



# FM5000C - FM5000PLUS $\left( \mathbf{\epsilon}_{0123} \right)$ Maternal/Fetal Monitor | User Manual

**IMPORTANTE** 

Leggere attentamente le istruzioni prima dell'utilizzo.

Read the instructions carefully before using the device. **IMPORTANT** 



Lisez attentivement la notice avant l'emploi.

Lea atentamente las instrucciones antes de utilizar el aparato. **IMPORTANTE** 

Ler atentamente as instruções antes de utilizar o aparelho.



# Preface

Thank you for purchasing our FM5000 maternal/ fetal patient monitor! This manual gives detailed description to the Monitor concerning its performance, operation, safety guide, and precautions. Reading through this manual is the first step to get familiar with the equipment and make the best use of it.

Following symbols indicates some important notes that you have to pay special attention to:

$\triangle$	Warning	Points to be noted to avoid injury to the patient and the operator.
①	Note	Important points to be noted.

#### **Intended Use**

This product is intended to be used in surgeries, ICU wards, CCU wards and other places requiring monitoring for patients. It can display in real time the fetal heart rate (FHR), TOCO, fetal movement mark, maternal heart rate, ECG, non-invasive blood pressure (NIBP), SpO<sub>2</sub>, pulse rate, RESP, and TEMP etc.

#### **Working Environment**

1. Working temperature: 5°C~40°C

2. Relative humidity: ≤80%

3. Atmospheric pressure: 860hPa~1060hPa

4. Supply voltage: 220V ±22V 5. Power frequency: 50Hz ± 1Hz

#### Storage Temperature

1. Ambient temperature: -20°C~55°C

2. Relative humidity: ≤95%

3. Atmospheric pressure: 50kPa~106kPa

Please read through this Manual carefully before use.



### **Contents**

Chapter	1 Safety Guide	1-1
1.1	Safety Information	1-1
1.2	Symbols	1-3
Chapter	2 Overview	2-1
2.1	Intended Use	2-1
2.2	Components	2-1
2.3	Contraindictions	2-1
2.4	Appearance Introduction	2-2
	2.4.1 Front View	2-2
	2.4.2 RightView	2-3
	2.4.3 LeftView	2-3
	2.4.4 RearView	2-3
	2.4.5 Bottom View	2-4
2.5	On-screen Display	2-4
Chapter	3 Installation	3-1
3.1	Unpack and Check	3-1
3.2	Connect the AC Power Cord	3-1
3.3	Turn on the Monitor	3-1
3.4	Connect the Sensors	3-2
Chapter	4 Patient Safety	4-1
4.1	Safety Instruction	4-1
4.2	Enviroment Requirements	4-1
4.3	Grounding protection	4-1
4.4	Equipotential Grounding	4-2
4.5	Condensation	
Chapter	5 Basic Operations	5-1
5.1	Using the Main Menu	
5.2	General Settings	5-1
	5.2.1 Setting the System time	
	5.2.2 Changing System Language	
	5.2.3 Adjusting Alarm Volume	
	5.2.4 AdjustingHeartbeat Volume	5-2
	5.2.5 AdjustingFHR Volume	5-2
	5.2.6 Adjusting Key Volume	
	5.2.7 Adjusting Screen Brightness	
5.3	Module Setup	
5.4	Monitor Information	
5.5	Demo Function	
5.6	Locking the Touch Screen	
5.7	Network Settings	
5.8	Freezing Waveform	
Chapter	_	
6.1	Admitting Patient	
	6.1.1 Discharging Patient	
6.2	Patient Case Management	6-2



	6.2.3	Import or Export Patient Case via USB Flash Disk	6-3		
Chapter	7 Use	er Screens	7-1		
7.1	Overv	view	7-1		
	7.1.1	Fetal Monitoring Screen	7-1		
	7.1.2 Mother/Fetus Monitoring Screen				
	7.1.3	Mother Monitoring Screen			
	7.1.4	List Screen			
	7.1.5	Trend Screen	7-4		
	7.1.6	OxyCRGScreen	7-5		
	7.1.7	Big FontScreen	7-6		
7.2	Swipe	e the Screen	7-6		
7.3	Tailo	ring Your Screens	7-7		
	7.3.1	Changing the Waveform Sweep Speed	7-7		
	7.3.2	Setting the DisplayColor	7-7		
	7.3.3	Setting the Waveform Display Style	7-7		
	7.3.4	Waveform Exchange	7-7		
Chapter	8 Ala	nrm	8-1		
8.1	Alarn	n Type	8-1		
8.2	Alarn	n Level	8-1		
8.3	Alarn	n Mode	8-2		
	8.3.1	Visual Alarm	8-2		
	8.3.2	Audio Alarm			
	8.3.3	Alarm Message	8-3		
	8.3.4	Alarm Parameter Flashing			
8.4	Adjus	sting the Alarm Volume	8-3		
	8.4.1	Adjusting the Minimum Alarm Volume			
	8.4.2	8.4.2 Adusting the Alarm Volume			
	8.4.3	Setting the Reminder Tone			
8.5	Alarn	n Settings			
	8.5.1	Setting the Alarm Level			
	8.5.2	Setting the Alarm Limit			
	8.5.3	Alarm Recording			
	8.5.4	Setting the Alarm Delay Time			
8.6		ng Alarms			
	8.6.1	Setting the Maximum Alarm Pause Time			
	8.6.2	Setting the Alarm Pause Time			
8.7		hing off Alarms			
	8.7.1	Switching off Individual Parameter Alarm			
	8.7.2	Switching off All Parameter Alarms			
8.8		ing Alarms			
8.9		n Reset			
8.10		n Presets			
8.11		k the Alarm System			
Chapter		ttery			
9.1		ral Introduction			
9.2		Battery Alarm			
9.3	9.3 Power Management9-2				



9.6	Batte	ry Recovery	9-3
Chapter	r 10 Re	view	10-1
10.	1 Trend	l GraphReview	10-1
10.	2 Trend	l Table Review	10-2
10.	3 NIBP	Measurement Review	10-3
10.	4 Alarn	n Event Review	10-4
10.	5 Wave	form Review	10-5
Chapter	r 11 Pri	inting	11-1
11.	1 Loadi	ing Recording Paper	11-1
11.	2 Printi	ng	11-2
	11.2.1	Real-time Printing	11-2
	11.2.2	Frozen printing	
	11.2.3	Stored Patient Case Printing	
	11.2.4	Printing Settings	
11.		Criterion	
Chapter		eaningand Disinfection	
12.		view	
12.		ning and Disinfection of the Monitor and Accessories	
	12.2.1	Cleaning and Disinfection of the Cuff	
	12.2.2	Cleaning the Belt	
-		nintenance	
13.		tenance Check	
13.		tenance Schedule	
13.		calibration	
13.		P Air Leakage Test	
13.		Calibration	
13.		h Screen Calibration	
_		tus Monitoring	
14.		rence between Antepartum and Intrapartum Monitor	
	14.1.1 14.1.2		
14.		Terms about Monitor	
14.	2 FHK 14.2.1		
	14.2.1	Connect the FHR Transducer  Cross-Channel Verification	
	14.2.2	Trace Separation	
	14.2.3	FHR Settings	
1	4.2.4.1	Setting the Source of Maternal Heart Rate	
	4.2.4.2	Setting the FHR Sound Channel	
14.		O Monitoring	
1 1.	10.2.1	Connect the TOCO Transducer	
	14.3.1	Setting the TOCO Zero Value	
14.		Counting	
	14.4.1	Counting FM manually	
	14.4.2	Counting FM automatically	
	14.4.3	Setting the FM Sensitivity Threshold	
	14.4.4	Setting the FM Counting Mode	
14.		-awakening Acoustic Stimulator	



Chapter 15	5 ECG Monitoring	15-1			
15.1	Overview	15-1			
15.2	ECG Display	15-1			
15.3	15.3 Safety Information				
15.4	Steps of Monitoring	15-3			
15	5.4.1	15-3			
15	5.4.1 Preparation	15-3			
15	5.4.2 Placement of ECG Electrodes	15-3			
15.4	1.2.1 Identifiers and Color Code of Electrodes				
15.4	1.2.2 Placement of 3-lead ECG Electrodes				
15.4	1.2.3 Placement of 5-lead ECG Electrodes	15-4			
15.4	Placement of Reformed 12-lead ECG Electrodes				
15.4	ECG Lead Connection Recommended for Surgical Patients				
15.5	Waveform quality	15-7			
15.6	ECG Settings	15-8			
15	5.6.1 Setting the Lead Type				
15	5.6.2 Setting the Lead Name	15-8			
15	5.6.3 Setting the Gain	15-9			
15	5.6.4 Setting the Filter Mode	15-9			
15	5.6.5 Setting the Calculation Channel	15-9			
15	5.6.6 Setting the Notch	15-10			
15.7	ST Segment Analysis	15-10			
15	5.7.1 About ST Segment Analysis	15-10			
15	5.7.2 Impact on ST-segment	15-10			
15	5.7.3 Enabling ST Segment Analysis	15-11			
15	5.7.4 Adjusting the ST Segment Analysis Point	15-11			
15.8	j j				
15	5.8.1 Enabling Arrhythmia Analysis				
15	5.8.2 Arrhythmia Alarm Settings	15-13			
15	5.8.3 Arrhythmia Relearning	15-13			
	5.8.4 Arrhythmia Review				
Chapter 16	6 RESP Monitoring	16-1			
16.1	Overview				
16.2	RESP Display				
16.3	Placing Electrodes for RESP Measurement				
16.4	RESP Settings	16-2			
16	6.4.1 Setting the Gain	16-2			
16	6.4.2 Setting the Apnea Alarm Time				
	6.4.3 Setting the RESP Lead				
16	6.4.4 Setting the RESP Filter				
Chapter 17	7 SpO <sub>2</sub> Monitoring	17-1			
17.1	Overview				
	7.1.1 Principle of Measuring SpO <sub>2</sub>				
17	7.1.2 Recognition of the type of SpO2 Sensor				
17.2	SpO2/PR Display				
17.3 Safety Information					
17.4	Steps of Monitoring	17-3			

### **User Manual**

17.6.1	Setting theIntelligent Alarm	17-5		
17.6.2	Setting the Pulse Sound	17-6		
17.6.3	Setting the Signal IQ	17-7		
17.6.4	Setting the Average Time	17-7		
17.6.5	Setting the Quick SpO <sub>2</sub>	17-7		
17.6.6	Setting the Calculation Sensitivity	17-7		
17.7 SPC	02 Accuracy Test	17-8		
17.8 Low	Perfusion Accuracy Test	17-8		
17.9 PR	Accuracy Test	17-9		
17.10 M	Iasimo Information	17-9		
Chapter 18 N	TBP Monitoring	18-1		
18.1 Ove	rview	18-1		
18.2 NIB	P Display	18-1		
18.3 Safe	ety Information	18-2		
18.4 NIB	SP Measurement	18-2		
18.4.1	Measurement Steps	18-2		
18.4.2	Operation Prompt	18-4		
18.4.3	18.4.3 Measurement Limitations			
18.5 NIB	P Settings	18-6		
18.5.1	Setting the Measure Mode	18-6		
18.5.2	Setting the Interval Time	18-6		
18.5.3	Setting the Pressure Unit	18-6		
18.5.4	Setting the Pre-inflation Value	18-6		
18.6 NIB	P Reset	18-7		
Chapter 19 T	EMP Monitoring	19-1		
19.1 Ove	rview	19-1		
19.2 TEN	MP Display	19-1		
19.3 Safe	ety Information	19-1		
19.4 Step	19.4 Steps of TEMP Measurement 19-2			
19.5 Sett	ing the TEMP Unit	19-2		
Appendix I	Accessories	I-1		
Appendix II	Product Specification	II-1		
Appendix III	System Alarm Message	III-1		
Appendix IV Factory Default SettingsIV				
Appendix V	EMC	V-1		



User manual of Specialized Fetal & Materna! Monitor

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### **Chapter 1** Safety Guide

#### 1.1 Safety Information

### **Warning**

• To warn you of the conditions where serious consequence, disadvantageous matters or danger may occur. Failure to comply with the warning will result in severe personal injury or death of the user or the patient.



#### Caution

• To indicate potential danger or unsafe operation. If not avoided, it may lead to mild personal injury, product malfunction, damages or property loss. It may also give rise to more severe harm.

### Attention

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

## **Warning**

- This monitor is used for monitoring the clinical patients, and only the doctors and nurses who are qualified through training can use this monitor.
- Check whether this instrument and its accessories can work normally and safely prior to use.
- The alarm volume and alarm limits shall be set for different patients. When a patient is monitored, the audible alarm system cannot be merely depended on. If the alarm volume is set too low or is completely turned off, the alarm will not be heard and the patient will be endangered. The most reliable patient monitoring method shall be keeping the patient under close surveillance.
- This instrument can only be connected to a power socket with protective grounding. If the
  power socket is not connected to grounding conductor, do not use this socket, but use the battery
  for power supply.
- Do not open the enclosure of this instrument to avoid the possible electric shock. The maintenance and upgrading of this instrument must be conducted by the service personnel trained and authorized by our company.
- The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. Keep the packaging materials out of the reach of the children.



- Do not use this instrument at the place where there are flammable articles such as anesthetic to prevent explosion or fire from happening.
- Please carefully install the power lines and the cables for various accessories to avoid entanglement or potential strangulation and keep the patient free from electrical interference.
- Do not use mobile phone near the monitor, because the mobile phone will generate a very strong radiation field and disturb the functions of the monitor.
- For the patient with pacemaker, cardiotachometer might measure the pacing pulsein case of cardiac arrest or arrhythmia. Do not completely rely on the alarm of cardiotachometer. The patient with pacemaker shall be closely monitored.
- The operators shall not touch the patients, tables and instruments during defibrillation. Before
  reusing thecables, check whether their functions are normal.
- The equipment connected with the monitor shall form an equipotential body (the protective grounding wire is effectively connected).
- When the monitor is used in conjunction with electrosurgery unit, the user (doctor or nurse) shall ensure the patients' safety.
- The physiological waveforms, physiological parameters and alarm message, etc. displayed by this monitor shall be for the doctors' reference only and cannot be directly used as the clinical treatment basis.
- The electromagnetic field will affect the performance of this monitor, so the use of the other equipments, for example Mobile phone, X-ray or MRI equipment, near this monitor must meet corresponding EMC requirements, because they will transmit high-strength electromagnetic radiation.
- Conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact any other conductive parts including earth.
- This is not a treatment device.
- Do not posit the equipment to make it difficult to operate the power plug which uses to isolate the equipment circuits electrically from the supply mains.
- The installation and replacement of fuse should be performed by trained and qualified serviceman.
- The use of this monitor is restricted to one patient at a time.
- When the monitor is used with HF surgical equipment, the transducer and the cables must be avoided conductive connection to the HF equipment to protect against burns to the patient.
- After defibrillation, the ECG wave will recover within 5s, others will recover within 10s.

### **△**Caution

- To avoid damage to this instrument and guarantee patient safety, please use the accessories designated in this user manual.
- Please properly install or move this instrument and prevent the instrument from being damaged due to fall, collision, strong vibration or other external mechanical forces.
- Before the instrument is switched on, please confirm that the power supply used meets the requirements for power supply voltage and frequency designated in the nameplate label or in the user manual of this instrument.
- When this instrument and its accessories are about to exceed the service life, they must be disposed of according to local relevant laws and regulations or the rules and regulations of the hospital.



### **Attention**

- Please install the equipment in a place that is convenient for observation, operation and maintenance.
- This user manual is based on the maximum configuration, and therefore some contents may not apply to your monitor.
- Please place this user manual near the instrument for easy and timely reference.
- This instrument cannot be used at home.
- The service life of the monitor is 5 years.
- The analysis report is for reference only and the doctor should sign to ensure the correctness.

### 1.2 Symbols

#### (1) Product Symbols

(1) Fronter Symbols			
$\triangle$	Caution		Refer to instruction manual/booklet
<b>┤</b>	Defibrillation-proof type BF applied part	4 <b>\\</b>	Defibrillation-proof type CF applied part
<u></u> 1	Battery indicator	$^{\sim}$	Dateof manufacture
0,0	On/Off key	SN	Serial number
$\sim$	AC power indicator	$\bigvee$	Equipotential
(M)	Freeze key	<del>2</del>	Network
***	Alarm reset key		NIBP start key
Ę	Print key	→()← TDV1	TOCO zero key
EC REP	Europeancommunity representative	IFXI	The monitor is Protectedfrom vertically falling water drops
No.	Manufacturer	IP67	The transducers are dust-tight and protected against the effects of temporary immersion in water
	Separate collection for electric and electronic equipment	Œ	Conformité Européenne Complies with medical device directive 93/42/EEC
<u></u>	Warning: Only use the ECG cable provided by Our company. Other types of ECG cable may decrease the defibrillation energy delivered to the patient.		



etr	This side up	r  t,	Maximum stacking layer
Ç ,	Fragile	- ;   ,	Keep dry
I	•	<u> </u>	,



### Chapter 2 Overview

The monitor is mainly used to monitor the fetus, the maternal uterine activity and vital signs. It can give alarms for fetus parameters and mother parameters and display, save and record the relevant data and waveform. Therefore, it is suitable for use in the parturient room, delivery room and antepartum examination room.

The monitor is equipped with a 12.1 inch TFT touch screen. All operations on the monitor can be performed by keys and touch screen.

The monitor can be configured with the maximum configuration including fetus parameter and maternal vital signs monitoring functions.

#### 2.1 Intended Use

The monitor is applicable to monitoring FHR, FM and TOCO as well as pregnant woman's and patient's ECG, PR, NIBP, SpO2, TEMP and RESP in clinic units.

#### 2.2 Components

The monitor is composed of the main unit (including battery, display screen, recorder and enclosure) and functional accessories (including ECG cable, NIBP cuff, SpO2 sensor, TEMP probe, FHR transducer, TOCO transducer, FM marker, and fetal acoustic stimulator).

#### 2.3 Contraindictions

None



### 2.4 Appearance Introduction

#### 2.4.1 Front View

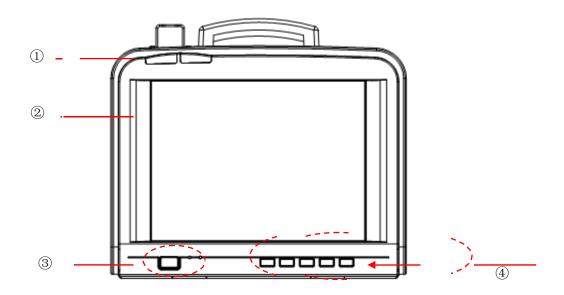


Figure 2-1Front view

1	Physiological alarm lamp(left); Technical alarm lamp (right)		
2	Display screen		
③ Power ON/OFF switch		ON/OFF	Power on: press to turn on the monitor when AC power supply is connected.  Power off: press and hold for 2 seconds to turn off the monitor.  There is an indicator inside the power ON/OFF switch. It turns on when the monitor is on and turns off when the monitor is off.
	~	AC indicator	On: when the monitor is connected with AC power supply Off: when the monitor is disconnected with AC power supply
	-+	Battery indicator	On: when the battery is being charged. Off: when no battery is installed or no AC power supply is connected Flash: when the monitor operates on battery power.
(4)	×	Freeze key	Press to freeze or unfreeze the waveforms on the screen.
	<u> </u>	Alarm reset key	Press to reset the alarm system.
	<b>L</b>	NIBP start key	Press to start or stop the NIBP measurement.
	È	Print key	Press to start printing or stop printing
	<b>→</b> 0←	TOCO zero key	Press to perform TOCO zeroing.



#### 2.4.2 RightView

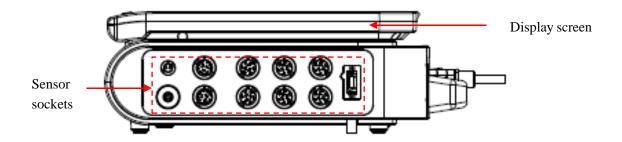


Figure 2-2 Left view

#### 2.4.3 LeftView

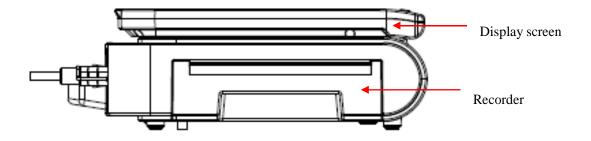


Figure 2-3 Left view

#### 2.4.4 RearView

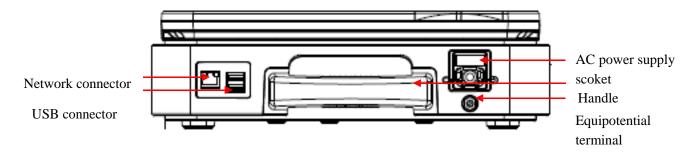


Figure 2-4Rear view



- The network connector is designed for Our company central monitoring system only.
- Only the analog or digital equipments complying with the specified IEC standards (like IEC 60950 for data processing equipments, IEC 60601-1 for medical equipments, etc.) are allowed



- to be connected to the monitor. The configuration of these equipments should comply with the valid version of IEC 60601-1-1 standards. The person who connects external equipments to the signal I/O ports should configure the medical system and ensure the medical system complies with IEC 60601-1-1 standards. If you have any question, please contact the supplier.
- If more than one external equipment are connected to the monitor at one time through the patient cable socket, network connector or other signal interfaces, the total leakage current should not exceed the allowance.

#### 2.4.5 **Bottom View**

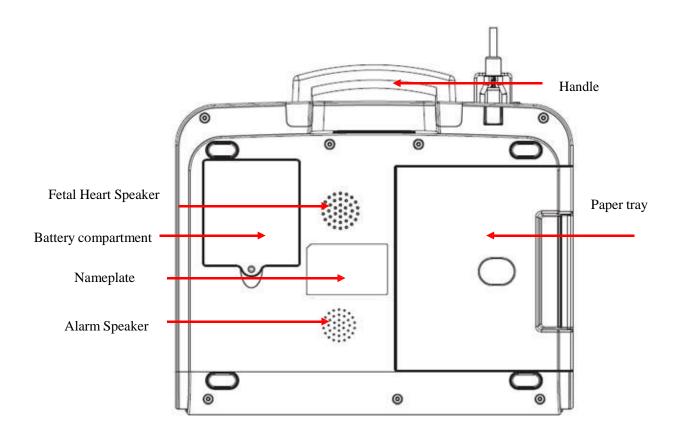


Figure 2-2 Bottom View

#### 2.5 On-screen Display

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



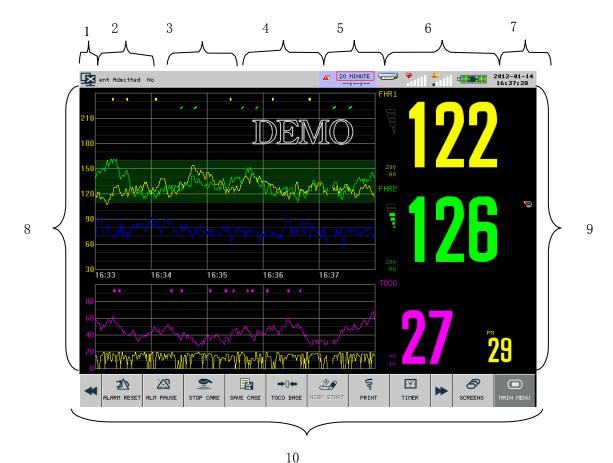


Figure 2-6 Main screen

#### 1. Network Connection Icon

- Show the network connection status between monitor and central monitoring system.
- indicating that the network between the monitor and central monitoring system has not been connected successfully;
- indicating that the network between the monitor and central monitoring system has been connected successfully;
- Click the network connection icon to directly access [NETWORK SET] menu.

#### 2. Patient information area

- If no patient is admitted, the promt message "No Patient Admitted" will be displayed here. If a patient has been admitted, the patient name, bed number, etc. will be displayed here circularly.
- Click here to directly access [PATIENT INFO] menu.

### 3. Technical alarm message area

Display technical alarm message and status message. When there are multiple messages, they will be displayed circularly.

#### 4. Physiological alarm message

- Display physiological alarm message. When there are multiple messages, they will be displayed circularly.
- Click here to directly access [ALARM RECALL] window.

#### 5. Timed monitoring information area

Display the timed monitoring information here;



- Click here to directly access [TIMER] menu.
- 6. Icons area
  - Printer icon: display the printing status. During printing, this icon will show moving paper. Click it to directly access [PRINT SETUP] menu.
  - FHR volume icon: click to adjust the FHR volume directly.
  - Alarm volume icon: clike to adjust the alarm volume directly.
  - Battery icon: display the battery charge level. Click to directly access [POWER MANAGE] menu.
- 7. System time
  - Display the system time
  - Click here to directly access [DATETIME SETUP] menu.
- 8. Waveform area
  - Display the measurement waveforms with the waveform name at the left top corner.
  - Click the waveform area and the corresponding setup menu will be displayed.
- 9. Parameter area
  - Display the measured value and the set alarm limit of each measurement parameter.
  - The color of a certain parameter is the same as that of its waveform.
  - Click each parameter area and the corresponding setup menu will be displayed.
- 10. On-screen keys



- Click each on-screen key and the corresponding setup menu will be displayed or a certain operation will be performed.
- Click or to show more on-screen keys.



### **Chapter 3** Installation

### 3.1 Unpack and Check

Carefully unpack monitor and accessories from the box, and save the packaging materials for later transport or storage. Please check the accessories according to the packing list. Check if there is any mechanical damage. Check all the external wires and connect accessories for test. If there is any question, please contact our sales department or agency immediately.

#### 3.2 Connect the AC Power Cord

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

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

### ⚠Note

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

#### 3.3 Turn on the Monitor

Press the power on/off switch on the front panel and the system begains self-test. The physiological alarm lamp and technical alarm lamp turn red and blue respectively, and then turn yellow and off respectively. The system will enter the main screen and gives a beep at the same time after showing the company logo and loading configuration files.



### **⚠** Note

- If there are significant errors in the self-test, the system will alarm.
- Check all monitoring functions to ensure that the monitor is functional.
- Turn on the monitor again one minute after turning off.

### ⚠ Warning

 If any damage to the monitor or an error message is found, do not use this monitor for patient monitoring. Please contact the biomedical engineer of your hospital or maintenance engineer of Our company.

#### 3.4 Connect the Sensors

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



### **Chapter 4** Patient Safety

### 4.1 Safety Instruction

The design of the fetal& maternal monitor complies with the international safety standard regarding medical electrical equipment. The monitorhasthe functions of defibrillation protection with floating input and surgical electrotome protection. Use the correct electrodes and place them according to the guidance of the manufacturer, andthe display will resume 10 seconds after defibrillation.

#### 4.2 Environment Requirements

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

Vibration, dust, corrosives or explosive gas, extreme temperature and humidity should be avoided at the place where the monitor is used.

If the monitor is installed in a cabinet, enough space in front and behind should be left for convenient operation, maintenance and repair. The monitor should be at least 2 inches or 5 centimeters away from around the cabinet for good ventilation.

The monitoring system should be in the ambient temperature  $5\,^{\circ}\text{C} \sim 40\,^{\circ}\text{C}$  (runing) to satisfise the requirements, An ambient environment out of this range may impair the instruments accuracy and cause damages to its components and circuits.

### 4.3 Grounding protection

To protect the patients and operator, the enclosure of the monitor must be grounded. The monitor is equipped with a removable three-wire cable. When the cable plugs in a matching plug connector, the grounding wire of the power line ground the monitor. In case a three-plug connector is not available, the electrical operating staff should be consulted.



#### Replacement of the three-plug connector with a two-plug connector is strictly prohibited.

The grounding wire should be connected with the equipotential grounding terminal of the instrument. The instrument users who do not know whether a given combination of instruments may invite dangers, e.g. due to accumulations of leaked currents should consult relevant manufactures or experts in this field so as to



guarantee that the required safety of the combined instruments are not compromised when the given combination is in use.

#### 4.4 Equipotential Grounding

The primary protection of the instrument is embodied in the building protective grounding (protective ground) system by means of power plugs grounding. The multi-parameter monitor should be separately connected with the equipotential grounding system for examinations of hearts or skulls. One end of the euquipotential grounding leads (potential equilizing leads)should be connected onto the equipotential grounding terminals on the rear panel of the instrument and the other should be connected onto one connector of the equipotential system. The equipotential grounding system should be in place for safety functions of the protective grounding leads in case of any damage to the protective grounding system. Cardiac or brain examinations should be conducted only in the rooms equipped with protective grounding systems. A check of the instruments should be conducted to guarantee the instruments are in good repair before each examination. The cables connecting with patients and instruments should be guaranteed not having been subjected to electrolytic pollution.



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

#### 4.5 Condensation

The working instruments should be guaranteed not to form any condensation. Transferring of the instrument from one room to another may cause condensation on the instrument. This is attributed to its exposure to humid air at different temperatures. Unnecessary problems can be avoided by placing the instrument in a dry place before putting it into use.

Note: Condensation is defined as coagulation of gases or liquids when cooled, e.g. water vapor when cooled is transformed into water and water when cooled into ice. The lower the temperature is, the faster condensation is formed.



- The monitor is prohibited to use in the presence of combustible anesthetics so as to avoid any risk of explosions.
- Do not operate the monitor in the MRI scanning process, or you could be burnt by the induced current.



### **Chapter 5 Basic Operations**

### 5.1 Using the Main Menu

How to access [Main Menu]:

Click the on-screen key to access [MAIN MENU] and perform operations and settings.



Figure 5-1 Main menu



• All settings you've made will be saved and memorized by the system without being changed due to power failure or power interruption, unless you restore the factory default settings manually. In case of power interruption, the mointor will save all the settings and saved patient data; when restarting the monitor, the monitor will restore to the settings before power interruption.

### 5.2 General Settings

#### 5.2.1 Setting the System time

There are two methods of setting the system time:

- 1. Click the system time area to enter the [DATETIME SETUP] menu;
- 2. Or access [MAIN MENU] → [MAINTAIN] → [MONITOR SETUP] → [TIME SETUP];
- 3. Set the system time according to your local time.



#### 5.2.2 Changing System Language

- 1. Access [MAIN MENU] → [MAINTAIN] and enter the password;
- 2. Click [LANGUAGE] to select the required system language.

#### 5.2.3 Adjusting Alarm Volume

For specific methods of adjusting alarm volume, please refer to *ALARM*.

#### 5.2.4 AdjustingHeartbeat Volume

- 1. Access [MAIN MENU] →[SELECTION] →[BEAT VOL];
- 2. Select the heartbeat volume in the pop-up list box;
- 3. Available volume levels are 0 to 6. 0 means off and 6 is the maximum volume.

#### 5.2.5 AdjustingFHR Volume

There are two methods of adjusting the FHR volume:

- 1. Access [MAIN MENU] →[SELECTION] →[FHR VOL];
- 2. Or click FHR volume icon ;
- 3. Select the FHR volume in the pop-up list box;
- 4. Available volume levels are 0 to 6. 0 means off and 6 is the maximum volume.

When the FHR volume is 0, the FHR volume icon turns to the indicating the FHR volume is 0.

#### 5.2.6 Adjusting Key Volume

- Access [MAIN MENU]→[SELECTION]→[KEY VOL];
- 2. Select the key volume in the pop-up list box;
- 3. Available volume levels are 0 to 6. 0 means off and 6 is the maximum volume.

#### 5.2.7 Adjusting Screen Brightness

- 1. Access [MAIN MENU]→[SELECTION]→[LCD LIGHT];
- 2. Select the screen brightness level in the pop-up list box;
- 3. Available brightness levels are 1 to 6. 1 is the least brightness and 6is the brightest.



#### 5.3 Module Setup

- 1. Access [MAIN MENU]→[MONITOR SETUP]→[MODULE SETUP];
- 2. Click the a certain parameter module to enable or disable its measurement function;

The fetal module defaults to on under fetal monitoring screen and mother/fetus monitoring screen and cannot be disabled. While the fetal module defaults to off under mothering screen, trend screen and oxyCRG screen and cannot be enabled.

#### **5.4** Monitor Information

Monitor information is mainly for viewing the software version information operated by the monitor, so as to facilitate the manufacturer to maintain and trace the monitor.

Access [MAIN MENU] and click [INFO] to view the software version information.

#### 5.5 Demo Function

To enable Demo function:

- 1. Access [MAIN MENU];
- 2. Click [DEMO] and enter the password



Demo waveform is a kind of simulation of waveforms, which is made by the manufacturer only to demonstrate the machine performanceand help users to conduct training. In actual clinical use, the demo function should be disabled, because the medical staff may mistake it as the monitoring waveforms and parameters of the patient, which affects monitoring and delays diagnosis and treatment.

### **5.6** Locking the Touch Screen

To lock the touch screen:

Press on-screen key and hold for more than three seconds until the turns to , which indicates the touch screen is locked.

To unlock the touch screen:

Press and hold for more than three seconds until it turns to , which indicates the touch screen is unlocked.



#### 5.7 Network Settings

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

- Click the network connection status icon to enter [NETWORK SET] menu;
- 2. Click [NET BED] to enter the network bed number of this monitor on central monitoring system. Valid range is 1 to 64;
- 3. Click [IP ADDRESS] to enter the IP address of this monitor, for example, 200.200.200.X. The valid range of X is 1∼254. If the entered value is out of this range, the valid range will be displayed.
- 4. Click [MAC] to enter the MAC address of this monitor;
- 5. Click [SUBNET MASK] to enter the subnet mask of this monitor;
- Click [SERVER IP] to enter the IP address of the central monitoring system. The server IP and IP address of the monitor must be in the same network segment.

How to recognize whether the network has been connected successfully:

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

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

### **Attention**

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

### 5.8 Freezing Waveform

#### How to freeze waveforms on the screen:

- 1. Press the key on the front panel or click [FROZEN] on-screen key;
- 2. The on-screen key area turns to the figure as below:



**User Manual** 



3. All displayed waveforms are frozen without being refreshed or scrolling. But the measured parameter values are refreshed normally.





#### How to view frozen waveforms:

The users can freeze the waveforms on the screen during patient monitoring and view the waveforms in detail. Totally 240s frozen maternal parameter waveforms and 60h frozen fetal waveform can be reviewed on this monitor.

- 1. Under frozen waveform status, click [PRE PAGE] or [NEXT PAGE] to view the frozen waveforms on previous page or next page respectively;
- 2. Click [FIRST PAGE] or [LAST PAGE] to view the frozen waveforms on the first page or on the last page respectively;
- 3. Click [BACK] or press the key to unfreeze the displayed waveforms.

#### How to record the frozen waveforms:

Please refer to *Printing* for the specific steps of recording the frozen waveforms.



### **Chapter 6 Patient Management**

#### **6.1 Admitting Patient**

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

#### To admit a patient:

- 1. Click patient information area or click [PAT MANAGE] on-screen key and the [PATIENT MANAGE] menu will displayed.
- 2. If a patient has been admitted, please click [DISCHARGE] to discharge the patient;
- 3. If no patient is admitted, please enter the patient information in detail, especially for the pacemaker status. If you set the item [PACE] to [ON], when pacemaker signal is detected, the symbol will appear above the ECG waveform and the icon will appear in the ECG parameter area. If the item [PACE] is set to [Off], you will see the icon in the ECG parameter area.
- 4. Click [ADMIT] and a dislogbox "Will erase previous patient's hist data! ADMIT?" will be displayed. Select [Yes] to admit the patient, and the [ADMIT] item turns to [DISCHARGE]; select [No], the patient will not be admitted.

### ⚠ Warning

- When change the patient type or admit a new patient, the monitor will restore to the alarm settings of that patient type set previously. Therefore, the users should check whether the alarm settings are suitable for the patient prior to monitoring.
- For patients without pacemaker, you should set [PACE] to [OFF]; otherwise, the system cannot detect arrhythmias associated with ventricular premature beats (including PVCs count) as well as perform ST segment analysis.
- For patients with pacemaker, you should set [PACE] to [ON]; otherwise, pacing pulse may be counted into normal QRS waves, causing the alarm "ECG signal is too weak" cannot be detected.

### **Attention**

- If the patient information is wrong, it will be impossible to print the correct basic information and auto scoring information. Discharge the patient before admitting a new patient, or the monitor will auto take the previous patient as the current patient.
- After discharging the patient, the [PACE] defaults to [OFF].



#### 6.1.1 **Discharging Patient**

How to discharge a patient:

- Click patient information area or click [PAT MANAGE] on-screen key and the [PATIENT MANAGE]menu will displayed.
- 2. Click [Discharge] and the patient will be discharged.
- 3. Then the patient information area shows prompt message "No Patient Admitted".

#### **6.2** Patient Case Management

#### 6.2.1 Save Patient Case

The patient cases can be saved manully or automatically. Saving patient case manually means the patient cases are saved manully by users during real-time monitoring; while saving patient case automatically means a new patient case will generate automatically during real-time printing.

How to save patient case manually:

- 1. Access [MAIN MENU]→[Case List]
- 2. Click [Case save] and set it to [ON]. If [Case save] is set to [OFF], no patient cases will be saved.
- 3. During monitoring, click [SAVE CASE] on-screen key and start to save the patient case. Any patient case which has been saved for more than 10 seconds will be stored after pressing the [Stop Save] on-screen key;
- 4. All the saved patient cases can be viewed in the [Case list] window.

How to save patient case automatically:

- 1. Access [MAIN MENU]→[Case List]
- 2. Click [Case save] and set it to [ON]. If [Case save] is set to [OFF], no patient cases will be saved.
- 3. Click [Least time] and select the least print time so that the printed waveform can be saved as a patient case. Available options include 5 minutes, 10 minutes, 15 minutes and 20 minutes. For example, 5 minutes means if the print time for real-time fetal waveform printing is less than 5 minutes, the printed waveform will not be saved as a patient case in [Case List] window; and so on.
- 4. All the saved patient cases can be viewed in [Case List] window.

#### 6.2.2 View Patient Case

All the saved patient cases can be viewed, deleted and loaded in the [Case list] window. The specific steps are as follows:

- 1. Access [MAIN MENU]→[Case List]→[Case list];
- 2. The [Case list (SD)] window displays all the saved patient cases. [Case list (SD)] means the displayed



patient cases are saved in the SD card.

- 3. Click or and view the patient cases not in current page;
- 4. Click [Delete All] and all the patient cases in the case list window will be deleted;
- 5. Select a certain patient case and view it in the [Patient Review]. Click [Delete] and this patient case will be deleted; click [Load] and enter the patient case review interface where the users can view this patient case in detail and print it.

#### 6.2.3 Import or Export Patient Case via USB Flash Disk

The monitor allows you to import or export patient cases via USB flash disk. Specific methods are as follows:

- 1. Connect the USB flash disk to your computer and format it. Select FAT or FAT32 as the file system format. Remove the USB disk when formatting is finished.
- 2. Connect the USB flash disk to your monitor;
- 3. Access [MAIN MENU]→[Case List]→[Case list];
- 4. If the items [Remove USB] and [USB Copy] appear in the case list window, the monitor has recognized the USB flash disk; or please reconnect the USB flash disk.
- 5. To export patient cases, select[USB Copy] and a dialogue box will appear, and then select[Copy to USB] to export all patient cases to USB flash disk; oryou can also select a certain patient, and then select [Copy to USB] and this patient case will be exported to the USB flash disk;
- 6. To import patient cases from the USB flash disk to the case list window, select [USB Copy] and a dialogue box will appear, select [Enter USB Case List], then select[USB Copy], and then select [Copy to SYS]. You can also select a certain case in the [Case list (USB)]windowand then select [Copy to SYS] to import this patient case to the system.
- 7. The patient cases in the USB flash disk can also be loaded or deleted in the case list window. The specific methods are the same as that of the patient cases in the system. When entering the USB case list window, the window name will be [Case List (USB)].
- 8. Click [Remove USB] and disconnect the USB flash disk from the monitor;
- 9. Connect the USB flash disk to the computer and store the patient cases.



## **Chapter 7** User Screens

#### 7.1 Overview

The monitor provides several screens for the user to select, including fetal monitoring screen, mother/fetus monitoring screen, mother monitoring screen, list screen, trend screen, oxyCRG screen and big font screen. User can get different screen messages from different screens.

#### 7.1.1 Fetal Monitoring Screen

You can see the FHR value, FHR trace, TOCO value, TOCO waveform, manual/auto FM mark and auto FM waveform on the fetal monitoring screen.

To open the fetal monitoring screen:

- (a) Click [SCREENS] on-screen key;
- (b) Or access [MAIN MENU] and select [SCREENS]
- (c) Select [FETAL SCREEN] to open the fetal monitoring screen, as shown below:

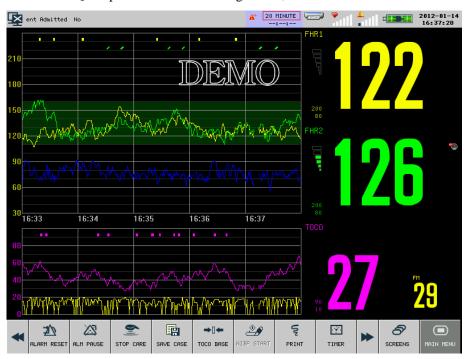


Figure 7-1Fetalmonitoring screen



#### 7.1.2 Mother/Fetus Monitoring Screen

The mother/fetus monitoring screen can display fetal parameter value and waveform as well as mother parameter value and waveform simultaneously. It is especially suitable for use in the delivery room.

To open the mother/fetus monitoring screen:

- (d) Click [SCREENS] on-screen key;
- (e) Or access [MAIN MENU] and select [SCREENS]
- (f) Select [MOTHER/FETUS CARE FACE] to open the mother/fetus monitoring screen, as shown below:

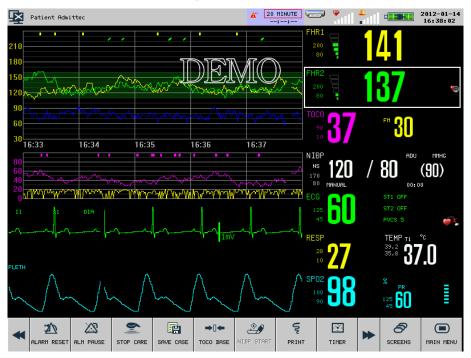


Figure 7-2 Mother/fetus monitoring screen

#### 7.1.3 **Mother Monitoring Screen**

The mother monitoring screen can only display mother parameter value and waveform. Up to 4 channels of waveform can be displayed with a separate parameter area.

To open the mother monitoring screen:

- (a) Click [SCREENS] on-screen key;
- (b) Or access [MAIN MENU] and select [SCREENS]
- (c) Select [MOTHER CARE FACE] to open the list screen, as shown below:



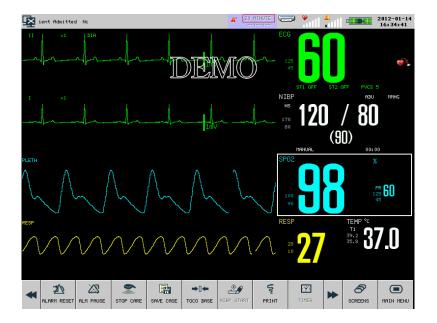


Figure 7-3 Mother monitoring screen

#### 7.1.4 List Screen

List screen can display the list of the measured values for parameters. The list occupieshalfof the entire waveform area. On the list screen, you can review the recently measured data, which is stored 10groups per page.

To open the list screen:

- (d) Click [SCREENS] on-screen key;
- (e) Or access [MAIN MENU] and select [SCREENS]
- (f) Select [LIST FACE] to open the mother monitoring screen, as shown below:

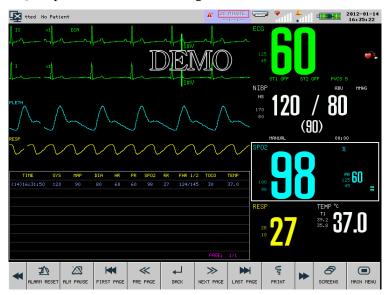


Figure 7-4 List screen



Under the list screen, you can activate the FETAL module to display the fetus parameter value and waveform. To activate the FETAL module, access[MAIN MENU]  $\rightarrow$ [MONITOR SETUP]  $\rightarrow$ [MODULE SETUP] and set [FETAL] to [ON].

#### 7.1.5 Trend Screen

What displayed on the trendscreen is the dynamic short tendency chart. From the dynamic short tendency chart, you can see the recent tendency of each parameter. The label of the tendency is displayed above each tendency chart, with the scale on the leftand the time below, as shown in the figure below:

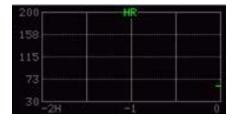


Figure 7-5 HR dynamic short tendency

The position of the dynamic short tendency chart of each parameter is not fixed. You can change the position of the tendency chart as needed. Take the SpO2 dynamic short tendency for example, with the steps as follows: Select the SPO2 dynamic short tendency and select HR in the pop-up list, and then the HR dynamic short tendency appears at the original position of  $SpO_2$  dynamic short tendency.

To open the trend screen:

- (a) Click [SCREENS] on-screen key;
- (b) Or access [MAIN MENU] and select [SCREENS]
- (c) Select [TRENDSCREEN] to open the trend screen, as shown below:

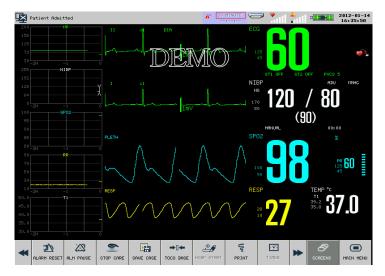


Figure 7-6 Trendscreen



Position of short tendency chart

Short tendency chart is located at the left of the corresponding waveform in the waveform area with the same as that of the corresponding parameter and waveform.

Tendency length

The dynamic tendency length is 2hours, with the right end of the tendency chart being 0h and the left end being 2h.

#### 7.1.6 OxyCRGScreen

OxyCRG screen displays the oxyCRG chart which is comprised of HR tendency, SPO2 tendency and RR tendency or compressed respiratory wave and occupies one half of the entire waveform area.

To open the OXYCRGscreen:

- (a) Click [SCREENS] on-screen key;
- (b) Or access [MAIN MENU] and select [SCREENS]
- (c) Select [OXYCRGSCREEN] to open the oxyCRG screen, as shown below:

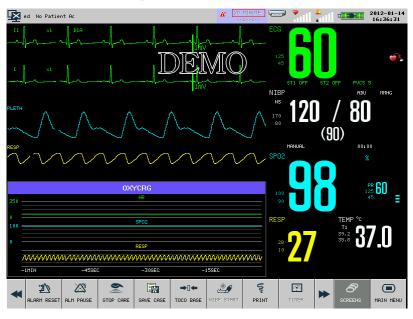


Figure 7-7 OxyCRG screen

■ Select the length of time for OXYCRGchart

Select the oxyCRG chart and one menu [OXYCRG] will be displayed. Select [TIME] and adjust the length of time among 1 mimute, 2 mimutes and 4 minutes.

■ Display compressed respiratory wave or RR tendency

Select the oxyCRG chartand one menu[OXYCRG] will be displayed. Select [TYPE] and select [RESP WAVE] or [RR] to display compressed respiratory wave or RR trendency respectively.



#### 7.1.7 **Big FontScreen**

Big font screen can display four parameters with super-large font, which facilitates the doctor to observe the monitored value within a certain distance.

The users can select to display the mother parameters. Take FHR1 as an example: select the FHR1 parameter area and the menu [FHR1 SETUP] will be displayed; select [SUBMIT MODULE] and then select [RESP]; then the RESP parameter will appear at the position of FHR1 parameter.

To open the Big font screen:

- (a) Click [SCREENS] on-screen key;
- (b) Or access [MAIN MENU] and select [SCREENS]
- (c) Select [BIG FONT] to open the big font screen, as shown below:

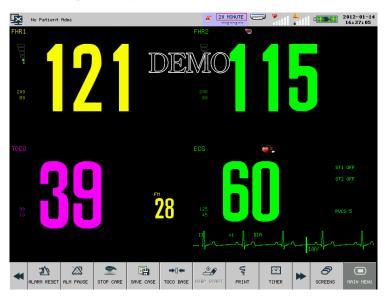


Figure 7-8 Big font screen

### 7.2 Swipe the Screen

The monitor allows you to swipe the screen up and down or left and right to switch the screens.

#### 1. Swipe Up and Down

Byswiping the screen from up to down, the waveform area and parameter area will expand and hide the screen keys so that the doctor can observe the measured data more clearly. Swipe the screen from down to up to show the screen keys.

#### 2. Swipe Left and Right

Byswiping the screen from right to left, the screens will be switched in such sequence as[FETAL SCREEN]

→ [MOTHER/FETUS CARE FACE] → [MOTHER CARE FACE] → [LIST FACE] → [TREND SCREEN] → [OXYCRG SCREEN] → [BIG FONT] → [FETAL SCREEN]. If you swipe the screen from left to right, the screens will be switched in the reverse sequence.



## 7.3 Tailoring Your Screens

You can tailor your monitor's screen by setting:

- Waveform sweep speed;
- Waveform display style;
- Parameter and waveform display color;
- Waveform exchange;
- ◆ Gain.

#### 7.3.1 Changing the Waveform Sweep Speed

- Select fetal monitoring waveform, for example FHR waveform, and the menu [FHR SETUP] will be displayed. Select [SWEEP] and choose the sweep speed for FHR waveform from [1 CM/MIN], [2 CM/MIN] and [3 CM/MIN].
- 2. Select mother monitoring waveform, for example ECG waveform, and the menu [ECG WAVE] will be displayed. Select [SWEEP] and choose the sweep speed for ECG waveform from [6.25mm/s], [12.5mm/s], [25.0mm/s] and [50.0mm/s].

### 7.3.2 **Setting the DisplayColor**

- 1. Select fetal monitoring waveform, for example FHR1 waveform, and the menu [FHR SETUP] will be displayed. Select [FHR1 DISP COLOR] and choose the display color for FHR1 waveform from [GREEN], [CYAN], [RED], [YELLOW], [WHITE], [BLUE] and [PURPLE];
- Select mother monitoring waveform, for example ECG waveform, and the menu [ECG WAVE] will be displayed. Select [WAVE COLOR] and choose the display color for ECG waveform from [GREEN], [CYAN], [RED], [YELLOW], [WHITE], [BLUE] and [PURPLE].

#### 7.3.3 Setting the Waveform Display Style

This operation is not available for fetal monitoring waveforms.

- Select mother monitoring waveform, for example ECG waveform, and the menu [ECG WAVE] will be displayed.
- 2. Select [WAVE TYPE] and choose the waveform display style from [LINE], [COLOR] and [BOLD]

#### 7.3.4 Waveform Exchange

This operation is not available for fetal monitoring waveforms.

- Select mother monitoring waveform, for example ECG waveform, and the menu [ECG WAVE] will be displayed.
- 2. Select [WAVE EXCHANGE] and select the waveform to be exchanged.



## Chapter 8 Alarm

### 8.1 Alarm Type

The monitor can give an alarm of two types, physiological alarm and technical alarm.

#### (1) Physiological alarm

Physiological alarm is usually caused by a certain physiological parameter of the patient which exceeds the set upper/lower limit scope or by the physiological abnormality of the patient. The alarm message of the physiological alarm will appear in the physiological alarm message area.

#### (2) Technical alarm

The technical alarm is also referred to as a system error message, indicating the alarm is caused by a misoperation or system malfunction thereby causing improper operation of a system function or distortion of monitored results. The alarm message of the technical alarm will appear in the technical alarm message area.

Prompt message is to display the information relative to the system conditions themselves, which have nothing to do with the patient's vital sign. Prompt message will appear in the prompt message area.

#### 8.2 Alarm Level

The monitor can give an alarm in three levels:high, medium and low, based on the severity.

	Physiological alarm	Technical alarm
High level	The patient is in a critical condition, endangering the patient's life, emergent attention required.	Indicate a severe device malfunction or an improper operation, which could make it possible that the monitor cannot detect critical patient status and thus threaten the patient's life, such as low battery and so forth.
Medium level	The patient's vital signs are abnormal, relevant measures and treatment are immediately required.	
Low level	The patient's vital signs are abnormal and relevant measures and treatment may be required.	Indicate a device malfunction or an improper operation, which may compromise a certain monitoring function but will not threaten the patient's life.

All alarm levels for technical alarms and some physiological alarms have be set before the monitors are delivered, and the users are not allowed to change them. But the level of some physiological alarms can be modified.



### 8.3 Alarm Mode

When giving an alarm, the monitor will prompt the users in both audio and visual modes:

- Visual alarm
- Audio Alarm
- Alarm Message
- Parameter's flashing

In which light signal, audio signal and alarm message are differentiated with those in different alarm levels.

#### 8.3.1 Visual Alarm

The alarm lamp will flash at different frequencies and in different colors for different alarm levels. Physiological alarm:

- High level alarm: the left alarm lamp flashes twice every second in red;
- Medium level alarm: the left alarm lamp flashes once every two second in yellow;
- Low level alarm: the left alarm lamp turns yellow without flashing.

#### Technical alarm:

- High level alarm: the left alarm lamp flashes twice every second in red;
- Medium level alarm: the left alarm lamp flashes once every two second in yellow;
- Low level alarm: the right alarm lamp turns cyan without flashing.

When physiological alarm and technical alarm are triggered simultaneously, the flashing frequency and color of alarm lamp are based on alarm level priority. But when only physiological alarm and technical alarm of the same level are triggered, the flashing frequency and color of alarm indicator are that of physiological alarm.

#### 8.3.2 Audio Alarm

The audio alarm is to prompt the alarm in different levels of severity with different sounds.

- High level alarm: Do-Do-Do-Do-Do-Do-Do-Do-Do-Do.
- Medium level alarm: Do-Do-Do.
- Low level alarm: Do.

## $ilde{ ext{$igwedge}}$ Warning

- Both bedside machines and central monitoring systems have audio alarm function.
- Once the bedside machine is connected to a central monitoring system, although both the bedside machine and central monitoring system can coordinate the alarm level as well as the the alarm limit, the bedside machine may not give an alarm simultaneously when the central monitoring system is giving an alarm due to the alarm delay function of the bedside machine.



• When alarms of multiple alarm level are triggered simultaneously, the monitor will give the alarm in audio and visual mode based on alarm level priority.

## 8.3.3 Alarm Message

When there is a technical or physiological alarm, you will find a technical or physiological alarm message in the technical alarm message area or physiological alarm message area respectively. Physiological alarm messages for different levels of alarms are displayed in different background colors:

- High level alarm: red (Physiological alarm), blue(Technical alarm)
- Medium level alarm: yellow
- Low level alarm: yellow

Messages for different levels starting with different marks:

- High level alarm: \*\*\*
- Medium level alarm:\*\*
- Low level alarm: \*

#### 8.3.4 Alarm Parameter Flashing

When a parameter is alarming, the parameter will flash once every second. The upper alarm limit or lower alarm limit will also flash in the same frequency indicating the parameter has violated the upper limit or lower limit repectively.

## 8.4 Adjusting the Alarm Volume

#### 8.4.1 Adjusting the Minimum Alarm Volume

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

How to adjust the minimum alarm volume:

- 1 Access [MAIN MENU], press [MAINTAIN] and enter the password.
- 2 Select [ALARM SETUP];
- 3 Select [MIN ALARM VOL] to adjust the minimum alarm volume from 0 to 5.

#### 8.4.2 Adusting the Alarm Volume

There are two ways to adjust the alarm volume:

1 Access [MAIN MENU], select [SELECTION], select [ALARM VOL] and then adjust the alarm



volume in the pop-up list box from X to 6. X is the set minimum alarm volume;

2 Or press alarm volue icon to adjust the alarm volume in the pop-up list box from X to 6. X is the set minimum alarm volume.

When the alarm volume is set to 0, the icon will appear on the screen indicating the alarm volume is 0.

The alarm signal sound pressure level from level 0 to level 6 of this monitor is between 45 dB to 85dB.

## ⚠ Warning

- If alarm volume is 0, you will not hear the alarm sound when there is an alarm. Please set the alarm volume with caution.
- Auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm conditions.

#### 8.4.3 **Setting the Reminder Tone**

When alarms are switched off, the monitor will give periodic reminder signal: Ting---Ting---. How to set reminder tone:

- 1 Access [MAIN MENU], select [MAINTAIN] and enter the password.
- 2 Select [ALARM SETUP];
- 3 Select [REMINDER TONE] toadjust the reminder volume from 0 to 6. 0 means off and there is no reminder tone when alarms are switched off. 6 means the maximum reminder tone.
- Select [REMINDER INTERVAL] to adjust the reminder interval. Available options include [OFF], [6SEC], [15SEC], [30SEC], [60SEC], [300SEC] and [600SEC].

## 8.5 Alarm Settings

### 8.5.1 Setting the Alarm Level

How to set the alarm level, here we take RESP as an example:

- 1. Select RESP parameter area;
- 2. Select [ALM LEV];
- 3. Select the alarm level in the pop-up list box.

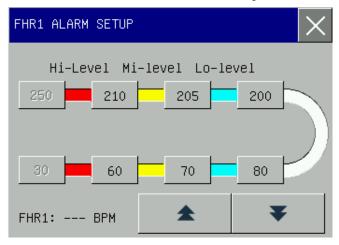


#### 8.5.2 **Setting the Alarm Limit**

The smart alarm system is the feature of our company. For smart alarm parameter, the users can set the upper and lower limit of the high level alarm, medium level alarm and low level alarm together with no need to set the alarm level. When the measured value of a certain parameter violates the alarm limits, the monitor will auto give a corresponding alarm according to the alarm limits of which alarm level having been violated. For normal alarm parameter, the users need to set the alarm level and only the alarm limits of the selected alarm level can be set. When the measured value violates the alarm limits, the monitor will only give alarms of the selected alarm level. Except for TEMP and RESP parameter, the alarm of ECG, NIBP, PR and SpO2 parameter is smart alarm.

The methods to set the alarm limits for all smart alarm parameters are similar, and here we take FHR1 as an example:

- 1. Select FHR1 parameter area and the [FHR1 SETUP] menu will be displayed;
- 2. Select [FHR1 ALARM SETUP] and enter FHR1 alarm limit setup menu, as shown below:



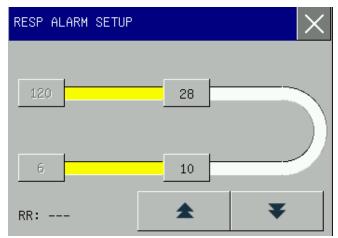
Here we can set the alarm limits of high level alarm, medium level alarm and low level alarm together.

- [Hi-Level] means high level alarm. When the measured value is higher than the upper limit of high level alarm or lower than the lower limit of high level alarm, the monitor will give a high level alarm.
- [Mi-level] means medium level alarm. When the measured value isbetween the the upper limit of high level alarm and medium level alarm, or between the lower limit of medium level alarm and high level alarm, the monitor will give a medium level alarm.
- [Lo-level] means low level alarm. When the measured value is between the upper limit of medium level alarm and low level alarm, or between the lower limit of medium level alarm and low level alarm, the monitor will give a low level alarm.
- 3. Select the upper limit and lower limit of a certain alarm level and click a or to adjust the alarm limits. The red area means high level alarm, yellow area means medium level alarm, cyan area means low level alarm and white area means the normal range.



The methods to set the alarm limits for all normal alarm parameters are similar, and here we take RESP as an

- Select RESP parameter area and the [RESP SETUP] menu will be displayed;
- Select [ALM LEV] and select [HIGH] or [MED];
- Select [RESP ALARM SETUP] and enter the RESP alarm limit setup menu, as shown below:



Here only the alarm limit of the selected alarm level can be set.

Select the upper limit and lower limit and click  $\triangleq$  or  $\checkmark$  to adjust the alarm limits.



- Setting alarm limits to extreme values will render the alarm system useless.
- It is very important to set the high limit for HR alarm to an appropriate value. Do not set it to be 20bpm higher than the patient's HR.

## ∠!\Attention

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

#### 8.5.3 **Alarm Recording**

The monitor can record alarms automatically when the alarms are triggered if the parameter alarm function and alarm recording function are activated. The methods of activating the alarm recording function for all parameters are similar. Here we take ECG as an example:

- Access [MAIN MENU]→[MONITOR SETUP]→[ALARM SETUP]→[MONITOR SETUP] and select [ON]
- Press ECG parameter area 2.
- Press [ALM REC] and select [ON].
- When the measured ECG value violates the alarm limit, the monitor will auto record the ECG waveform with the recording time of 4 seconds before and after the alarm moment.



### 8.5.4 Setting the Alarm Delay Time

The alarm system provides five kinds of alarm delay time: [DISABLED], [5SEC], [10SEC], [15SEC] and [20SEC]. [DISABLED] indicates that the monitor will give alarms immediately once the measured parameter value violated the alarm limit; [5SEC] indicates the monitor will give alarms only when the measured parameter value exceeds the alarm limit for continual 5 seconds; and so forth. The alarm delay function is not available on ECG parameter.

How to set the alarm delay time:

- 1. Access [MAIN MENU], select [MAINTAIN] and enter the password;
- 2. Select [ALARM SETUP]
- 3. Select [ALM DELAY TIME] to adjust the alarm delay time.

### 8.6 Pausing Alarms

The users can press the key on the front panel or click [ALM PAUSE] on-screen key to pause the alarm triggered and put the alarm system into alarm paused status.

- 1. Stop all the indications of physiological alarms and no new physiological alarm will be triggered.
- 2. The remaining pause time "ALM PAUSE xxS" will appear at the physiological alarm message area.
- 3. [ALM PAUSE] on-screen key flashes in red.
- 4. For technical alarm, the audio and visual alarm indication will be paused but alarm message still appears in technical alarm message area. If new technical alarm is triggered during alarm pause, only the alarm message of this technical alarm will be displayed without audio and visual alarm indication.

When the remaining alarm pause time ends, the alarm paused status will be automatically cancelled. You can also cancel the alarm paused status by pressing the keyboard or clicking [ALM PAUSE] on-screen key.

#### 8.6.1 Setting the Maximum Alarm Pause Time

- 1. Access [MAIN MENU], select [MAINTAIN] and enter the password;
- 2. Select [ALM SETUP]
- 3. Select [MAX ALM PAUSE TIME] to adjust the maximum alarm pause time. Available options are 2 minutes to 10 minutes.

#### 8.6.2 **Setting the Alarm Pause Time**

1. Access [MAIN MENU]



- 2. Select [MONITOR SETUP]
- 3. Select [ALARM SETUP]
- 4. Select [ALM PAUSE TIME] to choose the alarm pause time from 1 minute to X. X is the maximum alarm pause time set in [MAX ALM PAUSE TIME].

### 8.7 Switching off Alarms

#### 8.7.1 Switching off Individual Parameter Alarm

How to switch off individual parameter alarm, here we take ECG as an example:

- 1 Select ECG parameter area;
- 2 Select [ALM] to toggle between [ON] and [OFF].

When the alarm function of an individual parameter is deactivated, the icon will appear in corresponding parameter area.

#### 8.7.2 Switching off All Parameter Alarms

Switching off all parameter alarms is password protected and can only be operated by the authorized personnel. How to switch off all parameter alarms:

- 1. Access [MAIN MENU], select [MAINTAIN] and enter the password;
- 2. Select [ALARM SETUP];
- 3. Select [ALM] and toggle between [ON] and [OFF].

Moreover, the operator can be authorized to switch off all parameter alarms following the steps below:

- 1. Access [MAIN MENU], select [MAINTAIN] and enter the password;
- 2. Select [ALARM SETUP];
- 3. Select [ALM OFF Authorize];
- Select [ON], and the operator can access [MAIN MENU] →[MONITOR SETUP] →[ALARM SETUP]
   →[ALARM OFF] and select [ON] to switching off all parameter alarms.

When all parameter alarms are switched off, the system will give reminder tone periodically as the interval set in [REMINDER INTERVAL]. During alarms off status:

- 1. For physiological alarms, no alarm lamp flashes, no alarms are sounded and no measured parameter value and alarm limit flash. Physiological alarm message are not be displayed.
- 2. Prompt message "\*\*\*ALARM OFF" is displayed in the physiological alarm message area with red background.
- 3. For technical alarms, no alarms are sounded but with visual alarm and alarm message unchanged.



**User Manual** 

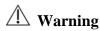


How to cancel all alarms off status:

1. Access [MAIN MENU]  $\rightarrow$  [MONITOR SETUP]  $\rightarrow$  [ALARM SETUP];



2. Select [ALARM OFF] and select [OFF].



• When alarms are switched off or paused, the monitor will not give alarm signals. Therefore, the patient should be kept under close surveillance.

### 8.8 Latching Alarms

For this monitor, only three alarms can be latched: asystole, Ventricular fibrillation/Ventricular tachycardia and RESP Apnea.

The alarm latching setting defines how the alarm indicators behave when you do notacknowledge them. When the latching alarm function is deactivated, the alarm indications of those three alarms will end when the alarm condition ends. When the latching alarm function is activated, all visual and audible alarm indications of those three alarms last until you reset the alarms, except that measured parameter value and violated alarm limit stop flashing as soon as the initial alarm condition goes away.

How to activate or deactivate latching alarm function:

- 1 Access [MAIN MENU], select [MAINTAIN] and enter the password
- 2 Select [ALARM SETUP]
- 3 Select [LATCH ALARM] and toggle between [ON] and [OFF].

#### 8.9 Alarm Reset

By pressing the [ALARM RESET] screen key, the following operations can be conducted:

- 1 Clear the latching alarm signals for which no associated alarm condition currently exists.
- 2 Cease the audio alarm signals of all physiological alarms and technical alarms.
- 3 Clear the alarm signals for which no associated alarm condition currently exist, thus re-enabling the alarm system to respond to future alarm conditions.
- 4 For lead off and sensor off technical alarm condition, clear the alarm lamp flashing and audio alarm indication and the alarm messages turn to prompt messages displayed in the technical alarm message area.

#### 8.10 Alarm Presets

This monitor has two alarm presets: the factory adult/pediatric/neonate default settings and user adult/pediatric/neonate default settings. Refer to *Appendix IV* for the factory alarm default settings. The factory adult/pediatric/neonate default settings can no be changed by users, but the users can modify the default settings and save as user adult/pediatric/neonate default settings.



How to save user adult/pediatric/neonate default settings:

- 1 Change the alarm settings, for example, change alarm limit or alarm level;
- 2 Access [MAIN MENU], select [MAINTAIN] and enter the password;
- 3 Select [SAVE CURRENT AS USER CONFIG] to save current settings as user adult or pediatric or neonate default settings based on current patient type.

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

- 1. Access [MAIN MENU]→[MONITOR SETUP] →[RESTORE DEFAULT CONFIGURATION];
- Select [ADOPT FACTORY DEFAULT ADU CONFIG], [ADOPT FACTORY DEFAULT PED CONFIG] or [ADOPT FACTORY DEFAULT NEO CONFIG], the alarm limit will restore to the factory default settings.

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

- Access [MAIN MENU]→[MONITOR SETUP] → [RESTORE DEFAULT CONFIGURATION];
- 2. Select [USER DEFAULT ADU CONFIG], [USER DEFAULT PED CONFIG] or [USER DEFAULT NEO CONFIG], the alarm limit will restore to the user default settings.

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

- Once the alarm settings have been modified, the monitor will always save the modified alarm settings.
   When changing the patient type, the monitor will restore to the alarm settings of that patient type set previously. Therefore, the users should check whether the alarm settings are suitable for the patient to be monitored prior to monitoring.
- 2. The user can press the parameter area of a certain parameter to enter the setup menu, and then press [DEFAULT] to restore the default settings of that parameter.



#### Warning

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

## 8.11 Check the Alarm System

How to check the alarm system:

- 1. Connect the SpO2 cable with the monitor;
- 2. Select SpO2 parameter area and enter [SpO2 SETUP] menu;
- 3. Enable the SpO2 alarm function;
- 4. Enter SpO2 alarm limit setup menu and set the upper alarm limit to 97 and lower alarm limit to 90.
- 5. When the measured SpO2 value exceeds the alarm limits, please observe the audio and visual alarm and check whether the alarm indications complies with what introduced in this chapter.
- Disconnect the SpO2 sensor from the monitor, and you will find the technical alarm message "SPO2 SENSOR OFF" in the technical alarm message area.



## **Chapter 9** Battery

#### 9.1 General Introduction

The monitor is equipped with a built-in rechargeable batterywhich will be auto charged when the AC power supply is connected no matterwhether the monitor is turned on or not. In case of sudden power failure, the monitor will be auto powered by the battery without operation interruption and the battery workindicator will be lit up 30s after the power failure.

To understand the battery icon:

- indicating the battery is fully charged.
- indicating moderate battery power.
- : indicating low battery power.
- : indicating critically low battery power, please charge the battery immediately.
- : indicating no battery installed or damaged battery.

## **Attention**

- Please remove the battery if it will be not be used for a long time and store it properly.
- If a battery is installed in the moitor, the battery must be recharged after each use to ensure enough battery power.

## Marning

- The battery liquid is harmful, In case the liquid contacts your skin or eye, wash it immediately with clean water or seek medical advise.
- Keep the battery out of the reach of children.

## 9.2 Low Battery Alarm

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



## 9.3 Power Management

The power management function is designed to save power and reduce emission for the sake of environmental protection.

Click battery icon to enter [POWER MANAGE] menu and set the following items:

- [TIMER]: click to select time interval of from 1 minute to 30 minutes, within which if no operation command is received, the monitor will trigger a command set in [TIMER CALL].
- [TIMER CALL]: set the command that the monitor will trigger if no operation command is received within the time interval set in [TIMER], including [NONE], [HIDE BTTM BTTN](hide bottonshortcut keys), [LOCK SCREEN], [STANDBY] or [SHUTDOWN].
- [RECOVER FROM]: select [TOUCH SCREEN], [KEY] or [ANY OPERAT](any operation) as the method of making the monitor return to the main screen after a command set in [TIMER CALL] is triggered.

## 9.4 Installing Battery

Procedure of changing or installing the battery:

- (1) Turn off the monitor, and disconnect the power cord and other connection lines.
- (2) Place the monitor with the back up.
- (3) Unscrew the battery cover.
- (4) Take out the used battery and put the new one into the battery holder making sure the positive and negative poles match what is indicated on its shell.
- (5) Replace the battery and screw it on, and turn the monitor upright.

## **M**Warning

- Use only the supplier's designated battery.
- Don't dismantle the battery while the monitor is turned on.
- The installation and replacement of the battery should be performed by trained and qualified personnel.

## 9.5 Optimization and check of battery performance

#### (1) Optimization of battery performance

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

This will ensure the battery is in optimization process:



# FM5000C - FM5000PLUS Maternal/Fetal Monitor

- (a) Disconnect the monitor from the patient and suspend all monitoring and measuring procedures.
- (b) The optimized battery should be kept in the battery compartment of the unit.
- (c) When charging the battery, at least six hours of charging should be ensured until it is fully charged.
- (d) When you disconnect the AC power supply, the monitor is powered with the battery until the battery runs out and the monitor automatically shuts off.
- (e) This completes the battery optimization process.

#### (2) Check of Battery Performance

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

Procedure for checking the battery is as follows:

- (a) Confirmwhether or not the battery is damage. When the battery shows the symbol " , it indicates the battery is damaged or no battery.
- (b) Check whether the battery can be normally charged when the battery is connected to alternating current;
- (c) Disconnect the monitor from the patient and suspend all monitoring and measuring procedures.
- (d) When charging the battery, at least six hours of charging should be ensured until it is fully charged.
- (e) Disconnect the AC power supply, power on the monitor with the battery until it is fully discharged and the monitor shuts off automatically Record the start and stop time.
- (f) The duration of battery discharge will reflect the battery performance.
- (g) Once the discharge duration is down to 50% of the original time, it requires changing the battery.

## **Attention**

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

## 9.6 Battery Recovery

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

## **Warning**

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



## **Chapter 10 Review**

What can be reviewed on the monitor are the trend graph, trend table, NIBP measurement data, alarm event andparameter waveform.

The monitor can save 150h trend data, 2,000 groups of NIBP data and 300 parameter alarm events, 120 minute parameter waveform, 60 hour fetal frozen waveformand 240s maternal frozen waveform for review.

## 10.1 Trend GraphReview

The trend graph in the latest 1 hour can be displayed with the resolution of one data every second or every 5 seconds; and the trend graph in the latest 120 hours can be displayed with the resolution of one data every minute, or every 5 or 10 minutes.

How to enter trend graph review window:

- 1. Click [INFO RECA.] on-screen key;
- 2. Select [TREND GRAPH] to enter the trend graph review window, as shown below:

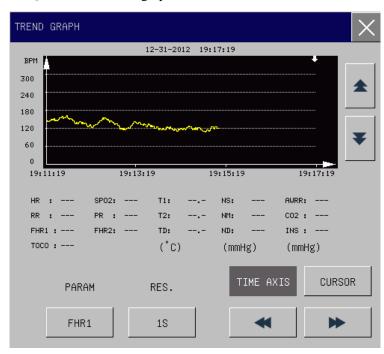


Figure 10-1 Trend graph review window

The vertical and horizontal axis respectively represents the measured value and the measuring time.

The following operations can be performed in the trend graph review window:

### 1. Display the trend graph of different parameters

Click the option box below [PARAM]andselect the parameter in the pop-up list box, and the trend graph of the selected parameter will be displayed.



#### 2. Display 1h or 120h trend graph

Click the option box below [RES.], in the pop-up list box, select 1 or 5 seconds to review thetrend graph in the latestone hour and select 1, 5 or 10 minutes to review thetrend graph in the lastest 120 hours.

#### 3. Observethe earlier or latertrend curves

Select [TIME AXIS] and then press ◀ or ▶ to observe the earlier trend curves or thelater trend curves respectively.

#### 4. Change the Display Scale

Press or to change the scale of the vertical axisand the scale of the trend curve will change accordingly.

#### 5. Obtain trend data at a certain moment

Click [CURSOR] and then press ◀ or ▶to move cursorand the selected moment will change when the cursor moves. The measured parameter values at the selected moment will be displayed below the trend graph.

#### 10.2 Trend Table Review

The trend table data in the latest 150 hours can be displayed with the resolution of one data every minute, every 5minutes, 10minutes, 30minutes or 60minutes.

How to enter trend table review window:

- 1. Click [INFO RECA.] on-screen key;
- 2. Select [TREND TABLE] to enter the trend table review window, as shown below:



Figure 10-2 Trend table review window



The following operations can be performed in the trend table review window:

### 1) Display thetrend tables of different resolutions

Select [RES.] and select the resolution in the pop-up list box. Available resolutions includes 1 minute, 5minutes, 10minutes, 30minutes, and 60minutes.

#### 2) Display trend data of different parameters

Press ★ or ▼ to show the trend data of the parameters not in current view.

## 3) Observe earlier or later trend data

Press or to observe the earlier or later trend data respectively.

### 10.3 NIBPMeasurement Review

This monitor can display the latest 2000 groups of NIBP measurement data in the NIBP measurement review window.

How to enter NIBP measurement review window:

- 1. Click [INFO RECA.] on-screen key;
- 2. Select [NIBP RECALL] to enter the NIBP measurement review window, as shown below:

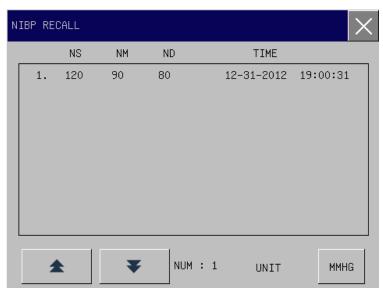


Figure 10-3 NIBP measurement review window

Data is displayed in the sequence of time from earlier to later. Each screen can display 10groups of NIBP measurement data. Select ★or▼ to view the later or earlier data respectively. Maximum data of2000 groups can be displayed. But if NIBP measurement data are more than2000 groups,the monitor will only save the latest 2000 groups and theearlier ones will be overwritten.



#### 10.4 Alarm Event Review

Maximum 300 physiological alarm events can be reviewed in the alarm event review window.

How to enter the alarm event review window:

- 1. Click the physiological alarm message area;
- 2. Or click [INFO RECA.] on-screen key;
- 3. Select [ALARM RECALL] to enter the alarm event review window, as shown below:



Figure 10-4 Alarm event review window

The following operations can be performed in the alarm event review window:

#### (1) Set the starttime

Click [START TIME] and set the start time in the pop-up menu. All the physiological alarm events occurredafter the start time will be displayed in this windowin chronological order.

#### (2) Select the alarm event

Click [RECALL EVE.] and select the alarm event in the pop-up list box. Available options include [ALL] and sperate parameter [FETAL], [ECG], [SpO<sub>2</sub>], [RESP], [NIBP], [TEMP] and [ARR TYPE].

#### (3) View a certain alarmevent

Select a certain alarm event in this window, for example "\*HR TOO LOW" and enter the review window of this alarm event, as shown below:



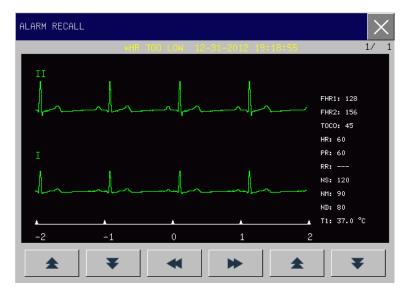


Figure 10-5Alarm event review window

What displayed in this window are follows:

- ➤ Alarm Time
- ➤ Alarm event
- ➤ Alarm level
- > The waveform and parameter value at the alarm moment



- When the alarm events are more than 200, the monitor will only store the latest 200 events and the earlier ones will be overwritten.
- The alarm log is not maintained when the alarm system is powered down and the time of powering down is not captured in the alarm log, neither. All the physiological alarm events will be cleard after the alarm system has experienced a total loss of power for a finite duration.

### 10.5 Waveform Review

The monitor can save 120 minute parameter waveform for review in the waveform review window.

How to perform waveform review:

- 1. Click [INFO RECA.] on-screen key;
- 2. Select [WAVE RECALL] to enter the [WAVE RECALL] menu, as shown below:





Figure 10-6 Waveform review menu

- 3. Set the [RECALL DATE], [RECALL TIME], [END DATE] and [END TIME] respectively.
- 4. Select [WAVE RECALL] and enter the waveform review window, as shown below:



Figure 10-7 Waveform review window

5. Press 

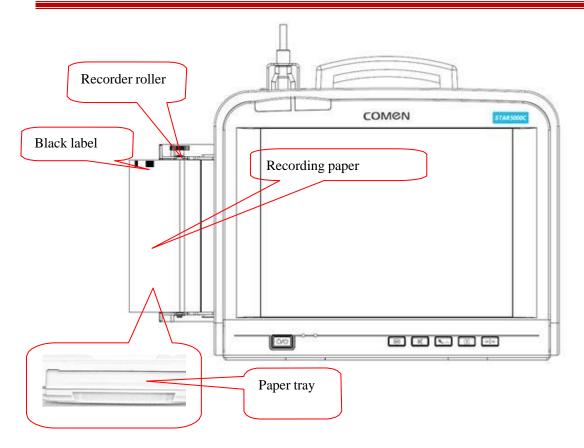
✓ or 

to observe earlier or later paramter waveform respectively.



## **Chapter 11 Printing**

## 11.1 Loading Recording Paper



- (1) Pull out the paper tray, see the figure above.
- (2) Put the recordingpaper into the paper tray with the grid side facing up and the black labelat the left.
- (3) Pull the recording paper slowly out of the recorder tray, and then adjust the position of the recording paper.
- (4) Push the paper tray in until it is locked.



- Please do not pull the recordingpaper when it is out from the recorder at a constant speed, or the recorder could be damaged.
- Do not use the recorder without recording paper inside.



## 11.2 Printing

The monitor supports three kinds of printing: real-time printing, frozenprinting and stored patient case printing. What can be printed under different user screens is different, see the table below:

User Screen	Printing contents						
	Real-time Printing		Frozen Printing				
Fetal monitoring screen	Fetal way	eform		Fetal waveform			
Mother/Fetus monitoring	Fetal way	eform		Fetal	waveform	1	
screen							
Mother monitoring screen	All	the	maternal	All	the	frozen	maternal
	parameter waveforms			parameter waveforms			
List screen	List of measured parameter values		List o	f measure	ed parameter	values	
Trend screen	All	the	maternal	All	the	frozen	maternal
	parameter waveforms			paran	neter wave	eforms	
OxyCRG screen	All	the	maternal	All	the	frozen	maternal
	parameter waveforms		parameter waveforms				
Big font screen	Fetal waveform			None			

#### 11.2.1 **Real-time Printing**

Real-time printing means the printing triggered by pressing the print key on the front panel or clicking the [PRINT] on-screen key during real-time monitoring.

#### How to print fetal waveform during real-time monitoring:

- 1. During real-time monitoring, press the print key on the front panel or click the [PRINT] on-screen key and enter the [Patient Info & Fischer Grade] window;
- 2. Confirm the patient information and score results and click [Confirm]. The monitor starts to print the fetal waveoform according to the speed set in [REAL SPEED] and the time set in [REAL TIME].
- 3. To stop printing during printing process, just press the print key on the front panel or click the [PRINT] on-screen key. If [REPORT] is set to [ON], the monitor will output the score report immediately and then stop printing; if [REPORT] is set to [OFF], the monitor will stop printing immediately.

How to print maternal parameter waveform during real-time monitoring:

- 1. During real-time monitoring, press the print key on the front panel or click the [PRINT] on-screen key and the monitor will start printing immediately according to the speed set in [PRINT RATE] and the time set in [PRINT TIME];
- 2. To stop printing during printing process, just press the print key on the front panel or click the [PRINT] on-screen key and the monitor will stop printing immediately.

#### 11.2.2 Frozen printing

Frozen printing means the printing triggered by pressing the print key on the front panel or clicking the [PRINT] on-screen key under frozen waveform status.

#### How to print the fetal waveform under frozen waveform status:

1. Under frozen waveform status, press the print key on the front panel or click the [PRINT] on-screen key and



# FM5000C - FM5000PLUS Maternal/Fetal Monitor

enter the [Patient Info & Fischer Grade] window;

- 2. Confirm the patient information and score results and click [Confirm]. The monitor will start to print the frozen fetal waveform from the very left waveform on current screen according to the time length set in [FREEZE TIME].
- 3. If the [REPORT] is set to [ON], the score report will be printed after frozen fetal waveform.

#### How to print the maternal parameter waveform under frozen waveform status:

Under frozen waveform status, press the print key on the front panel or click the [PRINT] on-screen key and
the monitor will start to print the frozen maternal parameter waveform from the very left waveform on
current screen according to the time length set in [PRINT TIME].

#### 11.2.3 Stored Patient Case Printing

Stored patient case printing means the printing triggered by pressing the print key on the front panel or clicking the [PRINT] on-screen key after loading the patient case and enter patient case review interface. What can be printed is only fetal waveform.

How to print stored patient case:

- 1. Access [Case List] window;
- 2. Select a certain patient case and enter [Patient Review] window;
- 3. Click [Load] and enter the patient case review window;
- 4. Press the print key on the front panel or click the [PRINT] on-screen key and enter the [Patient Info & Fischer Grade] window;
- 5. Confirm the patient information and score results and click [Confirm]. The monitor will start to print the fetal waveform from the very left waveform on current screen according to the time length set in [FREEZE TIME].

#### 11.2.4 **Printing Settings**

How to access print setup menu:

- 1. Access [MAIN MENU]→[MONITOR SETUP]→[PRINT SETUP] and enter the print setup menu;
- 2. Or click the printer icon and enter the print setup menu.

The items vary with different user screens. The items which cannot be selected means they are not available on current user screen.

- Click [GRADE] and select [ON] or [OFF] to activate or deactivate the auto scoring function respectively.
- Click [REPORT], select [ON] and the monitor will print score report after printing fetal waveform; select [OFF] and the monitor will not print score report.
- Click [PAPER TYPE] and select proper paper type. Available paper type includes [30~240], [50~210] and [OTHER].
- Click [PRINTER TYPE] and select the printer. Available options include [INLAY PRINTER], [OUTLAY PRINTER] and [PRINTER IMAGE].



#### FM5000C - FM5000PLUS Maternal/Fetal Monitor

- > [INLAY PRINTER] means using the 150mm recorder equipped with the moitor to print and the print paper is the recording paper.
- ➤ [OUTLAY PRINTER] means using the external USB printer to print and the print paper is A4 paper. Supportive external USB printer includes Lenovo LJ2650DN and HP2055d. This item is only available when connecting the external USB printer to the monitor.
- PRINTER IMAGE] means the waveform will be saved as picture in USB device and the users can view it on other devices, for example, computer. The size of the picture is the same as that of A4 paper. This item is only available when connecting the USB device to the monitor.

  The monitor can auto recognize external USB printer and USB device. When connecting the external USB printer or USB device to the monitor, there will be prompt message "External printer access" or "USB storage device access". When connecting the external USB printer, the [PRINTER]
- Click [SCORE SELECT] and select [FHR1] or [FHR2] to score FHR1 or FHR2 respectively.

TYPE] will auto switch to [OUTLAY PRINTER].

- Click [Grad Criterion] and select the score criterion, including [KREBS], [Fischer], [Advance Fischer]
   and [NST].
- Click [REAL SPEED] and select the print speed for real-time fetal waveform printing. Available print speed includes [1 CM/MIN], [2 CM/MIN] and [3 CM/MIN].
- Click [REAL TIME] and select the print time for real-time fetal waveform printing. Available print time includes [1 MIN], [3 MIN], [5 MIN], [10 MIN], [15 MIN], [20 MIN], [30 MIN], [45 MIN], [60 MIN], [90 MIN], [120 MIN] and [Infinite].
- Click [FREEZE TIME] and select the print time for frozen fetal waveform printing and stored patient case printing. Available print time includes [1 MIN], [3 MIN], [5 MIN], [10 MIN], [15 MIN], [20 MIN], [30 MIN], [45 MIN], [60 MIN], [90 MIN], [120 MIN], [150 MIN], [180 MIN], [210 MIN], [240 MIN] and [480 MIN]. [1 MIN] means the monitor will print fetal waveform of 1 minute from the very left waveform on the current screen after pressing the print key; and so on.
- Click [PRINT WAVEFORM] and select [ON] or [OFF] to activate or deactivate the function of printing ECG waveform.
- Click [PRINT RATE] and select the print speed for real-time maternal parameter waveform printing. Available print speed includes 25.0mm/s and 50.0mm/s.
- Click [PRINT TIME] and select the print time for real-time maternal parameter waveform printing and frozen maternal parameter waveform printing. Available print time includes [CONT PRINT](Continual print), [3s], [5s] and [8s].

During printing, the printer icon will show moving paper , indicating the printing is under process.

#### 11.3 Score Criterion

The monitor supports four kinds of score criteria: KREBS, Fischer, Advance Fischer and NST. The



following tables are instructions of the four criteria.

#### NST score criterion is as follows:

Items	0 point	1-point	2-point	Results	Score
FHR baseline (bpm)	<100,>180	100~109,161~180	110~160		
FHR upgoing time during FM (s)	0~9	10~14	>14		
FHR upgoing range during FM (bpm)	0~9	10~14	>14		
Variation range (bpm)	0~4	5~9,>30	10~30		
FM (bpm)	None	10~2	>2		

### KREBS score criterion is as follows:

Items	0 point	1-point	2-point	Results	Score
FHR baseline (bpm)	<100,>180	100~109,161~180	110~160		
Variation range	0~4	5~9,>25	10~25		
(bpm)					
Variation frequency	0~2	3~6	>6		
(cpm)					
Accelerate	None	1~4	>4		
(times/20mins)					
Decelerate	>2	1~2	None		
(times/20mins)					
FM (bpm)	None	1~4	>4		

### Advanced Fischer score criterion is as follows:

Items	0 point	1-point	2-point	Results	Score
FHR baseline (bpm)	<100,>180	100~109,161~180	110~160		
Variation range	0~4	5~9,>30	10~30		
(bpm)					
Variation frequency	0~1	2~6	>6		
(cpm)					
Accelerate	None	1~4	>4		
(times/20mins)					
Decelerate	Decelerate	Slight variation	None		
(times/20mins)	later or severe				
	variation				

### Fischer score criterion is as follows:

Items	0 point	1-point	2-point	Results	Score
FHR baseline (bpm)	<100,>180	100~109,161~180	110~160		
Variation range	0~4	5~9,>25	10~25		
(bpm)					
Variation frequency	0~1	2~5	>5		
(bpm)					
Accelerate	None	Periodic acceleration	Non-Periodic		
(times/20mins)			acceleration		
Decelerate	Decelerate	Slight variation	none		
(times/20mins)	later or severe				
	variation				





### FM5000C - FM5000PLUS Maternal/Fetal Monitor

#### & Attention

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



## **Chapter 12 Cleaning and Disinfection**

Use only the substances approved by Our company and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover the damage caused by unapproved substances or methods. Our companymake no claims regarding the effectiveness of the listed chemicals or methods as a means for controlling infection. For the method to control infection, please consult the Infection Control Officer or Epidemiologist in your hospital and also refer to the local policies.

#### 12.1 Overview

Keep your equipment and accessories free of dust and dirt. After cleaning and disinfection, please check the equipment and if any damage is found, stop use it. To avoid damage to the equipment, please follow the rules below:

- Always dilute the cleaning agents and disinfectants following the manufacturer's instructions or use the lowest possible concentration.
- Do not allow liquid to enter the enclosure.
- Do not pour liquid onto any part of the equipment or accessories.
- Do not immerse any part of the equipment into liquid;
- Do not use abrasive materials, bleaching powder or erosive cleaners (such as acetone or acetone-based cleaners).

## 12.2 Cleaning and Disinfection of the Monitor and Accessories

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

#### Steps of cleaning:

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

To avoid damage to the monitor and accessories, disinfection is recommended only when regulated as



necessary in the Hospital Maintenance Schedule. Please wash the monitor and accessories first before disinfection.

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

Components	Selectable Cleaning Agents	Selectable Disinfectants
Monitor enclosure  Isopropyl alcohol(70%), Hydrogen peroxide		Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
Power cord	Isopropyl alcohol(70%), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
ECG cable	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
ECG electrode	Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide	Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
Temperature probe  Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide		Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
SpO2 sensor	Isopropyl alcohol(70%)	Glutaraldehyde solution(2%), Sodium hypochlorite
TOCO transducer  Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide		Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
FHR transducer  Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide		Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite
FM marker	FM marker  Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide  Isopro Glutarald Sodi	
Wake probe  Alcohol-free soap, Sodium hypochlorite (with chlorine bleaching powder and 3% water), Hydrogen peroxide		Isopropyl alcohol(70%), Glutaraldehyde solution(2%), Sodium hypochlorite

## **Warning**

- Do not use the cleaning agents and disinfectants other than those recommended in this user manual, because permanent damage to the monitor or accessories may occur, or safety hazards may be caused.
- Before cleaning the monitor, make sure that it is switched off and disconnected from AC power.
- Never use acetone on any part of the monitor.
- Never pour or spray liquid on the monitor.



- Use a cloth to wipe off any cleaning agent remaining on the monitor or accessories.
- Do not mix the cleaning agents, or dangerous gas will be produced.
- Do not clean or disinfect the disposable accessories. Do not reuse the disposable accessories to avoid cross infection.
- To protect environment, the disposable accessories must be disposed of properly according to local regulations and requirements.
- After cleaning, inspect the sensor cable for damage or aging. If any damage or aging is found, please replace the sensor cable.
- Do not sterilize the monitor and accessories by autoclave.
- Do not use ETO gas to disinfect the monitor or accessories.
- Do not immerse the sensor or connector into any cleaning agent or disinfectant.



## ∠!\ Caution

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

#### 12.2.1 Cleaning and Disinfection of the Cuff

Take out the rubber bag before cleaning the cuff.

The cuff can be hand washed or machine washed in warm water or with mild detergent. Hand wash can extend the service life of the cuff. Air dries the cuff after cleaning.

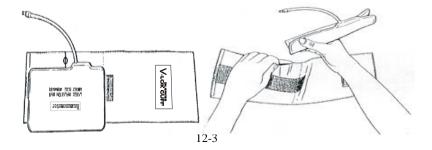
The cuff may be disinfected with a cloth moistened with 70% ethanol or 70% isopropanol. Prolonged use of disinfectant may cause discoloration of the cuff.

## $\Delta$ Warning

- Don't compress the rubber pipe on a cuff.
- Do not allow the liquid to enter the rubber bag when cleaning it.
- Do not dry clean the cuff.
- The disposable cuff must be disposed of according to the local laws and regulations.

After cleaning, put the rubber bag into the cuff as following steps:

- Place the rubber bag on the top of the cuff. 1
- 2 Roll the rubber bag lengthwise and insert it into the large opening;
- 3 Hold the hose and the cuff and shake the complete cuff until the rubber is in position.
- 4 Thread the hose from inside the cuff and out through the small hole under the internal flap, as shown below:





## 12.2.2 Cleaning the Belt

The belt should be cleaned with soapy water with warmth lower than +60"C.



## **Chapter 13 Maintenance**

#### 13.1 Maintenance Check

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

Before using the monitor, do the following:

- (a) Check if the work environment and power supply meet the requirements.
- (b) Check if there is any mechanical damage.
- (c) Check if the cables are worn and ensure insulation is in good condition.
- (d) Check all the functions of the monitor to make sure that the monitor is in good condition.
- (e) Check if the accessories used are specified by the manufacturer.
- (f) Check the battery.
- (g) If the monitor is equipped with a recorder, please check if the recorder is normal and recording paper meets the specified specification.
- (h) Check if the wiring resistance and leakage current meet the requirements.

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

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

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



• If the hospital or agency that is responsible for using the monitor does not follow a satisfactory maintenance schedule, the monitor may become damaged, and human health may be endangered.

### 13.2 Maintenance Schedule

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



# FM5000C - FM5000PLUS Maternal/Fetal Monitor

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

### 13.3 ECG calibration

During the use of monitor, ECG calibration is required when the ECG signal is inaccurate. ECG calibration should be conducted by the serviceman approved by Our company at least once a year or when you doubt the measured value. Specific steps are as follows:

- 1. Press ECG parameter area, in the pop-up [ECG SETUP] menu, press [ECG CAL]. Then the screen displays square wave signal and displays prompt message "ECG CALIBRATING....".
- 2. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%. After calibrating, press [STOP CAL].

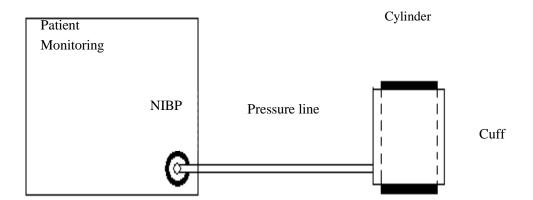
## 13.4 NIBP Air Leakage Test

It is used to check if the NIBP measuring pump has a leak. If the leakage test is passed, the system will not give any prompt; if not, there will be a corresponding error prompt in the NIBP information area.NIBP air leakage test should be conducted by the serviceman approved by Our company at least once a year or when you doubt the measured value.

#### Leakage test process:

- (1) Connect the cuff and NIBP to the openning of the monitor.
- (2) Wrap the cuff around a cylinder with proper size, as the figure shows.





- (3) Enter [NIBP SETUP] menu.
- (4) Select [PNEUMATIC] and the monitor starts to perform NIBP air leakage test with [PNEUM TESTING...]status message displayed in the NIBP parameters area.
- (5) System automatically inflates to the pressure of 180mmHg.
- (6) After about 20 seconds, the system will automatically open the valve, which means leakage measurement is complete.
- (7) If there is no error message in the NIBP parameter area, it means that the system has no sign of air leakage. If error message [Pump Leaking...] is displayed, it means that the air circuit may have an air leakage fault. Under such a circumstance, the operator should check the entire connection for loosening, and run the leakage test again after having made sure that the connection is errorless.
- (8) If the error message still appears, please contact the manufacturer for repair.



• This air leakage test, different from those described in the standard EN 1060-1, is for users to simply test air leakage in NIBP inflation. If the system displays an error message [Pump Leaking...] at the end of testing, please contact the Our company maintenance engineers.

#### 13.5 NIBP Calibration

Calibration of NIBP measurements should be carried out once a year when you doubt the measured NIBP by the serviceman approved by Our company.

Manufacturers recommend a calibrated pressure gauge (or mercury sphygmomanometers) with a precision more than 1mmHg to be used for calibration. Enter [Maintenance], enter the pasrword, and select [Calibration] to begin calibration and this item becomes [Stop Calibration].

Pressure sensor calibration steps:

Metal containers with a volume of  $500\text{ml} \pm 5\%$  instead of cuffs. Connect a calibrated standard gauge with measurement error of less than 0.8mmHg, a spherical air pumps with a t-interface and inflatable tubes attached



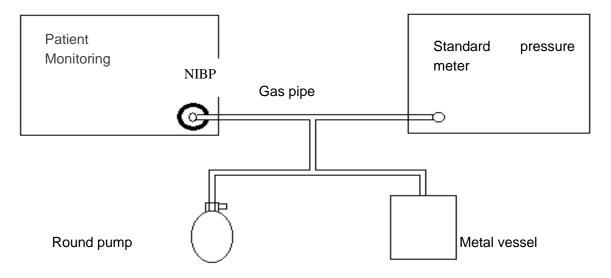
# FM5000C - FM5000PLUS Maternal/Fetal Monitor

**User Manual** 

to NIBP jack on the module. Set the monitor to "calibration" mode, and then inflate the metal



containers with ball type air pump to pressure of 0,50 and 200 mmHg respectively. The difference of pressure value between standard pressure gauge and monitor should be within the 3mmHg. Otherwise, please contact the Our company maintenance engineer.



## 13.6 Touch Screen Calibration

Touch screen calibration should be conducted at least once a year or when the touch screen is insensitive or after changing the touch screen. Calibration methods are as follows:

- 1. Enter [MAIN MENU].
- 2. Press [MAINTENANCE] and enter the password.
- 3. Press [SCREEN ADJUST].
- 4. Press the five symbols one by one following the indication on the screen
- 5. After calibration, the system will return to main screen automatically.



# **Chapter 14 Fetus Monitoring**

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

### 14.1 Difference between Antepartum and Intrapartum Monitor

The antepartum monitor ensures the accuracy and reliability for FHR measuring by using the high-sensitivity ultrasound transducer, high-performance signal processing circuit and advanced FHR calculation method. The intrapartum monitor is acceptable to few pregnant women as it is not easy to operate, not cost effective (use one-off electrode or pressure pipe) and likely to cause trauma to the patient.

### 14.1.1 Antepartum Monitoring Principles

Below is the ultrasound Doppler FHR monitoring principles:

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

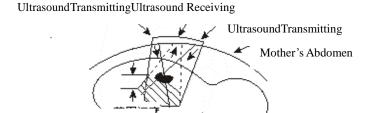
It is the best time to do the Doppler FHR monitoring when the fetus faces the mother's abdomen with the back. If the fetus faces the mother's abdomen with the front, his/her arms and legs will impact the echo signals. When the fetus turns, his/her heart will deviate from the irradiation area of the transducer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

### 14.1.2 Terms about Monitor

Continuous wave working mode: the receiver and transmitter of the ultrasound transducer work



simultaneously and continuously; faster or lower sometimes; simple circuit; can not recognize the distance of the target; likely to include other noise; large transmitting power; small effective receiving area (transducer).



Depth

Figure 14-1 Continuous Wave Transmitting/Receiving

Pulse wave working mode: small transmitting power; large effective receiving area (transducer); can receive the ultrasound signals of a selected depth; can eliminate other interference and noise; complex circuit. The transmitting frequency used for fetus monitoring is usually 1MHz~3MHz. A higher (or lower) transmitting frequency will lead to a weaker (or stronger) penetrability and a higher (or lower) resolution for tissue structure. Therefore, the transmitting frequency of the ultrasound transducer used for superficial vascular disease diagnosis can reach 810MHz. According to national safety standards, the transmitting power of the ultrasound transducer should not exceed 10MW/cm²; otherwise the fetus tissue could be affected adversely.

### 14.2 FHR Monitoring

#### 14.2.1 Connect the FHR Transducer

- (1) Let the patient lie on her back with the belt placed under her back, and then use the FHR transducer to find the position of the fetal heart.
- (2) Apply conductive gel to the contact surface of the transducer to ensure the largest FHR monitoring area. Before applying the transducer to the pregnant woman, please apply conductive gel to the middle 2/3 part of the contact surface. The conductive gel will be pressed to cover the whole contact surface (shaded part in Figure 14-2) after the transducer is fixed to the pregnant woman's abdomen.





Figure 14-2 FHR Transducer



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

⚠ Note

- Make sure the belt is tied to the proper position with proper tightness.
- (5) Make sure you can hear the fetal heart beats in the monitoring process. Do not adjust FHR volume to zero. The FHR curve is not reliable without strong fetal heart signals.
- (6) If there is any strong fetal movement or uterine contraction or the pregnant woman moves her body, the fetal heart position may change a lot. Please check whether you can hear clear fetal heart beats from time to time. If not, please adjust the position of the ultrasound transducer to find strong fetal heart signals again.

### 14.2.2 Cross-Channel Verification

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

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

How to activate the cross-channel verification feature:

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

#### 14.2.3 **Trace Separation**

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



### **■** Enable Trace Separation

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

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

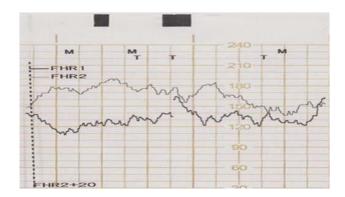


Figure 14-3 Trace separationenabled

The FHR2 trace on the recording paper has an offset, but the FHR2 value on the screen remains unchanged. Subtract 20 from the recorded trace for FHR2 to obtain the true FHR2. For example, if the recorded FHR2 trace is 180bpm, the true FHR2 is 160bpm.

### **■** Disable Trace Separation

Select FHR waveform, in the pop-up [FHR SETUP] menu, select [FHR OFFSET] and select [+0bpm]. The FHR2 trace recorded on the recording paper is thinner with light color, and the FHR2 trace is the true one, see the figure below:

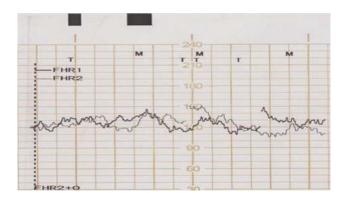


Figure 14-4Trace separation disabled

### 14.2.4 FHR Settings

### 14.2.4.1 Setting the Source of Maternal Heart Rate

Except for the FHR waveform, there is one maternal heart rate waveform displayed in the FHR waveform

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area, which helps the users to record the FHR waveform and maternal heart rate waveform together.

How to set the source of maternal heart rate:

- 1. Select FHR waveform area and the [FHR SETUP] menu will be displayed;
- 2. Select [MHR] and select the source of maternal heart rate from [OFF], [HR], [PR] and [AUTOMATIC].
- [OFF] means the function of displaying maternal heart rate waveform in the FHR waveform area will be deactivated:
- [HR] means the source of maternal heart rate is the measured maternal heart rate;
- [PR] means the source of maternal heart rate is the measured maternal pulse rate;
- [AUTOMATIC] means the monitor will auto select the measured maternal heart rate or pulse rate as the source of maternal heart rate.

The users can also set the display color for maternal heart rate waveform by entering [FHR SETUP] menu and selecting [MHR DISP COLOR].

### 14.2.4.2 Setting the FHR Sound Channel

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

How to set the FHR sound channel:

- 1. Select FHR1 parameter area, select [Sound channel] and select [FHR1] or [FHR2];
- 2. Select FHR2 parameter area, select [Sound channel] and select [FHR1] or [FHR2];

### 14.3 TOCO Monitoring

The TOCO indicates the delivery strength. The uterine contraction has been clinically proven to impact the fetal heart activities and delivery. The recorded TOCO trace provides such information as the strength, frequency, duration, regularity and shape of uterine contraction. The uterine contraction can increase or reduce the FHR. The monitor can monitor the TOCO of the mother in the fetus monitoring process, so the doctor can diagnose the FHR changes as per the uterine contraction.

The external pressure monitoring is to monitor the TOCO through the mother's abdomen. In case of any uterine contraction, the tension of the abdominal wall will compress the TOCO transducer, which will convert such compression into electrical TOCO signals. The electrical TOCO signals will be magnified by the monitor for you to view or print.



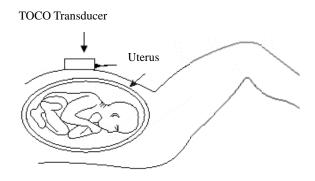


Figure 14-5 TOCO Measuring

### 10.2.1 Connect the TOCO Transducer



Figure 14-6 TOCO Transducer

- (1) Make the belt pass through the back of the TOCO transducer, place the TOCO transducer at the bottom of the patient's uterus, and then tie the belt to the proper position with proper tension.
- (2) Perform TOCO zeroing with one of the following three methods:
  - Enter [TOCO SETUP] menu and select [TOCO BASE];
  - Or click the [TOCO BASE] on-screen key;
  - Or press the TOCO zero key → 0 on the front panel.
- (3) When the TOCO transducer is placed on the pregnant woman, please observe the TOCO value on the screen.

### 14.3.1 Setting the TOCO Zero Value

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

- 1. Select the TOCO waveform area or parameter area and the [TOCO SETUP] menu will be displayed;
- 2. Select [TOCO Base] and select the TOCO zero value from 0, 5, 10, 15 and 20.



# 14.4 FM Counting

### 14.4.1 Counting FM manually

Counting FM manually means let the pregnant woman hold the FM marker and press it when she feels any FM.



Figure 14-7 Manual FM Mark

The FM mark displayed on the screen is with green color and the FM mark recorded by the recorder is "M".



• The patient should press the FM marker when a fetal movement starts and should not press it again until such fetal movement ends.

### 14.4.2 Counting FM automatically

Counting FM automatically means the monitor will auto count the FM according to the FM threshold value set in [FM Limen] and clinical situations. Please place the FM marker at the place where is no interference and impact.

The FM mark displayed on the screen is with the same color as that of the AFM (Auto Fetal Movement) waveform. To change the AFM color, select TOCO waveform area, enter the [TOCO SETUP] menu and select [AFM COLOR]. The FM mark recorded by the recorder is "T".

### 14.4.3 Setting the FM Sensitivity Threshold

The FM sensitivity threshold means auto FM counting sensitivity. For example, if you set it to 10%, the system will auto countthe FM once (only once within 8 seconds) when the auto FM trace value is greater than 3. See the table below for more information:

FM Threshold	AFM trace value(bpm)		
10%		>3	
20%	14-7	>5	
30%		>10	



# FM5000C - FM5000PLUS Maternal/Fetal Monitor

40%	>15
50%	>20
60%	>25
70%	>30
80%	>35

How to set the FM Threshold:

- (1) Select TOCO parameter area or waveform area and the [TOCO SETUP] menu will be displayed;
- (2) Select [FM Limen] and select [10%], [20%], [30%], [40%], [50%], [60%], [70%], or [80%].

### 14.4.4 Setting the FM Counting Mode

There are three kinds of FM counting mode supported by the monitor, [Auto/Manual], [MANUAL] and [OFF].

- [Auto/Manual] means the monitor can count the FM automatically according to the clinical situations and also the pregnant woman can hold the FM marker and count the FM manually when she feels the fetal movement.
- [MANUAL] means the pregnant woman holds the FM marker and counts the FM manually when she feels the fetal movement.
- [OFF] means the FM will not be counted.

How to set the FM counting mode:

- 1. Select FHR waveform area, in the pop-up [FHR SETUP] menu, select [Fetal Move.] and select the FM counting mode;
- 2. Or select FHR1 or FHR2 parameter area, in the pop-up [FHR1 SETUP] or [FHR2 SETUP] menu, select [Fetal Move.] and select the FM counting mode.

# 14.5 Fetus-awakening Acoustic Stimulator

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



### 10.4.1 Appearance Introduciton

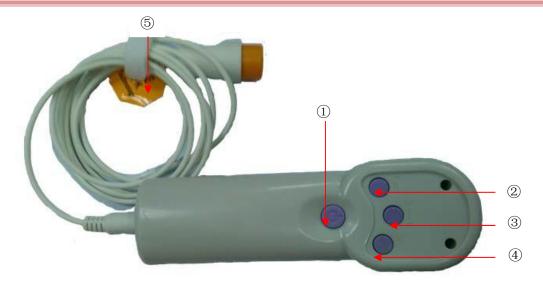


Figure 14-8 Front View



Figure 14-9Side View

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

# **Attention**

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



patient to avoid cross infection.

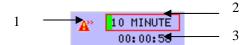


• The surface temperature of the vibration part may exceed  $41^{\circ}$ C but won't exceed  $43^{\circ}$ C.

### 14.6 Timed Monitoring

The monitor supports timed monitoring (Mainly for fetus monitoring) and manual real-time monitoring. The patient monitoring will also ends when the timed monitoring ends.

Users can view the timed monitoring information on the screen directly:



- 1. Show whether there is prompt when the timed monitoring ends. means the monitor will give a high level technical alarm with alarm message of "\*\*\*MONITOR STOP" when the timed monitoring ends. means the monitor will not give any alarm when the timed monitoring ends.
- 2. Show the duration of this timed monitoring, for example 10 minutes.
- 3. Show the elapsed time of this timed monitoring, for example, the elapsed time of this timed monitoring is 58 seconds.

#### How to start timed monitoring:

- 1. Click the timed monitoring information area on the screen, or click [TIMER] on-screen key, and the [TIMER] menu will be displayed;
- 2. Select [TIME END PROMPT] and toggle between [ON] and [OFF]. [ON] means the monitor will give a high level technical alarm when the timed monitoring ends.
- 3. Select [TIMING CARE] and select the duration for timed monitoring from 10 minutes to 120 minutes.
- 4. Select [STARUP TIMER] and the timed monitoring starts. The [STARTUP TIMER] turns to [STOP TIMER] and the item [CLEAR TIMER] will be displayed in the [TIMER] menu.
- 5. During timed monitoring, to stop monitoring, select [STOP TIMER]. The [STOP TIMER] turns to [STARTUP TIMER]. At this time, select [STARTUP TIMER] again and the monitor will continue the timed monitoring till it ends.
- 6. Select [CLEAR TIMER], the timed monitoring will end immediately and the item [CLEAR TIMER] disappears.
- 7. Select [STARTUP TIMER] again, a new timed monitoring will start.

During timed monitoring, the recorder will continuously output the fetal waveform till the timed monitoring ends. To stop printing during timed monitoring, press the print key on the front panel or click [PRINT] screen key, the printing will stop immediately and the timed monitoring will also ends.



# **Chapter 15 ECG Monitoring**

### 15.1 Overview

The ECG measures the electrical activity of the patients' heart and displays it on the monitor in the form of waveform and valueso as to accurately assess the physiological status of the patient. To get accurate measured value, the ECG lead wired should be placed correctly.

This monitor is applicable to 3-lead, 5-lead and 12-lead ECG monitoring. Different waveformscan be displayed according to different lead wires.

# 15.2 ECG Display

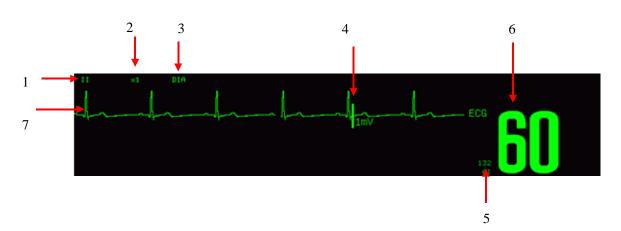


Figure 15-1 ECG display

- 1. ECG lead name
- 2. Waveform gain
- 3. Filter mode
- 4. 1 mV scale
- 5. The alarm limits
- 6. ECG measured value
- 7. ECG Waveform



### **15.3 Safety Information**

# **Warning**

- The operators shall not touch the patients, tables and instruments during defibrillation.
- Only use the ECG lead wire designated by Our company.
- Pacemaker failure: during the heart's complete conduction blockage or when pacemaker can't wrestle/took away,the high P waves (larger than the 1/5 of the average height of R wave) may be wrongly counted by the monitor, leading to asystoles being undetected
- During the defibrillation, the ECG cable connected with patient may be damaged. Before reusing these cables, check whether its function is normal.
- After defibrillation, the ECG waveform will recover within 5 seconds without losing any stored data. For electrosurgery (ESU) or defibrillation, measurement accuracy may temporarily drop, but it does not affect the safety of patients or equipment
- Never expose the equipment under x-ray or strong magnetic field (MRI)
- When connecting the electrodes or patient cable, make sure that the conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact any other conductive parts including earth and make sure that all the electrodes are placed on the patient to prevent them from contacting the conductive parts or earth.
- Inspect the electrode application site for skin irritation daily. If there is sign of allergy, replace the electrodes or change the application site.
- Before ECG monitoring, check that the function of ECG cable is normal. After disconnecting
  the ECG cable, the monitor will trigger an audible alarm and displayalarm message "SENSOR
  OFF".

# Attention

- Interference from ungrounded equipment near the patient and ESU interference may cause waveform problems. If you operate under the conditions regulated by EN60601-1-2 (with the anti-radiation capacity of 3V/m), the electric field strength more than 1V/m may cause measurement errors at various frequencies. Therefore, it is recommended not to use electrical radiation equipment near the ECG / respiration monitoring devices.
- If ECG electrodesareplaced correctly, but the ECG waveform is not accurate, please replace the lead wires.
- In order to protect the environment, the electrodes used should be recycled or be disposed of properly.



# 15.4 Steps of Monitoring

### 15.4.1 Preparation

Ask the patient to remove outer clothing on upper body:

- (a) As skin is poor conductor of electricity, to get a good contact of the electrode and the skin, it is important to make preparation of the patient s' skin.
- (b) If necessary, shave the area for the electrode.
- (c) Thoroughly clean the skin with soap and water. (Do not use ether or pure alcohol, because they will increase the resistance of the skin).
- (d) Dry and rub the skin in order to increase the capillary blood flow and remove skin debris and oil.
- (e) Attach the alligator clip prior to placement of the electrode.
- (f) Place electrodes on the patient. If the electrodes used do not have conductive gel, apply the conductive gel before placement.
- (g) Connect the electrode lead and the patient cable.
- (h) Check that the monitor power is on.

### 15.4.2 Placement of ECG Electrodes

### 15.4.2.1 Identifiers and Color Code of Electrodes

The table below shows the lead names in the European and American standards. (The leads are represented by RA, LA, RL, LL, and V in the American standard, while by R, L, N, F, and C in the European standard.): Identifier and color code of 3-lead and 5-lead electrodes are as follows:

American standard		European standard		
Name of lead	Color	Name of lead	Color	
RA	White	R	Red	
LA	Black	L	Yellow	
LL	Red	F	Green	
RL	Green	N	Black	
V	brown	С	White	

Identifier and color code of 12-lead electrodes are as follows:

	American standard		European standard	
Lead	Marking	Color	Marking	Color
Right arm	RA	White	R	Red



Left arm	LA	Black	L	Yellow
Right foot	RL	Green	N or RF	Black
Left foot	LL	Red	(f)	Green
Chest 1	V1	Red	C1	Red
Chest 2	V2	Yellow	C2	Yellow
Chest 3	V3	Green	C3	Green
Chest 4	V4	Blue	C4	Brown
Chest 5	V5	Orange	C5	Black
Chest 6	V6	Purple	C6	Purple

### 15.4.2.2 Placement of 3-lead ECG Electrodes

The position of electrode of 3-lead ECG cable is divided into American standard and European standard:

White/red (right arm) electrodes - placed under the clavicle, near the right shoulder.

Black/yellow (left arm) electrodes - placed under the clavicle, near the left shoulder.

Red/green (left leg) electrodes - placed in the left lower abdomen.

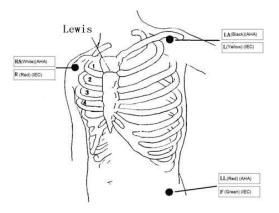


Figure 15-2 Positions of 3-lead ECG electrodes

### 15.4.2.3 Placement of 5-lead ECG Electrodes

The position of electrode of 5-lead ECG cable is divided into American standard and European standard:

White/red (right arm) electrodes - placed under the clavicle, near the right shoulder.

Black/yellow (left arm) electrodes - placed under the clavicle, near the left shoulder.

Green/black (right leg) electrodes – placed at the right lower quadrant.

Red/green (left leg) electrodes - placed in the left lower abdomen.

Brown/white (chest) electrode-as on the chest wall



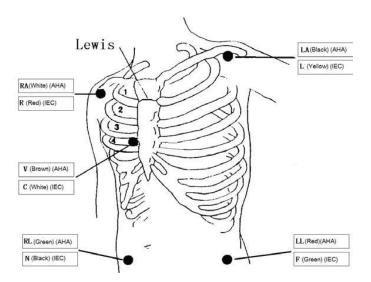


Figure 15-3 Positions of 5-lead ECG electrodes

As with 5-lead ECG cable, the chest lead electrodes should be put in one of the positions as follows:

V1: in the fourth intercostal space on the right edge of the sternum.

V2: in the fourth intercostal space on the left edge of the sternum.

V3: in the middle position of V2 and V4.

V4: in the fifth intercostal space of the left mid-clavicular line.

V5: at the left anterior axillary line, with horizontal position the same as the V4.

V6: at the left median axillary line, with horizontal position the same as the V4.

V3R-V6R: in the right chest wall, with its position corresponding to the left position.

VE: at the eminence of xiphoid.

V7: in the fifth intercostal space of left posterior axillary line on the back.

V7R: in the fifth intercostal space of right posterior axillary line on the back.

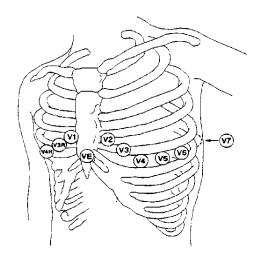


Figure 15-4 Position of Chest electrode of 5-lead ECG cable



### 15.4.2.4 Placement of Reformed 12-lead ECG Electrodes

The position of electrode of 12-lead ECG cable after being improved is divided into American standard and European standard.

White/red (right arm) electrodes - placed under the clavicle, near the right shoulder.

Black/yellow (left arm) electrodes - placed under the clavicle, near the left shoulder.

Green/black (right leg) electrodes – placed at the right lower quadrant.

Red/green (left leg) electrodes - placed in the left lower abdomen.

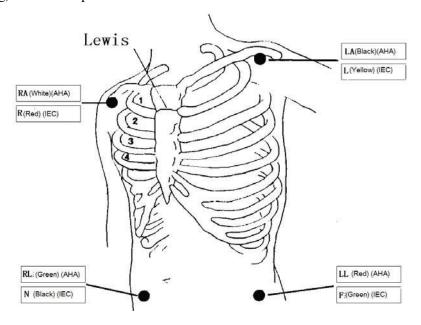


Figure 15-5Position of electrodes of 12-leadECG cable

The chest electrode placement sites are generally six, taking spatiuminterosseum of costal bone as the locating basis,  $V1 \sim V6$ :

V1/C1: in the fourth intercostal space on the right edge of the sternum

V2/C2: in the fourth intercostal space on the left edge of the sternum

V3/C3: at the midpoint of the C2 and C4

V4/C4: at the intersection of the fifth intercostal space on the left edge of the sternum and the left mid-clavicular line

V5/C5: at the parallel previous axillary line of C4 level on the left

V6/C6: at the parallel median axillary line of C4 level on the left



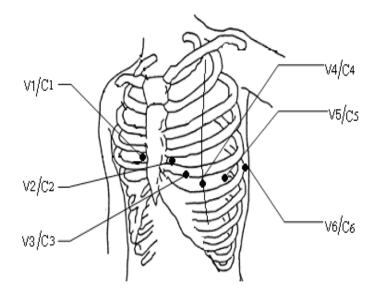


Figure 15-6Position of chest electrodes of 12-lead ECG cable

#### 15.4.2.5 ECG Lead Connection Recommended for Surgical Patients

# $ilde{ extstyle extstyl$

- When using electricity surgical unit (ESU), put the ECG electrode at the middle position between ESU earth plate and electrosurgical knife to avoid burn. The cable of electricity surgical unit and the ECG cable can't be entangled.
- In the use of electricity surgical unit (ESU), never allow the electrodes to be close to the earth plate of electricity surgical unit, or ECG signal would be interfered seriously.

The position of ECG lead depends on the type of surgery. For example, for the thoracotomy, electrode can be put on the chest or the back. In the operating room, because of using electrosurgical knife equipment, sometimes artifact may affect ECG waveform, in order to cut the artifact, you can put the electrode on left and right shoulder, near the abdomen of left or right side, and the breast lead can be put on the left side of chest quiet near the center. To avoid the electrode beingput on the upper arm, or ECG wave will become very small.

## 15.5 Waveform quality

Users can choose to display the ECG waveform with the best signal.

Feature of a good signal:

- Tall, narrow and without notch.
- R wave tall, completely above or below the baseline.
- T waves less than 1/3 height of R wave.
- P wave should be much smaller than T wave



In order to obtain 1 mV calibration ECG waveform, ECG calibration should be conducted. During ECG calibration, the screen displays the status message "CAL, CAN'T MONITOR!" (Cannot monitor the patient during calibration).

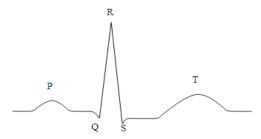


Figure 15-7Standard ECG waveform

# 15.6 ECG Settings

### 15.6.1 Setting the Lead Type

This monitor is applicable to the 3-lead, 5-lead and 12-lead ECG monitoring. When ECG cables of different leads are used, the ECG leads that can be monitored are different.

When using 3-lead ECG lead wire, the leadscan be monitored include I, II and III.

When using 5-lead ECG lead wire, the leadscan be monitored include I, II, III, aVR, aVL, aVF and V1.

When using 12-lead ECG lead wire, the leadscan be monitored include I, II, III, aVR, aVL, aVF, V1 and V2, and V3, V4, V5and V6.

When using the 3-lead ECG lead wire, only one channel ECG waveform can be displayed on the screen; while when using the 5-lead or 12-lead ECG lead wire, only one ECG waveform can be displayed on the fetal /mathor monitoring screen and big font screen, and ECG waveform of two channels can be displayed on the mother monitoring screen, trend screen, list screen and oxyCRG screen.

Steps for setting the lead type:

- (a) Click ECG parameter area and [ECG SETUP] menu will be displayed;
- (b) Set the [LEAD TYPE] to [3 LEADS], [5 LEADS] or [12 LEADS].

### 15.6.2 **Setting the Lead Name**

- (a) Click ECG waveform and [ECG WAVE] menu will be displayed;
- (b) Click [LEAD NAME] and select the lead name from the pop-up list box, for example, lead II.



### 15.6.3 **Setting the Gain**

Gain is used to adjust the size of ECG waveform. Available gains include  $\times$  0.25  $\times$  0.5  $\times$  1,  $\times$  2 and auto. Auto mode automatically adjusts the gain by the monitor. The right side of each ECG waveform channel has given 1mv scale. The height of the 1mv scale is proportional to the amplitude.

- (a) Click ECG waveform and [ECG WAVE] menu will be displayed;
- (b) Set [GAIN] to  $[\times 0.25]$ ,  $[\times 0.5]$ ,  $[\times 1]$ ,  $[\times 2]$  or [AUTO]

### Attention

When the input signal is too large, the peak may be truncated. The user can refer to the
actual waveform to manually change the gain of the ECG waveform in order to avoid the
incomplete waveform display.

### 15.6.4 Setting the Filter Mode

There are four filter modes: diagnostic mode, monitor mode, surgical mode and ST mode. The diagnostic mode shows unfiltered ECG wave; the monitor modecan filter out the artifacts which may lead to false alarms. The surgical mode in the operating room can reduce the artifact and interference from electrical surgical unit. Filter mode is displayed above the first ECG waveform.

ST filter mode is user-friendly to conduct more accurate ST segment measurements. Frequency response range of this mode is 0.05Hz-40Hz. The good scalability of low frequency ensures undistorted interpretation of patient's ST segment, and can effectively filter high-frequency interference signals over 40Hz including power frequency interference. In this mode the user can more accurately acquire the measured ST segment value by adjusting the position of the ST segment analysis points.

- (a) Click ECG waveform and [ECG WAVE] menu will be displayed;
- (b) Set [FILTER] to [DIA] (diagnostic), [MON] (monitor), [SUR] (surgical) or [ST];

# **Warning**

Only under diagnostic mode will the actual ECG signal will be provided. ECG waveforms have varying degrees of distortion under monitor mode and surgical mode. At this time, the system can only provide the basic status of the ECG signal, which may have a great impact on the result of the ST segment analysis. Under surgical mode, the arrhythmia analysis result is also affected to some degree. So we recommended that when the interference is small, try to use the diagnostic mode to monitor the patient.

### 15.6.5 Setting the Calculation Channel

Heart rate calculation channel means the waveform from which lead is used to calculate heart rate. Calculation channel options vary with different lead types:

For 3-lead ECG cable, the default calculation channel islead I.

For 5-lead ECG cable, the available calculation channel includes I, II and V.



For 12-lead ECG cable, the available calculation channel includes I, II, V1, V2, V3, V4, V5 and V6.

- (a) Select ECG parameter area and the [ECG SETUP] menu will be displayed;
- (b) Select[HR CHANNEL]and select the lead from the pop-up list box.

### 15.6.6 **Setting the Notch**

Notch inhibits the 50Hz or 60Hz frequency components of signals collected. When the filter mode is not the diagnostic mode, the system automatically enables the notch; while when filter mode is the diagnostic mode, the user should select to enable or disable the notch functionaccording to the need.

- (a) Select ECG parameter area and the [ECG SETUP] menu will be displayed;
- (b) Select [NOTCH] and select [ON] or [OFF] to enable or disable the notch function respectively.

### 15.7 ST Segment Analysis

### 15.7.1 About ST Segment Analysis

The normal heart beat and atrioventricular pacing are used for ST segment analysis. The monitor analyzes these heart beats and calculates the elevation and depression of the ST segment. The monitor can display the information in ST numerical form. It can continuously monitor all available leads. For ST-segment analysis, the ECG waveform is not required to be displayed on the monitor. For ST analysis, it usually uses a special filter which ensures diagnostic quality. If you use the diagnostic filter mode to monitoring ECG, the ST segment of the ECG wave will be slightly different from the ST segment in the ST fragment with the same waveform. In order to diagnostically assess the ST-segment, please always switch to ST filter mode. You can also select the monitor or surgical filter mode, but ST-segment data will have a serious distortion.

ST segment analysis can measure the elevation or depression of the specified ST-segment of a lead.

Meaning of ST-segment measurement: A positive number indicates the elevation, a negative number indicates depression

Measurement range of the ST segment:  $-2.0 \sim +2.0 \text{ mV}$ .

### 15.7.2 Impact on ST-segment

Some clinical conditions makeit difficult to get reliable ST monitoring, such as:

- Unable to obtain the leads with low noise;
- The irregular baseline resulting from arrhythmia such as atrial fibrillation / atrial flutter;
- The patient is continuous ventricular pacing



**User Manual** 



■ Patients have left bundle branch block

When these things happen, you should consider to turning off ST monitoring



# **Warning**

 The clinical significance of ST level change information provided by this monitor should be decided by the physician.

### 15.7.3 Enabling ST Segment Analysis

- (a) Select ECG parameter area;
- (b) Enter the [ST ANALYSIS]menu;
- (c) Set [ST ANALYSIS] to [ON] or [OFF].

When it is set to [ON], ST value would be displayed in the ECG parameter area.

### 15.7.4 Adjusting the ST Segment Analysis Point

Set the ST measurement point as R peak point. The ST measured values of every cardiac integrated wave is the vertical distance between the peak point and the two measurement points, as shown below:

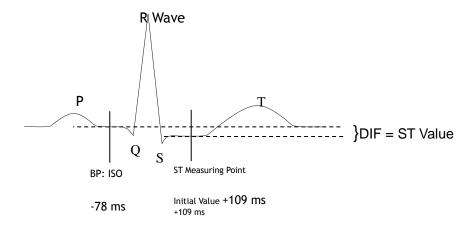


Figure 15-8 ST analysis point

# Attention

If the patient's heart rate or ECG waveform changes obviously, you need to adjust the location
of ISO and ST point. The abnormal QRS complex are not considered when the ST analysis is
made.

Method to adjust the ISO and ST point:

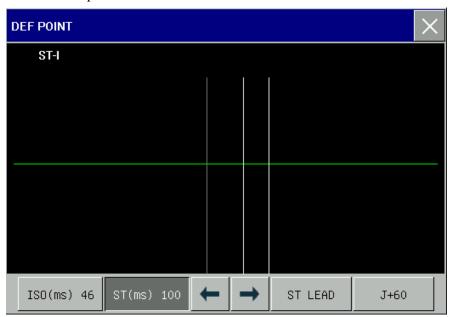
- (a) Select ECG parameter area, in the pop-up [ECGSETUP] menu, enter the menu[ST ANALYSIS];
- (b) Set [ST ANALYSIS] to [ON];
- (c) Select the [DEF POINT] to enter the [DEF POINT] window; the three vertical lines in the window stand for the position of ISO, J, and ST respectively.
  - The ISO cursor is to decide the equipotential point position against R peak point. Locate the ISO point in the middle of the flattest part (between P wave and Q wave or before P wave) in the



baseline.



- The J cursor is to decide the J point position against R peak point, which is conducive to correctly locate ST point. Locate the J point at the end of QRS wave group and the start point of ST.
- > ST point is located in a certain position with a fixed distance from J point—J+40, J+60 or J+80. Move the J cursor to locate the ST point in the middle of the ST.
- (d) Select [ST LEAD] to choose an ECG lead whose J point and P wave are obvious. Click once, name of ST would change from ST-I, ST-II, ST-III, ST-aVR, ST-aVL, ST-aVF, ST-V1, ST-V2, ST-V3, ST-V4, ST-V5, ST-V6 circularly.
- (e) Select [ISO (ms)] and [ST (ms)] point respectively. Press ◀ and ▶ to make adjustment. Select [J] to decide position of each point.



### Warning

Please ensure that the location of the ST measurement points suitable for the patients.

### 15.8 Arrhythmia Analysis

Arrhythmia analysis is used for the clinical monitoring of patients' ECG to detect changes in heart rate and ventricular premature beat, to save the arrhythmic events and to generate alarm information. Arrhythmia analysis can be used to monitor pacemaker and non-pacemaker patients. Doctors may, based on the arrhythmia analysis, evaluate the patient's condition (such as heart rate, the PVCs (premature ventricular contraction) frequency, rhythm, and abnormal heartbeat) and give the appropriate diagnosis and treatment. In addition to the detection of ECG changes, the arrhythmia analysis can also be used to monitor patients and give appropriate alarms.

The arrhythmia monitoring is disabled by default. Users can turn on this function according to your need.



The function of arrhythmia monitoring can, by testing and classification of arrhythmias and heart abnormalities, remind doctors to pay attention to the rhythm of the patient, and then give alarm.

The monitor can make 14 kinds of arrhythmia analysis.

Arrhythmia analysis system will store 200 alarm events and the operator can edit the arrhythmic events in the menu.

### 15.8.1 Enabling Arrhythmia Analysis

- (a) Select ECG parameter area;
- (b) Enter the [ARR ANALYSIS]menu;
- (c) Select [ARR ANALYSIS] and toggle between[ON] and [OFF].

### 15.8.2 Arrhythmia Alarm Settings

- (a) Select ECG] parameter area, in the pop-up [ECG SETUP] menu, enter [ARR ANALYSIS]menu;
- (b) Select [ARR ALARM];
- (c) Select [ARR TYPE], select [ALL] or separate arrhythmia [ASYSTOLE], [VFIB/VTAC], [R ON T], [VT> 2], [COUPLET], [PVC], [BIGEMINY], [TRIGEMINY], [TACHY.], [BRADY], [PNC], [PNP], [MISSED BEATS],[ARRHYTHMIA];
- (d) Others:

Upper and lower limit of alarm:

Name	Maximum	Minimum	One-time adjustment
PVCs	31	1	1

### 15.8.3 Arrhythmia Relearning

During ECG monitoring, when great changes of patient's ECG template takes place, the users should start the arrhythmia relearning process, which can help the monitor learn new ECG template tocorrect arrhythmiaalarm and HR valuesandrestore ST measurement.

Particular procedures are:

- (a) Select ECG parameter area, in the pop-up [ECG SETUP] menu, enter [ARR ANALYSIS]menu;
- (b) Select [ARR RELEARN].

### 15.8.4 Arrhythmia Review

- (a) Select ECG parameter area, in the pop-up[ECG SETUP] menu, enter [ARR ANALYSIS] menu;
- (b) Select[ARR RECALL]to enter the arrhythmia review window, as shown below:



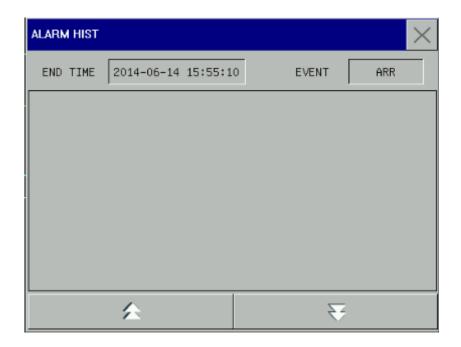


Figure 15-8 Arrhythmia review

- (c) Adjust the [END TIME];
- (d) Click an alarmevent (like \* \* BIGEMINY) to enter the review window, as shown below;and view the parameter values and waveform related to such alarm.

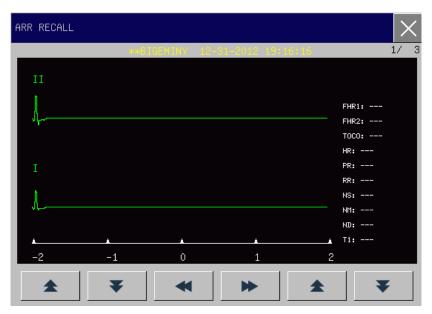


Figure 15-9 Arrhythmia review

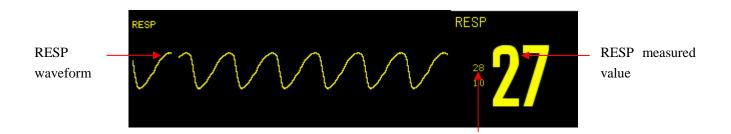


# **Chapter 16 RESP Monitoring**

### 16.1 Overview

The monitor measures respiration according to the thoracic impedance values between two electrodes and display a channel of RESP waveform on the screen.

### 16.2 RESP Display

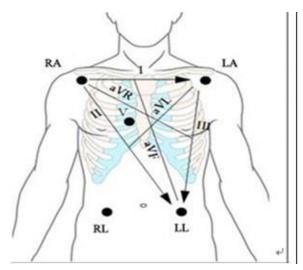


Alarm limit

Figure 16-1 RESP display

# 16.3 Placing Electrodes for RESP Measurement

RESP measurement applies the same electrodes and placement methods as that of ECG monitoring. For example, if the 5-lead ECG cable is applied, the placement method is shown on the figure below (for the placement methods of the ECG cable of other lead types, please refer to *ECG Monitoring*):



RA: under the clavicle, next to R-shoulder LA: under the clavicle, next to L-shoulder RL: on the R-lower abdomen LL: on the L-lower abdomen V: on the chest U

Figure 16-2 Positions of electrodes of 5-lead ECG cable

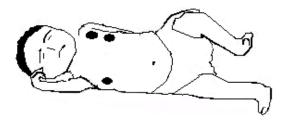


# **Attention**

• Put the green and the red electrodes at opposite angle so as to get the best respiration wave. You should avoid putting the electrodes over the liver area and the ventricle of the heart in the line between the respiratory electrodes, which can help to avoid cardiac overlay or artifacts from the pulsing blood flow. This is particularly important for neonates.

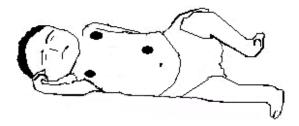
### Lateral thoracic expansion

Some patients' thorax may expand laterally, especially for the neonates. At the right time, two RESP electrodes shall be placed on the right mid-axillary line and the left lateral thorax where the patient has the maximum breathing movement to make sure that the breathing waveform is distinct. See the following figure:



### **Abdominal respiration**

For some patients the chest movement is limited so they primarily conduct a abdominal respiration And right now, you shall remove the electrode which was placed on the left leg to the left abdomen where there is maximum expansion to make sure the breathing waveform is clear. See the following figure:



# **Attention**

• RESP monitoring cannot be applied to the patient who moves frequently, because it may lead to wrong alarms.

## 16.4 RESP Settings

#### 16.4.1 **Setting the Gain**

Gain is used to adjust the size of RESP waveform. The alternative gains are  $\times 0.25$ ,  $\times 0.5$ ,  $\times 1$  and  $\times 2$ .

(a) Select RESP waveform and the [RESP WAVE]menu will be displayed;



- (b) Select [GAIN];
- (c) Select [ $\times 0.25$ ], [ $\times 0.5$ ], [ $\times 1$ ] or [ $\times 2$ ].

### 16.4.2 **Setting theApneaAlarmTime**

- (a) Select RESP parameter area and the [RESP SETUP]menu will be displayed;
- (b) Select [APNEA ALM] and then select [10S], [15S], [20S], [25S], [30S], [35S], [40S] or [OFF].
  - [10S] meansthat if apnea lasts for more than 10s and RESP alarm function is enabled, the monitor will give an apnea alarm.
  - [OFF] means the apnea alarm function is disabled.

### 16.4.3 **Setting the RESP Lead**

RESP lead is where the current respiratory waveform comes from. There are RA-LA (I) and RA-LL (II) to choose.

- (a) Select RESP parameter area and he [RESP SETUP]menu will be displayed;
- (b) Select [RESP LEAD] and select [RA-LA (I)]or[RA-LL (II)].

### 16.4.4 Setting the RESP Filter

Enhancing filter is to enhance filtering the interference of heart beat.

- (a) Select RESP waveform area and he [RESP WAVE]menu will be displayed;
- (b) Select [FILTER] and select [ON] or [OFF] to enable or disable the RESP filter function respectively.



# Chapter 17 SpO<sub>2</sub> Monitoring

### 17.1 Overview

SpO<sub>2</sub> parameters measure blood-oxygen saturation, that is, the percentage of the total oxyhemoglobin. When 97% of the total number of hemoglobin molecules combines with oxygen in the arterial blood's red blood cells, this blood will have 97% SpO<sub>2</sub>, and at the same time the monitor reads 97% SpO<sub>2</sub> value. This value shows the percentage of oxygen-carrying hemoglobin molecules, constituting oxyhemoglobin. Furthermore parameters of the SpO<sub>2</sub> can also provide pulse rate signal and plethysmography wave (PLETH).

### 17.1.1 Principle of Measuring SpO<sub>2</sub>

Pulse oximetry is a measurement of oxygen saturation. It is a continuous, non-invasive way of determining the hemoglobin oxygenation saturation. It is involved in measuring how much light emitting from the sensor side passes through the patient's tissue (such as a finger or ear) and then reaches the other side of the receiver.

Though the amount of light passing through depends on many factors, most of them are constant. However, one of the factors is that blood flow in the arteries changes with time, since it is pulsatile. It is possible to obtain arterial blood oxygen saturation by measuring the amount of light absorbed during the pulse. And surveying pulse itself can supply a "PLETH" waveform and pulse rate signal.

The main screen can display "SpO2" value and "PLETH" waveform.



• If there is carbonyl hemoglobin, methemoglobin, or dye dilution chemical present, the SpO2 value will deviate.

### 17.1.2 Recognition of the type of SpO2 Sensor

The types of SpO2 sensor have been configured when the equipment is delivered from the factory, which is recognizable by the socket connected to the SpO2 sensor:

- Digital SPO2: SpO2 logo marked on the left side of the monitor.
- Nellcor SPO2: SpO2 logo and NELLCOR logo marked on the left side of the monitor.
- Masimo SPO2: SpO2 logo and MasimoSET logo marked on the left side of the monitor.

The wavelength range and maximum light output power of different transducers are very important information to clinical doctors, such as, when proceeding photodynamic therapy

• Measurable wavelength of analog SpO2 module sensor: red light 660nm, infraredlight 905nm.



- Measurable wavelength of Masimo SpO2 module sensor: red light 660nm, infraredlight 940nm.
- Measurable wavelength of Nellor SpO2 module sensor: red light 660nm, infraredlight 890nm.

The sensor's maximum output light power is less than 18mW.

# **Warning**

• This monitor can automatically identify the SpO2 sensor. However, as the internal hardware has been fixed before delivery from factory, the use of improper SpO2 sensor will lead to wrong measured values.

### 17.2 SpO2/PR Display

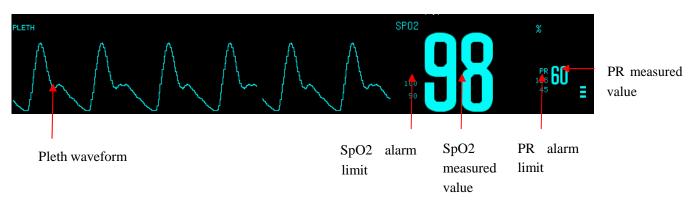


Figure 17-1 SpO2 display

### 17.3 Safety Information



#### Warning

- Check whether the sensor cable is in good condition prior to monitoring. When you
  discennect the SpO2 sensor cable from the monitor, the monitor will trigger a technical alarm
  and display alarm message "SpO2 NO SENSOR" on the screen.
- If the sensor or its packaging has signs of damage, do not use it and return to the factory.
- Continuous and prolonged monitoring may increase the risk of undesirable changes in skin characteristics, such as irratation, reddenning, blistering, or even pressure necrosis etc, especially for the neonates or patients with perfusion disorders and varying or immature forms of skin. Check thesesor application site every two hours and move the sensor if the skin quality changes. More frequent checkis required due to different status of individual patents.
- High oxygen levels will have premature children been in danger of infecting the crystal-like fibrous tissue disease. Therefore, the SpO2 alarm limit must be set carefully based on generally accepted clinical practice.
- Do not entangle the cable of the sensor and electrical surgical unit.
- Do not placethe sensor on limbs with an arterial catheter or intravenous tube.
- Do not place the sensor and the cuff on the same limb while measuring, because the NIBP



measurement may occlude the blood flow and affect the readings of SpO2.

- A functional tester or SpO2 simulator cannot be used to access the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
- The pulse oximeter monitor is calibrated to display functional oxgen saturation.

# Attention

- Make sure that the nail covers the light inside the sensor. The sensor cable should be placed on the back of hands.
- SpO2 waveform and pulse volume are out of proportion.

### 17.4 Steps of Monitoring

# **Warning**

- Select the appropriate placement according to the instrument and its supporting probe, which is fundamentally vital to neonates.
- 1. Turn on the monitor;
- 2. Insert the connector of the sensor cable into the SpO<sub>2</sub>socket.
- 3. Attach the sensor to the appropriate position on the patient.

Placement of finger adult/pediatric SpO2 sensor:



Figure 17-2Placement of finger adult/pediatric SpO2 sensor

### Placement of neonate SpO2 sensor:

NeonateSpO2sensor consists of the Y-shaped SpO2sensor and sensor jacket. Insert the LED side of the Y-shaped sensor in the upper groove of the sensor jacket, and respectively the PD side of the sensor in the lower (See Figure 17-3), then the neonateSpO2sensor is shown in Figure 17-4.



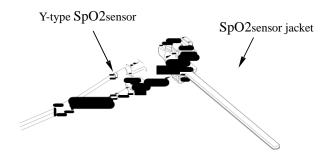


Figure 17-3Neonatal SpO2sensor (1)



Figure 17-4Neonatal SpO2sensor (2)

Attach the sensor to the neonatal hand or foot as shown below.



Figure 17-5Placement of the neonatal SpO2sensor

# Attention

- When the accurate positioning between the test site and the probe fails, it may result in wrong readings of SpO2, and even stop monitoring because of the failure of searching pulse. In this case you should re-position these two.
- Excessive movement of measured sites may affect the accuracy of the measurement, therefore, you should calm the patient or replace sites in order to reduce the impact of excessive movement.

# **Warning**

- The maximum measuring time of SpO2 sensor on a single measuring site is 2 hours.
- In a long and continuous monitoring process, it is advisable to check periodically the
  positioning of the sensor to avoid inaccurate measurement due to changing in the positioning
  because of moving or other factors.



### 17.5 Measurement Limitations

During operation, the following factors can affect the accuracy of SpO2 measurement:

- High-frequency radio interference, for instance, interference self-generated from the host system or from electrical scientific instruments connected to the system.
- During magnetic resonance imaging scanning (MRI), do not use the photoelectric oximeter and oxygen sensor, since induced currents may cause burning.
- Intravenous dye.
- Patient's excessive movement.
- External radiation.
- Improper installation of sensor or improper contact position with the object.
- Sensor's temperature (optimal temperature should be among 28  $^{\circ}$ C 42  $^{\circ}$ C).
- The sensor is placed on the limbs with a blood pressure cuff, arterial catheter, or the pipeline of body cavity.
- The concentrations of non-functional hemoglobin such as carboxyhemoglobin (COHb) and methemoglobin (MetHb) etc.
- Extremely low degree of blood-oxygen saturation.
- The measured area has poor circulation.
- Syndromes such as shock, a Extreme low degree of blood-oxygen saturation, .anemia or low temperature etc and application of vasoconstrictor drugs can reduce blood flow to the level of not being able to be measured.
- Measurement also depends on both the oxyhemoglobin and reduced hemoglobin's absorption of specific wavelengths of light. If any other factors absorb the same wavelength, they will generate false measurement, lower SpO₂ values. These factors are as follows: carbonization of hemoglobin, methemoglobin, methylene blue , indigo rouge.It is recommended to use only the SpO₂sensor described in the accessories.

### 17.6 SpO<sub>2</sub>Settings

### 17.6.1 Setting theIntelligent Alarm

- 1. Select SpO<sub>2</sub> parameter area and the [SpO2 SETUP] menu will be dispalyed;
- 2. Select [SAT SECOND]
- 3. Select [10], [25], [50], [100]seconds or [Disable];

### NOTE: This feature is only available on NELLCOR SpO2.

Intelligent alarm is designed to reduce false alarms, help the doctor grasp more accurate and timely changes



in SpO2. For example, set the intelligent alarm range as 50, the upper limit of NELLCOR SpO2 alarm as 97%, and lower limit as 90%, the measured SpO2 value turns out to be 80% and remains for 3 seconds, then, it decreases to 78% and remains for 2 seconds, so calculating from the time the alarm limit is exceeded, the sound-light alarm will initialize instantly only when the SpO2 value is out of the alarm range for 5 seconds. Meanwhile, the circle beside the SpO2 value returns to origin. Its calculation is as follow:

Minus percentage points x seconds = SatSeconds integer

values of the calculated SatSeconds are shown:

%SpO2	second	SatSeconds
(90%-80%) x	3 =	30
(90%-78%) x	2 =	24
Total SatSeconds	=	54

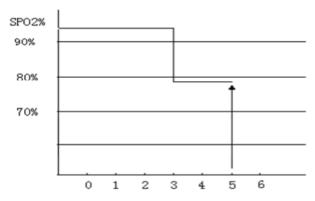


Figure 17-6 Example figure

### SatSeconds Example:

After about 4.9 seconds, the instrument will report SatSeconds alarm, because 54 is beyond the intelligent alarm range 50 SatSeconds.

Within a few seconds, saturation will fluctuate a bit, and not be stable. Generally, the patient's SpO2 value may fluctuate between the upper and lower limits of the alarm, and may re-enter to non-alarm range several times. In this volatile period, the system will store the positive and negative points of the SpO2, till it reaches the SatSeconds limit or patient's SpO2 values returned to and remains in the non-alarmrange.

### 17.6.2 Setting the Pulse Sound

- 1. Select SpO<sub>2</sub> parameter area and the [SpO<sub>2</sub> SETUP] menu will be dispalyed;
- 2. Select [BEEP];
- 3. Select [ON] and you can get a prompt of pulse sound;
- 4. Select [OFF] and there is no prompt of pulse sound.

NOTE: This feature is only available on Masimo SpO<sub>2</sub>.



### 17.6.3 Setting the Signal IQ

When it is turned on, below the PLETH waveform, there is a logo for signal collection, which is mainly reflecting the quality of the signal during the acquisition process. This signal disappears as it is turned off.

- 1. Select SpO<sub>2</sub> parameter area and the [SpO2 SETUP] menu will be dispalyed;
- 2. Select [SIGNAL ON/OFF];
- 3. Select [ON] or [OFF].

NOTE: This feature is only available on Masimo SpO2.

### 17.6.4 Setting the Average Time

The average time, SpO2 value displayed on the monitor, is the result of averaged data collected during a period of time. The shorter (or longer) the average time is, the faster (or more slowly) the monitor will respond to the patient's SpO2 value changes, but with lower (or higher) measurement accuracy. Please set a shorter average time for critically ill patients so as to analyze the disease in time.

- 1. Select SpO<sub>2</sub> parameter area and the [SpO2 SETUP] menu will be dispalyed;
- 2. Select [AVG TIME(s)];
- 3. Select [2-4], [4-6], [8], [10], [12], [14] or [16].

NOTE: This feature is only available on Masimo SpO<sub>2</sub>.

### 17.6.5 Setting the Quick SpO<sub>2</sub>

Quick SpO2 enables rapid response to, and display of, fast changes in SpO2 by giving priority to the most recent data.

- When the [AVG TIME(s)] is set to [2-4] or [4-6], the [FAST SAT] turns to [ON] automatically and the users can perform the rapid SpO2 measurement.
- When [AVG TIME(s)] is set to [8], [10], [12], [14] or [16], the [FAST SAT] turns to [OFF] automatically and the users cannot perform the rapid SpO2 measurement.

NOTE: This feature is only available on Masimo SpO<sub>2</sub>.

#### 17.6.6 Setting the Calculation Sensitivity

There are three kinds of calculation sensitivities, including normal, sensitive and APOD. For typical patient monitoring, use "normal" sensitivity. As for those patients who have moist skin, active exercise, or for other reasons, the sensor may be dropped off a patient's body, then use the "sensitive" sensitivity. If the patient has very low perfusion levels and wants to improve the sensitivity performance, please use the "APOD" sensitivity.

- 1. Select SpO<sub>2</sub> parameter area and the [SpO2 SETUP] menu will be dispalyed;
- 2. Select [SENSITIVE];
- 3. Select [Normal], [High] or [APOD].



NOTE: This feature is only available on Masimo SpO<sub>2</sub>.

### 17.7 SPO2 Accuracy Test

The recommended method of determining the SpO2 accuracy of the monitor is to compare its SpO2 readings with the readings of a CO-oximeter.

# **Warning**

 A functional tester or SpO2 simulator cannot be used to access the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

# $\triangle$ Note

- Confirmation about SpO2 measurement accuracy: accuracy of SpO2has been confirmed in the comparison between experiment on human being and referential value of arterial blood measured by CO-oxygen pressure gauge. Measurement results of Pulse Oxygen Meter are subject to statistical distributions, which are, compared to measurement results by CO-oxygen pressure gauge, expected to fall in designated accuracy range with 2/3 results.
- Masimo SpO2 has passed the non-motion accuracy verification by compared to the laboratory joint photoelectric oximeterand monitor in the human blood research where healthy adult volunteers' SpO2 value are at 70% to 100% under the inducible hypoxic condition. This difference equals to  $\pm$  one standard deviation, which contains 68% of the sample.
- Masimo SpO2 has passed the motion accuracy verification in the human blood research where healthy adult volunteers conduct friction motion or tapping motion at 2 to 4 Hz to induce a hypoxic condition. There is no repeated movement at range from 1 to 2 cm and frequency from 1 to 5 Hz. When set at inducible hypoxic condition (SpO2 70% ~100%) with range from 2 to 3 cm, the results should compare those of laboratory joint photoelectric oximeterand monitor. This difference equals to  $\pm$  one standard deviation, which contains 68% of the sample.

### 17.8 Low Perfusion Accuracy Test

This monitor can measure low perfusion and the recommended method of determining the low perfusion accuracy of the monitor is to compare its low perfusion readings with the readings of a simulator.



# 17.9 PR Accuracy Test

The recommended method of detenining the PR accuracy of the moitor is to compare its PR readings with the readings of ECG from the same time.

### 17.10 Masimo Information



#### Masimo Patent

It contains one or more of the following U.S. patents: RE38,492, RE38,476, 6,850, 787, 6,826,419, 6,816,741, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,584,336, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,206,830, 6,157,830, 6,067, 462, 6,011,986, 6,002,952, 5,919,134, 5,823,950, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international patents or a item or a number of patents referred to in the www.masimo.com/patents. Including functions from products of Satshare ® and the U.S. Patent 6,770,028. Other patents are under application.

#### Other Information

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RadNet, Radicalscreen, signal IQ, FastSat, fastStart are trademarks of APOD and Masimo Corporation.



# **Chapter 18 NIBP Monitoring**

### 18.1 Overview

The non-invasive blood pressure (NIBP) measurement uses oscillation method and is available for adults, pediatric, neonates, pregnant and pre-eclamptic patient.

In order to understand how the oscillation method works, you can compare it to the auscultatorymethod.

- Auscultatorymethod: doctors listen to the blood pressure through stethoscope and know the systolic pressure and diastolic pressure. As long as the arterial pressure curve is normal, then mean blood pressure can be calculated through systolic pressure and diastolic pressure.
- Oscillation method: the monitor cannot hear the blood pressure but only measure the vibration scope of pressure in cuff. The changes of blood pressure cause the vibration of the cuff and cuff pressure at the maximum scope is the mean blood pressure. The systolic pressure and diastolic pressure can be calculated after measuring the mean blood pressure.

Generally speaking, auscultatorymethod measures the systolic pressure and diastolic pressure to calculate the mean blood pressure. Oscillation method measures mean arterial pressure to calculate systolic pressure and diastolic pressure.

When perfoming NIBP measurement on a pediatric and neonate, you must ensure that the correct measure mode is selected. Wrong measure mode could jeopardize patient safety, because high blood pressure of adults is not suitable forpediatric and neonates.

According to the IEC601-2-30/EN60601-2-30 standard, NIBP measurement can be conducted during electrosurgical operation and during the discharging period of defibrillator

# 18.2 NIBP Display

NIBP measured values are displayed in the parameter area. The following figure is for reference only. The NIBP display on your monitor might be somewhat different:

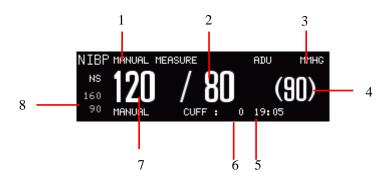


Figure 18-1 NIBP display



1	Measure mode: manual, auto, or	2	Diastolic pressure
	continuous measurement		
3	Pressure unit: mmHg or kPa	4	Mean arterial pressure
5	Time of last measurement	6	Cuff pressure
7	Systolic pressure	8	Alarm limit of systolic pressure

### 18.3 Safety Information

# $\triangle$ Warning

- Before starting the measurements, make sure the selected measure mode applies to your patients. Using other than the neonatal mode on a neonatal patient may put the patient in danger.
- Do not install the cuff on a limb with an intravenous infusion tube or a catheter. During cuff
  inflation, if infusion is lowed down or clogged, the area around the tube may be damaged.
- Ensure the connection tubing that attached blood pressure cuff and monitor is with no kinking.
- Too frequent measurements can cause injury to the patient due to bloodflow interference.
- Do not place the cuff over a wound, as this can cause further injury.
- Do not place the cuff on any limb whereintravascular access or therapy, or an arterio-venous (A-V) shunt is present, as this could cause temporary interference to blood flow and result in injury to the patient.
- Do not place the cuff on the arm on the side of a mastectomy.
- Pressurization of the cuff can temporarily cause loss offunction of simultaneously used monitoring equipment on the same limb.
- NIBP measurement cannot be performed onthose patients suffering from sickle-cell disease or skin damage or any anticipated damage.
- For a patient suffering from serious disturbance of blood coagulation, the decision to operate automatic blood pressure measurement must be made according to the clinical evaluation, because the friction area between body and sleeves has the risk of hematoma.

### 18.4 NIBP Measurement

#### 18.4.1 **Measurement Steps**

- 1. Conenct the NIBP cuff to the monitor and turn on the monitor.
- 2. Verify that the cuff is completely deflated.
- 3. Use a cuff with suitable size on the patient. Be sure that the cuff is not too tightly wrapped around the limb, otherwise it may cause discoloration or even ischemia to the far end of the limb.



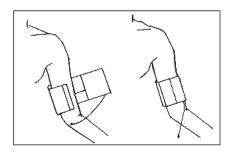


Figure 18-2 Cuff usage

# **Attention**

• The width of the cuff should be 40% (or 50% for neonates) of the circumference of the limb, or 2/3 of the length of the upper arm. The length of the inflated part of the cuff should be long enough to wrap 50~80% of the limb; a cuff of wrong size will produce a wrong reading. If you have a problem about the size of the cuff, use a larger cuff in order to reduce errors.

### Adult/pediatric/neonateresuable cuff:

Patient type	Limb Circumference	Cuff width	Gastube length
Neonate	6~11cm	5cm	
Infant	10∼19 cm	8 cm	
Pediatric	18∼26 cm	10.6 cm	2 m
Adult 1	25~35 cm	14 cm	
Adult2	33~47 cm	17 cm	
Leg	46∼66 cm	21 cm	

### Neonate disposable cuff:

Size	Limb Circumference	Cuff width	Gastube length
Neonate 1	$3.0 \sim 5.5 \mathrm{cm}$	2.6cm	
Neonate 2	$4.0 \sim 7.6\mathrm{cm}$	3.7 cm	
Neonate 3	5.6 ∼ 10.6 cm	4.5 cm	2 m
Neonate 4	7.0 ~ 12.8 cm	5.3 cm	
Neonate 5	8.9 ~ 15.0 cm	6.0 cm	



- 4. Check if the edges of the cuff are located inside the range marked by < >. If not, replace the cuff with a more suitable one.
- 5. Check that the monitor mode is correct (displayed in the NIBP parameter area). To change the measure mode, please enter the menu [NIBP SETUP] to change [MEASURE MODE].
- 6. Press the key on the front panel or click [NIBP START] on-screen key to inflate the NIBP cuff.

Body parts used for pressure-measuring should be in the same horizontal location with patient's heart. If unable to do so, it is necessary to use the following correction method to modify the measurement results:

- If cuff is above the heart level location, 0.75mmHg (0.10kPa) should be added to the displayed value for per centimeter gap.
- If cuff is below the heart level location, the displayed value should minus 0.75mmHg (0.10kPa) for per centimeter gap.

In order to obtain accurate blood pressure measurement for the hypertension patient, the patient position should be as follows:

- a) Comfortably seated
- b) Legs uncrossed
- c) Feet flat on the floor
- d) Back and arm supported
- e) Middle of the cuff at the level of the right atrium of the heart

#### 18.4.2 **Operation Prompt**

(1) Start an auto measurement:

Enter the menu[NIBP SETUP] and select[INTERVAL] to select the time interval for auto measurement, and then press the key on the front panel or click [NIBP START] on-screen key to inflate the NIBP cuff and measure the NIBP as per the set time interval.

- (2) Start a manual measurement:
  - Enter the menu[NIBP SETUP] and set [INTERVAL] to [MANUAL], and then press the on the front panel or click [NIBP START] on-screen key to start a manual measurement.
  - You can press the key to start a manual measurement after the auto measurement stops. If you press the key again, the manual measurement will be stopped and auto measurement resumes.
- (3) Start a continuous measurement:

Enter the menu[NIBP SETUP] and select[CONTINUAL] to start a continuous measurement lasting for 5 minutes.

(4) Stop the measurement:

In the measurement process, you can press the \to key to stop at any time.



# **Warning**

• If the NIBP measurement under the auto or continuous measure mode lasts too long, the limb with the cuff may suffer from purpura, ischemia or nerve damage. During patient monitoring, you should check the color, warmness and sensitivity of the far end of the limb from time to time. Once you observe any anomaly, place the cuff on another place or stop measurement immediately.

# **Attention**

- The patient should relax as much as possible and not talk during the measurement procedure.
- 5 min should elapse before the first reading is taken.
- If unexpected readings are obtained, first the operator should use the same method to take measurement and then check the monitor function.

#### 18.4.3 Measurement Limitations

According to the patient's condition, oscillatory measurement has some restrictions. Such measurements are looking for regular impulse waves produced by arterial pressure. In case the patients' condition makes this kind of detection difficult, measurement values will become unreliable and load time will increase. Users should be aware that the following conditions will interfere with the measurement method, so that pressure is not reliable or load time increases. In this case, the patient's condition will make measurement impossible.

#### (1) Patient Mobility

If patient is moving, shaking or in spasms, measurement will be unreliable or even impossible, as these may interfere with the detection of the arterial pressure pulse and load time will be extended.

### (2) Arrhythmia

If patient has shown arrhythmia caused by irregular heart beats, measurements are unreliable or even impossible and load time will be extended.

### (3) Heart-Lung Machine

If patient is connected to an artificial heart-lung machine, measure cannot be conducted.

### (4) Pressure Change

If within a certain time, arterial pulse pressure is being analyzed to get the measurements, when blood pressure in patients is rapidly changing, measurement will be unreliable or even impossible.

#### (5) Severe Shock

If a patient is in serious shock or hypothermia, the pressure will be unreliable. The reducing blood flowing to periphery would cause a decline in arterial pulse.

#### (6) Limit Heart Rate



**User Manual** 

Blood pressure measurement cannot be performed when heart rate is lower than 40bpm (beats per minute) or higher than 240bpm (beats per minute).



#### (7) Obese Patients

A thick layer of fat around a limb damps oscillations from the artery, thus preventing them from reaching the cuff. The accuracy is lower than the normal one.

### 18.5 NIBP Settings

### 18.5.1 **Setting the Measure Mode**

Measure mode includes adult, child and neonate, which is the same as the patient type.

- (a) Select NIBP parameter area and the [NIBP SETUP]menuwill be displayed;
- (b) Select [MEASURE MODE]
- (c) Select[ADU], [PED] or[NEO];

### 18.5.2 Setting the Interval Time

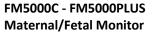
- (a) Select NIBP parameter area and the [NIBP SETUP]menuwill be displayed;
- (b) Select [INTERVAL];
- (c) Select [MANUAL] to conduct a manual measurement;
- (d) Select [1MIN], [2MIN], [3MIN], [4MIN], [5MIN], [10MIN], [15MIN], [30MIN], [60MIN], [90MIN], [120MIN], [180MIN], [240MIN] or [480MIN] for auto measurement;

### 18.5.3 **Setting the Pressure Unit**

- (a) Select NIBP parameter area and the [NIBP SETUP] menuwill be displayed;
- (b) Select [UNIT];
- (c) Select [mmHg] or [kPa];

### 18.5.4 Setting the Pre-inflation Value

- (a) Select NIBP parameter area and the [NIBP SETUP] menuwill be displayed;
- (b) Select [INFLATION] and select the suitable pre-inflation value;
- Neonates: the range of the pre-inflation value is 60-120 mmHg, the default value is 100mmHg
- Pediatric: the range of the pre-inflation value is 80-200 mmHg, the default value is 120mmHg
- Adults: the range of the pre-inflation value is 80-240 mmHg, the default value is 160mmHg;







# 18.6 NIBPReset

Select NIBP parameter area and select [RESET]. Reset can restare the inflation value of the blood pressure pump to the initial setting. If the blood pressure pump is working abnormally, it can be checked by means of reset and will recover from any anomaly caused by an accidental reason.

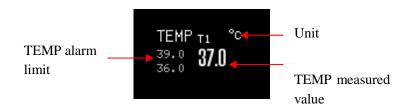


# **Chapter 19 TEMP Monitoring**

### 19.1 Overview

The probe should be applied to skin or anus according to the type of the probe you bought. The recommended minimum measuring time is 1 minute, or the measured value will not be accurate

### 19.2 TEMP Display



### 19.3 Safety Information

# $ilde{ ext{$igwedge}}$ Warning

- Check whether the TEMP probe cable is in good condition prior to monitoring. When you
  discennect the TEMP probe cable from the monitor, the monitor will trigger a technical alarm
  and display alarm message "T1 SENSOR OFF" on the screen.
- Be careful in handling the TEMP probe and cable, when not in use, the probe and cable should be pulled into the loose ring. If the wire is pulled too tight, it will lead to mechanical damage.
- Calibrate the temperature measuring instrument at least once every two years (or according to the required time in the hospital directive rules). Please contact the manufacturer when calibration is needed.

# $\triangle$ Attention

- Disposable temperature probe can only be used once.
- During the monitoring process, the temperature measuring instrument will automatically check itself once per hour. Self-checking will last 2 seconds and will not affect the temperature monitoring.



# 19.4 Steps of TEMP Measurement

- (1) If you are using a disposable temperature probe, first connect the temperature probe to the cable first and then connect the cable to the TEMP socket on the monitor. For reusable temperature probe, it can be directly connected to the TEMP socket.
- (2) Securely attach the temperature probe onto the patient's body.
- (3) Turnon the monitor.

# 19.5 Setting the TEMP Unit

- (a) Select TEMP parameter area and the [TEMP SETUP]menu will be displayed;
- (b) Select [TEMP UNIT];
- (c) Select [°C] (Celsius degree) or [°F] (Fahrenheit degree) according to your habit.



# **Appendix I Accessories**

### ⚠ Warning

- Only use the accessories designated in this user manual, or the monitor could be damaged.
- To avoid cross infection, do not reuse any disposable accessory.
- The disposal of the reusable or disposable accessories shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital.

PN	Model	Description
40-000195-00	250ML	Ultrasonic coupling agent
040-000616-00	CM-FSUS1	Primary FHR probe, Waterproof
040-000617-00	CM-FSUS2	Secondary FHR probe, Waterproof
040-000618-00	CM-FST	TOCO Probe, Waterproof
040-000619-00	CM-FSM	FM Marker, Waterproof
040-000226-00	HX-1	Wake Probe
040-000867	FS-TC1	Adult Electrode
040-000868	13-101	Adult Electrode
040-000320-00	98ME01AC473	ECG Cable
040-000321-00	98ME01AC474	ECG Cable
040-000322-00	98ME01AC475	ECG Cable
040-000368-00	98ME01EC477	ECG Cable
040-000369-00	98ME01EC478	ECG Cable
040-000370-00	98ME01EC479	ECG Cable
040-000479-00	98ME01AC458	ECG Cable
040-000480-00	98ME01AC457	ECG Cable
040-000487-00	98ME01EB075	ECG Cable
040-000481-00	98ME01AB076	ECG Cable
040-000485-00	98ME01EC681	ECG Cable
040-000486-00	98ME01EC680	ECG Cable
040-000312-00	SAL104 REV:A.0	Adult SPO2 probe for finger
040-000726-00	SAS104 REF:AS104-068-01	Adult SPO2 probe for finger
040-000730-00	SES104 REF:ES104-068-01	Neonate SPO2 probe
040-000646-00	A1418-SA203MV	Adult SPO2 probe for finger
040-000334-00	A1418-SW203MU	Neonate SPO2 probe



Masimo SpO2		
040-000203-00	M-LNCS DCI/>30KG PN:2501	Adult SPO2 probe for finger
040-000361-00	M-LNCS YI >1KG PN:2505	Reusable neonate Y-model SPO2 probe
Nellcor SpO2		
040-000010-00	DS-100A >40KG	Nellcor SpO2 sensor
040-000075-00	DURA-Y® D-YS	Nellcor SpO2 sensor
040-000243-00	SLZ068	Cable extender
040-000769-00	SLZ122	Cable extender
040-000313-00	S-A1202026	Cable extender
NIBP Cuff		
040-000591-00	U1880S	NIBP Cuff
040-000592-00	U1880S	NIBP Cuff
040-000593-00	U1881S	NIBP Cuff
040-000594-00	U1882S	NIBP Cuff
040-000595-00	U1883S	NIBP Cuff
040-000596-00	U1884S	NIBP Cuff
040-000597-00	U1885S	NIBP Cuff
040-000598-00	U1869S	NIBP Cuff
040-000599-00	U1889S	NIBP Cuff
Temp Probe		
040-000246-00	TAS03-04	Surface Probe
040-000387-00	TPS03-03	Surface Probe
040-000385-00	TAE03-03	Cavity Probe
040-000386-00	TPE03-04	Cavity Probe
040-000534-00	TPS03-07	Surface Probe
040-000650-00	TPS03-06	Surface Probe
040-000652-00	TAE03-08	Cavity Probe
040-000651-00	TAE03-07	Cavity Probe



# **Appendix II Product Specification**

# 1. Monitor Type

Item	Туре	
Type of protection against	Class I with interna	ıl power supply.
electric shock		
Degree of protection	BF applied parts	TOCO, FHR, FM, WAKE, NIBP, TEMP, SpO2
against electic shock	CF applied parts	ECG
Safety standard	MDD 93/42/EEC as amended by MDD 2007/47/EC, EN ISO13485:2012+AC2012, EN ISO14971: 2012, EN60601-1:2006/A1:2013, EN 60601-1-2:2007/AC:2010, EN 1041: 2008, EN980:2008, EN ISO 80601-2-56:2009, EN60601-2-27:2006, IEC 60601-2-49: 2011, IEC 80601-2-30:2009, EN 1060-1:1995+ A2:2009, EN60601-1-8:2007/AC:2010, EN ISO10993-1:2009, EN 1060-3:1997+A2:2009, EN ISO 80601-2-61:2011, EN1060-4:2004, EN62304:2006, EN62366:2008, EN60601-1-6:2010, EN60601-2-37:2008, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 80601-2-55:2011	
Ingress protection	IPX1	
Safety level if there is any	The monitor is not	allowed to be used if there is any mixture of flammable
mixture of flammable	anesthetic gas and	air, or mixture of flammable anesthetic gas and oxygen
anesthetic gas and air or	or nitrous oxide.	
oxygen/nitrous oxide (not		
applicable)		
Work mode	Continuous running	g equipment

# 2. Monitor Specifications

# (1) Dimension and Weight

Item	Specification	
Dimension and weight	Dimension: 340mm (L) ×270mm (W) ×95 mm (H)	
	Weight: 5.5Kg (including battery)	
Fuse	Φ5×20MM T1.6A L250V	

### (2) Environmental Requirements

Item	Specification		
Work	Ambient temperature		5°C~40°C
environment	Relative humidity		≤93%
	Atmospheric pressure		700hPa~1060hPa
Transport and	Ambient temperature		-20℃~+60℃
storage	Relative humidity		≤93%
environment	Atmospheric pressure		700hPa~1060hPa
	Please protect the Monitor against violent impact, vibration and water in transport.		lent impact, vibration and water in transport.
Power supply	Rated input voltage	100-240V∼	
	Rated frequency	50Hz/60Hz	
	Rated input power	80VA	



### (3) Display Screen

Item	Specification	
Display	12.1-inch TFT color touch screen	
Display capacity	Up to 6 channels of waveform	
Resolution	800×600	

### (4) Battery

Item	Specification
Battery specification	4400mAh, 14.8V lithium battery
Charge time	At least 5 hours from depletion to 90% charge and at least 5.5 hours from
	depletion to 100% charge when the monitor is switched off.
Operatingtime	At least 5 hours for a new and fully charged battery under DEMO mode.

# (5) Data Storage

Item	Specification	
Trend data	Short trend	1 hour with resolution of 1 second and 5 seconds
	Long trend	120 hours with resolution of 1 minute, 5 minutes and 10
		minutes
Trend chart and	120hours	
trend table		
Alarm events	300parameter alarm events and related parameter waveform	
Measured NIBP data	2,000 groups	
Waveform history	Up to 120 minutes, subject to the type and quantity of the saved waveform.	
Frozen waveform	240s mother waveform, 60h fetus waveform.	

# (6) Fetus Monitoring

Item	Specification
Work mode	Pulse wave
Ultrasound working frequency	(1MHz~3MHz) ±1%
Mechanical index(MI)	<1
Thermal index of soft tissure(TIS)	<1
Thermal index of bone(TIB)	<1
P- (peak negative acoustic pressure)	<1MPa
I <sub>ob</sub> (Intensity of output beam)	<5mW/cm <sup>2</sup>
I <sub>spta</sub> (spatial peak - temporal average	$<100 \text{mW/cm}^2$
intensity)	
FHR measuring range	30bpm~250bpm
FHR measuring accuracy	±1bpm
FHR alarm range	30bpm~250bpm
FHR alarm error	±1bpm
TOCO measuring range	0~100
Non-linear TOCO measuring error	±8%
TOCO alarm range	0~100



TOCO alar	rm error			±1%
Harmful	ingress	protection	of	IPX7
transducer	s			

### (7) ECG

Item	Specification				
Lead select	3 leads, 5 leads, 12 leads; auto recognition				
Lead mode	12 leads (R, L, F, N, C; or RA, LA, LL, RL, V)-(R, L, F, N, C1, C2, C3, C4, C5,				
	C6 or RA, LA, LL, RL, V1, V2, V3, V4, V5, V6)				
Lead form	I, II, III, avR, avL, avF, V-V1,	V2, V3,	V4, V5, V6		
Lead mode	5 leads (R, L, F, N, C or RA, L	A, LL, R	L, V)		
Lead form	I, II, IIII, II, III, avR, avL, av	F, V			
Lead mode	3 leads (R, L, F or RA, LA, LI	۲)			
Lead form	I, II, III				
Sensitivity (Gain) and	$2.5 \text{mm/mV} (\times 0.25)$ , $5 \text{mm/mV}$	$7(\times 0.5)$	10 mm/mV( $\times$ 1), 20mm/mV( $\times$ 2) and		
error	` '		arity voltage, the error is $\pm 5\%$ .		
Frequency	Surgical mode: 1 Hz~20 Hz (	$-3.0$ dB $\sim$	+0. 4 dB);		
characteristics	Monitor mode: $0.5 \text{ Hz} \sim 40 \text{ Hz}$	(-3.0dB	~+0. 4 dB);		
(Display and	Diagnostic mode: 0.05Hz~13	0 Hz (-3.	0dB∼+0. 4 dB);		
recording)					
Notch	Monitor and surgical mode: the	e 50/60H	z notch function is auto activated;		
	Diagnostic mode: the 50/60H	Iz notch	function can be select to activate or		
	deactivate mannually.				
	Power frequency interference rejection capability ≥ 20dB				
Noise level	≤25 µ V <sub>P-P</sub> .	<u> </u>	1 -		
CMRR	≥105dB				
Overload protection	Load 1V, power frequency, differentialmode AC voltage for 10s without				
	damage (p-v)				
Respiration, lead-off,	<0.1μA				
sensing and active					
noise suppression					
QRS wave amplitude	Amplitude (p-v RTI)	0.5mV	~5mV		
and interval	Width (adult)	70ms~1	120ms		
	Width (pediatric/neonate)	40ms~1	120ms		
	No response to the signals:	a) with	amplitude not exceeding 0.15mV (p-v		
		RTI) (e	xcept for pediatric/neonate mode); or		
		b)with	10ms width (except for pediatric/neonate		
			in case of 1mV amplitude.		
Voltage tolerance	>100μV (p-v)				
Drift tolerance	Triangular wave amplitude (p-v RTI) 4mV				
	QRS wave amplitude (p-v RTI) 0.5mV				
	QRS wave width 100ms				
	QRS wave recurrence frequency 80bpm				
HR measurement	Adult	- J	15~300bpm		
range and accuracy	Pediatric/Neonate		15~350bpm		
range and accuracy	Accuracy		$\pm 1\%$ or $\pm 1$ bpm, whichever is the		
	1 100 di de j		_		
			larger		



HR Alarm range	Adult	1	5~300b	pm		
	Pediatric/Neonate	e 1	5~350b	pm		
Alarm error	$\pm 1$ bpm					
Alarm start time for asystole	<10s					
Alarm start time for heart rate too low or too high	<10s					
Input dynamic range	Input signal amplitude ±5mV					
	Rate (RTI)			320mV/s		
	DC offset voltage	e		-300 ~ +300mV	V	
	Output signal cha	ange		±10%		
	Failure display prior to display)	(atten	uation	Not reduced to	belo	w 50%
Input impedance	≥5MΩ					
System noise (p-v RTI)	<30μV	$<30\mu V$				
Multi-channel crosstalk	<5%					
Time reference	selection		nanent display		25n	mm/s
selection and accuracy			permanent display 12		12.:	5mm/s, 25mm/s, 50mm/s
	Accuracy	±10%	ó			
Output display	Channel width		30mm	1		
	Aspect ratio		0.4s/mV			
Input signal	Total system erro		±20% or ±100μV, whichever is larger			•
reproduction accuracy	Response to 0.3 mV·s shock in the shock range  Electrode weighting factor		Sinus	Sinusoidal input		0.67~40Hz (attenuation-3dB)
			Respo	Response to 20ms		0~25Hz attenuation in
			(width) triangular wave		e	amplitude of wave peak
			Offset	Offset (RTI)		≤0.1mV
			Slope (RTI)			≤0.30mV/s
			≥±5%	Y		
			≤0.5m	nm		
Calibration voltage	1mV, error: ±5%	ó	•			
Common mode rejection	<1mV (p-v RTI)					





Baseline control and	Reset time	3s
stability	Drift rate in 10s	$10\mu V/s$
	Baseline drift in 1h	≤500μV
	Baseline drift under working temperature	≤50μV/°C
Pulse inhibition of	Amplitude: ±2mV~±700mV; width: 0.1ms~2.	Oms (method A).



non-overshoot	
pacemaker	
Pulse inhibition of	Can not inhibit
overshoot pacemaker	
Inhibition of	Minimum input slew rate: 320mV/s RTI
pacemaker pulse	
detector on quick ECG	
signals	
Display capability of	Amplitude: $\pm 2mV \sim \pm 700mV$ ; width: $0.5ms \sim 2ms$ ; $\geq 0.2mV$
pacemaker pulse	maximum rise time: 100μS; the ECG display when the
	pacemaker pulse appears at 100 per minute.
Arrhythmia types	Asystole, VFIB/VTAC, R ON T, VT>2, COUPLET, PVC, BIGEMINY,
	TRIGEMINY, Supraventricular Tachy, BRADY, MISSED BEATS, NOISY
	SIGNAL, ARRHYTHMIA, TACHY
Leakage current	<10uA
Electrosurgical	HR: change by ±10% or less compared to that before interference
interference inhibition	
ESU protection	Cut mode: 300W; condense mode: 100W; recovery time: ≤10s.

HR Calculation	
Tall T-wave rejection capability	1.0mV
Heart rateaveraging	Meet the requirements of IEC 60601-2-27: Clause 201.12.1.101.17 b) 3). The HR is computed like this: If the last 3 continousRR intervals are greater than 1200ms, the last 4 RR intervals are averaged to compute the HR. Otherwise, the last 12 RR intervals with the longest interval and shortest interval excluded are averaged to compute the HR.
Heart ratemeter accuracy and response to irregular rhythm	Meet the requirementsofIEC 60601-2-27: Clause 201.12.1.101.17 b) 4), the HR is displayed as follows after the 20s stable segment:  Figure A1, Ventricular bigeminy: 80±1bpm  Figure A2, Slow alternating ventricular bigeminy: 60±1bpm  Figure A3, Rapid alternating ventricular bigeminy: 120±1bpm  Figure A4, Bidirectional systoles: 90±2bpm
Response time of heart rate meterto change in heart rate	Meet the requirementsofIEC 60601-2-27: Clause 201.12.1.101.17 b) 5): the response time to HR change from 80bpm to 120bpm or from 80bpm to 40bpm is less than 10s.
Time to alarm for tachycardia	Meet the requirementsofIEC 60601-2-27: Clause 201.12.1.101.17 b) 6), the waveform:  Figure B1 1 - range: 10s  Figure B1 0.5 - range: 10s  Figure B2 1 - range: 10s  Figure B2 0.5 - range: 10s  Figure B2 0.5 - range: 10s  Figure B2 0.5 - range: 10s



# (8) Respiration

Name	Specification				
Method	Thoracic impedance method				
Measurement	Range	Adult 6~120 rpm			
range and accuracy		Pediatric/neonate	6∼150 rpm		
	Accuracy	7rpm~150rpm: ±1rpm or 1%, whichever is the larger; 0rpm~6rpm: Not specified			
Alarm range and	Adult	7rpm~120rpm			
accuracy	Pediatric/ neonate	7rpm~150rpm			
	Accuracy	±1bpm			
Apnea alarm time	10s, 15s, 20s, 25s, 30s, 35s, 40s,error: ±5s.				

### (9) **NIBP**

Name	Specification					
Measuring method	Oscillation method					
Measurement	Adult	Systolic pressure 40mmHg~270mmHg(5.3kPa~36.0kPa)				
range and accuracy		Mean arterial pressure	20mmHg~235mmHg(2.7kPa~31.3kPa)			
		Diastolic pressure	10mmHg~215mmHg(1.3kPa~28.7kPa)			
	Pediatric	Systolic pressure	40mmHg~200mmHg(5.3kPa~26.7kPa)			
		Mean arterial pressure	20mmHg~165mmHg(2.7kPa~22.0kPa)			
		Diastolic pressure	10mmHg~150mmHg(1.3kPa~20.0kPa)			
	Neonate	Systolic pressure	40mmHg~135mmHg(5.3kPa~18.0kPa)			
		Mean arterial pressure	20mmHg~110mmHg(2.7kPa~14.7kPa)			
		Diastolic pressure	10mmHg~100mmHg(1.3kPa~13.3kPa)			
	Accuracy	The maximum mean d	eviation is $\pm 5$ mmHg( $\pm 0.667$ kPa) and the			
		maximum standard devi	ation is $8$ mmHg( $\pm 1.067$ kPa).			
Overpressure	Adult	300mmHg				
protection	Pediatric	240mmHg				
	Neonate	150mmHg				
	Error	±3mmHg				
Static pressure	0mmHg~30	0mmHg,				
measurement						
range						
Accuracy	±3mmHg					
Alarm range and	Adult	Systolic pressure:				
accuracy		40mmHg~270mmHg(	5.3kPa~36.0kPa)			
		Mean arterial pressure:				
		20mmHg~235mmHg(2.7kPa~31.3kPa)				
		Diastolic pressure				
		10mmHg~215mmHg(1.3kPa~28.7kPa)				
	Pediatric	Systolic pressure:				
		40mmHg~200mmHg(5.3kPa~26.7kPa)				



		Mean arterial pressure: 20mmHg~165mmHg(2.7kPa~22.0kPa)		
		Diastolic pressure		
		$10$ mmHg $\sim$ 150	0mmHg(1.3kPa~20.0kPa)	
	Neonate	Systolic pressu	re:	
		40mmHg~135	5mmHg(5.3kPa~18.0kPa)	
		Mean arterial p	ressure:	
		$20\text{mmHg} \sim 110\text{mmHg}(2.7\text{kPa} \sim 14.7\text{kPa})$		
		Diastolic pressure		
		10mmHg~100mmHg(1.3kPa~13.3kPa)		
	Accuracy	±0.1kPa or ±1m	mHg, whichever is the larger.	
Measuremode	Manual, auto	o, continuous		
	Time interval available for		1min, 2min, 2.5min, 3min, 4min, 5min, 10min, 15min,	
	auto measur	e mode	30min, 60min, 90min, 120min, 180min, 240min,	
			480min	
	Continuous		5min	

### (10) SpO<sub>2</sub>

Item	Specification
Display resolution	1%
Measurement	a) Analog SpO <sub>2</sub> module:
range and accuracy	Measurement range: 0%~100%;
	Accuracy: ±2% (measured without motion in adult/pediatric mode) or ±3%
	(measured without motion in neonate mode) within the measurement range of
	70%~100%.
	b) MasimoSpO <sub>2</sub> module:
	Measurement range: 1%~100%;
	Accuracy: $\pm 2\%$ (measured without motion in adult/pediatric mode), $\pm 3\%$
	(measured with motion in adult/pediatric mode) or ±3% (measured without
	motion in neonate mode) within the measurement range of 70%~100%.
	c) NellcorSpO <sub>2</sub> module:
	Measurement range: 0%~100%;
	Accuracy: $\pm 2\%$ (measured without motion in adult/pediatric mode) or $\pm 3\%$
	(measured without motion in neonate mode) within the measurement range of
	70%~100%.
	d) The accuracy is not specified within 0%~69%.



Alarm range and	Alarm range: 0%~100%
accuracy	Accuracy: ±1%
Data update period	2 seconds
Data and other	8 seconds
signal processing	
time	
Low perfusion	
Conditions	Pulse amplitude: > 0.2%
SpO2 Accuracy	±3%



### (11) Pulse Rate

Item	Specification		
Measurement	a) Analog SpO <sub>2</sub> module		
range and accuracy	Measuring range: 25bpm~250bpm;		
	Resolution: 1bpm;		
	Accuracy: ±1bpm.		
	b) Masimo SpO <sub>2</sub> module		
	Measurement range: 25bpm~240bpm;		
	Resolution: 1bpm;		
	Accuracy: ±3bpm (with motion) or ±5bpm (without motion).		
	c) Nellcor SpO <sub>2</sub> module		
	Measurement range: 25bpm~250bpm;		
	Resolution: 1bpm;		
	Accuracy: ±3bpm within the measurement range of 20bpm~250bpm;		
	Not specified within the measurement range of 251bom~300bpm.		
Alarm range and	Alarm range: 20 bpm~300 bpm		
accuracy	Accuracy: ±1bpm		

# (12) Body Temperature

Item	Specification
Measurement	0°C~50°C
range	
Accuracy	±0.2°C (sensor included)
Alarm range	0°C ~50.0°C(32°F ~122°F)
Alarm resolution	$\pm 0.1$ °C( $\pm 0.2$ °F)
Display resolution	0.1°C
Operating mode	Derect mode
Transient response	No less than 20 seconds



# Appendix III System Alarm Message

### (1) Physiological alarm message

alarm level Alarm Level  FHR1TOO HIGH Medium High, Medium, The measured parameter Check the patient's value is higher than the condition and check if the	(1) I Hysiological	alai III IIICSSage			
High, Medium   Low   Low   Low   High, Medium   Low   Low   High, Medium	Alarm Message			Causes	Solution
FHR1TOO LOW Medium High, Medium, Low  FHR2 TOO HIGH Medium High, Medium, Low  FHR2 TOO LOW Medium High, Medium, Low  TOCO TOO LOW Medium High, Medium, Low  HR TOO LOW Medium High, Medium ST1 TOO HIGH Medium High, Medium PVC TOO LOW Medium High, Medium PVC TOO LOW Medium High, Medium PVC TOO LOW Medium High, Medium PVC TOO HIGH M		alarm level	Alarm Level		
FHRITOO LOW   Medium   High, Medium, Low     FHR2 TOO HIGH   Medium   High, Medium, Low     FHR2 TOO LOW   Medium   High, Medium, Low     TOCO TOO LOW   Medium   High, Medium, Low     HR TOO HIGH   Medium   High, Medium, Low     HR TOO HIGH   Medium   High, Medium   High, Medium     High   Medium   High, Medium     High   Medium   High, Medium     ST1 TOO HIGH   Medium   High, Medium     ST2 TOO LOW   Medium   High, Medium     ST2 TOO LOW   Medium   High, Medium     ST2 TOO LOW   Medium   High, Medium     PVC TOO HIGH   Medium   High, Medium     PR TOO HIGH   Medium   High, Medium     PR TOO HIGH   Medium   High, Medium     NS TOO LOW   Medium   High, Medium     NS TOO LOW   Medium   High, Medium     NS TOO LOW   Medium   High, Medium     ND TOO LOW   Medium   High, Medium     NT TOO HIGH   Medium   High, Medium     NT TOO HIGH   Medium   High, Medium     NT TOO HIGH   Medium   High, Medium     RR TOO HIGH   Medium   High, Medium     High, Medium   High, Medium     RR TOO HIGH   Medium   High, Medium     High, Medium   High, Medium     High   Medium   High, Medium     High   Medium   High, Medium     RR TOO HIGH   Medium   High, Medium     RR TOO HIGH   Medium   High, Medium     High   Medium   High, Medium     High   Medium   High   Medium     High   Medium   High   Medium     High   Medium   High   Medium   High   Medium     High   Medium   High   Medium   High   Medium   High   Me	FHR1TOO HIGH	Medium	High, Medium,	The measured parameter	1
FHR2 TOO LOW FHR2 TOO LOW Medium High, Medium, Low  TOCO TOO HIGH Medium High, Medium, Low  TOCO TOO HIGH Medium High, Medium, Low  HR TOO HIGH High, Medium High, Medium High, Medium High, Medium High, Medium STI TOO LOW Medium High, Medium High, Medium STI TOO HIGH Medium High, Medium High, Medium High, Medium STI TOO LOW Medium High, Medium PVC TOO HIGH Medium High, Medium RT TOO LOW Medium High, Medium RR TOO HIGH Medium High, Medi			Low	value is higher than the	condition and check if the
FHR2 TOO HIGH Medium Low FHR2 TOO LOW Medium High, Medium, Low TOCO TOO HIGH Medium High, Medium, Low TOCO TOO LOW Medium High, Medium RT TOO HIGH Medium High, Medium ST1 TOO HIGH Medium High, Medium ST2 TOO LOW Medium High, Medium ST2 TOO LOW Medium High, Medium PVC TOO HIGH Medium High, Medium SPO2 TOO HIGH Medium High, Medium SPO2 TOO HIGH Medium High, Medium SPO2 TOO HIGH Medium High, Medium PR TOO HIGH Medium High, Medium PR TOO HIGH Medium High, Medium RT TOO LOW Medium High, Medium PR TOO HIGH Medium High, Medium PR TOO HIGH Medium High, Medium NS TOO LOW Medium High, Medium NS TOO LOW Medium High, Medium NS TOO HIGH Medium	FHR1TOO LOW	Medium	High, Medium,	upper alarm limit or lower	alarm limit is suitable for
FHR2 TOO LOW Medium Low  TOCO TOO HIGH Medium High, Medium, Low  TOCO TOO LOW Medium High, Medium, High, Medium High, Medium High, Medium ST1 TOO HIGH Medium High, Medium High, Medium ST2 TOO LOW Medium High, Medium High, Medium High, Medium PVC TOO LOW Medium High, Medium High, Medium PVC TOO LOW Medium High, Medium NS TOO HIGH Medium High, Medium High, Medium ND TOO LOW Medium High, Medium ND TOO HIGH Medium High, Medium ND TOO LOW Medium High, Medium ND TOO HIGH Medium High, Medium ND TOO LOW Medium High, Medium ND TOO LOW Medium High, Medium ND TOO HIGH Medium High, Medium ND TOO LOW Medium High, Medium ND TOO HIGH Medium High, Medium ND TOO LOW Medium High, Medium ND TOO LOW Medium High, Medium ND TOO HIGH ND TOO LOW Medium High, Medium ND TOO LOW Medium ND TOO LOW Medium ND TOO LOW Med			Low	than the lower alarm limit.	the patient type.
FHR2 TOO LOW Medium High, Medium, Low  TOCO TOO HIGH Medium High, Medium, Low  TOCO TOO LOW Medium High, Medium HR TOO LOW Medium High, Medium ST1 TOO HIGH Medium High, Medium ST2 TOO LOW Medium High, Medium PVC TOO LOW Medium High, Medium PVC TOO LOW Medium High, Medium SP02 TOO HIGH Medium High, Medium PVC TOO LOW Medium High, Medium PVC TOO LOW Medium High, Medium PVC TOO HIGH Medium High, Medium PVC TOO HIGH Medium High, Medium PR TOO HIGH Medium High, Medium PR TOO HIGH Medium High, Medium NS TOO HIGH Medium High, Medium NS TOO LOW Medium High, Medium ND TOO LOW Medium High, Medium NT TOO HIGH Medium High, Medium RR TOO LOW Medium Hi	FHR2 TOO HIGH	Medium	High, Medium,		
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T1 TOO HIGH Medium High, Medium  T1 TOO LOW Medium High, Medium  RESP APNEA High High The respiration signal is so weak that the monitor condition and check the	RR TOO HIGH	Medium	High, Medium		
T1 TOO LOW Medium High, Medium  RESP APNEA High High The respiration signal is check the patient's so weak that the monitor condition and check the	RR TOO LOW	Medium	High, Medium		
RESPAPNEA High High The respiration signal is Check the patient's so weak that the monitor condition and check the	T1 TOO HIGH	Medium	High, Medium		
so weak that the monitor condition and check the	T1 TOO LOW	Medium	High, Medium		
	RESP APNEA	High	High	The respiration signal is	•
cannot perform respiration connection of lead wires.				so weak that the monitor	
				cannot perform respiration	connection of lead wires.



			analysis.	
RESP ARTIFACT	High	High	The patient's heartbeat has	
			interfered with his	
			respiration,	
ECG LOST	High	High	The ECG signal is so weak	
			that the monitor cannot	
			perform ECG analysis.	
NO PULSE	High	High	The pulse signal is	Check the patient's
			so weak that the monitor	condition and check the
			cannot perform pulse	connection of SpO <sub>2</sub> sensor.
			analysis.	
ASYSTOLE	High	High	Arrhythmia has occurred	Check the patient's
VFIB/VTAC	High	High	to the patient.	condition and check the
R ON T	Medium	High, Medium		connection of lead wires
VT > 2	Medium	High, Medium		and electrodes.
COUPLET	Medium	High, Medium		
PVC	Medium	High, Medium		
BIGEMINY	Medium	High, Medium		
TRIGEMINY	Medium	High, Medium		
Supraventricular	Medium	High, Medium		
tachycardia				
TACHY	Medium	High, Medium		
BRADY	Medium	High, Medium		
MISSED BEATS	Medium	High, Medium		
ARRHYTHMIA	Medium	High, Medium		
PNC	Medium	High, Medium		
PNP	Medium	High, Medium		

### (2)Technical alarm message

There is only one alarm level for a certain alarm condition and the user cannot change it.

Alarm Message	Default Alarm level	Causes	Solution
ECG LEAD OFF	Low	ECG electrode has fallen off	Check the connection of
V LEAD OFF	Low	from the patient.	lead wires and electrodes.
LL LEAD OFF	Low		
LA LEAD OFF	Low		
RA LEAD OFF	Low		
ECG V1 LEAD OFF	Low		
ECG V2 LEAD OFF	Low		
ECG V3 LEAD OFF	Low		
ECG V4 LEAD OFF	Low		
ECG V5 LEAD OFF	Low		
ECG V6 LEAD OFF	Low		
ECG I OVER LOAD	Low	ECG signal is not within the	Check the connection of
ECG II OVER LOAD	Low	specified measurement	electrodes and lead wires



ECG III OVER LOAD	Low	range.	and clean the patient's skin
ECG V OVER LOAD	Low	Tungo.	if necessary.
ECG LL OVER LOAD	Low		J. C.
ECG LA OVER LOAD	Low		
ECG RA OVER LOAD	Low		
ECG V1 OVER LOAD	Low		
ECG V2 OVER LOAD	Low		
ECG V3 OVER LOAD	Low		
ECG V4 OVER LOAD	Low		
ECG V5 OVER LOAD	Low		
ECG V6 OVER LOAD	Low		
ECG COMM ERR	High	There is a problem with the	Restart the monitor. If the
SPO2 COMM ERR	High	communication between the	problem is still there, please
TEMP COMM ERR	High	module and the monitor.	contact the serviceman.
NIBP COMM ERR	High		
HR ALM LMT ERR	High	The alarm limit for a certain	Please contact the
PVCS ALM LMT ERR	High	parameter has been	serviceman.
ST ALM LMT ERR	High	accidentally changed.	
RR ALM LMT ERR	High		
SPO2 ALM LMT ERR	High		
NS ALM LMT ERR	High		
NM ALM LMT ERR	High		
ND ALM LMT ERR	High		
PR ALM LMT ERR	High		
TEMP1 ALM LMT ERR	High		
ECG NOISE	High	There is too much interference signal in ECG signal.	Check if there is any possible source of signal noise from the area around the cable and electrodes and check the patient for great motion.
HR EXCEED	High	The measured parameter	Please contact the
PVCs EXCEED	High	value is not within the	serviceman.
ST EXCEED	High	specified measurement	
ST1 EXCEED	High	range.	
ST2 EXCEED	High		
ST3 EXCEED	High		
ST4 EXCEED	High		
ST5 EXCEED	High		
ST6 EXCEED	High		
ST7 EXCEED	High		
RR EXCEED	High		
SPO2 EXCEED	High		
PR EXCEED	High		



NS EXCEED	High		
NM EXCEED	High		
ND EXCEED	High		
TEMP1 EXCEED	High		
SPO2 FINGER OFF	Low	SpO2 sensor has fallen off from the patient's finger, or the SpO2 sensor is short circuit.	-
SPO2 SENSOR OFF	Low	SpO <sub>2</sub> sensor has not been connected well, or the SpO <sub>2</sub> sensor is open circuit or short circuit.	
SPO2 NO SENSOR	Low	The SpO2 sensor has not been connected well with the monitor.	Check the connection of SpO2 sensor.
NELLC ERR,RESETING	Low	An error occurred to Nellcor module and the system is resetting.	If the system failed to reset or if the error is there after restarting the monitor, please contact the serviceman.
UNKNOWN SENSOR	Low	The SpO2 sensor has damaged or the SpO2 sensor not specified is being used.	Replace the SpO2 sensor.
DEFECTIVE SENSOR	Low	Masimo SpO2 sensor is open circuit.	
INTERFERENCE	Low	There is interference signal when measuring SpO2	Check if there is any possible source of signal noise around the SpO2 sensor and check the patient for great motion.
MUCH LIGHT	Low	There is too much light around SpO2 sensor.	Move the sensor to a place with lower level of ambient light.
SIGNAL IQ LOW	Low	The SpO2 signal is too low or too weak.	Check the patient's condition, or apply the SpO2 sensor to a suitable measuring site. If the fault is still there, please change the SpO2 sensor.
SEARCH PULSE	Low	The system is searching pulse.	
SPO2 INIT ERR	High	An error occurred to the	Restart the monitor. If the
TEMP INIT ERR	High	module during initialization	problem is still there, please



**User Manual** 

NIBP INIT ERR	High	process. contact the serviceman.
SPO2 COMM STOP	High	The module failed to



TEMP COMM STOP	High	communicate with the	
		system.	
T1 SENSOR OFF	Low	TEMP probe has not	Check the connection of
		connected well.	TEMP probe.
Low power level! Please	Medium	Low battery	Please charge the battery
charge the battery			immediately.
CNNT PRS PRB	Low	The pressure transducer has	Check the connection of
		not connected.	pressure transducer.
CNNT 1ST FHR PRB	Low	FHR1 transducer has not	Check the connection of
		connected.	FHR1 transducer.
CNNT 2ND FHR PRB	Low	FHR2 transducer has not	Check the connection of
		connected.	FHR2 transducer.
The first fetal wireless	High	The battery level of	Change the battery of
probes battery is low.		FHR1 wireless transducer is	FHR1 wireless transducer.
		too low.	
The second fetal wireless	High	The battery level of	Change the battery of
probes battery is low.		FHR2 wireless transducer is	FHR2 wireless transducer.
		too low.	
Uterine	High	The battery level of	Change the battery of
contractions wireless		TOCO wireless transducer	TOCO wireless transducer.
probes battery is low.		is too low.	
ADJT ULTRAS	High	FHR is the same as maternal	Please adjust the position of
POSITION		heart rate.	FHR transducer.
RECORDER PAPER	High	No record paper loaded.	Load record paper.
LACK			
Paper Tray Not Closed	High	The paper tray has not	Close the paper tray well.
		closed well.	
MONITOR STOP	High	Timed monitoring stops.	
TIMED MONI FINISH	High	Timed monitoring ends.	
		1	

### (3) Prompt Message

Prompt message	Causes
LOOSE CUFF	NIBP cuff is too loose or has not connected with the monitor.
AIR LEAK	There is a leak in NIBP airway.
PNEUMATIC LEAK	
AIR PRESSURE ERROR	An error occurred to the air pressure when measuring NIBP.
WEAK SIGNAL	The patient's pulse is too weak or the cuff is too loose when measuring NIBP.
RANGE EXCEEDED	The NIBP measured value is not within the specified measurement range.
EXCESSIVE MOTION	The patient's arm moves too frequently.
OVER PRESSURE	NIBP airway is occluded.
SIGNAL SATUATED	The NIBP signal is saturated due to excess motion or other sources.
NIBP SYSTEM FAILURE	An error occurred during NIBP measurement and the monitor cannot perform
NIBP TIME OUT	analysis correctly.



**User Manual** 

MEASURE FAIL	
CUFF TYPE ERR	Wrong type of NIBP cuff is being used.



NIBP RESET ERR	An improper reset occurred during NIBP measurement.	
ARR LEARNING	Arrhythmia is learning.	
ECG Calibrating	ECG is calibrating.	
External printing	External printer is being used to print.	
MANUAL MEASURE	Manual NIBP measurement is being performed.	
PNEUM TESTING	Pneumatic test is being performed.	
RESETTING	Manual reset is being performed.	
CONT MEASURING	Continual NIBP measurement is being performed.	
PLEASE START	Please press NIBP start key to start NIBP measurement.	
AUTO MEASURING	Auto NIBP measurement is being performed.	



# **Appendix IV** Factory Default Settings

1. System Default Settings

Items	Factory adult/pediatric/neonate default settings	Remarks
Alarm volume	4	
Minimun alarm volume	0	
Heartbeat volume	2	
FHR volume	4	
Key volume	4	
LCD brightness	5	
Case save	On	
Case save least time	5 minutes	
Alarm recording	Off	
Alarm pause time	2 minutes	
Maximun alarm pause time	10 minutes	
Alarm delay time	10 seconds	
Language	English	
Time end prompt	On	
Timedmonitoring	20 minutes	
Grade	On	
Print report	On	
Paper type	30~240	
Printer select	Internal printer	
Score select	FHR1	
Grade criterion	Advanced FISCHER	
Real-time print speed	3cm/minute	
Real-time print time	20 minutes	
Review print time	20 minutes	
Print ECG waveform	On	
ECG print speed	25	
ECG print time	8 seconds	

2. FHR1 Default Settings

Items	Factory adult/pediatric/neonate default settings	Remarks
Display color	Yellow	
FM count	Auto/Manual	
Sound channel		The FHR sound channel will be locked if there is only on FHR transducer connected.
Trace offset	0bpm	



Sweep	3cm/minute	
Cross validation duration	60s	
Cross validation error	5bpm	

3. FHR2 Default Settings

Items	Factory adult/pediatric/neonate default settings					
Display color	Green					
FM count	Auto/Manual					
Sound channel	FHR2	Locked				
Trace offset	0bpm					
Sweep	3cm/minute					
Cross validation duration	60s					
Cross validation error	5bpm					

4. TOCO Default Settings

Items	Factory adult/pediatric/neonate default settings	Remarks
Display color	Purple	
FM threshold	50%	
TOCO zero	10	
AFM color	Yellow	

5. NIBP Default Settings

NIBI Belaute Bet	·····gs			
Items	Factory de	efault settings	Remarks	
	Adult	Pediatric	Neonate	
Unit	mmHg			
Display color	White			
Measure mode	Adult	Pediatric	Neonate	
Interval	Manual		·	
Initial inflation	160	120	100	

6. ECG Default Settings

Items	Factory adult/pediatric/neonate default settings	Remarks
HR channel	П	
HR source	ECG	
Lead type	5-lead	
Notch	On	
ST segment analysis	Off	
ST analysis point	ISO:80 ST: 108	
ARR analysis	Off	
Gain	×1	
Sweep	25.0mm	



Filter	Diagnosis	
Wave type	Line	

7. RESP Default Settings

Items	Factory adult/pediatric/neonate default settings	Remarks
Display color	Yellow	
Apnea alarm	10s	
Gain	×1	
Sweep	12.5mm	
Wave type	Line	

8. SpO2 Default Settings

Items	Factory adult/pediatric/neonate default settings	Remarks	
Signal indication	On		
Pulse tone	On	Only available on	
Sat-second	Off	Masimo SpO2	
Average time	8S	module	
Sensitivity	Normal		
Intelligent alarm	10	Only available on NELLCOR SpO2 module	
Sweep	25.0mm		
Wave type	Line		

9. TEMP Default Settings

Items	Factory adult/pediatric/neonate default settings	Remarks
Display color	White	
Unit	${\mathbb C}$	

10. Default Alarm Settings

Items			Factory default settings
	Alarm recordi	ing	Off
	Alarm switch		On
FHR1/FHR2	A.1 1' '.	Upper limit	200
	Alarm limit	Lower limit	80
	Alarm recordi	ng	Off
	Alarm switch		On
тосо	Alarm limit	Upper limit	90
	Alaini illilli	Upper limit	10



Items					Factory default settings			
	1	ttems			Adult	Pediatric	Neonate	
	Alarm recording				On		•	
FCC	ECG Alarm sv				On			
ECG			Up	per limit	125	165	180	
	Alamin	111111	Lo	wer limit	45	70	110	
	Alarm re				On			
	Alarm s	witch	ı		On			
ST	Alarm li	mit	Up	per limit	0.18			
	7 Harmin	ııııı	Lo	wer limit	-0.18			
	PVCS a	larm r	ecord	ing	On			
	PVCS a	larm l	evel		Medium			
	PVCS a	larm s	witch		On			
400			Arrl sele	nythmia ct	ASYSTOL	Е		
ARR analysis	ARR a	larm	Alaı	m switch	On			
·	settings		Alaı	rm level	Medium			
		Al		m recording	On			
	PVCS Upp			er limit	10			
	alarm	· ·		er limit	0			
	settings Alarm re	ecordi			On			
	Alarm le		5		Low			
	Alarm switch				On			
RESP	Apnea a	larm			10s			
			Upper limit		28	28	100	
	limit		Lower limit		10	10	30	
	Alarm re	ecordi	ng		On			
	Alarm le	evel			Medium			
TEMP	Alarm s	Alarm switch		On				
	Alarm Upper li			39.0				
	limit			r limit	36.0			
	Alarm re	ecordi	ng		On			
	Alarm s	witch			On			
		SYS	5	Upper limit	170	130	95	
NIBP	A 1			Lower limit	80	60	35	
	Alarm limit	MA	P	Upper limit Lower limit	120 55	100	75 20	
	IIIIIt			Upper limit	100	75	65	
		DIA		Lower limit	45	35	15	
	Alarm re	ecordi	ng		On			
	Alarm s	witch			On			
SpO2	SnO2 al	arm li	mit	Upper limit	100			
	SpO2 alarm limit		11111	Lower limit	90	1.5	100	
			Upper limit	125	165	190		



# FM5000C - FM5000PLUS Maternal/Fetal Monitor

**User Manual** 

PR alarm limit	Lower limit	45	70	110
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# **Appendix V EMC**

# Attention

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

# **Warning**

- The monitor should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.
- Class A equipment is intended for use in an industrial environment. The monitor may be
  potential difficulties in ensuring electromagnetic compatibility in other environments, due to
  conducted as well as radiated disturbances.

## Guidance and manufacturer's declaration -electromagnetic emissions

The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions		The monitor uses RF energy only for its internal function.	
CISPR 11	Group 1	Therefore, its RF emissions are very low and are not likely to	
		cause any interference in nearby electronic equipment.	
RF emissions	Class A	The monitor is suitable for use in all establishments other	
CISPR 11	Class A	than domestic and those directly connected to the public	
Harmonic emissions	Class A	low-voltage power supply network that supplies buildings	
IEC 61000-3-2	Class A	used for domestic purposes.	
Voltage fluctuations /			
flicker emissions	Complies		
IEC 61000-3-3			

## Guidance and manufacturer's declaration – electromagnetic immunity

The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic	±6 kV contact	± 6 kV contact	Floors should be wood, concrete or
discharge (ESD)	±8 kV air	± 8 kV air	ceramic tile. If floors are covered with
			synthetic material, the relative
IEC 61000-4-2			humidity should be at least 30 %.



Electrical fast	±2 kV for power	±2 kV for power	Mains power quality should be that of a	
transient/burst	supply lines	supply lines	typical commercial or	
IEC 61000-4-4			hospitalenvironment.	
Surge	± 1 kV line(s) to	± 1 kV line(s) to	Mains power quality should be that of a	
	line(s)	line(s)	typical commercial or	
IEC 61000-4-5	$\pm$ 2 kV line(s) to	$\pm$ 2 kV line(s) to	hospitalenvironment.	
	earth	earth		
Voltage dips, short	<5 % <i>U</i> T	<5 % <i>U</i> T	Mains power quality should be that of a	
interruptions and	(>95 % dip in <i>U</i> T)	(>95 % dip in <i>U</i> T)	typical commercial or hospital	
voltage variations	for 0.5 cycle	for 0.5 cycle	environment. If the user of the monitor	
on power supply	40 % <i>U</i> T	40 % <i>U</i> T	requires continued operation during	
input lines	(60 % dip in <i>U</i> T)	(60 % dip in <i>U</i> T)	power mains interruptions.	
	for 5 cycles	for 5 cycles		
IEC 61000-4-11	70 % <i>U</i> T	70 % <i>U</i> T		
	(30 % dip in <i>U</i> T)	(30 % dip in <i>U</i> T)		
	for 25 cycles	for 25 cycles		
	<5 % <i>U</i> T	<5 % <i>U</i> T		
	(>95 % dip in <i>U</i> T)	(>95 % dip in <i>U</i> T)		
	for 5 s	for 5 s		
Power frequency	3 A/m	3 A/m	Power frequency magnetic fieldsshould	
(50/60 Hz)			be at levels characteristic of a typical	
magnetic field			location in a typical commercial or	
IEC 61000-4-8			hospital environment.	
NOTEUT is the a.c. mains voltage prior to application of the test level.				

Guidance and manufacturer's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below.			
The customer or the user of the monitor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test	Compliance	Electromagnetic
	level	level	environment — guidance



## FM5000C - FM5000PLUS Maternal/Fetal Monitor

			Portable and mobile RFcommunications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency
	of the transmitter.		
			Recommended separation distance
Conducted RF	3Vrms	3Vrms	d = 1.2 P
IEC 61000-4-6	150kHz to 80MHz		
Radiated RF	3V/m		d = 1.2 P 80MHz to 800MHz
IEC 61000-4-3	80MHz to 2.5GHz		d = 2.3 <i>P</i> 800MHz to 2.5GHz
25 01000 . 5			where $P$ is the maximum output power rating
			of the transmitter in watts (W) according to the
			transmitter manufacturer and $d$ is the recommended separation distance in meters
			and the second s



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

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor.
- b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

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

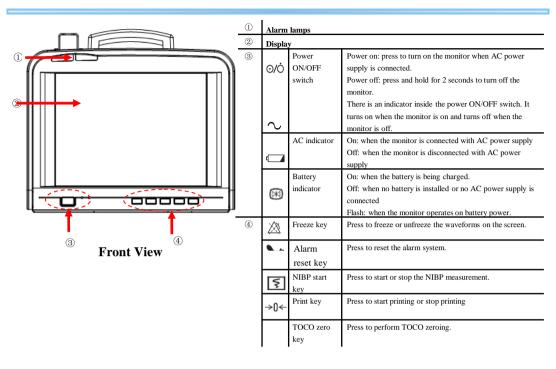
The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters)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

Rated maximum	Separation distance according to frequency of transmitter (m)			
output power of	150kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz	
transmitter (W)	d = 1.2 P	d = 1.2 P	d =2.3 P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

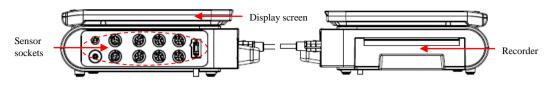
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

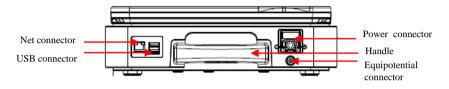
### **Product Introduction**



## **Product Introduction**

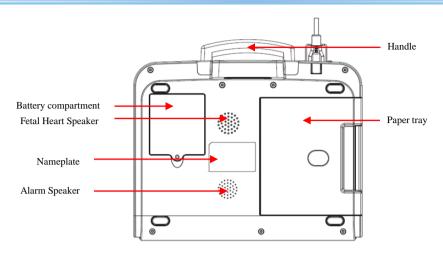


Right View Left View



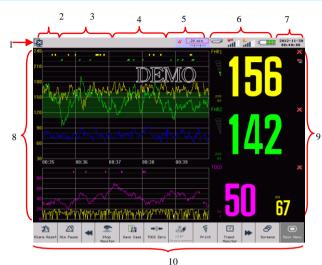
**Rear View** 

## **Product Introduction**



**Rear View** 

## **On-screen Display**



Main screen

- Network Connection Icon, Click the network connection icon to directly access [NETWORK SET] menu.
- Patient information area, Click here to directly access [PATIENT INFO] menu.
- 3. Technical alarm message area
- Physiological alarm message area, Click here to directly access [ALARM RECALL] window.
- 5. Timed monitoring information area, Click here to directly access [TIMER] menu.
- Icons area, Printer icon, FHR volume icon, Alarm volume icon, Battery icon.
- 7. System time
- 8. Waveform area
- 9. Parameter area
- 10. On-screen keys

The monitor is equipped with a 12.1 inch TFT touch screen. All operations on the monitor can be performed by keys and touch screen.

Press on-screen key and hold for more than three seconds until the turns to

## **Basic Operations**

#### Using the Main Menu

Click the on-screen key to access [MAIN MENU] and perform operations and settings.

#### Setting the system time

- Click the system time area to enter the [Date time Setup] menu:
- Or access [Main Menu] →[Monitor Setup]→[Time Setup];
   Set the system time according to your local time.

#### **Changing System Language**

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

#### **Adjusting Alarm Volume**

- Access [Main Menu], select [Option Setup], select [Ala Vol] and then adjust the alarm volume in the pop-up list box from X to 6
- Or press alarm volume icon to adjust the alarm volume in the pop-up list box from X to 6.

#### **Adjusting Heartbeat Volume**

Access [MAIN MENU] →[Option Setup] →[Beat Vol.]
 Select the heartbeat volume in the pop-up list box.

#### Adjusting FHR Volume

- 1. Access [MAIN MENU]  $\rightarrow$  [Option Setup]  $\rightarrow$  [FHR Vol];
- 2. Or click FHR volume icon Select the FHR volume in the pop-up list box.

#### Adjusting Key Volume

- 1. Access [Main Menu]→[Option Setup]→[Key Vol];
- 2. Select the key volume in the pop-up list box.

#### Adjusting Screen Brightness

- Access [Main Menu]→[Option Setup]→[Brightness];
- Select the screen brightness level in the pop-up list box.

#### Review

 Click [Info Reca.] on-screen key; Select [Trend Graph Review] to enter the trend graph review window.

#### Network settings

Click the network connection status icon to enter [Network Setup] menu.

#### Changing screens

- Click [Screens] on-screen key;
- Or access [Main Menu] and select [Screens]

## **Basic Operations**

#### **Printing Settings**

- Access [Main Menu]→[Monitor Setup]→[Print Setup] and enter the print setup menu;
- Or click the printer icor and enter the print setup menu.

#### Alarm Settings

- Access [Main Menu]→[Monitor Setup] → [Alarm Setup].
   Select [Alm Pause Time] to choose the alarm pause time.
- Access [Main Menu], select [Maintain] and enter the password; Select [Alm Setup]. Select [Max Alm Pause Time] to adjust the maximum alarm pause time.
- Select each parameter area. Take FHR1 as an example. Select FHR1 parameter area and the [FHR1 Setup] menu will be displayed; Select [FHR1 Alarm Setup] and enter FHR1 alarm limit setup menu.

#### **Patient Management**

- Click patient information area or click [Patient Management] on-screen key.
- In the pop-up menu, go to admit the patient, modify the patient information and discharge the patient.

#### How to save user default settings:

- Access [Main Menu], select [Maintain] and enter the password;
- Select [Save Current As User Config] to save current settings.

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

- Access [Main Menu]→[Monitor Setup] →[Restore Default Configuration];
- Select [Adopt Factory Default Adu Config], [Adopt Factory Default Ped Config] or [Adopt Factory Default Neo Config], the alarm limit will restore to the factory default settings.

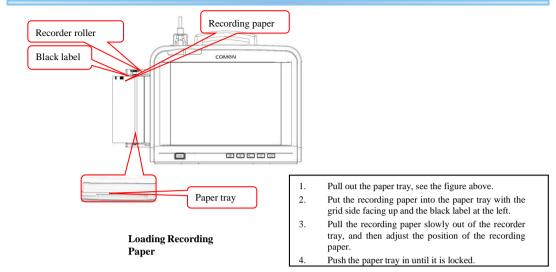
#### How to use user a dult/pediatric/neonate default settings:

- Access [Main Menu]→[Monitor Setup] →[Restore Default Configuration];
- Select [Default User Adu Config], [Default User Ped Config] Or [Default User Neo Config], the alarm limit will restore to the user default settings.

#### How to start timed monitoring

- 1. Click the timed monitoring information area on the screen ,s (10 MINUTE)
- Or click [Timed Monitor] on-screen key;
- 3. Enter the [Timed Monitor] menu to set the related parameters.

## **Printing**



## **Printing**

#### **Real-time Printing**

Real-time printing means the printing triggered by pressing the print key on the front panel or clicking the [Print] on-screen key during realtime monitoring.

#### How to print fetal waveform during real-time monitoring:

- During real-time monitoring, press the print key on the front panel or click the [Print] on-screen key and enter the [Patient Info & Fischer Grade] window;
- Confirm the patient information and score results and click [Confirm]. The monitor starts to print the fetal waveform according to the speed set in [Real Speed] and the time set in [Real Time].
- To stop printing during printing process, just press the print key on the front panel or click the [Print] on-screen key. If [Report] is set to [ON], the monitor will output the score report immediately and then stop printing; if [Report] is set to [OFF], the monitor will stop printing immediately.

#### **Stored Patient Case Printing:**

Stored patient case printing means the printing triggered by pressing the print key on the front panel or clicking the [Print] on-screen key after loading the patient case and enter patient case review interface.

#### How to print stored patient case:

- 1. Access [Case List] window; Select a certain patient case and enter [Patient Review] window;
- 2. Click [Load] and enter the patient case review window;
- 3. Press the print key on the front panel or click the [Print] on-screen key and enter the [Patient Info & Fischer Grade] window:
- 4. Confirm the patient information and score results and click [Confirm]. The monitor will start to print the fetal waveform from the very left waveform on current screen according to the time length set in [Freeze Time].

## **Printing**

# How to print the fetal waveform under frozen waveform status:

- 1. Under frozen waveform status, press the print key on the front panel or click the [Print] on-screen key and enter the [Patient Info & Fischer Grade] window;
- 2. Confirm the patient information and score results and click [Confirm]. The monitor will start to print the frozen fetal waveform from the very left waveform on current screen according to the time length set in [Freeze Time].
- 3. If the [Report] is set to [ON], the score report will be printed after frozen fetal waveform.

#### How to select score:

- Enter [Main Menu] -> [Monitor Setup] -> [Print Setup];
- 2. Or click print icon on icon area.
- Click [Score Select] to show the scores on the case report.
- Click [Score Criterion] to select scoring criterion you use (options: [KREBS], [Fischer], [Advanced Fischer], [NST]).

# **Battery**

The monitor is equipped with a built-in rechargeable battery which will be auto charged when the AC power supply is connected no matter whether the monitor is turned on or not. In case of sudden power failure, the monitor will be auto powered by the battery without operation interruption and the battery work indicator will be lit up 30s after the power failure.

To understand the battery icon:

indicating the battery is fully charged.

indicating moderate battery power.

indicating low battery power.

indicating critically low battery power, please charge the battery immediately.

· indicating no battery installed or damaged battery.