glutaraldehyde solution (2%),sodium hypochlorite disinfectant
Fetal stimulator	Alcohol-free hand soap, sodium hypochlorite (bleaching powder containing chlorine, 3% aqueous solution), hydrogen peroxide	Isopropanol (70%), glutaraldehyde solution (2%),sodium hypochlorite disinfectant

⚠ WARNING

- Only use detergents and disinfectants recommended in this Instruction Manual; use of other detergents and disinfectants will result in damage to the device or safety risks.

- Before cleaning the monitor, please power it off and disconnect it from the AC power supply. Do not use acetone to disinfect the monitor. Do not spray or pour any liquid directly on the monitor. Do not leave any disinfectant on any surface and accessory of the monitor; please use a wet cloth to clean it immediately. Do not use detergent mixture; otherwise hazardous gases will be generated. To avoid cross-infection, do not re-use disposable accessories. To protect the environment, disposable accessories must be properly disposed of in accordance with local laws and regulations. After cleaning, if the sensor cable is damaged or shows any evidence of ageing, it should be replaced with a new cable. High-temperature sterilization of the monitor and all accessories is not allowed. Do not use EtO (ethylene oxide) to disinfect the monitor. Do not use any cleaning solution not recommended in this manual; failure to do so could result in permanent damage to the device, sensor or cable. Do not soak the sensor or connector in any solution for cleaning or disinfection. In order to prevent the entry of cleaning solution and dust into the ISA gas analyzer via LEGI port, the Nomoline sampling line should always be connected when cleaning the ISA analyzer. Do not soak the ISA sidestream gas analyzer in any liquid for disinfection. The Nomoline sampling line is not a sterile device. In order to avoid damage, do not sterilize any part of the sampling line under high pressure. Before cleaning the IRMA sensor, remove the disposable IRMA airway adapter. Do not disinfect the IRMA sensor or soak it in any liquid. The IRMA oxygen sensor and the IRMA airway adapter are not sterile devices. In order to avoid damage, do not sterilize the device under high pressure.

⚠ CAUTION

- If you carelessly pour any liquid onto the device or any accessory, contact the maintenance personnel or our Company immediately.

11.3 Cleaning of the Belt

The belt can be cleansed with soap water under +60℃.

Chapter 12. Maintenance

12.1 Maintenance Checks

Before using the monitor, or every 6 to 12 months or after each maintenance or upgrade, a comprehensive check, including functional safety check of the device should be carried out by qualified technical maintenance personnel having received training. Items for checking should include:

a) Check whether the operating environment and the power supply for the monitor conform to relevant requirements.
b) Check whether the device and accessories have any mechanical damage.
c) Check whether the power cord is free from abrasion and has good insulation performance.
d) Check whether all functions of the device that can be used for patient monitoring, and whether the device is in good working status.
e) Check whether all accessories used are those designated by the manufacturer.
f) Check whether the battery performance is OK.
g) If the monitor is equipped with a recorder, check whether the recorder works normally and if the record paper conforms to the specified requirements.
h) Check whether the wiring impedance and the leakage current conform to relevant requirements.

If there is any evidence of functional failure of the device, do not use this monitor for patient monitoring and contact our company or a biomedical engineer of your hospital. All safety checks or maintenance work requiring disassembly of the device should be performed by professional maintenance personnel; operation by unprofessional personnel could result in malfunction of the device or safety hazards, and could also endanger operator and patient safety. Upon request by the user, Comen will conditionally provide relevant circuit diagrams to help the user to repair user-serviceable components of the device by appropriate and qualified technicians.

⚠ WARNING

- The hospital or organization using this monitor should establish a sound maintenance plan; failure to do so could result in malfunction of the device and unpredictable consequences, and could also endanger operator and patient safety.

12.2 Maintenance Plan

The following tasks can be fulfilled only by professional maintenance personnel recognized by the Company. If the following maintenance is needed, contact the maintenance personnel. Prior to test or maintenance, the device must be cleaned and disinfected.

Test and Maintenance Items	Frequency
Safety check according to IEC 60601-1	At least once a year; after drop of monitor, replacement of power supply or as needed.
Performance check of all measurement functions	At least once a year or when measurement inaccuracy is suspected of.
Battery performance check	Refer to the battery-related chapter in this manual.

Chapter 13. Fetal Monitoring

Fetal monitoring comprises fetal heart rate (FHR) monitoring by an ultrasound transducer placed on the maternal abdomen and uterine contraction pressure monitoring via a tocotonometer(or TOCO transducer) placed at the bottom of the uterine.

13.1 Fetal Monitoring

13.1.1 Principle

Ultrasound Doppler FHR monitoring principle: FHR monitoring is realized through Doppler Effect: when ultrasound wave of a certain frequency encounters an object on the way of transmission, it is reflected back. If the object is still, the frequency of the reflected wave remains the same. When the object moves, the reflected frequency changes——it increases when the object moves towards the sound source and decreases when the object moves away from the sound source. The faster the object moves, the greater the frequency changes. In FHR monitoring, ultrasound transducer transmits ultrasonic waves into human body, and the waves are reflected back when encountering moving organ (heart), causing changes in the frequency of reflected waves, which can be used as indicator of fetal heart activity. The best position for FHR monitoring is where the fetus's back faces the maternal abdomen. When the fetus faces the maternal abdomen, its hands and feet interfere with the echo signal, and fetus movement also causes weakened echo signal.

13.1.2 Terminology

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.

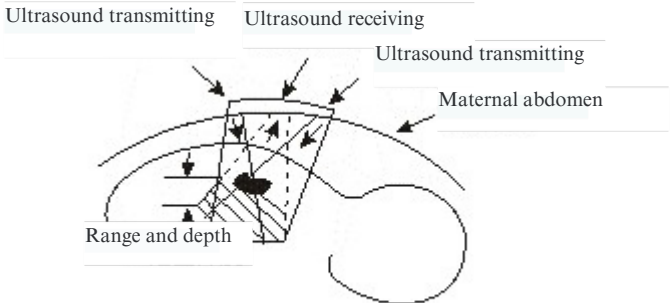


Fig. 13-1 Continuous transmitting/receiving

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/cm2. Higher power could have harmful effect on the fetus.

13.2 FHR monitoring

13.2.1 Procedures

(1) Place a belt under the back of a pregnant woman and let her lie in supine position, then determine the fetus heart location with a stethoscope.

(2) Apply some acoustic couplant on the middle 2/3 area of the sensor surface. When you move the sensor around the fetus site, the couplant is spread to cover the full sensor surface (see the shaded area in fig. 13-2).

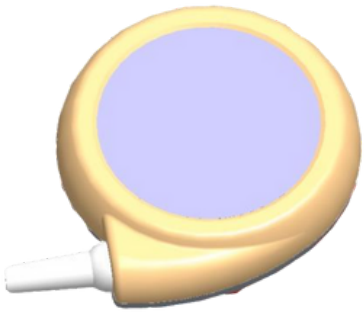


Fig. 13-2 FHR Sensor

(3) Place the ultrasonic sensor on the maternal abdomen and adjust position to find the best signal.

(4) Fasten the sensor belt with appropriate tightness to fix the sensor.

(5) Make sure fetal heartbeats can be heard clearly during monitoring. Do not mute the sound. A good signal

of fetal heart beat is crucial for getting reliable FHR curves.

(6) When there's intense fetal movement or uterine contractions or when the pregnant women moves her body, the fetal heart position changes. It is recommended to move the sensor along with the fetus for better signal.

13.2.2 Cross-channel validation

There are possibilities that maternal heart rate signal is mistaken for FHR signal. It is highly recommended to confirm that the fetus is the signal source continuously. During FHR monitoring, if the detected heart rates (of the fetus or mother) are the same during a time period, maybe the same heart beat signal is received by multiple sensors. Cross-channel validation function can help distinguishing such situation. To activate cross-channel validation: (1) Click FHR wave to enter [FHR Setup] menu. (2) Click [Cross Duration], then select from [Off], [30s], [60s], [90s], and [120s]. The default setting is [Off], indicating there is no alarm when ultrasound waves are the same. If [30s] is selected, the monitor gives a high level technical alarm when FHR1 and FHR2, or fetal heart rate and maternal heart rate are the same for over 30 seconds, and so forth. (3) Click on [Cross Error], and select from 0bpm, 1bpm, 2bpm, 3bpm, 4bpm, 5bpm. If 0bpm is selected, once FHR1 and FHR2, or fetal heart rate and maternal heart rate are the same and last longer than the time set in [Cross Duration], the monitor gives a technical alarm; If 1bpm is selected, once the difference between FHR1 and FHR2, or fetal heart rate and maternal heart rate is less than 1bpm and last longer than the time set in [Cross Duration], the monitor gives a technical alarm, and so forth. When FHR1 and FHR2, or fetal heart rate and maternal heart rate coincide, the monitor gives a high level technical alarm saying "Adjust Ultras Position" (Please adjust locations of ultrasonic transducers) and FHR1 and FHR2 parameters are presented as "_?_".

13.2.3 Trace Separation

This function help users to better observe and interpret two FHR traces with similar baseline levels.

- Turning on "Separation of Traces"

Click FHR waves, [FHR Setup] menu pops up. Click [FHR2 Offset] (FHR2 Trace Separation) and select [+20 bpm] or [-20bpm].

If you select [+20 bpm], the displayed FHR2 is 20bpm higher than actual FHR; if you select [-20bpm], the displayed FHR2 is 20bpm lower than actual FHR (twins deviation).

The recorder prints a light, thin FHR line. For example, when [FHR2 Offset] is set to [+20 bpm], the FHR2 trace printed out is 20bpm higher than actual FHR. See the figure below.

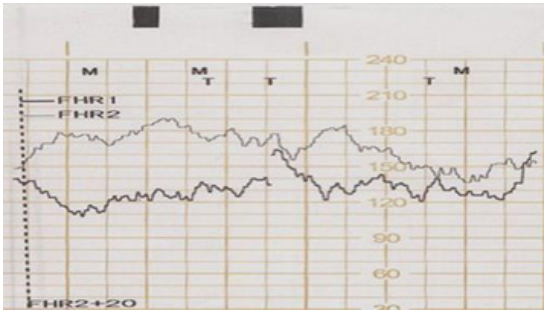


Fig. 13-3 Turning on FHR2 Offset

Note: only FHR2 trace can be deviated. The FHR value displayed on the screen remains unchanged.

- Turning off “Separation of Traces”

Click FHR wave, [FHR Setup] menu pops up. Click [FHR2 Offset] and select [+0 bpm].

The recorder still prints a light and thin FHR2 trace, which is the actual trace of FHR2. See the figure below.

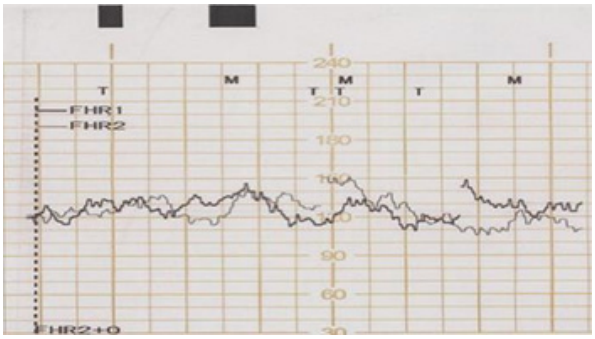


Fig. 13-4 Turing off FHR2 Offset

13.2.4 FHR Setup

13.2.4.1 Setting up FHR Source

When both FHR sensors are connected, you can select FHR signal source between [FHR1] and [FHR2]. When there’s only one sensor connected, the FHR source is automatically set to [FHR1].

To choose a FHR source:

1. Click FHR1 parameter area, then click [Fetal Sound Channel] to select a FHR sound channel. Click FHR2 parameter area, then click [Fetal Sound Channel] to select a FHR sound channel.

13.3 Uterine Contraction Pressure 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.

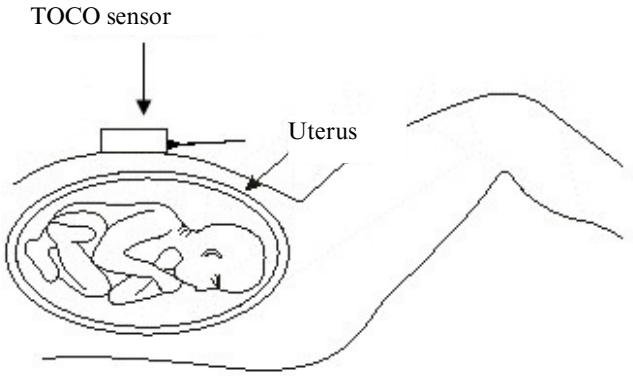


Fig. 13-5 TOCO Measurement Diagram

13.3.1 Measuring Procedures

(1) Put the belt through the back of the pressure sensor (see figure below), place the sensor at the fundus, fasten the belt and adjust it to appropriate condition.

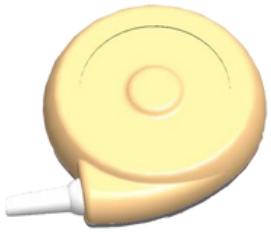


Fig. 13-6 Contraction Pressure Sensor

(2) There are two approaches to rest TOCO baseline.

- Enter [TOCO Setup] menu, click [TOCO Zero].
- Press "→0←" on the front panel.

(3) Pay attention to contraction pressure value after fixing the sensor to the pregnant women.

13.3.2 Setting up TOCO Zero

Contraction pressure can be reset by TOCO Zero. If the value is set to 0, consequently the minimum value

after reset turns to 0 and TOCO trace is reset.

1) Click TOCO parameter area or wave area to enter [TOCO Setup] menu;
2) Click [TOCO Base], and select from 0, 5, 10, 15, and 20.

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 10 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 10 seconds, they are counted as one.

13.4.2 Counting Fetal Movement Automatically

Place the marker at somewhere with the least interference and impact. The device automatically counts fetal movements according to value set in [FM Limen] (FM sensitivity limen) and clinical conditions.

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

13.4.3 Setting up FM Sensitivity Limen

FM sensitivity limen determines the frequency and number of AFM. For example, when it is set to 10% and slope of AFM curve is above 3, an AFM is marked (only once in 8 seconds). From 20%, each gain of 10% in FM limen comes with an increase of 5 in AFM curve. See the chart below:

FM limen	Slope of AFM curve
10%	＞3
20%	＞5
30%	＞10
40%	＞15
50%	＞20
60%	＞25
70%	＞30
80%	＞35

(1) Click TOCO wave area to enter [TOCO Setup] menu.

(2) Click [FM Limen] (FM sensitivity limen) and select from 10%, 20%, 30%, 40%, 50%, 60%, 70%, and 80%.

13.4.4 Setting up FM Counting Mode

The monitor provides three counting mode: [Auto/Manual], [Manual], [Off]. In [Auto/Manual] mode, the monitor automatically counts FM according to clinical conditions. When the pregnant woman feels fetal movement, she can also use the marker to count manually. In [Manual] mode, the fetal movements are manually marked by the pregnant woman. To set FM counting mode: (1) Choice 1: Click FHR wave to enter [FHR Setup], then click [Fetal Move.] (Fetal Movement Count) to

select a mode.

(2) Choice 2: Click FHR1 or FHR2 on parameter area to enter [FHR1 Setup] or [FHR2 Setup], then click [Fetal Move.] to select a mode.

13.5Fetal Stimulator

Fetal stimulator is a device for waking up fetus in ultrasonic test.

13.5.1 External Structure

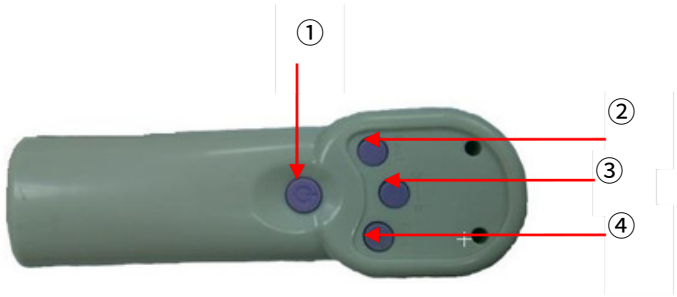


Fig. 13-8 Front View

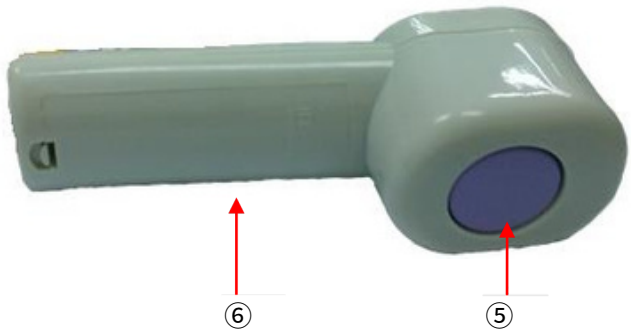


Fig. 13-9 Side View

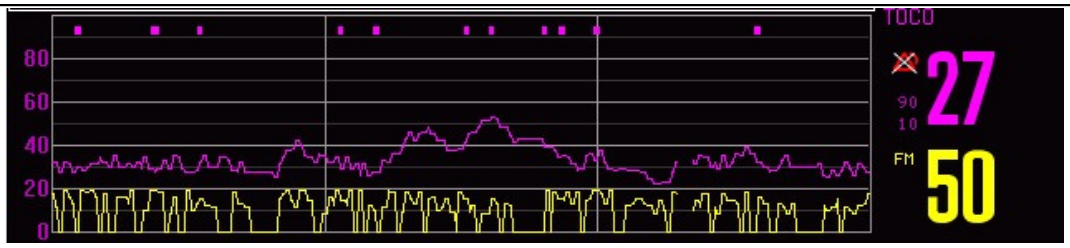
- On/Off switch: press to turn on or off the device.
- Fast: press to speed up vibration (by a doctor based on maternal conditions and speed level)
- Speed level: press to select a speed level from 3 to ∞.
- Slow: press to slow down vibration speed (by a doctor based on maternal conditions and speed level).
- Source of vibration.
- Battery: battery compartment. The device is powered by two AA batteries.

⚠NOTE

- Do not touch maternal skin directly with the stimulator.
- Before using the stimulator, wrap the vibration area with disposable medical gauze and fix it with adhesive tape. Change medical gauze before using the stimulator on the next patient to avoid cross infection.

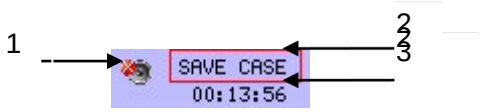
13.5.2 Screen Display

Each stimulation is represented by purple dots on onscreen and is marked with the letter “A” if printed out.



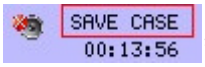
13.6 Timed Monitor

The doctor can choose timed monitoring (TM) or manual monitoring accordingly to patient types. TM is mainly used for fetal monitoring. TM starts automatically at preset time and stops when the monitoring time period ends, making it a convenient choice. Users can see TM information directly on screen.



1. If the icon "  " appears, it means the monitoring end prompt is activated. The monitor generates a high level technical alarm when TM ends. The alarm message is "*** stop monitoring". If the icon "" appears, it means the prompt is off so the monitor gives no prompt when TM stops.
2. In this area the total monitoring time is displayed. For example, the monitoring time in the figure above is 20 minutes.
3. In this area the elapsed time is displayed. For example, in the figure above, the monitoring started 2 minutes and 27 seconds ago.

To activate TM:

1. Click in TM information area, such as this " 

" area, to enter [Timed Monitor] setup menu.
2. Click [Time End Note] and select [On]/[Off] to turn on/off the prompt at the end of monitoring.
3. Click [Timing Monitor] to set the monitoring duration from 10 to 60 minutes.
4. Click [Startup Timer] to start TM. The [Clear Timer] option is displayed in [Timed Monitor] setup menu.
5. You can click [Stop Timer] to pause TM, and the option turns into [Start Timer]. Click [Start Timer] again to resume TM.
6. Click [Clear Timer] to instantly stop TM. [Clear Timer] disappears after you click it.
7. Click [Start Timer] again to start a new TM process.

During TM, the monitor prints fetal monitoring wave in real-time until TM stops. To stop printing, press the Print button on the front panel, and both printing and TM are stopped.

Appendix I Product Configuration

functional parameter	Product Model	
	STAR5000D	STAR5000E
Fetal Heart Rate 1 (FHR 1)	√	√
Fetal Heart Rate 2 (FHR 2)	/	√
TOCO	√	√
Fetal Movement Marker	√	√
Recorder	√	√
Rotary knob	√	√

Notes

1. "√"means the device of the corresponding type has the function parameter in the table.
2. "/" means the device of the corresponding type has no function parameter in the table.
3. All of the instrument models have the same structure, safety and reliability.

Appendix II Accessories

Here we recommend the following accessories for the monitor.

⚠Warning

- Use the accessories specified by Comen only, or the monitor could be damaged.

No.	PN	Model	Type	Description
1	040-000186-00	CM-FSUS1	Reusable	Primary FHR probe
2	040-000332-00	Waterproof	CM-FSUS2	Secondary FHR probe
3	040-000185-00	Reusable	Waterproof Reusable	TOCO probe
4	040-000530-00	Waterproof	Reusable	FM probe

Appendix III Product Specifications

1. Monitor Type

Classified by	Type	
Electric shock protection type	Class-I equipment; defibrillation resistant equipment with internal power supply;	
	Equipment with BF applied part	TOCO, FHR, FM
Safety standards	IEC 60601-1, IEC 60601-1-8, IEC 60601-1-2 IEC60601-2-37; IEC 61157.	
IP rating	Ordinary equipment (IPX0, No protection from liquids)	
Safety level when used in environment with flammable anesthetizing gas mixed with air, oxygen or nitrous oxide (N/A)	Equipment cannot be used in environment with flammable anesthetizing gas mixed with air, oxygen or nitrous oxide.	
Work mode	Continuous operation equipment	

2. Monitor Specifications

(1) Dimensions and Weight

Item	Specification
Dimensions and Weight	L×W×H: 287mm×232mm×90mm
	Total weight: 2.1Kg

(2) Environmental Requirements

Item	Specification	
Working conditions	Ambient temperature	5°C-40°C
	Relative	⩽93%

	Humidity (RH)	
	Barometric pressure	70kPa to 106kPa
Power supply conditions	Supply voltage	100-240V～
	Supply frequency	50Hz/60Hz
	Input power	80VA
Transport conditions	Avoid intense impact, vibration, rain and snow.	
Storage conditions	Store packaged monitors in a well-ventilated indoor place, with a temperature between -20°C-60°C, RH ≤93%， and free from erosive gas. Atmospheric Pressure:700hPa to 1060 hPa	
Fuse type	T1,6AL250V	

(3) Screen Specification

Item	Specification
Screen size	5.6 inch

(4) Power Supply

Item	Specification
Battery Specification	2200mAh d.c.14.8V lithium-ion battery
Charge time	Power off status: a minimum of 5 hours to 90%, and 6 hours to 100%.

(5) Fetal Monitoring

Item Work mode Ultrasound	Specification
working frequency Ultrasonic	Impulse wave
sensor MI Ultrasonic sensor TIS	1MHz,±10%
Ultrasonic sensor TIB	<1 <1 <1
P- (Negative Peak Sound	<1MPa
Pressure)	
I_{ob}(Output beam intensity)	<20mW/cm²
Ispta (Spatial-peak	<100mW/cm²

Temporal-average Derived Intensity)	
FHR measurement range	30bpm-250bpm
FHR measurement accuracy	±1bpm
FHR1/2 alarm preset limit	High alarm: Upper limit ≥ (medial alarm higher limit - 250bpm); Lower limit ≥ (30bpm- medial alarm lower limit). Medial alarm: Upper limit ≥(low level higher limit - high level higher limit); Lower limit ≥ (high level lower limit - low level lower limit). Low alarm: Upper limit ≥ (low level lower limit+1 - medial alarm higher limit); Lower limit≥ (medial alarm lower limit-(low level lower limit-1)).
FHR alarm error	≤±1bpm
Uterine pressure measurement range	0-100
Uterine pressure measurement nonlinear error	±8%
Waterproof rating of FHR and TOCO sensors	IP67

Appendix IV System Alarm Messages

1. Physical Alarm Message

Alarm Message	Default Level	Cause	Solution
FHR1 Too High	High, medial, low	Measured value of the parameter is higher than the upper limit of alarm.	Check if alarm limit is set in good condition.
FHR1 Too Low	High, medial, low	Measured value of the parameter is lower than the lower limit of alarm.	
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
Low power! Please charge the battery	Medial	Low battery.	Charge battery instantly.
Pressure Sensor Off	Low	Pressure sensor is not connected.	Check connection of pressure sensor.
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.
The first fetal wireless sensors battery is low.	High	Wireless FHR1sensors battery is low.	Change battery of wireless FHR1 sensors.
The second fetal wireless sensors battery is low.	High	Wireless FHR2sensors battery is low.	Change battery of wireless FHR2 sensors.
Uterine contractions wireless sensors battery is low.	High	Wireless uterine contractions sensors battery is low.	Change battery of wireless uterine contractions sensors.

Printer out of paper	High	Printer runs out of paper	Install printing paper.
Paper Tray Not Closed	High	Paper tray is open.	Close paper tray.
Stop Monitoring	High	Timed monitoring (TM) is manually stopped.	Resume TM.
Finish Timed Monitoring	High	TM is finished.	Click to finish.

Appendix V Default Factory Settings

System default configuration

Item	Default Factory Adult Configuration	Note
Alarm Volume	4 0 4 4 On 5 minutes Off 10 seconds	
Minimum Alm Volume	Off Off 4 6 seconds English Off On 20	
FHR Volume	minutes On On 30-240 (COMEN)	
K Key Volume	Built-in printer FHR1 Improved	
Save Case	FISCHER 3cm/minute 20 minutes	
Least Time (to save case)		
Alarm Records Print		
Alarm Delay Time		
Alarm Off		
Alarm Off Authorize		
Reminder Volume		
Reminder Interval		
Language		
WIFI Switch		
Time End Note		
Timing Monitor		
Auto Score		
Print Report		
Paper Type		
Select Printer		
Score Select		
Score Criterion		
Real Print Speed		
Real Print Time		

Review 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
Module Color	Green	
Fetal Movement Count	Auto/Manual	
Fetal Sound Channel	FHR2	Locked.
Trace Separation	0bpm	
Sweep	3cm/minute	
Cross Duration	Off	
Cross Error	5bpm	

TOCO default configuration

Item	Default Factory Adult Configuration	Note
Module Color	Purple	
FM sensitivity limen	50%	
TOCO Base	10	
AFM Color	Yellow	

TOCO default configuration

Default Factory Settings

Item				Default Factory Configuration
FHR1/FHR2	Alarm Record			Off
	Alarm (on/off)			On
	FHR1/FHR2 Alarm Setup	High Alarm	Higher limit	210
			Lower limit	60
		Medial Alarm	Higher limit	205
			Lower limit	70
		Low Alarm	Higher limit	200
			Lower limit	80
TOCO	Alarm Record			Off
	Alarm (on/off)			Off
	TOCO Alarm Setup	High Alarm	Higher limit	100
			Lower limit	0
		Medial Alarm	Higher limit	95
			Lower limit	5
		Low Alarm	Higher limit	90
			Lower limit	10

Appendix VI EMC

⚠Attention

- The monitor meets the requirement of electromagnetic compatibility in IEC60601-1-2.
- The user needs to install and use according to electromagnetism compatibility information which is attached with it.
- Portable and mobile RF communication devices may influence the monitor performance, so the monitor should be kept away from them during using.
- Guidance and manufacturer's declaration stated in the appendix.

⚠Warning

- The monitor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.
- Class A equipment is intended for use in an industrial environment. The monitor may be potential difficulties in ensuring electromagnetic compatibility in other environments, due to conducted as well as radiated disturbances.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of the monitor could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
- It may lead to inaccurate consequences if the physiological parameters measured by the device are less than the specified minimum.
- 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, the equipment/system may be disrupted by the operation of nearby equipment.
- 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 monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

Guidance and manufacturer's declaration –electromagnetic emissions
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.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions 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	

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. If ESD interfere with the operation of equipment, measurements be such as wrist strap, counter grounding shall considered.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/output lines 100 kHz repetition frequency	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 dips, short	0 % UT	0 % UT	Mains power quality

interruptions and voltage variations on power supply input lines IEC 61000-4-11	(100 % dip in UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300 cycles 30 A/m	(100 % dip in UT) for 0,5 cycle 0 % UT (100 % dip in UT) for 1 cycles 70 % UT (30 % dip in UT) for 25/30cycles 0 % UT (100 % dip in UT) for 250/300 cycles 30 A/m	should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8			Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE:UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 0.15 MHz 6 V in ISM and 6 V in ISM between 0.15 MHz and between and 80 MHz	3 V MHz to 80 MHz 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150MHz to 80MHz $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7GHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3V/m	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, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol 

NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.

[b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended separation distances between
portable and mobile RF communications equipment and the monitor

The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor 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 to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 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 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity to proximity fields from RF wireless communications equipment						
The monitor 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 VII Toxic/Hazardous Substances/Elements

Component		Pb	Hg	Cd	Cr(VI)	PBB	PBDE
Housing	Front	O	O	O	O	O	O
	housing Back	O	O	O	O	O	O
	housing Keys	O	O	O	O	O	O
	Facing	O	O	O	O	O	O
	Labels	O	O	O	O	O	O
Monitor	Monitor	O	O	O	O	O	O
Main unit	Hardware	O	O	O	O	O	O
	Internal wires	O	O	O	O	O	O
	PCBA	O	O	O	O	O	O
Package	Packing materials	O	O	O	O	O	O
General components	Connectors	O	O	O	O	O	O
	Power cord	O	O	O	O	O	O
Battery	Lithium battery	O	O	O	O	O	O
Note	O: Such hazardous/toxic substance contained in all homogeneous materials of such component falls within the content limit specified in SJ/T11363-2006. ×: Such hazardous/toxic substance contained in one or more homogeneous materials of such component goes beyond the content limit specified in SJ/T11363-2006.						

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