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Name: Obstetric Monitor

Model: PC-8000Pro

Type: Single Fetal Monitor

REF 29550

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

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TABLE OF CONTENT

1 Introduction ..... - 1 -

2 Description of System ..... - 3 -

Intended Use ..... - 3 -

Configuration and Principal Characteristics: ..... - 3 -

3 Functional Description ..... - 5 -

3.1 Front View of the Equipment. ..... - 5 -

3.2 Back of the Equipment ..... - 6 -

3.3 Left Side of the Equipment ..... - 7 -

3.4Right Side of the Equipment ..... - 7 -

3.5 Front Panel of the Equipment ..... - 8 -

3.6 Bottom Part of the Equipment ..... - 9 -

3.7 Function Keys, Switch, Indicators ..... - 9 -

4 Safety ..... - 13 -

4.1Environment requirement ..... - 13 -

4.2Grounding Monitor ..... - 14 -

4.3Equipotential Ground ..... - 14 -

4.4Condensation ..... - 15 -

4.5Notes on the Safety ..... - 15 -

5 Installation ..... - 17 -

5.1 Unpacking ..... - 17 -

5.2 Standard Packing List of Fetal Maternal Monitor ..... - 17 -

.5.3 Power Supply ..... - 18 -

5.4 Boot ..... - 19 -

5.5 Thermal Printer ..... - 19 -

5.6 Connection of the Transducer ..... - 20 -

5.7 Test of Ultrasound Transducer ..... - 21 -

5.8 Test of TOCO Transducer ..... - 21 -

5.9 Test of Event Maker ..... - 22 -

5.10 Installation and Implementation of the Wall-mount Support ..... - 22 -

6 Operation ..... - 24 -

6.1 Main Interface of the Fetal Maternal Monitor ..... - 24 -
6.1.1 Message/Main menu Area ..... - 25 -
6.1.2 Waveform Area ..... - 26 -
6.1.3 Parameter /Alarm Area ..... - 26 -
6.1.4 Status /Time zone Area ..... - 27 -
6.1.5 Network ..... - 27 -
6.1.6 Integrated Battery and AC input ..... - 27 -
6.2 Main menu ..... - 28 -
6.3 Information ..... - 28 -
6.4 Freeze ..... - 30 -
6.5 Configuration ..... - 31 -
6.5.1 Fetal Monitor Parameter ..... - 31 -
6.5.2 ECG Parameter ..... - 32 -
6.5.3 NIBP Parameter ..... - 33 -
6.5.4 SpO2 Parameter ..... - 34 -
6.5.5 RESP Parameter ..... - 35 -
6.6 Alarm Setting ..... - 35 -
6.6.1 Setting Alarm Limit ..... - 35 -
6.6.2 Description of Alarm ..... - 36 -
6.6.3 Level of Alarm ..... - 36 -
6.6.4 Mode of Alarm ..... - 36 -
6.6.5 Silence of Alarms ..... - 37 -
6.6.6 Fetal Monitor Alarm ..... - 38 -
6.6.7 ECG Alarm ..... - 39 -
6.6.8 NIBP Alarm ..... - 40 -
6.6.9 SpO2 Alarm ..... - 41 -
6.6.10 RESP Alarm ..... - 42 -
6.6.11 TEMP Alarm ..... - 43 -
6.7 Print ..... - 44 -
6.7.1NST Report Fuction(Optional) ..... - 45 -
6.8 System ..... - 46 -

6.9 Sever ..... - 47 -
6.10 maintenance ..... - 47 -
6.11 About ..... - 48 -
6.12 Records ..... - 49 -
6.13 Switch ..... - 50 -
6.14 NST timer(Optional) ..... - 51 -
6.15 Doctor Remark ..... - 52 -
7 Pre-Monitoring Preparation ..... - 53 -
7.1 Switching On the Monitor ..... - 53 -
7.2Connecting Transducers ..... - 53 -
8 Fetal Monitoring ..... - 55 -
8.1Confirming Fetal Life ..... - 55 -
8.2Monitoring FHR with Ultrasound ..... - 55 -
8.2.1Parts Required ..... - 55 -
8.2.2FHR Monitoring Procedure ..... - 55 -
8.3 Alarm ..... - 58 -
8.4 Signals Overlap Verification (SOV) ..... - 58 -
8.5 Monitoring of the Uterine Activity ..... - 59 -
8.5.1 Introduction ..... - 59 -
8.5.2 Parts Required ..... - 59 -
8.5.3 TOCO Monitoring Procedure ..... - 59 -
8.5.4 Message of Alarm ..... - 61 -
8.6 Monitoring of the Fetal Movements ..... - 61 -
8.6.1Auto Fetal Movement (AFM) Monitoring ..... - 61 -
8.6.2Manual Fetal Movement (MFM) Monitoring ..... - 61 -
8.6.3Clinician Marker ..... - 61 -
8.6.4Patient Marker ..... - 61 -
9 Maternal Monitoring ..... - 63 -
9.1Maternal ECG Monitoring ..... - 63 -
9.1.1Principle of ECG Measurement ..... - 63 -
9.1.2Preparation of ECG Measurement ..... - 63 -

9.1.3Preparation of the Contacting Area on Skin ..... - 63 -
9.1.4 Menu Setup ..... - 65 -
9.1.5 Alarm setup ..... - 65 -
9.6 Maternal RESP Monitoring ..... - 65 -
9.6.1Principle ..... - 65 -
9.6.2 Operation ..... - 65 -
9.7 SpO_2 / Pulse Monitoring ..... - 66 -
9.7.1General Information ..... - 66 -
9.7.2 Operation ..... - 66 -
9.8Maternal NIBP Monitoring ..... - 67 -
9.8.1Principle ..... - 67 -
9.8.2Operation ..... - 67 -
9.8.3MeasurEment Steps ..... - 68 -
9.9TEMP Monitoring ..... - 69 -
9.9.1Operation: ..... - 69 -
9.9.2Set Up the TEMP Menu ..... - 69 -
10 Maintenance ..... - 70 -
10.1 Maintenance Inspection ..... - 70 -
10.2Maintenance of the Battery ..... - 71 -
10.3Maintenance of the Monitor ..... - 71 -
10.4Maintenance of the Sensor ..... - 71 -
10.5Maintenance of the Belts ..... - 72 -
10.6 Maintenance of the Record Papers ..... - 72 -
11 Cleaning ..... - 73 -
11.1Cleaning Inspection ..... - 73 -
11.1.1Cleaning of the Monitor ..... - 73 -
11.1.2Cleaning of the Accessories ..... - 74 -
11.1.3Cleaning of the Cuff ..... - 74 -
11.1.4 Cleaning of the SpO_2 Sensor ..... - 75 -
11.1.4Cleaning of the ECG Cables ..... - 76 -
11.1.5Cleaning of the TEMP Sensor ..... - 76 -

11.1.6Cleaning of the Recorder - 76 -
11.2Detergents - 76 -
11.3Sterilization - 77 -
12 Troubleshooting - 78 -
13 Guarantee - 81 -
13.1Manufacture, Safety, Reliability and Performance - 81 -
13.2Service - 81 -
13.2.1 Procedure of Return - 81 -
14 Design Feature - 83 -
14.1 Specifications - 83 -
14.2 Safety - 85 -
14.3 Environment of Work - 85 -
14.4 Transportation and Storage Environment - 85 -
14.5Power - 85 -
14.6Classification - 86 -
15 Appendix 1 - 87 -
15.1EMC - 87 -
15.2Meaning of Icons - 91 -

1 Introduction

This handbook explains how to install, use, maintain and clean the fetal maternal monitor.

	To ensure the safety of the patients，this apparatus must be used under the supervision of a doctor or a nurse.
	In case of failure, the technical staff of breakdown service will occur by telephone or repairs will be ensured on site by us or the system will be turned over for repair, according to the opinion of our company
	Not to use the equipment in place where anaesthetic gauzes or other flammable substances are placed.
	The user must make sure that the material is in good condition before using it.
	When the equipment is used, certain electromagnetic radiation may be produced, which may interfere the electronic equipment or device nearby. The potential of jamming would be reduced to a great extent when the electronic equipment or device is far away from the equipment.
	Please ensure the devices connected with the monitor form an equipotential body (ensure effective connection). The discarded materials must be treated in accordance with the regulations on the management of these products to prevent the pollution of the environment. Directly contact the manufacturer for the technical questions.
	To make sure that all the lines of connection use, the hoses or pipes are far from the neck of the patient.
	Although the majority of the components used received tests of biocompatibility, they can involve an anaphylaxis at certain individuals.

	To ensure the safety and the curative effect of a patient, use the accessories recommended by the manufacturer. If not, the patient can be wounded or curative effects can be reduced.
	If a portable monitor falls accidentally it is not more available for the use, you must supervise its results attentively, to continue to use the monitor that when the results of measurements in conformity with the standard.
	A bad application can lead to the erroneous data acquisition, so you must work according to the procedures described in the handbook of corrective measurements to ensure of the results.
	Not to use the equipment in room of imagery (such as CT or IRM). If you use the monitor and the sensor when the equipment of imagery is used, it can cause currents induced on the sensor connected with the patient and cause potential wounds. The monitor can influence the function of the equipment of imagery and the equipment of imagery can influence the exactitude of measurements of oxygen of the hemoglobin and other parameters of the monitor.

2 Description of System

The fetal maternal monitor is a non-invasive perinatal monitoring system of measurement and to post the contractions the uterus and fetal heartbeat rate on a nonpermanent screen graph and possibly on a diagram recorder. This information is used to help to evaluate the wellbeing of the fetus during the last quarter of the pregnancy (not-stress test). This apparatus is used by a medical personnel qualified in hospitals, private clinics, cabinets of doctors and in the residence of the patient.

Intended Use

The fetal maternal monitor is intended for monitoring physiological parameters of pregnant women during ante partum examination, labor and delivery. They are intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms. They are not intended for use in intensive care units, operating rooms or for home use.

Configuration and Principal Characteristics:

Fetal monitor (configuration A) = FHR1 + TOCO + MFM + AFM

Fetal monitor (configuration B) = FHR1 + FHR2 + TOCO + MFM + AFM

Fetal monitor (configuration C) = FHR1 + TOCO + MFM + AFM + maternal ECG/HR + maternal TEMP + maternal RESP + maternal NIBP + maternal SpO_2

Fetal monitor (configuration D) = FHR1 + TOCO + MFM + AFM + maternal ECG/HR + maternal TEMP + maternal RESP + maternal NIBP + maternal SpO_2

Configuration:

Item	Configuration A	Configuration B	Configuration C	Configuration D
FHR(Single)	√	√	√	√
FHR(Twins)	—	√	—	√
TOCO	√	√	√	√
FM	√	√	√	√
Maternal ECG/HR	—	—	√	√
Maternal NIBP	—	—	√	√
Maternal RESP	—	—	√	√
Maternal TEMP	—	—	√	√
Maternal SpO_2/PR	—	—	√	√
Central Monitoring Station	Option	Option	Option	Option

NST Report	Option	Option	Option	Option
HMDI	Option	Option	Option	Option
Keyboard/mouse	Option	Option	Option	Option
Touch screen	Option	Option	Option	Option

A fetal stimulator can be provided to give a mild vibrating stimulation to the fetus.

A TCP/IP interface is built in the monitor. With it, the series monitors can be connected to a CNS central nurse station via LAN network.

The monitor adopts a 12.1" TFTLCD, which displays the collected data, traces, and monitoring parameters on the same screen. The built-in thermal recorder prints the fetal traces. Rechargeable lithium-ion battery is provided as standard configuration.

Principal characteristics:

• Display: 12.1 inches TFT LCD

• Printer: 112mm, 150mm of width paper of the printer for choice

• Alarm: three level of acousto-optic alarm

• Power: 100-240V

• Transducer: 12-crystal high-sensitive ultrasound transducer

• Network: support connected to a nurse station (central monitor station) via TCP/IP (LAN) (option) or wireless connection (option)

• Range: Fetal heartbeat rate: 30-240bpm

Toco pressure: 0-100 relative units

Movements of the fetus: marker of detection of the fetal movements manually and automatically

Description of the fetal movements: 0-100 relative units

3 Functional Description

3.1 Front View of the Equipment.

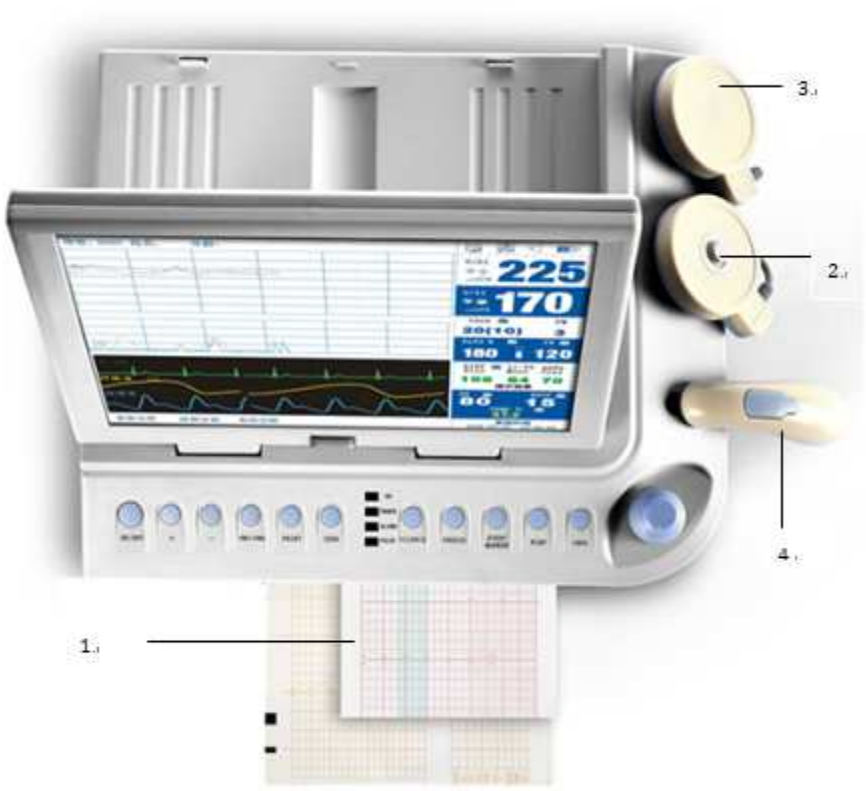


Figure 1 Front view

1. Printer
2. Toco transducer
3. Ultrasound (FHR) transducer
4. Marker of the fetal movements

	During the normal use of the monitor, keep the door of the printer closed and locked to avoid the deterioration of the performance of the printer.

3.2 Back of the Equipment

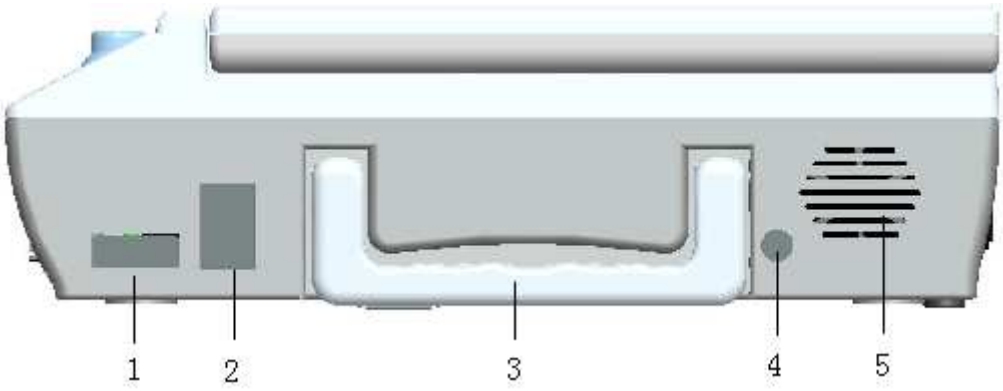


Figure 2 Rear panel

1. Port HDMI
2. Network (TCP/IP)/USB (option)
3. Handle
4. Earthing
5. Ventilator

1. VGA (CRT): Support to connect fetal monitor to external color VGA monitor
   a) Operating mode: 1024 × 768, 256 colors
   b) Signal: Analogical RGB 0,7 Vcc/750 Ohm
   c) Hor. /Green. Pos TTL. /NR
2. Network (TCP/IP)/port USB: standard port TCP/IP and a port USB (in option)

   The network port of fetal monitor can only be used to connect with our company.
3. Handle : Portable handle for transportation
4. Earthing: Equipotential Terminal port
5. Air: ventilator, and the ventilation of the system

	All analog digital materials connected to the monitor answers for the requirements safety (IEC60950) and the safety medical of the electric components (IEC60601-1), and are connected according to the last version of the standards above. All the connections are fixed with the system in force of standards IEC 60601-1-1. The personnel which connects the additional equipment to the entry and of exit of the terminal, ensure that the system conform to the standards above. In case of doubt, contact the supplier.

3.3 Left Side of the Equipment

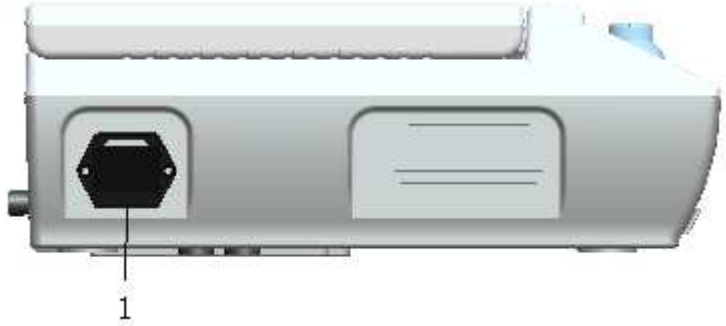


Figure 3 left-side view

1. Socket-outlets: A connector used to connect the electrical supply networks.
Connect the power AC in strict conformity with chapter 5.3 of the handbook.
Ensure that the input AC power is similar to the requirements of the product. If not, use the equipment supplied with battery.

3.4Right Side of the Equipment

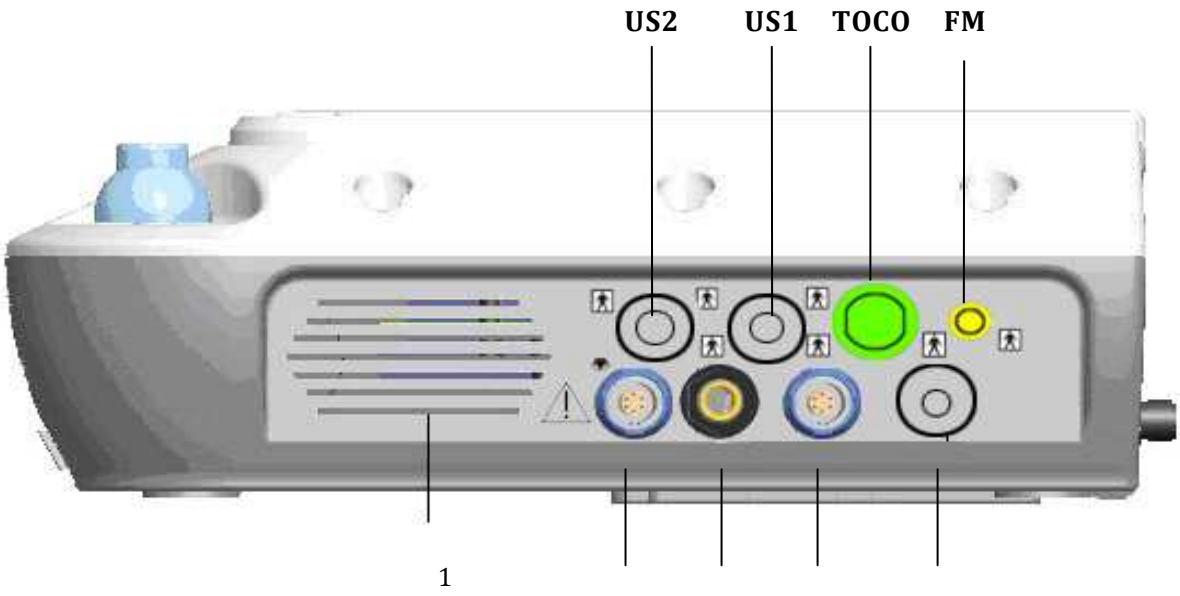


Figure 4 Right-side view of connections of the transducer.

1. Speaker
2. US2 : Fetal Heart Rate Sensor Connector(Option for twins)
3. US1 : Fetal Heart Rate Sensor Connector
4. TOCO Socket for Toco transducer(green color)
5. FM :Socket for marker of the fetal movements (FM)
6. ECG: Socket for ECG Cable Connector
7. TEMP : Socket for Temperature Sensor
8. SpO_2 : Socket for SpO_2 Sensor
9. NIBP: Socket for NIBP Cable Connector

3.5 Front Panel of the Equipment

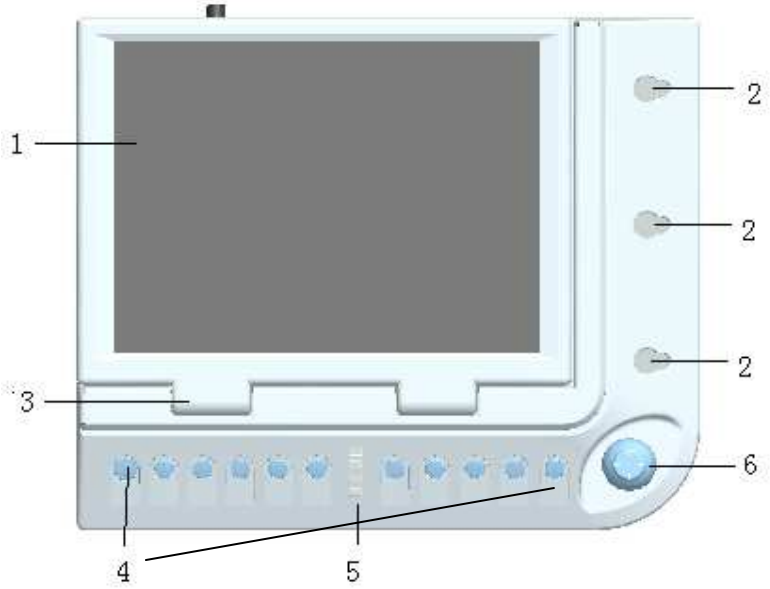


Figure 5 Front panel of the equipment-control panel

1. LCD screen: 12.1 inches (31cm) TFT true color screen LCD, rotation at the interior of 0-90 degrees

2. Transducer Support for temporary detention of ultrasonic transducer, transducers Toco and marker of the fetal movements.

3. Screen rolling axis

4. Function Keys

5. Indicator light: Four indicator lights, please refer to chapter 3.7 for details

6. Rotary select control knob (coder): Used for the selection, page up/ down, confirmation and the moving of the cursor.

3.6 Bottom Part of the Equipment

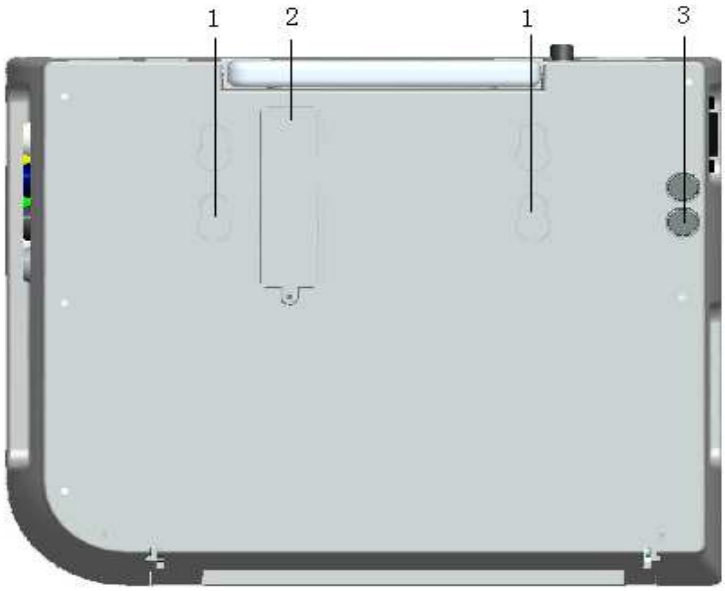


Figure 6 Bottom view of the equipment

1. Wall mount hole: User can use the screwdriver to break the holes reserved on the bottom panel and then install the wall mount as indicated in chapter 5.10

2. Cover of the battery: Engineer can use the screwdriver to open and replace the lid of the battery to open it.

3. Fuse: Fuse requirement: Φ5 T2A 250V * 20mm. (To ensure the safety of the user, replace the fuse with the same specification only)

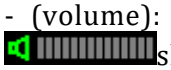
3.7 Function Keys, Switch, Indicators

As showing in figure 7, there are eleven function keys and one control knob (encoder). The eleven keys are **the On/Off (power), + (volume), - (volume), FHR1 /FHR2, Print, Zero, Silence, Freeze, Event Marker, NIBP, Info.** There are four indicators in the middle of central panel.

Figure 7 Function keys, switch, indicators

1. “ON/OFF: Press on this button to Switch on or off the monitor

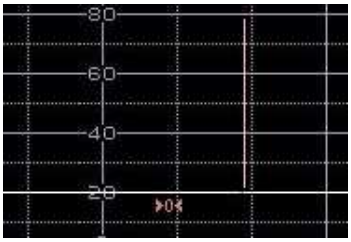
2. + (volume): to increase the volume of the fetal heartbeat sound, the volume status icon  showed on the bottom right of the screen.

3. - (volume): To decrease the volume of the fetal heartbeat sound, the volume status icon  showed on the bottom right of the screen.

4. “FHR1/FHR2”: Press on this button to select the sound source from FHR1 or FHR2 (when monitoring twins). (Configuration in option). The monitor default fetal heart audio is US1. When two ultrasound transducers are connected to the monitor, press this key to switch the audio to US2; press it again to switch the audio back to US1.

5. “Print”: Press on this button to start the printing, press it again to stop printer from working while printing.

6. “Zero”: Reset Toco baseline into initialization pressure value (20). This test must be used when begin to monitor uterine pressure each time. When the user press the button, there will be a mark on the TOCO wave like this



7. The four indicators from top to bottom are the **Power on, Charge, Alarm, Print** indicators.

Alarm Indicator	Flash or light up in yellow	An alarm is active
	Yellow or off	No alarm is active
Charge Indicator	On	The battery is being charged
	Off	No battery or the battery is fully charged
Power Indicator	On	Power on
	Off	Power off
Printer Indicator	On	Printing
	Off	Not printing

”POWER ON “： Working status indicator. Green light means monitor is on working status; No light means monitor is not working (power-off).

”CHARGE “： Battery charging indicator. Green light flashing means monitor is on charging; Green light on (without flash) means charging finish.

”ALARM “： Alarm indicator. It will only light when machine giving alarm. It shows yellow light when alarming. The flashing mode and color means relative alarm grade. Please refer to chapter 6 for description of alarm grade.

"PRINT "：Printing indicator. It shows green light when printing. It shows green light when printing.

8. "Silence": Disable/Enable audio alarm. Press this key once to switch the alarm sound off, and there will be an icon" "on top right of the screen. But the alarm information displays and indicator flashes as normal; press this key again to switch the sound back on; the icon will be changed to "Freeze": Press to freeze all the waveforms on the screen for waveform review and press again to unfreeze to restore the waveforms.

9. "Freeze": Press to freeze all the waveforms on the screen and press again to unfreeze to restore the waveforms.

10. "Event Marker": Doctor or the nurse can use this button for the special events marking; please refer to 6.18 for description of doctor maker.

11. "NIBP": This button is used to start or stop the process of blood pressure measurement, if the blood pressure in a non-test mode, press this key to inflate the cuff and start a NIBP measurement. During the measuring process, this key can be pressed to cancel the measurement and deflate the cuff

12. "INFO": Give the dialog box of information of the patient, the doctor/nurse can input the relating information of the patient.

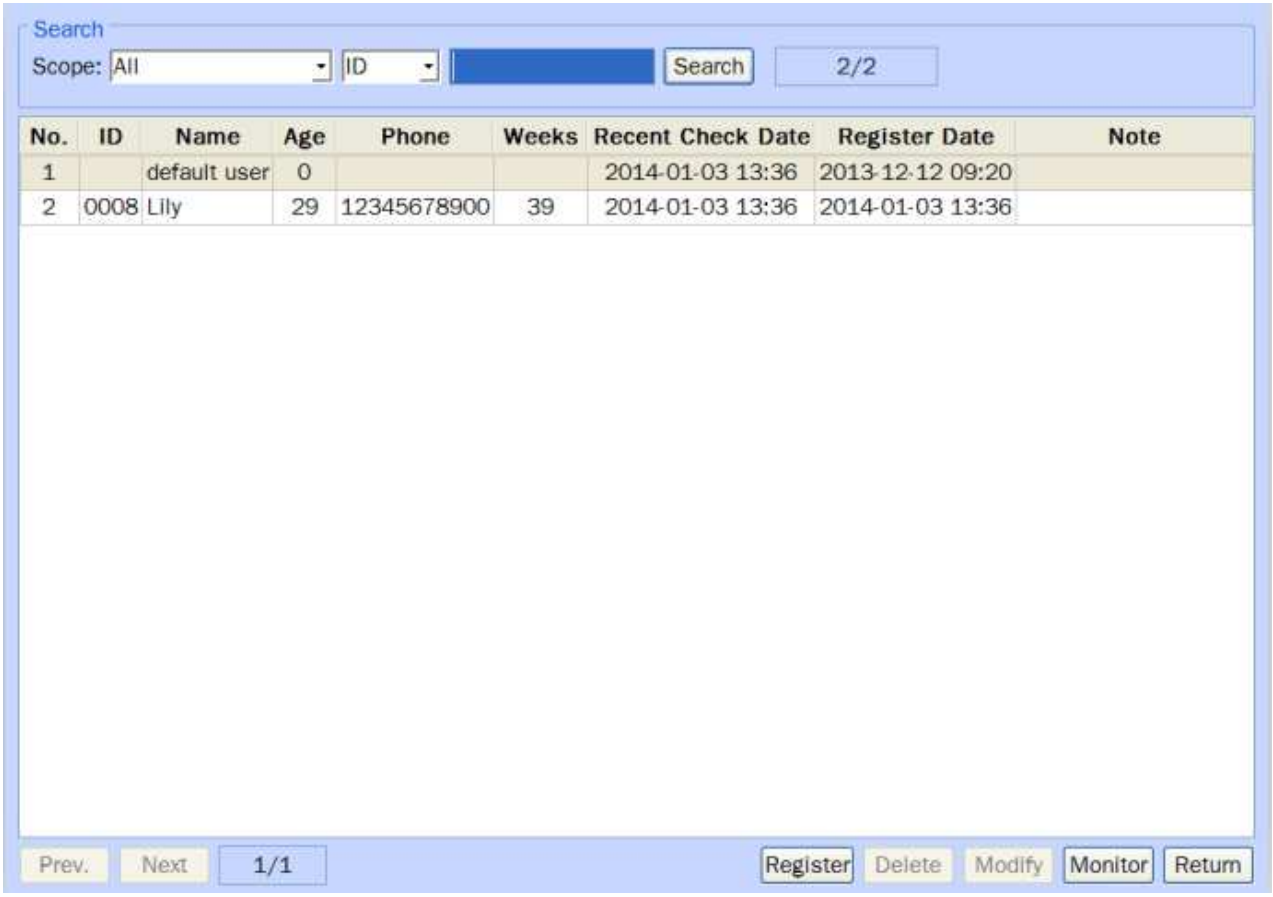
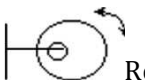


Figure 8 Patient information

13. Control Knob (encoder): Anti-clockwise rotation or clockwise rotation to select, page up/down, to confirm and the displacement of the cursor, support above to confirm your choice or in the sub-menu. All operations on the screen or in the menu can be completed by using the control knob. The rectangular mark on the screen that moves with the rotation of the control knob is called “cursor”. Operations can be performed in the position on the screen where the cursor stays.


Rotate Select Control Knob

- **Basic operations of the encoder**

The high-light rectangular mark that moves on the screen when turning the rotary encoder is referred to as "cursor". The user can only operate to the item when cursor remains on it.

- **How to make a selection of menu?**

Move the cursor on the desired menu and press on the inserted key.

- **How to select the sub-menu?**

Move the cursor on the sub-menu which you wish and press on the inserted key.

- **How to modify all the selections in the menu:**

Move the cursor to select the box which you want to modify and press on the button. To turn the button clockwise or anticlockwise to carry out selections or changes, press on the button to confirm your selections or changes.

	If a new alarm occurs in silent state, it will automatically cancel alarm silence. For detailed information, please refer to the requirements of alarm settings.
	The word “select” hereinafter stands for rotating the control knob cursor to an item then pressing the knob.
	This monitor is a normal medical device; please avoid violent operations such as continuous pressing the keys or control knob.

4 Safety

Configuration of the monitor conforms to the international requirements of safety for medical electrical appliance, such as IEC60601-1, IEC60601-2-37, IEC60601-1-2, IEC60601-1-4, IEC60601-1-8 and IEC60601-1-8.

	Do not connect several monitors when using, otherwise it may cause cumulative leakage which may raise risk of electric shock to the patient or the operator. In case of doubt, to contact the supplier.

4.1Environment requirement

To guarantee the absolute safety of the electric environment, installation of the equipment should reasonably avoid jolts, dust, corrosive installation or gas explosion, of the extreme temperatures and moisture, etc. At the time of the installation of the equipment in wall mount, leave sufficient space for the operation. If the door is open, make sure there is a sufficient space behind the equipment to facilitate maintenance. Ensure good ventilation inside the cabinet.

If the monitor functions at a temperature of 5 ℃ ~ 40 ℃, it can meet the technical requirements index. If the temperature exceeds the range, it will affect the precision of the monitor and the components and circuits.

	To leave at least 2 cm (or 5 inches) of the device to ensure an adequate ventilation.

Environment of work

Operating temperature: 5 ℃ ~ 40 ℃

Relative humidity: ≤ 80%

Atmospheric pressure: 80kPa ~ 110 kPa;

Transportation and storage:

Temperature: -20 ℃ ~ 50 ℃

Relative humidity: ≤ 93%

Pressure 60kPa atmospheric ~ 110.0kPa;

	Keep the device far from the direct light of the sun; Not to store in a place with over high/low air pressure, or when the temperature and moisture are higher than the standards or ventilation is bad, or in a place with accumulated dust, or with sulphur, salt, gas and other chemicals. Try to avoid the contact of water. The apparatus must be managed and stored according to the standard specification

4.2Grounding Monitor

To protect the patients and the medical personnel, the monitor must be grounded. For this reason, the monitor is equipped with a detachable triplex cable, and is grounded via the ground wire (protective ground) of power line once the cable is inserted into the match three-pin socket.

If there are no three pins, please consult electrician of the hospital.

Connect the ground wire to the equipotential ground terminal of device. If you are not sure whether a special device combination has risk or not according to the specifications, for example an accumulation of leakage current would lead to a risk, you should consult the relevant manufacturer or other experts of this field to ensure the safety of this device is not damaged by the suggested combination.

	Do not connect the removable three-pin cable to a two-pin socket
	Connect the AC and ground wire according to the user manual. AC voltage or frequency should meet the user manual's requirements, and should have enough current capacity. The ground wire should be connected with the special ground wire system of the hospital firmly and effectively.

4.3Equipotential Ground

For the first class of the protection of the device, it is realized by grounding the attaching plug, which is included in the system of earthing of protection of the house. For the internal audit of heart, the device should be individually connected to the equipotential system. One end of the equipotential grounding wire (potential equalization conductor) is connected to the equipotential grounding terminal at the rear panel of device, and the other end is connected to the other connector of the equipotential system. If protective grounding system is damaged, the equipotential grounding system could take on the safety function of ground wire. Heart (or brain) check should be done inside the clinical room with a protective grounding system. Device should be checked before using each time to see whether it works properly or not. Cable between the patient and device should not be polluted by electrolyte.

	Ensure that the power socket is properly grounded. If you doubt the integrity of protective grounding wire, please run the device with the internal power supply.
	If you doubt the round wire integrity of protection, please use the device with internal battery

	To protect the patients and the medical personnel, the device must be grounded. For this reason, the monitor is equipped with a detachable three-pin cable, and is grounded by an intermediary wire (protective ground) of power line once the cable is connected to a three pin socket. If there is no three- pin socket, please consult electrician of the hospital. Do not plug the removable three-pin cable to a two-pin socket.

4.4Condensation

Make sure there is no condensation during the operation since it would form condensation if the device is transferred from one room to another, which is caused by the humid air and the different temperature.

	Not to use your monitor close to a zone with the anesthetic flammable ones.

4.5Notes on the Safety

For your safety, please read below contents attentively and follow the instructions for the medical devices.

	If there is something wrong with the patient or the device in the course of use, stop the device and adopt some effective measures to ensure the safety of patients.
	Check the apparatuses and the accessories for a use any time to see whether there are risks or unusual conditions. If it is the case (C. - cable is broken or the shell is cracked, etc.), do not use it.
	If the apparatus is connected with other medical electronic instruments, attention with connection to avoid an erroneous diagnosis or other problems. To avoid any risk of leakage current hazard in reason of the electric imbalance of potential enters the apparatuses; please connect the equipotential terminal of monitor with the equivalent terminal of other device using the supplied grounding wire.
	If the package of sensor is broken, do not use it

	The disposable material or accessory of equipment for the monitor must be used for only one patient. The disposable materials or accessories should be abandoned immediately, and they should not be re-used or discarded at random. They must be treated in conformity with the local State or payments
	Do not withdraw the batteries if the apparatus is powered by the battery
	The accessories and the sensor do not contain any emulsion
	This product does not contain formic acid, and would not cause uncomfortable feeling if it contacts your skin or eye.

5 Installation

5.1 Unpacking

Before opening the package, check the package box first. If the box is damaged, do not open the parcel, and contact the service engineer of supplier immediately.

Take out the material and the accessories from the box. Preserve packing for transport or possible future storage.

Check the parts according to packing list. Check whether any mechanical damage occurs on the equipment or surface of the sensors.

If you have questions, contact the service engineer of supplier immediately.

	Not to use a knife to open the package, to avoid damaging the surface of the machine
	If you have questions, contact the service engineer of supplier immediately
	If there is any problem when you unpack, do not connect the power supply of the monitor

5.2 Standard Packing List of Fetal Maternal Monitor

Quantity / Configure / Item	Specification	A	B	C	D
FHR Sensor	8310400004, yellow, 5 pin connector, 2.5m	1	2	1	2
TOCO Sensor	8310400003, green, 5 pin connector, 2.5m	1	1	1	1
FM Marker	8310400012, audio Φ3.5 frequency connector, 2.5m	1	1	1	1
NIBP Cuff	8189007009，Cuff for adult	—	—	1	1
SpO_2 Sensor	8310400016，6 pins	—	—	1	1

ECG Cable	5 leads	—	—	1	1
Electrode plate (bag)	25 pieces in one bag	—	—	1	1
TEMP Sensor	8189007072, 2.25K	—	—	1	1
Printer Paper (pad)	8111810022, □ Paper width 150mm, 150P	2	2	2	2
	8111810003,□ Paper width: 112mm, 150P,	Option	Option	Option	Option
Ultrasound gel	8190100001, Bottle	1	1	1	1
Rechargeable battery	Internal Li-on battery, 4.5Ah,12V	1	1	1	1
Power cable	International 3 hole 0.75GB 3m 3 pin, 220V power	1	1	1	1
Grounding cable	8310100008 3m clip-type	1	1	1	1
Belt	8189007031 1.5m*50mm	2	3	2	3
Trolley	8212900052	Option	Option	Option	Option
Wall mount	□ mural Fixing	option	option	option	option
User Manual	English version, A4.01	1	1	1	1

.5.3 Power Supply

Ensure that the AC current supply conforms to the following specifications:
AC 100-240V, 50/60 Hz;

Use the provided power. Connect the power to the AC input port of the device, and the other end to the three pins power socket grounded.

If necessary, connect the equipotential ground wire. With this intention, please refer to the part equipotential of the requirements of safety and the notes of chapter 4

	Connect the power line to the dedicated socket of hospital, and ground it properly.

	Regarding equipping the batteries, the battery capacity may be decreased due to the long journey or storage, it is therefore necessary to charge the battery before use. In this way, the device may not work properly due to the deficient power if you start the device without connecting to AC power supply. Connect the device to AC power supply, and the batteries would be charged regardless whether the monitor is on or off.
	In case of connection of the monitor to other apparatuses, please connect the equipotential points of these two devices with supplied ground wire

5.4 Boot

Once the switch is activated, the system would give out a “Bi” sound, and the alarm indicator is lit and the warning light flickers in several colors once. Approximately 10 seconds later, the system shows the principal menu which the user can use on.

	If the device is found to have malfunction or if an error prompt occurs, do not use it to monitor the patients. Contact the biomedical engineer of hospital or the maintenance engineer of the company immediately
	If a fatal error is detected at the time of self-test, the system emits an alarm
	Check all usable monitor functions to ensure the monitor works properly.
	If the apparatus is provided with batteries, recharge the batteries after each use in order to make sure that they have sufficient capacities
	Not to start again within 1 minute commencing from last shutdown. The system preserves the preceding parameters when the apparatus starts again

5.5 Thermal Printer

Hold the buckles of paper holder of the device (on both sides of the paper holder) with your forefingers and press on the buckle toward inside and draw the door of paper holder outside at the same time. Regulate the thermal paper Z-type into the paper holder with a small section drawn out according to the diagrammatic drawing, then to reposition the

paper holder in its initial position until you hear sound of two clicks, which indicates the door is closed.

Output information from printer includes patient information, parameter list, record time, waveform and etc.

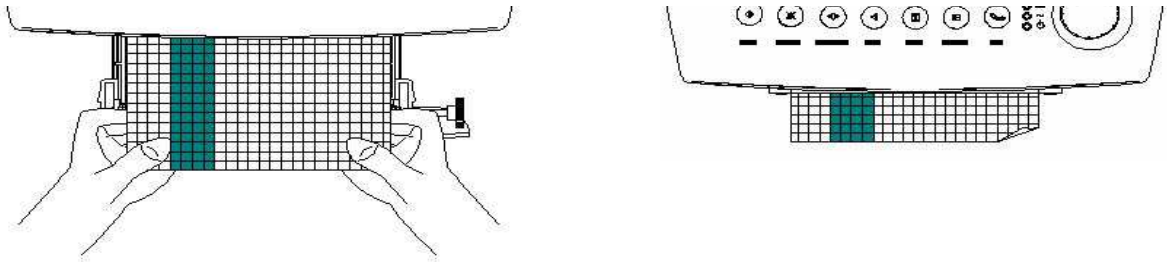


Figure 9 Print

How to close the printer cabinet:

Press both side of printer cabinet simultaneously, and you will hear two “ka” beep, then the printer cabinet is correctly closed.

Notice: Incorrectly close of printer cabinet may cause non-work of printer.

	Note that the position of record paper should not be deflected when feeding paper; otherwise, it would influence the printing effect.
	Make sure to be gentle when you are changing paper, and do not touch the thermal head. Do not keep the door of printer open unless you are changing the paper or troubleshooting.
	When placing the thermal sensitive paper, keep the side with grids upwards; otherwise, it may not work properly.

5.6 Connection of the Transducer

Insert the sensors correctly in the connector of the sensor on the right side of the monitor. If you are not going to monitor a certain parameter, then it is not necessary to connect sensor corresponding.

	For a good connection of all the sensors, please refer to all the related sections of measurements of parameters.

	Please choose the good sensor according to the accessory list listed in the. Improper Sensor can lead to the reduction of safety and performance

5.7 Test of Ultrasound Transducer

This 12-crystal, broad beam US transducer is used for monitoring fetal heart rate (FHR). The US transducer operates at a frequency of 1.0MHz. The FHR transducer on maternal abdomen transmits low energy ultrasound wave to fetal heart and receives the echo signal. The monitor acquires the fetal heart rate after calculating.

To test an ultrasound transducer:

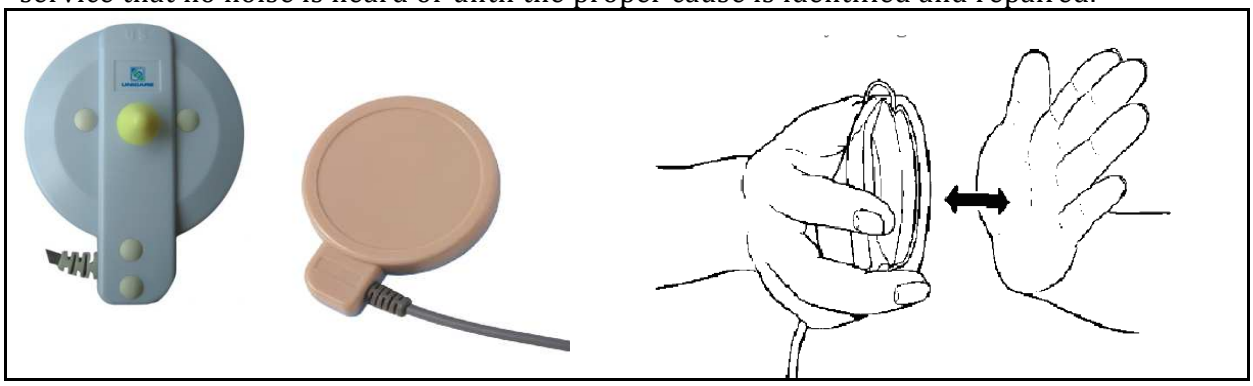
1. Properly connect the transducer to the right of the monitor

2. Switch on the apparatus.

3. Adjust volume of loudspeaker to an audible level.

4. Hold the transducer on one hand and tap on the transducer face with the other hand. The tapping should be heard from the monitor.

The transducer is operating properly if you can hear noise from the speaker. Remove from service that no noise is heard or until the proper cause is identified and repaired.



5.8 Test of TOCO Transducer

This transducer is a tocotonometer whose central section is depressed by the forward displacement of the abdominal muscles during a contraction. It is used for assessment of frequency and duration of uterine contractions. It gives a subjective indication of contractions pressure.

Test of the Toco transducer:

1. To connect the transducer to the right-hand side of the apparatus

2. Switch on the apparatus.

3. Gently apply pressure to the button centered on the face of the sensor as shown in figure

The display and printout should show a change in pressure when the transducer functions properly. Remove from service if this does not occur.

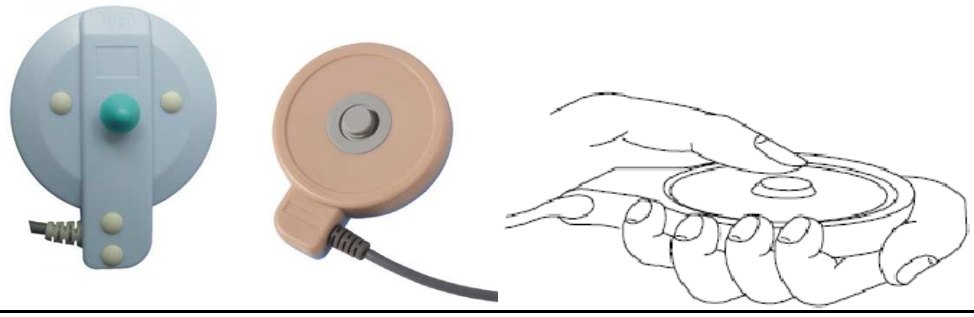


Figure 8 fast tests Toco transducer

5.9 Test of Event Maker

The fetal Movement Marker is a hand-hold device used by the pregnant woman to detect fetal movement from the mother's feeling.

Press and then slacken the marker, you will hear a "di" sound, and a marker " ↑ " posts himself on the screen.

If the apparatus passes the above fast test, which means that the apparatus functions well and can be activated.

Figure 9 fast tests Event Marker

5.10 Installation and Implementation of the Wall-mount Support

For the convenience of different installation requirement of the monitor, the users can choose the optional support as shown in figure 10.

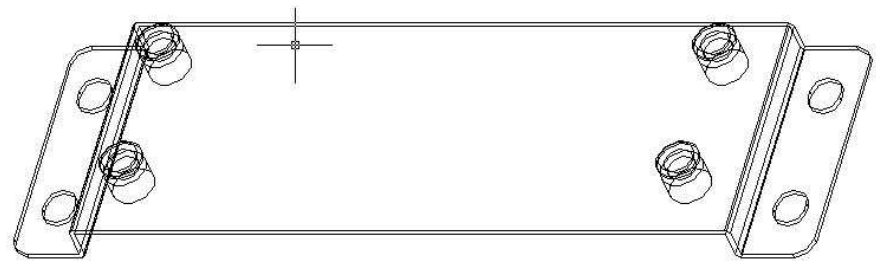


Figure 10 mural Support

Use the supplied expansion bolt to fix the wall-mounted support (wall-hung panel) on wall horizontally at general human height or higher, on the condition that there is no barrier

blocking the view of LCD data display. The wall-mounted support should be installed parallel to the ground.

Once the wall-mounted support is fixed, knock off the four wall-mounted holes on the base of monitor with screwdriver and point them to the protuberant post on the support, and then press the support and draw it downwards to lock it with the monitor. You can keep your hands off once the device is hung steadily. To take off the monitor, just do it in the opposite way.

	Ensure that the panel is solid and the apparatus is fixed on the panel, if not , the apparatus is likely to fall and injure people or cause damage with the apparatus
	The installation of the wall mount panel must be made by our qualified personnel.

6 Operation

6.1 Main Interface of the Fetal Maternal Monitor

Below shows the screen of the fetal maternal monitor

Figure 11 Main Interface (Single fetus monitoring)

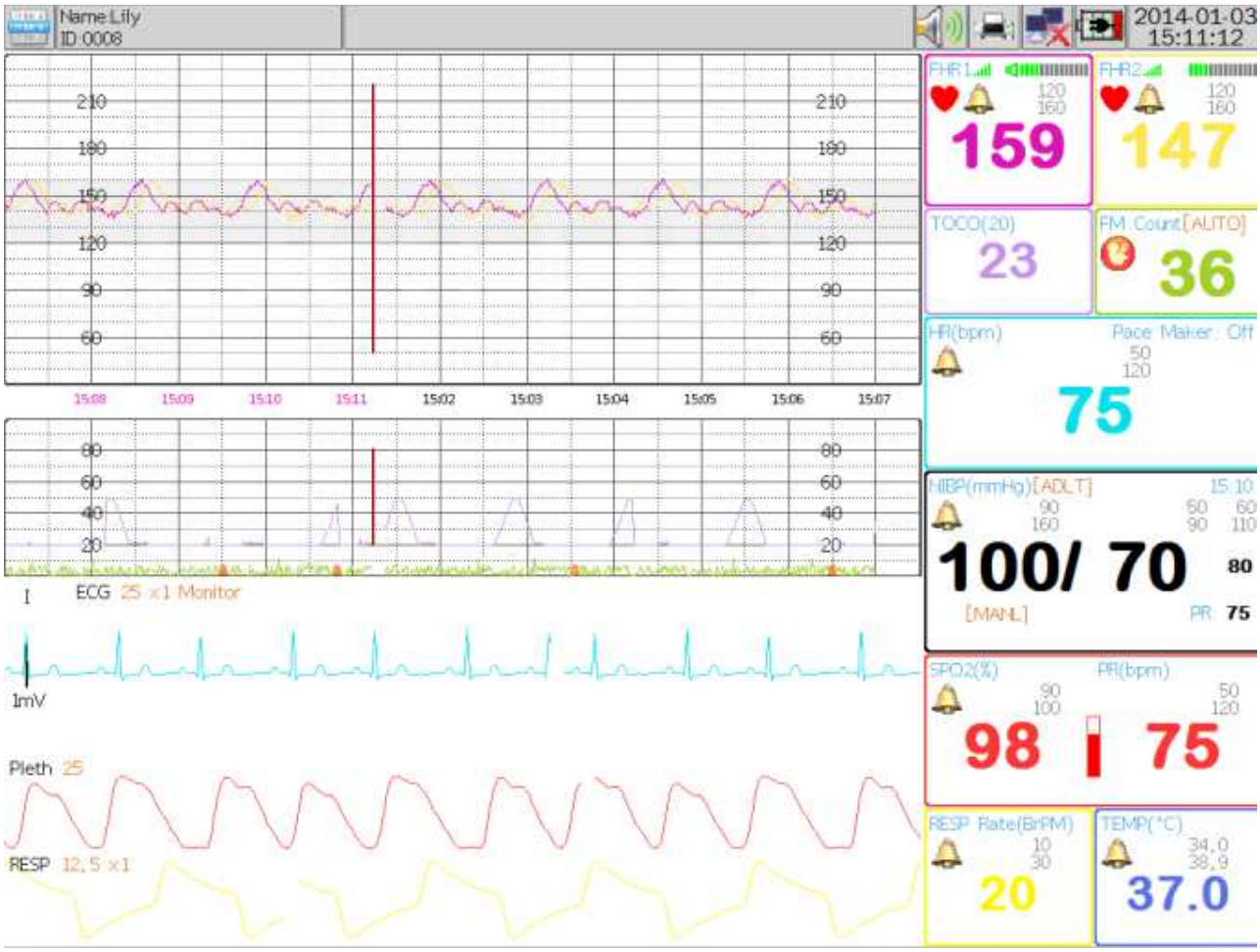


Figure 12 Main Interface (Twins fetus monitoring)

The screen of the Fetal maternal monitor is divided into four fields:

- Message/Main menu area
- Waveform area
- Parameter/alarm area
- Status/Time zone area.

6.1.1 Message/Main menu Area

Zone of Message/main menu area is on the left top of the screen, which posts the current status of the monitor and the patient. Messages from left to right are “ID”, “Name”,

1) ID (refer to patient bed No.)

2) Name of the patient (If operator has not entered any patient name, it shows “Not setted Tester” here);

3) Main menu (we can enter into main menu by pressing control knob or if it is equipped with touch, you can touch the icon.)

Notice: all the setting relating to the parameter should enter into the main menu and concerned submenus.

6.1.2 Waveform Area

The waveforms displayed in the area are for the fetal heart rate (FHR), the pressure of the uterine contractions (TOCO) and the movements of the fetus (FM), maternal ECG, SpO_2 and RESP.

Up to 6 waveforms can be displayed at the same time. The waveforms from top to bottom are: FHR1 (FHR2), TOCO, ECG, SpO_2, and RESP. For each waveform, the name of waveform displays on the top left. Especially for ECG, 5 leads names are supported, there are “I”, “II”, “III”, “AvR”, “AvL”, “AvF”, “V” for choosing

6.1.3 Parameter /Alarm Area

The zone of parameters is on the right part of the screen for the fundamental parameters of the vital signs of the patient such as the fetal heartbeat rate, the pressure of the uterine contractions, etc. The specific parameters posted in this area are as follows:

1) Fetal heartbeat rate 1 (FHR1): digital number showing fetal heartbeat rate of the single fetus (Unit: bpm/min)

2) Fetal heartbeat rate 2 (FHR2): digital number showing fetal heartbeat rate of the second (twins) fetus (Unit: bpm/min)

FHR: The fetal heart rate is displayed in (bpm) beats per minute. In the absence of a signal (or with a signal of poor quality) the display reads ’000’. The heart rate value shows the most recent calculated fetal heart rate. The volume icon provides an indication of the speaker volume setting for the fetal echo sounds. The icon changes when the speaker volume setting is adjusted. The alarm icon is a bell. A diagonal line through the bell indicates alarms are disabled. A bell missing a diagonal line indicates alarms are enabling.

3) Pressure of the contraction of uterus (Toco): Relative strength of uterine activity. 0~100 is displayed. This frame contains the numeric value from the TOCO transducer representing uterine activity.

4) Figures of fetal movements: recording of fetal activity (Unit: time)

5) ECG: Heart Rate (unit: bpm)

6) SpO_2: (unit: %); Pulse Rate (unit: bpm)

7) NIBP: (From left to right) Systolic, Diastolic, Mean (Unit: mmHg or kPa)

If automatic measurement is set, the next measurement time will be displayed or

If manual measurement is set, the latest measurement time are displayed (unit sec)

8) RESP/TEMP: Respiration Rate (unit: Bpm); Temperature (unit: ℃ or ℉)

9) Message of the alarms will showed in the area of corresponding parameter

The monitored parameter value, individual parameter alarm message and lead status messages display in the parameter area. The parameters refresh every second.

6.1.4 Status /Time zone Area

Status/time zone of the system is located at the right top of the screen to display the status of alarm sound, printer, network, and battery/AC input and system time.

1) The status of the alarm sound: It indicates the sound status of monitor's speaker (mute or volume on).

2) The status of the printer: It indicates the working status of the printer.

3) The status of the network: it indicates the networking status of the apparatus (connect or disconnected).

4) The status of the battery and AC input: it indicates the current status of the electric provisioning of the apparatus (AC power supply or battery capacity).

5) System time: it indicates the current time of system, you can set it according to the user configuration.

	The system cannot send out the alarm sound when the alarm information area displays alarm silencing, therefore, the operator shall use this function in caution.

6.1.5 Network

The network of the screen is in accordance with standard RJ45, one can carry out the communication via Internet by using an Ethernet cable to connect the nurse station of remote monitoring with the apparatus. The icon of network in the corner bottom right of the screen posts the status of the current network.

	Communication between the monitor and the nurse station is normal
	Cable network is disconnected between the monitor and the nurse station

6.1.6 Integrated Battery and AC input

The monitor is equipped with a rechargeable integrated battery. The symbol posts in the corner top right of the screen indicates the state of the battery. When the battery is recharging, the recharging status will be displayed in flash.

	Battery completely charged
	Battery partially charged one yellow box means the battery will be used out and one red box means the battery will be used out immediately and the monitor will be turned off automatically.
	When the monitor connects AC power, the recharging status will be displayed like this.

6.2 Main menu

Press the encoder to enter into menu setting as follows. (If armed with touch screen, please click the icon:  then it will pop up the main menu.)

Notice: If the monitor armed with touch screen, you can use finger or touch pen to click it, it has the same functions which we introduce in this manual.

INFO: Enter into patient information management system. And it is the same with "INFO "button.

Silence: The same function with "Silence" button. It will turn off the alarming sound when you choose it.

Print: The same function with "Print" button. Press it to start printing, press it again to stop printing.

FM Zero: Set the Fetal movement's counter to zero. When new patient register, the FM counter should return back to zero.

TOCO Zero: Zero the TOCO baseline. It is the same function of "ZERO" button.

Freeze: When it is selected, the screen will be frozen. It is the same function to the "FREEZE" function.

Configuration: Use it to set the system parameters.

Record: Check the historic records. All the patient records can be found through it.

Switch: Switch between standard interface and big font interface and other interfaces.

NST timer: set NST timer's time. After setting, it will begin to count down.

NIBP: start or stop NIBP operation. It has the same function with button NIBP on the control panel.

Doctor Mark: Mark the related events.

6.3 Information

Press Info Key in the main menu to enter into the information menu.

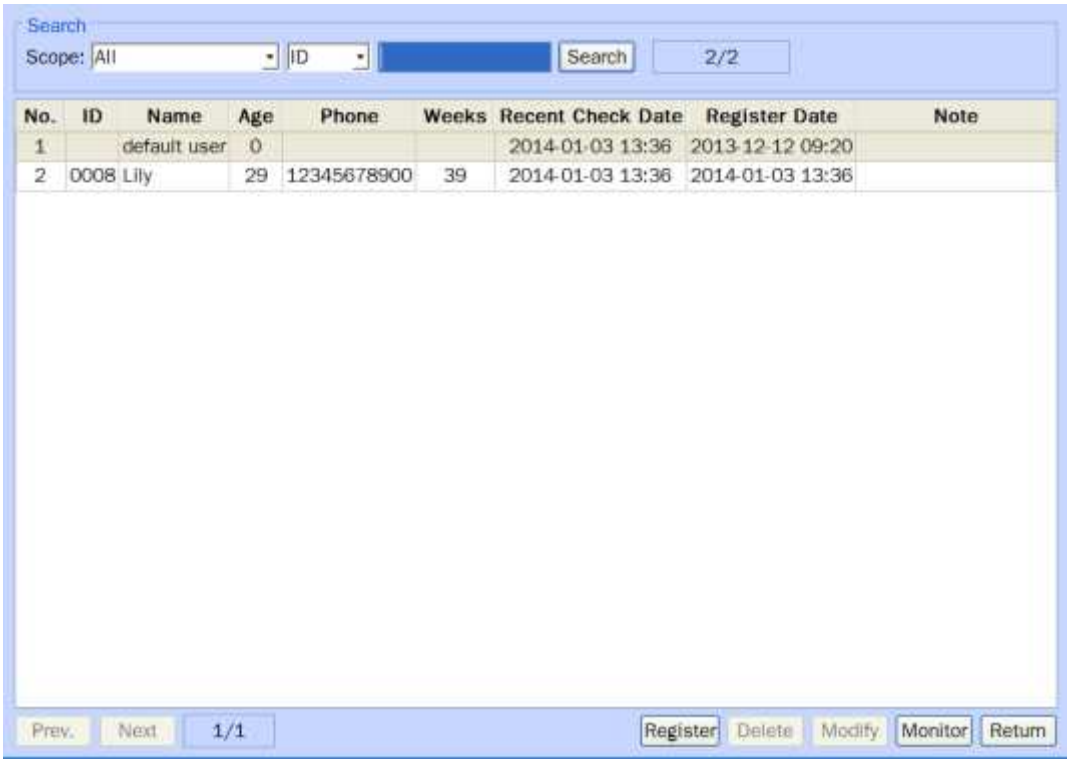
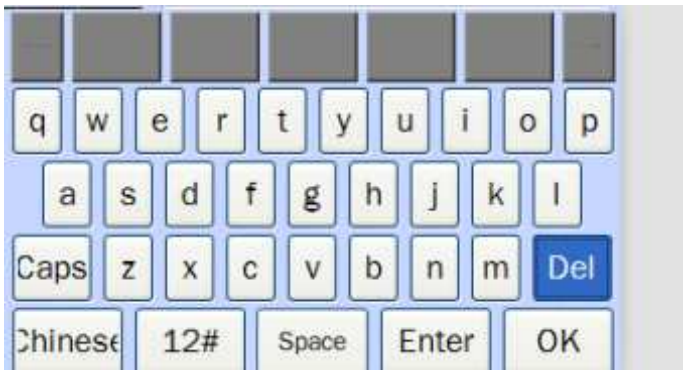


Figure 13 patient information

Search

Scope: All, Last month, Last three month, Last six month, Last year.

Then choose searching keyword via ID, Phone or Name and fill in the information. When the cursor moves to the blank, the background turn into blue, when you click it , the keyboard will pop up as follows.

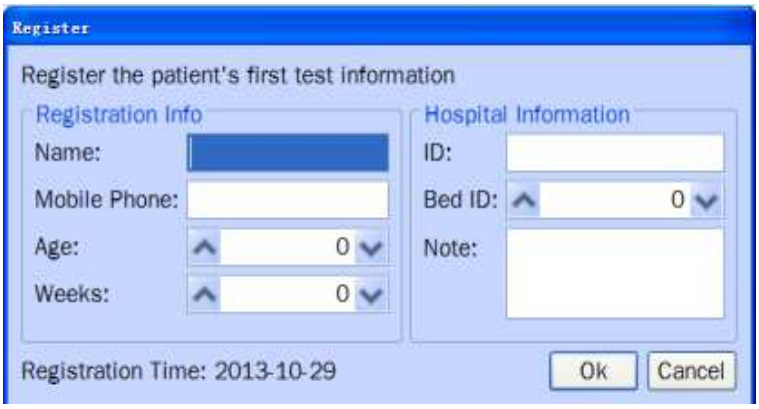


You can input English, Chinese, Numbers and most of punctuations by shifting the input methods. Then you can click the “search” button to find the patient information which you want to acquire.

If there are more than one pages, you can use “Prev.” or “Next” to turn over the pages.

Notice: The keyboard which appears in this manual has same functions; we will not introduce it again.

Register



Register the patient's first test information

You can input the patient information: Name, Mobile Phone, Age, Weeks, and Hospital information, like ID, Bed ID and Note.

When selected one registered case, you can choose "delete" or "Modify" to delete or modify it.

When you click the "Monitor" in the information management menu, it enters into monitoring interface.

When you choose "Return", the screen will return to the last interface.

6.4 Freeze

When we choose the freezing function, the waveform will be frozen, if you want to unfreeze it, please press FREEZE button or freeze icon again, then the waveforms will begin to scan again. Please see the following freezing figure.

Figure 13 Freeze

6.5 Configuration

This menu will show all parameter settings and other information about the monitor.

6.5.1 Fetal Monitor Parameter

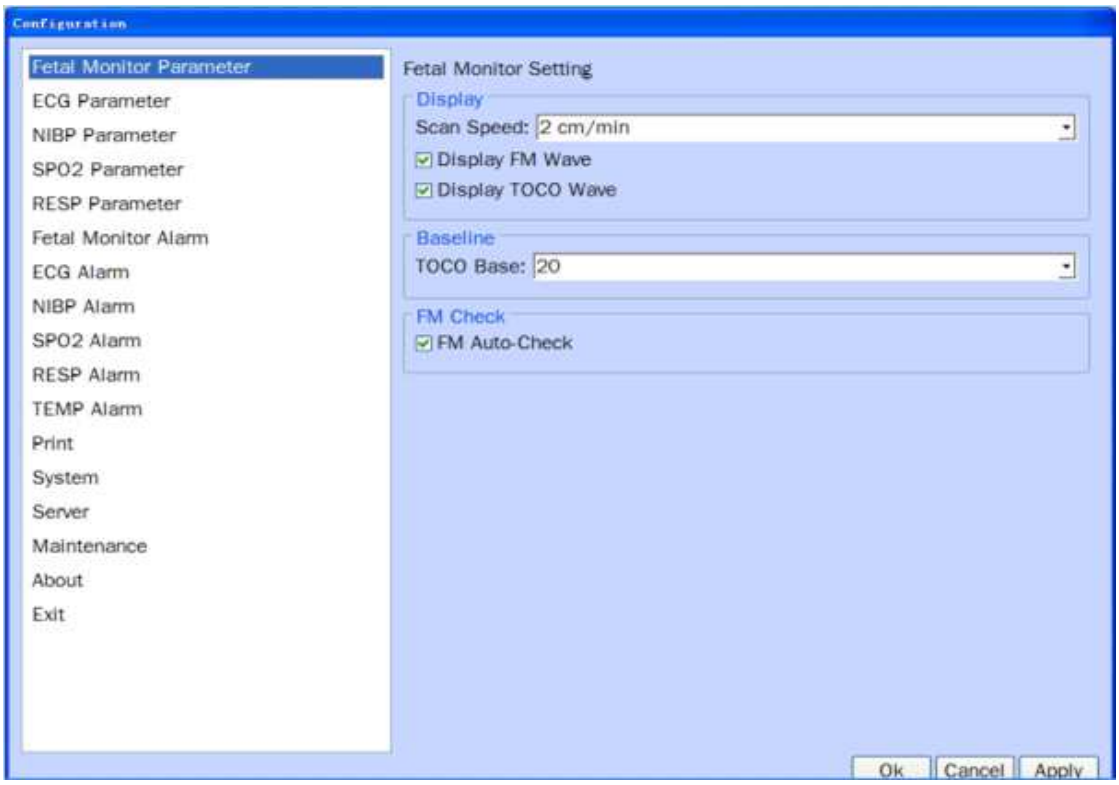


Figure 14 fetal monitor setting

Fetal Monitor Setting

Display

Scan Speed: 1, 2, 3 cm/min

Display FM wave: when ticked, it will display on the screen.

Display Toco wave: when ticked, it will display on the screen.

Baseline

Toco base: 0, 5, 10, 15, 20.

FM check

FM auto check: when ticked, it will check fetal movement automatically.

6.5.2 ECG Parameter

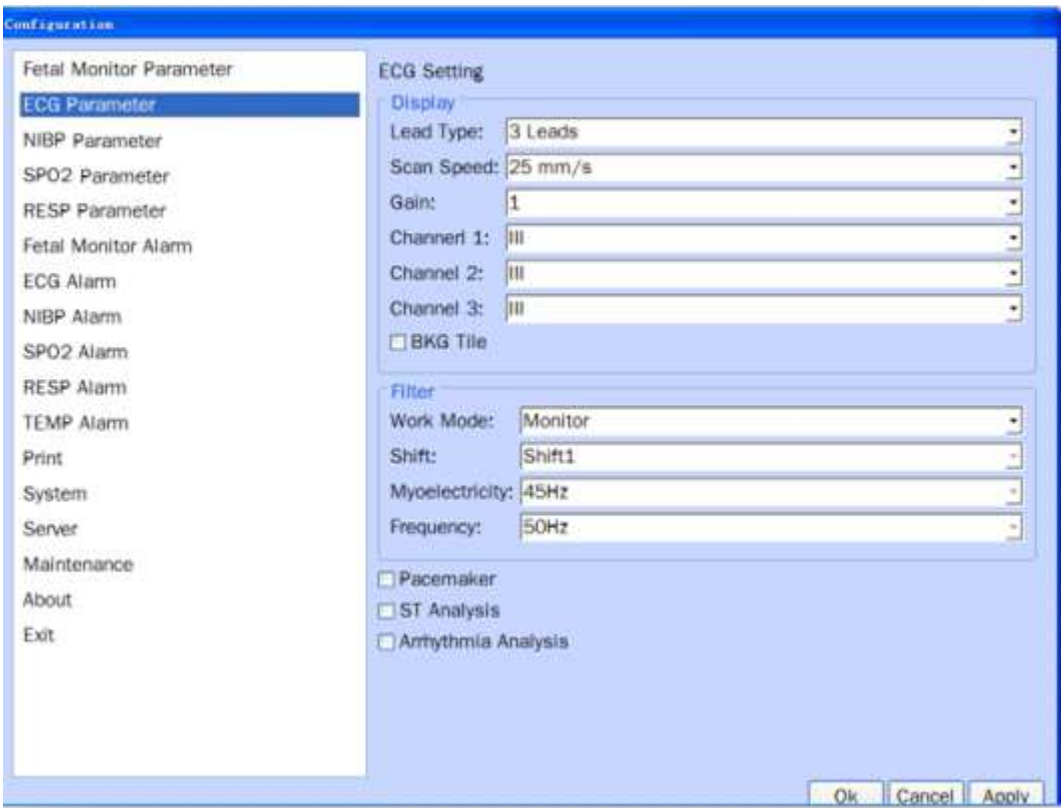


Figure 15 ECG setting

ECG Setting

Display

Lead Type: 3leads, 5 leads.

Scan Speed: 6.25mm/s, 12.5mm/s, 25mm/s.

Gain: 0.25, 0.5, 1, 2.

Channel 1: I, Ⅱ, Ⅲ, AvR, AvL, AvF, V.

Channel 2: I, Ⅱ, Ⅲ, AvR, AvL, AvF, V.

Channel 3: I, Ⅱ, Ⅲ, AvR, AvL, AvF, V.

BKG Tile: When ticked, the ECG waveform area will show background tile.

Filter

Work Mode: Surgery, Monitor, and Diagnosis User.

Shift: shift1, shift2, off.

Myoeletricity: select myoeletric filtration and options are off, 25Hz, 45Hz.

Frequency: off, 50Hz

Pacemaker: When ticked, it will conduct pace-making analysis on patient with pacemaker.

ST analysis: when ticked, it will conduct ST-segment analysis.

Arrhythmia Analysis: When ticked, it will conduct arrhythmia analysis.

6.5.3 NIBP Parameter

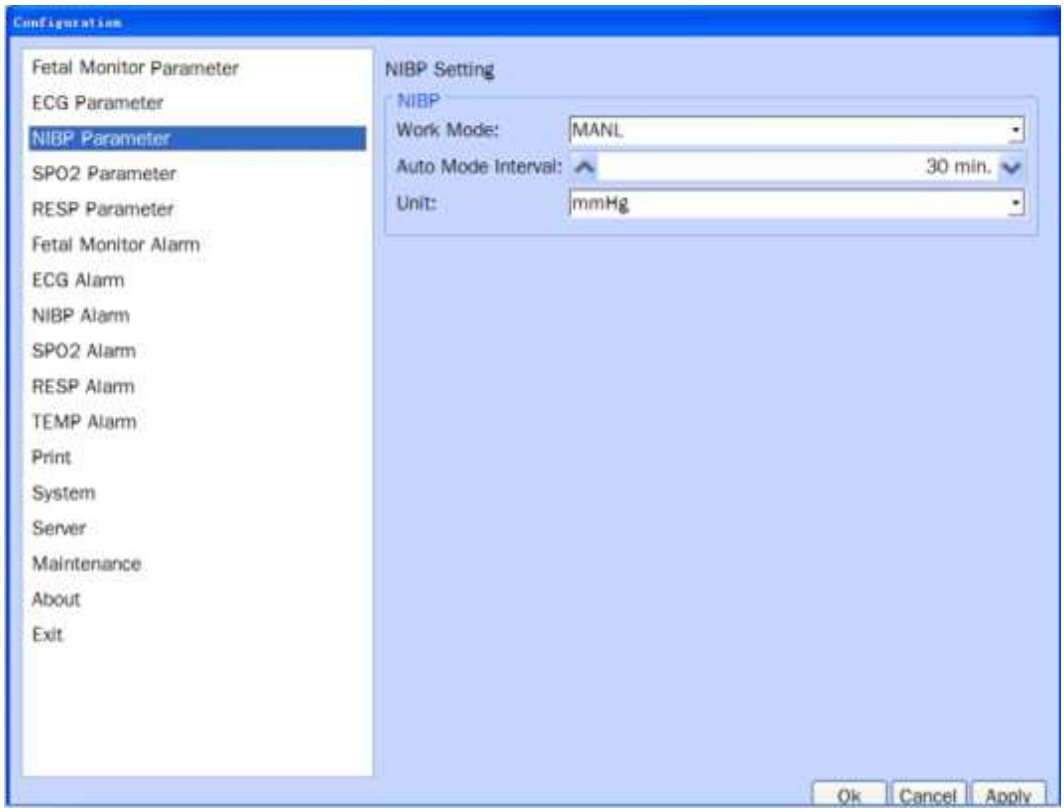


Figure 16 NIBP Setting

NIBP Parameter

NIBP

Work Mode: MANL, Auto, STAT.

Auto mode interval: 1-99 minutes.

Unit: mmHg, KPa.

6.5.4 SpO2 Parameter

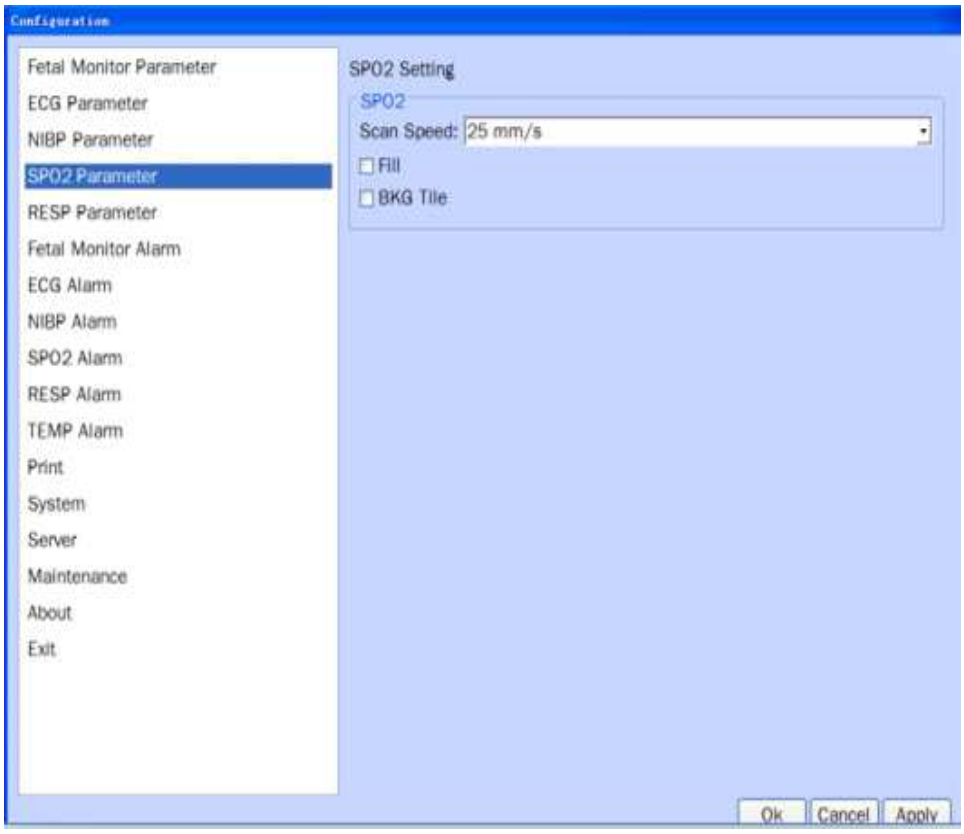


Figure 17 SpO2 setting

SpO2 Setting

SpO2

Scan Speed: 12.5mm/s, 25mm/s, 50mm/s.

Fill: when ticked, the waveform will display in a form of filling mode.

BKG tile: when ticked, the SpO2 waveform area will show background tile.

6.5.5 RESP Parameter

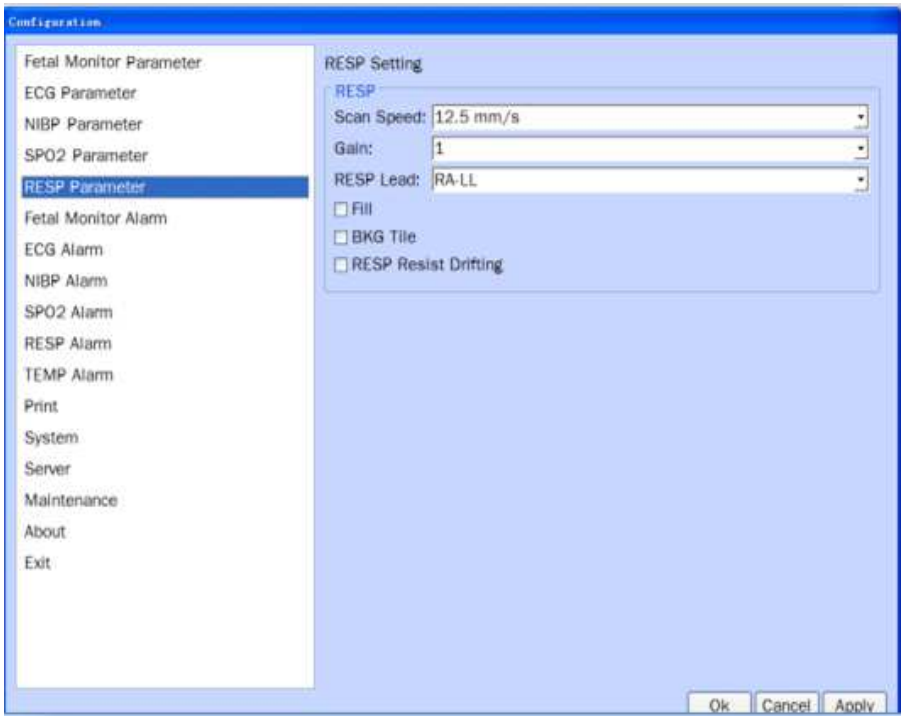


Figure 18 RESP Setting

RESP Setting

RESP

Scan Speed: 6.25mm/s, 12.5mm/s, 25mm/s.

Gain: 0.25, 0.5, 1, 2.

RESP Lead: RA-LL, RA-LA.

Fill: when ticked, the waveform will display in a form of filling mode.

BKG: when ticked, the RESP waveform area will show background tile.

RESP Resist Drifting: when ticked, it will enable to resist drift.

6.6 Alarm Setting

6.6.1 Setting Alarm Limit

We can set each parameter's alarm limit according to enter into the relating parameter's alarm setting.

	Please carry out sufficient alarm settings for each patient to avoid treatment delay. At the same time, you should ensure the alarm can send out alarm sounds
	Set alarm limits according to the clinical situations of each patient.
	The setup of alarm limit is important and the alarm limits shall be carefully selected according to the recognized clinical practice.

6.6.2 Description of Alarm

Fetal monitor has two types of alarm: patient alarm and technical alarm.

Patient alarms indicate the situation of vital sign exceeding its configured limit. They can be disabled. The adjustable alarm limits determine the conditions that trigger the alarm.

Technical alarms indicate that the monitor cannot measure and therefore not detect critical patient conditions reliably. When a patient alarm is switched off, the technical alarms relative to it will be disabled as well.

6.6.3 Level of Alarm

Three alarm levels are available: High, medium and low

The monitor has preset the alarm level for technical alarm and patient alarm.

6.6.4 Mode of Alarm

The monitor sends an alarm in three modes, respectively, acoustic alarm, emergency lighting and textual description.

	The mode of alarms is related to the level of alarm. When the measuring parameters exceed the patient alarm limit, the apparatus will show in three alarms mentioned above.

Zone of showing technical alarm and patient alarm: the flashing background with texts indicates the alarm. For example, the background with texts of “Heart rate too high” indicates medium alarm.

Level of alarm	Alarm visual	Audible alarm
High	Indicator flash flickering quickly	3 aural signals every 8 seconds
Medium	Indicator flash flickering slowly	3 aural signals every 20 seconds
Low	Indicator lights constantly	An aural signal every 20 seconds

The nurse station will send audio alarm at the same time; the screen of apparatus and the nurse station are posted the same contents of alarm.

6.6.5 Silence of Alarms

Press on the key “Silence” on the control panel to cut the sound of alarm and the light ; Press again to exit silent status and reactivate related alarm sound and back to normal alarm status.

If alarm appeared still exists after machine turning into “Silence” status, information of alarm would be shown in the field of the information of alarm.

	When the system is in “Silence” status, any new alarm can eliminate the “Silent” status and automatically changes system back to normal acoustic and visual alarm status.
	When the system is in “Alarm silence” status, which can be seen in alarm information area, the system will not give out any acoustic alarm, therefore the operator should use this function with prudence.
	When various levels of alarm exist, the alarm sound is in the highest level.

6.6.6 Fetal Monitor Alarm

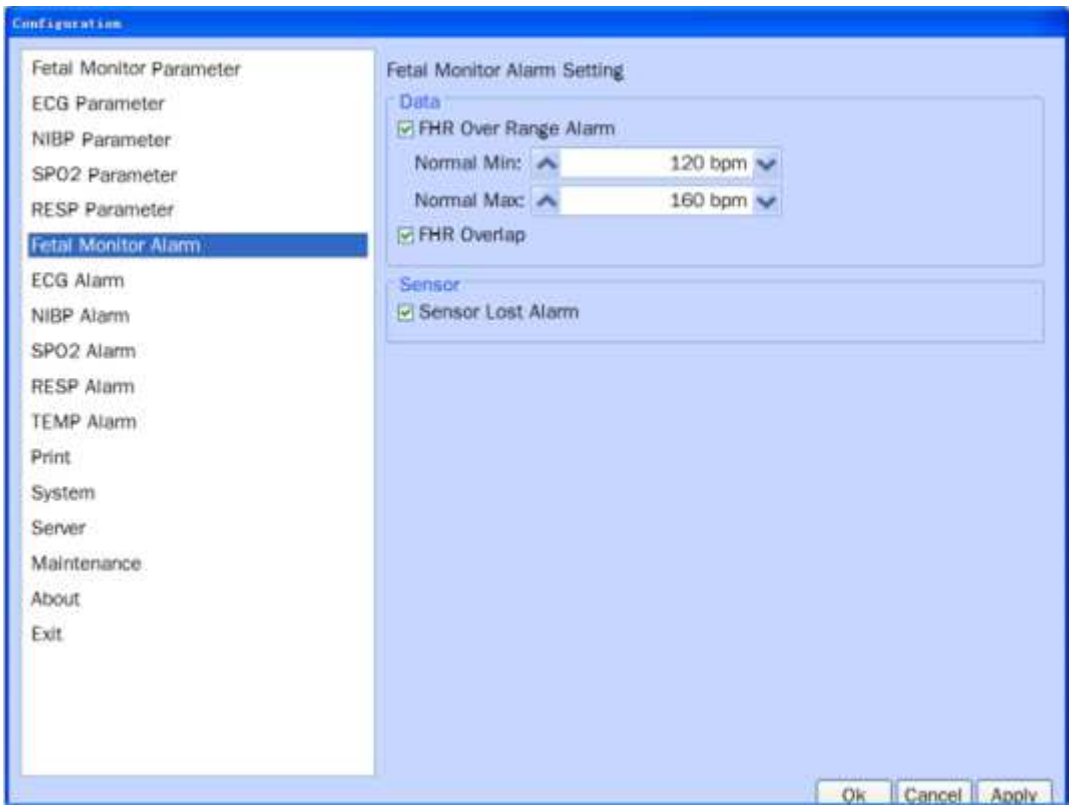


Figure 19 fetal monitor alarm setting

Fetal Monitor Alarm Setting

Data

FHR Over Range Alarm: When ticked, if the FHR value exceeds the range, it will give the relating alarms.

Normal Min: 30-239 bpm.

Normal Max: 31-240 bpm

FHR Overlap: When the monitor is for twins, you should tick it, when the twins have the same FHR value, it will give alarms.

Sensor

Sensor Lost Alarm: when ticked, if the monitor doesn't connect ultrasonic sensor or TOCO sensor and FM probe, it will give alarms.

6.6.7 ECG Alarm

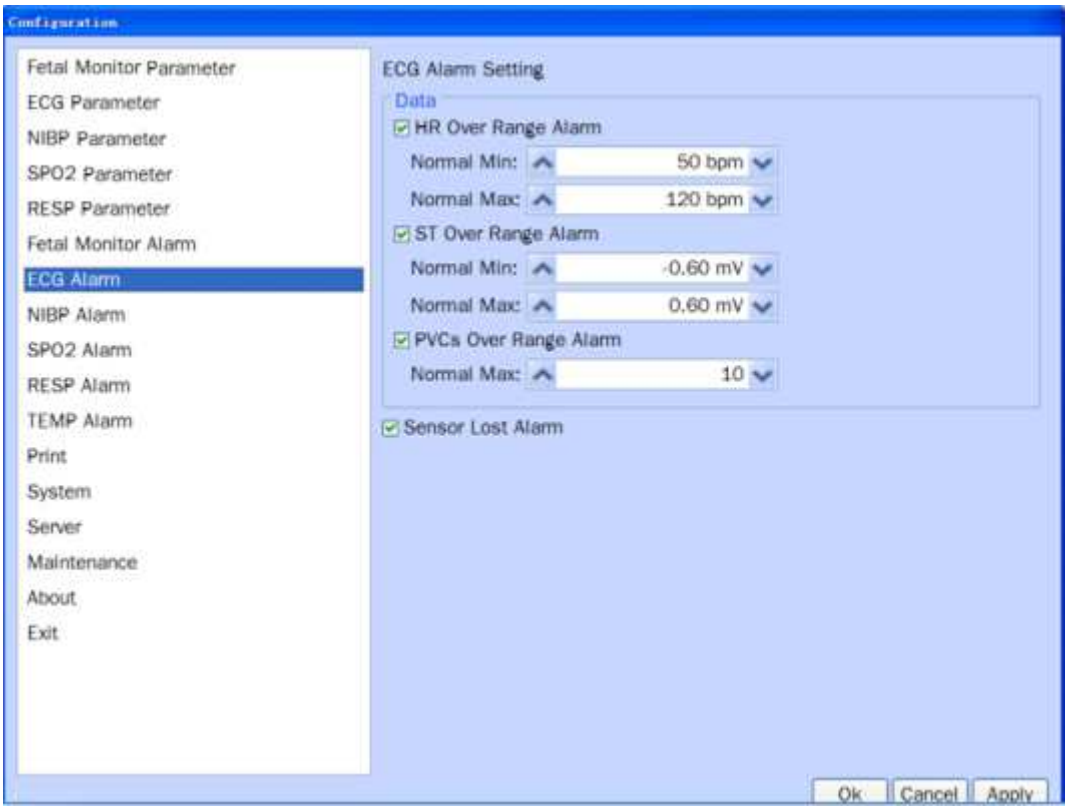


Figure 20 ECG Alarm setting

ECG Alarm Setting

Data

HR Over Range Alarm: when ticked, if the HR value exceeds the defined range, it will give the relating alarms.

Normal Min: 10-299 bpm,

Normal Max: 11-349 bpm

ST Over Range Alarm: when ticked, if the ST value exceeds the defined range, it will give the relating alarms.

Normal Min: -2 to 1.99 mV

Normal Max: -1.99 to 2 mV

PVCs Over Range Alarm: when ticked, if the PVCs value exceeds the defined range, it will give the relating alarms.

Normal Max: 0-99.

Sensor Lost Alarm: when ticked, if the monitor doesn't connect ECG leads, it will give alarms.

6.6.8 NIBP Alarm

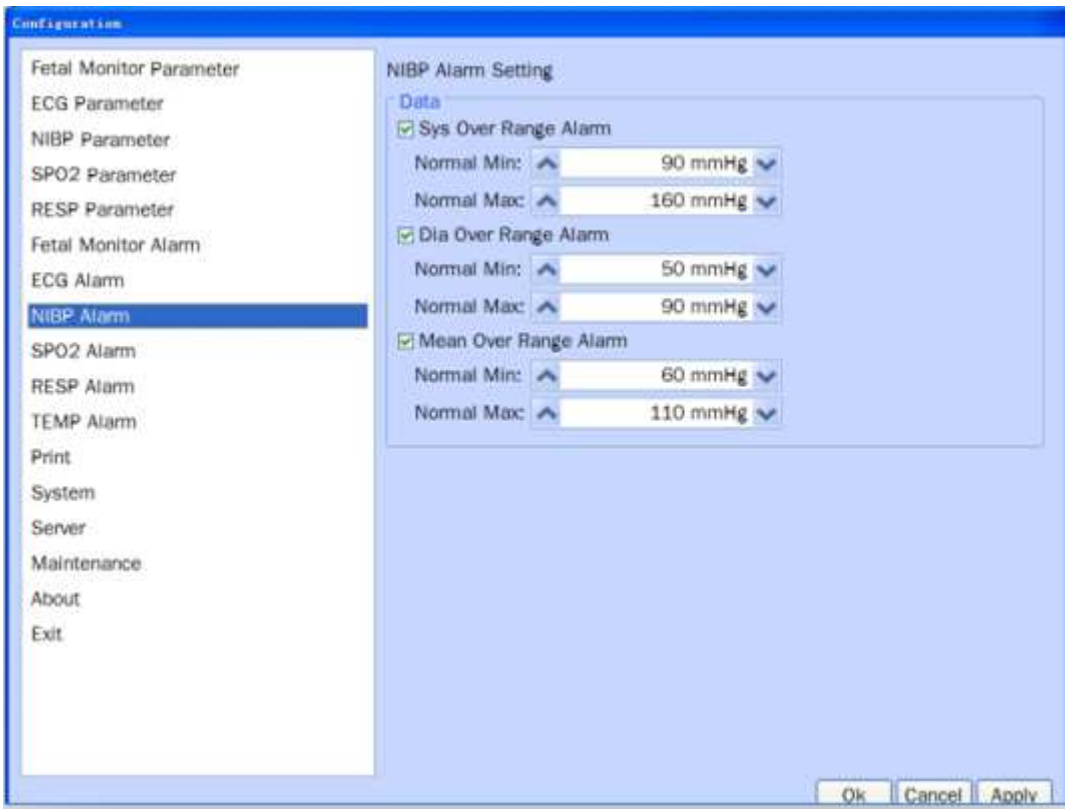


Figure 21 NIBP setting

NIBP Alarm Setting

Data

Sys Over Range Alarm: when ticked, if the systolic pressure exceeds the defined range,it will give alarms.

Normal Min: if the patient is adult, it can set: 40～269 mmHg

if the patient is child, it can set: 40～199 mmHg

if the patient is Neonate, it can set: 40～134 mmHg

Normal Max: if the patient is adult, it can set: 41～270 mmHg

if the patient is child, it can set: 41～200 mmHg

if the patient is Neonate, it can set: 41～135 mmHg

Dia Over Range Alarm: when ticked, if the diatolic pressure exceeds the defined range,it will give alarms.

Normal Min: if the patient is adult, it can set: 10～209 mmHg

if the patient is child, it can set: 10～149 mmHg

if the patient is Neonate, it can set: 10～94 mmHg

Normal Max: if the patient is adult, it can set: 11～210 mmHg

if the patient is child, it can set: 11～150 mmHg

if the patient is Neonate, it can set: 11～95 mmHg

Mean Over Range Alarm: when ticked, if the systolic pressure exceeds the defined range,it will give alarms.

Normal Min: if the patient is adult, it can set: 20～229 mmHg

if the patient is child, it can set: 20～164 mmHg

if the patient is Neonate, it can set: 20～104 mmHg

Normal Max: if the patient is adult, it can set: 21～230 mmHg

if the patient is child, it can set: 21～165 mmHg

if the patient is Neonate, it can set: 21～105 mmHg

6.6.9 SpO2 Alarm

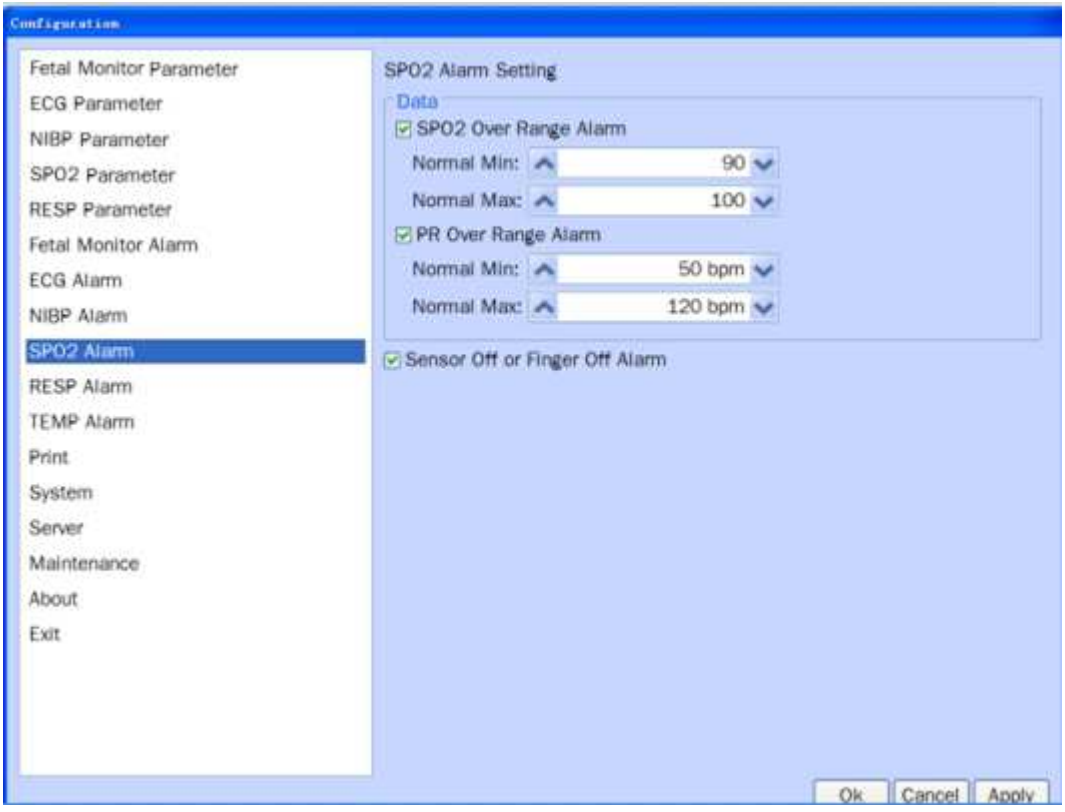


Figure 22 SpO2 setting

SpO2 Alarm Setting

Data

SpO2 Over Range Alarm: when ticked, if the SpO2 value exceeds the defined range,it will give alarms.

Normal Min: 0-99

Normal Max: 1-100

PR Over Range Alarm: when ticked, if the PR value exceeds the defined range,it will give alarms.

Normal Min: 25- 249 bpm

Normal Max: 26-250 bpm

Sensor Off or Finger Off Alarm: when ticked, it will give alarms if the sensor is off or the finger is off.

6.6.10 RESP Alarm

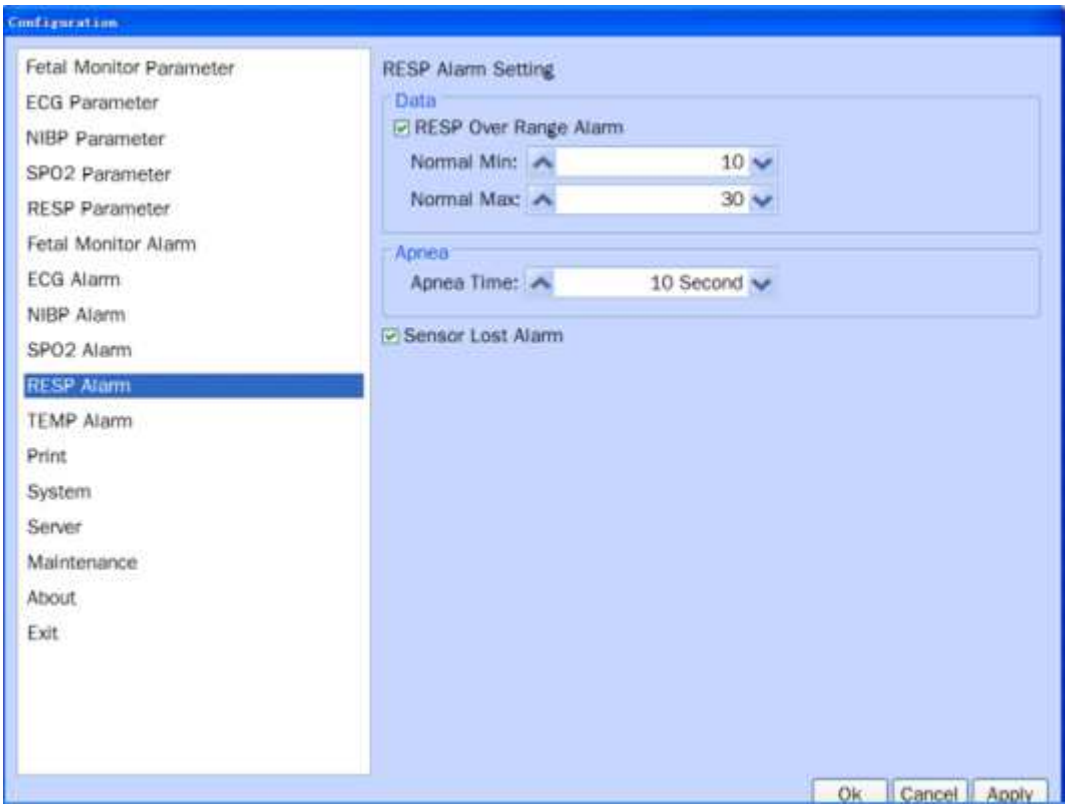


Figure 23 RESP alarm setting

RESP Alarm setting

Data

RESP Over Range Alarm: When ticked, if the respiration value exceeds the defined range, it will give alarms.

Normal Min: 8-29

Normal Max: 9-30

Apnea

Apnea Time: 1-60 seconds

Sensor Lost Alarm: When ticked, if the sensor is off, it will give alarms.

6.6.11 TEMP Alarm

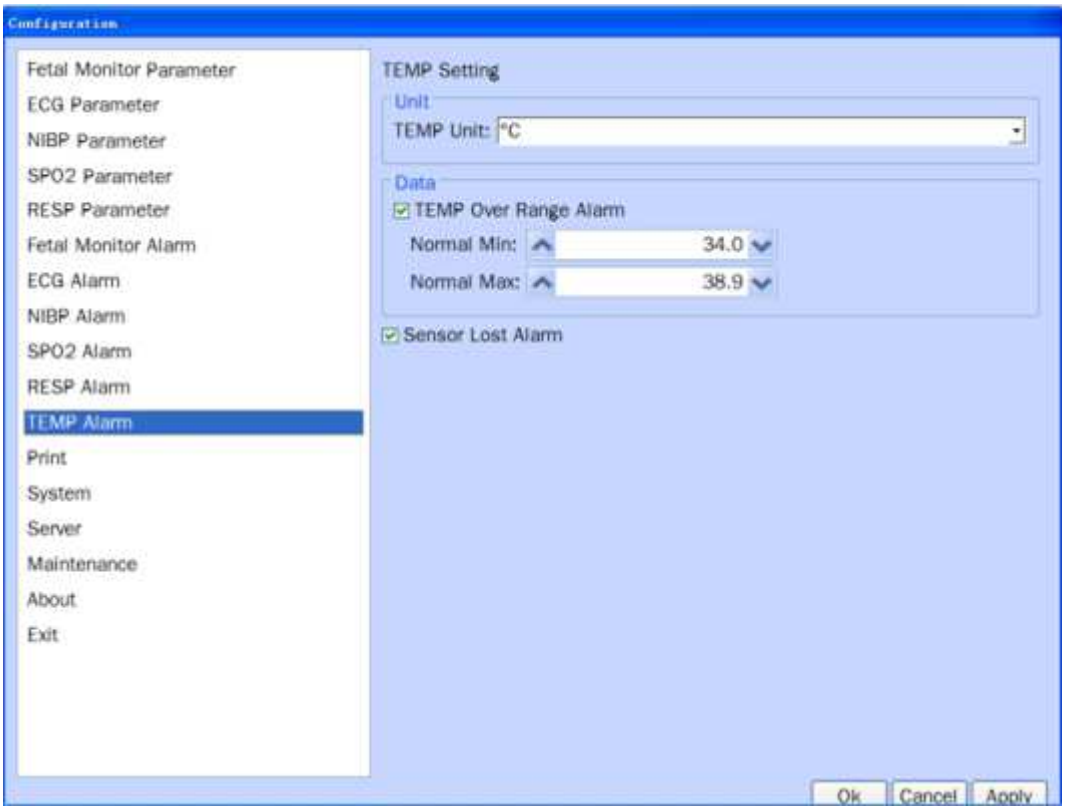


Figure 24 TEMP setting

TEMP Setting

Unit

TEMP unit: ℃, ℉

Data

TEMP Over Range Alarm: when ticked，if the temperature exceeds the defined value, it will give alarms.

Normal Min: 0—38.8℃（32—101.9℉）

Normal Max: 34.1—50.0℃（93.3—122℉）

Sensor Lost Alarm: when ticked, if the sensor is off, it will give alarms.

6.7 Print

All printing parameters can set according to this menu, if you want to print other report except fetal monitor report, you should check it before printing.

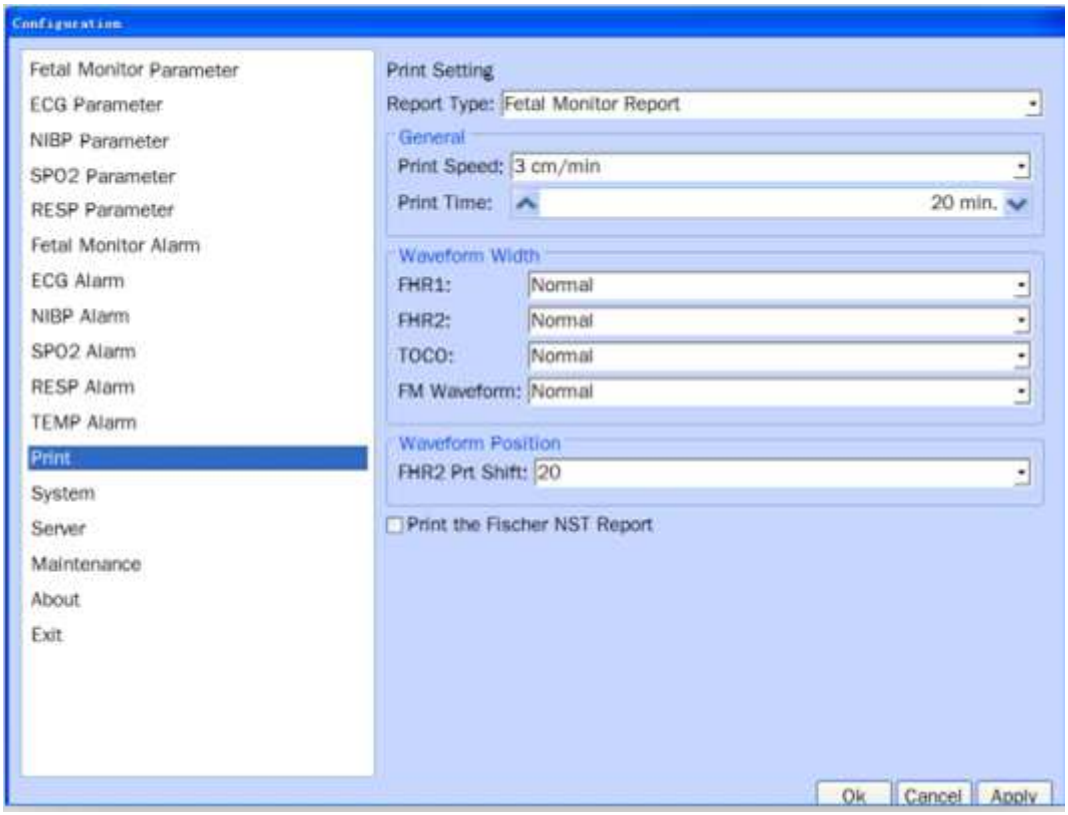


Figure 25 Print

Print Setting

Report Type: Fetal Monitor report, vital signs report

General

Print Speed: 1, 2, 3cm/min

Print time: 1-99 minutes

Waveform width:

FHR1: Normal, Bold

FHR2: Normal, Bold

TOCO: Normal, Bold

FM wavform: Normal, Bold

Waveform Position:

FHR2 Prt Shift: -30, -20, -10, 0, 10, 20, 30

Print the Fischer NST Report: if your monitor armed with the NST module, you can tick it, then it will print the report.

6.7.1NST Report Fuction(Optional)

The fetal monitors can be equipped with NST (Non Stress Test) Report function (option) based on advanced Fischer evaluation method to give a score of fetal wellbeing after 20 minutes continuous monitoring, thus helping the doctors make judgment about fetal health condition.

Base line, LTV Amplitude, Period, Acceleration, and Deceleration are 5 indexes of analyzing FHR wave. Fischer is an evaluation method to give corresponding scores for different condition of the 5 indexes after 20 minutes continuous monitoring.

ITEMS	**0**	**1**	**2**
Base Line	<100, >180	100-120 160-180	120-160
LTV Amplitude	<5	5-10 or 30	10-30
Period	<2	2-6	>6
Acceleration	No	Periodic	Acyclic
Deceleration	LD, or Series VD	Mild VD	No

Using the total scores of the 5 indexes to judge the fetal health condition by following standard:

Judgment Standard of Fetal Wellbeing:

If the total score is between 8-10, it indicates excellent fetal wellbeing.

If the total score is between 5-7, it indica suspicious risk of fetal wellbeing. The doctors should take further check for confirmation.

If the total score is below 4, indicating Fetal Hypoxia, the doctors should take urgent measures.

The NST Report (Fetal Health Report) will be printed out as follows.

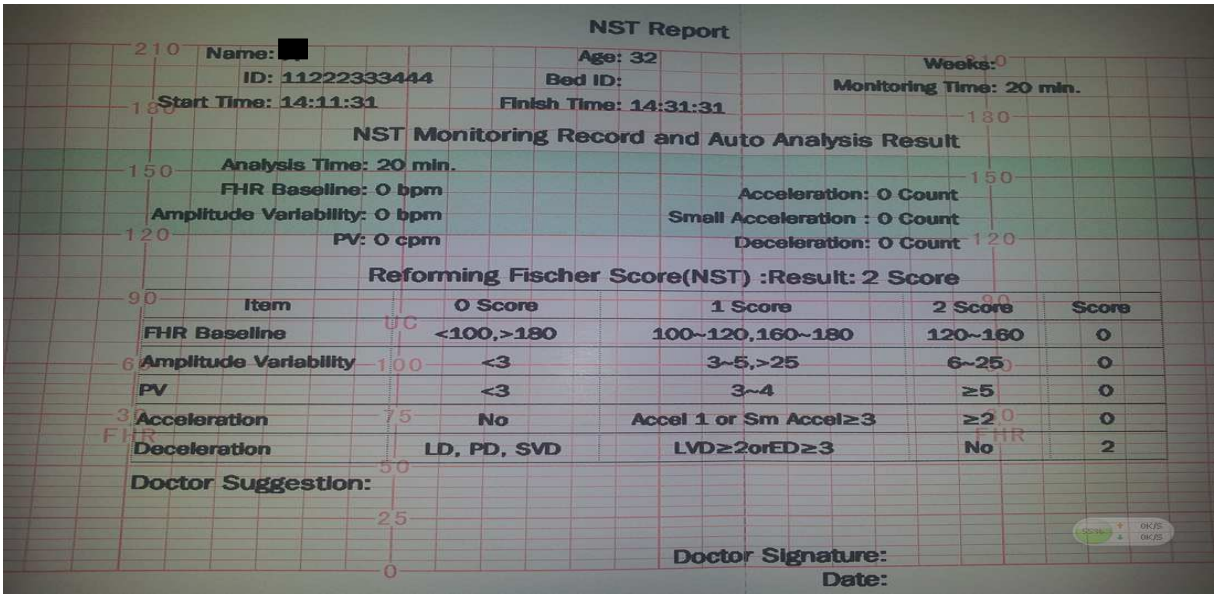


Figure 26 NST Report

6.8 System

This menu will show you how to set system parameter.

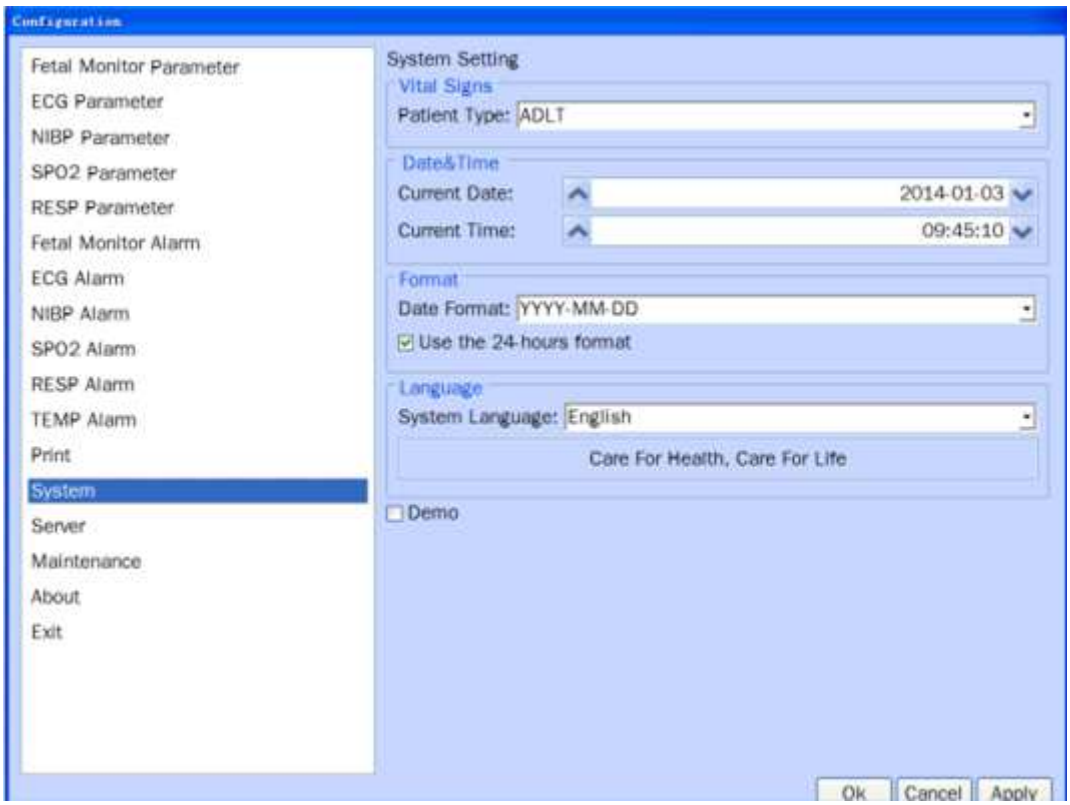


Figure 27 System setting

System Setting

Vital Signs

Patient type: ADLT, Pediatric and Neonate.

Date& Time

Current Date: Set the current date.

Current Time: Set the current time.

Format

Date Format: YYYY-MM-DD，MM/DD/YYYY，DD/MM/YYYY

Use the 24 hours format: when ticked, the system will use 24-hours format.

Language

System language: English, Chinese,French,Italian,Polish, Portuguese, Spanish, Russian, Turkish.

Demo: when ticked, the system will enter into the demo mode, and if it uses the demo mode, the monitor can not be used in clinical.

6.9 Sever

If you want to set a CMS (Central Monitoring System), then you should set this menu. The CMS is a set of integrated management software. It can save time and human labour.

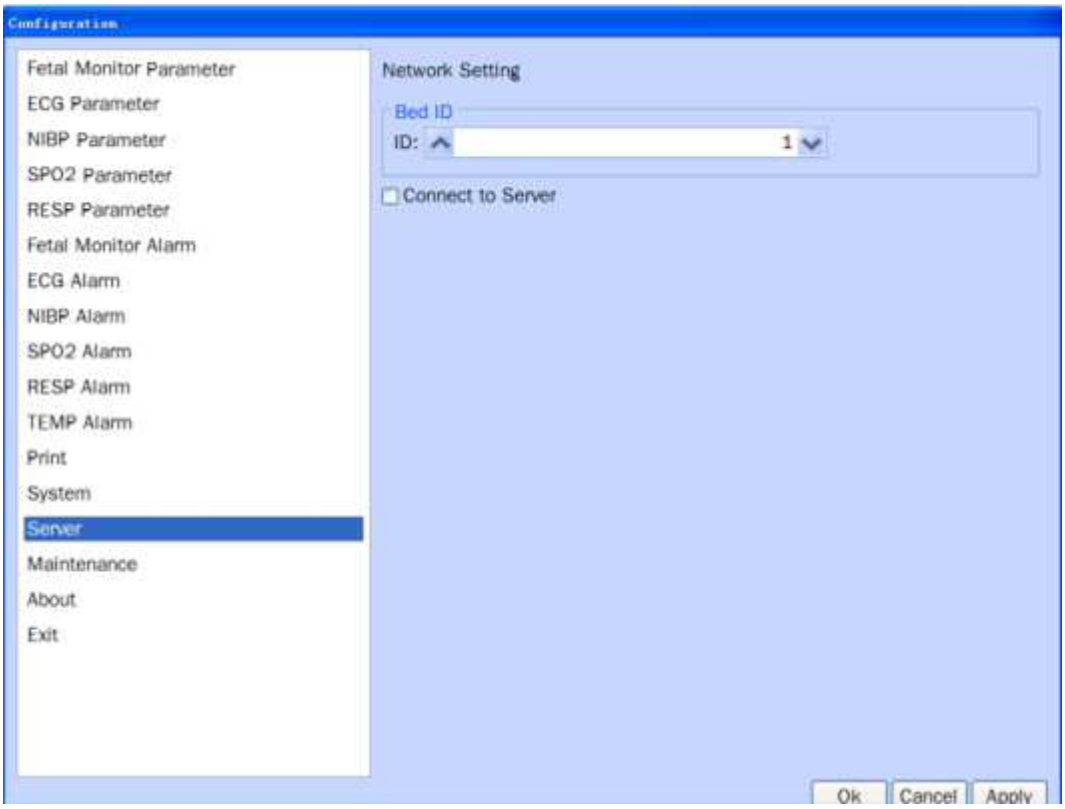


Figure 28 Sever

Network Setting

Bed ID

ID: 1-245, it should be different from each bed and also different from other network instruments.

Connect to Server: If the monitor connects to CMS, you should tick it.

6.10 maintenance

This item is merely open to the service engineer appointed by the factory. Usually, please do not change any settings without consent from the factory. You can set the printer and skin type and other general settings, also you can upgrade the software through it, if you want to change these settings, please contact company service department.

Notice: if you monitor armed with USB mouse, you can enter into maintenance menu to select whether display the cursor or not.

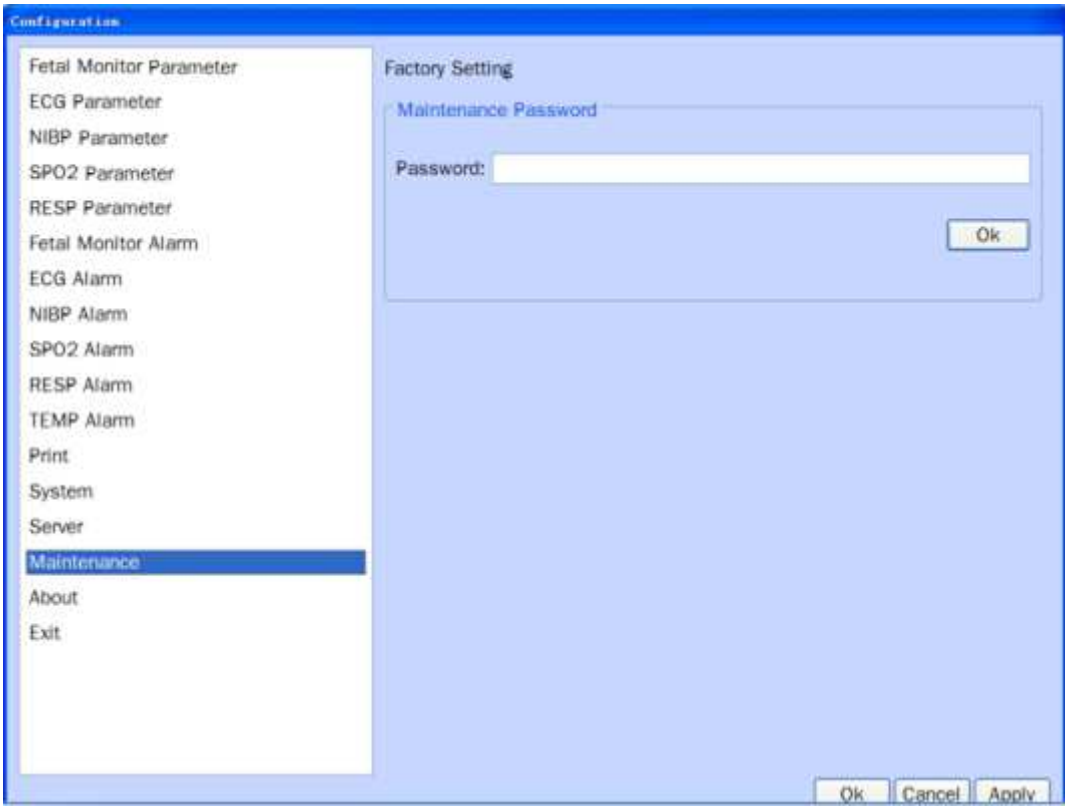


Figure 29 factory setting

6.11 About

This Item shows the monitor's all hardware and software configurations.

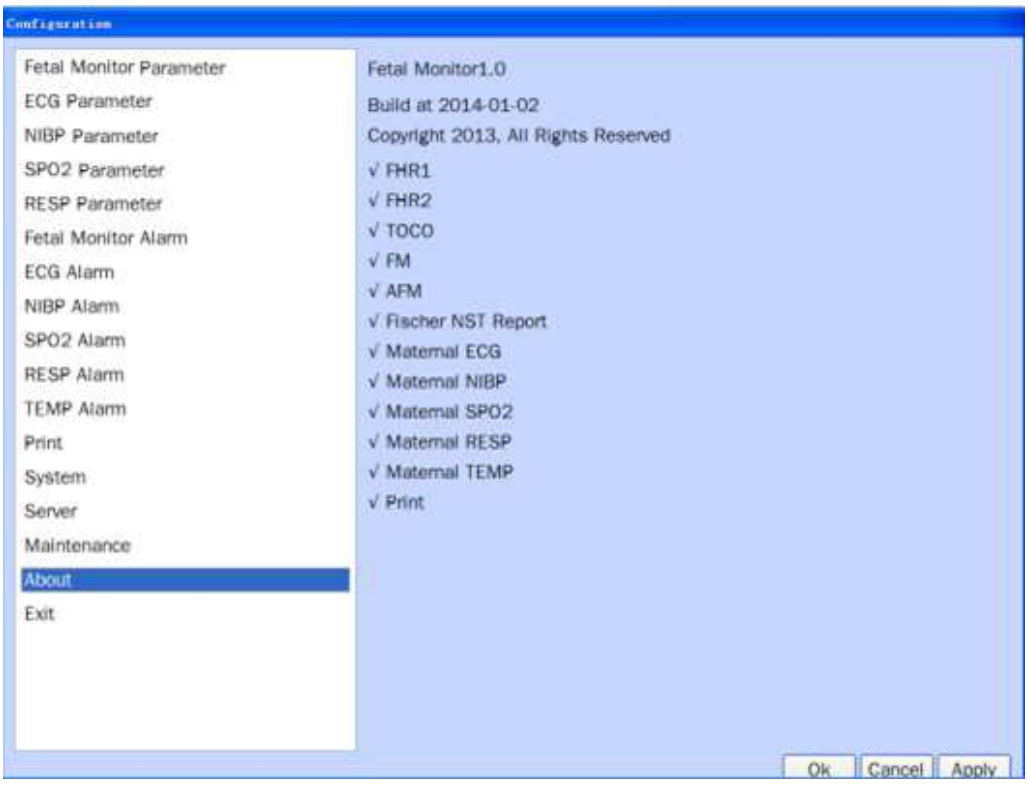


Figure 30 About

6.12 Records

The screen will show the current monitoring case's records, you can use "Choose" icon to enter into the patient information menu to choose the case which you want to check. When enter into patient information menu, you can manage the patient's information.

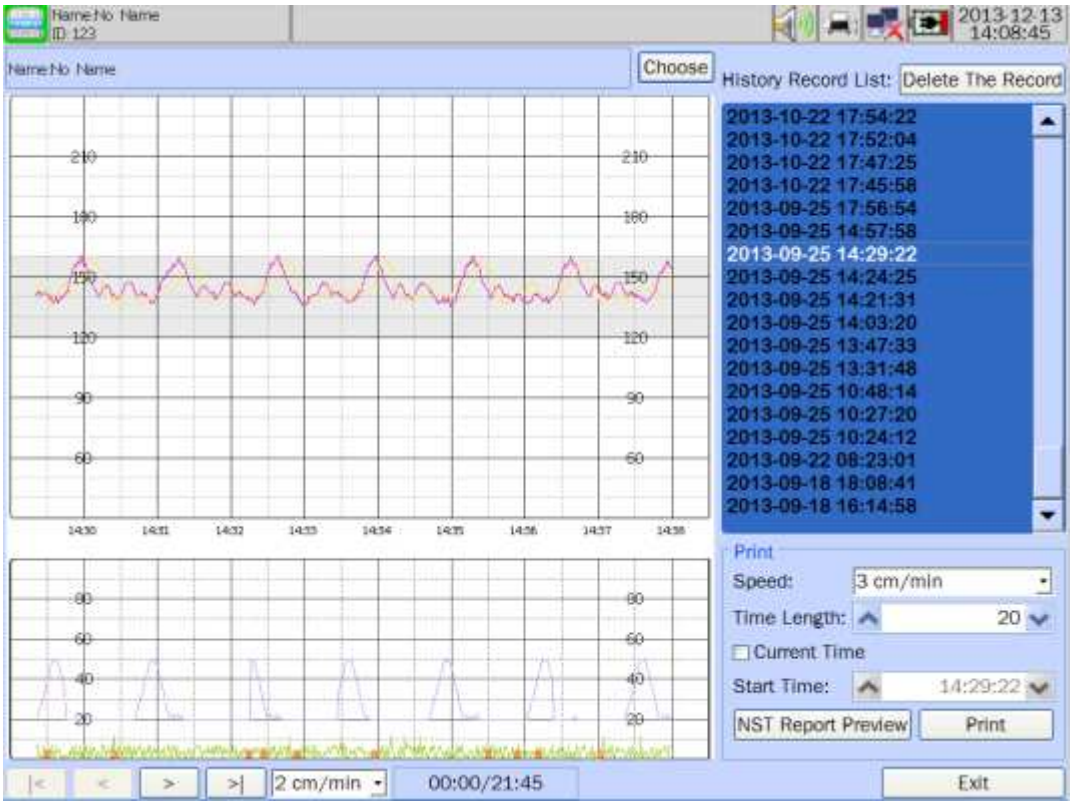


Figure 31 Records

History Record List

All the historic records can be checked here. If you choose one of the records, the historic waveform will be displayed. And the patient information can be checked by pressing the "Choose" key. Also you can delete the records by choosing "delete the record", when it is selected, the menu will pop up as follows.

You can delete the selected item or all the records, which can't be restored.

Print

Speed: 1.2.3 cm/min,

Time length: 1-99 min

Current time: When ticked, the printing will start from the current time, or it will begin from the initial time.

Start time: set the print start time.

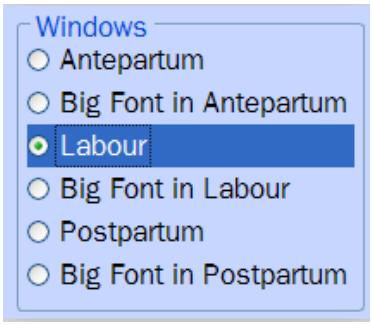
NST Report Preview: Previewing the selected records' NST report. When ticking it, the preview interface will be displayed. And there is a "print" button, You can print the records.

Print: Press this key to start printing.

At the bottom of waveform area, you can use |< < > >| to review other pages, and you can zoom in/out via setting zoom value: 1, 2, 3 cm/min.

6.13 Switch

When you choose the switch menu, it will give following dialog to choose.



You can choose the item according to your requirement, for example, if you choose the Big Font in labour, the interface will change into the following figure.

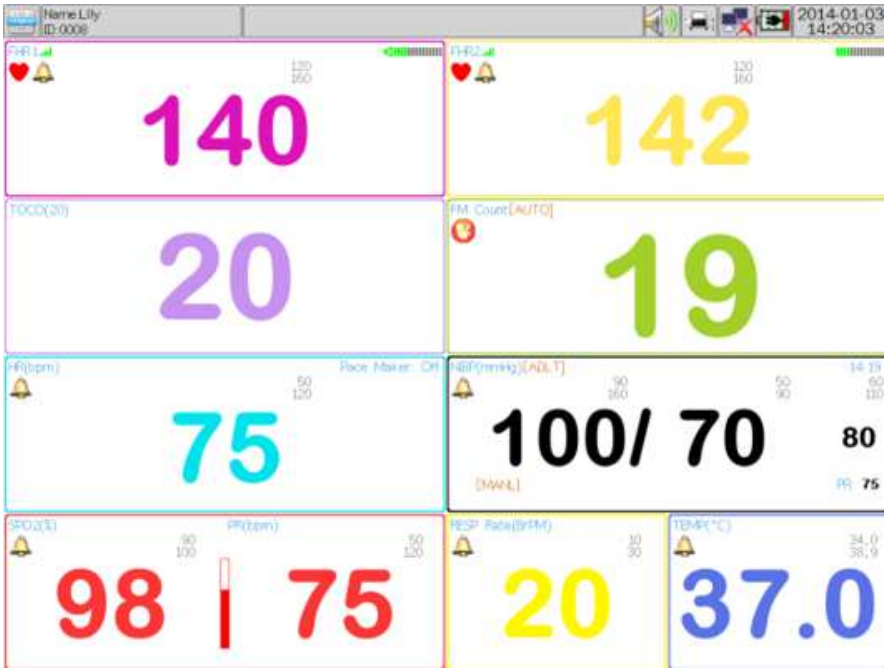
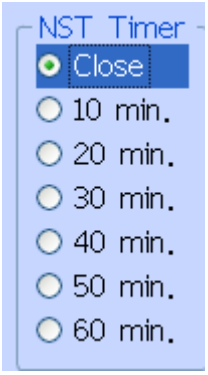


Figure 32 Big Font

6.14 NST timer(Optional)

If you want to start NST timer, you can choose it, then the following dialog will show.



After you choose the time, the counter will work after 15 seconds.

Figure 33 NST timer

After the time is out, it will give the relating alarms to remind the doctor or nurse.

6.15 Doctor Remark

Select this menu to mark the event, when you mark one event, it will appear on the screen and print out on the paper. And marked information will also be stored in the records.

You can pre-store the events by adding new mark; this will be very convenient to mark the event. And the system has already preset three items: Adjust the belt and sensor, left turn and right turn.

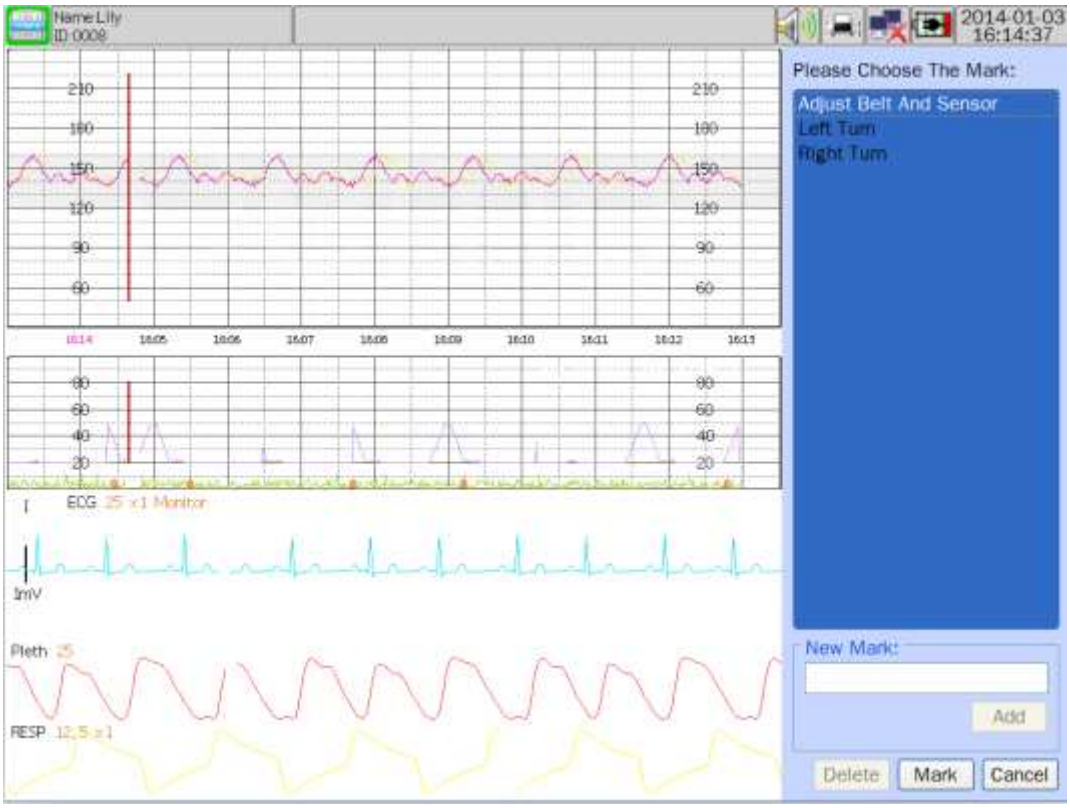


Figure 35 Doctor Remark

7 Pre-Monitoring Preparation

7.1 Switching On the Monitor

- Turn the monitor on and verify that the normal monitoring screen appears on the display. Remove the monitor from service if an error occurs.
- Determine whether the monitor is powered from internal battery or the battery eliminator. If operates on the internal battery, check the power status frame on the display to determine whether the battery has sufficient charge to complete the monitoring session. Use the battery eliminator if the battery is too low.

Caution of Electromagnetic Interference

Certain strong electromagnetic fields can interfere with the ultrasound transducer and cause a false heart rate reading that does not originate from the patient. This interference is rare, and usually found in the vicinity of large machinery. In order to avoid the possibility of these interfering signals being misinterpreted as fetal heart rates, the following procedure should be followed whenever the monitor is to be used in a new location, or if it is known that electrical machinery is being operated in the vicinity.

After connecting the ultrasound transducer(s) turn on the monitor and observe the heart rate indications on the screen for 30 seconds. Intermittent display of random heart rates is acceptable. However, if there is a constant display of a physiological heart rate lasting more than 5 seconds, this is an indication that there is a source of electromagnetic interference in the vicinity. The following steps should be taken to determine if it is possible to use the monitor in this environment.

- Move all line cords and line-powered equipment at least 6 feet away from the fetal monitor. Check for extension cords running behind or under the bed and equipment in adjacent rooms. If the artefact heart rate indication ceases, the monitor may be used normally.
- Remove the line cord from the monitor's power supply. If the artifact heart rate indication ceases, the monitor may be used normally.

If these measures do not result in cessation of the heart rate artifact, the monitor cannot be safely used in this environment.

7.2Connecting Transducers

- Check the ultrasound transducer to verify proper attachment to the monitor. For twins monitoring, make sure the second ultrasound transducer is properly connected.
- Adjust heart rate channel one speaker volume to mid-level.
- Apply ultrasound gel to the face of the transducer.

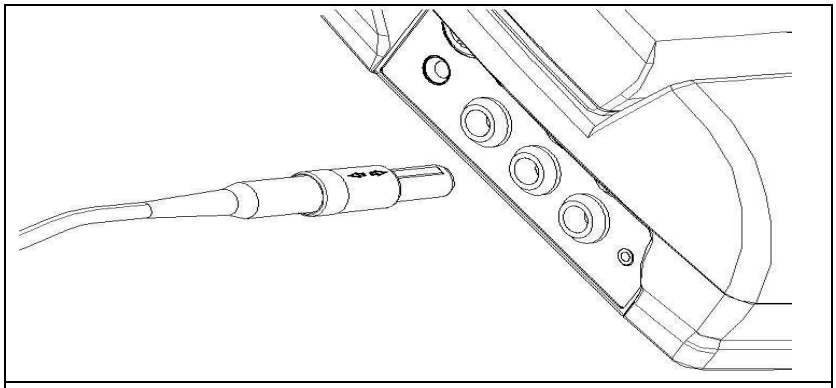


Figure 36-1 Connecting the transducer

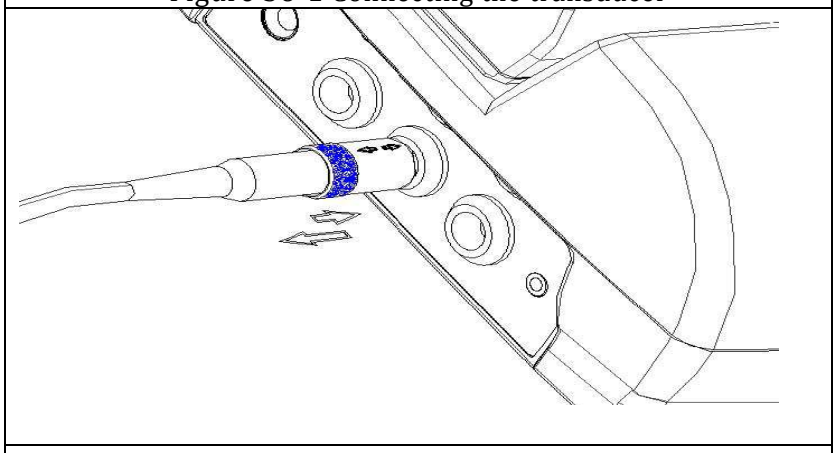


Figure 36-2 Disconnecting the transducer

	Check for visible damages of the transducers every time before connecting them to the monitor. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid. If damage is found, replace them with good ones at once.
	When plugging transducers into the monitor, make sure the arrow symbol of the connector is facing up; When disconnecting a transducer, hold the afterbody of the transducer outshells with fingers and push it in slightly, then pull it out. Refer to Figure 29-2.

8 Fetal Monitoring

8.1Confirming Fetal Life

Fetal heart rate is measured by placing an ultrasound transducer on the maternal abdomen and processing the Doppler echo signal to produce a heart rate and an audio representation of the echo signal.

The monitoring of heartbeat rate of the fetus by echography is recommended after the 28th week of pregnancy for non-stress or routine fetal monitoring.

♦ Confirming Fetal Life

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

High maternal heart rate signal.

Maternal aorta or other large vessels signals.

Electrical impulse from the maternal heart transmitted through a recently deceased fetus.

Movement of the deceased fetus during or following maternal movement.

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

8.2Monitoring FHR with Ultrasound

The ultrasound monitoring is a method to obtain FHR on maternal abdominal wall, which can be used for antepartum monitoring. Place the FHR transducer on maternal abdomen, it will transmit low energy ultrasound wave to the fetal heart, and receive the echo signal.

8.2.1Parts Required

1) Ultrasound transducer 2) Aquasonic coupling gel 3) Belt

8.2.2FHR Monitoring Procedure

1) Placing Transducer Belt

Place the transducer belts across the bed.

Lay the patient on the bed with her abdomen over the belts.

2) Acquiring FH Signal

Search for the location of the fetal heart using a stethoscope or a fetoscope. Apply certain amount of acoustic gel on the transducer and move it slowly around the fetus site until a clear characteristic hoof-beat sound of the fetal heart is heard. Refer to figure 30 for the transducer position.

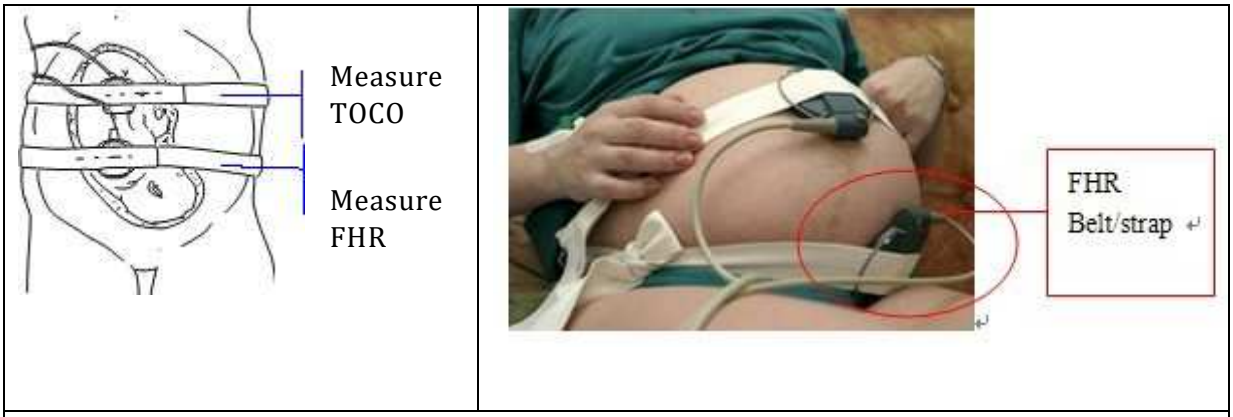


Figure 37 Ultrasound transducer & TOCO transducer positioning (single fetus)

3) Monitoring Twin FHRs

To monitor twin FHRs externally, you need connect an US transducer to US1 socket and the second US transducer to US2 socket of the monitor. Follow the instructions described in Section 8.2.2 to acquire FHR signals for both channels. Press FHR1/FHR2 key to switch the FH sound from one channel to the other.

When the two US transducers are fixed, make sure FH sound from both channels are clear, two FHR traces and two FHR values are displayed on the screen.

	The US transducer must be connected to US1 socket. If the US transducer connects to US2 socket while DECG cable is connected to DECG socket, the FHR trace and value from US2 will not be displayed.

4) Fixing the Transducer

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt.

Make sure the belt is neither too tight nor too loose and the patient is monitored comfortably. Meanwhile, fetus heart beat sound is heard; the FHR trace and value are displayed on the screen.

NOTES:

1) Do not mistake the high maternal heart rate for fetal heart rate.

2) The best quality records will only be obtained when the transducer is placed in the optimum position.

3) Positions with strong placental sounds (swishing) or fetal cord pulse (indistinct pulse at fetal rate) should be avoided.

4) If the fetus is in the cephalic position and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During monitoring prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and

may be more comfortable to the mother.

5) It is not possible to measure FHR unless an audible fetal heart signal is present. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.

	It is suggested that, except particular required by clinicians, 20-30 minutes of fetal monitoring is sufficient to obtain data of information useful. Meanwhile, to use the ultrasonic inspection only if necessary.

	The transducer used for the fetal monitor can only be provided by our company
	Since the fetus frequently moves in the uterus, the position of the transducer should be timely adjusted according to the monitoring situation to ensure getting a good signal and the efficiency of the measured results.
	It may be difficult to measure the heart rate of the fetus for the obese or specific pregnant women. We recommend taking another clinical method.
	When monitoring the fetal heart rate for a long time, we'd better let the pregnant woman lie on one side or sit comfortably in order to prevent the pregnant woman suffering from hypotension.
	The ultrasound scan cannot be used for childbirth in water because it can't prevent the entry of the liquid.
	Echography Doppler fetal monitor can be used with eletrosurgery (ES) instrument at the same time, but shall be far away from ES grounding plate and electronic surgical scalpel. The cable of electronic surgical equipment cannot be winded with that of ultrasound transducer to avoid burning.
	The ultrasound transducer cannot prevent the entry of liquid, therefore, the rest parts expect cables cannot be immersed into the liquid in normal use and property assessment.

8.3 Alarm

You can set the FHR alarm via the alarm setup menu, which includes setting alarm switch, regulating the upper/lower limit of alarm, etc.

Conditions of occurrence of alarm: alarm is activated when the FHR exceeds the limit of alarm.

Alarm parameter	Condition	Vision indication	Acoustic indication
FHR alarm	FHR exceeds the alarm limit	1)FHR value flickers 2)Alarm icon flickers 3)Alarm light flickers	Alarm sound

Setting on fetal heart rate monitoring:

Volume of the fetal heart: It is divided into 8 levels, and you can adjust the volume of the sound of the fetal heart according to the environment during monitoring.

Scanning speed: It is divided into three grades (X1, X2 and X4).

There can be messages of alarm during FHR monitoring, and the reasons and the level are described in table 1 below.

Table of FHR 1 alarm, and reason and grade

Alarm message	Reason	Level
FHR is too high	The measured FHR value is higher than the set High limit of alarm	Medium
FHR is too low	The measured FHR value is lower than the set Low limit of alarm	Medium
Transducer is broken off	Monitor transducer is not connected to the device	Low

Monitor would be limited when they are used under a special condition. To pay attention to the following differences:

	This monitor is used to measure the FHR of pregnant women in more than 28 weeks after pregnancy. If the pregnant women have been pregnant less than 28 weeks, it would be difficult to measure because of the weak signal.

8.4 Signals Overlap Verification (SOV)

If the two US transducers are aiming at the same fetal heart, or the US transducer is aiming at the fetus that the fetal spiral electrode is attached to, an alarm message “Signals Overlap” will appear on the screen to warn you.

If you are monitoring externally, adjust one of the transducers' position to find the second fetal heart.

If you are monitoring internally, adjust the US transducer's position to find the second fetal heart.

8.5 Monitoring of the Uterine Activity

8.5.1 Introduction

Uterine activity is measured externally by placing a pressure sensitive device (Tocotonometer) on the maternal abdomen and recording relative pressure changes.

8.5.2 Parts Required

1) TOCO transducer 2) Belt

8.5.3 TOCO Monitoring Procedure

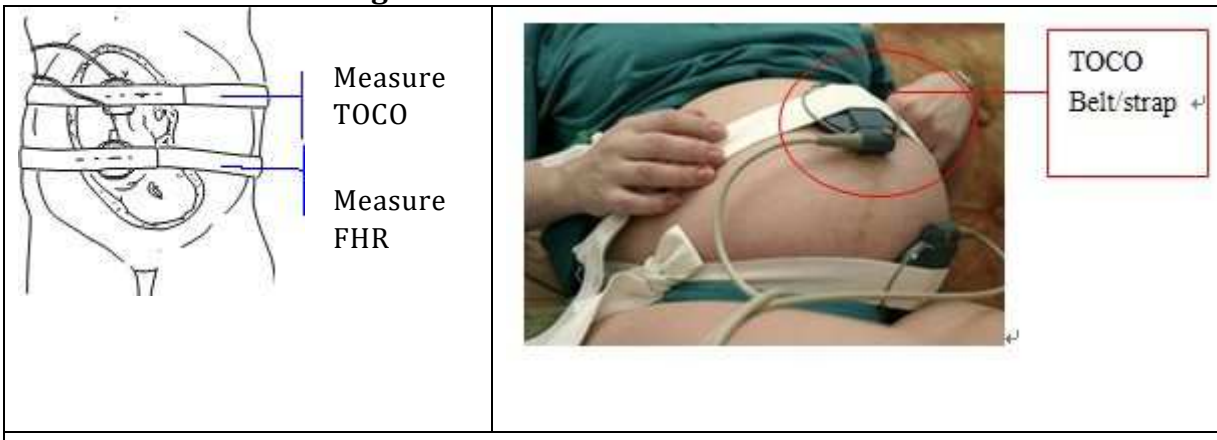


Figure 38 Ultrasound transducer & TOCO transducer positioning (single fetus)

1) Placing Transducer Belt

Place the transducer belt across the bed.

Lay the patient on the bed with her abdomen crossing the belts.

2) Fixing the Transducer

Set the TOCO baseline.

Place the transducer on the patient's abdomen to get optimum recording of uterine activity. Refer to figure 31 for the TOCO transducer position.

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt. Make sure the belt is neither too tight nor too loose and the patient is monitored comfortably.

3) Adjust the Value to Zero

Press the AUTO ZERO key to adjust the value to the baseline. Make sure this is not done during a contraction.

The uterine activity reading at this point should be 30 ~ 90. A flat-top at lower than 100 units on the TOCO scale indicates the belt is too tight, you need to adjust it.

Wipe off any gel presents on abdomen around this area.

NOTES:

1) Do not apply Aquasonic coupling gel on a TOCO transducer or its contact area.

2) Check the function of the TOCO transducer by applying pressure on it to see if this is displayed on the screen.

	No gel is required on using TOCO transducer ((Tocotonometer))
	Warning of the transducer of pressure cannot help to prevent the entry of liquid, therefore inapplicable for the monitoring childbirth in water.
	Only the pressure pick-up of the uterine contractions provided by us is available for the fetal monitoring.
	The difficulty of detection of the pressure can occur on the pregnant obese woman and certain particular patients, and other methods of diagnosis are recommended to this moment.
	When monitoring the contraction pressure for a long time, we'd better let the pregnant woman lie on one side or sit comfortably in order to prevent the pregnant woman suffering from hypotension
	Attention the cable of the unit of electrosurgery cannot touch cables transducers of pressure transducer, otherwise they will burn.
	Transducer pressure must be prevented from being striped by the pointed articles, and enters in collision with the hard objects, in order to avoid the mechanical loss of the parts under pressure or to make the reading of the incorrect data. To clean the transducer with a soft rag or a compress after use and to arrange correctly.

8.5.4 Message of Alarm

Alarm, the cause and the extent of what can be posted in the uterine pressure controlet are presented at table 2.

Table 2: alarm, Cause and the level

Message of alarm	Cause	Level
Pressure transducer disconnected	The transducer is not connected to the monitor	Low

8.6 Monitoring of the Fetal Movements

8.6.1Auto Fetal Movement (AFM) Monitoring

Auto fetal movement is also detected from the ultrasound Doppler signal. The fetal movement signals differ from the Doppler heart rate signal in that they have larger extent and lower frequency. The larger extent is because of the bigger scope of moving areas (e.g., the fetal arms or legs); lower frequency is because of the lower velocity of the fetal movements compared with those of the fetal heart.

The movement of the fetus will be detected and displayed in the form of a trace on the screen and the record paper.

AFM monitoring can be switched off; its gain is adjustable.

8.6.2Manual Fetal Movement (MFM) Monitoring

MFM monitoring result comes from the patient's feeling of fetal movement. The count will be displayed on the screen in MFM numeric area.

1) Insert the FM marker connector into MARK socket on the monitor.
2) Let the patient hold the marker in hand; ask her to press the top key of it when a fetal movement is felt. Continuous movements in 5 seconds are considered to be one movement and only press the key once.

8.6.3Clinician Marker

The nurse's marker arrow "↓"is provided so that the mother can record the time of important events. The clinician merely presses the marker button located on the front-panel keypad ("Event Marker" key) at the time an event occurs. This marker time is recorded in the patient record in the monitor.

The nurse marker icon is a downward pointing arrow. The monitor will display this downward pointing arrow and memo in the information frame of the display. A strip chart printout of patient record will also show this mark accompanied by the time and date.

8.6.4Patient Marker

The patient marker arrow is provided so that the patient can record the time of important events like fetal movement. The patient merely presses the marker button located on the middle of the marker cable at the time an event occurs. This marker time is recorded in the patient record in the monitor.

The patient marker icon is an upward point arrow. The monitor will display this upward pointing arrow in the information frame of the display. A strip chart printout of patient record will also show this mark.

9 Maternal Monitoring

9.1Maternal ECG Monitoring

9.1.1Principle of ECG Measurement

The electrocardiogram (ECG or EKG) is primarily a tool for evaluating the electrical events within the heart. The action potentials of cardiac-muscle cells can be viewed as batteries that cause charge to move throughout the body fluids. These currents represent the sum of the action potentials occurring simultaneously in many individual cells and can be detected by recording electrodes at the surface of the skin.

9.1.2Preparation of ECG Measurement

First of all, the hospital should be equipped with a standard power supply system with a standard grounding wire. If big interference in ECG continues, connect one end of the grounding wire provided with this equipment to the grounding wire on the back panel of this monitor, and the other end of the special grounding wire, to water pipe or radiator.

The common ECG plate of electrode being used together with this monitor has short shelf life. Generally, the shelf life is only one month after the package is opened. When outdated electrode plate is used, due to skin's contact impedance and big electrode potential, the chance of interference will be increased, and the ECG baseline will have an unstable inclination. Therefore, always use valid plates of electrodes.

Notes:

- **Do not** touch the patient, table or devices during the defibrillation.
- **Do not** use the ECG cable manufactured by other company with our monitor when monitoring ECG.
- The electrode and the cable **must not** touch the conductive parts and ground. Especially all the ECG electrodes, including the neutral ones, must be set on the patient to avoid the touch with conductive parts and ground.
- The devices near the patient that are not grounded may disturb the waveforms.
- The ECG electrode must be checked periodically to ensure that there is no anaphylaxis. If the patient still has anaphylaxis, please change the electrode or change the position of the electrode every 24 hours.
- When using the electro surgical devices, put the ECG electrode on the middle position of the grounding board and electro surgical knife to avoid burn. Do not twist the ECG cable with the wires of electro surgical devices.

9.1.3Preparation of the Contacting Area on Skin

The quality of ECG depends on the tightness of connection of electrodes and the skin humidity and cleanness, and the thickness of skin. For the good contact between the electrodes and the skin, the skin must be carried out preparation before placement of the electrodes.

Thoroughly clean the skin with soap water. (Do not use alcohol)

The desired area of the skin may be gently polished in order to remove the thick rough skin and oil.

Conductive gel may be apply to the area where the skin is not good conductive for the electrodes.

To check the patient's ECG signal, make sure the plates of electrodes are properly located on the body. Connect each plates of electrode with the ECG lead cord, with the other end to be inserted into the ECG and respiratory lead cord connectors (ECG/RESP), respectively, on the side panel of the apparatus.

Symbol		**Position**
RA		The intersection between the centerline of the right clavicle and Rib 2
LA		The intersection between the centerline of the left clavicle and Rib 2
LL		Left part of the upper abdomen
RL		Right part of the upper abdomen
V Chest electrode	V1	Between the right edge of the breast bone and Rib 4
	V2	Between the left edge of the breast bone and Rib 4
	V3	Halfway between Points V2 and V4
	V4	Intersection between the centerline of the left clavicle and Rib 5
	V5	the front line of the left armpit, Horizontal position as Point V4
	V6	the center line of the left armpit, Horizontal position as Point V4

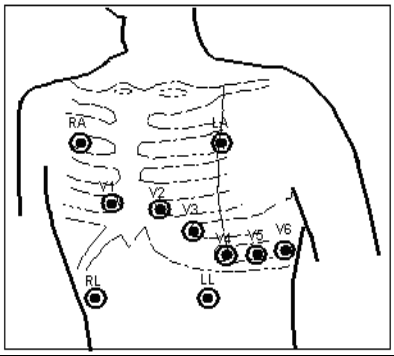


Figure 39 Electrodes positioning

Note: Lead V [see chest electrodes above] may be located at any of the six positions as shown in the table above and the figure below (Points V1, V2, V3, V4, V5 and V6), in other words, the chest electrodes (Lead V) should be located at only one of the six positions to be measured. Only measure of the position where such leads are located will be taken.

9.1.4 Menu Setup

Scan speed: The refresh speed of the ECG waveform could be 12.5mm/s, 25mm/s and 50mm/s.

Leads: I 、II、III、aVR、aVL、aVF、V

Gain: X0.25.X0.5,X1, X2, In order to get good signal of ECG, please set the suitable gain to get the best result.

Mode: Diagnosis, Operation, Monitor

9.1.5 Alarm setup

The alarm of ECG is set up to On or Off, the upper limit and lower limit of HR are set up in the ECG setup menu.

When the HR is more than the upper limit or less than the lower limit, the alarm indicator will flash.

9.6 Maternal RESP Monitoring

9.6.1Principle

The monitor measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen. Normally select the lead II as signal source of Respiration monitoring.

9.6.2 Operation

To check the patient's ECG signal, make sure the plates of electrodes are properly located on the body. Connect each plates of electrode with the ECG lead cord, with the other end to be inserted into the ECG and respiratory lead cord connectors (ECG/RESP), respectively, on the side panel of the apparatus.

It's very important to put the electrodes on the body properly, in order to get good RESP waveform, put the electrodes as figure 33

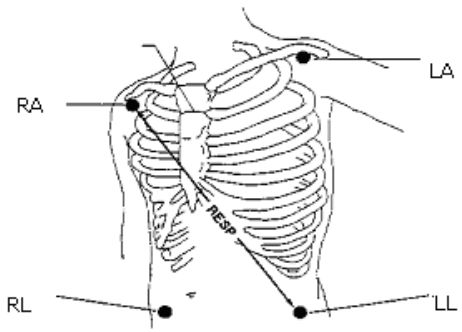


Figure 40 Electrodes positioning

9.7 SpO_2 / Pulse Monitoring

9.7.1General Information

SpO_2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 97%. The SpO_2 value on the monitor will read 97% .The SpO_2 value shows the percentage of hemoglobin molecules that have combined with oxygen molecules to form oxyhemoglobin. The SpO_2 parameter can also provide a pulse rate signal (PR), pulse strength signal and a Plethysmogram wave.

9.7.2 Operation

When the SpO_2 sensor is to be used, connect the SpO_2 sensor to the SpO_2 connector on the side panel. Make sure the power cable is not bent or twisted. Insert one finger into the sensor (index finger, middle finger or ring finger with proper nail length) according to the finger mark on the sensor, as shown in the figure 34.

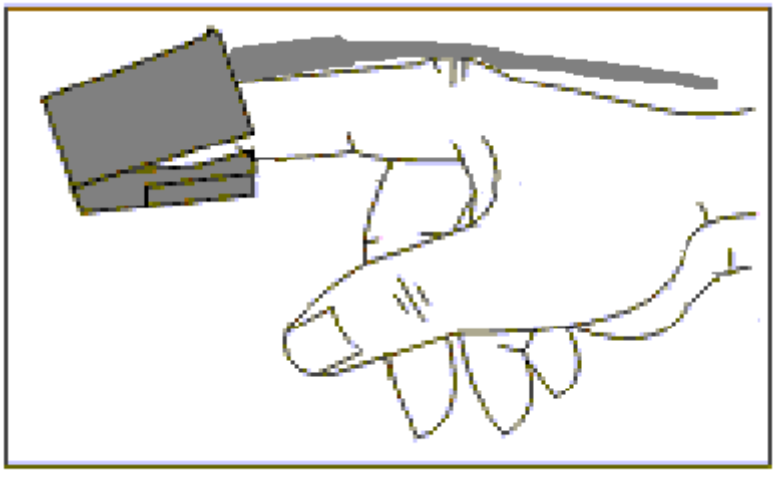


Figure 41 the use of SpO_2 sensor

Notes

a) The pulse oximeter sensor could cause skin irritation. Move the sensor to a different location if any skin irritation is present.

b) The pulse oximeter sensor is light sensitive. Excessive ambient light makes it difficult for the system to provide accurate readings.

c) Do not place the pulse oximeter sensor on the same extremity with the blood pressure cuff. Place the pulse oximeter sensor on the opposite side of the blood pressure cuff or an arterial line.

d) Please set the alarm limitations according to clinical condition of monitored patient.

9.8Maternal NIBP Monitoring

9.8.1Principle

The Non-invasive Blood Pressure (NBP) module measures the blood pressure using the oscillometric method. It is applicable for adult, pediatric, and neonatal usage. There are two modes of measurement available: manual, automatic. Each mode displays the systolic (SYS), diastolic (DIA), and mean (MEAN) blood pressure. In the Auto measurement mode, the measurement is cycled, you can set the interval time to 2, 5, 10, 30, 60, 120 minutes for choice.

9.8.2Operation

First of all, select a cuff of appropriate size according to the age of the subject. Its width should be 40% (or 50% for neonate) of the arm circumference, or 2/3 of the length of the upper arm. The cuff inflation part should be long enough to permit wrapping 50-80% of the limb concerned. See the table below for the dimensions:

Cuff Model	Arm Circumference	Cuff Width
Neonate Cuff	6.0cm～9.5cm	3cm
Small-sized Pediatric Cuff	6cm～11cm	4.5cm
Middle-sized Pediatric Cuff	10cm～19cm	8cm
Large-sized Pediatric Cuff	18cm～26cm	10.6cm
Adult Cuff	25cm～35cm	14cm

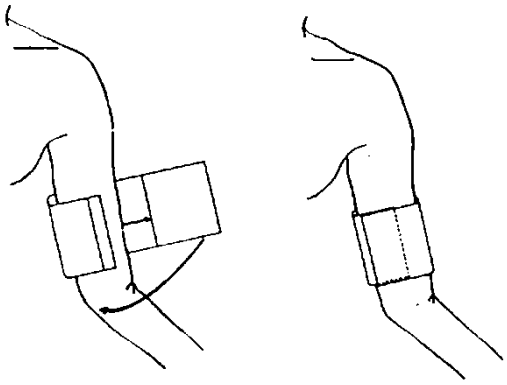


Figure 42 put the cuff properly

Connect the cuff's plug to the NIBP connector on the side panel, and make sure the connection is secure. Prior to use of the cuff, empty the cuff until there is no residual air inside it. Unveil and wrap it around the upper arm evenly to appropriate tightness as shown above.

9.8.3MeasurEment Steps

- To start a manual measuring:

  Press the NIBP button on the front panel

- To stop a manual measuring:

  Press the NIBP button on the front panel again

- To start auto measuring:

  Enter NIBP window and setup mode to "AUTO" and setting the measuring interval, then press NIBP to start auto measuring.

- To cancel auto measuring:

  Press the NIBP button on the front panel again

- To stop auto measuring:

  Enter NIBP window and set the mode to "MANUAL"

Notes

Ensure the interval time between the two measurements is longer than 1 minute for blood vessel release totally, otherwise may lead mistake measurement.

If any doubt about the result, please measure the patient's blood pressure by a manometer first and compare the two results. Cuff will inflate up to 180mmHg at the first measurement.

Check the patient type is appropriately selected at first measurement to avoid mistake of measurement and patient safety.

9.9TEMP Monitoring

This monitor can monitor the body temperature or inner temperature of patient. The transducer used in temperature monitor must be approved by the manufacturer.

9.9.1Operation:

Connect the TEMP sensor to the monitor; plug it directly into the monitor.

Attach the TEMP sensor securely to the patient and power on the monitor.

9.9.2Set Up the TEMP Menu

The body temperature will display on the screen.

10 Maintenance

10.1 Maintenance Inspection

(1) Visual Inspection

Prior to every time use, do the following inspection:

- Check the monitor and accessories to see if there is any visible evidence of damage that may affect patient safety. Pay special attention to the cracks on the sensors and cables before immersing them into conductive fluid.
- Check all the outer cables, power socket and power cables.
- Check if the monitor functions properly to make sure it is in good condition. If any damage is detected, stop using the monitor on the patient. Replace the damage part(s) or contact our company for service before reusing it.

(2) Routine Inspection

The overall check of the monitor, including the safety check and functions check, should be performed by qualified personnel once every 6 to 12 months, and each time after service.

The equipment should undergo periodic safety testing to insure proper patient isolation from leakage currents. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

(3) Mechanical Inspection

Make sure all exposed screws are tight.

Check the external cables for splits, cracks or signs of twisting.

Replace any cable that shows serious damage.

Pay particular attention to the supply socket.

	Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
	The fetal monitor requires yearly preventive maintenance.
	The use of the damaged sensor can involve erroneous data. Each sensor, cables and card must be control during the daily inspection and the routine maintenance of the apparatus.

	To carry out a daily inspection and routine maintenance on the monitor and its accessories in a normal way, although, while the methods of sterilization and disinfection must be strictly in conformity with the specifications of this handbook.
	The material must be placed at the good place, handled with prudence.

10.2Maintenance of the Battery

If the fetal monitor is not used for one month, to reload the battery before use. We recommend that the battery of the fetal monitor must be replaced with a 2 years interval.

10.3Maintenance of the Monitor

Keep the exterior surface of the monitor clean, free of dust and dirt.

The gathering of dew in the screen may occur with abrupt temperature or humidity changes. A table environment is recommended.

Scratching and damaging the screen should be avoided.

Operate the touch screen with special stylus pen or finger. Sharp edged or hard particles like ball pen or propelling pencil are prohibited.

Keep the touch screen surface clean, no adhesive should be applied.

Avoid high voltage and static charge.

	Unplug the monitor from the AC power source and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.
	Take extra care when cleaning the display surfaces, which are sensitive to rough handling. Rub the lens that covers them with a soft, dry cloth.

10.4Maintenance of the Sensor

Keep the transducers in a dry environment, where the temperature had better be lower than 45°C.

Gel must be wiped from the US transducer after use. These precautions will prolong the life of the transducer.

Although transducers are designed for durability, they should be handled with care. Rough handling could damage the cover, piezoelectric crystals and mechanical movement. Contacting the transducers with hard or sharp objects should be avoided. Do not excessively flex the cables.

	Do not autoclave. Do not sterilize with gas.
	Do not immerse in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the sensor.

10.5Maintenance of the Belts

Wash soiled belts with soap and water.

	The water temperature must not exceed 60℃ (140℉)

10.6 Maintenance of the Record Papers

When storing recorder paper (including used paper with traces):

Do not store in plastic envelopes.

Do not leave exposed to direct sunlight or ultraviolet light.

Do not exceed a storage temperature of 40 ℃ (104 ℉).

Do not exceed a relative humidity of 80%.

Storage conditions outside these limits may distort the paper and adversely affect the accuracy of grid lines or make the trace unreadable.

11 Cleaning

11.1 Cleaning Inspection

In order to avoid infection, clean and disinfect the monitor and accessories after each use.

11.1.1 Cleaning of the Monitor

Regular cleaning of the monitor enclosure and the screen is strongly recommended.

The solutions recommended for monitor cleaning are: soft soap water, Tensides, Ethylate and Acetaldehyde.

	Unplug the monitor from the AC power source and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

Clean the monitor enclosure with soft cloth and diluent non-caustic detergents recommended above.

Clean the screen with dry soft cloth.

Clean the touch screen with soft cloth and neutral detergent or isopropyl alcohol. Do not use and chemical solvent, acidic or alkali solution.

	Although the monitor is chemically resistant to most common hospital cleaners and non-caustic detergents, different cleaners are not recommended and may stain the monitor.
	Many cleaners must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.
	Don't use strong solvent, for example, acetone.
	Never use an abrasive such as steel wool or metal polish.
	Do not allow any liquid to enter the product, and do not immerse any part of the monitor into any liquid.

	Don’t remain any cleaning solution on the surface of the monitor.
	Avoid pouring liquids on the monitor while cleaning.
	The monitor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.
	We have no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

11.1.2Cleaning of the Accessories

(1) Cleaning of Transducers

To clean the US transducer, TOCO transducer by follow these steps:

1) Wipe them with a soft cloth dampened in cleaning solution;

2) Clean them with a soft cloth dampened in water;

3) Air-dry them or wipe off the remained moisture with a soft dry cloth.

The recommended cleansers for accessories are list below:

Accessory	Cleansers
Ultrasound Transducer TOCO Transducer	BURATON LIQUID MIKROZID ETHANOL 70% SPORACIDIN CIDEX

(2) Cleaning of Belt

Wash soiled belts with soap and water. The water temperature must not exceed 60 ºC (140 ºF).

11.1.3Cleaning of the Cuff

11.1.3.1 Reusable Pressure Cuff

Before cleaning Please take out the internal rubber band. The cuff can be sterilized with conventional high-pressure sterilization, gas sterilization or radiation sterilization method, or immersed in decontamination solution. Cuff can also be hand-washed or by washing machine, but not dry cleaning, hand washing can extend service life. After cleaning, the cuff should be dry, and then re-enter the rubber band. To reload the cuff in, put the band on the tip of cuff, so

the rubber tube and the long side of the cuff are in a line, the rubber band will now be rolled up vertically and inserted into large open cuff, to hold the rubber tube and the cuff, jitter the cuff until the rubber band into place. And then pull the rubber tube into cuff, come out through the hole lining beneath. See in Figure36

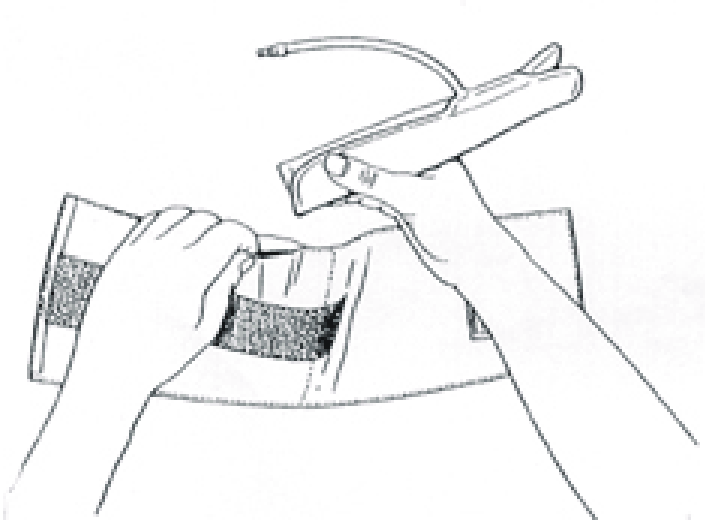


Figure 43 Reusable Pressure Cuff

11.1.3.2 Single use pressure Cuff

Cuff can only be used one-time for only one patient; the same cuffs can't be used for different patients. The single use high-pressure cuff can't be disinfected or reused after high-pressure steam sterilization.

	Disposable blood pressure cuff recycling or disposal must comply with the relevant provisions of national or regional.
	Do not squeeze the rubber tube on the cuff
	Do not allow water or cleaning fluid into the front of the monitor connection socket, to prevent damage to equipment

11.1.4 Cleaning of the SpO_2 Sensor

Recommend using cotton ball soaked in medical alcohol or soft cloth to clean SpO_2 sensor, and then dry with a cloth, this method can also be used to clean the sensor light-emitting and receiving parts. Please do not use organic solvents, acid or alkali cleaning agent to clean SpO_2 sensor, otherwise could result in corrosion or discoloration of the sensor.

Sensor cable is recommended to use 3% hydrogen peroxide or 70% isopropyl alcohol cleaning; the plug cannot be immersed in the solution

	Before cleaning, disconnect the SPO2 sensor and instrument. Before re-use after cleaning, it should be allowed to dry in the air
	Do not immerse the sensor cable in any liquid, do not use steam or ethylene oxide sterilization on the sensor
	Do not use high-pressure sterilization on the sensor
	If the sensor or cable is damaged or have deteriorated signs, re-use should be prohibited

11.1.4Cleaning of the ECG Cables

ECG cables can be cleaned by medical alcohol, natural air-dry or by clean, dry cloth. If you need sterilization, firstly please do a good cleaning, proposed to use sterilization with 70% alcohol

11.1.5Cleaning of the TEMP Sensor

After each use, temperature sensor should be disinfected by alcohol. The steam sterilization cannot be used.

11.1.6Cleaning of the Recorder

The recorder platen, thermal print head and paper sensing mechanism must be cleaned at least once a year or when needed (when traces become faint).

To do this:

1) Clean the recorder platen with a lint-free cloth and soap/ water solution.

2) Wipe the thermal array using a cotton swab moistened with 70% Isopropyl alcohol-based solution.

3) Check the paper sensing mechanism is free of dust.

	Only use the recorder paper provided by us, or it may damage

11.2Detergents

Caution: the sensors' external surface can be cleaned by using medical menthol spirit, natural air dry or clean dry cloth.

Caution: MANUFACTURER will not accept any legal responsibilities for possible medical contaminations caused by the suggestions to apply the above-mentioned cleaning agents or detergents for the purpose of cleaning this monitor. Please consult the official in your hospital or medical specialist in contaminations for further opinions before apply the above mentioned cleaning agents and detergents if you have any doubts.

11.3Sterilization

To avoid the cause of long term damages to this monitor. MANUFACTURER only agrees that when it is necessary, under the hospital guideline of normal sterilization procedures, to perform the sterilization to the monitor. And we also suggest that clean up the monitor before perform sterilization.

12 Troubleshooting

Prior to apply this monitor to the patient, the operator must check the following:

1. To see if any mechanical damaged to this monitor and all accessories.
2. To see if there's any damaged cables leads and plugs.
3. To make sure that all functions or operations which will be applied to the patient are functioning correctly and try to ensure the monitor in such good working order.

If any sights of the above mentioned damages or malfunctions, do not use this monitor to any application or any part of the medical monitoring! Contact the service agent as soon as possible!

The monitor must have at least once comprehensive maintenance including the safety checking between 6~12 months, and can only performed by the qualified technician authorized by MANUFACTURER.

	No person is allowed to open the case of this monitor to perform any kind of services except those authorized by MANUFACTURER.

Problem	Possible Reason	Recommended Action
No Display	1. The Power supply is not connected or battery exhausted. 2. Power cut, or bad contact of plug / socket. 3. Fuse damaged.	1. Adopt AC to charge the machine for 8 hours. 2. Check Power supply and Power cable. 3. Check fuse.
Abnormal Fetal Heart Rate	1. Bad contact between sensor and equipment. 2. Put sensor in wrong position where cannot detect fetal heart. 3. Forget using Gel. 4. Fetus / Mother is moving. 5. Sensor damaged. 6. Fetal monitoring module damaged.	1. Re-connect sensor to equipment. 2. Re-adjust position of the sensor. 3. Adopting Gel. 4. Re-adjust position of the sensor after signal resumed. 5. Replace new sensor. 6. Replace new module.
Abnormal Uterine Contraction Pressure	1. Bad contact between sensor and equipment. 2. Put sensor in wrong position where cannot detect fetal heart.	1. Re-connect sensor to equipment for checking the situation of lead. 2. Re-adjust position of the sensor. 3. Press "ZERO" key every time after putting sensor into the

	3. Do not zero TOCO to default value (20). 4. Mother has no uterine contraction. 5. Sensor damaged. 6. TOCO sensor is highly sensitive.	right position. 4. Waiting for uterine contraction. 5. Replace new sensor. 6. Loose belt a little.
ECG Abnormal	1. Bad contact of ECG cable. 2. Do not grounding the machine. 3. Bad contact between ECG electrodes and patient skin. 4. Do not choose correct filter mode.	1. Re-connect ECG cable. 2. Grounding the machine 3. 4. Re-connect ECG electrodes. And cleaning patient's skin. 5. 6. Choose "Surgical" filter mode to filtrate clutter.
SpO_2 Abnormal	1. Use one arm to measure SpO_2 and NIBP at the same time. 2. No nail or nail is not cleaning; Nail is not opposite to red light in sensor. 3. Arm moving during measurement.	1. Measure SpO2 in one arm and measure NIBP in the other arm. 2. Cleaning nail and put nail opposite to red light in sensor. 3. Keep arm still during measurement.
NIBP Abnormal	1. Obvious warp of NIBP result. 2. Cannot normally inflate the cuff. 3. Deflate too slow	1. Check airtightness of cuff and pipe. 2. Check whether pipe has been jammed or malfunction of pump. 3. Check whether there is something in pipe.
No sound	1. Choose the low volume or set silent function.	1. 1. Increase the volume. 2. Check speaker cable or speaker.
Printer malfunction	1. Put thermal printer paper in bad position. 2. The printer is not correctly closed. 3. Incorrect setup of print mode.	1. Ensure the thermal paper side is upward. 2. Closed the printer hardly by hearing two "ka" sounds (follow the instruction in printer). 3. Choose correct print mode (ECG print, 1cm/min, 2cm/min, 3cm/min)
Printer result is not clear or some area cannot be printed out	1. Use disqualified printer paper. 2. Printer head is polluted.	1. Replace new thermal printer paper. 2. Cleaning printer head according to regulation in operation manual

Printing deviation Error in printing curve	1. Thermal paper is not put in right place. 2. Used printer paper of incorrect width.	1. Adjust position and place of thermal printer paper. 2. Using correct paper.

13 Guarantee

13.1Manufacture, Safety, Reliability and Performance

We guarantee that the systems Fetal maternal monitor to be free of defects in workmanship and materials for a period of one (1) year after the installation, except following exceptions:

- The product is repaired or modified by unauthorized personnel
- The product is not used as per the instruction of the handbook

Any part composing of the Fetal maternal monitor judged by our company for the period of guarantee will be repaired or replaced by us, with its whole discretion and its expenses. The recourse of the purchaser under the terms of the present guarantee are limited to the repair or the replacement of failing parts, the replacement of the system or the refunding of the purchase price, the recourse specific being left to the exclusive and reasonable appreciation of our company.

We will not in any case hold responsible for damage particular, indirect, additional or immaterial, including, but without being limited to, any loss of real or perceived pleasure, benefit or profits.

The requests for guarantee must be addressed to us in thirty (30) days following the discovery of the dysfunction.

EXCEPT CONTRARY SPECIFICATION IN THIS DOCUMENT, OUR COMPANY DOES NOT PROVIDE ANY GUARANTEE OF WHICH TYPE THAT EC IS, EXPRESSE OR IMPLICIT, CONCERNING THE SYSTEM FETAL MATERNAL MONITOR, INCLUDING, BUT WITHOUT BEING LIMITED TO, ALL GUARANTEED IMPLICIT OF MARKETING AND ADAPTATION TO A USE OR A PARTICULAR OBJECTIVE. WE WILL NOT BE TO IN NO CASE HOLD RESPONSIBLE For OTHER DAMAGE, Including, BUT WITHOUT BEING LIMITED To, the DAMAGE PARTICULAR, INDIRECT, ADDITIONAL OR IMMATERIAL OR RISING FROM OR IN CONNECTION WITH the USE OR the PERFORMANCES OF the FETAL MATERNAL MONITOR
.

13.2Service

13.2.1 Procedure of Return

In the case where it becomes necessary to return the product to US, please refer to following procedure:

To obtain an authorization of return.?

To contact the service department of US to obtain a RMN (Return Materials Authorization number). This number must appear outside the container.

The returns are not accepted as RMN is not visible. Enter the number of model, serial number and a short description of the reason of the return.

The customer is responsible for the transport charges when the? product is dispatched to us for the service (including the custom charges).

NOTWITHSTANDING ALL CONTRARY DECLARATIONS CONTAINED IN THIS HANDBOOK, WE WILL NOT BE IN NO CASE HELD FOR PERSON IN CHARGE TOWARDS the PURCHASER OR a THIRD, FOR the PARTICULAR DAMAGE, ADDITIONAL, IMMATERIAL OR SPECIMENS OF WHICH NATURE THAT EC IS, Including, BUT WITHOUT BEING LIMITED To, the COMMERCIAL LOSS DUE TO an UNSPECIFIED REASON OR the COMMERCIAL INTERRUPTION OF WHICH NATURE THAT EC IS. LOSSES OF PROFITS OR INCOMES, the LOSS OF REAL OR PERCEIVED PLEASURE, LOSSES RISING From a DEFECT OF DESIGN, VICE OF MATERIAL AND/OR MANUFACTURE OR RISING FROM NON-OBSERVANCE BY the PURCHASER OF WHOLE OR PART OF the PROVISIONS OF THIS HANDBOOK AND/OR FAILURE OF the SYSTEM FETAL MATERNAL MONITOR AS SPECIFIED, EVEN IF OUR COMPANY AT SUMMER INFORMED OF THE POSSIBILITY OF SUCH DAMAGE.

THE FETAL MATERNAL MONITOR WILL HAVE TO BE USED BY OR UNDER THE DIRECT AND IMMEDIATE MONITORING OF AND THE CONTROL Of AN APPROVED DOCTOR, ASSISTED BY ANOTHER MEMBER OF THE QUALIFIED PERSONNEL. CONSEQUENTLY, OUR COMPANY REJECTS ANY RESPONSIBILITY AND THE PURCHASER AGREES TO GUARANTEE AND RELEASE the RESPONSIBILITY FOR US FOR ALL PHYSICAL INJURIES, DEATH OR MATERIAL DAMAGES AND ALL OTHER COMPLAINTS, LEGAL PROCEEDINGS, LEGAL COSTS, JUDGEMENTS OR EXPENSES WHILE RISING, IN CONNECTION WITH the USE OF the SYSTEM FETAL MATERNAL MONITOR BY ANOTHER PERSON THAT QUALIFIED PERSONNEL DESCRIBED ABOVE.

The declarations and guarantees contained in this handbook can be exclusively changed, modified or be amended by an agreement signed by a duly authorized officer of our company

14 Design Feature

14.1 Specifications

Physical Specifications			
Dimension and Weight	Dimension	35cm (W)*30cm (D)*11cm (H)	
	Weight	standard configuration: 4 kg	
Operation Environment	Power requirements	AC100-240V , 50/60Hz	
	Power	100VA	
	Temperature	5-40℃	
	Humidity	30-93% non-condensing	
Fetal/Maternal Performance Specifications			
Performance Specifications	Display	12.1 inch (1024×768 pixel) color TFT –LCD	
	Indicator	Visual on-display and integrated, alarm light, audible alarm	
	Battery	Internal rechargeable Li-ion battery power	
	Alarm	Visual on-display and integrated, alarm light, audible alarm	
	Memory	24-hours memory for fetal traces	
	Printer	America standard/international standard Built-in thermal printer (112mm, 150mm for option) 1/2/3cm/min real-time printing speed, fast print speed (stored traces)	
		Paper	Z-fold, thermosensitive
		Record Message	Bed ID, name, age, date, time, print speed etc.
	CMS	Support connecting to central monitoring station through LAN (TCP/IP) or wireless connection	
Fetal/Maternal Technical Specifications			
Ultrasound (FHR)	Measurement range	US	30 to 240 bpm
	Resolution	Display	1bpm
		Printer	1bpm
	jitter@200 bpm		≤3bpm

	Display update rate		0.25second
	Beat to bea change(max.) for ultrasound		28bpm
	US frequency		1MHz±5%Hz
TOCO	Measurement method		Strain gauge sensor element
	Sensitivity		1 unit =2.5g
	Resolution		1 unit
	Measurement range		500 units
	Baseline setting		0, 5,10, 15, 20 can be selective
	Update rate		0.25 second
	Auto offset correction		3 second after connecting the transducer
	Auto zero adjust		TOCO value is set to zero negative following a negative Measure value for 5 seconds
Auto Fetal Movement (AFM)	Technique		Pulsed Doppler ultrasound
	Range		0-100%
	Resolution		1%
	Automatic fetal movement actograph		
	Manual fetal movement marker		
NIBP	Operation mode		Manual/automatic/ STAT
	Measurement unit		mmHg / kPa selectable
	Test interval		0-480 minutes
	Accuracy		Max.Std.deviation:8 mmHg(1.1kPa)
			Max. mean Error: ±5mmHg(±0.7kPa)
	Measurement range	Systolic	30 to 270 mmHg(4 to 36 kPa)
		Diastolic	10 to 245 mmHg(1.5 to 32kPa)
		Mean	20 to 255 mmHg(2.5 to 34kPa)
	Pulse rate range		40~240bpm
	Over-pressure protection		Yes
Maternal ECG (MECG)	Heart rate range		30~300bpm
	Resolution		1bpm

	Accuracy	±1bpm/ ±1%
	Leads	I, II, III, aVL, aVR, aVF, V
	Sweep speed	12.5mm/s, 25mm/s, 50mm/s
	Gain selection	x 0.25, x0.5 ,x1,1, x2
	Operation mode	diagnostic, monitor, surgery
Maternal SpO_2 ($MSpO_2$)	Measurement range	0%-100%
	Resolution	1%
	Accuracy	±2%
	Pulse rate range accuracy	±3bpm
Temperature (TEMP)	Technique	Thermistor sensor CYSI 400 series compatible
	Measurement range	0℃-50℃
	Accuracy	±0.1℃

14.2 Safety

Electricity is in conformity with safety IEC60601-1.

The EMC of the equipment fulfills the requirements of the IEC 60601-1-2-2007 Group I of the class B

With regard to the anti-electric shock type, the equipment is class I equipment with the anti-electric shock degree of BF

14.3 Environment of Work

Temperature: 5 ° C ~ 40 ° C

Relative humidity: ≤ 80%

Pressure of air: 80.0 kPa, 106.0 kPa

14.4 Transportation and Storage Environment

Temperature: -20 ° C with +50 ° C

Relative humidity: ≤ 93%

Pressure of air: 60.0 kPa, 110.0 kPa

14.5Power

Power supply requirement:

Operating voltage: 100-240 VAC

Frequency: 50/60Hz;

Input power: 70 to 100 VA

Battery: 1800 mAh ±20%, Voltage: 14.8 V

Fuse:

External fuse: 250V T2 A

Internal fuse: 250V T2.5A

14.6Classification

According to the European Commission:

- Medical device: MDD 93/42/EEC
- Electric of the medical equipment, non-invasive monitor
- Classification of management: IIb
- Classification according to the anti-electric shock type
  Class I equipment with the anti-electric shock degree of BF
- Classification by the degree of protection against the harmful penetration of water

  General, not protected
- Classification according to the degree of safety in the presence of fuel gases of the anaesthetic hybrids gas and the air or flammable gases of the anaesthetic hybrids gas and of oxygen or nitrogen

The equipment is not adapted for a use in the presence of flammable gases anaesthesia.

- Classification according to the operating mode

  The apparatus can work uninterrupted.
- Method of classification according to disinfection method

  See the document in chapters 11.

15 Appendix 1

15.1 EMC

Guidance and manufacturer´s declaration – electromagnetic emission –

for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The Fetal Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of *the Fetal Monitor* should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	*The Fetal 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 emission CISPR 11	Class B	*The Mars B Fetal MONITOR* is suitable for use in all establishments, other than domestic establishments 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity –

for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The Mars B Fetal MONITOR is intended for use in the electromagnetic environment specified below. The customer or the user of *Mars B Fetal 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	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should

			be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of *the Mars B Fetal Monitor* requires continued operation during power mains interruptions, it is recommended that *the Mars B Fetal Monitor* be powered from an uninterruptible power supply or a battery.

Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity –

for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The Mars B Fetal MONITOR is intended for use in the electromagnetic environment specified below. The customer or the user of *Mars B Fetal 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 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *Mars B Fetal MONITOR*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]

			Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic 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 Mars B Fetal Monitor* is used exceeds the applicable RF compliance level above, *the Mars B Fetal Monitor* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Fetal Monitor.

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and *the Mars B Fetal MONITOR*			
The Mars B Fetal MONITOR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of *the Mars B Fetal MONITOR* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and *the Mars B Fetal 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)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

15.2Meaning of Icons

Sign	Significance
	A warning precedes an action which can involve the damage or by dysfunction of the Fetal maternal monitoring; or a warning precedes an action which can result in wounds or death for the patient or the user.
	Type BF Applied part symbol
	Go
	Stop
	Date of manufacture
	Use before this date
	Batch codes
	Manufacturer
	Attention, risk of electric shock
	Caution, hot Surface
	Alternating current
	Equipotentiality terminal
	Protection by earthing

***Disposal:* The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.**

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA. During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included. All components subject to wear are not included in the warranty. The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc.
The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed. The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.