Product Information

Product model: ZD120

Product name: Patient Monitor

Manufacturer

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Distributor

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CE 0123

Regulatory and Safety Specifications

Standard

The product is made under the ISO13485 quality system certified by TUV PS. The product has passed the CE certification.

Declaration

The ZD120 Patient Monitor is a Class IIa device and complies with the requirements of the Council Directive 93/42/EEC concerning medical devices and carries CE-marking accordingly.

Authorized EU Representative

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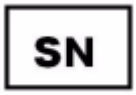
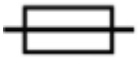
Explanation of Symbols

The following symbols appear on the monitor and its packaging.

Table 1 Monitor and Packaging Symbols

Symbol	Description	Symbol	Description
CE 0123	CE mark		Caution, consult accompanying documents
	Keep dry	55℃ -20℃	Temperature limitations
107.4kPa 22kPa	Atmospheric pressure limitations	93% 10%	Humidity limitations
	Keep upright		Fragile, handle with care
CB	Recovery	4	Maximum stacking
	Recyclable		Power On key
	Silence Key		NIBP key
	AC Power LED		Charging LED
	System setup	**NIBP**	NIBP cuff hose connector
	USB port	**SpO_2**	SpO_2 probe connector
	BF applied part: including F applied part (float/insulation)		BF applied part: including F applied part (float/insulation) and defibrillation-proof function.

Table 1 Monitor and Packaging Symbols (continue)

Symbol	Description	Symbol	Description
	CF applied part: including F applied part (float/insulation) and defibrillation-proof function.		Ethernet port
	Equipotential grounding		Protective grounding
	Date of manufacture		Dangerous Voltage
	Serial Number		Manufacturer
	Batch code		Configuration number
	Catalogue number		EU representatives
	Protection against fluid ingress		Consult Instructions for Use
	Compliance to WEEE standard		Fragile
	Note, Check the documents		Stacking Limit
	Electronic Products Use limit (20 years)		Use Limit
	Fuse		

Safety Standards

The following table describes the safety standards of the ZD120 Patient Monitor.

Table 2 Safety Standards

Parameter	Specification
Protection class	Class I, anti-shock, externally and internally powered equipment, per IEC 60601-1
Degree of protection	Type CF and BF defibrillator-proof: per IEC 60601-1 Degree of noxious-liquid proof as IPX1
Sterilization and disinfection	As recommended by manufacturer
Mode of operation	Continuous

Product Support and Warranty Information

MEDHealth Supplies warranties the ZD120 Patient Monitor for 12 months. Keep the packing case for transport, storage, or maintenance.

ZONDAN is responsible for the safety, reliability, and performance of the monitor when the:

- Product is assembled, upgraded, altered, or maintained by authorized service representatives.
- Location where the product is placed is that of a typical hospital environment.
- Product is used according to this guide.

MEDHealth Supplies is not responsible for damage to the monitor when the:
Damage is caused by:

- Improper operation.
- Improper connection of the monitor to other devices.
- Accidental impact.
- Water/liquid damage

- Monitor is altered without written authorization from the manufacturer.
- Serial number of the monitor is removed or becomes illegible.

After-Sales Service

The South African call center can be reached during the following time: Monday–Friday (except public holidays)

1. Contact your local MEDHealth representative.
2. For further support, contact Medhealth' Customer Service Department.

Customer Service Department of MEDHealth Supplies (Pty) Ltd, Corner of Barbara and North Reef Road, Elandsfontein, Henville, 1429, Germiston, Johannesburg, Gauteng, South Africa

E-mail: technical@medhealthsup.com

Portal for technical support: www.medhealthsup.com

Tel: +27 10 013 3010

Before calling for technical support, note the following information:

- Model and serial number of the monitor
- Monitor problem

The international call center can be reached during the following time: Monday–Friday (except Chinese statutory holidays)

BJT 08:30–12:00, 13:30–18:00 (GMT+8)

Tel: +86 755 26865970/8037

Fax: +86 755 26860497

E-mail: service1@zondan.com

Service and support are available in Chinese and English only. Before calling for service, note the following information:

- Model and serial number of the monitor
- Monitor problem

Safety Conventions

The manual uses the following conventions for Note, Cautions, and Warnings.

Note — A **Note** calls attention to an important point in the text.

Caution **A Caution calls attention to a condition or possible situation that could damage or destroy the product or the user.**

Warning **A *Warning* calls attention to a condition or possible situation that could cause injury to the user and/or patient.**

Safety Requirements

Note — The safety indications in this chapter apply to general monitor use. Safety indications in other chapters apply to specific monitor measurements.

Follow the instructions in this user manual when using the monitor. However, conventional medical practices always supersede this document. Significance of safety requirements set forth here in this manual is not in order of reading sequence.

Warning **The monitor is not for home use.**

The monitor is only for use on one patient at a time. The monitor is not for diagnostic or therapeutic use.

The monitor is not an apnea monitor. The respiration measurement does not recognize obstructive and mixed apneas — it only indicates when a user-defined time has elapsed since the last detected breath.

Anyone who connects to additional equipment to the signal input port or signal output port configures a medical system and is therefore responsible to ensure that the system complies with the requirements of standard IEC60601-1. Never permanently install equipment connected to the signal input or output ports. If in doubt, contact MEDHealth Supplies.

To avoid mixture, clear all historical data of the last patient before monitoring a new patient. Ensure that the patient monitor is in good working condition and is placed in proper position before clinical use.

Never rely exclusively on the alarm system for patient monitoring. You must periodically check that monitor alarms are working properly. The most reliable method of patient monitoring combines close, personal surveillance along with the correct operation of the monitor.

For pacemaker patients, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or come arrhythmia. Do not rely entirely upon rate meter alarms. Keep pacemaker patients under close surveillance. See this manual for disclosure of the pacemaker pulse rejection capability of this instrument.

Never use the monitor during MRIs or CT scans.

Never use cables with exposed conductors. Only use undamaged cables and connectors to avoid personal injury.

Never simultaneously touch the patient and the input or output terminal of the monitor.

The monitor can be used with electrosurgical devices. To avoid burns or death, ensure that the electrosurgical circuitry is properly connected.

Ensure that the patient is not connected to any metal, the surface of any conductors, or grounded parts of any devices when a defibrillator is in use. Never touch the patient, table, or instruments during defibrillation.

Never use the monitor in an environment of anesthetic gases.

No modification of this device is allowed.

Do not modify this device without authorization of the manufacturer.

If this device is modified, appropriate inspection and testing must be conducted to ensure continued safe use of device.

Disconnect the AC power supply and remove the battery before disassembling the monitor.

The device will be battery powered after interruption of the Supply Mains exceeding 30s.

Caution **To avoid personal injury, only use accessories and parts produced or recommended by the Supplier. Otherwise, damage to the monitor can occur.**

Position power cords and other cables to prevent tangling, patient contact, or electrical interference.

Always use a three-wire receptacle in order to properly ground the monitor. Use the monitor on battery power only if you suspect any problem with external grounding or wiring.

To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth. If no grounded power is available, only use the monitor with internal batteries.

The battery will discharge over time when stored inside a monitor with no AC power. Keep the monitor plugged in when storing it and perform a monthly check of battery power.

If multiple devices are connected to a patient, the sum of the leakage currents may cause a dangerous situation. Therefore, qualified service representatives should always perform current leakage tests before setting up the connections. This ensures that leakage is within limits and prevents personal injury and environmental damage. If any question remains, consult the manufacturer for correct usage.

The monitor must conform to the international standard IEC 60601-1-2 and other applicable EMC standards. Interference takes place when electromagnetic energy is extremely high. Ensure that any nearby instruments are also in compliance with EMC standards. Never turn on or use portable communication devices like mobile phones or portable dual-channel radios near a monitor.

Unknown electromagnetic interference could be caused by radio transmitters or nearby televisions. Move patient monitors away from these devices or insert shielding materials around the monitor.

Any devices connected to the monitor must comply with the IEC standard for that device. For example, data processing devices must comply with IEC 60950 and medical devices must conform to IEC 60601-1. The whole system must comply with the most recent IEC 60601-1-1 standards.

To ensure monitor safety, all service parts and accessories must comply with IEC 60601 standards. The system configuration of the monitor must comply with IEC 60601-1-1 medical electrical standards.

If patient data is lost, closely monitor the patient, or replace the monitor immediately until the monitor restores normal function again.

Monitoring will be stopped while user configurations will be saved automatically when the monitor is powered off.

To reduce the hazard of burns in high-frequency surgical neutral connections, the leads and connectors must be located away from the surgical site. Keep cables away from other devices.

Ensure that qualified service representatives annually calibrate and maintain the monitor.

Periodically check all reusable accessories for damage. Replace and dispose of damaged accessories. When necessary, according to your local hospital waste disposal regulations.

ECG electrodes are disposable accessories. Always properly dispose of ECG electrodes according to your local hospital waste disposal regulations.

Clean and sterilize the monitor and accessories according to local requirements. Turn off the monitor and disconnect the power cords before cleaning or sterilization.

Keep all monitor packing materials away from children or dispose of them in accordance with your local environmental regulations.

Always properly dispose of the monitor and all accessories at the end of their service life. Dispose of batteries according to your local regulations. Never incinerate batteries or expose them to high temperatures.

Ensure that no water condenses into or on the monitor. Condensation can occur from changes in temperature or exposure to humidity.

Contents

Chapter 1 Overview

The ZD120 Patient Monitor is used for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates. The monitor stores data in trend and event databases. You can view measurement trend graphs and alarming events to help you identify changes in the patient's physiological condition. The ZD120 Patient Monitor can be connected to the manufacturer's Central Monitoring System for remote monitoring.

The monitor can monitor NIBP, SpO_2 and PR. In addition, the monitor has options as thermometer and 50mm recorder.

This document is an integral part of the monitor and provides detailed instructions on how to use and maintain it. Keep the document next to the monitor for reference. In addition, read and keep any documents that come with any accessories, since these contain important information not in this guide.

This guide describes all the monitor features and options. Your monitor may not have all of them. What you see on the screen, how the menus appear and so forth, depends on the way it has been configured for your hospital.

1.1 Indications for Use

The ZD120 Patient Monitor is for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.

1.2 Intended Use

The ZD120 Patient Monitor is intended for monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in healthcare environments. Additionally, the monitor is for use in transport situations and for connectivity to clinical networks.

1.3 Configurations

The following table lists the available configurations, and the standard features as well as optional features. In the table, a solid circle indicates this feature available, and a hollow circle indicate this feature is unavailable.

Table list 1.1

Model	SpO_2	NIBP	TEMP	Recorder	Infrared Ear Thermometer
MHSZD120	●	●	◐	◐	◐

Note —● means standard configuration; ◐ means optional configuration; ○ means not available

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Chapter 2 General Description

This chapter describes how to set up and begin using the ZD120 Patient Monitor.

2.1 Before You Begin

Before patient monitoring, ensure that the monitor is in good condition and used in the proper environment.

2.1.1 Unpacking the Equipment

1.Unpack the equipment and ensure that you have the following:

– One patient monitor

– Set of accessories

If anything from the packing list is missing, immediately contact MEDHealth Supplies or the agent.

2.Keep the packing case for future transport or storage. If it is damaged, immediately contact the courier company.

3.Examine the monitor for cleanliness and general physical condition. Ensure that:

– The housing is not cracked or broken.

– Power plugs and cords are in good condition and plug prongs are not bent.

– The accessory cables are intact.

Caution	**If the equipment, accessories, or their packaging show signs of damage, do not use the equipment.**

2.1.2 Setting up the Monitor

Basic

Place and use the monitor in an appropriate location that conforms to the environmental specifications in the section, Environmental Specifications on page 105. Locate the monitor in an area that:

- Is convenient for observation and operation.
- Is free from movement, dust, corrosive, or explosive gases.
- Has a five-centimeter space around to ensure good ventilation and smooth heat dissipation.

Installation

You can put the monitor on a flat surface or mount it with the following mounting accessories:

- Roll stand
- Wall mount

Exit Menu

This monitor offer two operation to exit the menu:

Select the menu save icon in the upper right corner of the current menu ☑，Back to previous menu.

Select the menu save icon in the upper left corner of the current menu ☒，Back to previous menu.

Warning **Never attempt to open the monitor case. Only qualified personnel should service the monitor.**

Never block the monitor's air vent during operation

2.1.3 Networking Capabilities

You can use the ZD120 Patient Monitor independently or with other ZONDAN equipment to create a central monitoring system that allows remote monitoring. The monitor communicates with the ZONDAN Central Monitoring System via the Ethernet ports on the back of the monitor. Network setup of the ZD120 Patient Monitor is not user configurable. Please contact your service personnel.

2.1.4 Monitor Power Supply

You can power the monitor with either an AC power source or its internal battery. You can switch back and forth between supplies without powering off the monitor.

When the monitor is connected to an AC power source, you can turn on and operate the patient monitor.

When powered on, the monitor is in normal working condition. It can be used to measure vital signs, communicate with the central monitoring system, and charge the battery.

When the monitor is in standby mode, the monitor battery is charging.

When AC power is lost, the battery powered monitor continues to run without interruption on battery power. For more information on battery power, see Chapter 10, maintaining the Battery.

2.1.5 Inspecting the Monitor

Before you start using the monitor, ensure that:

1.There is no damage to the monitor or the accessory. Before turning on the power, check the monitor and all the cables, connectors and accessories and ensure that the extension cables are correctly connected to the fittings.

2.AC power is in conformity with standards. Plug one end of the specified power cord into an AC power supply with a protection-grounded wire. Plug the other end into the power connector on the monitor. When the power cord is correctly connected, the AC power LED is green. If the monitor is powered by battery, verify that adequate power remains, and the battery power gauge is full.

3.The accessories are correctly connected. For further testing of individual measurement alarms, perform the measurement on yourself (for example, SpO_2) or use a simulator. Adjust the alarm limits and ensure that you observe the appropriate alarm behavior.

4.All settings like patient type, alarm limits and so on, are correct. Ensure that the monitor is in

good working condition and that all functions of the monitor meet the technical requirements mentioned in this guide.

5.When you press the **Power** button on the front panel for 2 seconds, the main screen appears.

2.2 Product Description

The monitor has a color TFT screen that displays waveforms, menus, alarm status and physiological measurements.

2.2.1 The Front Panel

The front panel of the main unit of this monitor is shown in Fig. 2-1.

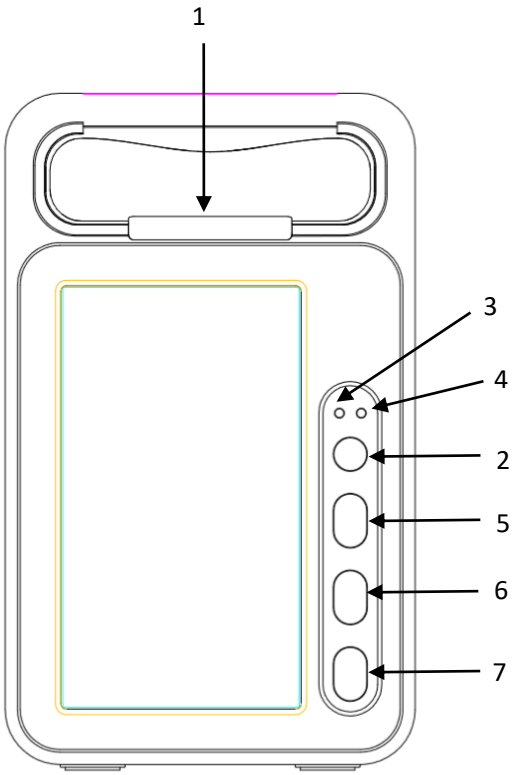

Figure 2-1 Front Panel

The following table describes the controls on the monitor.

Table 2-1 Monitor Controls

No.	Icon	Name	Description
1	--	Alarm indicator	See chapter 4 Alarm Settings for more information
2	⊙/Ö	Power indicator	Press and hold for two seconds to turn the monitor on or off. Power ON/OFF f light (Green) Power on the green light stays on; Power off: No light

3		AC Power indicator	AC Power LED (Green) Connect AC Power: the green light stays on. No AC Power: No light;
4		Charging indicator	Charging LED (Yellow) Connect AC Power: No battery: Yellow, flash every second. Battery charging: the yellow light stays on. Battery finished charging: no light. No AC Power: Yellow, flash every second;
5		Main menu key	Main menu setup
6		NIBP key	Press to start or stop an NIBP measurement
7		Mute key	Turn off the alarm sound temporarily

2.2.2 The Rear Panel

The rear panel of the main unit is shown in Fig. 2-2.

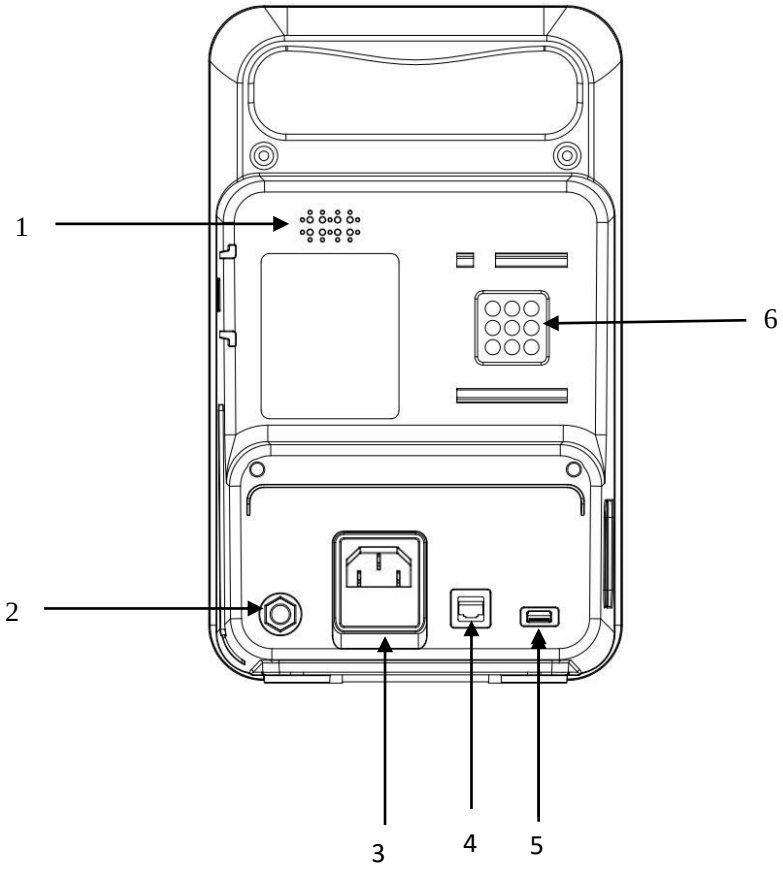

Figure 2-1 Rear Panel

The following table describes each item on the rear panel.

Table 2-2 Rear Panel

Item Number	Item	Name	Description
1	--	Speaker	Speaker of monitor
2		Equipotential grounding	Connects to the grounding system
3	--	External AC power connector	Connects to an external AC power supply
3	--	Fuse	F3.15AL 250V fuse
4		Ethernet port	Standard network connector
5		USB Port	Used for software upgrade or date input/output
6	--	Module box contract	Used for power supply and date transfer

2.2.3 The Side Panel

The side panel of the main unit is shown in Fig. 2-3.

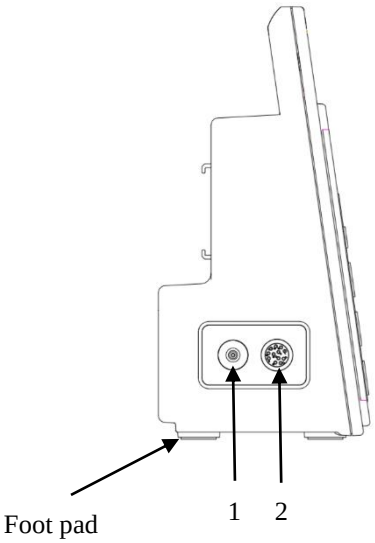

Figure 2-3 Side Panel

The following table describes the side panels.

Table 2-3 Side Panels

Item Number	Item	Name
1	**NIBP**	NIBP connector
2	**SpO2**	SpO2 connector

2.3 Screen Display

The monitor's display is a TFT color LCD, which displays the patient's monitoring parameters, monitoring waveforms and their status, current monitoring time and other information. When the monitor is set to the body temperature interface, it can communicate with the ear thermometer to transmit measurement data through Bluetooth connection.

The display interface of the monitor is shown in Fig. 2-4.

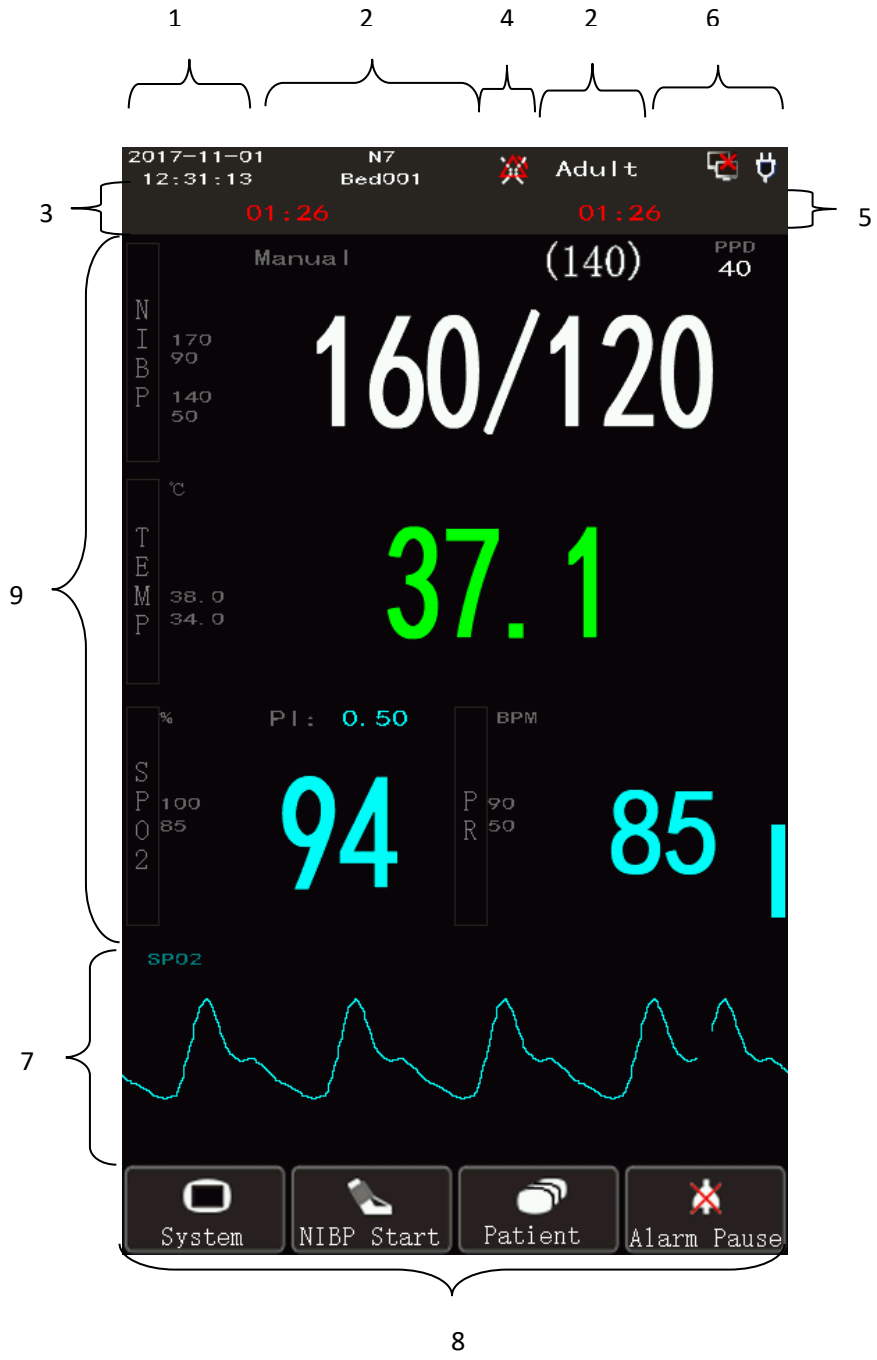

Figure 2-4 Example of Screen Display

The following table describes the screen display.

Table 2-4 Screen Display Description

No.	Description	No.	Description
1	Time display area	6	Status information area
2	Patient information area	7	Waveform area

3	Technical alarm area	8	Menu area
4	Alarm status prompt area	9	Parameter area
5	Physiological alarm area		

2.3.1 Time display area

The time display area displays the current monitoring time.

2.3.2 Patient information area

The patient information area is located at the top of the interface and displays relevant information about the monitored patient. The information includes:

- Bed number and name
- Monitoring mode

2.3.3 Technical alarm area

The technical alarm area is on the upper left of the NIBP parameter area and displays technical alarm information and notification. When there are multiple alarm messages, the alarm information will flash and display cyclically; when there is no technical alarm information, no content is displayed in this area.

Note-2 minutes after the "SpO_2 finger undetected" alarm prompt, The alarm sound and the alarm light will be turned off.

2.3.4 Alarm status prompt area

The alarm status prompt area is located directly on the top side of the main interface and displays the alarm status. When the alarm mute or alarm pause button is triggered, the area displays the "alarm off" icon, and the technical and physiological alarm area will display the countdown of the mute time. The alarm mute time can be 2 or 5 minutes. When the alarm mute is not triggered and the countdown to alarm mute ends, the area displays the "alarm on" icon.

Table 2-5 Alarm status prompt area

Status	Icon	Description
Alarm silence and pause		Alarm sounds pause

2.3.5 Physiological alarm area

The physiological alarm area is located at the upper right of the NIBP parameter area and displays patient physiological alarm information. When there are multiple alarm messages, it will flash and display cyclically. When there is no monitoring, no content is displayed in this area.

2.3.6 Status information area

The status information area is located at the upper right side of the display interface and mainly displays the status information of the monitor, see Table 3-6.

Table 2-6 Status information area

Status	Icon	Description
Network		No network connection
		Network connected
Battery level		No battery installed
		Battery is installed
Wireless network		The wireless network connection is successful
AC power		AC power connected

Note - The status information area can’t display AC power and battery power at the same time.

2.3.7 Waveform area

If the user selects the SpO_2 waveform interface, it displays the SpO_2 monitoring parameter waveform.

2.3.8 Menu area

The menu area is located at the bottom of the main interface and displays the function setting menu.

Table 3-7 Description of function keys

Status	Icon	Description
Main menu		Enter main menu settings
NIBP start		Press to start or stop NIBP Measurement.
Patient information		Set patient information
Alarm pause		Temporarily turn off the alarm sound

2.3.9 Parameter area

The parameter area is located in the middle of the display interface. The parameter area is composed of small parameter areas, which displays the parameter measurement values under the parameter module.

2.4 Trend chart interface display

Through the trend chart interface, you can view the dynamic trend of SpO2 and PR monitoring parameters in the last 8 minutes. The dynamic trend chart is displayed below the SpO2 and PR parameter area. The parameter values are distributed vertically along the y-axis of the chart and time is represented by the horizontal x-axis; the latest measurement results appear on the right side of the trend chart. The data is recorded from right to left, so the earliest data appears on the left side. You can also look back at the trend chart throughout

the whole process and view the dynamic trend of SpO2 and PR monitoring parameter compression within one day. The look-back interface exit automatically 1 minute if left idle. Alternatively, you can click “Exit” to exit the look-back interface.

Enter the trend chart display interface in the following steps:

Method 1:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.
2. Select the **Trend chart interface**.

2.5 Spot check interface display

Through the spot check interface, you can view the trend list data of NIBP monitoring parameters; it can record 5000 pieces of NIBP measurement results and time. The data are sorted from the most recent to the oldest. Each screen can display 6 pieces of measurement data.

Enter the Spot check display interface in the following steps:

Method 1:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.
2. Select **System Settings**.
3. Select **ON** for the **Spot check interface** to enter the **Spot check interface** and you will not be able to switch to other interfaces.
4. Select **OFF** on the **Spot check interface**, exit the **Spot check interface,** enter the main menu and you will be able to switch the interface normally.

The NIBP trend list occupies the lower part of the monitor and displays of time, SYS/DIA, MAP, SpO_2 and PR (pulse rate of SpO_2) parameters.

Use the following methods to view the NIBP trend list:

1. Swipe the touch screen to view the “NIBP Trend List”.

Note - The Spot check interface only displays and records the measured values of NIBP, SpO2, and PR, and the alarm function is off.

2.6 Large font interface display

When the user selects the large font interface, this will display larger fonts. It is convenient for medical staff to observe the measurement parameters from a distance.

Enter the large font display interface in the following steps:

Method 1:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.
2. Select the **Large font interface.**

2.7 SpO2 waveform display

When the user selects the SpO_2 waveform interface, the SpO_2 waveform is displayed at the bottom of the screen, which helps medical staff observe SpO_2 changes more intuitively.
Enter the SpO_2 waveform display interface through the following steps:

Method 1:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.
2. Select the **SpO_2 waveform interface.**

2.8 Body temperature interface

When the user selects the body temperature interface, the TEMP measurement parameters are displayed in the middle of the screen, which helps medical staff view the patient's temperature changes in real-time.

Enter the body temperature display interface in the following steps:

Method 1:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.
2. Select the **Body temperature interface.**

Note - The parameters displayed on the Spot check, SpO_2 waveform, trend chart and large font interface is NIBP, SPO2, and PR.
- The parameters displayed on the body temperature interface are NIBP, TEMP, SPO2 and PR.

2.9 ECG interface

When the user selects the ECG interface, the main interface displays the real-time waveform and heart rate of the patient's ECG to accurately assess the patient's physiological state. Thus, adequate preparations are required before monitoring to obtain correct measurements.

Enter the ECG display interface through the following steps:

Method 1:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.
2. Select the **ECG interface.**

Note - The parameters displayed on the ECG interface are HR, RR and real-time waveforms.

Chapter 3 Basic Operation

This chapter mainly describes some menu operations and monitor settings.

3.1 Menu operation

The monitor operates the menu through the touch screen.

3.1.1 Menu settings

In the menu area, you can complete **NIBP settings, system settings, interface switching, alarm settings, alarm sound settings, sound settings, system standby, trend chart display, alarm event record review, and screen brightness settings.**

The monitor allows entering the menu in the following step:

- Directly select a function key in the menu area through the touch screen to enter the function menu.

In the menu area, you can also complete quick function operations: **mute, alarm pause, NIBP.**

Note - The content of the setting menu is based on the factory settings of the product.

3.1.2 Submenu of different levels

The setting menu and parameter setting menu include submenus, and all submenus can be directly accessed through the touch screen.

3.1.3 Exit menu

The monitor provides two methods to exit the:

- Select the Save icon ☑ in the upper right corner of the current menu to return to the previous menu.
- Select the close icon ☒ in the upper (lower) right corner of the current menu to return to the previous menu.

3.2 General settings

This chapter only introduces the general settings of the monitor. For the settings of parameters and other functions, please refer to the corresponding chapters.

3.2.1 Sound settings

The user can set the sound volume and alarm mute time by entering the **Main Menu** to make the following settings: **system volume (heartbeat volume, pulse volume, keyboard volume)** and **alarm volume.**

Set the volume and mute alarm in the following steps:

1. Select **Main Menu** in the menu area.
2. Select the corresponding sound volume. The available volume and alarm volume are shown in Table 4-1.
3. Exit the menu.

Set the alarm silence time in the following steps:

1. Click the **alarm pause button** or the **mute button**; each click will switch the options once.
2. Select the corresponding alarm silence time. The available alarm silence time is shown in Table 3-1.
3. Exit the menu.

Table 3-1 Volume and alarm silence time selection

Available volume	
Volume	Maximum volume, medium volume, minimum volume, off
Alarm silence time	2 minutes, 5 minutes
Alarm volume	Maximum volume, medium volume, minimum volume

3.2.2 Screen brightness

Adjust the screen brightness through the following steps:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.

2. Select the corresponding **screen brightness**, including **normal, brightness level 1, brightness level 2, brightness level 3, brightness level 4, brightness level 5, brightness level 6, brightness level 7, brightness level 8,** and **night.**

3. Exit the menu.

3.2.3 System settings

Select the **System Settings** in the **Main Menu interface**, enter the **System Settings interface**, and perform the following operations:

- Time setting
- Language selection
- View software version

3.2.3.1 Time setting

The monitor displays the real-time date and time. Every time it is turned on, the system will display the current date and time in the time display area at the top left of the screen.

Set the date and time in the following steps:

Method 1:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.

2. Select **System Settings**.

3. Set an appropriate time.

4. Exit the menu.

Note - Changing the date or time will affect the storage of trends and events.

3.2.3.2 Language selection

The user can set the language displayed by the monitor system, and the available languages include **English**, **SIM. Chinese**, and **Portuguese**.

3.2.3.3 View software version

Enter the **Main Menu** interface, select **System Settings** to enter the **System Settings** interface and view the software version of the monitor.

3.2.4 Export data

The computer and the monitor are connected via a USB data cable. When the USB device is inserted, the computer will automatically detect the USB storage device. When it prompts that the **USB storage device is connected**, copy the XpsConf.Ini configuration file to the USB disk, unplug the USB storage device when it automatically ejects, and then reinsert it. The computer can automatically issue commands according to the XpsConf.Ini configuration file.

The XpsConf.Ini configuration file command is parsed as follows:

- Print Screen =1 //Screenshot of the monitor
- Nibp Test =0 //Hide static pressure, leak detection, life test
- Panel Enable =0 //Standard interface
- Panel Enable =1 //Simple interface
- 1 means on, 0 means off

3.2.4.1 Software program upgrade

When the USB device is inserted, the computer will automatically detect the USB storage device. When it prompts that the **USB storage device is connected**, copy the XpsBurn.txt, MHSZD120AV1S.xin, and 1.xgf configuration files to the USB disk. The monitor will automatically update software according to the configuration files; the monitor then automatically restarts and complete the software update.

The XpsBurn.txt configuration file command is resolved as follows:

- MHSZD120AV1K.xin //Version number
- //1.xgf //Company LOGO configuration file
- //Indicates a comment, “1.xgf” is a separate LOGO configuration file.

Note - The USB data cable needs to be used in conjunction with a USB adapter, otherwise the computer system may not be compatible and can’t recognize USB.

3.2.5 Demo mode

When the monitor is turned on, quickly click the Main Menu button twice to enter the demo mode.

Warning The demo mode is mainly used to demonstrate the performance of the machine and for user training. In actual clinical use, the demo function should be disabled so that the operator will not mistake the demo as the condition of the patient, affecting patient monitoring and delaying diagnosis or treatment.

3.2.6 Standby mode

The standby mode can be set as automatic standby and manual standby. Any operation will cause the system to exit the standby mode.

Automatic standby means that the monitor will automatically enter the standby mode in 10 minutes if there are no operation and alarm (except for technical alarms).

Manually enter standby mode in the following steps:

1. Select the **Main Menu** button in the menu area to enter the **main menu**.

2. Select **Enter standby** mode, as shown in Fig. 3-1.

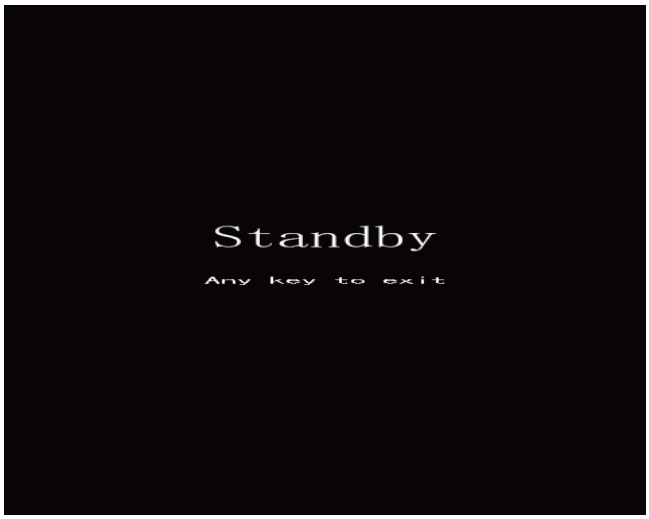

Fig. 3-1 Standby mode

3.3 Patient information

To better manage patients and store their monitoring data, patients need to be registered. It is very important to enter a patient's information correctly so that the patient can be clearly identified in the records and reports. As shown in Fig. 4-2.

Select the **Patient Management** button in the menu area to enter the user information interface, and perform the following operations:

- Input name, bed number
- User settings (adult, child, newborn)
- Clear stored data (off, on)
- Use the default value (off, on).

Fig. 3-2 Patient information

3.3.1 Input name and bed number

The user can input the patient's name and bed number.

3.3.2 User settings

Set user settings in the following steps:

1. Touch the screen to select the Patient Information button and enter the user information interface.

2. Select **adult, child, or newborn** in user settings.

3. Exit the menu.

Note - The default value will not be restored when the user setting is changed. It will only use the default value when "Use default" is on.

3.3.3 Clear stored data

Clear stored data in the following steps:

1. Touch the screen to select the Patient Information button and enter the user information interface.

2. Choose clear stored data.

- Select the option as "on" to clear the monitor alarm event record, NIBP measurement record, trend list data, and trend chart data.
- The default option is Off.

3.3.4 Use default values

Set the default value in the following steps:

1. Select the **Patient Information** button in the menu area.

2. Choose "**Use default**" and select on or off.

- When “**ON”** is selected, loading the selected settings will change the current module and system settings.
- When “**OFF”** is selected, the current settings are discarded, and the system will keep the original configuration unchanged; the default operation is “OFF”.

3.4 Information review

3.4.1 NIBP review

Using NIBP review, you can view 10,000 NIBP measurement results and measurement time. The data are sorted from the most recent to the oldest. Each screen can display 6 pieces of measurement data.

Enter the NIBP review menu in the following steps:

1. Select the Main Menu key to enter the **Spot check interface** and view the **NIBP trend list**.
2. Swipe the touch screen to view the NIBP measurement data of the previous or next page.

3.4.2 Alarm event review

The monitor allows reviewing the alarm event records that was triggered. When an alarm event occurs, the related information of the alarm will be automatically stored in the system; up to 1000 pieces of alarm information can be stored. You can view the date and time of the alarm and the corresponding alarm description information in the alarm event review window.

Enter the alarm event review menu in the following steps:

1. Select the **Main Menu** button in the menu area to enter the **main menu** and select View alarm records and enter the Alarm event review menu. Each screen can display 14 alarm events.
2. Select ↑ or ↓ to view the alarm events on the previous or next page.
3. Exit the menu.

Note - When the alarm system is powered off, the system will not erase the alarm event records.

The alarm event record will not change 30s after the alarm system loses all power (AC and/or

battery).

3.4.3 Trend list display

The trend data of the monitored patients will be displayed in the trend list in the form of a list. You can view 10,000 measurement data and view the trend data SYS/ DIA, MAP, SpO2, PR (SpO2 pulse rate) every minute through the trend list.

Enter the trend list menu in the following steps:

1. Select the **Main Menu** button in the menu area to enter the **main menu** and select View trend list to enter the Trend list display menu.

2. The resolution of the trend list is **1 minute.**

3. Select ↑ or ↓ to view the trend list data on the previous or next page.

4. Exit the menu.

Chapter 4 Alarms

This chapter describes how to configure alarms, including alarm levels and alarm limits. The alarm information in this chapter applies to all measurements. Alarms for specific measurements are described in their respective chapters.

Alarms sound when the monitor senses an irregular condition either in monitor operation or alarm limits.

Alarms include:

- Visual alarms
- Audible alarms

Note — To correctly identify visual alarms, always observe the monitor within 1 meter of its position.

4.1 Alarm Types

Alarms consist of physiological alarms and technical alarms. For more information on physiological and technical alarms table.

Physiological alarms are triggered by physiological values exceeding the limits or by a patient's abnormalities.

Technical alarms are triggered by equipment malfunction or improper equipment use. When a technical alarm occurs, there might be problems with readability of patient data; however, measurements are not interrupted. Such as, ECG electrodes fall off, SpO2 sensor fall off, etc.

Note — In addition to physiological alarms and technical alarms, the monitor also

displays some information related to system status and patient status. Prompt information is generally displayed in the technical alarm area and prompt information area. In addition, some prompt information is displayed in the parameter area, for example: NIBP related prompt information is displayed in the NIBP parameter area.

The time limit of the "SpO2 sensor falls off" is 2 minutes, and the sound and LED will be automatically turned off 2 minutes.

4.2 Alarm Levels

Both physiological alarms and technical alarms are classified by priority:

High: indicates a potentially life-threatening or another serious situation. These alarms require an immediate response from the clinician.

Medium: indicates a physiological condition that requires timely handling. These alarms can be exceeded values or system irregularity. Most medium priority alarms are triggered by values exceeding alarm limits.

Low: indicates equipment malfunctions. These alarms require less immediate handling. For example, a low priority alarm might indicate low battery power.

4.3 Alarm indicator

The monitor uses the following four alarm indicators: audible, flashing LEDs, flashing numeric values, and alarm messages.

Note — To correctly identify visual alarms, always observe the monitor within 1 meter of its position.

4.3.1 Audible Alarm

When audible alarms are turned on, the audible alarms are repeated at certain intervals. If alarms of more than one priority are triggered, the monitor sounds the most severe. Audible alarms are configurable. You can turn the alarm sound on or off, pause the alarm, or adjust the alarm

volume.

The frequency of audible alarm is 200 Hz ~500Hz.

Note — Changing the alarm sound does not affect visual alarm indicators.

On startup, if the monitor is not connected to a patient, technical alarms are silent (except for the low battery). If the monitor is connected to a patient on startup, technical alarms sound (SPO2 Probe off, for example)

The alarm sound depends on the alarm priority. The sound pressure range of the audible alarm is 45dB-70dB. The following table describes the alarm sound on different alarm priority.

Table 4-1 Alarm Sound

Alarm Priority	Alarm Sound
High	Three short beeps followed by two short beeps. This repeats twice, then every 13 seconds. PEEP-PEEP-PEEP-----PEEP-PEEP -----PEEP-PEEP-PEEP-PEEP-PEEP
Medium	Three short beeps repeat every 21 seconds, PEEP-PEEP-PEEP
Low	Two short beeps repeat every 30 seconds. PEEP-PEEP

Warning **Do not rely exclusively on the audible alarm system for patient monitoring. Changing the alarm volume to a low level or turning it off during patient monitoring could result in patient danger. The most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.**

The auditory alarm signal sound pressure levels, which are less than ambient levels, can impede OPERATOR recognition of ALARM CONDITIONS and the ALARM SYSTEM.

4.3.2 Flashing LEDs

There is an alarm LED on the front panel of the monitor. The following table describes the alarm LED colors:

Table 4-2 Alarm LEDs

Light	Color
High priority alarm	Red, fast flicker
Medium priority alarm	Yellow, slow flicker
Low priority alarm	Yellow, keep lighting without flicker

Note — If more than one alarm condition is active, the monitor signals the most severe.

4.3.3 Flashing Numeric Values

When a parameter value exceeds the preset alarm limits, the corresponding numeric flashes.

4.3.4 Alarm Messages

When an alarm is triggered, the alarm message appears in the corresponding alarm area, such as NIBP alarm messages display in the NIBP parameter list.

Higher priority alarm messages pre-empt other priority alarm messages for the same parameter. If multiple alarms of the same priority occur at the same time, the alarm messages rotate every 2 seconds. For more information on alarm messages.

In addition, the monitor also uses different marking and color to distinguish the alarm levels.

Table 4-3 Marking and Color

Type	Level	Marking	Color
Physiological alarm	High priority	***	Red
	Medium priority	**	Yellow
Technical alarm	Medium priority	N/A	Yellow
	Low priority		Yellow

4.4 Alarm control

4.4.1 Turning On/ Off

When all audible alarms are turned off, the alarm off icon displays in the Alarm Silence remind the screen.

To turn on/ off all audible system alarms:

1. Enter the **System** menu.
2. Enter **Medium** menu.
3. Enter **"Turn off Volume"**

To turn ON/OFF f individual audible alarms:

Method 1:

1. Enter the **Alarm Setup** menu.
2. Choose a parameter setup menu press to enter it. A parameter alarm setup menu appears.
3. Choose turn ON/OFF an individual alarm.
4. Click icon X to confirm and back to previous menu.
5. Exit the menu.

Method 2:

1. Enter individual parameter at numeric panes. The individual parameter setup will appear.
2. Choose to turn **ON**/**OFF** alarm.

3. Click icon to confirm and back to previous menu.

4. Exit the menu.

Note —When all audible alarms are off, pressing the Alarm Silence menu turns on alarm sounds again. The Alarm Off configuration is not saved when the monitor is turned off. When you turn the monitor on again, audible alarms are on by default.

Warning **When all alarms are turned off, no audible alarm appears for any alarm-triggered event. However, visual alarm indicators and messages continue to appear. You cannot turn these off.**

4.4.2 Silencing Alarms

If you want to mute the alarm, you can select the alarm pause button or the silence button in the menu area. The alarm sound can be paused for 2 minutes or 5 minutes. When the time countdown displays to 00:00, the alarm sound will be turned on again.

Setup Alarm Silence for **2** or **5 minutes**.

1. Click the alarm pause button or silence button, the alarm mute time can be 2 minutes and 5 minutes.

2. Long press the silence button to enter the alarm silence state.

3. During the silence state, press the alarm pause button or the silence button to turn on the alarm sound again.

To activate all audible alarms before the timeout counter reaches **00:00**, press the **Alarm Silence** button again.

Note —Audible alarms reactivate when new alarm-triggered events occur during an alarm silence. These audible alarms sound according to the alarm priority.
The low battery alarm is not controlled by the silence button. As long as the battery is low, the monitor will alarm.

4.4.3 Adjusting the Alarm Volume

You can adjust the alarm volume from one to four. The minimum volume is one.

To adjust the alarm volume:

1. Enter **System** menu.
2. Enter Minimum **Alarm Volume**, choose **Maximum Alarm Volume**, **Medium Alarm Volume** or **Minimum Alarm Volume**

4.5 Setting Alarm Limits

You can set alarm limits based on an individual patient's vital signs measurements. These limits determine the conditions that trigger alarms based on the high and low limits set. You set alarm limits in the specific parameter alarm setup menu. See the chapters in this guide for setting specific parameter alarm limits.

Warning **Always check that the alarm settings are appropriate for your patient before you start monitoring.**

4.5.1 Setting Individual Alarm Limits

Warning **You can set certain parameter alarm limits (SpO_2, for example) from 0 to 100. Setting the upper limit to 100 or setting the lower limit to zero is equivalent to no alarm limit. In these instances, the screen does not display an alarm off icon.**

To set an individual alarm limit:

Method 1:

1. Enter **System** menu**.**
2. Enter **Alarm Setup**.

3. Set up alarm limit at **Upper Limit** and **low limit** of **SPO2, PR, SYS, DIA** and **TEMP.**
4. Choose “ ⬅ to delete the value.
5. Enter the value
6. Click “  to confirm.

Method 2:

1. Enter **Alarm setup** at menu area
2. **SpO_2**, **NIBP**, **TEMP Alarm Setup** are options. Choose one parameter and press to confirm.
3. Setup Alarm **ON**/**OFF**, Alarm limits and Alarm Level.
4. Click  to exit the menu.

Note — Both alarm limits remain in the system until they are changed, including when you turn the monitor on and off, or after a power loss.

4.5.2 Restoring Default Alarm Limits

The monitor has alarm limit settings based on patient type. To restore the default alarm limits:

1. Enter **Main** menu.
2. Enter **Default** menu.
3. Choose an option **No** or **Yes**.
   - Yes, keeping current alarm limits.
   - NO, restoring adult default alarm limits.

Note —User cannot change default alarm limit.

Table 4-4 Default Alarm Limits

Parameter		Adult	Pediatric	Neonate
SpO_2 (%)	High limit	100	100	100

	Low limit	85	85	85
PR (bpm)	High limit	90	90	90
	Low limit	50	50	50
NIBP SYS (mmHg/ kPa)	High limit	160/21.3	120/16.0	/
	Low limit	90/12.0	70/9.3	/
NIBP DIA (mmHg/ kPa)	High limit	90/12.0	70/9.3	/
	Low limit	50/6.7	40/5.3	/
Temp (℃/℉)	High limit	39/102.2		
	Low limit	36/96.8		

4.6 Reviewing Alarm Events

You can review alarm events that occurred during monitoring in the Alarm Event Review window. The monitor can store 1000 groups of alarm events in the system, including date; time, parameter values, and the corresponding alarm description.

To review alarm events:

1. Enter **System** menu.
2. Enter **Event Review.** The **Alarm Recall Condition** window appears
3. Adjust recall time, choose **Alarm Event Review**
4. Click ⬇ or ⬆ to page down or page up the window.
5. Click "  " to exit the menu.

Note —The log is maintained when the alarm system is powered down and the time of powering down is captured in the log.

The contents of the log will no change after the alarm system has experienced a total loss of power for a finite duration.

The first contents of the log will be sequentially overwritten as it reaches capacity.

When a patient is discharged; the monitor clears the previous patient data and deletes all alarm events from the **Alarm Event Review** window.

Chapter 5 Monitoring SpO_2

Pulse oximetry uses a motion-tolerant signal processing algorithm. It provides these measurements:

- Oxygen saturation of arterial blood (SpO_2) percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
- Pleth waveform – A visual indication of a patient's pulse.
- Pulse rate – rate of arterial pulsations.

5.1 Selecting an SpO_2 Sensor

Read the Instructions for Use supplied with your sensor before using it. See SpO_2 accessories on page 60 for recommended SpO_2 sensors.

5.2 Applying the Sensor

Follow the SpO_2 sensor's Instructions for Use, adhering to all warnings and cautions.

To correctly apply the sensor:

- Remove colored nail polish from the application site.
- Ensure that the sensor is applied to smooth skin sites with sufficient arterial blood flow and that no excessive patient movement and/or vibration occur.
- Apply the sensor at the same level as the patient's heart.
- Ensure that the sensor is not on extremities with an arterial catheter or intra vascular venous infusion line.
- Ensure that the sensor is the appropriate size. The sensor should not be so loose as to fall off, nor should it be too tight.
- Ensure that the light emitter and the photodetector are directly opposite each other. All light from the emitter must pass through the patient's tissue.

Warning **At elevated ambient temperatures be careful with measurement sites that are not well perfused because this can cause severe burns after prolonged application. All listed sensors operate without risk of exceeding 41 ℃(105.8 ℉) on the skin if the initial skin temperature does not exceed 35℃ (95 ℉).**

5.3 Connecting SpO_2 Cables

Connect one end of the sensor cable (or use an extension cable) to the SpO_2 connector on the monitor and attach the other end to the patient site.

Warning **Position the sensor cable and connector away from power cables, to avoid electrical interference.**

For neonatal patients, make sure that all sensor connectors and adapter cable connectors are outside the incubator. The humid atmosphere inside can cause inaccurate measurements.

5.4 Measuring SpO_2

Note — Clean the sensor surface with 70% ethanol before and after use. Never immerse the sensor in liquid.

To start monitoring SpO_2:

1. Select a sensor of the correct type and size and attach it to the patient site.
2. Connect the SpO_2 cables and ensure a good connection.
3. Configure the appropriate SpO_2 alarm limits. See Setting Individual Alarm Limits on page 34.

The monitor displays the SpO_2 waveform and the SpO_2 value when it detects the patient SpO_2. During measurement, the following factors can influence SpO_2 readings:

- Nail polish, especially blue or purple.
- Excessive patient smoking which causes temporary high CO levels and results in higher readings.
- Injected dyes like methylene blue or intra vascular dyshemoglobins (methemoglobin and carboxyhemoglobin).
- Strong ambient lighting and patient motion.
- Misplacing the sensor.
- Poor perfusion.

Warning **Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the sensor position at least every four hours.**

5.5 Assessing Suspicious SpO_2 Readings

Inaccurate readings may be caused by patient motion or weak signals, especially for neonatal patients. Observe the following guidelines when monitoring neonatal patients:

- There should be a six-second uninterrupted, non-artifact SpO_2 waveform.
- A stable SpO_2 value should remain for at least six seconds.

When the pulse rate is very low, or serious arrhythmia occurs, the SpO_2/ Pleth pulse rate may differ from the heart rate calculated from the ECG. However, this does not indicate an inaccurate SpO_2 value.

If you suspect the measured SpO_2 value, use the pleth wave and perfusion indicator to assess the signal quality.

5.6 The SpO_2 Display

The following figure shows an example of the Pleth wave and the SpO_2 numeric pane.

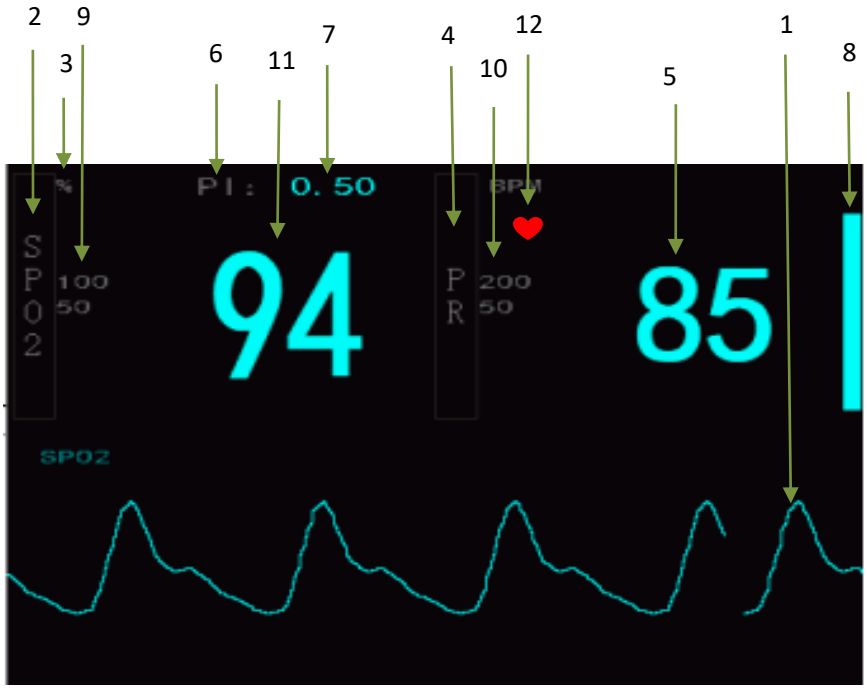

Figure 6-1 Pleth Wave and SpO_2 Numeric Pane

1 = Pleth wave

2 = SpO_2 numeric label

3= SpO_2 unit

4= PR numeric label

5= PR value

6= Perfusion index numeric label

7= Perfusion index value

8= Perfusion bar graph

9= SpO_2 alarm high and low limit

10= PR value

11= SpO_2 value

12= Pulse beat

Figure 6-1 shows a normal SpO_2 waveform. When the SpO_2 signal is inadequate, the waveform becomes abnormal.

5.7 Changing the SpO_2 Display

You can change the SpO_2 display screen according to your needs.

For more information on changing the SpO_2 waveform color, pls contact the manufacturer or distributor.

5.8 Changing the SpO_2 Alarm Settings

To turn on the SpO_2 audible alarm, see Turning ON/OFF f Audible Alarms on page 31. For more information on SpO_2 alarm limits, see Setting Individual Alarm Limits on page 34.

5.9 Changing the PR Alarm Settings

To configure the PR alarm limits:

Method 1:

1. Enter **SpO_2 Setup** menu at numeric panes.
2. Set up **PR** limits at **PR Upper Limit** and **PR Low Limit**.
3. Exit the menu.

Method 2:

1. Enter **Alarm Setup** menu at menu area.
2. Enter **SpO_2 Alarm Setup**.
3. Set up **PR** limits at **PR High Limit** and **PR Low Limit**.
4. Exit the menu.

5.10 Safety Information

Warning **Continuous monitoring might make skin red, blistered, or cause compression necrosis. This is especially true for neonates or patients with perfusion disorder or unhealthy skin. Periodically inspect the sensor application site and change the application site at least every four hours.**

Never use disposable sensors on patients who have allergic reactions to the adhesive.

Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line.

If a sensor is too loose, it might compromise the optical alignment or fall off. If it is

too tight, for example because the application site is too large or becomes too large due to edema, excessive pressure may be applied. This can result in venous congestion distal from the application site, leading to interstitial edema, hypoxemia, and tissue malfunction.

The SpO_2 function of the device is calibrated to display functional oxygen saturation.

The operator needs to verify the compatibility of the monitor. Probe and cable before use, otherwise patient injury can result.

The misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.

The functional tester cannot be used to assess the accuracy of the SpO_2 function.

Caution **The sensor consists of sensitive electronic components which may be damaged if misused. Keep sharp-edged objects away from the cable.**

Improper cleaning of the sensor could compromise the SpO_2 sensor life span. Use only the specified sensors and cables or patient injury may result.

Do not use a SpO_2 sensor if it shows signs of damage or deterioration, or its packing is damaged.

Chapter 6 Monitoring NIBP

The monitor uses the oscillometer method for measuring NIBP. The principle of the Oscillometer method of measuring blood pressure is stopping the arterial blood stream with the pressure of the inflation cuff. As the cuff pressure decreases, the air pressure oscillation wave caused by the blood stream can be measured in the cuff. The Systolic (SYS), Diastolic (DIA) and Mean Arterial Pressure (MAP) are recognized by amplitude changes of the oscillometer wave under different cuff pressures.

6.1 Connecting the NIBP Cuff and Hose

To monitor NIBP:

1. Select an NIBP cuff of proper size (marked on the cuff). Ensure that the cuff is completely deflated.
2. If possible, roll up the patient's sleeve and wrap the cuff around the patient's left arm at heart level with the palm upwards. The index line should fall between the two range lines and the arterial marking should be over the patient's brachial artery with the cuff correctly on the brachial artery.
3. Place the cuff 2 cm-5 cm above the elbow and make sure that the cuff is in the correct position.
4. Place the hose along the left or the right side of the patient's arm to avoid tangling.

The following figure show correct cuff placement.

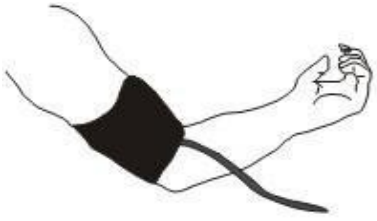

Figure 6-1 NIBP Cuff Placement

5. Attach the cuff hose to the NIBP connector on the monitor. The hose clicks into place when seated correctly. Make sure that there is no blockage between the monitor and the hose.
6. Press the **NIBP** key on the right panel of the monitor or press the NIBP menu at menu area to start or stop the NIBP measurement at any time.

Warning **Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth, and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site or stop the blood pressure measurements immediately. Check more frequently when making automatic or stat measurements.**

Please avoid compression or restriction of the connection tubing.

If the cuff is too small or too tight, the unexpected readings are obtained. And select a proper cuff for different patients and correctly place the cuff to collect reliable results.

The performance of the device may be affected by extremes of temperature, humidity, and altitude. Make sure that the device operating environment meets the specifications. Otherwise, unexpected consequences, e.g., damage to the device, could result.

The continuous CUFF pressure due to connection tubing kinking may cause the blood flow interference and resulting harmful injury to the patient.

Any Blood Pressure reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition.

Do not re-use disposable NIBP cuffs.

For more information on NIBP cuffs, see NIBP Accessories on page 60.

6.2 Measurement Limitations

NIBP measurements are impossible with heart rate extremes of less than 40bpm or greater than 300bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

- If a regular arterial pressure pulse is hard to detect.
- With cardiac arrhythmias.
- With excessive and continuous patient movement such as shivering or convulsions.
- With rapid blood pressure changes.
- With severe shock or hypothermia that reduces blood flow to the peripheries.
- With obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery.
- On an edematous extremity.

6.3 The NIBP Display

The following figure shows an example of the NIBP numeric pane.

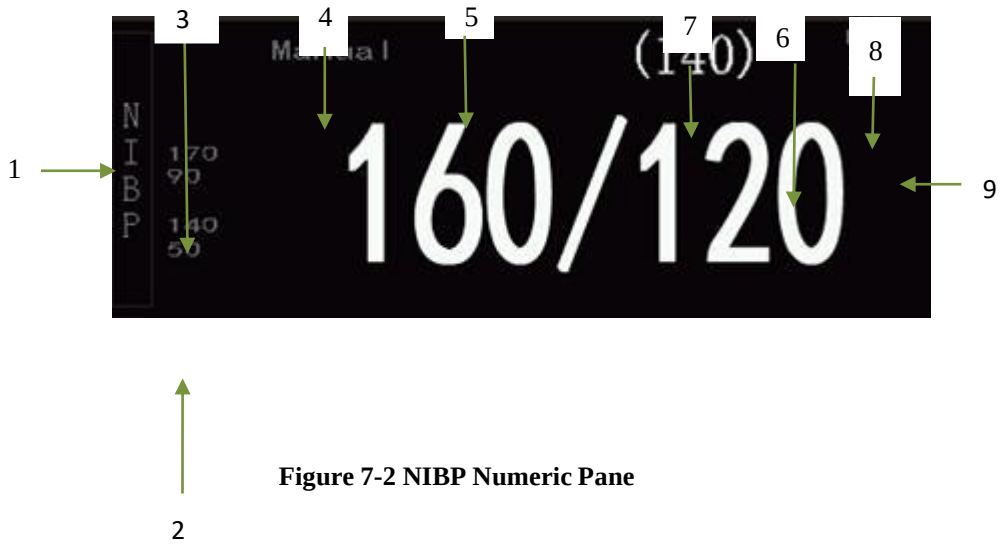

Figure 7-2 NIBP Numeric Pane

1 = NIBP Numeric Pane label

2 = NIBP Diastolic pressure alarm high and low limit

3 = NIBP Systolic pressure alarm high and low limit

4 = Work mode (Manual mode in this example)

5 = Systolic pressure value

6 = Diastolic pressure value

7 = Mean arterial pressure value

8 = Pulse Pressure Difference

9 = Pulse Pressure Difference Value

6.4 Selecting the NIBP Measurement Modes

There are three NIBP measurement modes:

Manual

Selecting **Manual** lets you manually take NIBP readings. When you press the **NIBP** key on the front panel the monitor starts/stops NIBP measurement. When a NIBP measurement is started, the monitor inflates the cuff to a certain pressure and then deflates it to get an NIBP value.

Auto

Selecting **Auto** specifies that the monitor take NIBP measurements at regular intervals. The monitor inflates the cuff at the start of each measurement cycle and collects NIBP values. In **Auto** mode, if the patient blood pressure is high, the monitor adjusts the maximum inflation pressure by re-inflating the cuff. The NIBP measurement automatically stops if NIBP values cannot be correctly collected in the **Auto** mode.

Stat

Selecting **Stat** specifies that the monitor continuously measure patient NIBP for 5 minutes. Use **Stat** for continuous NIBP monitoring of supervised patients in special cases. The monitor displays **Stat** in the NIBP numeric pane and starts to count down after starting the first NIBP measurement.04:59 will appear also.

Rule 1 and Rule 2

Continually automatic measurement at set durations and intervals

When **Stat** mode times out or **Auto** mode pauses due to a measurement error or technical malfunction, the monitor switches to **Manual** mode.

To change the NIBP measurement mode:

1. Enter **NIBP Setup** menu at numeric panes.
2. Press **mode**, a list box appears.
3. Choose option of **Manual**, **Auto, Stat**, **Rule 1 or Rule 2**, press to confirm.
4. Exit the menu.

Note —When monitoring, the initial inflation pressure is adjusted (except in **Manual** mode) according to the previous measurement value. The initial inflation pressure specifies the maximum amount that the cuff will inflate for the first NIBP measurement.

In **Auto** mode, the interval time displays in the NIBP numeric pane. The monitor starts to count down after an NIBP measurement completes. When the measurement is paused, it reverts to the present time display until the next measurement.

6.5 Selecting the NIBP Interval Time

An interval is measured from the end of one NIBP measurement to the start of the next measurement and is shown in the NIBP numeric pane. For example, 1min is displayed as 1min in the numeric pane. You can configure the NIBP interval time only in Auto mode.

To change the NIBP interval time:

1. Enter **NIBP Setup** menu at numeric panes.
2. Press **Interval Time**, a List box appears.
3. The options are: **2min**, **3min**, **4min**, **5min**, **10min**, **15min**, **30min**, **60min**, **90min**, **120min**.
4. Press to confirm an interval time.
5. Exit the menu.

Warning **Under Auto or Stat mode, prolonged measurements may increase friction between the cuff and patient skin which may cause purpura, ischemia, and neuropathy. 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 abnormality occurs, place the cuff on another site or stop NIBP monitoring.**

6.6 Changing the NIBP Unit

You can configure the NIBP unit to mmHg or kPa. The unit displays in the NIBP numeric pane.

To change the NIBP unit:

1. Enter NIBP Setup menu at numeric panes.
2. Press Unit, a List box appears.
3. Choose **mmHg** or **kPa** and press to confirm.
4. Exit the menu.

Note — When you change the NIBP unit, this change displays wherever pressure parameters are displayed on the monitor.

6.7 Viewing NIBP Measurement Data

After a complete NIBP measurement, the NIBP measurement value displays in the NIBP numeric pane.

When no menu is on the monitoring screen, choose Review menu to view the data in the NIBP list. The monitor displays up to 5000 groups of measurement data in time sequence, with the latest reading at the top.

6.8 Changing the NIBP Alarm Settings

To turn on the NIBP audible alarm, see Turning ON/OFF f Audible Alarms on page 30. To turn off the NIBP audible alarm, see when all audible alarms are off, pressing the Alarm Silence menu once turns on alarm sounds again. The Alarm Off configuration is not saved when the monitor is turned off. When you turn the monitor on again, audible alarms are on by default on page 30.

For more information on NIBP alarm limit settings see Setting Individual Alarm Limits on page 30.

6.9 Calibrating NIBP and Compensating Pressure

NIBP calibration and pressure compensation is not user configurable. A qualified service professional should perform NIBP calibration and pressure compensation every twelve months or when you suspect that the NIBP reading is not correct.

6.10 Safety Information

Warning **Continual NIBP measurements can cause injury to the patient being monitored. Weigh the advantages of frequent measurement and/or use of Stat mode against the risk of injury.**

In some cases, rapid, prolonged cycling of an NIBP cuff has been associated with any or all of the following: ischemia, purpura, or neuropathy. Apply the cuff according to the directions and check the cuff site and cuffed extremity regularly when blood pressure is measured at frequent intervals or over extended periods of time.

Check the patient's limb to assure that circulation is not constricted, i.e., no discoloration or ischemia of the extremities. Check the limb at regular intervals based on the circumstances of the specific situation.

Never place the cuff on an area where circulation is compromised or has the potential to be compromised. Never measure NIBP on patients with sickle-cell

disease or any condition where skin damage has occurred or is expected.

Never use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.

Never apply the blood pressure cuff to the same extremity as the one to which an SpO_2 sensor is attached because the cuff inflation disrupts SpO_2 monitoring and leads to nuisance alarms.

Select an appropriate cuff and ensure that the correct patient type is selected before monitoring. Wrong cuff sizes can overload inflation pressure on pediatric or neonatal patients.

Use clinical judgment before using NIBP monitoring on patients with serious blood clot disease due to the risk of hematoma in the limb with the cuff.

Use clinical judgment before using the CUFF and its pressurization on the arm on the side of a mastectomy or lymph node clearance.

The pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring device on the same limb.

Any Blood Pressure reading can be affected by the measurement site, the position of the Patient, exercise, or the patient's physiologic condition.

Chapter 7 Monitoring Temperature

Body temperature monitoring (TEMP) uses an ear thermometer to detect the infrared spectrum emitted by the eardrum (equivalent to the hypothalamus) to measure body temperature. Body temperature monitoring only displays body temperature values without waveforms. The body temperature values are displayed in the TEMP parameter area. For ear thermometer related instructions and precautions, see the thermometer manual.

7.1 Influencing Factors

The following factors can affect temperature measurements:

- Improper measurement position.
- Poor heat balance, heat dissipation.
- Patient temperature fluctuation.

7.2 Set TEMP

This monitor allows measuring body temperature. In the TEMP parameter settings menu, you can:

- Change the TEMP alarm switch
- Change high and low TEMP limits
- Change TEMP unit

Enter the TEMP settings menu, touch the TEMP parameter area on the touch screen to enter the **TEMP Settings** menu.

7.2.1 Set TEMP alarm

The TEMP alarm setting determines the TEMP alarm mode during monitoring. For the method of setting the TEMP alarm switch and upper and lower limits, see 5.5 “Alarm Settings”.

7.2.2 Change TEMP unit

You can set the body temperature unit of this monitor to Celsius (°C), or Fahrenheit (°F) as needed. The body temperature unit is displayed in the body temperature parameter area.

Change the TEMP unit in the following steps:

1. Enter the **Main Menu** and select the **Body temperature interface**.

2. Touch the TEMP parameter area, enter the **Body temperature setting** menu, select **Unit**, and then select °C or °F.

3. Exit the menu.

Note - After changing the body temperature unit, the temperature units of other monitoring parameters will change accordingly.

7.3 TEMP Measurement

To measure the temperature:

1. Connect ear thermometer with the monitor.
2. Apply the ear thermometer to the ear on the patient.
3. Set the temperature unit and appropriate alarm limits.
4. Start temperature monitoring.

The temperature parameter value stabilizes and displays in the temperature numeric panes.

7.4 Precautions for using ear thermometer

- Before use, check the product to ensure the product has no damage that will affect the safety or testing performance. If any obvious damage is found, stop using it.
- It is forbidden to submerge the infrared thermometer into any liquid.
- It is forbidden to leave the infrared thermometer in a low-temperature or high-temperature environment for a long time.
- Do not touch the top of the probe with your fingers, and do not blow the infrared sensor with your mouth.
- It is prohibited to disassemble, repair, or modify infrared thermometers without permission.

- Please use original accessories. Replacing the original parts with parts provided by other manufacturers may cause measurement errors.
- Do not measure the body temperature within 30 minutes after exercising, eating, or bathing. At this moment, the body temperature may deviate from the normal value.
- When the ambient temperature changes greatly (for example, from indoor to outdoor), please wait about 2 hours before measuring.
- The measurement interval is recommended to be more than 10 seconds.
- Keep the infrared thermometer out of the reach of children.
- When you tell the doctor your body temperature, please specify your measurement site.

7.5 Troubleshooting of ear thermometer

If there is an error (or anomaly) during use, you can troubleshoot according to the items listed in the following table.

Failure (or exception)	Possible cause	Solution
The LCD screen has no display after installing the battery and pressing the [START] scan key.	1. The battery is incorrectly installed; 2. The battery is dead.	1. Place the battery in correct polarity; 2. Replace with a new battery.
The LCD display shows “Hi”	The measured body temperature exceeds the upper limit of the measuring range (42.3°C)	Check whether the probe is clean, and measure again.
The LCD display shows “Lo”	The measured body temperature is lower than the lower limit of the measuring range (32.0°C)	Check whether the probe is clean, and measure again.

7.6 Safety Information

Warning **The disposable probe is sterile and must be operated as sterile items. See "Expiration Date" on the probe package.**

Only use ear thermometers designated by our company.

When the probe becomes loose or falls off, the temperature measurement is stopped, but there is no alarm sound. To ensure reliable monitoring of patients, it is recommended that medical staff regularly check whether the temperature probe is properly connected.

Do not use the temperature probe if there are any signs of damage.

Chapter 8 Review

8.1 Trend Table display

The Trend Table window displays patient data in a list format.

To Trend Table:

1. Enter Trend Table Menu at menu area.

   Or Enter **Review Menu** at menu area, press Trend Table comes to menu.
2. Press ⏫ or ⏬ to watch earlier or later data with different parameters
3. Exit the menu.

8.2 Trend Graph display

The Trend Display menu displays patient data in graphic form. It may display the most recent data in the past 168 hours.

The latest 1 hour trend graph can be displayed at a data resolution of 1 second or 5 seconds.

The latest 168 hours trend graph can be displayed at a data resolution of 1 minute, 5 minutes or 10 minutes.

To Trend Graph:

1. Enter Trend Graph Menu at menu area.

   Or Enter **Review Menu** at menu area, press Trend Graph comet to menu.
2. Press parameter at left area. SpO2，PR，NIBP SYS／MAP／DIA
3. Choose RES, a List box appears. Options of 1s, 5s,1min,5min, 10min.
4. Press ⏪ or ⏩ can do page turning to check the Trend graph earlier or later; press ◀ or ▶ can check the Trend datum in some points of moment.
5. Press record to print current graph.
6. Exit the menu.

Note —The Trend Graph display window only show the channel of the selected parameters, totally 3 channels can be displayed on this window, the selected parameters can't be repeated.

Waveform Recall

The Waveform Recall display 2h waveform.

7. Enter Waveform Recall Menu at menu area.

   Or Enter **Review Menu** at menu area, press **Waveform Recall** comes to menu.
8. Press parameter at left area. SpO_2.
9. Press ⏪or ⏩，to check the waveform which happens in every minute earlier or later, press ◀ or ▶，to check the waveform which happens in every second earlier or later.
10. Choose Waveform Speed, 6.25mm/s，12.5mm/s and 25.0mm/s are options.
11. Exit the menu.

8.3 Alarm Recall (Physiological alarm)

You can review alarm events that occurred during monitoring in the Alarm Event Review window. The monitor can store 60 groups of alarm events in the system, including date; time, parameter values, and the corresponding alarm description.

To review alarm events:

1. Enter Review menu.
2. Enter Alarm Event Review. The Alarm Recall Condition window appears.
3. Adjust recall time, choose Alarm Event Review.
4. Choose Event type, the alarm type window appears.
5. Press ⏫ or ⏬ to watch earlier or later alarm event. Press ⏪ or ⏩ to observe trend data with different parameters.
6. Exit the menu.

Alarm events and time are shown on the left of the physiological alarm window. The details of the alarming events which selected will be displayed on the right include alarming types, time and waveforms.

Note —The system will automatically keep the alarm event records when its power cut off. But if the power cut is caused by the un-normal ways such as lightning stroke or artificially damaged, the system can’t ensure to keep records.

Chapter 9 Recording

The monitor provides a recorder to print real-time parameters and waveform record. The recorder can:

- Could choose the type and amount of parameter to print.
- The real-time parameters and waveform record.

9.1 Loading the Recorder

Note —Use only the manufactured-supplied thermal paper with a width of 50 mm. using the wrong paper can damage the recorder or cause it not to print.

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1. Open paper warehouse, insert the paper with spindle.

Figure 9-1 Loading paper

2. Pull at least 25mm of the paper out of the door, use screwdriver fix the recorder.

Figure 9-2 Loading paper

3. Put the recorder into slot, when you heard "Ka", the recorder set well. Show in figure 9-3.

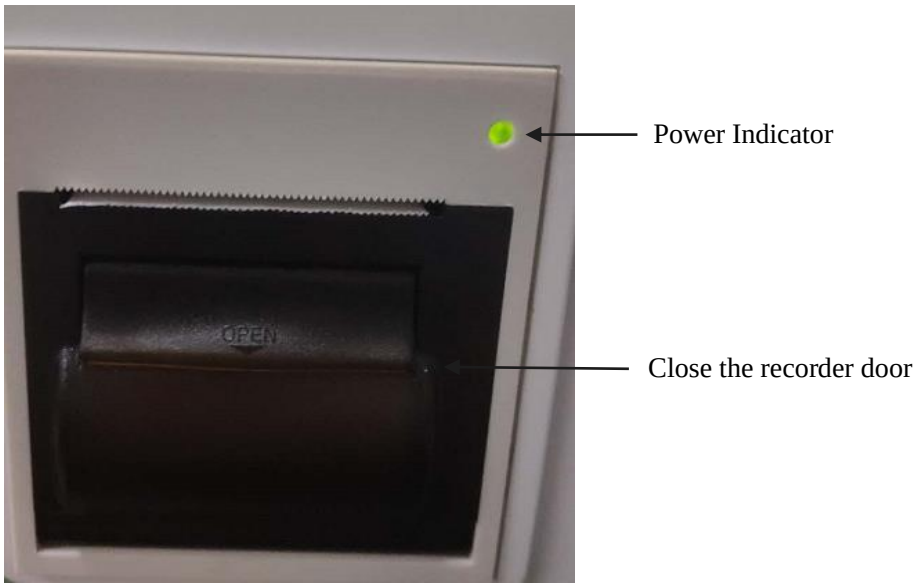

Figure 9-3 Fix recorder

Note — The recorder has 2 indicators. Generally, “Power” indicator is on when monitor has power; “Error” indicator on indicates the recorder door is open or other malfunction occurred.

9.2 Recording

- Press the Record key to start a printout. or press the Record icon at menu area.
- To stop recording, press the Record key again. or press the Record icon again at menu area.

Recording stops if the recorder paper runs out or for technical problems.

9.3 Selecting the Record Content

The monitor records waveforms and values of the selected parameter. Before recording, select an option from the **Record Content** menu to record either the real-time waveform or associated data.

To select the record content:

1. Select the print logo in the menu.
2. The recorder will record the measured values of all parameters.
3. Exit the menu.

9.4 Recording Waveforms

The monitor can generate printouts with up to two waveforms. Before recording, you must configure the channels.

9.5 Recorder Paper Guidelines

Caution **For long term storage, make copies of the printouts.**

- Use only manufactured-approved recorder paper.
- Keep the recording strips in a dry, dark, and cool place.
- Avoid exposure to:

– High temperature, humidity, direct sunshine, and fluorescent lighting and radiation.
– Ambient temperatures over 50℃.
– Liquids.
– Starch, adhesive agent, oily paper, or carbon paper.
– Ethane, oxide, plastic rubber, adhesive tape, fluorescent ink, or red inks.

- Never squeeze, apply friction, or scratch the paper.
- Never place two recording surfaces together.

Chapter 10 Cleaning and Care

This chapter gives general guidelines on the cleaning and care of your monitor and accessories. Use only the approved cleaning methods and agents listed in this chapter. The warranty does not cover damage caused by using unapproved substances. Cleaning methods described in this chapter have been tested by the manufacturers. Other methods and cleaning agents may contaminate or damage the monitor. In addition, qualified professionals should perform periodic calibration and maintenance of the monitor.

10.1 General Guidelines

Keep the monitor, cables, and accessories free of dust and dirt. After cleaning and disinfecting, check the equipment carefully. Do not use if you see signs of deterioration or damage. If you need to return any equipment to MEDHealth Supplies, decontaminate it first.

Follow these general precautions:

- Always dilute cleaning agents according to the instructions in this chapter or use lowest possible concentration.
- Never allow liquid to enter the case.
- Never immerse any part of the equipment in liquid or allow any liquid to enter electrical contacts.
- Never use abrasive material (such as steel wool or silver polish).
- Never use bleach or strong solvents such as acetone or acetone-based compounds.
- Never autoclave, steam sterilize, or ultrasonically clean the monitor or cables.
- Never use alcohol on the patient cables. Alcohol can cause the plastic to become brittle and fail prematurely.

Caution **If you spill liquid on the exterior of the monitor, use a clean cloth to dry the monitor. If you believe the liquid may have gotten inside the monitor, power off the monitor and contact your service representative.**
Use the accessories according to instructions accompanied. The manufacturer information might be more current.

To clean the monitor:

1. Turn off the patient monitor and unplug the power cord.
2. Clean the monitor at room temperature. Use a soft cloth and any of the following cleaning agents:
   - Isopropyl alcohol (70% solution in water)
   - Mild soap and water
   - Sodium hypochlorite (chlorine bleach), 3% solution in water
3. Dry the cleaned parts with a cloth.

Note — Do not permit any liquid to enter the monitor and avoid pouring liquids on the monitor while cleaning. Do not allow water or cleaning solution to enter the measurement connectors.

10.2 Cleaning the Accessories

When possible, clean the accessories according to the manufacturer's instructions. Use the general guidelines in this chapter if you do not have specific product cleaning instructions.

10.2.1 Cleaning the Cables

Dampen a soft cloth with one of the following cleaning agents:

- Alcohol-free hand soap
- Sodium hypochlorite (chlorine bleach), 3% solution in water

Note — This solution might discolor the cable.

Wring any excess moisture from the cloth and gently clean the cables.

10.2.2 Cleaning the SpO_2 Sensor

To clean the SpO_2 sensor:

1. Wipe all sensor surfaces, including finger pads and cable, with a clean cloth dampened with any of the following validated cleaning solution:
   - mild detergent
   - salt solution (1%)
2. Wipe the sensor with a water-dampened cloth to remove all cleaner residue. Then dry all sensor and cable surfaces with a clean, dry cloth. Set the sensor aside allowing it to dry completely.

Note — If you notice any signs of deterioration or damage to the sensor or cable, immediately dispose of them following proper procedures defined by your medical facility.

10.2.3 Cleaning the NIBP Cuff

To clean the NIBP cuff:

1. Remove the rubber bladder from the cuff.
2. Clean the cuff in detergent (mild soap washes).
3. Air dries the cuff.
4. Check the cuff and tube. If you see any signs of deterioration or damage, do not use it.
5. Put the rubber bladder back into the cuff.

Note — Never dry-clean the cuff.

10.2.4 Cleaning the Ear Thermometer

To clean the ear thermometer:

1. Hold the thermometer with one hand and clean the thermometer from the top with a wet lint-free cloth.
2. Use a dry cloth to clean the surface of the thermometer.
3. Check the thermometer and do not use if you see signs of deterioration or damage.

10.3 Disinfecting the Monitor

To avoid long-term damage to the equipment, do not disinfect unless directed by the hospital.

Warning **Never mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.**

Clean the equipment before disinfecting. Wipe the monitor after disinfection. You can use the following disinfectants:

- Ethanol (up to 70%), 1- and 2- Propanol (up to 70%)
- Glutaraldehyde (up to 3.6%)

Note —Disinfect the accessories according to the manufacturer's instructions. Use the general guidelines in this chapter if you do not have specific product cleaning instructions.

10.4 Sterilizing the Monitor

Sterilization is not recommended for this monitor, related products, accessories or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies.

Chapter 11 Maintaining the Battery

You can power the monitor with either an AC power source or its optional Lithium-ion battery.

Warning **Only use batteries specified by the manufacturer. Other batteries can cause monitor damage or personal injury.**

11.1 Charging LED

A battery symbol on the front panel indicates the charging LED.

- Flashing green: the monitor is connected to an AC power and charging the battery.
- Steady green: the monitor is fully charged.
- Off: the monitor is not connected to an AC power.

When the battery begins charging, the charging LED flashes. The battery needs 10 hours before it is fully charged. After the charging is complete, the charging LED is steady on.

Note — Always leave the monitor plugged into an AC power source when not in use. This ensures that the battery is charged. Check the battery status at least once a month.

11.2 Battery Indicators

When the monitor is powered by the internal battery, a battery power gauge displays on the top right corner of the screen and shows the remaining battery capacity. More lines inside the indicator mean a larger capacity remains.

The battery capacity depends on the method and frequency of use. A new, fully charged battery can support a continuously working monitor for at least 2 hours. However, NIBP measurements and printing might use more battery power.

When the gauge has 2 lines, the gauge flashes and the monitor sound an alarm, indicating a low battery. The monitor shuts off in 15 minutes if you do not plug it into an AC power source.

Note — When the battery does not have enough power to support normal monitor use, the monitor shuts off and will not function until you plug it into an AC power source.

11.3 Installing and Changing the Battery

Caution **Only authorized service representatives should install the monitor battery. Always remove the battery when transporting the monitor.**

To remove the battery:

1. Power off the monitor, unplug the power cable or other wires.
2. Lay the monitor, keep its screen up, and open the battery cover by screwdriver.
3. Push the battery holders to the side and pull the battery strap to release the battery.

To install the battery:

1. Push the battery into the compartment until it clicks into place.
2. Install the battery cover and tightening the screw.

Note — The monitor can use the battery specified by the manufacturer only, using other batteries might hurt the patient, user, and monitor.

Warning **Ensure that the battery is completely inserted into the monitor and that the battery door is firmly closed. An improperly installed battery could result in serious injury to neonatal patients if it falls out of the monitor.**

11.4 Recharging the Battery

Before putting the monitor into service, fully charge the battery. You can charge a battery in a monitor used to monitor patients.

To charge the battery:

1. Insert the battery into the monitor. See Installing and Changing the Battery on chapter 10.3.
2. Connect the monitor to an AC power source. The charging LED flashes, indicating the charging status.
3. Charge the battery at least 8 hours. The charging LED is steady on, and the battery power gauge is full. Continue charging the battery for at least 2 more hours.

11.5 Optimizing the Battery

The battery life depends on the time and frequency of usage. Correctly maintain and use the battery to extend the battery life span. The battery optimization function is password-protected. If the battery does not work according to specifications, replace the battery, or contact your service representative.

11.6 Disposing of a Battery

When a battery displays signs of damage or when it no longer charges, replace it. Dispose of the used battery in accordance with local laws and regulations.

11.7 Safety Information

Warning **Never open a battery or incinerate it. The battery could ignite, explode, leak or heat up, causing personal injury if not disposed of properly.**

Never heat the battery above 40℃.

Keep the battery out of the reach of children and in its original package until you are ready to use it. Under extreme conditions, the battery could leak, causing corrosive liquids to enter eyes and burn skin. If this occurs, flush with water and seek immediate medical attention.

The leakage current of the battery compartment may cause injury, please do not open the battery cover when the device is running.

Chapter 12 Maintenance and Troubleshooting

Warning **Failure to implement a satisfactory maintenance schedule for this equipment may cause undue equipment failure and potential health hazards.**

If you meet a problem with any of the equipment, pls contact professional service personnel.

12.1 Inspecting the Equipment and Accessories

Perform a visual inspection before every use.

1. Examine the unit exterior for general physical condition. Make sure that the monitor is clean, and the housings and connectors are not cracked or broken.
2. Inspect all accessories (cables, transducers, sensors and so on). If any show signs of damage, do not use.
3. Examine all system cables, the power plug and cord for damage. Make sure that the prongs of the plug do not move in the casing. If damaged, replace it with an appropriate one.
4. Inspect the patient cables, leads and their strain reliefs for general condition. Make sure there are no breaks in the insulation. Make sure that the connectors are properly engaged at each end to prevent rotation or other strain.

12.2 Maintenance Tasks and Test Schedules

The following tasks are for qualified service professionals only. Ensure that these tasks are carried out as indicated by the monitor's maintenance schedule, or as specified by local laws. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Table 12-1 Maintenance Tasks and Test Schedules

Maintenance Task and Test Schedule	Frequency
Safety checks	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the monitor has been dropped.
Performance assurance (including alarm system) listed below	At least once every two years or if you suspect that the measurement values are incorrect.
NIBP calibration	At least once every two years, or as specified by local laws.
Battery	See Chapter 11, Maintaining the Battery.

12.3 Troubleshooting

If you suspect a problem with an individual measurement, read the related section in this guide and double check the measurement settings.

Use the following tables to troubleshoot problems with the monitor and accessories.

Table 12-2 SpO_2 Problems

Problem	Solution
There is no SpO_2 waveform or values.	• Check the position of the sensor on the patient. • Check whether the red light of the finger probe is flashing. If there is no red light flashing, there might be poor contact. Check the extension cable and the connector. • Check whether the patient's arm is under pressure. Never make blood pressure and SpO_2 measurements on the same arm. • Check whether the environmental temperature is too low. Do not expose the patient's arm to cold air since this can affect readings.
The SpO_2 values turn on and off during SpO_2 monitoring.	In long term monitoring or operation, patient movement may result in SpO_2 interruptions. Keep the patient stabilized. Patient hand motion resulting in SpO_2 interruptions is normal.

Table 12-3 NIBP Problems

Problem	Solution
Measurement Timeout displays in the NIBP channel.	There is a malfunction during measurement and the monitor cannot process the measurement data. • Check the patient's status and connection. • Replace the cuff and restart the measurement.
Cuff Loose displays in the NIBP numeric pane.	Ensure the proper cuff size is being used. • Check the cuff position. • Check the extension tube for breakage and if the tube is damaged, replace it.

Pressure Range Exceeded displays in the NIBP numeric pane.	A blood pressure reading has exceeded the pressure range. The monitor cannot take any more NIBP readings until the alarm is acknowledged.
Measurement Error displays in the NIBP numeric pane.	This error can be caused by system self-testing, excessive patient and/or limb movement, or air leakage. Consult your service representative.

12.4 Disposing of the Monitor

Warning **To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the monitor appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.**

Do not dispose of waste electrical and electronic equipment as unsorted municipal waste. Collect it separately, so that it can be safely and properly reused, treated, recycled, or recovered.

Accessories

This appendix describes the accessories that are compatible with the ZD120 Patient Monitor.

Table A-1 Accessories list

Accessories	Specification
SpO_2 probe	Reusable Adult Clip Sensor, A1816-SA105PV
	Reusable Pediatric Clip Sensor, A1816-SP105PV
	Reusable Pediatric Rubber Sensor, A1816-SW105PU
NIBP cuff	Adult Y000A1
	Pediatric
Thermometer	IRT101B Ear Thermometer

Warning **Reusing single-use accessories can result in poor accessory performance or infections. Never use an accessory if there is damage to the packaging or the accessory.**

Only use accessories recommended by the manufacturer. Using other kinds of accessories might cause damage or personal injury.

The accessories specified above have passed toxicity and biocompatibility tests.

Always check the package for production and expiration dates, and validity and storage periods before using an accessory on a patient.

B Specifications

This appendix describes the specifications of the ZD120 Patient Monitor.

B.1 SpO_2 Specifications

The update rate for the SpO_2 value and pulse rate is typically 1 second. Data averaging and other signal processing on the displayed and transmitted data values of SpO_2 and pulse rate is not more than 20 seconds. Depending on the magnitude of difference between the alarm limit and the displayed value, the alarm signal generation delay may be from 1 second to 20 seconds.

Because pulse oximeter measurements are statistically distributed, only approximately two-thirds of pulse oximeter equipment measurements can be expected to fall within the Arms value measured by a CO-oximeter.

Note — It is not necessary to have a SpO_2 calibration when the monitor is in use.

The following table describes the SpO_2 specifications.

Table B-1 SpO_2 Specifications

Parameter	Specification
SpO_2 measuring range	0% - 100%
SpO_2 measuring accuracy	70%-100%: 2% (non-motion) 0%-69%: No defined.
Pulse rate range	20bpm -254bpm
Pulse rate accuracy	±3bpm
Display updated period:	≤2s
SpO2 / Pulse Rate averaging processing:	8 beat exponential
Pulse sound	Non-modulated
SpO_2 speed	25.0 mm/s
Measuring site	Finger
Wavelength range	500nm - 1000nm for all specified sensors
Maximum optical output power	150mW for all specified sensors
Pulse rate display	Numeric

1. Information about wavelength ranges can be useful for clinicians performing photo dynamic therapy.

2. Sensor accuracy was obtained by performing controlled hypoxia studies on healthy, non-smoking adult volunteers (according to EN ISO 80601-2-61). The SpO_2 readings have been compared to CO-oximeter measurements on arterial blood samples. To represent the general population, data from at least 10 subjects (male and female) with a wide range of skin color was taken to validate SpO_2 accuracy. Accuracy data for Masimo sensors is included in the sensor package insert.

B.2 Non-invasive Blood Pressure Specifications

The following table describes the NIBP specifications.

Table B-2 NIBP Specifications

Parameter	Specification
Measuring method	Oscillometric method
Measuring parameter	SYS, DIA, MAP
Unit	mmHg or kPa
Work mode	Manual, Auto, Stat, rule 1, rule 2
Cycle time	2,3,4,5,10, 15, 30, 60, 90, 120 minutes
SYS range	Adult: 30mmHg -270mmHg (4.0kPa - 36.0kPa) Pediatric: 30mmHg - 200mmHg (4.0kPa - 26.7kPa) Neonate: 30mmHg - 135mmHg (4.0kPa - 18.0kPa)
DIA range	Adult: 10mmHg - 210mmHg (1.3kPa - 28.0kPa) Pediatric: 10mmHg - 150mmHg (1.3kPa - 20.0kPa) Neonate: 10mmHg -95mmHg (1.3kPa - 13.3kPa)
MAP range	Adult: 20mmHg -230mmHg (2.7kPa - 30.7kPa) Pediatric: 20mmHg -165mmHg (2.7kPa - 22.0kPa) Neonate: 20mmHg -110mmHg (2.7kPa - 14.7kPa)
NIBP accuracy	Maximum mean difference: ±0.80kPa

	（±5mmHg） Maximum standard deviation: 1.06kPa (8mmHg)
Cuff pressure range	Adult/pediatric: 0mmHg - 300mmHg (0kPa - 40.0kPa) Neonate: 0mmHg - 150mmHg (0kPa - 20.0 kPa)
Static pressure accuracy	±3mmHg（0.4kPa）
Initial inflation pressure	Adult:160mmHg (21.3kPa) Pediatric: 140mmHg (18.6kPa) Neonate: 100mmHg (13.3kPa)
Deflation pressure	30mmHg above the last measured systolic value
Deflation time	<10 seconds (typical adult cuff)
Pulse rate range	30bpm -254bpm
Pulse rate accuracy	±5bpm or ±5%
Alarm delay	<10s

B.3 Temperature Specifications

The following table describes the TEMP specifications.

Table B-3 TEMP Specifications

Parameter	Specification
Measuring range	32℃～42.2℃（90.0～108.0°F）
Unit	℃ or °F
Accuracy	±0.1℃
Resolution	0.1℃
Updating time	Approximately 1 second
Alarm delay	<10s

B.4 Power Specifications

The following table describes the power specifications.

Table B-4 Power Specifications

AC Power Parameter	Specification

Mains power input	100V-240V～, 50 Hz/60 Hz, 1.4A-0.59A
Power input	140VA
Fuse	F3.15AL 250V
Battery Power Parameter	**Specification**
Capacity	Lithium ion 8.4V/5200 mAh
Charging time	10 hours (to 90% battery capacity)
Typical operating time	No less than 8 hours (with SpO2 measurement and NIBP measured every 15 minutes)
Charge mode	Automatic (with charge protection feature) when the monitor is connected to an AC power source.
Discharge protection	When the monitor is powered by battery, the monitor powers off if the battery power is almost depleted.

B.5 Display Specifications

The following table describes the display specifications.

Table B-5 Display Specifications

Parameter	Description
Type	Color TFT LCD
Display Size	7inch

B.6 Recorder Specifications

The following table describes the recorder specifications.

Table B-6 Recorder Specifications

Parameter	Description
Type	Thermal array recorder
Mode	Real time recording
Channel	1, 2, 3 channel(s)
Speed	50.0 mm/s

B.7 Physical specifications

The following table describes the physical specifications.

Table B-7 Recorder Specifications

Model	Net weight	Size
MHSZD120	1.652kg	148 mm (L) X 120 mm (W) X 247 mm (H)

B.8 Environmental Specifications

The following table describes the environmental specifications.

Table B-8 Environmental Specifications

Parameter	Specification
Temperature	Operating: 0℃ - 40 ℃ Storage: -20 ℃ - 55 ℃for the device
Relative humidity	Operating: 15% - 80% (non-condensing) Storage: 10% - 93% (non-condensing)
Barometric pressure	Operating: 59kPa ～ 107.4kPa Storage: 22kPa ～ 107.4kPa

B.9 Interface Specifications

The following table describes the interface specifications.

Table B-9 Interface Specification

Parameter	Specification
Isolation	1.5kV
Delay time	<0.5 s
Data output	Via Ethernet port
Defib sync	0 to 5V pulse
Software upgrade	USB port

C Alarm

C.1The physiological alarm information

Table C-1 Physiological alarm information

Source	Alarm information	Level	Reason and Solution
XX	XX Too High	HIGH or MED	XX value has exceeded the high alarm limit or below the low alarm limit. Check the patient physiological status, patient type and alarm limit setup.
	XX Too Low	HIGH or MED	
SpO_2	No Pulse	HIGH	The PR signal is too weak. The system cannot analyze the data. Check the patient, SpO_2 sensor and measure site.

Note — XX is representative of NIBP, SpO_2 and PR

Table C-2 Technical alarm information

Source	Alarm information	Level	Reason and Solution
SpO_2	SpO_2 Probe Off	LOW	The SpO_2 sensor disconnected from the patient or monitor or module. Check the sensor connection.
	SpO_2 No Sensor	LOW	
	Sensor Malfunction	LOW	
	SpO_2 Init Error	MED	There is a SpO_2 module error, or module or communication between the module and main board has failed, restart.
	SpO_2 Communication Stop	MED	
	SpO_2 Communication Error	MED	
	SpO_2 Alarm Limit	LOW	SpO_2 parameter value is over range, please contact your service representative
	SpO_2 Exceed	LOW	
	PR Alarm Limit Error	LOW	
	PR Exceed	LOW	
	PI Alarm Limit Error	LOW	
	PI Exceed	LOW	
NIBP	SYS Alarm Limit Error	LOW	NIBP parameter alarm limit is accidental modified; please contact your service representative.
	MAP Alarm Limit Error	LOW	
	DIA Alarm Limit Error	LOW	
	SYS Exceed	LOW	NIBP parameter value is over range, please contact your service representative
	MAP Exceed	LOW	
	DIA Exceed	LOW	
	NIBP Communication Stop	MED	There is a NIBP module error, or module or communication between the module and main board has failed, restart.
	NIBP Initialization Error	MED	
	NIBP Self-test Error	MED	
	NIBP Communication Error	MED	
	Cuff Loose	LOW	The blood pressure cuff is not connected or placed correctly or there is air leakage.
	Air Leak	LOW	
	Air Pressure Error	LOW	Ambient atmospheric pressure is abnormal, confirm whether the environment is fit for monitor specification, if any special cause impact

Table C-2 Technical alarm information continue)

Source	Alarm information	Level	Reason and Solution
NIBP (continue)	Low Signal	LOW	The patient PR is too weak or cuff loose, check the patient and replace the cuff site. If it fails replace the cuff.
	Range Exceeded	LOW	Probably the patient blood pressure is over range.
	Excessive Motion	LOW	Check the patient, stop movement on patient arm.
	Over pressure	LOW	Probably the air circuit is blocked, check if and try again.
	Signal Saturated	LOW	Excessive signal amplitude caused by movement or other reasons.
	NIBP Time Out	LOW	There is an error in the NIBP measurement. The system cannot analyze. Check the patient, connection or replace the cuff.
	Measurement Error	LOW	
	Cuff Type Err	LOW	The blood pressure cuff is different from patient type, check the patient type and replace.
	NIBP Illegally Reset	LOW	There is a malfunction during NIBP measurement, check whether air circuit blocked and remeasure.
	Temp Communication Error	MED	There is a communication malfunction between the monitor and thermometer has failed, restart.
	Temp Communication Stop	MED	
	Alarm Limit Error	LOW	TEMP parameter alarm limit is accidental modified, please contact your service representative.
	Exceed	LOW	TEMP parameter value is over range, please contact your service representative
Parameter's module	Module Initialization Error1	MED	There is a module error, or communication between the module and main board has failed, restart.
	Module Initialization Error2	MED	
	Module Initialization Error3	MED	
	Module Initialization Error4	MED	

	Module Initialization Error5	MED	
	PM 5V Too High	MED	The parameter module power failed, restart.
	PM 5V Too Low	MED	
	PM 3.3V Too High	MED	
	PM 3.3V Too Low	MED	
Power supply	Low Battery	MED	Charge the battery

D Glossary

This appendix defines some terminology and abbreviations.

D.1 Terminology Definitions

Table D Terminologie Definition

Term	Definition
DIA	Diastolic
HR	Heart rate
NIBP	Non-invasive blood pressure
PR	Pulse rate
SpO_2	Arterial oxygen saturation from pulse oximetry
SYS	Systolic pressure
TEMP	Temperature

E Electromagnetic Compatibility

This appendix lists the tests and compliance levels that make the ZD120 Patient Monitor suitable for use in the specified electromagnetic environment according to IEC 60601-1-2: 2014

E.1 Instructions for Use

Medical electrical equipment can either generate or receive electromagnetic interference. This product has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC60601-1-2: 2014, the international standard for EMC for medical electrical equipment. This IEC standard has been adopted in the European Union as the European Norm, EN IEC60601-1-2: 2014. Radio frequency (RF) interference from nearby transmitting devices can degrade performance of the product. Electromagnetic compatibility with surrounding devices should be assessed prior to using the product.

Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of medical equipment. See your service provider for assistance with the minimum recommended separation distance between RF communications equipment and the product.

The cables, sensors/transducers, and other accessories for which compliance is claimed are listed in this manual.

Warning **Use of accessories, transducers, and cables other than those specified may result in increased emissions and/or decreased immunity of the ZD120 Patient Monitor.**

The ZD120 Patient Monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it is used.

Caution

The following ports on the ZD120 Patient Monitor sensitive to electrostatic discharge during patient monitoring:

- **SpO_2**
  - **Follow these guidelines to reduce electrostatic discharge:**
  - **Do not touch the connector pins of the port.**
  - **When connecting and disconnecting cables to the ports, use ESD precautionary measures.**
- **Precautionary measures may include the following:**
  - **Make sure you are grounded prior to connection or touch grounded metal.**
  - **Wear an ESD grounding strap and an ESD protective garment.**
  - **Provide ESD training to all users. Users should understand what electrostatic discharge is, how damage can occur, and how to prevent ESD.**

E.2 Guidance and Manufacturer's EMC Declaration

The ZD120 Patient Monitor is intended for use in the electromagnetic environment specified in the following tables. The customer or the user of the ZD120 Patient Monitor should assure that it is used in such an environment.

E.2.1 Electromagnetic Emissions for all Equipment and Systems

Table E-1 Electromagnetic Emissions for all Equipment and Systems

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPR 11	Group 1	The ZD120 Patient Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The ZD120 Patient Monitor is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

E.2.2 Electromagnetic Immunity for all Equipment and Systems

Table E-2 Electromagnetic Immunity for all Equipment and Systems

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete, or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or

IEC 61000-4-4	±1kV for input/ output lines (length greater than 3m)	±1kV for input/ output lines (length greater than 3m)	hospital environment. If interference occurs, use filters on power input lines. Or ensure enough separation between signal and power lines.
Surge IEC 61000-4-5	±1kV line (s) to line(s) ±2kV line (s) to earth	±1kV line (s) to line(s) ±2kV line (s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle 0% U_T for 1 cycle and 70% U_T for 25/ 30 cycles 0% U_T for 250/ 300 cycles	0% U_T for 0.5 cycle 0% U_T for 1 cycle and 70% U_T for 25/ 30 cycles 0% U_T for 250/ 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ZD120 Patient Monitor requires continued operation during power mains interruptions; power the
Power frequency (50/60Hz) magnetic field IEC61000-4-8	30A/m 50Hz/ 60Hz	30A/m 50Hz/ 60Hz	Mains power quality should be that of a typical commercial or hospital environment.
Note — U_T is the AC mains voltage prior to application of the test level.			

E.2.3 Electromagnetic Immunity for Equipment and Systems not Life-Supporting

Table E-3 Electromagnetic Immunity for Equipment and Systems not Life-Supporting

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity Test	**IEC60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ZD120 Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[1] should be less than the compliance level in each frequency range.[2] Interference may occur in the vicinity of equipment marked with the following symbol: 

1.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 ZD120 Patient Monitor is used exceeds the applicable RF compliance level above, the ZD120 Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ZD120 Patient Monitor.

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

E.2.4 Recommended Separation Distances for Equipment and Systems not Life-Supporting

The ZD120 Patient Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ZD120 Patient Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ZD120 Patient Monitor is recommended below, according to the maximum output power of the communications

equipment.

Table E-4 Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and ZD120 Patient Monitor

	Separation Distance According to Frequency of Transmitter (m)[1]		
Rated Maximum Output Power OFF Transmitter (W)	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meter (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note —** 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.			