## Introduction

Thank you for using Multi-Parameter Patient Monitor produced by Wuhan Zoncare Bio-Medical Electronics Co., Ltd.

In order to enable you to skillfully operate Multi-Parameter Patient Monitor as soon as possible, the monitor is equipped with a detailed User Manual (operating instruction). Please read all the chapters and sections carefully at the first time you installing and using this monitor.

We may make some changes (including hardware or software) on the basis of improving the reliability of the components and equipment performance. On the occasion, we will try to modify or optimize the document. But please forgive some describes existing differences. If there are any errors and omissions in this User Manual, please contact us.

Manufacturer information:

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- The electrical installation of the relevant room complies with the applicable national and local requirements;
- The product is used in accordance with the instructions for use.

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## Exemptions

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- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

# Preface

## **Manual Purpose**

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed

## **Intended Audience**

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

## Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your patient monitor.

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#### FOR YOUR NOTES

## **Chapter 1 Safety**

### **1.1 Safety Information**

## \rm 🖳 DANGER

• Indicates an imminent hazard that, if not avoided, will result in death, serious injury or property loss.

#### 

• Indicates a potential hazard or unsafe practice that, if not avoided, could result in death, serious injury or property loss.

## 

• Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury, product failure or property loss.

### NOTE

• Emphasize important matters need to pay attention, provide instructions or explain to better use this product.

#### 1.1.1 Danger

This product is not involved dangerous levels information.

#### 1.1.2 Warning

## 

• For patients with pacemakers, Heart Rate Meter might count the pacing pulse in when

cardiac arrests or arrhythmia. Do not rely entirely on the alarms. Patients with pacemakers should be closely guardian. The associated equipment inhibiting capacity to pacing pulse please refer to this handbook.

- The monitor is limited to one patient at same time.
- The monitor is used for clinical monitoring, which could only be used by professional clinical doctor or nurses under specified situations. Any person without authorization, or any untrained personnel is not allowed to do any operation.
- User should check the patient monitor and accessories before using the patient monitor to ensure they work in a normal and safe way.
- In case of fire or explosion, it is not allowed to use patient monitor in the environment of

placing a flammable or explosive material like anesthetics .

- User should set the alarm setting according to the patient reality and ensure when the alarm is triggered, the monitor could make alarm sound.
- It is not allowed to open the monitor shell. Or there is electric shock risk. The maintenance and upgrades should be operated by authorized or trained personnel.
- Do not touch patient while defibrillation. Or else, there is risk of severe harm or death.
- User should ensure patient safety when monitor and electrosurgery unit are using together.
- The monitor should avoid to using together with other equipment, like electrical stimulator.
- The packaging must be treated in accordance with the current waste control standard and keep the packaging out of reach of children.
- To protect the environment, the used ECG electrode, disposable BP cuff, disposable temperature probe, battery have to be recycled or dealt properly.
- When dealing with packaging, should comply with local associated laws and rules, or waste control standards. Keep the packaging out of reach o children.
- The monitor could only connect to a power socket with protective grounding cable. Or else, please do not use the socket. A charging battery could be used.
- Connect the grounding cable to equipment equipotential grounding terminal. If user could not make it clear from the equipment specification that if the equipment combination is dangerous or not, like the danger of the accumulation of leakage current, please refer to associated manufacturer or specialist to ensure the safety.
- This patient monitor is used in non-home and not directly connected to residential public low voltage power networks.
- The physiological waveform, physiological parameters and alarm information displayed on the patient monitor screen are only for doctor reference, could not be used directly as the basis for clinical treatment.
- Do not change the monitor power cable. The three core power cord cannot be connected with the two core socket.
- This equipment could not be used in the environment of flammable anesthetic mixture with air or oxygen or Nitrous Oxide anesthetic mixture.
- It is not available to evaluate the accuracy of the function of the monitor and related pulse oxygen probe by functional tester.

### 1.1.3 Caution

## 

- To ensure patients safety, please use the accessory specified in this specification.
- One time equipment could only be used once. Repeated use may lead to performance degradation or cross infection.
- When the monitor and accessories are about to exceed the duration of their use, user should deal according to local associated laws and rules. If any question, please contact us.
- The electromagnetic field affects the performance. Thus the equipment near the monitor should comply with the requirements of associated EMC. Mobile phones, X rays or MRI devices are possible sources of interference, as they all emit high intensity electromagnetic radiation.
- Before the monitor connects to the power supply, please ensure the voltage and frequency of the power supply is in accordance with the equipment requirement.
- Please install or carry the monitor properly, preventing falling, colliding, strong oscillations or other mechanical forces of the monitor.
- Please do not mixes use the different types and brands electrodes. Mix using may lead to a larger baseline drift or the lengthening of the baseline recovery time after defibrillation.

#### 1.1.4 Note

### NOTE

- Install the equipment in a position where is easy to observe, operate and maintain.
- Please put the instructions together with accessory so that user could easily and timely obtain when in need.
- Please verify the correctness and ensure the normal work of the equipment before using.
- Pay attention to the placement of power lines, tubes and all cables so as to avoid the risk of patient or other person.
- The equipment back is strictly prohibited from clogging in order to distribute heat.
- If liquid is sprinkled into the equipment shell, please disconnect the power immediately and contact maintenance personnel immediately.
- This equipment cannot be used in home.

## 1.2 Device Label

Some symbols may not appear on your equipment.

		1	
Â	Attention: Consult accompanying documents (this manual).	<b>©</b>	Power On/Off
$\sim$	Alternating current (AC)		Battery indicator
效	Alarm silenced.	潋	Alarm Paused
*	Freeze /unfreeze waveforms	¢€>	NIBP
5	Record	đ	Main Menu
\ ↓	Equipotential grounding	÷	Protective grounding
RJ45	Internet Port	$\sim$	Manufacture date
SN	Serial number		Manufacture adress
20	Enviroment-friendly use period		Limited indoor use
i	Reference Reading	EC REP	European community representative
4 <b>W</b> ł	This symbol indicates that the instrument is IEC 60601-1 Type CF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.		
┤∕Ҟ	This symbol indicates that the instrument is IEC 60601-1 Type BF equipment. The unit displaying this symbol contains an F-Type isolated (floating) patient applied part providing a high degree of protection against shock, and is suitable for use during defibrillation.		
<b>C €</b> <sub>2460</sub>	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive.		
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only.		

## 1.3 Abbreviations

Name	Define or abbreviations
ECG	Electrocardiogram
RESP	Respiration
ТЕМР	Temperature
NIBP	Non-invasive blood pressure
SpO2	Oxyhemoglobin saturation
IBP	Invasive blood pressure
HR	Heart Rate
RR	Respiratory Rate
PR	Pulse Rate
ART	Aortic pressure
РА	Pulmonary artery pressure
CVP	Central venous pressure
LAP	Left Atrial Pressure
RAP	Right Atrial Pressure
ІСР	Intracranial Pressure
P1	Auxiliary pressure channel 1
P2	Auxiliary pressure channel 2
CO2	Carbon dioxide

#### FOR YOUR NOTES

## **Chapter 2 Overview**

## 2.1 Overview

### 2.1.1 Intended Use

This patient monitor is intended to be used for monitoring, displaying, reviewing, storing and transferring of multiple physiological parameters including ECG, respiration (RESP), temperature (TEMP), SpO2, pulse rate (PR), non-invasive blood pressure (NIBP) of single adult, pediatric and neonatal patients.

It's intended to be used in OR(operating room), Postoperative observation room, ICU/CCU, ER(emergency room) and clinical monitoring.

## 

- This patient monitor is intended for use only by clinical professionals or under their guidance. It must be only used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.
- Don't use the monitor outside the specified temperature and humidity range, otherwise it will not reach Appendix I claimed performance specifications.

### 2.1.2 Contraindication

None

### 2.1.3 Components

This patient monitor consists of a main unit, ECG cables, SpO2 sensor, NIBP cuff, ECG electrodes,

Temp sensor, Recorder, Battery, etc.

## 2.2 The host

### 2.2.1 Front view





#### 1. Alarm lamp

When a physiological or technical alarm occurs, this lamp will flash as defined below.

- High level alarms: the lamp flashes 2 times in one second and in red.
- Medium level alarms: the lamp flashes 2 times in one second and in yellow.
- Low level alarms: the lamp lights yellow without flashing.

#### 2. Display screen

#### 3. Power On/Off Switch

After connect power cable, press power key and hold for 2 seconds to turn the patient monitor on.

#### 4. Battery LED

On: when the patient monitor operates on battery power or AC source is connected.

Off: when no battery is installed or no AC source is connected.

Flashes: when the battery is being charged.

#### 5. AC power LED

It turns on when AC power is connected

### 6.

Press to silence or restore all alarm sounds or clear alarms.

## 7. 🔊

Press the key one time, the monitor will pause alarm. Press the key two times, the monitor restore alarm.

## 8. 🗱

Press to freeze or unfreeze waveforms.

## 9. 📚

Press to start or stop NIBP measurements.

## 10. 🗧

Press to start or stop recordings.

## 11. P

If no menu is displayed on the screen, pressing it will enter the main menu. If there is a menu displayed on the screen, pressing it will close that menu.

#### 12. Rotary knob

Rotate the Knob clockwise or anti-clockwise. With each click, the highlight jumps to the neighboring item. When you reach your desired item, press the Knob to select it.

### 2.2.2 Side View



#### 1. Handle

- 4. TEMP connector(Double channels)
- 7. ECG connector

2. Battery cover

5. SpO2 connector

- 3. Recorder
- 6. NIBP connector
- 8. IBP connector(Double channels)
- 9. CO2 connector

#### 2.2.3 Rear View



1. Handle

2. Thermovent

3. Nameplate

4. Network Connector

It is a standard RJ45 connector, through which the patient monitor can be networked.

5. USB Connectors 6. RS232 serial port

7. Equipotential Grounding Terminal

When the patient monitor and other devices are to be used together, their equipotential grounding terminals should be connected together, eliminating the potential difference between them.

8. Fuse: standard specifications FUSE T1.6AL250V

9. AC Power input: requirements AC100V-240V, 50Hz/60Hz

### 2.2.4 Bottom View



## 2.3 Display Screen

#### 2.3.1 Standard Main Screen



The monitor uses LED screen. It displays patient parameters, waveforms, alarm information, bed number, monitor state, date, time and some other information simultaneously.

The screen is divided into four areas: Information Area, Waveform Area, Parameter Area and QuickKeys Area.

#### 1. Information Area

The Information Area displays bed number, type of patient, technical alarm information, physiological alarm information, date and time, network connection state and battery state.

"BED": Refers to the hospital bed number of patient monitored.

"TYPE": Refers to the patient type.

"2017-12-19 21:38": Updating current date and time every second.

The other information displayed in the information area: The monitor alarm information, please refer the detail the chapter "Alarm".



Alarm silence symbol

Presses "SILENCE" key on the control panel to silence or restore all alarm sounds or clear alarms.

Alarm pause symbol

Press "PAUSE" key on the control panel to PAUSE or restore alarm. There are three options of alarm pause state: "1 minute", "2 minutes" and "3 minutes".



Alarm close symbol

It means that the alarm function has been closed forever until it will be turn on again.

## NOTE

- There will be no alarm information and voice when 🔀 the close symbol appears, so the user should be careful when use this feature.
- 🖄 the close symbol There will be no alarm information and voice permanently when appears, so the user should be careful when use this feature.

#### 2. Waveform Area

It displays the waveform of parameters; the name of waveform appears on the upper left of each waveform.

There are 5 waveforms: 3 ECG waveforms, 1 SpO2 waveform and 1 RESP waveform. There will be 8 waveforms in the max configuration. It will increase 2 IBP waveforms and 1 CO2 waveform according to the configuration of monitor.

In "Standard" 5 waveform interface, the name of waveform in other waveform can not be operated except the ECG waveform area. Move the cursor to change ECG leads (I/II/III/aVR/aVL/aVF/V), gain, filter and the waveform speed.

#### 3. Parameter Area

Parameters area is on the right of waveform area. The left is the name of the parameters and the matched waveform will be displayed at the same line.

The parameters in the parameters area contain:

■ ECG

—Heart Rate or Pulse Rate(unit: bpm beat per minute)

#### ■ SpO2

-----Oxygen saturation SpO2(unit: %)

-----Pulse Rate(PR)

——Perfusion Index (PI)

#### ■ NIBP

—Systolic pressure, Diastolic pressure, Mean pressure(Unit: mmHg or kPa)

#### ■ TEMP

——Temperature(unit: centigrade °C or Fahrenheit °F)

#### ■ RESP

-----Respiration Rate (unit: breaths per minute BrPM)

#### 4. QuickKeys Area

A QuickKey is located at the bottom of the main screen. They give you fast access to functions.

The following QuickKeys can be selected:

 More	More	Screens	Change Screens
Silenced	Alarm Silenced	Review	Review
28 Paused	Alarm Paused	Freeze	Freeze
Alarm Setup	Alarm Setup	্রাট NIBP Start	NIBP Start
Ratient Setup	Patient Setup	(U) Standby	Standby
Hain Menu	Main Menu		

#### FOR YOUR NOTES

## **Chapter 3 Basic Operations**

## 3.1 Installation

## 

- The software copyright of the equipment is solely owned by ZONCARE. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
- All of the analog and digital devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1-1.If you have any question, please contact us.
- If it is not evident from the equipment specifications whether a particular combination is hazardous, for example, due to summation of leakage currents, consult the manufacturers or else an expert in the field, to ensure the necessary safety of all devices concerned will not be impaired by the proposed combination.

### 3.1.1 Unpacking and Checking

Open the package and remove the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check all materials against the packing list.

- Check that is there any mechanical damage.
- Check all the cables, modules and accessories.

Keep at least 2 inches (5cm) clearance around the instrument for proper air circulation. The environment where the monitor will be used should be reasonably free from vibration, dust, corrosive, flammable and explosive substances, extremes of temperature, humidity, and so on.

If there is any problem, contact the distributor immediately.

### NOTE

• Save the packing case and packaging material as they can be used if the equipment must be reshipped.

#### 

- When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.
- The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.

### **3.1.2 Environmental Requirements**

The operating environment of the equipment must meet the requirements specified in this manual.

The environment where the equipment is used shall be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances. If the equipment is installed in a cabinet, sufficient space in front and behind shall be left for convenient operation, maintenance and repair. Moreover, to maintain good ventilation, the equipment shall be at least 2 inches (5cm) away from around the cabinet.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

## 

• Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.

## 3.2 Getting Started

### **3.2.1 Connecting Power**

Make sure the AC power supply meet specification: AC 100~240V, 50/60 Hz. Plug the power line to AC interface of the monitor and connect to AC Supply.

## 

- Only use the AC power cable which provided by the manufacturer.
- Use the built-in battery to power the monitor when there is any damage of the power cable. Otherwise, the patient and the monitor operator will have an electric shock hazard.
- Connect the grounding wire to the Equipotential Grounding Terminal correctly.
- Don't touch the metal parts or socket of the machine and patient at the same times.

#### **Connecting Battery**

The Patient Monitor is equipped with a rechargeable built-in battery.

The battery symbol is at the top right corner of the screen which indicates capacity status

of the battery.

The battery symbol is flashing when the battery is charging. The battery symbol will show as

" after the battery is full-charged.

When the battery symbol shows as " minicating no battery.

The Patient Monitor will alarm if the battery is in low state. There will be continuous voice and information of alarm until the AC power plug in. At this time you must connect to AC Power immediately.

## 

• The battery should be recharged before the monitor turn on which has been transported and stored. So the monitor will turn off automatically because of the power shortage when the AC Power is not connected.

### 3.2.2 Switching On

1. Before you start to make measurements, check the patient monitor for any mechanical damage and make sure that all external cables and accessories are properly connected.

2. Plug the power cord into the AC power source. If you run the patient monitor on battery power, ensure that the battery is sufficiently charged.

3. Check all functions you need to monitor your patient, and ensure that the monitor is in good working order.

After the inspection is finished, you can switch on the monitor:

Press the power on/off switch on the monitor's front. The monitor performs a self test. The system gives a beep, and at the same time, the alarm lamp turns yellow and then red. The start-up screen is displayed.

The monitor enters the main screen.

## 

• Do not use the patient monitor for any monitoring procedure on a patient if you suspect it is not working properly, or if it is mechanically damaged. Contact your service personnel or us.

## NOTE

- If the monitor finds any fatal error during self-test, it will alarm.
- The battery must be recharged to the full electricity to ensure adequate electricity reserve after when using.
- The time between twice presses of POWER should be more than 1 minute.

### 3.2.3 Starting Monitoring

1. Check that the patient cables and sensors are correctly connected.

2. Check that the patient settings are appropriate for your patient.

3. Refer to corresponding measurement sections for details of how to perform the measurements you want to make.

### 3.2.4 Turn Off the Monitor

- 1. Confirm whether to end the monitor of the patient
- 2. Disconnect the patient cable and sensor from the patient
- 3. Make sure to save and clear the patient data
- 4. Press the power switch seconds, then the monitor will be turn off.

## 

• If you can't turn off the monitor, please press the power switch some seconds to turn off the monitor. But it will make the monitor lose some data or damage, so it is no recommended to do like this.

## 3.3 Using Keys

The monitor has three different types of using keys:

- Softkey: A softkey is a graphic key on the screen, giving you fast access to certain menus or functions. The monitor has three types of softkeys:
  - Waveform keys: Each waveform area can be seen as a softkey. You can enter a waveform setup menu by selecting its corresponding waveform area.
  - Parameter keys: Each parameter area can be seen as a softkey. You can enter a parameter setup menu by selecting its corresponding parameter area.
  - QuickKeys: QuickKeys are located at the bottom of the main screen. For details, refer to the section QuickKeys.
- Hardkeys: A hardkey is a physical key on a monitoring device, such as the main menu hardkey on the monitor's front.
- Knob key: With this key, the user may enter the menus and windows and change the monitor settings.

## **3.4 Measurement Settings**

### 3.4.1 Setting the parameter switch

The main interface selects [Main Menu]  $\rightarrow$  [Parameter Setup]  $\rightarrow$  [Parameter Switch] to set the switching status of the measurement parameters. When a parameter display switch is off, the parameter value and waveform of the parameter will not be displayed on the monitor interface.

• The ECG parameter switch is fixed to on and cannot be set.

#### 3.4.2 Parameter Settings

Turn the knob of the physical button to move the cursor on the main screen to the QuickKey of a parameter area, then press the knob to pop up the parameter setting menu. Then, you can enter the setting menu of each parameter to set the parameters. Or select [Main Menu]  $\rightarrow$  [Parameter Setup] on the main interface, and select the parameter to be set after entering the parameter setting interface.

### 3.5 System Setup

#### 3.5.1 WiFi

Select [Main Menu]  $\rightarrow$  [System Setup]  $\rightarrow$  [WiFi] on the main interface to open the [WLAN] switch. The list displays the searched hotspot name, encryption status, and signal strength. Select the searched hotspot name in the list and enter the password to connect to the hotspot.

#### 3.5.2 Ethernet

The main interface selects [Main Menu]  $\rightarrow$  [System Setup]  $\rightarrow$  [Ethernet]. When the connection type is Auto, the Ethernet information will be automatically obtained. When the connection type is manual, the Ethernet IP can be set. DNS, network mask, gateway address.

#### 3.5.3 Volume

#### **Alarm Volume**

1. Select [More]  $\rightarrow$  [Volume], or [Main Menu]  $\rightarrow$  [System Setup]  $\rightarrow$  [Volume].

2. Select [Alarm Volume]: 1~10.Select 1 for the minimum alarm volume and 10 for the maximum alarm volume.

#### **Pulse Volume**

1. Select [More]  $\rightarrow$  [Volume], or [Main Menu]  $\rightarrow$  [System Setup]  $\rightarrow$  [Volume].

2. Select [Pulse Volume]: 1~10.Select 1 for the minimum pulse volume and 10 for the maximum pulse volume.

#### **Heartbeat Volume**

1. Select [More]  $\rightarrow$  [Volume], or [Main Menu]  $\rightarrow$  [System Setup]  $\rightarrow$  [Volume].

2. Select [HR Volume]: 1~10.Select 1 for the minimum heartbeat volume and 10 for the maximum heartbeat volume.

#### **Keypad Switch**

1. Select the [Volume Settings] hotkey, or [Main Menu]  $\rightarrow$  [Interface Settings >>].

2. Select [Keypad Sound]: After the key sound is turned on, the key operation has sound. When the key sound is turned off, the key operation has no sound.

#### 3.5.4 Brightness

1. Select [Main Menu]  $\rightarrow$  [System Setup].

2. Select [Brightness]:  $1 \sim 10$ . 1 is the darkest and 10 is the brightest. When using battery, you can set a lower brightness to save power. When the monitor is in night mode, the screen brightness is automatically adjusted to the darkest.

#### 3.5.5 Time

- 1. Select [Main Menu]  $\rightarrow$  [System Setup]  $\rightarrow$  [Time].
- 2. Set [Date] and [Time].
- 3. Select [Date Format]: [Year-Month-Day], [Month-Day-Year] or [Day-Month-Year].
- 4. Select [Time Format]: [24-hour clock] or [12-hour clock].

If the monitor is connected to a central monitoring system or clinical information system, the system time of the monitor will be automatically adjusted based on the time of the central monitoring system or clinical information system. You cannot set the system time of the monitor.

#### 3.5.6 Language

- 1. Select [Main Menu]  $\rightarrow$  [System Setup]  $\rightarrow$  [Language].
- 2. Select the language as needed in the [Language] menu.

#### 3.5.7 Record

- 1. Select [Main Menu] → [System Setup] → [Record] on the main interface. The recording time can be set to 16s to record the data of 8 seconds before and after the current time.
- 2. Select [Main Menu] → [System Setup] → [Record] on the main interface, and set the recording speed to 50mm/s, 25mm/s, 12.5mm/s.
- 3. In the main interface, select [Main Menu] → [System Setup] → [Record] to open/close the recording grid. When the grid is opened, there are records in the report.

The grid display, when closed, there is no grid display in the record report.

4. Select [Main Menu] → [System Setup] → [Record] on the main interface to select the number of recorded waveforms and the waveform to be recorded.

#### 3.5.8 System Log

The system logs information about the operation of the monitor.

#### 3.5.9 Central Monitoring Station

Connection configuration of the monitor and the central monitoring station: the central station switch and the IP address of the central station.

#### 3.5.10 Night Mode

Night mode can be used when you want to avoid the monitor disturbing the patient.

Turn on the night mode: Select [Main Menu]  $\rightarrow$  [System Setup] to open the [Night Mode] switch with the lowest brightness and the lowest alarm volume.

Exit night mode: Select [Main Menu]  $\rightarrow$  [System Setup], turn off the [Night Mode] switch, and the brightness and alarm sound will return to the value before the night mode is turned on.

#### 3.5.11 Privacy Mode

After selecting the privacy mode, the screen turns black to display "privacy mode, press any key to exit", in the privacy mode, the sound and alarm light are shielded; press any key (except the power on/off button, switch the machine to control the switch and standby mode), sound, the alarm light returns to normal.

### 3.6 Equipment Maintenance

#### 3.6.1 User Maintenance

1. Select [Main Menu]  $\rightarrow$  [Device Maintenance]  $\rightarrow$  [User Maintenance] on the main interface.

2. Enter the user maintenance password to enter the user maintenance interface.

3. User maintenance interface can set the monitor, department name, select lead type, module maintenance, set parameter color, export log and modify user maintenance password.

#### Monitor and Department Name

The user maintenance interface enters the name of the monitor and department, and the name of the department is displayed in the patient information.

#### Lead type

User maintenance interface selects lead type AHA or IEC.

#### Module maintenance

User maintenance interface selection [module maintenance] enters the module maintenance interface; module maintenance can perform pressure check and NIBP leak detection on NIBP.

#### **Parameter color**

User maintenance interface select [Parameter color] to enter the parameter color setting interface, the parameter color can be set to: red, orange, yellow, green, Cyan, blue, purple, gray and white.

#### **Export** log

User maintenance interface select [Export Log], you can export the log to the u disk, which is easy to find errors.

#### 3.6.2 Demo Mode

1. Main interface select [Main Menu] → [Device Maintenance] → [Demo Mode]

2. Enter the demo password and enter the demo mode interface mode.

3. In the main interface, select [Main Menu]  $\rightarrow$  [Device Maintenance]  $\rightarrow$  [Exit Demo Mode] to exit the demo mode.

### 3.7 Data Management

Monitoring records

The guardianship record can be used to view information about the connected patient, including name, gender, access time, and release time.

Configuration management password

Import configuration: Import the configuration from the monitor into the u disk.

Export configuration: Import the configuration file from the u disk into the monitor.

Data review

The data review includes trend graphs, trend tables, event reviews, and holographic waveforms. See the review section for details.

#### FOR YOUR NOTES
# **Chapter 4 Managing Patients**

## 4.1 Admit New Patient

The patient monitor displays physiological data and stores them in the trends as soon as a patient is connected. This allows you to monitor a patient that is not admitted yet. However, it is recommended that you fully admit a patient so that you can clearly identify your patient, on recordings, reports and networked devices.

If the patient monitor already admits a patient, it is recommended to discharge this patient before admitting a new patient. Otherwise, the new patient's data will be stored into that patient's data.

To admit a patient:

- 1. Select [Patient Setup]  $\rightarrow$  [Admit Patient], or select [Main Menu]  $\rightarrow$  [Patient Setup]  $\rightarrow$  [Admit Patient].
- 2. If the monitor has admitted a patient, select [Patient Setup] → [Remove Patient] to cancel the current patient or admit the patient.

Select to clear the patient has stored data, admitting new patients. If the monitor does not admit the patient and you can directly admit the patient and select [Apply Data]

Use the data stored by the monitor or select [Confirm] to create new patient information and not use the data stored by the monitor.

3. Enter or select the patient's information in the [Patient Information] menu:

[Patient ID]: The case number of the patient.

[Name]: The name of the patient.

- [Bed number]: The bed number of the patient.
- [Patient Type]: Determines the algorithm that the monitor uses to process and calculate certain measurements, as well as the safety limits and alarm limits used for certain measurements. Choice of "adult", "child", "neonate"

[Gender]: The gender of the patient.

- [Pace]: Determines whether the monitor displays the pacing pulse. When set to "Off", the pacing pulse will not be displayed on the ECG waveform.
- [Date of Birth]: The date of birth of the patient.
- 4. After finishing the edit of the information, close the menu, the monitor will start to monitor the current patient.

# 

• For paced patients, you must set [PACE] to [ON]. If it is incorrectly set to [OFF], the

patient monitor could mistake a pace pulse for a QRS and fail to alarm when the ECG signal is too weak.

• For non-paced patients, you must set [PACE] to [OFF] .If it is incorrectly set to [ON], the patient monitor may be unable to detect premature ventricular beats (including PVCs) and perform ST segment analysis.

## 4.2 Editing Patient Information

To edit the patient information after a patient has been admitted, or when the patient information is incomplete, or when you want to change the patient information:

1. Select the [Patient Setup] hotkey, or select [Main Menu]  $\rightarrow$  [Patient Setup]  $\rightarrow$  [Patient Information]. Edit the information you want to modify in the patient information interface.

2. After the information is filled in, close the menu and the monitor starts the current patient monitoring.

## 4.3 Discharging a Patient

Select the [Patient Setup] hotkey, or select [Main Menu] → [Patient Setup] → [Discharge Patient].
Select [Yes] in the pop-up confirmation to cancel the patient. The monitor will perform the patient release procedure. Select [No] to exit the patient operation and cancel the patient operation to clear all historical data in the monitor.

# 4.4 Connecting to a Central Monitoring System

If your patient monitor is connected to a central monitoring system (CMS):

1. All patient information, measurement data and settings on the patient monitor can be transferred to the CMS.

2. All patient information, measurement data and settings can be displayed simultaneously on the patient monitor and CMS. For some functions such as editing patient information, admitting a patient, discharging a patient, starting/stopping NIBP measurements, etc., bi-directional control can be achieved between your patient monitor and the CMS.

For details, refer to the CMS's instructions for use.

# **Chapter 5 User Interface**

【ECG full screen 7 leads】, 【ECG half screen 7 leads】, 【NIBP Review】, 【OxyCRG】, 【Minitrend】, 【Big Numerics】, 【normal】 total of 7 interfaces to choose from.

#### **ECG Full-screen 7 leads**

7-lead ECG waveforms, including I/II/III/aVR/aVL/aVF/V, make it easy for doctors to observe ECG waveforms.

#### **ECG Half-screen 7 leads**

The 7-lead ECG waveforms, including I/II/III/aVR/aVL/aVF/V, which is convenient for doctors to observe the ECG waveforms.

#### ■ NIBP Review

The test review record is based on the NIBP measurement interval.

The default interval for NIBP manual testing is once per measurement and NIBP is recorded. Under the automatic measurement of NIBP, the recording is based on the automatic measurement interval.

#### • OxyCRG

An OxyCRG analysis interface is available for physician reference. The OxyCRG interface occupies the lower half of the waveform region, and the OxyCRG interface is composed of HR trend, SpO2 trend and RR trend/RESP waveform.

#### Minitrend

In addition to displaying each waveform and parameter, a short trend graph of each parameter value can be displayed at the same time.

#### Big Numerics

Display in large fonts, and the values of each parameter can be clearly seen from a long distance. Four sets of parameters can be displayed. For waveforms with parameters, a waveform is displayed at the same time.

#### Normal

Standard 5-channel waveform, three ECG waveforms, one oximetry waveform and one respiratory waveform.

#### FOR YOUR NOTES

# Chapter 6 Alarm

# 6.1 Description

Alarms are triggered by a vital sign that appears abnormal or by technical problems of the patient monitor, are indicated to the user by visual and audible alarm indications.

# 

- A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.
- If your patient monitor is connected to a CMS, remote suspension, inhibition, silence and reset of monitor alarms via the CMS may cause a potential hazard.

## 6.2 Alarm Categories

By nature, the patient monitor's alarms can be classified into three categories: physiological alarms, technical alarms and prompt messages.

#### 1. Physiological alarms

Physiological alarms, also called patient status alarms, are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition.

Physiological alarm messages are displayed in the physiological alarm area.

#### 2. Technical alarms

Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems. Technical alarm messages are displayed in the technical alarm area.

#### 3. Prompt messages

As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the patient monitor will show some messages telling the system status.

Messages of this kind are included into the prompt message category and usually displayed in the prompt information area. But for some measurements, their related prompt messages are displayed in their respective parameter windows.

Example of Physiological alarms and Technical alarms:

Situation of patient or machine	Alarm Type
Patient's heart rate is 114BPM which surpass the user's preset range	Physiological Alarm
Patient occur ventricular fibrillation	Physiological Alarm
ECG lead off	Technical Alarm
SpO2 module failure	Technical Alarm

# 6.3 Alarm Level

By severity, the patient monitor's alarms can be classified into three categories: high level, medium level and low level.

	Physiological Alarm	Technical Alarm
	Indicate that your patient is in a	Indicate a severe device malfunction or an
	life threatening situation, such as	improper operation, which could make it
High level	Asystole, Vfib/Vtac and so forth,	possible that the monitor cannot detect critical
	and an emergency treatment is	patient status and thus threaten the patient's life,
	demanded.	such as low battery and so forth.
		Indicate a device malfunction or an improper
Madium	Indicate that your patient's vital	operation, such as ECG/SpO2 lead off, which
laval	signs appear abnormal and an	may not threaten the patient's life but may
level	immediate treatment is required.	compromise the monitoring of vital
		physiological parameters.
	Indicate that you patient's vital	Indicate a device malfunction or an improper
Low level	signs appear abnormal and an	operation, which may compromise a certain
	immediate treatment may be	monitoring function but will not threaten the
	required.	patient's life.

Each alarm has a level, the monitor system will use different ways to remind health care person, higher level will use a way more serious. Users cannot change any Technical Alarm. Some of Physiological Alarm level can be changed by user but some of them are fixed by system which cannot change.

# 6.4 Alarm Indicators

When an alarm occurs, the patient monitor will indicate it to the user through visual or audible alarm indications.

- Alarm lamp
- Alarm message
- Flashing numeric
- Audible alarm tones

## 6.4.1 Alarm Lamp

If an alarm occurs, the alarm lamp will flash. The flashing color and frequency match the alarm level as follows:

- High level alarms: the lamp flashes quickly in red.
- Medium level alarms: the lamp flashes slowly in yellow.
- Low level alarms: the lamp turns yellow without flashing.

Additionally, the alarm message uses different background color to match the alarm level:

- High level alarms: red
- Medium level alarms: yellow
- Low level alarms: yellow

You can view the alarm messages by selecting the physiological or technical alarm area.

### 6.4.2 Alarm Message

When an alarm occurs, an alarm message will appear in the technical or physiological alarm area. For physiological alarms, the asterisk symbols (\*) before the alarm message match the alarm level as follows:

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

## 6.4.3 Flashing Numeric

If an alarm triggered by an alarm limit violation occurs, the numeric of the measurement in alarm will flash every second, and the corresponding alarm limit will also flash at the same frequency indicating the high or low alarm limit is violated.

## 6.4.4 Audible Alarm Tones

Alarm Lamp and Alarm Audi	o of different levels
---------------------------	-----------------------

Alarm Level	Audio prompt	visual
High	"DO-DO-DODO-DO"	lamp flashes quickly in red
Medium	"DO-DO-DO"	lamp flashes slowly in yellow
Low	"DO"	lamp turns yellow without flashing

# 6.5 Alarm status

## 6.5.1 Description

Each alarm has two different statuses: trigger status and clear status. It only stays in one status. Trigger status: alarm is on. Clear status: alarm is off.

All alarms are in clear status when the monitor turns on, which will be triggered into state when the alarms satisfy condition.

There have several status of the whole system of alarm  $(all \ alarm)$  :

- 1. Normal status.
- 2. Alarm paused status.
- 3. Alarm silence status.
- 4. Alarm sound off status.

## 6.5.2 Alarm Status Logo



💐 Alarm close

Alarm silence

# 6.6 Alarm basic settings

In the [Main Menu], select [Alarm Setup], and the alarm settings include basic settings, parameter alarms, arrhythmia, and arrhythmia thresholds.

### 6.6.1 Setting the alarm volume

1. Select [Main Menu]  $\rightarrow$  [Alarm setup]  $\rightarrow$  [General Setup]  $\rightarrow$  [Alarm Volume]

2. There are ten levels 1-10 in the alarm volume, 1 is the minimum volume and 10 is the maximum volume.

#### 6.6.2 Alarm pause time

Select [Pause Time] to temporarily stop all alarm indications of the monitor.

- Both the light alarm and the audible alarm are suspended.
- The parameters of the physiological alarm and the upper and lower limits stop flashing.
- Text alarm messages will not be displayed.
- The status bar shows the remaining time of the alarm pause and the alarm pause icon The user can set the time when the alarm is paused as needed.
- 1. Select [Main Menu]  $\rightarrow$  [Alarm Setup]  $\rightarrow$  [General Setup]
- 2. The alarm basic setting interface selects the appropriate alarm pause time.

### 6.6.3 Latching alarm

The parameter alarm can be set to "non-latching", "latching high", "latching high & mid".

Non-latching: After the cause of a parameter alarm is cleared, the system will not give any prompt for this alarm.

Latch: Even if the cause of the alarm is cleared, the system will still "latching" and display the last trigger after the alarm message in the alarm zone.

Select [Latching high] to latch only the high alarms; select [Latching High & mid] to latch the high and medium alarms.

## 6.7 Parameter Alarm

Select [Main Menu]  $\rightarrow$  [Alarm Setup]  $\rightarrow$  [Parameter Alarm], you can view and modify the alarm switch status, alarm upper and lower limit values, alarm level and alarm record switch status of all parameters in the current measurement.

When an alarm occurs in a parameter, only when [Alarm Switch] and [Alarm Record] of the parameter are set to [On], the alarm will trigger the recorder to output the waveform related to the alarm and the values of all parameters. When the alarm switch is selected as "On", the alarm will be given when the parameter is alarmed. If "Off" is selected, the alarm will not be given and the prompt will be displayed next to the screen parameter area.

For the parameter setting alarm, when the value of one or several parameters exceeds the alarm limit, the monitor automatically alarms

- 1) A prompt appears on the screen, as described in the form of an alarm prompt;
- 2) If the alarm volume is set, an alarm sounds according to the set alarm level and alarm volume;
- 3) The alarm light flashes or is always on;
- 4) The parameter area alarm upper/lower limit value and measured value flashes

## 6.8 Measures to be taken when an alarm occurs

According to the alarm information, it is necessary to identify this alarm and take corresponding measures according to the cause of the alarm.

- 1) Check the patient's condition.
- 2) Identify which parameter is alarming or which type of alarm is occurring.
- 3) Identify the cause of the alarm.
- 4) The alarm is muted if needed.
- 5) After the alarm condition is removed, check if the alarm is cleared.

# $\triangle$ warning

• When an alarm occurs, the patient's condition should be checked first.

# **Chapter 7 Monitoring ECG**

# 7.1 ECG Introduction

## 7.1.1 Introduction

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the patient monitor as a waveform and a numeric. Make sure ECG lead to connect correctly to have correct testing value.



## 7.1.2 Safety



- Do not touch patient, desk or equipment during defibrillation.
- It is necessary to use the electric cable provided by our company when using a portable monitor to monitor ECG signal.
- When user connect electrodes or patient cable, it should be assured that there is absolutely no contact with any other conductor or the earth. Especially it should be assured that all ECG electrodes, including neutral electrode, are attached to the patient to prevent them from contacting with the conductor parts or the earth.
- When the defibrillator is used simultaneously, it is necessary to use the auxiliary accessories provided by us. The monitor can't be used for defibrillation when using ECG cable without resistance. In other monitor, the monitor can't be used for defibrillation if the monitor itself does not have a defibrillation resistance.
- Interference from ungrounded instruments near patient and ESU interference may lead to a wave problem. If operate according to the conditions specified in EN60601-1-2(Anti Radiation Ability is 3 Volts/Meter), the electric field strength of more than 1Volt/Meter may cause errors at various frequencies. Therefore, it is recommended not to use an electric radiation device near the ECG/Respiration measuring position.

# 7.2 ECG Operation

## 7.2.1 Prepare

1. Prepare the patient's skin. Proper skin preparation is necessary for good signal quality at the electrode, as the skin is a poor conductor of electricity. To properly prepare the skin, choose flat, non-muscular areas and then follow this procedure:

- Shave hair from skin at chosen sites.
- Gently rub skin surface at sites to remove dead skin cells.
- Thoroughly cleanse the site with a mild soap and water solution. We do not recommend using ether or pure alcohol, because this dries the skin and increases the resistance.
- Dry the skin completely before applying the electrodes.
- 2. Attach the clips or snaps to the electrodes before placing them.
- 3. Place the electrodes on the patient.
- 4. Attach the electrode cable to the patient cable and then plug the patient cable into the ECG connector.

# 

- Place the electrodes carefully and make sure good contact.
- Check the electrodes every day whether they irritate to the skin or not. Change electrodes or position in 24 hours if there have skin irritation or irritability.
- Check the monitor work well before monitoring patient. The monitor will display "ECG sensor off" alarm message when disconnecting ECG cable, and also trigger an audible alarm.

## NOTE

• Used electrodes must be recycled or proper disposal to protect the environment.

## 7.2.2 ECG Lead Placements

The electrode placement illustrations in this chapter adopt the AHA standard.

### **3-Lead Electrode Placement**

Following is an electrode configuration when using 3 lead:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement: on the left lower abdomen.



#### 5-Lead Electrode Placement

Following is an electrode configuration when using 5 lead:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- RL placement: on the right lower abdomen.
- LL placement: on the left lower abdomen.
- V placement: on the chest.



The chest (V) electrode can be placed on one of the following positions:

- V1 placement: on the fourth intercostal space at the right sternal border.
- V2 placement: on the fourth intercostal space at the left sternal border.
- V3 placement: midway between the V2 and V4 electrode positions.
- V4 placement: on the fifth intercostal space at the left midclavicular line.
- V5 placement: on the left anterior axillary line, horizontal with the V4 electrode position.
- V6 placement: on the left midaxillary line, horizontal with the V4 electrode position.
- V3R-V6R placement: on the right side of the chest in positions corresponding to those on the left.
- VE placement: over the xiphoid process.
- V7 placement: on posterior chest at the left posterior axillary line in the fifth intercostal space.
- V7R placement: on posterior chest at the right posterior axillary line in the fifth intercostal space.

U.S standard		European standard	
Lead name	Color	Lead name	Color
RA	white	R	red
LA	black	L	yellow
LL	red	F	green
RL	green	N	black
V	brown	С	white

The following table lists the name of lead in European and U.S. standards (European standard used in R, L, N, F, C indicates the lead, and in the U.S. standard with RA, LA, RL, LL, V represents).

#### **Lead Placement for Surgical Patients**

The surgical site should be taken into consideration when placing electrodes on a surgical patient. e.g. for open-chest surgery, the chest electrodes can be placed on the lateral chest or back. To reduce artifacts and interference from electrosurgical units, you can place the limb electrodes close to the shoulders and lower abdomen and the chest electrodes on the left side of the mid-chest.

Do not place the electrodes on the upper arm. Otherwise, the ECG waveform will be very small.

## NOTE

• In order to ensure patient safe, all leads must be connected to the patient.

# 

- When using electrosurgical units (ESU), patient leads should be placed in a position that is equal distance from the Electrosurgery electrotome and the grounding plate to avoid burns to the patient. Never entangle the ESU cable and the ECG cable together.
- When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.

# 7.3 ECG settings

Turn the knob to move the cursor on the main screen to the ECG hotkey in the parameter area, then press the knob to pop up the ECG setting menu. Or select [Main Menu]  $\rightarrow$  [Parameter Setup]  $\rightarrow$  [ECG] to enter the ECG setting menu.

#### 7.3.1 Lead type

- 1. Select [Main Menu]  $\rightarrow$  [Parameter Setup]  $\rightarrow$  [ECG]
- 2. Set [Lead Setup] to [3 Lead], [5 Lead] or Auto according to the lead used.

3. Select [Main Menu]  $\rightarrow$  [Maintenance]  $\rightarrow$  [User Maintenance]  $\rightarrow$  [Lead Type] set to [AHA] or [IEC].

#### 7.3.2 Filtering method

A cleaner or more accurate waveform can be obtained by filtering:

- [Monitor]: The monitoring method will filter out the artifacts that may cause false alarms.
- [Diagnostics]: The unfiltered ECG wave is displayed in the diagnostic mode.
- [Surgery]: Surgical methods can reduce artifacts and interference from electrosurgical equipment.

## ∕\_\_\_Warning

• The system can only provide unprocessed real signals when in diagnostic mode. In the "monitoring" and "surgical" filtering modes, the ECG waveforms will have different degrees of distortion. It is recommended to use the diagnostic mode for normal patient monitoring.

#### 7.3.3 Notch Filter

When the filtering method is diagnostic, the notch filter can be set.

- 1. Select [Main Menu]  $\rightarrow$  [Parameter Setup]  $\rightarrow$  [ECG]
- 2. Set [Notch Filter] to [50Hz] or [60Hz] according to the lead used.

#### 7.3.4 Waveform speed

1. Select [Main Menu]  $\rightarrow$  [Parameter Setup]  $\rightarrow$  [ECG]

2. Select the waveform speed according to your needs: 12.5mm/s, 25.0mm/s and 50.0mm/s.

The larger the value, the faster the scan speed and the wider the waveform.

#### 7.3.5 Waveform Gain

1. Select [Main Menu]  $\rightarrow$  [Parameter Setup]  $\rightarrow$  [ECG]

2. Select the waveform gain as needed: x0.125, x0.25, x0.5, x1, x2 and automatically selectable. The higher the gain, the higher the waveform amplitude.

### 7.3.6 Heart rate source

[HR source] You can choose ECG or SpO2 to detect heart rate

### 7.3.7 Pace Switch

It is important to correctly set the patient's pacing state before starting ECG monitoring. When the [Pace Switch] is [On], when the system detects the pacing signal, it will display a bright color in the

ECG parameter area. In the diagnostic state, when you set [Pace Switch] to [Off], the dark color is

displayed in the ECG parameter area.

You can change the pacing status in any of the following ways:

- Select [Patient Information Management] to set the pacing status.
- Select [Main Menu]  $\rightarrow$  [Parameter Setup]  $\rightarrow$  [ECG] to set the pacing switch status.

# Warning

• For pacing patients, you must select [Pace Switch] as [On]. Otherwise, the pacing pulse is

treated as a regular QRS group, and when the ECG signal is too weak, the system cannot detect and alarm. Do not rely solely on heart rate calculations for alarms. Patients with pacemakers should be placed in close monitoring.

• For patients with non-pacemakers, select [Pace Switch] as [Off].

### 7.3.8 Pace Reject

[Main Menu]  $\rightarrow$  [Parameter Setup]  $\rightarrow$  [ECG]  $\rightarrow$  [Pace Reject] Select [Pacing Reject] to [On] or [Off]. When the [Pace Switch] switch is set to [On]:

■ Turning on [Pace Reject] suppresses the display of the pacing signal, but when the pacing signal is detected, the pacing pulse | mark is still displayed above the ECG waveform;

• Turning off [Pace Reject] does not suppress the display of the pacing pulse. When the pacing signal is detected, the pacing pulse flag is displayed above the ECG waveform.

When [Pace Switch] is [Off], [Pace Reject] is automatically off.

### 7.3.9 Smart Lead Calculation

Turn off the [ECG Self-learning] switch. Only II can calculate the heart rate value. Turning on the [ECG Self-learning] switch will calculate the heart rate value from the better guide of the I, II lead selection signal.

## 7.3.10 ECG alarm settings

Select [Parameter Alarm] in the alarm setting, you can set the HR alarm switch, alarm high/low limit, alarm level, alarm record.

#### Note

- The upper and lower limits of the alarm should be set according to the clinical situation of each patient.
- It is important that the heart rate alarm upper limit is set during monitoring. The upper limit should not be set too high. Considering the factors of change, the upper limit of the heart rate alarm is not set.

It is 20 beats/min higher than the patient's heart rate.

# 

• As the "Monitor" or "Surgery" filter may cause ECG waveform distortions, try to use the "Diagnostic" filter for ST analysis as possible as you can. Besides, the "Surgery" filter may also affect arrhythmia analysis results.

# 7.4 ECG Alarm Information

Physiological alarms:

Message	Cause	Alarm level
HR too high	HR measuring value is above the upper alarm limit	User-selectable
HR too low	HR measuring value is below the lower alarm limit	User-selectable

#### **Technical alarms:**

Message	Cause	Alarm level	Solution	
ECG lead off	ECC states for fall		Malaa aana dhad all	
ECG LL lead off or ECG F lead off	ECG electrodes fall		Make sure that all	
ECG LA lead off or ECG L lead off	oil the skin of ECG	LOW	electrodes. leads and patient	
ECG RA lead off or ECG R lead	cables fall off the		cables are property	
off			connected.	
ECG INIT ERR				
ECG INIT ERR1	-			
ECG INIT ERR2				
ECG INIT ERR3				
ECG INIT ERR4	ECG module failure	HIGH		
ECG INIT ERR5				
ECG INIT ERR6			Stop using ECG function,	
ECG INIT ERR7	-		Call the professional	
ECG INIT ERR8			engineer or service staff.	
	ECG module or			
ECG COMM STOP	communication	HIGH		
	failure		_	
	Occasional			
ECG COMM ERR	communication	HIGH		
	failure			
			Stop using HR alarm	
HR ALMIMT FRR	Functional safety	HIGH	function, Call the	
	failure	mon	professional engineer or	
			service staff.	
			Make sure the patient is	
	ECG measuring		quiet, the electrodes are	
ECG NOISE	signal is greatly	LOW	properly connected and AC	
	interfered.		power system is well	
			grounded.	

# **Chapter 8 Monitoring RESP**

## 8.1 Introduction

Impedance respiration is measured across the thorax. When the patient is breathing, the volume of air changes in the lungs, resulting in impedance changes between the electrodes.

Respiration rate (RR) is calculated from these impedance changes, and a respiration waveform appears on the patient monitor screen.



## NOTE

- When monitoring the patient's respiration, do not use ESU-proof ECG cables.
- If you do not set the detection level for the respiration correctly in manual detection mode, it may not be possible for the monitor to detect apnea. If you set the detection level too low, the monitor is more likely to detect cardiac activity, and to falsely interpret cardiac activity as respiratory activity in the case of apnea.
- The respiration measurement does not recognize obstructive and mixed apneas. It only indicates an alarm when a preset time had elapsed since the last detected breath. Therefore, it cannot be used for diagnostic purpose.
- Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.

# 8.2 Placing RESP Electrodes

As the skin is a poor conductor of electricity, preparing the skin is necessary for a good Respiration signal. You can refer to the ECG section for how to prepare the skin.

As the respiration measurement adopts the standard ECG electrode placement, you can use different ECG cables (3-lead, 5-lead). Since the respiration signal is measured between two ECG electrodes, if a standard ECG electrode placement is applied, the two electrodes should be RA and LA of ECG Lead I, or RA and LL of ECG Lead II.

#### NOTE

• To optimize the respiration waveform, place the RA and LA electrodes horizontally when monitoring respiration with ECG Lead I; place the RA and LL electrodes diagonally when monitoring respiration with ECG Lead II.



Diagonal position RA and LL electrode to get the best RESP waveform. You should avoid to put the liver and ventricle under the connection lines of RESP electrode, it would avoid the error which caused by heart covered or pulse blood flow, it's very important for newborn.

#### 8.2.1 Optimizing Lead Placement for Respiration

If you want to measure RESP when you are measuring ECG, you may need to optimize the placement of the two electrodes between which RESP will be measured. Repositioning ECG electrodes from standard positions results in changes in the ECG waveform and may influence ST and arrhythmia interpretation.

#### 8.2.2 Cardiac Overlay

Cardiac activity that affects the Respiration waveform is called cardiac overlay. It happens when the RESP electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrodes placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes. This is particularly important for neonates.

#### 8.2.3 Abdominal Breathing

Some patients with restricted movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.

### 8.2.4 Lateral Chest Expansion

In clinical applications, some patients (especially neonates) expand their chests laterally, causing a negative intrathoracic pressure. In these cases, it is better to place the two respiration electrodes in the right midaxillary and the left lateral chest areas at the patient's maximum point of the breathing movement to optimize the respiratory waveform.

## 8.3 RESP Setup

Turn the knob to move the cursor to the RESP hotkey in the parameter area of the main screen, then press the knob to enter the [RESP setup] menu.

### 8.3.1 Lead Setup

In the [RESP Setup] menu, [RESP Lead] can be selected as the I lead or II lead.

### 8.3.2 Apnea Delay

In the [RESP Setup] menu, you can set [Apnea Delay]; when the patient has a suffocation time, the monitor will trigger an alarm after the set time has elapsed.

#### 8.3.3 Waveform speed

Select [Waveform Speed]: Select the appropriate setting in the pop-up list. The larger the value, the faster the scan speed and the wider the waveform.

### 8.3.4 Waveform Gain

Select [Waveform Gain]: the user can set the enlarged display of the RESP waveform. The magnification options are x0.25, x0.5, x1, x2 or automatic.

#### 8.3.5 RR source

The RR source can set RESP or Auto.

## 8.3.6 Setting Alarm Properties

Select [Main Menu]  $\rightarrow$  [Alarm Setup]  $\rightarrow$  [Parameter Alarm] or select [Alarm Setup]  $\rightarrow$  [Parameter Alarm] to set the RR alarm switch, high and low limits, alarm level, alarm record switch.

# **8.4 RESP Alarm Information**

**Physiological Alarms:** 

Message	Cause	Alarm level
RR too high	RESP measured value is higher than alarm limit	User-selectable
RR too lower	RESP measured value is lower than alarm limit	User-selectable
RESP Respiration Asphyxia	Can not measure RESP in specific interval time	High

# **Chapter 9 Monitoring SpO2**

## 9.1 Introduction

SpO<sub>2</sub> measurement using continuous and noninvasive pulse blood oxygen quantify method. It measure the specific wavelength light emitted from the sensor light source, after absorbed by the oxyhemoglobin of patient tissue, the final arrival sensor light and electric probe light, to get the SpO<sub>2</sub> and pulse rate. This monitor has already calibrated to display functional SpO<sub>2</sub>.



1. Pleth waveform (Pleth): visual indication of patient's pulse. The waveform is normalized.

2. Perfusion indicator (PI): PI means the percent of pulse amount and non-pulse amount which caused by artery blood flow change. PI reflects the signal strength of SpO2, also partly reflects the signal quality. The value of PI above 1 means the best, 0.3-1 is acceptable, if PI less than 0.3, you need adjust the probe or choose a better part of finger to test.

3. Oxygen saturation of arterial blood (SpO2): percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.

4. Irrigation Pillar Chart: It's in proportion to pulse strength.

#### SpO2 Parameter Measurement Principle

Oxyhemoglobin (HbO2) and Reduced Hemoglobin (Hb) have different spectrum features in red light and infrared light area, HbO2 and Hb have great absorbing difference in red light area (600-700nm). The degree of blood absorbing and scattering light have great dependence on SpO2, but in infrared light area, there are no much difference, the degree blood absorbing and scattering light mostly depends on the content of Hemoglobin.

According to this principle, it emits 660nm and 940nm wavelength light from the sensor light source to periodic pulse blood-changing tissue, the strength of light will be changing by the tissue periodic pulse blood, the light detector of probe gets this change and transfers to electric signals offered to the micro processor, which depends on the light strength changing to measure the SpO2.

# NOTE

• If exists carbon oxygen hemoglobin (COHb), iron hemoglobin or dye dilute chemical drugs, SpO2 value will have some error.

# 

- If there is carbooxy hemoglobin, hemoglobin or dye dilution of chemicals, SPO2 value will deviate.
- The electrosurgical equipment cable can not be intertwined with the sensor cable.
- Do not put the sensor on a limb with an artery catheter or a venous injection tube.
- Do not put the SPO2 probe and BP cuff on the same limb, as blood flow occlusion affects oxygen saturation reading when measuring BP.
- Only use the pulse oxygen probe specified in the instruction, use the equipment complying with the instructions and all warning & precautions.
- When patients tend to have a tendency to be anoxic, Oximeter should be used to analyze blood samples to completely control patient condition.
- Avoid the use of monitors and sensors when using nuclear magnetic resonance equipment, because the induced current may cause severe burns to patient.
- When doing a continuous monitoring of the patient for a long time, users should check the pulse oxygen probe position every 2, and according to the skin changes, move the probe position properly every 4 hours. Especially should pay attention to the quality changes of skin, check the sensor position with right optical alignment and attachment way. Some patients may need more frequent examination, like neonatal, patients with perfusion disorder or skin sensitivity. Because continuous long time monitoring may increase unpredictable skin changes, such as allergy, redness, blister, or compression necrosis, etc.

# 9.2 Placing SpO2 Sensor

## 9.2.1 Adult Sensor

- 1. Select the right Adult Sensor according to patient type and weight.
- 2. Clean the measured part, such as the color nail varnish.
- 3. Attach the sensor to the appropriate site of the patient finger.
- 4. Select the extension cable according to the SpO2 interface type and connect it.
- 5. Connect the extension cable and the Monitor.



Finger clip

Fingerstall

## NOTE

- SpO2 value is always displayed in a fixed place.
- PR is displayed in the following cases only:

Set the "SpO2" or "BOTH" in the "HR FROM" of the "ECG SETUP" menu. Set the "AUTO", and it doesn't have the ECG signal at the same time.

• The SpO2 waveform is out of proportion to the PR.

# 

- Check the sensor and cable carefully before monitoring. The monitor will show "SpO2 NOT CONNECTS" error message when you pull out the SPO2 sensor cable from the socket, at the same time it will alarm.
- If the sensor package or sensor is damaged, don't use it.

### 9.2.2 Neonatal Sensor

Neonate SpO2 sensor consists of a Y-shape SpO2 sensor and sheath.

Insert the LED and PD of the Y-shape SpO2 sensor respectively into the upper and lower grooves of the sheath. The below figure shows the finished neonate SpO2 sensor:





Wind the SpO2 sensor around a hand or foot of a neonate, hold the SpO2 sensor, put the belt and fit one of its sides with "V" edge into the "V" groove on the corresponding side of the sheath. Appropriately elongate the belt to about 20mm. Then loosen the belt. After the "V" edges of the two sides of the belt fit well into the "V" grooves on the two sides of the sheath, put the belt into the first lock bar to fasten the belt. If the belt is too long, you may put it into the second lock bar, You must fix the position of the SpO2 sensor in this way so as to make the photoelectric component face the correct position. Besides, don't elongate the belt too long to cause the measurement inaccurately and block the blood circulation severely.



## NOTE

- If the testing location and probe can not be positioned accurately, it may lead to inaccurate reading of BP saturation, or even can not search for pulse wave and can not carry out blood oxygen monitoring. It should be relocated then.
- Excessive movement of measured parts may cause inaccurate measurement. Then the patient should keep quiet or change measured part to reduce the impact of overmovement on measurement.
- Check whether the monitor is matched when selecting probe or the extension line. Mismatched attachments may lead to inaccurate reading of BP saturation.

# 

• During a long and continuous monitoring process, check the peripheral circulation and skin condition of the measured part once every 2 hours. If any adverse changes, the

measurement site should be changed in time.

- During a long and continuous monitoring process, check the position of the probe periodically to avoid the accuracy change when there is probe position changing.
- During a long and continuous monitoring process, the measurement of the same part is not more than 2 hours.

## 9.3 SpO2 monitoring measurement limits

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

• High frequency electrical interference, including interference generated by the host system itself or interference from an electrosurgical instrument such as a system connected to the system.

• Do not use a photoelectric oximeter or a SpO2 sensor during a magnetic resonance imaging scan (MRI). The induced current may causes burns.

• Intravenous dyes. The patient moved too often.

- External light radiation.
- Improper installation of the sensor or improper contact with the object.
- Sensor temperature (optimal temperature should be in the range of 28  $^{\circ}$  C  $\sim$  42  $^{\circ}$  C).
- Place the sensor on a limb with a blood pressure cuff, an arterial catheter, or a lumen tube.
- Concentrations of non-functional hemoglobin such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Blood oxygen saturation is too low.
- Poor circulation in the test site.
- Shock, anemia, hypothermia, and the use of vasoconstrictor drugs may reduce arterial blood flow to unmeasurable levels.

•Measurements also depend on the absorption of light at specific wavelengths by oxyhemoglobin and reduced hemoglobin. If other substances that absorb the same wavelength are present, they can cause a false or low Sp02 value to be measured. Such as: carbonized hemoglobin, methemoglobin, methylene blue.

• It is recommended to use the SpO2 sensor described in above.

## 9.4 SpO2 Setup

Rotate the rotary button to move the cursor in the display interface to the SpO2 hotkey in the parameter area. Press the rotary button to enter the [SpO2] setting menu.

#### 9.4.1 Waveform speed

[Waveform Speed] can be set in the [SpO2] setting menu, 12.5mm/s, 25mm/s, 50mm/s.

## 9.4.2 Sensitivity and mode

Sensitivity can be set to normal and fast. The mode can be set to normal, anti-interference and fast. Normal mode: SpO2 value is 8 pulse averages

Fast mode: SpO2 value is 4 pulse averages

Anti-interference mode: SpO2 value is 16 pulse averages

The value of SpO2 displayed on the monitor is the result of the average calculation of the data collected over a period of time. The shorter the average time, the faster the monitor responds when the patient's SpO2 value changes, but the measurement accuracy is low. Conversely, the longer the average time, the slower the response of the monitor when the patient's SpO2 value changes, but the measurement accuracy is higher. When monitoring critically patients, setting a smaller average time is beneficial for timely analysis of the condition.

## 9.4.3 Waveform Style

Waveform styles can be set to Fill or Line.

### 9.4.4 Setting Alarm Properties

- Select [Main Menu] → [Alarm Setup] → [Parameter Alarm] or select [Alarm Setup] → [Parameter Alarm] to set the PR (pulse rate) alarm switch, high and low limits, alarm level, alarm record switch.
- 2. SpO2 alarm high and low limit: According to the set high limit and low limit, the alarm will be issued when SpO2 exceeds the high limit or falls below the low limit.
- 3. PR (pulse rate) alarm high and low limit: according to the set high limit and low limit, when RP exceeds the high limit or lower than the low limit, it will alarm.

#### SpO2 and PR alarm ranges:

Parameters	Maximum limit	Minimum limit	Single Adjustment
SpO2	100	0	1
PR	254	0	1



• The maximum limit of SpO2 alarm setting to 100% is equal to disconnect the maximum limit alarm. The High oxygen levels will make the premature baby suffering the Retrolental Fibroplasia. So maximum limit of SpO2 alarm must be selected carefully in accordance with accepted clinical practice.

SpO2 and PR default alarm range in the default settings:

Para	ameters	Maximum limit	Minimum limit
	Adult	100	90
SpO2	Child	100	90
	Neonate	95	90
	Adult	120	50
PR	Child	160	75
	Neonate	200	100

# 9.5 SpO2 Alarm Information

**Physiological Alarms:** 

Message	Cause	Alarm level
SpO2 too high	SpO2 measured value is higher than alarm limit	User-selectable
SpO2 too lower	SpO2 measured value is lower than alarm limit	User-selectable
PR too high	PR measured value is higher than alarm limit	User-selectable
PR too lower	PR measured value is lower than alarm limit	User-selectable

#### **Technical Alarm:**

Message	Cause	Alarm level	Solution
SpO2 Sensor fall off	SpO2Sensorfall off from thepatientormonitor	Low	Ensure that the sensor is placed in the patient's fingers or other parts, and monitors and cables connected properly
SpO2 Module initialization error SpO2 Module initialization error 1 SpO2 Module initialization error 2	SpO2 module error	High	Stop using SpO2 module measurement function, notice bio-medical engineers or customer services of our company

SpO2 Moduleinitialization error 3SpO2 Moduleinitialization error 4SpO2 Moduleinitialization error 5SpO2 Moduleinitialization error 6SpO2 Moduleinitialization error 7SpO2 Moduleinitialization error 7SpO2 Moduleinitialization error 8			
SpO2 module communication stop	SpO2 module error or Communication error	High	Stop using SpO2 module measurement function, notice bio-medical engineers
SpO2 Alarm limit error PR Alarm limit error	Functional safety failures		or customer services of our company

#### Prompt messages (include general alerts):

Message	Cause	Alarm Level
SpO2 measurement is out of bounds	SpO2 measured value is out of range	High
PR measurement is out of bounds	PR measured value is out of range	High
Search pulse	SpO2 module is searching the pulse	/
Pulse not find	SpO2 module can not detect the SpO2 signal for long time	High

# **Chapter 10 Monitoring TEMP**

## **10.1 Introduction**

This patient monitor allows you to monitor two temperature sites simultaneously and calculate the temperature difference between them.



## **10.2 Measurement Procedure**

- 1. Select an appropriate probe for your patient.
- 2. If you are using a disposable probe, connect the probe to the temperature cable.
- 3. Plug the probe or temperature cable to the temperature connector.
- 4. Attach the probe to the patient correctly.
- 5. Check that the alarm settings are appropriate for your patient.

### NOTE

- Check whether the probe cable is normal before starting monitoring. Pull the temperature probe cable of channel 1 out from the socket, the screen will display the error message"T11 Sensor Off" and make an alarm. Other channels are similar.
- Carefully in handing the temperature probe and cable. When not in use, the probe and cable should be in a loose ring. If the wire inside is pulled too tight, it will cause mechanical damage.
- Temperature meter must be calibrated every 2 years (Or according to the time indicated by hospital regulations).

# 

- A one-off temperature probe can be used only once.
- During the monitoring, the temperature meter will automatically check itself every hour. The self checking lasts for 2 seconds, and it does not affect the normal work of the temperature monitoring.

## 10.3 TEMP setup

The user can move the cursor to the parameter area temp hotkey in the main screen through the knob and press the knob to enter the temp setting menu.

### 10.3.1 Setting the TEMP unit

The unit can be set to °C or °F.

### 10.3.2 Setting Alarm

Select [Main Menu]  $\rightarrow$  [Alarm Setup]  $\rightarrow$  [Parameter Alarm] or select [Alarm Setup]  $\rightarrow$  [Parameter Alarm] to set the temperature alarm switch, high and low limits, alarm level, alarm record switch.

## **10.4 TEMP Alarm Information**

#### **Physiological Alarms:**

Message	Cause	Alarm level
T1 too high	TEMP value higher than the high limit of alarm	User-selectable
T2 too high	TEMP value higher than the high limit of alarm	User-selectable
T1 too low	TEMP value lower than the high limit of alarm	User-selectable
T2 too low	TEMP value lower than the high limit of alarm	User-selectable
TD too high	TEMP Different value higher than the high limit of alarm	User-selectable

#### Technical Alarm:

Message			Cause	Alarm level	Solution
TEMP	sensor	fall	TEMP cable fall off	Low	Make sure cable is connected
off			from monitor	Low Make sure cable is connected	
TEMD	~~~~~	mat			Stop using alarm function and inform
	sensor	not	Function safety fault	High	bioengineer or our company repair
connected					engineer

# **Chapter 11 Monitoring NIBP**

# 11.1 Introduction

This monitor uses the oscillometric method for measuring the non-invasive blood pressure (NIBP).

This measurement can be used for adults, pediatrics and neonates.

Automatic non-invasive blood pressure monitoring uses the oscillometric method of measurement.

To understand how this method works, we'll compare it to the auscultative method.

- With auscultation, the clinician listens to the blood pressure and determines the systolic and diastolic pressures. The mean pressure can then be calculated with reference to these pressures as long as the arterial pressure curve is normal.
- Since the monitor cannot hear the blood pressure, it measures cuff pressure oscillation amplitudes. Oscillations are caused by blood pressure pulses against the cuff. The oscillation with the greatest amplitude is the mean pressure. This is the most accurate parameter measured by the oscillometric method. Once the mean pressure is determined, the systolic and diastolic pressures are calculated with reference to the mean.

Simply stated, auscultation measures systolic and diastolic pressures and the mean pressure is calculated.

The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

As specified by IEC 60601-2-30/EN60601-2-30, NIBP measurement can be performed during electro-surgery and discharge of defibrillator.

NIBP diagnostic significance must be decided by the doctor who performs the measurement.

## NOTE

• Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers.

# 

- Patient type must be confirmed before measurement. The wrong settings may jeopardize the safety of patients, because higher adult settings are not suitable for pediatrics and infant.
- NIBP can not be measured on patients who have Sickle cell disease or been measured or expected to have skin damage.
- For patients with severe coagulation disorders, automatic BP measurement should be determined according to clinical evaluation, because there is a risk of creating hematoma of limb and cuff friction.
- When measuring children and newborns, it is necessary to ensure that the correct pattern setting has been selected(Refer to patient information menu settings). The wrong settings may jeopardize the safety of patients, because higher adult settings are not suitable for pediatrics and infant.
- When using ESU devices, the ESU device cable can not be intertwined with the tube. Do not contact the metal parts of tube with the patient and electrosurgical scalpel.
- During defibrillation, do not touch patient, including indirect contact patient by tube metal parts.

## **11.2 Measurement Limitations**

According to patients' situation, oscillation method measurement has some limitations. This method based on the regular pulse wave by artery pressure will be no reliable when it is difficult to check the wave caused by patients, and the time of measuring also will increase. Users should know that the below conditions will affect the measurement and make measurement not reliable or take more time to measure. On this situation, it's unable to get measurement.

- If a regular arterial pressure pulse is hard to detect
- Patient moving

If patient is moving, trembling or spasm, measurement will not reliable and even impossible, because these situations could disturb the check of artery pressure pulse, the measure time will prolonged.

Arrhythmia

If patient has irregular heart pulse by arrhythmia, measurement will not reliable and even impossible, he measure time will prolonged.

#### Heart-lung machine

If patient is connected with man-made heart-lung machine, it will be unable to measure.

#### ■ Pressure quickly changing

If during a period, you are analysis artery pressure pulse to get measurement, and patient blood pressure changing very fast, measurement will not reliable and even impossible.

#### Serious shock

If patient is in serious shock or TEMP is too low, measurement is not reliable. Because the reduce blood flow which flow to outside will caused the artery pulse reducing.

#### ■ The limit of Heart Rate

When the Heart rate is less than 40bpm (heart beat/minute) or higher than 240bpm (heart beat/minute), measurement will be not available.

• On the edema body

## **11.3 Measurement Methods**

There are three methods of measuring NIBP:

Manual: measurement on demand.

Auto: continually repeated measurements at set intervals.

Continual: continually rapid series of measurements over a five minute period, then return to the previous mode.

# **11.4 Measurement Procedure**

## 11.4.1 Preparing to Measure NIBP

- 1. Power on the monitor.
- 2. Verify that the patient category is correct. Change it if necessary.
- 3. Plug the air tubing into the NIBP connector.
- 4. Select a correct sized cuff and then apply it as follows:
- Determine the patient's limb circumference.
- Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb.
- Apply the cuff to an upper arm or leg of the patient and make sure the  $\Phi$  marking on the cuff matches the artery location. Do not wrap the cuff too tightly around the limb. It may cause

discoloration, and ischemia of the extremities. Make sure that the cuff edge falls within the marked range. If it does not, use a larger or smaller cuff that will fit better.



5. Connect the cuff to the air tubing and make sure that the bladder inside the cover is not folded and twisted.

# NOTE

• The use of the equipment is restricted to one patient at a time.

## 11.4.2 Cuff Selecting

There have different Cuffs according to patient type which affects the pressure testing result, so the correct NIBP Cuff is very important to the patient.

Patient Type	Limbs Perimeter	Gas Tube Length
Newborn	6~11cm	
Baby	10~19cm	
Child	18~26cm	1 5
Adult	25~35cm	1.5m <sup>2</sup> ~5m
Big Adult	33~47cm	
Leg	46~66cm	

#### Adult/Newborn/Baby reusable cuff

#### Newborn/Baby disposable cuff

Size	Limbs Perimeter	Gas Tube Length
1	3.3~5.6cm	
2	4.2~7.1cm	
3	5~9.5cm	1.5m~3m
4	6.9~11.7cm	
5	8.9~15cm	
# 

• Continuous non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If any abnormity occurs, move the cuff to another site or stop the blood pressure measurements immediately.

### 11.4.3 Starting and Stopping Measurements

You can start and stop measurements by using the 💝 hardkey on the monitor's front.

### **11.4.4 Correcting the Measurement if Limb is not at Heart Level**

The cuff should be applied to a limb at the same level as the patient's heart. If the limb is not at the heart level, to the displayed value:

- Add 0.75 mmHg (0.10 kPa) for each centimeter higher, or
- Deduct 0.75 mmHg (0.10 kPa) for each centimeter lower.

### 11.4.5 Enabling NIBP Auto Cycling and Setting the Interval

1. Select the NIBP parameter window to enter the [NIBP SETUP] menu.

2. Select 【INTERVEL】 menu, and then choose a desired time interval, select "MANUAL" switch to manual mode.

3. Start a measurement manually. The monitor will then automatically repeat NIBP measurements at the set time interval.

You can also start a measurement by pressing the "NIBP" QuickKey. Then monitor will then automatically repeat NIBP measurements at the set time interval per current settings.

### 11.4.6 Starting a Continual Measurement

1. Select the NIBP parameter window to enter the [NIBP SETUP] menu.

2. Select 【CONTINUAL】. The continual mode initiates 5 minutes of continuous, sequential, automatic NIBP measurements.

# 

• Continuous non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If any abnormity occurs, move the cuff to another site or stop the blood pressure measurements immediately.

## 11.5 NIBP Setup

The NIBP display shows numerics only as below. Your display may be configured to look slightly different.



#### 11.5.1 Interval for automatic measurement

Select the automatic measurement interval time (unit: minute) in the [NIBP] setting menu. It can be selected among 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240, 480 minutes. After the interval is selected, the interval time is displayed in the NIBP parameter area. This is automatically measured by pressing the "NIBP start" button. To end the automatic measurement, press "NIBP stop" and select "Manual" to return to manual mode during the measurement interval.

#### 11.5.2 Initial pressure

Select the initial pressure in the [NIBP] setting menu. The "Pre-inflation value" option is to help the user select the next cuff inflation pressure, but the pre-inflation value after the measurement will be based on the same patient last time. The measured value of systolic blood pressure. This value of system memory can shorten the measurement time of the same patient and increase the accuracy of the measurement.

#### NOTE

• When the user sets the "Patient Type" in "Patient Information Setup", the system will perform the initial setting of the relevant module parameters according to "Patient Type".

#### 11.5.3 Reset

Select the reset button in the [NIBP] setting menu, and reset to restore the inflation value of the blood pump to the initial setting. This button is recommended when the blood pump does not work properly but the monitor does not indicate the cause of the problem. Because this allows the blood pump to self-check, which automatically recovers when the pump malfunctions due to an accident.

#### 11.5.4 Continuous measurement

[Continuous measurement] is selected in the [NIBP setup] menu, and the measurement time will last for 5 minutes.

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• NIBP measurement must be calibrated every 2 years (or follow the hospital regulation).

#### **NIBP Leakage Test**

The NIBP leakage test checks the integrity of the system and of the valve. It is required at least once every two years or when you doubt the measured NIBP. If the test failed, corresponding prompt messages will be given. If no message is displayed, it means no leakage is detected.

Tools required:

- An adult cuff
- An air tubing
- A correct sized cylinder

Follow this procedure to perform the leakage test:

1. Set the patient category to "Adult".

2. Connect the cuff to the NIBP connector on the monitor.

3. Wrap the cuff around the cylinder as shown below.



4. Select [Main Menu] → [Device Maintenance] → [User Maintenance] → [Module Maintenance] → [NIBP Leak Detection], the NIBP parameter area will display [Leakage Detection].

5. After about 20 seconds, the monitor will automatically deflate. This means the test is completed.

6. If the message "NIBP Pneumatic Leak" is displayed, it indicates that the NIBP airway may have leakages. Check the tubing and connections for leakages. If you ensure that the tubing and connections are all correct, perform a leakage test again.

If the problem persists, contact your service personnel.

## NOTE

• The leakage test is intended for use to simply determine whether there are leakages in the NIBP airway. It is not the same as that specified in the EN 1060-3 standard.

#### **NIBP Accuracy Test**

The NIBP accuracy test is required at least once every two years or when you doubt the measured NIBP.

Tools required: T-shape connector Appropriate tubing Balloon pump Metal Vessel (volume 500±25 ml) Reference manometer (calibrated with accuracy higher than 0.75 mmHg)

Follow this procedure to perform the accuracy test:

1. Connect the equipment as shown.



2. Before inflation, the reading of the manometer should be 0.If not, disconnect the airway and reconnect it until the readings is 0.

Select [Main Menu] →[Device Maintenance] → [User Maintenance] → [Module Maintenance] → [NIBP Pressure Check], and the NIBP parameter area displays the pressure test.

4. Compare the manometer values with the displayed values. The difference between the manometer and displayed values should not be greater than 0 mmHg.

5. Raise the pressure in the metal vessel to 50 mmHg with the balloon pump. Repeat step 3 and 4.

6. Raise the pressure in the metal vessel to 200 mmHg with the balloon pump. Repeat step 3 and 4.

If the difference between the manometer and displayed values is greater than 3 mmHg, contact your service personnel.

#### 11.5.5 Setting Alarm Properties

Select [Main Menu]  $\rightarrow$  [Alarm Setup]  $\rightarrow$  [Parameter Alarm] or select [Alarm Setup]  $\rightarrow$  [Parameter Alarm] to set the alarm switch, high and low limit, alarm level of NIBP-s, NIBP-d, NIBP-m., alarm record switch.

### **11.6 NIBP Alarm Information**

**Physiological Alarms:** 

Message	Cause	Alarm level
NS too high	NIBP systolic pressure measurement value is higher than	User-selectable
	NIBP systolic pressure measurement value is lower than	
NS too low	the set alarm low limit	User-selectable

	-		
ND too high	NIBP diastolic pressure measurement value is higher	User-selectable	
	than the set alarm high limit		
ND too low	NIBP diastolic pressure measurement value is lower than	Usar salaatahla	
	the set alarm low limit	User-selectable	
NM too high	NIBP mean pressure measurement value is higher than	Usar salaatabla	
	the set alarm high limit	User-selectable	
NM too low	NIBP mean pressure measurement value is lower than	Ugar galagtable	
	the set alarm low limit	User-selectable	

#### Technical Alarm (Display in the parameter area under the NIBP value):

Message	Cause	Alarm level	Solution
Cuff too loosen or not connected	Cuff tied wrong or no cuff	Low	Tie the cuff well
Wrong air pressure	Can not get a stable pressure value, eg. Tube tied	Low	Check if tube tied, If fault continue, contact bio-medical engineer or our repair engineer
Signal too weak	Cuff loosen or patient pulse too weak	Low	Using other blood pressure measurement.
Arm moved	Signal noise too more or irregular pulse caused by arm moving	Low	Keep patient quite and stop moving.
Over pressure protection	Pressure beyond the set safety limit	High	Measure again, If fault continue, Stop using NIBP measure function, confirm bio-medical engineer or our repair engineer
Measurement overtime	Measurement time over 120 seconds(Adult/Children) or 90 seconds (Newborn)	High	Measure again or choose other measurement.
NIBP wrong reset	Module reset abnormally	High	Using reset function again.
Measurement wrong	System can not execute measurement analysis or calculation when measuring	High	Check the cuff, keep patient no moving, and measure again.

# **Chapter 12 Freezing**

During the monitoring of the patient, you can freeze the waveform on the screen and review it to see the patient's condition. You can also output the frozen waveform through the recorder.

### 12.1 Enters the frozen state

- 1. In the non-frozen state (except the big numerics interface), select the hotkey [Freeze] button or press the [freeze] button on the monitor control panel.
- 2. The system will pop up the [Freeze] menu, the waveform will be frozen, and that is, the waveform will not be refreshed or scrolled.

The frozen state does not affect:

- Display and refresh the trend graph under the minitrend interface.
- Display and refresh of the OxyCRG.
- The parameter area is displayed and refreshed.

### 12.2 Waveform Review

In the frozen state, you can use the following to browse frozen waveforms:

- Select the [Review] button and turn the knob clockwise or counterclockwise.
- Select the left and right arrow buttons on both sides of the [Review] button.
- The frozen waveform will move to the left or right, and a hand icon appears in the lower right corner of the bottom waveform. The time scale is marked at the bottom of the arrow, and the freeze time is recorded as [0S]. As the waveform shifts to the right, the time scale will change to [-1s], [-2s], [-3s]... in order. This time scale applies to all waveforms on the screen.

### 12.3 Unfreezing status

In the frozen state, you can choose by  $\times$  Exit the freeze interface to release the freeze state.

### 12.4 Recording frozen waveforms

1. Select the waveforms of [Waveform 1], [Waveform 2], and [Waveform 3] in the [Freeze] menu.

2. Select the [Record] button in the [Freeze] menu, and the recorder will output the selected waveform and the parameter values at the freezing time.

3. Recording grid: When the recording grid switch is [On], the recording paper prints a standard grid. "The recording paper does not print when the recording grid switch is [Off].

#### FOR YOUR NOTES

### **Chapter 13 Review**

#### 13.1 Open the review window

1. Select the [Review] hotkey or select [Main Menu]  $\rightarrow$  [Data Management]  $\rightarrow$  [Data Review].

2. Select [Graphics Trends], [Tabular Trends], [Events], [Hologram Waveform] to open the corresponding review window.

#### 13.2 Graphics Trends

Select [Graphics Trends] in the [Review] menu to enter the trend graph interface. High, mid, and low-level alarm events are displayed in the event bar with red, yellow, and yellow markers.

- Select [Upper and lower ruler], set the automatic switch to off in the pop-up menu, and select the upper and lower limits of the parameter to be set.
- Select [Window Time], select 4min, 20min window time to observe the trend chart of the last 4 hours, other window time can observe the trend chart of the last 120 hours
- Select [Waveform Number] to set the number of waveforms displayed in the review window.
- Select [Browse] on both sides or To move the trend cursor. Select left and right page turning arrows or To move the trend cursor. Select left and right page turning arrows or To move the trend to turn the page to move the waveform. The time above the trend data area shows the time corresponding to the current cursor position, and the trend data area displays the parameter data at that time, which will automatically change as the trend cursor moves. The background color of the parameter that causes the advanced alarm is red, and the background color of the parameter that causes the intermediate and low-level alarms is yellow.
- Select [Events] on both sides or You can quickly locate the moment when the event occurred.
- Select [Record] to record the trend graph displayed in the current window.
- Select [parameter] on both sides or To see the different parameters.

#### 13.3 Tabular Trends

Select [Tabular Trend] in the [Review] menu to enter the trend table interface. For high alarm events, the middle and low alarm events are displayed at the top of the window with red, yellow, and green markers.

- Select [Resolution] and select the 5s, 30s resolution to observe the trend of the last 4 hours according to the needs of observation. [NIBP] is the value of each parameter at the time of obtaining the NIBP measurement value. Choose a different resolution to observe the trend for the last 120 hours.
- Select [View] on both sides or To browse the trend table. Select left and right page turning

arrows so or the parameter that causes the

advanced alarm is red, and the background color of the parameter that causes the mid and low-level alarms is yellow.

• Select [Events] on both sides or The button quickly positions the cursor to the moment the event occurred.

• Select [Record] to record the trend table data of all parameters in the time period displayed in the current window.

■ Select [parameters] on both sides or To see the different parameters.

## **13.4 Events Review**

The monitor can save events in real time and the user can review saved events. In the [Review] menu, select [Events] to enter the event review interface. When an event occurs, the monitor stores the value of the relevant parameter at the time of occurrence, and the associated waveform for 8 seconds before and after the occurrence of the time, so that the user can review the event.

- Select the type of alarm: Select the type of event you want to review in the [Type] list as needed.
- Select the alarm level: Select the event level to be reviewed in the [Level] list as needed.
- Select [View] on both sides or To browse the event. Select left and right page turning

arrows Scroll left or right to view the event.

■ Select [Detail] to enter the event detail interface.

After selecting an event, select [Details] to enter the event details interface. The waveform area will display the waveform associated with the event, and the parameter area will display the parameter values associated with the time at which the event occurred.

- Select to view or The left and right arrow buttons move the waveform.
- Select [Events] on both sides or You can switch to the corresponding event.
- Select [Gain] to change the gain of the ECG waveform.
- Select [Waveform Speed] to change the wave speed of 3 leads waveforms at the same time.
- Select [Record] to record the currently selected alarm event, including all parameters and waveforms.
- Select [Events List] to display the events that have occurred in a list.

## 13.5 Holographic waveform

In the [Review] menu, select [Hologram] to enter the holographic waveform interface. To review the holographic waveform, the monitor must be configured with a TF memory card.

■ Select [Event Review] on both sides or You can quickly position the cursor to the moment the event occurs.

■ Select [View] on both sides ■ Come and browse the waveform within 48 hours. Select left

and right page turning arrows for toward

Right turn the page to view the waveform and the upper part of the window shows the time corresponding to the current cursor position.

- Select [Gain] to change the gain of the ECG waveform.
- Select [Wave Rate] to change the wave speed of 4 waveforms at the same time.
- Select [Waveform Setup] to select the waveform to display.

#### NOTE

• The stored patient history data is cleared after the monitor is turned off.

#### FOR YOUR NOTES

# **Chapter 14 Recording**

## 14.1 Introduction

The thermal recorder records patient information, measurement numerics, up to three waveforms, etc.

- Waveform record is printed out at a rate of 12.5, 25 or 50 mm/s.
- It can record up to 3 waveforms.
- The real time recording time and waveform are user-configurable.
- Auto recording interval is set by the user, the waveform is in accordance with the real time recording.
- The alarm recording waveform is automatically selected by the monitor.

## 14.2 Recording Types

By the way recordings are triggered; the recordings can be classified into the following categories:

- 1. Manually-triggered real-time recordings.
- 2. Timed recordings.
- 3. Alarm recordings triggered by an alarm limit violation or an arrhythmia event.
- 4. Manually-triggered, task-related recordings.

## 14.3 Starting and Stopping Recordings

To manually start a recording, you can either:

- Select the Select the shard key on the front of the patient monitor, or
- Select the "Print" HotKey on the bottom of window.

Automatic recordings will be triggered in the following conditions:

■ Timed recordings will start automatically at preset intervals.

If both 【alarm】 and 【alarm recorder】 for a measurement are setting "ON", an alarm recording will be triggered automatically as alarms occur.

To manually stop a recording, you can either:

- Select the hardkey again, or
- Select the "Print" QuickKey.

Recordings stop automatically when:

- The runtime is over.
- The recorder runs out of paper.
- When the recorder has an alarm condition.

### 14.4 Setting up the Recorder

- 【Record Time】: The time of record can choose 16s.
- 【Record Speed】: The default speed of recording is 25mm/s.
- 【Record Grid】: It has "ON" and "OFF" two options, when printing paper is empty, it should choose "ON", if printing paper have grid, it should choose "OFF"
- [Waveform Number] : The default is 2 waveforms, 3 waveforms can be selectable.
- ♦ 【Waveform 1】: ECG1、ECG2、SpO2、RESP, IBP1、IBP2、CO2 are selectable.
- Waveform 2] : ECG1、ECG2、SpO2、RESP, IBP1、IBP2、CO2 are selectable.
- [Waveform 3]: When [Waveform Number] choose 3 waveforms, this option can be used.

ECG1、ECG2、SpO2、RESP, IBP1、IBP2、CO2 are selectable.

## 14.5 Loading Paper

Use the latch at the upper right corner of the recorder door to pull the door open.

- 2. Insert a new roll into the compartment as shown below.
- 3. Close the recorder door.
- 4. Check if paper is loaded correctly and the paper end is feeding from the top.



# 

- Use only specified thermal paper. Otherwise, it may cause damage to the recorder's printhead, the recorder may be unable to print, or poor print quality may result.
- Never pull the recorder paper with force when a recording is in process. Otherwise, it may cause damage to the recorder.
- Do not leave the recorder door open unless you reload paper or remove troubles.

## 14.6 Removing Paper Jam

If the recorder works incorrectly or produces unusual sounds, check if there is a paper jam first. If a

paper jam is detected, follow this procedure to remove it:

- 1. Open the recorder door.
- 2. Take out the paper and tear off the draped part.
- 3. Reload the paper and close the recorder door.

## 14.7 Cleaning the Recorder Printhead

If the recorder has been used for a long time, deposits of paper debris may collect on the printhead compromising the print quality and shortening the lifetime of the roller. Follow this procedure to clean

the printhead:

- 1. Take measures against the static electricity such as Disposable Wrist Strap for the work.
- 2. Open the recorder door and take out the paper.
- 3. Gently wipe around the printhead using cotton swabs dampened with alcohol.
- 4. After the alcohol has completely been dried, reload the paper and close the recorder door.

#### 

- Do not use anything that may destroy the thermal element.
- Do not add unnecessary force to the thermal head.

## **Chapter 15 Battery**

### 15.1 Overview

This monitor is designed to operate on battery power during intra-hospital patient transfer or whenever the power supply is interrupted.

The battery is charged automatically when the monitor is connected to AC power, Whenever the AC power is interrupted during patient monitoring, the patient monitor will automatically run power from the internal batteries.

On-screen battery symbols indicate the battery status as follows:

- Indicates that batteries work correctly. The solid portion represents the current charge level of the batteries in proportion to its maximum charge level
- Indicates that the batteries have low charge level and need to be charged. In this case, the patient monitor provides an alarm message.

patient monitor provides an alarm message.

Indicates that no batteries are installed.

The capacity of the internal battery is limited. If the battery capacity is too low, a technical alarm will be triggered and the [Battery Depleted] message displayed. At this moment, apply AC power to the patient monitor.

## 15.2 Installing or Replacing a Battery

To install or replace a battery, follow this procedure:

- 1. Open the battery door.
- 2. Push aside the latch fixing the battery to be replaced and remove the battery.
- 3. Insert a battery into the slot with its face up and its contact point inward. Then restore
- the latch to the original position.
- 4. If necessary, repeat the steps above to replace the other battery.
- 5. Close the battery door.

## **15.3 Battery Guidelines**

Life expectancy of a battery depends on how frequent and how long it is used. For a properly maintained and stored lead-acid or lithium ion battery, its life expectancy is about 2 or 3 years respectively. For more aggressive use models, life expectancy can be less. We recommend replacing lead acid batteries every 2 years and lithium ion batteries every 3 years.

To get the most out of the battery, observe the following guidelines:

- The battery performance test must be performed every two years, before monitor repairs, or whenever the battery is suspected as being the source of the problems.
- Condition a battery once when it is used or stored for 3 months, or when its operating time becomes noticeably shorter.
- Take out the battery before the monitor is transported or will not be used for more than 3 months.
- Remove the battery from the monitor if it is not being used regularly. (Leaving the battery in a monitor that is not in regular use will shorten the life of the battery).
- The shelf life of a Lithium Ion battery is about 6 months when the battery is stored with the battery power being 50% of the total power. In 6 months the battery power must be depleted before the Lithium
- Ion battery is fully charged. Then run the monitor on this fully charged battery .When its battery power becomes 50% of the total power, take out the battery from the monitor and store it.

# 

- Keep the battery out of the reach of children.
- Use only the battery specified by the manufacturer.
- If the battery shows signs of damage or signs of leakage, replace it immediately. Do not use a faulty battery in the monitor.

## **15.4 Battery Maintenance**

#### **Conditioning a Battery**

A battery should be conditioned before it is used for the first time. A battery conditioning cycle is one uninterrupted charge of the battery, followed by an uninterrupted battery discharge and charge. Batteries should be conditioned regularly to maintain their useful life. Battery power can only be maintained for a period of time, too low battery voltage will trigger the senior technical report to the alarm [ serious shortage of battery], the monitor should be connected to the AC power to charge battery.

## NOTE

- Condition a battery once when it is used or stored for 3 months, or when its operating time becomes noticeably shorter.
- The actual battery capacity will decrease over time with use of batteries. When a monitor operates on batteries that have been used before, the full capacity battery symbol does not indicate the capacity and operating time of this battery can still fulfill battery specifications in the operator's manual. When conditioning a battery, please replace the battery if its operating time is significantly lower than the specified time.

#### To condition a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring or measuring.

2. Insert the battery in need of conditioning in the battery slot of the monitor, and leave the other slot empty if your monitor has two slots.

- 3. Apply AC power to the monitor and allow the battery to charge uninterrupted for 10 hours.
- 4. Remove AC power and allow the monitor to run from the battery until it shuts off.
- 5. Apply AC power again to the monitor and allow the battery to charge uninterrupted for 10 hours.
- 6. This battery is now conditioned and the monitor can be returned to service.

#### **Checking a Battery**

The battery performance test must be performed every two years, before monitor repairs, or whenever the battery is suspected as being the source of the problems. The performance of a rechargeable battery may deteriorate over time. To check the performance of a battery, follow this procedure:

- 1. Disconnect the monitor from the patient and stop all monitoring or measuring.
- 2. Apply AC power to the monitor and allow the battery to charge uninterrupted for 10 hours.
- 3. Remove AC power and allow the monitor to run from the battery until it shuts off.
- 4. The operating time of battery reflects its performance directly.

## NOTE

- The battery might be damaged or malfunctioned if its operating time is too short after being fully charged. The operating time depends on the configuration and operation. For example, measuring NIBP more frequently will also shorten the operating time.
- When a battery has visual signs of damage, or no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.

## **15.5 Battery Recycling**

When a battery has visual signs of damage, or no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly. To dispose of the batteries, follow local laws for proper disposal.

#### 

• Do not disassemble batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, leak or heat up, causing personal injury.

## **Chapter 16 Patient Safety**

This equipment is designed to comply with international safety requirements for medical electrical equipment, GB 9706.1-2007, GB 9706.25-2005 and GB/T14710-2009. The system has floating input anti-defibrillation and surgical electrosurgical protection. If the correct electrode (see ECG, RESP section) is used and placed according to the manufacturer's instructions, the screen display can be restored within 10 seconds after defibrillation.



This mark indicates that this application part is a GB 9706.1-2007 anti-defibrillation CF device designed to have special anti-shock protection (especially with F-type floating isolation in terms of allowable leakage current) and is suitable for use during defibrillation.

## ⚠Warning

• Do not touch patients, beds or instruments during defibrillation.

#### Environment

Follow the instructions below to ensure absolute safety in electrical installation.

The environment in which the equipment is used must be reasonably free from vibration, dust, corrosive or explosive gases, extreme temperatures, humidity, and the like.

When installed in the instrument cabinet, there must be enough space in front to facilitate operation. With the door open, there must be enough space behind for easy maintenance. The circulation of air in the cabinet should be guaranteed.

The equipment can meet the technical specifications when the ambient temperature is below 5  $^{\circ}$ C  $\sim$  40  $^{\circ}$ C. Ambient temperatures outside this range may affect the accuracy of the instrument and cause damage to components and wiring.

Allow at least 2 inches (5 cm) of space around the instrument to ensure air circulation.

#### **Power supply**

Please refer to the product specifications section.

#### Ground

To protect patients and medical staff, the enclosure of the portable monitor must be grounded. Therefore, the portable monitor is equipped with a detachable three-wire cable. When it is inserted into a matching three-wire socket, the instrument is grounded through the ground wire (protective ground) in the power cord. If you do not have a three-wire outlet, consult the hospital's electrical management staff.

Connect the ground wire to the equipotential ground terminal of the instrument. If it is not clear from the instrument specifications whether a particular combination of instruments is dangerous, for example, due to the accumulation of leakage current, the user should consult the relevant manufacturer or other experts in this area to ensure that all the instruments are The necessary safety is not damaged by the proposed combination.

# AWrning

• Do not connect the three-wire cable of this instrument to the second-line plug.

#### **Equipotential grounding**

The primary protection of the instrument has been grounded by the power plug in the system of protective earthing (protected ground) of the house.

For internal examination of the heart or brain, the portable monitoring system must be connected separately to the equipotential grounding system.

One end of the equipotential grounding conductor (potential equalization conductor) is connected to the equipotential grounding terminal on the rear panel of the instrument, and the other end is connected to a connector of the equipotential system. If the protective earthing system is damaged, the equipotential grounding system can assume the safety function of the protective earthing conductor.

Cardiac (or brain) examinations should only be performed in a medical home with a protective earthing system. Check that the instrument is in good working condition before each use. The cable connecting the patient and the instrument must be free of electrolyte contamination.

## **Warning**

• If the protective earth (protective ground) system is unstable, the monitor is powered by the internal power supply.

#### Condensation

During operation, ensure that the instrument is not condensed and condensation may form as the instrument moves from one room to another. This is because the instrument is exposed to moist air and different temperatures.

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• If used in a place with a flammable anesthetic, there is a danger of explosion.

## **Chapter 17 Care and Cleaning**

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.

## 17.1 Introduction

Keep you equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

#### 

• Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.

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• If you spill liquid on the equipment or accessories, contact us or your service personnel.

### NOTE

• To clean or disinfect reusable accessories, refer to the instructions accompanying the accessories.

## 17.2 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- mild soap (diluted)
- ammonia (diluted)
- sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (75%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

- 1. Shut down the patient monitor and disconnect it from the power line.
- 2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
- 3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
- 4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
- 5. Dry your equipment in a ventilated, cool place.

## **17.3 Disinfecting**

Disinfection may cause damage to the equipment and is therefore not recommended for this patient monitor unless otherwise indicated in your hospital's servicing schedule. Cleaning equipment before disinfecting is recommended.

The recommended disinfectants include: ethanol 75%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants

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• Never use EtO or formaldehyde for disinfection.

## **Chapter 18 Maintenance**

#### 

- Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may
- cause undue equipment failure and possible health hazards.
- The safety checks or maintenance involving any disassembly of the equipment should be performed by professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.
- If you discover a problem with any of the equipment, contact your service personnel or us.

## **18.1 Safety Checks**

Before every use, after your patient monitor has been used for 6 to 12 months, or whenever your patient monitor is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect all power cords for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Inspect if the alarm system functions correctly.
- Make sure that the recorder functions correctly and the recorder paper meets the requirements.
- Make sure that the batteries meet the performance requirements.
- Make sure that the patient monitor is in good working condition.
- Make sure that the grounding resistance and leakage current meet the requirement.

In case of any damage or abnormity, do not use the patient monitor. Contact the hospital's biomedical engineers or your service personnel immediately.

## 18.2 Service Tasks

The following tasks are for our qualified service professionals only. Contact a qualified service provider if your patient monitor needs the following services. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance schedule		Frequency	
Preventive maintenance			
Visual inspection		First installed or reinstalled.	
	Accuracy test	1. User suspects accuracy of NIBP.	
NIBP test		2. Maintain or replace the module of NIBP.	
	Leakage test	3. At least once every year.	
Performance test			
ECC test	Performance test		
ECG test	ECG calibrate	1. User suspects accuracy of NIBP.	
RESP test	Performance test	2. Maintain or replace the module of NIBP.	
SpO2 test	Performance test	3. At least once every two years.	
	Accuracy test	Note: NIBP once every years.	
NIBP test	Leakage test		
Electric safety test			
	Cover Leakage		
	current test		
	Earth Leakage		
Electric safety	current Test	<ol> <li>Maintain or replace the module of Power module.</li> <li>Detient Manitan fall</li> </ol>	
test	Patient Leakage	2. Patient Monitor falls	
	Current	5. At least once every two years of according to the needs.	
	Patient Auxiliary		
	Current		
Other test			
		1. When first installed or reinstalled.	
Power-on test		2. Following any repairs or replacement of any main unit	
		parts.	
Touchscreen calib	ration	1. When the touchscreen appears abnormal.	
	Tation	2. After the touchscreen is replaced.	
Recorder check		Following any repair or replacement of the recorder.	
	Functionality	1. When first installed.	
Battery check	test	2. Whenever a battery is replaced.	
Battery check	Performance test	Once every six months or if the battery run time reduced	
		significantly.	

# **18.3 Failures Correction**

Failures	Corrective Action		
Power On/Off Failure	<ol> <li>AC mains not connected or battery too low, check that AC mains is properly connected or battery capacity is sufficient.</li> </ol>		
	2. Power supply protection, replace the power board.		
	3. Cable defective, replace the cable.		
	4. Power board defective, Replace the power board.		
	5. The key board failed, Replace the key board.		
	<ul> <li>o. The main board failed, Replace the main board.</li> <li>1. Detterre defective replace the betterre</li> </ul>		
	1. Battery defective, replace the battery.		
	2. Cable defective, check that the cable between the battery interface		
Power Supply Failures	board and power board is properly connected. Check that the cables		
	and connectors are not damaged.		
	5. Battery interface board defective, replace the battery interface board.		
	4. Power board delective, replace the power board.		
	1. Cable defective, check if the cable between the display and main		
D' 1 D'1	board and the backlight cable are correctly connected. Check that the		
Display Failures	cables and connectors are not damaged.		
	2. Main board defective, replace the main board.		
	3. Display defective, replace the display.		
	1. Cable defective, check that the cable between the alarm lamp board		
	and main board is correctly connected. Check that the cables and		
Alarm Lamp Failures	connectors are not damaged.		
	2. Alarm lamp board defective, replace the alarm lamp board.		
	3. The main board failed, replace the main board.		
	1. Cable defective, check that the cable between the keypad board and		
	main board is correctly connected. Check that the cables and		
Button and Knob Failures	connectors are not damaged.		
	2. Keypad board failure, replace the keypad board.		
	3. Knob failure, replace the knob Rotary Knob.		
	1. The volume is set to zero or off. adjust the volume to appropriate		
	level.		
Sound Failures	2. Cable defective, check that the cable between the speaker and		
	interface board is properly connected and not damaged.		
	3. Speaker defective, replace the speaker.		
	4. The main board failed, replace the main board.		
	1. Paper reversed, re-install the paper roll.		
	2. Cable defective, check that the cable between the recorder and main		
Recorder Failures	board is correctly connected and not damaged.		
	3. Recorder defective, replace the recorder.		
	4. Paper roll not properly installed, stop the recorder and re-install the		

	paper roll.	
	5. Print head dirty check the thermal print head and the paper roller for	
	foreign matter. clean the thermal print head with an appropriate clean	
	solution.	
	6. Print head failure, replace the thermal print head.	
	1. Cable defective, check that the cable between the parameter and	
Communication Failures	main board is correctly connected and not damaged.	
Communication Fanures	2. Main board failure, replace the main board.	
	3. The parameter board failure, replace the parameter board.	
ECG no signal		
Didn't pressure, blood		
pressure measurement		
alarm "cuff loose	Refer to the section of Parameter alarm information.	
SpO2 No signal		
RESP No signal		
TEMP No signal		

# **Appendix I Product Specifications**

## I.1 Classification

Classification	Name	
Classification of China		
National Food and Drug	II	
Administration		
Type of electric shock protection	type I internal power supply equipment	
	NIBP	Anti Defibrillation BF
Protection of electric shock	ECG	Anti Defibrillation CF
	Other	BF
Explosion protection Level	Ordinary equipment, No explosion protection	
Protection of fluid intake	Ordinary equipment, No fluid protection (IPX0)	
Working mode	Run continuously	
Mobile Level	Portable	

## **I.2 Environmental Specifications**

	Temperature (°C)	Humidity	Atmospheric pressure (kPa)
Operating conditions	+5 ~ 40	20%~85%	70.0 ~ 106.0
Storage conditions	-20 ~ 55	10%~95%	50.0 ~ 106.0

## **I.3 Power Requirements**

AC Power Supply Specifications		
Input voltage	AC 100V-240V	
Input power	70 VA	
Frequency	50/60 Hz	
Battery		
Battery type	2.2 Ah 11.1V rechargeable lithium-ion battery	
Operating time	180 minutes when powered by fully-charged battery (25°C, ECG, SpO2,	
Operating time	Auto NIBP measurements at intervals of 15 minutes)	

# I.4 Physical Specification

Weight	Size (length×width×height)	
3.1kg	308mm × 141mm × 273mm	

# I.5 Hardware Specifications

Host display	
Screen type	Color TFT LCD
Screen Size (diagonal)	12.1"
Resolution	800×600 pixels

Monitor Interface Specifications	
Power	1 AC power input connector
Wire network	1 RJ45 connector
USB	2 connectors
Equipotential Grounding	1
Terminal	
VAG	1 connector

LED	
AC power LED	1 (Green)
DC power LED	1 (Green)
Battery LED	1 (Yellow)
Alarm LED	2 (Orange and Red)

Indicator	
	Give alarm tones (45 to 85 dB), key tones, QRS tones; support
Speaker	PITCH TONE and multi-level tone modulation; alarm tones
	comply with IEC60601-1-8.

Recorder		
Method	Thermal dot array	
Number of waveform channels	1, 2, or 3 (optional)	
Paper speed	12.5mm/s,25mm/s,50mm/s	
Paper width	48 mm	
Paper length	20 m	
Horizontal resolution	vertical: $\geq 8 \text{ dots/mm}$	
	Horizontal: 16 dots/mm (25 mm/s paper speed)	

# I.6 Parameter Specification

ECG		
Standards	Meet standards of EC11, EC13, EN60601-2-27/IEC60601-2-27,	
	IEC60601-2-25, YY91079, GB9706.25	
Testest	3-lead: I, II, III	
	5-lead: I, II, III, aVR, aVL, aVF, V	
ECG standard	IEC, AHA	
Sweep speed	12.5 mm/s, 25 mm/s, 50 mm/s	
Gain	×0.125, ×0.25, ×0.5, ×1, ×2	
Measure range	Adult:15~300bpm, Pediatric/ Neonate: 15~350bpm;	
Accuracy	$\pm 1\%$ or $\pm 1$ bpm, whichever is greater.	
Resolution	1 bpm	
Differential input	> 5 MO	
impedance	- 5 10152	
Common mode	Diagnostic mode: ≥112 dB	
rejection ratio	Monitor mode: ≥116 dB	
	Pace pulses meeting the following conditions are labelled with a	
Daga mulaa markara	PACE marker:	
race pulse markers	Amplitude: $\pm 2 \text{ mV} \sim \pm 700 \text{mV}$ ;	
	Amplitude: 0.2ms~2ms; Rise time: 10us~100µs	
	When tested in accordance with the ANSI/AAMI EC13:	
Pace pulse rejection	Sections 4.1.4.1 and 4.1.4.3, the heart rate meter rejects all	
	pulses meeting the following conditions.	
	Amplitude: $\pm 2mV \sim \pm 700mV$ ;	
	Amplitude: 0.2ms~2ms;	
	Rise time: 10us $\sim$ 100 $\mu$ s	
Baseline recovery time	<3 s (after defibrillation)	

	1) Adult
	Alarm high limit: 17bpm $\sim$ 300bpm;
	Alarm low limit: 15bpm~298bpm;
	2) Pediatric
Alarm limit	Alarm high limit: 17bpm~350bpm;
	Alarm low limit: 15bpm~348bpm
	3) Neonate
	Alarm high limit: 17bpm~350bpm;
	Alarm low limit: 15bpm~348bpm

RESP		
Technique	Trans-thoracic impedance	
Lead	Options are lead I and II. The default is lead II.	
	Adult: 10BrPM~120BrPM	
Measurement Range	Pediatric: 10BrPM~150BrPM	
	Neonate: 10BrPM~150BrPM	
Resolution	2 BrPM or 2%	
	1) Adult	
	Alarm high limit: 8BrPM~120 BrPM;	
Alarm limit	Alarm low limit: 6BrPM~118BrPM;	
	2) Pediatric / Neonate	
	Alarm high limit: 8BrPM~150 BrPM;	
	Alarm low limit: 6BrPM~148BrPM;	

NIBP		
Standards	Meet standards of EN60601-2-30/IEC60601-2-30, EN1060-1,	
	EN1060-3, EN1060-4 and SP10	
Technique	Oscillometry	
Mode of operation	Manual, Auto and Continual	
Auto mode	1 2 3 4 5 10 15 30 60 90 120 180 240 480 min	
repetition intervals	1,2,3,4,3,10,13,30,00,70,120,100,240,400 mm	
	Adult:	
	Systolic: $30 \sim 270$ mmHg (4.0kPa $\sim 36.0$ kPa),	
	Diastolic: 10~220mmHg (1.3kPa~29.3kPa)	
Measurement ranges	Mean: 20~235mmHg (2.7kPa~31.3kPa)	
	Pediatric:	
	Systolic: 30~270mmHg (4.0kPa~36.0kPa),	
	Diastolic: 10~220mmHg (1.3kPa~29.3kPa)	
	Mean: 20~235mmHg (2.7kPa~31.3kPa)	
	Neonate:	

	Systolic: 30~13 Diastolic: 10~13 Mean: 20~125n	5mmHg(4.0kPa~ 10mmHg(1.3kPa~ 1mHg(2.7kPa~16	18kPa) -14.7kPa) .7kPa)	
Accuracy	Max mean error: Max standard dev	±5 mmHg viation: 8 mmHg		
Resolution	1mmHg (0.1kH	Pa)		
Initial Pressure	Adult: 150mmHg Child: 140mmHg Newborn: 100mr	g (20.0kPa) g (18.7kPa) nHg (13.3kPa)		
Measure time	Manual or autom	Manual or automatic mode: 25s		
Measurement range	40 ~ 240bpm			
Accuracy	±2bpm or 2%			
Overvoltage protection	Hardware: Adult/Child 300mmHg, Newborn 150mmHg Software: Adult / Child 290mmHg, Newborn 145mmHg			
	The alarm error should be: ±1mmHg			
	blood pressure	Adult (mmHg)	Child (mmHg)	Newborn (mmHg)
Alarm setup ange	Systolic pressure alarm high limit	45 ~ 270	45~200	45 ~ 135
	Systolic pressure alarm low limit	40~265	40~195	40~130
	Mean pressure alarm high limit	25~230	25~165	25~110
	Mean pressure alarm low limit	20~225	20~160	20~105
	Diastolic pressure alarm high limit	15~210	15 ~ 150	15 ~ 100
	Diastolic pressure alarm low limit	10~205	10~145	10 ~ 95

SpO2	
Measurement range	30%~100%;

Resolution	1%
Accuracy	$70 \sim 100\%$ : $\leq \pm 2\%$ ; $40\% \sim 69\%$ : $\leq \pm 3\%$ ; $0\% \sim 39\%$ : not specified
Alarm limit	<ol> <li>Alarm high limit: 1%~100%: ±1%;</li> <li>Alarm low limit: 0%~99%: ±1%;</li> </ol>

PR		
Measurement range	30bpm~254bpm	
Resolution	1bpm	
Accuracy	≤±1bpm	
	1) Adult	
Alarm limit	Alarm high limit: 17bpm~300bpm;	
	Alarm low limit: 15bpm~298bpm;	
	2) Pediatric	
	Alarm high limit: 17bpm~350bpm;	
	Alarm low limit: 15bpm~348bpm;	
	3) Neonate	
	Alarm high limit: 17bpm $\sim$ 350bpm;	
	Alarm low limit: 15bpm~348bpm;	

ТЕМР		
Standards	Meet standard of EN12470-4	
Technique	Thermal resistance	
Measurement range	0 to 50°C (32 to 122 °F)	
Resolution	0.1°C	
Accuracy	±0.2°C	
	1) Alarm high limit: 0.2°C~50.0°C	
Alarm limit	2) Alarm low limit: 0.0°C~49.8°C	
	3) Accuracy±0.1°C	

# **I.7 Accessories Specifications**

Name	Model
Blood pressure tracheal	CZ00
Blood pressure cuff	CZ12
Integrated ECG cable	EC31
Integrated pulse oximeter probe	SP44
Temperature probe	TE10

# Appendix II EMC

The equipment meets the requirements of IEC 60601-1-2.

#### NOTE

- Use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the equipment.
- The equipment should not be used adjacent to or stacked with other equipment, and if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- The equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- The equipment may be interfered with by other equipment, even if that other equipment complies with CISPR emission requirements.
- Operation of the device, in the case that the patient physiological signal is lower than the minimum amplitude and/or value specified in the product specifications, may cause inaccurate results.

#### Guidance and declaration — electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Compliance Pst ,Tdt (ms) Dmax(%) Dc (%)	
### $\label{eq:Guidance} Guidance \ and \ declaration \ -- \ electromagnetic \ immunity$

The equipment is intended for use in the electromagnetic environment specified below.

The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic		
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.		
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (>3m).	±2 kV for power supply lines ±1 kV for input/output lines (>3m)	Mains power quality should be that of a typical commercial or hospital environment.		
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV different mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.		
Voltage dips, Short interruptions and voltage variation on power supply input lines IEC 61000-4-11	<5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycle 40% $U_T$ (60% dip in $U_T$ ) for 5 cycle 70% $U_T$ (30% dip in $U_T$ ) for 25 cycle <5% $U_T$ (>95% dip in $U_T$ ) for 5 sec	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycle 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycle <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.		
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic Fields should be at levels Characteristic of a typical location in a typical commercial or hospital environment.		
UT is the A.C. mains voltage prior to application of the test level.					

### Guidance and declaration—electromagnetic immunity

The customer or the user of the equipment should assure that it is used in such an environment				
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment — guidance	
Conduced RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3Vrms	Portable and mobile RF communications Equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.	
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3 V/m	Recommended separation distance $d = 1.2 \times \sqrt{P}$ $d = 1.2 \times \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \times \sqrt{P}$ 800 MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol: $((\mathbf{v}))$	

The equipment is intended for use in the electromagnetic environment specified below.

Note — At 80 MHz and 800 MHz, the higher frequency range applies.

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

<sup>a</sup> 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

<sup>b</sup> Over the frequency ranges 150kHz to 80MHz, field strengths should be less than 3V/m.

# Recommended separation distances between portable and mobile RF communication and the equipment

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

Rated Maximum		Separation Distance According to Frequency of Transmitter					
Output power of		M (Meters)					
Transmitter W (Watts)		150 kHz ~ 80 MHz	80 MHz ~ 800 MHz	800 MHz ~ 2.5 GHz			
		$d=1.2 \sqrt{P}$	$d = 1.2 \sqrt{P}$	$d = 2.3 \sqrt{P}$			
0.01	(	0.12 (0.35)	0.12 (0.35)	0.23 (0.70)			
0.1	(	0.38 (1.11)	0.38 (1.11)	0.73 (2.22)			
1	1	.20 (0.35)	1.20 (0.35)	2.30 (7.00)			
10	3	3.80 (11.07)	3.80 (11.07)	7.30 (22.14)			
100	1	2.00 (35.00)	12.00 (35.00)	23.00 (70.00)			

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined 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 — At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

## **Appendix III Environmental statement**

Part name	Lead (Pb)	Mercury (Hg)	Cadmium (Cd)	chromium VI (Cr(VI))	Polybrominated Biphenyl (PBB)	Polybrominated Diphenyl Ethers (PBDE)
Built-in						
circuit	0	0	0	0	0	0
board						
Built-in	0	0	0	0	0	0
connector						
Sheet metal	0	0	0	0	0	0
parts	0	0	0			
Cover	0	0	0	0	0	0
Display unit	0	0	0	0	0	0
Packing material	0	0	0	0	0	0
Accessory	0	0	0	0	0	0

Product poisonous and harmful substances:

o: It means the poisonous and harmful substances in the parts are under the SJ/T11363-2006 standard requested.

### NOTE

• Product and its components of waste disposal shall comply with the regulations for local laws, don't put them together with household garbage and discard together with the product.

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