

Manufactured for:  
Dynarex Corporation  
10 Glenshaw Street  
Orangeburg, NY 10962  
USA • www.dynarex.com  
Made in China

Reorder Nos.  
**10840-10841**



# *Vital Signs Monitor*

*with SpO<sub>2</sub>, Blood Pressure  
and Temperature Modules  
User Manual*



**IPX1**

**R<sub>x</sub> Only**

**CAUTION:** Federal (USA) law prohibits this device to sale by or on the order of a physician.

**Model No. VS1**

## **Product Information**

- Product Model: VSI
- Product Name: Vital Signs Monitor
- Manufactured for: Dynarex Corporation  
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## **Revision History**

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

- Document No.: J/V6-O-326-001
- Revision number: V1.0
- Release time: June.2020

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## **Statement**

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The contents contained in this manual are subject to amendments without notification.

## Manufacturer's Responsibility

Only under the following circumstances will manufacturer be responsible for the safety, reliability and performance of the instrument:

- All the installation, expansion, readjustment, renovation or repairs are conducted by the personnel certified by manufacturer.
- The storage condition, operation condition and electrical status of the instrument conform to the product specification.
- The instrument is used in accordance with the user's manual.

## About this manual

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

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

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

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

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

### Conventions:

- ***Bold Italic*** text is used in this manual to quote the referenced chapter or sections.
- **【** is used to enclose screen texts.
- → is used to indicate operational procedures.

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# Chapter 1 General Introduction

## 1.1 Intended Use

The vital signs monitor is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters of patients, including Pulse Oxygen Saturation (SpO<sub>2</sub>), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Carbon dioxide (CO<sub>2</sub>) and Temperature (Temp).

The vital signs monitor is used to monitor vital signals for patients and is suitable for use in hospital environments including out-patient department, wards and NICU. It is not intended for helicopter transport, hospital ambulance or home use. And it is applicable for adult, pediatric and neonatal patients.



## 1.2 Main Unit

### 1.2.1 Front View



Fig.1-1

#### 1. Physiological alarm indicating lamp

When a physiological alarm occurs, this lamp will light up as defined below:

- High level alarm: the lamp quickly flashes red.
- Medium level alarm: the lamp slowly flashes yellow.
- Low level alarm: the lamp lights yellow without flashing.


#### 2. Technical alarm indicating lamp


When a technical alarm occurs, this lamp will light up as defined below:

- Medium level alarm: the lamp slowly flashes blue.
- Low level alarm: the lamp lights blue without flashing.

3. Fast temp/Infrared ear temp(optional)

4. Display screen

5.  NIBP: press this button to start or stop NIBP measurement.

6.  RECORD: press this button to start or stop recording.

7.  SUSPEND/SILENCE:

- Press this button to pause or reactive the alarms.
- Press and hold this button for 1 second to silence the system sound.

8.  Press this button to:

- Change the screen.
- Return to the main screen when a menu is opened.

9. Trim Knob

The Trim Knob is used for:

- Turn left or turn right to move the cursor.
- Press down to perform an operation, such as open a menu dialog or select one option.

10. NIBP connector

11. CO2 connector

12. SpO2 connector

13.  Power button

- Press this button to turn on the monitor after AC power is connected or the battery is installed.
- Press and hold it for 2 seconds to turn the monitor off.

14. Power indicating lamp

It is a LED that lights green and orange, the status of the LED is specified as follows:

- Green: When the AC mains is connected.

- Orange: When the AC mains is not connected and monitor is powered by battery.
  - Off: When the AC mains is not connected.
15. Battery charging indicating lamp
- Light up: When the battery is being charged.
  - Off: When the battery is fully charged or no battery in monitor.
16. Handle

### 1.2.2 Side View

Left side:



Fig.1-2

### 1.2.3 Rear View



Fig.1-3

1. Temp connector
2. Grounding terminal

Base on the requirements of safety and anti-interference, the monitor must be connected with equipotentiality system individual. When connected together, the various parts of an equipment or of a system will be brought to the same potential, not necessarily being the earth (ground) potential.

Connected method: Use the green/yellow equipotential grounding cable and connect it to the equipotentiality terminal of the monitor and the equipotential grounding system.

3. AC power input connector  
Connect to USB device, such as keyboard and mouse.
4. Serial port
5. Wired network connector

Standard RJ45 socket, it is used for connection with the central monitoring system provided by manufacturer.

6. USB socket
7. Nurse call connector
8. Fan and horn orifice

### Caution

- 
- **The VGA, USB and SD interface can only connected to the equipment with standard interface.**
  - **All the simulation and digital equipment connected with this monitor must be the products certified by the designated IEC standards (e.g. IEC 60950 Data Processing Equipment Standard and IEC 60601-1 Medical Equipment Standard).Moreover, all configurations shall abide by the content of the valid edition of IEC 60601-1 System Standard. Connect the additional equipment to the staffing medical system at the input/output signal port and confirm whether the system conforms to the IEC 60601-1 Standard. If you have any question, please contact the supplier.**
  - **When the signal interfaces like patient cable socket and network connector are simultaneously connected with multiple equipments, the total leakage caused cannot exceed the tolerance.**
- 

### Note

- 
- **The wired network connector is used for connection with the central monitoring system provided by manufacturer.**
- 

### 1.2.4 Bottom View



Fig.1-4

## 1.3 Work mode

The monitor has two working modes: Clinic Mode and Monitor Mode.

### 1.3.1 Clinic Mode

Clinic Mode refers to that the monitor is used for monitoring of a number of patients one by one by outpatient doctor. Each patient has his/her own ID number, and the monitoring results of patients are saved according to their ID numbers. When a patient with the same ID number appears again, the device will automatically find out the previous monitoring data, and will add current data to the previous one.

Clinic mode may be used in one of the following occasions:

1. Medical personnel are present, e.g. monitoring of patients by outpatient doctor or house-call doctor;
2. A number of measurements of many patients, e.g. monitoring of patients by physical checkup doctor;
3. Rounds of wards, e.g. doctor or nurse can monitor relevant physiological status of patient by the monitor when checking in ward.

### 1.3.2 Monitor Mode

Monitor Mode refers to that the monitor is used to monitor the same patient in ward for long time. In this mode, the small-sized monitor is used to monitor the patient's SpO<sub>2</sub>, NIBP and CO<sub>2</sub>.

Monitor mode may be used in one of the following occasions:

1. Monitor of a single patient for a long time, e.g. hospitalized patient;
2. Ward without on-duty medical personnel;
3. Remote monitoring (connect to central unit through network).

### 1.3.3 Difference Between two Modes

	Monitor	Clinic
Alarm Pause	With	Without
Technical Alarm	With	With
Physiological Alarm	With	Without
Recording Review	With	With

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Alarm Review	With	With
Parameter Storage	With	With
Alarm Messages Storage	With	Without
Nurse Call	With	Without
Communicating with Center Computer	With	With
Multi-patient	Without	With

## Chapter 2 Safety

### 2.1 Safety Information

#### Warning

- 
- Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.
- 

#### Caution

- 
- Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
- 

#### Note

- 
- Provides application tips or other useful information to ensure that you get the most from your product.
- 

#### 2.1.1 Warning

##### Warning

- 
- No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.
  - The monitor is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operations on it.
  - The monitor can only be applied to one patient at one time.
  - Before using, please check the connecting cables and accessories are in correct working order and operating condition.
  - Please connect the monitor to a socket with protective earth. If the socket does



not have protective earth conductor, please do not use the socket and use battery to provide power to the monitor.

- To avoid explosion hazard, do not use the monitor in the presence of flammable anesthetics, vapors or liquids.
  - Do not open the monitor housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by manufacturer only.
  - When using the monitor with electrosurgical units (ESU), make sure the patient is safe.
  - If you spill liquid onto the equipment or accessories, particularly if there is a chance that it can get inside the tubing or the measurement device, contact your service personnel. Please insure the measurement device and its accessories dry during using electrosurgery and defibrillator.
  - Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.
  - Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring. Auditory alarm signal sound pressure levels, which are less than ambient levels, can impede operator recognition of alarm condition.
  - The physiological data and alarm messages displayed on the monitor are for reference only and cannot be directly used for diagnostic interpretation.
  - To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patient or personnel.
  - The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
  - The device is only for use by or on the order of a physician.
  - The device may not function properly due to the strong magnetic and radio frequency fields generated by the MR scanner.
-

## 2.1.2 Caution

### Caution

- 
- To ensure patient safety, use only parts and accessories specified in this manual.
  - At the end of its service life, the monitor, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the monitor, please contact us.
  - Magnetic and electrical fields are capable of interfering with the proper performance of the monitor. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
  - Before connecting the monitor to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the monitor's label or in this manual.
  - Always install or carry the monitor properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.
  - When THERMAL CUT-OUT operates, the monitor will function continually without any SAFETY HAZARD by using its rechargeable battery. However, the battery is not being charged anymore. While the battery is low the monitor will give both visible and audible warnings in 5 minutes.
  - The American mains plug whose ground is in the same plug with its other two cords is Hospital Only. The supply cord should be connected to the sockets which are Hospital Only to achieve grounding reliability.
- 

## 2.1.3 Note

- Put the monitor in a location where you can easily see the screen and access the operating controls.
- Keep this manual in the vicinity of the monitor so that it can be obtained conveniently when needed.

- **The software was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.**
- **This manual describes all features and options. Your monitor may not have all of them.**
- **The service life of this monitor is 5 years. At the end of its service life, the monitor, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact manufacturer or its representatives.**
- **Loss of data**

**Should the monitor at any time temporarily lose patient data, close patient observation or alternative monitoring devices should be used until monitor function is restored.**
















**When the AC power supply has been interrupted of the monitor, the monitor can change to use the battery supply DC power.**





**When the monitor lost of power and has been powered off, the settings prior to the power loss are restored. After restarting the monitor, if select continuing the current patient, the previous settings will be maintained, and if a new patient is selected, the corresponding factory default settings will be loaded.**

## 2.2 Safe Operation Conditions





Methods of sterilization or disinfection recommended by the manufacturer	Sterilization: not applicable Disinfection: Refer to <i>Maintenance and Cleaning</i> chapter
Electromagnetic interference	No mobile telephone nearby
Electrosurgical interference damage	No damage
Diathermy instruments influence	Displayed values and prints may be disturbed or erroneous during diathermy

## 2.3 Equipment Symbols

Symbol	Symbol Note
	Type CF applied part, defibrillation protected The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.
	Type BF applied part, defibrillation protected The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.
	Refer to instruction manual.
	Non-ionizing radiation
	Dangerous voltage
	Equipotential grounding
<b>100V-240V~</b>	Alternating current input range: 100V-240V
	USB socket
	Network connector
	Nurse call connector
	Manufacture date
	Manufacturer
	Serial number
	Authorized representative in the European Community. Indicates the authorized representative in the European Community. This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.
	CE mark
	NRTL mark

Symbol	Symbol Note
	Temperature limitation
	Humidity limitation
	Pressure limitation
<b>IPX1</b>	Degree of protection against ingress of liquid
<b>Hospital Only</b>	Symbol marked on a tag attached to the supply cord of the monitor to warn that the supply cord should be connected to the sockets which are Hospital Only to achieve grounding reliability.
<b>SpO<sub>2</sub></b>	Short for "Pulse Oxygen Saturation"
<b>NIBP</b>	Short for "Non-invasive Blood Pressure"
<b>CO<sub>2</sub></b>	Short for "Carbon dioxide"
<b>Temp</b>	Short for "Temperature"
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.

## 2.4 Packaging symbols

Symbol	Symbol Note
	Fragile. Show transport package contents fragile, so handling should be handled with care.
	Upward. It shows the correct position of the transport package is upright.
	Guard against wet. Show packages afraid be wet.
	Stacking layer limit. Same packing maximum stacking layers, N represents the number of layers limit. (N is 6).

## Chapter 3 Operations

### 3.1 Unpacking and Checking

#### 1. Unpacking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier. If the packing case is intact, open the package.

2. Remove the monitor and accessories carefully.

3. Keep all the packaging materials for future use in transportation or storage.

4. Check the monitor and accessories

Check the monitor and its accessories one by one in accordance with the packing list. Check to see if the parts have any mechanical damages. In case of problems, please contact us or our agent.

#### Warning

- 
- **Keep the packing materials out of children's reach. Disposal of the packing materials should observe the applicable waste control regulations.**
  - **The monitor might be contaminated during storage and transport. Before use, please verify whether the packages, especially the package of disposable accessories, are intact. In case of any damage, do not apply it to the patient.**
  - **Please ensure the monitor is working under specified conditions; otherwise, the technical specifications mentioned in this manual will not be met, thus possibly leading to damage of equipment and other unexpected results.**
- 

#### Caution

- 
- **Please put the monitor onto a horizontal and stable supporting plane. Avoid putting the monitor in the locations where it easily shakes or wobbles. Enough space shall be left around the monitor so as to guarantee normal ventilation.**
-

## 3.2 Getting Started

### 3.2.1 Inspecting the Monitor

1. Before you start to make measurements, carry out the following checks on the monitor including all connected modules.
  - Check for any mechanical damage;
  - Check for any incorrect connection of all the external cables and accessories.
2. Plug the power cord into the AC power source. If you are using battery power, ensure that the battery has sufficient power for monitoring. When you use a battery for the first time, you must charge it, following the instructions given in **Battery** chapter.

### 3.2.2 Starting the Monitor

Press the power switch, the technical alarm lamp will light up in blue, and then the physiology alarm lamp lights up in yellow and red, at last goes out. Meanwhile the system clanks and enters main screen and the temperature module displays screen information after a sound of “ba”.

#### Warning

- 
- **If the monitor is mechanically damaged, or if it is not working properly, do not use it for any monitoring procedure on a patient. Contact your service personnel.**
- 

#### Caution

- 
- **The monitor does not have mains switch. The monitor is switched completely only by unplugging the power cable from the AC power source.**
- 

#### Warning

- 
- **Mains plug is intended to be used as isolation device from the supply mains. Please always make mains plug easily to operate.**
-

### 3.2.3 Starting Monitoring

1. Decide which parameter should be monitored or measured.
2. Install required modules or sensors.
3. Check whether the installation of modules or sensors is correct.
4. Check whether all kinds of settings are correct.
5. Start monitoring on a patient. Detailed information refers to the related chapters.

### 3.3 Shutting off the Monitor



Please follow the below steps to shut off the monitor:

1. Confirm that the patient monitoring is finished.
2. Disconnect the cables and sensors from the monitor.
3. Confirm that the monitoring data is stored or cleared.
4. Press the power switch and hold it for 1s to turn off the monitor.

#### Caution

- 
- **If the monitor can't be switched off normally, forced close the monitor by pressing and holding the power switch for more than 5s. This may cause some damages to the device.**
- 

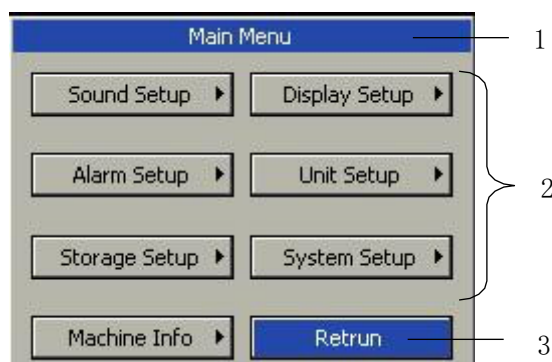
### 3.4 Operation Modes

1. Select  or  in the Icons Area after starting the monitor to enter **【 Mode Select 】** menu.
2. Select **【 Clinic Mode 】** or **【 Monitor Mode 】** to enter **【 Continue 】** menu.
3. If the patient you are going to monitor is the one displayed in **【 Continue 】** menu, please select **【 Continue 】** .
4. If the patient is a new one, please select **【 New Patient 】** .
5. Input the new patient's information in **【 New Patient 】** menu.

### 3.5 Using Menu

Turn the Trim Knob left or right to select **【 Menu 】** to open the following main menu. You can finish most operations and sets through **【 Menu 】** . The main menu under Monitor Mode is different from that under Clinic Mode. The following figure is main menu under Monitor Mode.





Style of other menus is the same as that of the main menu, parts of which are as follows.

1. Menu title: Name of the menu.
2. Main display area: Area to display options, buttons or prompt messages. “▶” means you can enter its submenu.
3. **【Return】** : Press this button to exit the menu.

## 3.6 General Setup

### 3.6.1 Changing the Language

1. Select **【Menu】** → **【System Setup】** .
2. Select **【Language】** →choose a desired language.
3. Select **【Return】** →exit the current menu.

### 3.6.2 Setting the Screen Saver

Under the Clinic Mode:

1. Select **【Menu】** → **【Display Setup】** .
2. Select **【Screen Save Time】** →choose a desired setup.

### 3.6.3 Setting the Date and Time

1. Select **【Menu】** → **【System Setup】** → **【Date time Setup】** .
2. Set **【Year】** , **【Month】** , **【Day】** , **【Hour】** , **【Min】** and **【Sec】** to a desired value.
3. Select **【Modify】** → **【Yes】** to finish setting.

### 3.6.4 Adjusting the Volume

#### ● Alarm Volume

Under the Monitor Mode:

1. Select **【Menu】** → **【Sound Setup】** .
2. Select **【Alarm Volume】** →choose a desired value.

#### ● Beep Volume

1. Select **【Menu】** → **【Sound Setup】** .
2. Select **【Beep Volume】** →choose a desired value.

### 3.7 Default Setups

#### Caution

- 
- **In case of power failure, after restart, the system will restore the setup before power failure automatically.**
- 

It is possible that you change some setup during operation, but these changes are not always appropriate or correct. Therefore, you may restore some setup to factory default setup during actual operation to ensure that various setup of the monitor is applicable to the monitored patient.

1. Select **【Menu】** → **【System Setup】** to open **【System Setup】** menu.
2. Select **【Default Config】** to enter **【Remind】** menu.
3. Select **【Yes】** to load the user config and alarm limit shown in the Remind menu. Select **【No】** to exit the Remind menu.

### 3.8 Nurse Call

Nurse Call is a function that the monitor will send signal to call nurse when the alarm conditions destined occur.

The monitor has a nurse call output connector, connect the connector to the nurse call system of the hospital by the nurse-call cable, the nurse call function can be realized.

The nurse call function is valid when the following conditions are concurrent:

- The nurse call function is open.

——An alarm condition destined occurs.

——The monitor is not in the state of alarm paused or system silence.

## Warning

- 
- **The nurse call function should not be used as the primary patient alarm inform source. It is necessary for combining the auditory and visual alarm signal and the patient clinical feature and symptom as the primary information to medical and nursing staff about the physiological condition of the patient.**
- 

### 3.8.1 Turning on/off Nurse Call

1. Select **【Menu】** → **【System Setup】** → **【Machine Mainte】** → enter the required password.
2. Select **【Factory Mainte】** → enter the required password.
3. Select **【Nurse Call】** , set it to **【on】** .

### 3.8.2 Setting Nursecall Type

1. Select **【Menu】** → **【System Setup】** → **【Machine Mainte】** → enter the required password.
2. Select **【Nurse Call】** to enter the nurse call menu.
3. Set **【Nursecall Type】** to **【Normally Open】** or **【Normally Closed】** .

### 3.8.3 Setting Call Time

1. Select **【Menu】** → **【System Setup】** → **【Machine Mainte】** → enter the required password.
2. Select **【Nursecall Setup】** to enter nurse call setup menu.
3. Set **【Call Time】** to **【1 Sec】** or **【Continuous】** .

### 3.8.4 Triggering Nurse Call

1. Select **【Menu】** → **【System Setup】** to enter system setup menu.
2. Select **【Nursecall Setup】** to enter nurse call setup menu.
3. Set **【PhyAlarm Trigger】** and **【TecAlarm Trigger】** to **【Off】** , **【Low】** , **【Med】** or **【High】** .



### 3.9 ID Name

You need to set ID name under the Clinic Mode.

1. **【Menu】** → **【System Setup】** → **【ID Name】** to enter ID Name menu.
2. Define the ID Name rule according to your usage.

### 3.10 Patient ID

You can use a barcode scanner to input the Patient ID, please go through the following steps before input the patient ID:

1. Open the barcode scanner switch in factory configuration;
2. Connect the barcode scanner to the monitor. “” shown in the bottom of the display screen indicates the barcode scanner is supported by monitor. Otherwise, “” displayed indicates the barcode scanner can't be used.

#### Caution

---

- **In case of interfere with other USB device, including USB keyboard, please use the barcode scanner provided or designated by the manufacturer.**
  - **Please check whether the switch of scanner is open before start the barcode scanner.**
  - **Only in the patient ID input interface can the barcode scanner work. The monitor will not process any input operation when using the scanner in other input interface.**
- 

### 3.11 Viewing the Machine Info

1. Select **【Menu】** → **【Machine Info】** .
2. View the detail information about this monitor.

## Chapter 4 User Interface

### 4.1 Display Style

Display style of user interface can be set according to your need.

Including:

- Screen brightness.
- Display color of wave and parameter.
- Sweep mode of wave.

#### 4.1.1 Adjusting the Screen Brightness

1. Select **【Menu】** → **【Display Setup】** .
2. Select **【Back Light】** →set its value.

#### 4.1.2 Selecting the Color

1. Select **【Menu】** → **【Display Setup】** .
2. Select **【Color Setup】** →choose a desired color for the parameter and waveform.
3. Select **【Default Setup】** →set all the parameters and waveforms to default color.

#### 4.1.3 Screen Switch

You can set the screen layout as required. The setting method is as follows:

1. Select **【Menu】** → **【Display Setup】** .
2. Select **【Screen Switch】** →choose a desired screens to display. There are **【NIBP Review】** , **【Trend Screen】** and **【Alarm Screen】** .

#### 4.1.4 Standby Mode

The monitor has standby function under the clinic mode. Please set as follows:

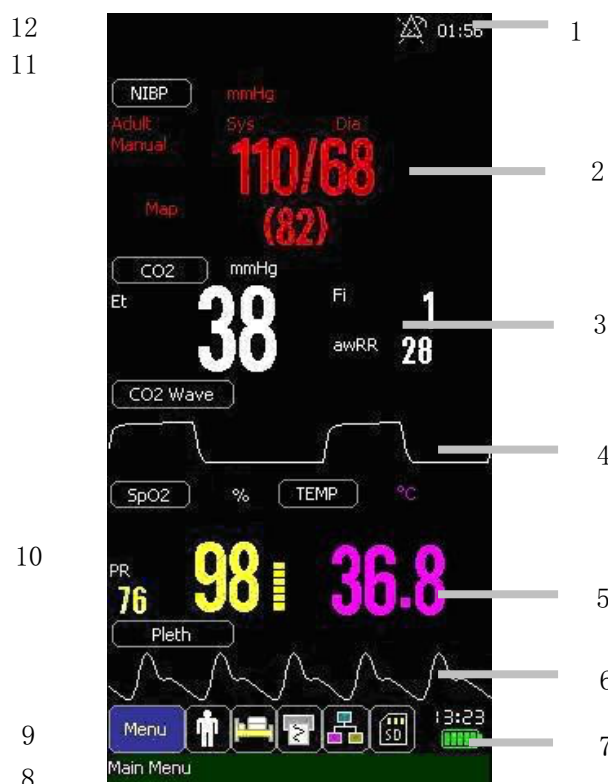
1. Select **【Menu】** → **【Display Setup】** → **【Screen Save Time】** .
2. Set the screen save time, the monitor will enter standby mode while with no operations during the setting time.
3. Press any button (including the touch screen) to exit the standby mode.

## 4.2 Screen Layout

The monitor has configured with a color TFT LCD to display parameters and waves of patient's SpO<sub>2</sub>, NIBP and CO<sub>2</sub>. The following figures are screens of the monitor.

### 4.2.1 Standard Screen

Parameters displayed under the screen are SpO<sub>2</sub>, CO<sub>2</sub>, SpO<sub>2</sub>, and TEMP. Waves displayed under the screen are SpO<sub>2</sub> and CO<sub>2</sub>.



1. Alarm Pausing/Silence Area

It is to display alarm pausing icon and time or silence icon.

2. NIBP Parameter Area

It is to display NIBP parameters. Select “NIBP” to enter **【NIBP Setup】** menu.

3. CO<sub>2</sub> Parameter Area

It is to display CO<sub>2</sub> parameters. Select “CO<sub>2</sub>”to enter **【CO<sub>2</sub> Setup】** menu.

4. CO<sub>2</sub> Wave Area

It is to display CO<sub>2</sub> wave. Select “CO<sub>2</sub> Wave” to enter **【CO<sub>2</sub> Wave Setup】** menu.

5. TEMP Parameter Area

It is to display temperature parameter. Select “TEMP” to enter **【TEMP Setup】** menu.

6. SpO<sub>2</sub> Wave Area

It is to display SpO<sub>2</sub> wave. Select ” SpO<sub>2</sub> Wave” to enter **【 SpO<sub>2</sub> Wave Setup 】** menu.

7. Time and Battery Status Displaying Area

It is to display system time and battery status.

8. Prompt Messages Area

It is to display the menu's meaning which the cursor is on or prompt messages.

9. Icons Area

From left to right, the icons are **【Menu】** , **【Patient Information】** , **【Recorder Setup】** , **【Network Setup】** and **【SD Card】** .

10. SpO<sub>2</sub> Parameter Area

It is to display SpO<sub>2</sub> parameters. Select “SpO<sub>2</sub>” to enter **【SpO<sub>2</sub> Setup】** menu.

11. Physiological Alarm Area

It shows the physiological alarm messages. When multiple alarms of different levels occur at the same time, the monitor will give visual and audible alarm indications according to the alarm level.

12. Technical Alarm Area

It shows technical alarm messages. When multiple alarms of different levels occur at the same time, the monitor will give visual and audible alarm indications according to the alarm level.





The screen is called “Trend Screen” under Monitor Mode while called “Clinic Review” under Clinic Mode. Under the screen you can view the measurement of each parameter.

- **Storage Setup**

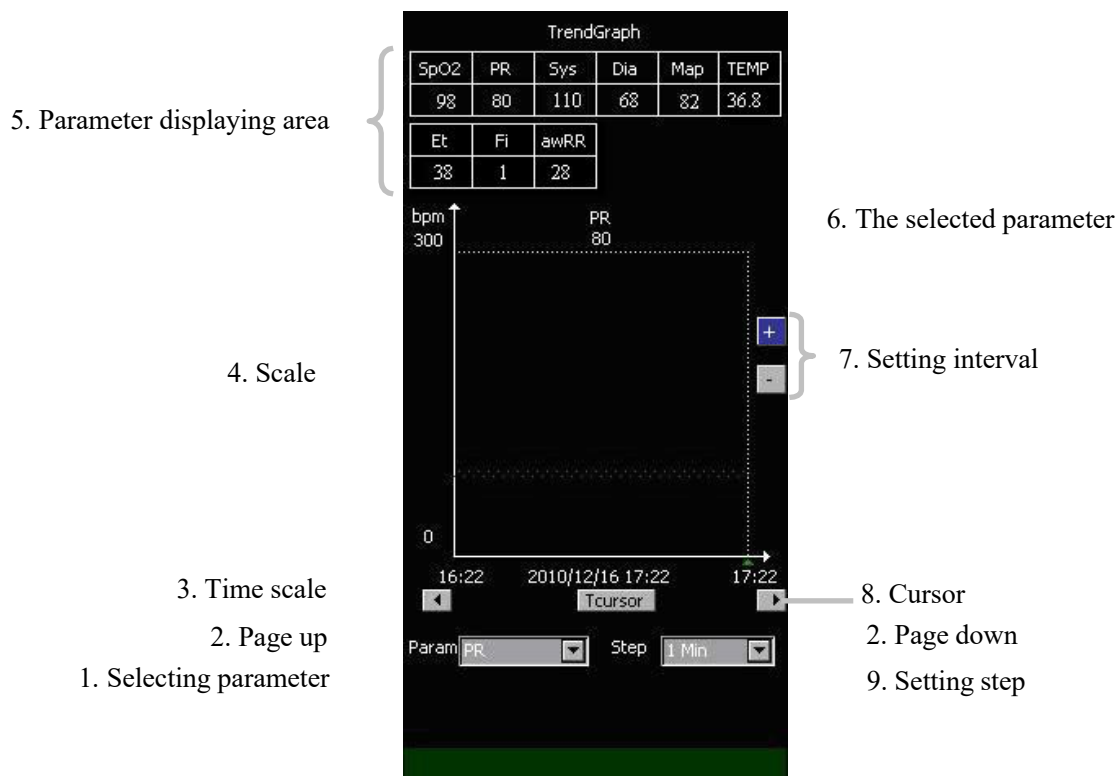
1. Select **【Menu】** → **【Storage Setup】** to enter **【Storage Setup】** menu.
2. Set **【Trend StorInter】** to a desired value between **【1 Min】** , **【1 Min】** and **【10 Min】** .

#### 4.2.4 Alarm Screen



Under the screen, you can view each alarm event including its data, time and the parameters leading the alarm.

### 4.2.5 Trend Graph



You can enter TrendGraph screen through the screen changing button as shown in *chapter 1 section 1.2 main unit*. Under the screen, you can do the following operations:

1. Selecting the parameter

Turn the Trim Knob to select **Param**, Press the Trim Knob, **Et/Fi**, **awRR**, **NIBP**, **SpO2**, **PR** and **TEMP** will pop up. Turn and press the Trim Knob to select the parameter you need to view its trend graph. And the selected parameter will turn to be the parameter you selected just now.

2. Turning pages

You can turn pages through the page up and page down button to browse more trendgraph information. The left button is page up button while the right one is page down button. As shown in the above figure.

3. Time scale

The scale is to display time. You can browse the selected parameter's trend graph during the time between the left time and the right time on the time scale. The date and time displayed under the time scale is the date and time the cursor now indicates.

4. Scale

It is to scale the value of parameters.

5. Parameter displaying area

It is to display values of all the monitored parameters at the time where the cursor indicates now.

6. The selected parameter

It is to display the name of the selected parameter and its value at the time where the cursor is.

7. Setting interval

Interval is the time between the left time and the right time on the time scale. It can be 1, 2, 3, 4 or 5 hours. Turn the Trim Knob to select **【Setting interval】**. The sign of “+” is to add the time value while “-” is to decrease it. Each time you press the two buttons, the time will add 1 hour or decrease 1 hour.

8. Cursor

It is to indicate the selected parameter's trend graph at the time where it is. Turn the Trim Knob to select **【Tcursor】** button, the color of the button will turn into green like the cursor. Then turn Trim Knob to move the cursor where you need.

9. Setting step

Step is the time the cursor move on the time scale at one time. Turn the Trim Knob to select **【Step】**, then the options of **【1 Min】**, **【5 Min】** and **【10 Min】** will pop up, select one you need.

## 4.3 Patient Information

Select “Patient Information” icon to enter **【Patient Info】** menu. In the menu you can view patient's ID, Name, Type, Gender and Age.

### 4.3.1 Continuous the same patient

When the patient to be monitored is the one displayed in **【Patient Info】** menu, please select **【Return】**. The monitor will continuous the monitoring of the same patient and add current data to the previous one.

### 4.3.2 Admitting a new patient

When the patient to be monitored is a new one, please select **【New Patient】** to enter **【New Patient】** menu. Input new patient's ID, Name, Type, Gender and Age. At last, select **【OK】** to keep the setting of new patient.

### 4.3.3 Patient ID

- Clinic Mode

In **【Patient Info】** menu, when selecting **【New Patient】** , **【Patient ID】** will be created according to **【ID Name】** automatically. You can also input **【Patient ID】** through barcode scanner or input manually. Through **【Patient Info】** menu, you can change the patient info. After amending the patient info, selecting **【Return】** to save the changing.

- Monitor Mode

In **【Patient Info】** menu, when selecting **【New Patient】** , you need to input **【Patient ID】** through barcode scanner or input it manually. Through **【Patient Info】** menu, you can change the patient info. After amending the patient info, selecting **【Return】** to save the changing.

### Caution

- 
- No matter where the current cursor is in the New Patient dialog box, the successful scanning result by using a barcode scanner will fill in the Patient ID automatically. The ID will be replaced instead of accumulating when repeated scanning occurs.
  - The history data will be deleted while admitting a new patient under Monitor Mode.
- 

## 4.4 Demo

### 4.4.1 Turn on Demo

1. Select **【Menu】** → **【System Setup】** to enter the system setup menu.
2. Set **【Demo】** to **【On】** , a password entering window will pop up.
3. Input the desired password and then select **【OK】** to enter the demo mode.

#### 4.4.2 Turn off Demo

1. Select **【Menu】** → **【System Setup】** to enter the system setup menu.
2. Set **【Demo】** to **【Off】** .

#### 4.5 Machine Maintenance

Select **【Menu】** → **【System Setup】** → **【Machine Mainte】** →input the required passwords to enter **【Machine Mainte】** menu.

1. NIBP Test: Select **【NIBP Test】** to test NIBP.
2. NIBP PR: Select **【On】** or **【Off】** .
3. Touch Adjust: Select **【Touch Adjust】** to adjust touch screen.
4. Nurse Call: Select **【Nurse Call】** to set nurse call.
5. Desat limit: Set SpO2 desat value.
6. Alarm suspend Time: Set the value of Alarm suspend Time.
7. Factory Mainte: Used for factory maintenance.

## Chapter 5 Alarm

Alarm refers to a prompt that is given by the monitor for medical personnel through visual, audible and other means when a vital sign appears abnormal or technical problem occurs.

### Note

---

- **The monitor generates all the audible and visual alarms through speaker, alarm lamp and screen. When the monitor powers on, the alarm lamp will be lighted one time and the speaker will give a beep voice, which indicates the alarm system of the monitor is working order.**
  - **When users find the alarm system is improper or the alarm indicators and alarm sound is not synchronous, verify the functionality of the alarm system is needed. Pull out and insert the probe to verify the technical alarm and change the alarm limit to exceed the physiological measure value to verify physiological alarm.**
  - **After the supply mains have been interrupted, the alarm system will run as before when restart the monitor.**
- 

### Warning

---

- **Do not set the alarm limits to extreme values that can render the alarm system useless.**
  - **To check the alarm pre-set before use, the alarm pre-set is default by the manufacture, the users may select different pre-set according to the patient. The alarm pre-set will recover to the defaulted one as soon as a new patient is connected.**
  - **If different alarm presets are used for the same or similar equipment in any single area, a potential hazard may exist.**
-

## 5.1 Alarm Category

According to character of alarm, the monitor's alarms can be classified into three categories: physiological alarms, technical alarms and prompt messages.

- **Physiological alarms**

Physiological alarms are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition. Physiological alarm messages are displayed in the physiological alarm area.

- **Technical alarms**

Technical alarms are triggered by a device malfunction due to improper operation or system problems. The problems may result in system abnormal operation or irresponsible monitoring parameters. Technical alarm messages are displayed in the technical alarm area.

- **Prompt messages**

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

## 5.2 Alarm Level

According to severity of alarm, the monitor's physiological alarms are classified into three categories: high level alarms, medium level alarms and low level alarms.

- **High level alarms:** Indicate that the patient is in a life threatening situation and an emergency treatment is necessary. This is the highest level alarm.
- **Medium level alarms:** Indicate that the patient's vital signs appear abnormal and an immediate treatment is required.
- **Low level alarm:** Indicate that the patient's vital signs appear abnormal and an immediate treatment may be required.

The levels of some physiological alarms are predefined before the monitor leaves the factory and can't be changed by users. While some levels of physiological alarms can be changed by users.

The monitor's technical alarms are classified into two categories: medium level and low level.

The levels of technical alarms are predefined before the monitor leaves the factory and can't be changed by users.

## 5.3 Alarm Indicators

When an alarm occurs, the monitor will indicate it through the following means:

- Alarm tone: According to alarm level, speaker in the monitor gives alarm sound in different tone.
- Alarm lamp: According to alarm level, alarm lamp on monitor flashes in different color and speed.
- Alarm message: Alarm messages are displayed on the screen.
- Flashing numeric: The numeric of parameter in alarm flashes.

### Caution

- 
- **The concrete presentation of each alarm prompt is related to the alarm level.**
- 

#### 5.3.1 Alarm Tone

The different level alarms are indicated by the system in following different audio ways:

Alarm level	Audible prompt
High	“DO-DO-DO-----DO-DO, DO-DO-DO----- DO-DO”
Medium	“DO-DO-DO”
Low	“DO-”

#### 5.3.2 Alarm Lamp

When a physiological alarm occurs, the alarm levels are indicated in the following different visual ways:

Alarm level	Visual prompt
High	Alarm lamp flashes in red with 2 Hz.
Medium	Alarm lamp flashes in yellow with 0.5 Hz.
Low	Alarm lamp lights on in yellow without flashing.



When a technical alarm occurs, the alarm levels are indicated in following different visual ways:

Alarm level	Visual prompt
Medium	Alarm lamp flashes in blue with 0.5 Hz.
Low	Alarm lamp lights on in cyan without flashing.

### Caution

- 
- **When multiple alarms of different levels occur at the same time, the monitor will select the alarm of the highest level and give visual and audible alarm indications.**
- 

### 5.3.3 Alarm Message

- **Physiological alarm**

Physiological alarm messages are displayed in the physiological alarm area. The system uses different symbols and background colors for the alarm messages to match the alarm level as follows:

Alarm level	symbol	background color
High	***	red
Medium	**	yellow
Low	*	yellow

### Caution

- 
- **The monitor won't give physiological alarm under clinic mode.**
- 

- **Technical alarm**

Technical alarm messages are displayed in the technical alarm area. The system uses different symbols and blue background color for the alarm messages to match the alarm level as follows:

Alarm level	symbol	background color
Medium	**	yellow
Low	*	cyan

### ● Prompt messages

Prompt messages are displayed in technical alarm area. Prompt messages have no color and visual and audible alarm indication.

## 5.4 Setting Alarm Volume

You need to set alarm volume only under monitor mode.

1. Select **【Menu】** → **【Sound Setup】** .
2. Select **【Alarm Volume】** →you can set the alarm volume of system.
3. And you can set the alarm volume values between X and 5. X can be set as 0, 1, 2, 3, 4, 5. X is the minimum alarm volume and 5 is the maximum volume. (The minimum alarm volume X can be set in the Maintenance Mode with password, the password can only be get from the factory.)

## 5.5 Parameter Alarm

You need to set **【Alarm Setup】** only under Monitor Mode.

### 5.5.1 Turn on/off the Alarm

Take SpO<sub>2</sub> for example:

1. Select **【Menu】** → **【Alarm Setup】** .
2. Set **【Class】** to any option but **【Off】** to turn on the alarm, while set **【Class】** to **【Off】** to turn off the alarm.

### 5.5.2 Setting Alarm Level

Take SpO<sub>2</sub> for example:

1. Select **【Menu】** → **【Alarm Setup】** .
2. Set **【Class】** to **【Medium】** or **【High】** .


### 5.5.3 Setting Alarm Limit


Take SpO<sub>2</sub> for example:


1. Select **【Menu】** → **【Alarm Setup】** .


2. Set **【High Lim】** and **【Low Lim】** to a desired value.

## 5.6 Pausing Alarms

Press the button  on the front panel of monitor, you can suspend all alarm indicators of the monitor:

- The visual alarm and audible alarm are all suspended.
- The parameters of physiological alarm stop flashing.
- The alarm message in the physiological alarm area will not be displayed.
- The remaining time and the icon  will be shown in the physiological alarm area.
- The technical alarm message will still be shown in the technical alarm area.

After the alarm paused time, the monitor will automatically cancel the alarm pausing. Press again the button , the alarm pausing can be cancelled by manual operation.




After returning to the normal status, whether the alarm still exists is dependent on whether the alarm condition is met. But when pressing the button , the alarm of lead-off/sensor-off/module-off are cease.

### ● Setting Alarm Pause time

Set the silence time only under Monitor Mode.

- 1 Select **【Menu】**→**【System Setup】**→**【Machine Mainte】**→enter the required password.
- 2 Set **【Alarm suspend Time】** to **【1Min】** , **【2Min】** or **【3Min】** .

## 5.7 Silence

Press and hold the button  on the front panel of monitor for 1 second to set the system silent. That is , all the sound of system is shut off. And the icon  will be displayed in the upper right corner of the screen . When in the silence status, the alarm indicators are valid except audible alarm. Press the button  again to exit the silence status. A new alarm will cancel the silence automatically.

## **5.8 Alarm when power is lost**

After a loss of power, the alarm settings prior to the power loss are restored.

After restarting the monitor, if select continuing the current patient, the previous settings will be maintained, and if a new patient is selected, the corresponding factory default settings will be loaded.

If you want to select the alarm settings from the default settings, please enter the alarm setting menu to select the setting you need.

## Chapter 6 SpO<sub>2</sub>

### 6.1 Introduction

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, usually shortened as SpO<sub>2</sub>) adopts the principles of light spectra and volume tracing. The LED emits lights with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.

$$\text{SpO}_2 \% = \frac{\text{Oxygenated hemoglobin}}{\text{Oxyhemoglobin} + \text{deoxyhemoglobin}} \times 100\%$$

Wavelengths of the light emitted by the pulse oximeter probe are nominally 660nm for red LED and 940nm for infrared LED.

### 6.2 Safety Information

#### Warning

---

- **Use only SpO<sub>2</sub> sensors specified in this manual. Follow the SpO<sub>2</sub> sensor's instructions for use and adhere to all warnings and cautions.**
- **When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's conditions.**
- **Do not use the monitor and the SpO<sub>2</sub> sensor during magnetic resonance imaging (MRI). Induced current could cause burns.**
- **Prolonged continuous monitoring may increase the risk of unexpected changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.**
- **Check the SpO<sub>2</sub> sensor and its package for any sign of damage before use. Do not use the sensor if any damage is detected.**

- **Before use, the operator must ensure the compatibilities of the monitor, SpO<sub>2</sub> sensor and extension cables; otherwise, this may lead to the burning of patients; do not use damaged sensor or extension cable. Do not soak the sensor into water or make it wet, otherwise it may be damaged.**
  - **When disposing the disposable SpO<sub>2</sub> probe or useless SpO<sub>2</sub> probe, please observe all local, state, and federal regulations that relate to the disposal of this products or similar products.**
- 

### **Caution**

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- **A function tester cannot be used to evaluate the accuracy of the SpO<sub>2</sub> Probe.**
  - **We use FLUK prosim8 SpO<sub>2</sub> simulator (software version: V2.06.04) to verify SpO<sub>2</sub> function of the monitor.**
- 

### **Note**

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- **To validate the PR accuracy, we reference to PULSE OXIMETER to compute the PR accuracy.**
- 

## **6.3 Monitoring Procedure**

1. Depending on the patient category, weight and application site, you can select the SpO<sub>2</sub> sensor as required.
2. Clean the application site, such as colored nail polish.
3. Apply the sensor to the patient
4. Select the extension cable according to the SpO<sub>2</sub> connector.
5. Plug the SpO<sub>2</sub> sensor into the extension cable.

## 6.4 SpO<sub>2</sub> Display

### 6.4.1 BLT SpO<sub>2</sub>

- **Waveform Display**



- **Parameter Display**



1. Pleth waveform
2. “%” indicates SpO<sub>2</sub>
3. SpO<sub>2</sub> value
4. Pleth bar
5. Pulse Rate (obtained from SpO<sub>2</sub>)
6. SpO<sub>2</sub> signal intensity

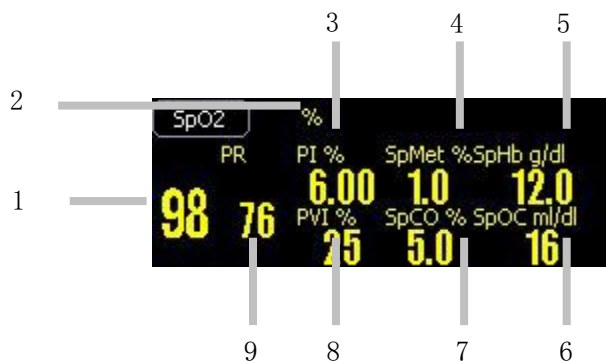
Indicator of signal intensity	Description
“Weak Signal”	The signal strength is too weak to measure.
“*”	The signal strength is low.
“**”	The signal strength is good.
“***”	The signal strength is best.

### Warning

- **When the “Weak Signal” is indicated, it means the signal obtained by the SpO<sub>2</sub> probe is too bad. User should check the patient’s condition and move the probe to other appropriate position.**

## 6.4.2 Masimo SpO<sub>2</sub>

The Masimo module is intended to monitor the SpO<sub>2</sub>, PR, PI, SpMet, SpHb, PVI, SpCO SpOC of patients. The following figure shows the SpO<sub>2</sub> display screen, the display on your monitor may be looked slightly different.



1. SpO<sub>2</sub> value;
2. SpO<sub>2</sub> unit;
3. PI (Perfusion Index) value and unit;
4. SpMet (Methemoglobin Saturation) value and unit;
5. SpHb (Total Hemoglobin) value and unit;
6. SpOC (Oxygen Content) value and unit;
7. SpCO (Carboxyhemoglobin Saturation) value and unit.
8. PVI (Pleth Variability Index) value and unit;
9. PR value

### Note

- When one of the above parameters' signals is weak, its label will fresh.

### ● Parameters Description

- a) Perfusion index (PI): PI is a value that indicates arterial pulse signal strength as the percentage of pulsatile signal to non-pulsatile signal. The perfusion index allows clinicians to place sensors on optimal sites.
- b) Methemoglobin Saturation (SpMet): SpMet is a value that represents the percentage of methemoglobin saturation within the blood.
- c) Total Hemoglobin (SpHb): SpHb is a measure of the total hemoglobin concentration in arterial blood.
- d) Oxygen Content (SpOC): SpOC is a measure of the total oxygen content present in the blood.



- e) Carboxyhemoglobin Saturation (SpCO): SpCO is a value that represents the percentage of carboxyhemoglobin saturation within the blood.
- f) Pleth Variability Index (PVI): PVI is a measure of peripheral perfusion changes secondary to respiration, or the PI amplitude modulation over a respiration, and can be closely related to intrathoracic pressure changes.

## 6.5 Setting SpO<sub>2</sub>

### 6.5.1 Opening the SpO<sub>2</sub> Menu

To open the SpO<sub>2</sub> Menu:

- Select "SpO<sub>2</sub>" to enter **【SpO<sub>2</sub> Setup】** menu.
- Select "Pleth" to enter **【Pleth Setup】** menu.

### 6.5.2 Setting Beep Volume

1. Select "SpO<sub>2</sub>" to enter **【SpO<sub>2</sub> Setup】** menu.
2. Set **【Beep Volume】** to **【Off】** or **【1~5】** .

### 6.5.3 Setting Scan Speed

- **SpO<sub>2</sub> Scan Speed**

1. Select "SpO<sub>2</sub>" to enter **【SpO<sub>2</sub> Setup】** menu.
2. Set **【Scan Speed】** to **【6.25mm/s】** , **【12.5mm/s】** , **【25 mm/s】** or **【50 mm/s】** .

- **Pleth Scan Speed**

1. Select "Pleth" to enter **【Pleth Setup】** menu.
2. Set **【Scan Speed】** to **【6.25mm/s】** , **【12.5mm/s】** , **【25 mm/s】** or **【50 mm/s】** .

### 6.5.4 Setting Average Time

The SpO<sub>2</sub> reading shown on the monitor is the average of data collected within a specific time. The shorter the averaging time is, the quicker the monitor responds to the change in the patient's oxygen saturation level. Contrarily, the longer the averaging time is, the slower the monitor responds to the change in the patient's oxygen saturation level, but the measurement accuracy will be improved. When a

critical patient is monitored, selecting shorter averaging time will help understanding the patient's state.

Select "SpO<sub>2</sub>" to enter **【SpO<sub>2</sub> Setup】** menu, Set **【Average Time】** to a desired value.

### 6.5.5 Setting Desat Limit

Desat Limit means that when the measuring value is lower than the limit, high alarm will be triggered. Set the Desat Limit as follows:

1. Select **【Menu】** → **【System Setup】** → **【Machine Mainte】** → enter the password to enter **【Machine Mainte】** menu.
2. Set **【SpO<sub>2</sub> Desat Limit】** to a desired value.

### 6.5.6 Setting Wave Color

1. Select "Pleth" to enter **【Pleth Setup】** menu.
2. Set **【Wave Color】** to a desired color.

### 6.5.7 Masimo SpO<sub>2</sub> module setup

When using Masimo SpO<sub>2</sub> module, You may need to do the following operations in the **【SpO<sub>2</sub> Setup】** menu.

- **Setting Sensitivity Mode**

You can set sensitivity mode of Masimo SpO<sub>2</sub> module according to use condition. Select **【Sensitivity Mode】** in the SpO<sub>2</sub> Setup menu with the options of **【Max】** , **【Normal】** or **【APOD】** .

**【Max】**: This mode should be used for the sickest patients, where obtaining a reading is most difficult. The mode is recommended during procedures and when clinician and patient contact is continuous.

**【Normal】** : This mode provides the best combination of sensitivity and probe-off detection performance. The mode is recommended for the majority of patients.

**【APOD】** : This mode is the least sensitive in picking up a reading on patients with low perfusion but has the best detection for probe-off conditions. The mode is useful for patients that are at particular risk of the sensor becoming detached (pediatric, combative, etc.)

- **Setting Fast Sat mode**

The Fast Sat mode is clinically applicable during procedures when detecting rapid changes in oxygen saturation is paramount such as induction, intubation and sleep studies.

Select **【Fast Sat Mode】** in the SpO<sub>2</sub> parameter setting menu, you can select **【On】** or **【Off】** to enable or disable the Fast Sat mode.

- **Setting Smart Tone Mode**

**【Smart Tone Mode】** is a feature that affects pulse beep and can be selected in the SpO<sub>2</sub> parameter setting menu. When you set it to **【On】**, it will allow the audible pulse beep to beep when the pleth shows signs of motion. The pulse beep is suppressed during signs of motion when Smart Tone is set to **【Off】**.

- **Setting Waveform Mode**

You can select **【Waveform Mode】** in the SpO<sub>2</sub> parameter setting menu, and select **【Resp. out】** or **【Resp. in】**. Resp. out is short for Respiration Signal Filtered Out, and Resp. in is short for Respiration Signal Included.

- **Setting Alarm Delay**

In the SpO<sub>2</sub> setting menu, select **【Alarm Delay】**, and you can select the delay time in the alarms as required in the options.

- **Setting SpHb Mode**

While monitoring Hemoglobin levels, there are two blood sample sources from which Hemoglobin readings can be obtained: arterial and venous. You can select **【SpHb Mode】** in the SpO<sub>2</sub> parameter setting menu, and you can select **【Arterial】** or **【Venous】**.

- **Setting SpHb Average Time**

You can select the averaging mode for SpHb value, select **【SpHb Average Time】** in the SpO<sub>2</sub> parameter setting menu, and you can select **【Short】**, **【Medium】** or **【Long】**.

- **Setting SpHb Precision**

You can select the SpHb precision to be displayed on the screen, select **【SpHb Precision】** in the SpO<sub>2</sub> parameter setting menu, and select a proper time as required.

- **Setting SpHb Unit**

You can select **【SpHbUnit】** in the SpO<sub>2</sub> parameter setting menu, and select the unit as required. The options are **【g/dL】** and **【mmol/L】** .

## 6.6 Masimo Information



- **Masimo Patents:**

This device is covered under one or more of the following U.S.A. patents: 5,758,644, 5,823,950, 6,011,986, 6,157,850, 6,263,222, 6,501,975 and other applicable patents listed at: [www.masimo.com/patents.htm](http://www.masimo.com/patents.htm).

- **No Implied License:**

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

## 6.7 Nellcor Information



This is the trademark of Covidien plc.

## Chapter 7 NIBP

### 7.1 Introduction

The monitor uses the oscillometric method for measuring NIBP. It is applicable for adult, pediatric and neonatal patients. The method of oscillometric indirectly estimates the systolic and diastolic pressures within the blood vessels by measuring the change of the pressure within blood pressure cuff along with the volume of the arteries and calculates the average pressure.

The NIBP measurement is suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator according to IEC 80601-2-30.

A physician must determine the clinical significance of the NIBP measurement.

### 7.2 Safety Information

#### Warning

- 
- **Check the patient category before monitoring. Incorrect settings may result in some risk for patient safety. Higher adult setting is not suitable for pediatric and neonatal patients.**
  - **Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.**
  - **The effectiveness of NIBP in pregnant women, including those with pre-eclampsia, has not determined.**
  - **Use clinical judgement to decide whether to perform frequent Auto BP measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
  - **Use clinical judgement to decide whether to perform Auto BP measurement on the patients of thrombasthemia.**
  - **Do not 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.**
  - **If you doubt the NIBP measurements, check the patient's vital signs by other device, and then check the monitor.**

- **The continuous cuff pressure due to connection tubing kinking may cause the effect of blood flow interference and resulting harmful injury to the patient.**
  - **Do not use the cuff over a wound, as this can cause further injury.**
  - **The pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.**
- 

## 7.3 Measurement Limitations

NIBP measurements are impossible with heart rate extremes of less than 40 bpm or greater than 240 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

- with excessive and continuous patient movement such as shivering or convulsions;
- if a regular arterial pressure pulse is hard to detect;
- with cardiac arrhythmias;
- with rapid blood pressure changes;
- with severe shock or hypothermia that reduces blood flow to the peripheries;
- on an edematous extremity.


## 7.4 Measurement Mode

There are three modes of measuring NIBP:

- **Manual:** measurement on demand.
- **Auto:** continually repeated measurements in the set interval.
- **STAT:** rapid series of measurements over a five minutes period, then the monitor returns to the previous mode. Use only on supervised patients.

## 7.5 Monitoring Procedure

### 7.5.1 Preparing to Measure NIBP

1. Check the patient category, if you want to change the patient category, Select  to enter **【Patient Info】** menu. And select the patient category as required.

## Note

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**To obtain accurate routine resting blood pressure measurements for the condition hypertension including as following steps:**

- **Keep the patient in a suitable position, including**
    - 1) **Comfortably seated;**
    - 2) **Legs uncrossed;**
    - 3) **Feet flat on the floor;**
    - 4) **Back and arm supported;**
    - 5) **Middle of the cuff at the level of the right atrium of the heart;**
  - **Suggest the patient to be relax as much as possible and not talk during the measurement procedure;**
  - **Suggest that 5 min should elapse before the first reading is taken;**
  - **Suggest that operator position on the right side of the monitor in normal use.**
- 

2. Select the appropriate cuff according to patient category.
  - Check the limb circumference of patient.
  - Select the appropriate cuff (The applicable limb circumference for cuff is marked on the cuff). The width of the cuff should be about 40% of the limb circumference (50% for neonate) or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle 50%~80% of the limb.

## Note

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- **The accuracy of measurement of BP depends on the suitability of the cuff.**
- 

3. Confirm the cuff has been entirely deflated.
4. Plug the air pipe plug of cuff into the connector (NIBP) of monitor until the plug and socket contact well. (Attention: you shall nip the part of air pipe plug of cuff close to socket with fingers before pulling it out.)
5. Tie the cuff to the upper arm or thigh of the patient.

Ensure the mark “Φ” on the cuff shall lie above artery while the air pipe shall be

under the cuff, ensuring the air pipe outside the cuff does not knot and the white line on the cuff shall be within the range “ $\longleftrightarrow$ ”, otherwise the cuff shall be replaced.



The monitor is applicable for standard neonatal cuff, pediatric cuff and adult cuff. (Including arm cuff and thigh cuff).

## Note

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- **While measuring blood pressure, the patient must keep calm without any talk.**
  - **The cuff tied on the limb shall be on the same level as the patient's heart so as to avoid the reading error resulting from the hydrostatics effect of the blood flow between the heart and cuff. If the cuff position is higher than heart level, the BP reading will be lower, the measured result shall be added 0.75mmHg (0.1kPa) for each centimeter higher; in case the cuff position is lower than heart level, the BP reading will be higher, the measured result shall be deducted 0.75mmHg (0.1kPa) for each centimeter lower.**
  - **The environment or operational factors which can affect the performance of the NIBP module and its BP reading:**
    - 1) **Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.**
    - 2) **A wrong cuff size, and a folded or twisted bladder, can cause inaccurate measurements.**
    - 3) **Do not wrap the cuff too tightly around the limb.**
- 



### 7.5.2 Starting/Stopping Measuring

Press the button  on the front panel of monitor to start NIBP measuring while press the button  again to stop NIBP measuring.

### 7.5.3 Auto Measurement

1. Select "NIBP" to enter **【NIBP Setup】** menu.
2. Set **【Interval】** to any option but **【Manual】** .



3. Start the Auto measurement manually for the first time, and then enter the Auto mode. The monitor will start the measurement continually repeated in the set interval after the first measurement. If you press the button  during the auto measurement, the measuring will be paused. You should press the button  again to start the auto measurement.

## Warning

- **Prolonged NIBP measurements in Auto mode are associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the NIBP measurements.**

### 7.5.4 STAT Measurement

1. Select "NIBP" to enter **【NIBP Setup】** menu.
2. Select **【STAT】** to start the STAT Measurement.

### 7.6 NIBP Display

There is no waveform displayed for NIBP measurement, the NIBP readings are displayed in the parameter area. The following figure shows the NIBP display screen, the display on your monitor may be looked slightly different.



1. Pressure unit
2. Systolic blood pressure
3. Mean arterial blood pressure
4. Pulse Rate (obtained from NIBP)
5. Diastolic blood pressure

## 7.7 Setting NIBP

Select "NIBP" to enter **【NIBP Setup】** menu.

### 7.7.1 Setting Unit

In **【NIBP Setup】** menu, set **【Unit】** to **【mmHg】** or **【kPa】** .

### 7.7.2 Setting Initial Press

In **【NIBP Setup】** menu, set **【Init Press】** to a desired value.

## 7.8 Setting Venipuncture Press

You can use the NIBP cuff to cause sub-diastolic pressure, and block the venous blood vessel to assist venous puncture.

1. Select "NIBP" to enter **【NIBP Setup】** menu.
2. Set **【Veni. Press】** to a desired value.
3. Select **【Venipuncture】** .
4. Puncture vein and draw blood sample.
5. Select **【 Venipuncture 】** again to deflate the cuff. The cuff deflates automatically after a set time if you do not deflate it.

## 7.9 NIBP Resetting

Select **【Reset】** in **【NIBP Setup】** menu to restore the inflation value of blood pressure pump to the initial value. In case the blood pressure pump doesn't work as normal but without any prompt, the blood pressure pump can be checked by reset, thus the blood pressure pump in abnormal condition due to unexpected reason will automatically restore.

## 7.10 Air Leakage Testing

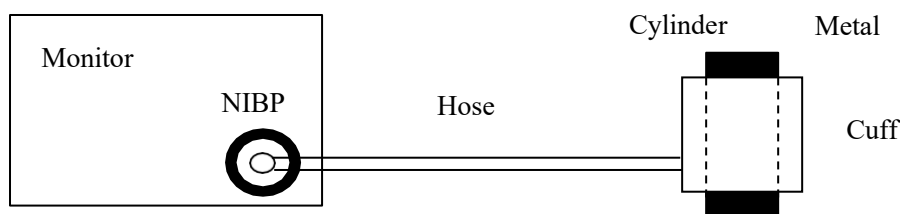
Air Leakage Testing is to test the status of air way's air leaking. If no error information displays on NIBP parameter area, it indicates that the airway is in good situation and no air leaks exist. However if the airway may have air leaks, the prompt message appears in NIBP displaying area. NIBP Air Leakage Testing should be done every two years or when you feel the reading is incorrect.

Before testing, please get ready the following things:

- One adult cuff
- One inflate hose
- One Cylinder Metal Vessel

**Procedure of the air leakage test:**

1. Enter **【Patient Info】** menu, set **【Type】** to **【Adult】** .
2. Connect the cuff securely with the socket for NIBP air hole.
3. Connect the cuff to a suitable Cylinder Metal Vessel, shown as follows:



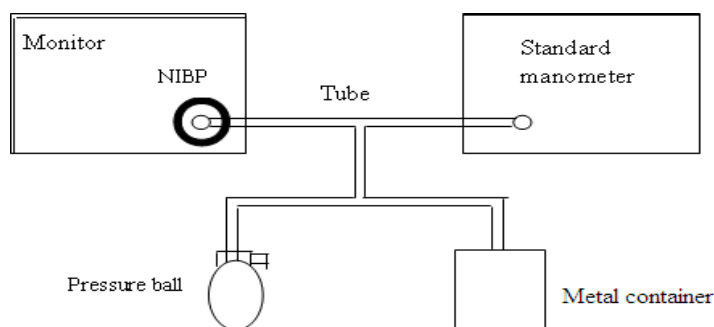
4. Enter **【NIBP Setup】** menu, select **【Leakage】** .
5. After 20 seconds or so, the system will automatically open the deflating valve, which marks the completion of an air leakage test.
6. If no error information displays on NIBP parameter area, it indicates that the airway is in good situation and no air leaks exist. However if the prompt **【 Air Leak】** appears in the place, it indicates that the airway may have air leaks. In this case, the user should check for loose connection. After confirming secure connections, the user should re-perform the air leakage test. If the failure prompt still appears, please contact the manufacturer for repair.

If the leakage still exists after all the above operations, please contact us.

## 7.11 NIBP Calibration

The maintenance and calibration of NIBP measurement is necessary for every year. If you need to maintain NIBP, please contact the professional service personnel. Calibration tools: 3 way connector, pipe, roundness pump, metal container(500±25 ml), standard manometer(Calibration already, precision over 1mmHg)

1. Connect monitor, manometer, roundness pump and metal container as follows.



2. Reading of manometer should be 0 before deflate, if not, cut the connection until it return to zero.
3. Select **【Menu】** → **【System setup】** → **【Maintenance】** → input password → **【NIBP Test】** → **【Calibration】** .
4. Turn up pump output pressure to 150mmHg, the pressure showed by monitor and consult manometer can't be over 3mmHg, if not, setting **【 Calibration 】** for 150mmHg, select **【Ok】** key in right of the menu.

## Chapter 8 CO<sub>2</sub>

### 8.1 Introduction

The monitor adopts infrared absorption technology to measure the carbon dioxide (CO<sub>2</sub>) concentration in the breathing airway of patient. Because CO<sub>2</sub> molecule can absorb infrared light of special wavelength, and the amount of absorbed infrared light directly relates to the concentration of CO<sub>2</sub>, therefore while the infrared light radiated from the infrared light source passing through the gas sample containing CO<sub>2</sub>, part of energy will be absorbed by CO<sub>2</sub> in the gas. At another side of infrared light source, a photodetector is used to measure the remaining infrared energy and convert it to electric signal, which will be compared with the energy of infrared light source and adjusted so as to correctly reflect the CO<sub>2</sub> concentration in the gas sample.

The method to measure carbon dioxide in the patient's airway for this monitor is Microflow. That is taking a sample of the respiratory gas with a constant sample flow from the patient's airway and analyzes it with the CO<sub>2</sub> sensor.

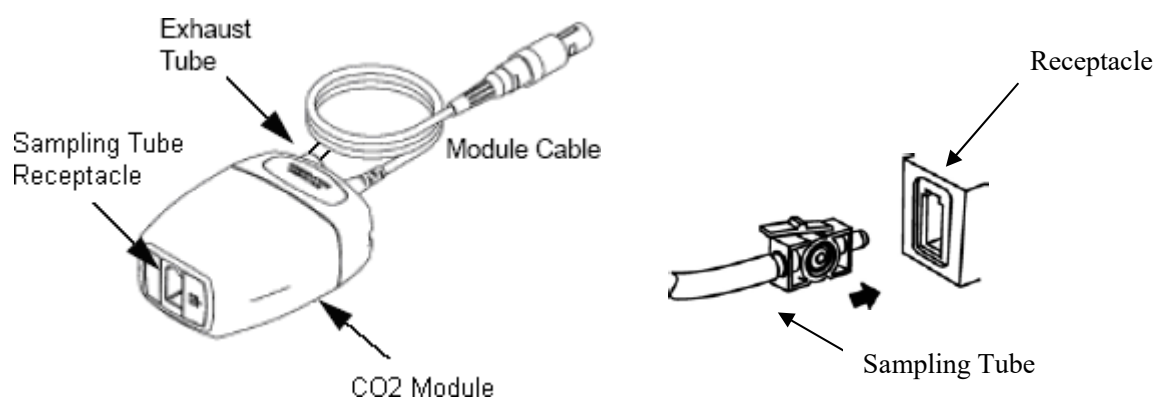
### 8.2 Monitoring Procedure

1. Attaching the CO<sub>2</sub> Module Cable

Plug the cable into the CO<sub>2</sub> connector on the monitor.

2. Attaching the Sampling Tube

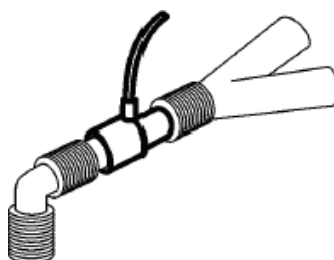
Insert the sampling tube into the sampling tube receptacle. Shown as follows:



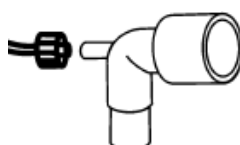
## Note

- 
- **Inserting the sampling tube into the receptacle automatically starts the sampling pump. Removal of the sampling tube turns the sample pump off.**
  - **To remove the sampling tube from the sampling tube receptacle, press down on the locking tab and pull the sampling tube from the receptacle.**
- 

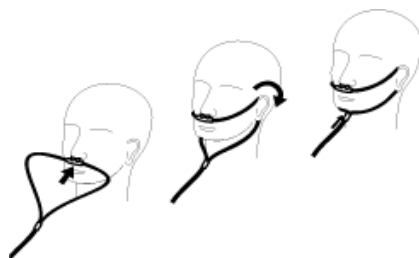
3. If the sampling pump fails to turn on, or runs intermittently, perform a “Zero” procedure.
4. Ensure that the CO<sub>2</sub> module exhaust tube vents gases away from the module environment.
5. Wait for the CO<sub>2</sub> module to warm up. The monitor will display the “Sensor Warm Up” message for approximately 1 minute while the module warms up to operating temperature. The message disappears when the module is ready for use.
6. Apply Microflow airway adapter or cannula.
  - 1) For intubated patients requiring an airway adapter: Install the airway adapter at the proximal end of the circuit between the elbow and the ventilator Y section. Shown as follows:



- 2) For intubated patients with an integrated airway adapter in the breathing circuit: Connect the male connector on the straight sample line to the female port on the airway adapter. Shown as follows:



- 3) For non-intubated patients: Place the nasal cannula onto the patient. Shown as follows:



- 4) For patients prone to mouth breathing use an oral-nasal cannula. Trim the oral sampling tip if necessary to fit the patient. It should extend down past the teeth and be positioned in the mouth opening. Remove the cannula from the patient if the tip needs to be trimmed. Shown as follows:



- 5) For nasal or oral-nasal cannulas with oxygen delivery, place the cannula on the patient as shown then attach the oxygen supply tubing to the oxygen delivery system and set the prescribed oxygen flow.

## Caution

- 
- Always connect the airway adapter to the sensor before inserting the airway adapter into the breathing circuit. In reverse, always remove the airway adapter from the breathing circuit before removing the sensor.
  - Always disconnect the cannula, airway adapter or sampling tube from the CO<sub>2</sub> sensor when not in use.
  - Do not insert the things other than sampling tube into receptacle of sampling tube.
  - Only use the CO<sub>2</sub> sampling tubes specified by our company.
  - The sampling tubes are disposable. Please keep the sampling tube clean, and prevent the tube from clogging by dust. It is advised to replace the sampling tube every 12h (up to 120h of use with filter tip), the sampling tube leaks or has been damaged and contaminated.
  - The monitor is not equipped with automatic barometric pressure compensation.
-

## 8.3 Factors affecting CO<sub>2</sub> measurement

Known adverse effects on CO<sub>2</sub> measurement due to the following:

1. Quantitative effects of gas sample humidity or condensate.
2. Leaks or internal venting of sampled gas.
3. Cyclical pressure of up to 10 kPa (100cmH<sub>2</sub>O)
4. When RR ≤ 80 rpm, the measuring EtCO<sub>2</sub> value is within the rated range;  
when RR > 80 rpm, all the range is ± 12% of reading.

## 8.4 CO<sub>2</sub> Display

- **Waveform Display**



1

- **Parameter Display**



2

3

5

4

1. CO<sub>2</sub> waveform
2. Unit of CO<sub>2</sub>
3. Inspired minimum CO<sub>2</sub> (FiCO<sub>2</sub>)
4. Airway respiration rate (awRR)
5. End-tidal CO<sub>2</sub> value (EtCO<sub>2</sub>)

## 8.5 Setting CO<sub>2</sub>

### 8.5.1 Entering CO<sub>2</sub> Menu

- Select "CO<sub>2</sub>" to enter **【CO<sub>2</sub> Setup】** menu.
- Select "CO<sub>2</sub> Wave" to enter **【CO<sub>2</sub> Wave Setup】** menu.

### 8.5.2 Setting Apnea Alarm

1. Select "CO<sub>2</sub>" to enter **【CO<sub>2</sub> Setup】** menu.
2. Set **【Apnea Alarm】** to **【10 Sec】**, **【15 Sec】**, **【20 Sec】**, **【30 Sec】**, **【45 Sec】** or **【60 Sec】**.



### 8.5.3 Setting Unit

1. Select “CO<sub>2</sub>” to enter **【CO<sub>2</sub> Setup】** menu.
2. Set **【Unit】** to **【mmHg】** , **【KPa】** and **【%】** .

### 8.5.4 Setting Scan Speed

- **CO<sub>2</sub> Scan Speed**

1. Select “CO<sub>2</sub>” to enter **【CO<sub>2</sub> Setup】** menu.
2. Set **【Scan Speed】** to **【6.25 mm/s】** , **【12.5 mm/s】** , **【25 mm/s】** or **【50 mm/s】** .

- **CO<sub>2</sub> Wave Scan Speed**

1. Select “CO<sub>2</sub> Wave” to enter **【CO<sub>2</sub> Wave Setup】** menu.
2. Set **【Scan Speed】** to **【6.25 mm/s】** **【12.5 mm/s】** **【25 mm/s】** or **【50 mm/s】** .

### 8.5.5 Setting Wave Color

1. Select “CO<sub>2</sub> Wave” to enter **【CO<sub>2</sub> Wave Setup】** menu.
2. Set **【Wave Color】** to a desired value.

## 8.6 Zeroing

Zeroing allows the CO<sub>2</sub> module to adjust to the optical characteristics, in order to obtain accurate readings. While zeroing is recommended the first time a CO<sub>2</sub> module is connected to the monitor, it is only absolutely necessary when the message “Zero Required” is displayed.

Follow these steps:

1. Ensure that the nasal cannula or airway adapter is not connected to the patient or close to any source of CO<sub>2</sub> (including the patient's, your own, exhaled breath and ventilator exhaust valves).
2. Select **【Zero】** in the CO<sub>2</sub> parameter setting menu, this will start zeroing. The monitor zeroes the module and displays the message “Zero In Progress” for about 15-20s on the screen. The message disappears upon completion of the zeroing.

## Caution

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- Always ensure that the sampling tube is properly connected to the microflow CO<sub>2</sub> module before zeroing.
  - Do not attempt zeroing for 20s after removing the adapter or cannula from the patient's airway. This time allows any CO<sub>2</sub> remaining in the adapter or cannula to dissipate before zeroing.
  - Do not attempt to zero the module while the adapter or cannula is in the patient's airway.
  - Do not attempt zeroing if the temperature is not stable.
  - Zeroing with CO<sub>2</sub> in the adapter or cannula can lead to inaccurate measurements or other error conditions. If you attempt zeroing while CO<sub>2</sub> remains in the adapter or cannula, the time required to zero the module may be increased.
- 

## 8.7 Calibrating

The monitor has been calibrated before leaving factory. You can use the monitor directly except the following three situations. When one of the following situations happens, please calibrate the CO<sub>2</sub> module.

- The CO<sub>2</sub> module has been used for half a year or a whole year.
- The therapist doubt about the reading of measurement.
- The atmospheric pressure or height above sea level has changed a lot after last calibrating.

## Caution

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- Please calibrate the monitor under the direction of the technician authorized by manufacturer. Incorrect calibrating process should lead incorrect reading.
-

## 8.8 Removing Exhaust Gases

### Warning

---

- **When using the microflow CO<sub>2</sub> measurement on patients who are receiving or have recently received anesthetics, connect the outlet to a scavenging system, or to the anesthesia machine/ventilator, to avoid exposing medical staff to anesthetics.**
  - **The exhaust gas cannot be returned to the breathing system, otherwise it will cause the risk of patient cross-infection.**
- 

Use an exhaust tube to remove the sample gas to a scavenging system. Attach it to the outlet connector of microflow CO<sub>2</sub> module.

# Chapter 9 Temp

## 9.1 Introduction

### 9.1.1 Principle of Temp measurement

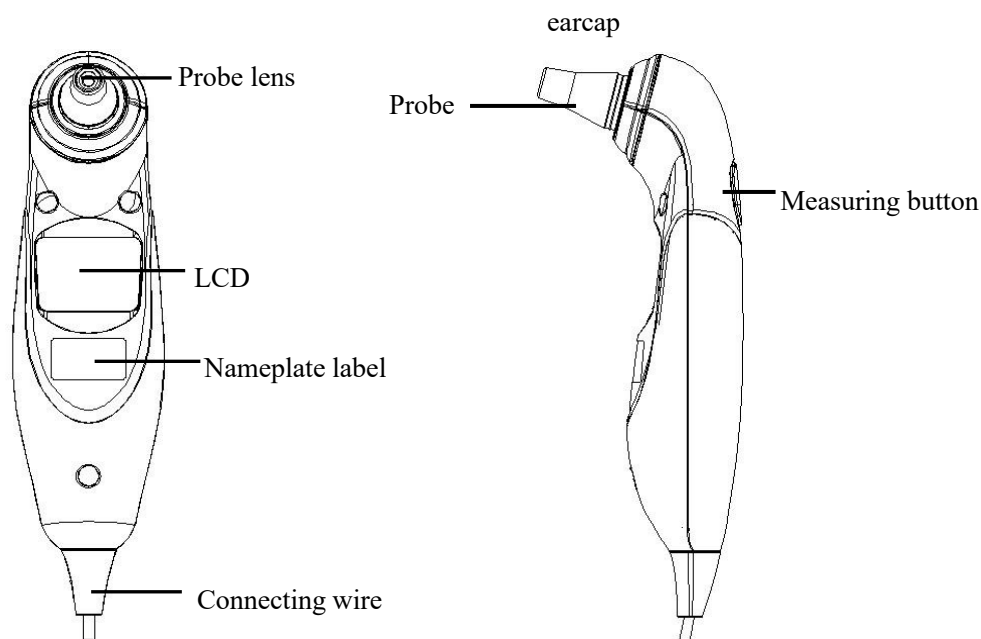
The monitor's temp measurement is divided into the infrared ear temp measurement and fast temp measurement.

Infrared ear temp is monitoring the human ear cavity's infrared launch through the infrared temperature measurement probe. After signal transforming and microprocessor processing, the relatively accurate human body temperature will be outputted.

Fast temperature measurement uses pre-heating mode for heating, and gives necessary temperature compensation in real time to make the probe's temperature approaching the human body temperature rapidly. After that the temperature will be converted into electrical signals that send to the main system.

### 9.1.2 Introduction of Temp probe

The structure of the Infrared ear Temp probe is as follows:



The structure of the Fast Temp probe is as follows:



## 9.2 Monitoring Procedure

### 9.2.1 Infrared ear temp measurement

1. Connect the temperature module to the main unit, press the power button of the main unit to turn on the monitor.
2. Installs earmuffs to the temperature probe.

While monitoring, please use new clean earmuffs with non-breakage and ensure that the ear cavity is clean. Please install the earmuffs as follows to ensure the monitoring accuracy.

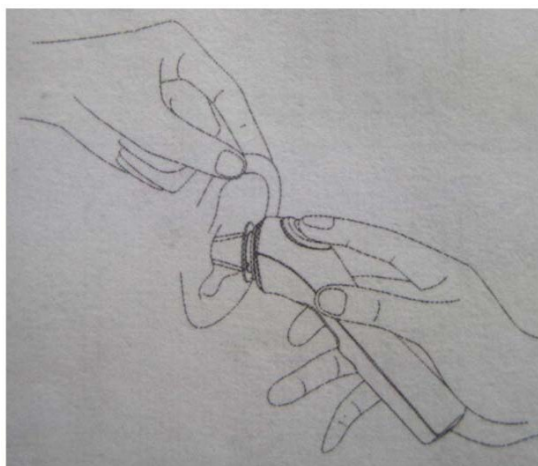
The earmuffs installing way:

- 1) Put the earmuffs paper film into the assistant ring groove.
- 2) Insert the probe to the end when its center is at the center of the assistant ring.
- 3) Ensure that the earmuffs on the probe is fixed on.

Refer to the following pictures:



3. Pull back the ear cavity gently to make it straight, and fix the head of the patient.



4. Measuring method: When the temperature module is in the off state or the unit sign glints, please carry out the monitoring. Insert the temperature probe into the ear at the ear hole, then press “START”, please don't read the temperature information until you hear the buzzer sound.

The temperature measured value is displayed on the module screen, while it is transmitted simultaneously to the main unit to display.

### **Caution**






- 
- **After each monitoring, the temperature module will locks for 12 seconds. Please do not carry out the next monitoring until the temperature unit sign glints.**
  - **If there is no operation in 40 seconds, the temperature module will enter standby mode automatically and turn off the screen.**
- 

### **Note**

- 
- **Infrared ear temp measurements have two measurement modes: test mode and clinical mode. Generally, the users perform measurements in clinical mode.**
-


## 9.2.2 Fast temp measurement

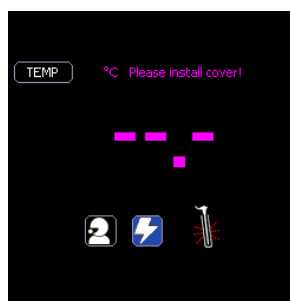
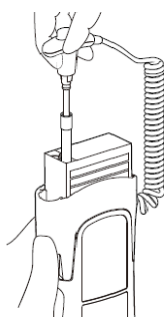
### Fast Temp:


1. First on the basis of the patient's condition, select the appropriate measurement sites: Oral  or Axillary  ;
2. Three modes of measurement: Fast , Cold , Monitor ;
  - Oral measurement: Fast mode and Cold mode are available;
  - Axillary measurement: Fast mode, Monitor mode and Cold mode are available;

### Note

- **Fast mode:** it is suitable for normal patients whose body temperature between 36 °C to 38 °C.
- **Cold mode:** it is suitable for low temperature patient, contacting temperature is 33 °C.
- **Monitor mode:** it can measure and display the patient's temperature continuously to achieve the patient's temperature monitoring.

3. Once set up mode and site, extracting temperature probe rapidly, temperature measurement instrument interface  flashing and prompts: "Please install cover! "(see the following figure).

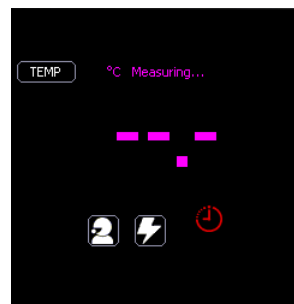
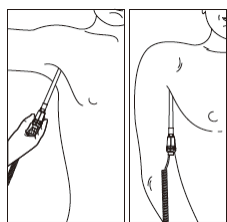



4. Replace the disposable Temp measuring cover, put the measuring probe in the corresponding parts of the patient, the screen  flashes and appears: "Measuring ..."(see the following figure), you can quickly complete temperature measurement (under normal circumstances, oral temperature needs 8 seconds,

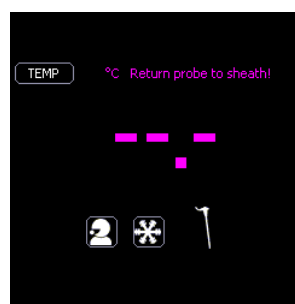
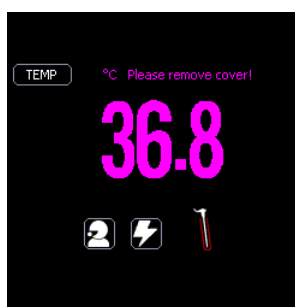
axillary temperature needs about 16 seconds);

If the patient is measured in monitor mode, the measurement interface remains in this state, and the real-time measurement data will be displayed all the time.





5. After the measurement is completed, the screen  flashes and prompts the operator "Please remove cover!" and "Return probe to sheath!". Plug the probe back into place.



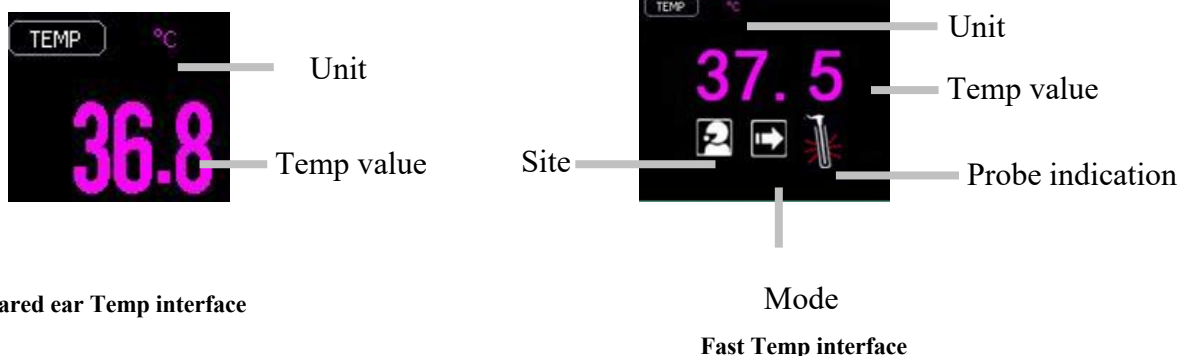
### Caution

- When oral temp measurements and axillary temp measurements are operated, the unstable contact of probe with the patient measurement site, or the patient can't meet the fast temp measurement requirements, the system will automatically switch the temperature mode, and directly output the temperature results. Then when the temperature is close to the patient's temperature, the system will lock the measurement data, and display the measurement results on the screen.
- Only when the probe is not pulled out (i.e. non-measurement state), measurement modes and sites can be changed.

### Warning

- If measure without the probe cover, the measurement result may be inaccurate.

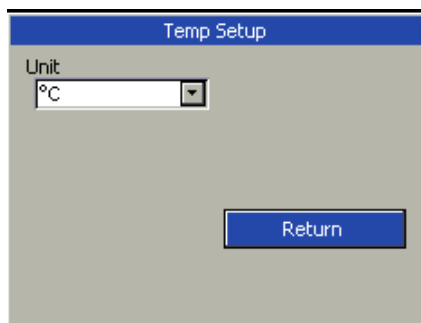
## 9.3 Temp Display



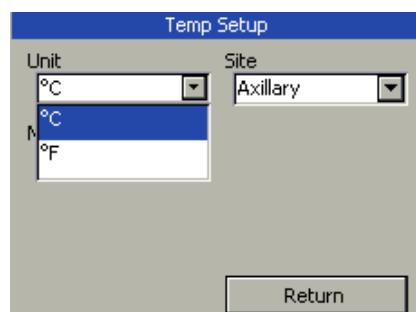
## 9.4 Setting Temp

### 9.4.1 Setting Unit

1. Select “TEMP” to enter the temp setup menu.
2. Set **Unit** to **°C** or **°F** . The new unit will become effective at the next monitoring.



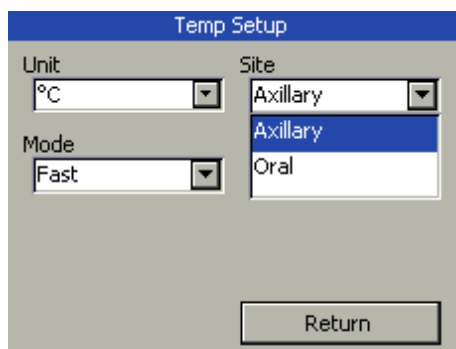
Infrared ear temp measurement



Fast temp measurement

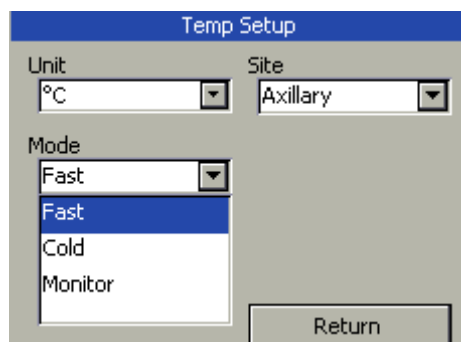
### 9.4.2 Setting measuring sites (only for fast temp measurement)

1. Select “TEMP” to enter the temp setup menu.
2. Set **Site** to **Oral** or **Axillary** . The new setup will become effective at the next monitoring.



### 9.4.3 Setting measuring modes (only for fast temp measurement)

1. Select “TEMP” to enter the temp setup menu.
2. Set **【Mode】** to **【Fast】** or **【Cold】** or **【Monitor】**. The new setup will become effective at the next monitoring.



### 9.4.4 Setting Alarm

Select **【menu】** → **【Alarm Setup】** to enter the alarm setup menu. Set the alarm level and alarm limit. The setting value will become effective at the next monitoring.

## 9.5 Temp Alarm

### 9.5.1 Infrared ear temp measurement alarm

#### 1. The main unit temperature alarm:

- If the measured value is lower than 34.0°C, an alarm for that the temperature is lower than the low limit occurs.
- If the measured value is higher than 43.0°C, the alarm for that the temperature is higher than the high limit occurs.
- If the ambient temperature is lower than 10.0°C, the alarm for that the ambient temperature is lower than the low limit occurs.
- If the ambient temperature is higher than 40.0°C, the alarm for that the ambient temperature is higher than the high alarm occurs.
- If the measured temperature value is higher than the high limit or is lower than the low limit, the alarm for that the temperature is high or low occurs.

#### 2. The temperature module alarm:

- If the measured value is lower than 34.0°C, the LCD will display “Lo” and the buzzer sounds “B-B-B-B-B”;
- If the measured value is higher than 43.0°C, the LCD will display “Hi”, and the buzzer sounds “B-B-B-B-B”;

- If the ambient temperature is lower than 10.0°C, the LCD will display “AL” and the buzzer sounds “B-B-B-B-B”;
- If the ambient temperature is higher than 40.0°C, the LCD will display “AH” and the buzzer sounds “B-B-B-B-B”;
- The temperature module has a fever alarm function: While the temperature is higher than 37.5°C, the buzzer sounds “B-B-B”.

### 9.5.2 Fast temp measurement alarm

- If the measured value is lower than 30.0°C, an alarm for that the temperature is lower than the low limit occurs, the LCD will display “Lo”.
- If the measured value is higher than 43.0°C, the alarm for that the temperature is higher than the high limit occurs, the LCD will display “Hi”.
- When the measuring result is higher or lower than the alarm setup range, the alarm will occur too.

## 9.6 Calibrating

The monitor has already been calibrated before leaving factory(only for Infrared ear temperature measurement). User can directly apply it to measuring in normal conditions, to the exclusion of the below conditions.

For temp module, please carry out temperature deviation calibration, when the following conditions happened: (More details refer to *Service Manual*.)

- The temperature module has been used for half a year or one year;
- The accuracy of Temp reading has been doubted by clinical physician.

### Caution

- 
- **User may only calibrate the device under the instruction of the technical personnel authorized by manufacturer. Moreover, incorrect calibrating procedure may result in incorrect reading.**
-

## 9.7 Safety Information

### Warning

- 
- **Please change the earcap after each use to ensure the veracity and avoid cross infecting.**
  - **At least every half year or one year carries out a temperature measure calibration, or carries out the calibration according to the hospital regulation.**
  - **If the temperature exceeds the measurement range, alarm will appear on the screen. Check whether the temperature probe is placed on the patient's appropriate site.**
  - **If the temperature probe's damage can't be repaired or the service life of it has to end, obsolete temperature probe should be disposed according to the local laws and regulations of the product or similar products.**
-

## Chapter 10 Reviewing

Review means reviewing the patients' relevant data that have been saved by the monitor previously. Review function is available in Clinic Mode only. In Monitor Mode, you may review the trend data, NIBP measurement data and alarm events of the monitored patient by use of screen changing key.


### 10.1 Entering the Reviewing Menu

You can enter the reviewing menu by the following two methods:

- Select **【Menu】** → **【History Review】** to enter the reviewing window.
- Select **【Menu】** → **【Data Manage】** to enter **【Data Manage】** window.

### 10.2 Reviewing Details

- **Through 【History Review】 window:**

1. Select **【History Review】** to enter **【History Review】** menu.
2. Turn the Trim Knob to select a patient in the window, then select **【LookUp】** to view patient's **【Detail Record】** .
3. Select **【Record】** or press the button  the front panel of monitor to print out the current page.

- **Through 【Data Manage】 window:**

1. **View one patient's ID record**

- a. Use a barcode scanner to input the patient's ID number in **【Lookup ID Record】** or input the ID number manually.
- b. Select the button **【Lookup ID Record】** on the right to view patient's **【Detail Record】** .

2. **View record during a time**

- a Set**【Lookup】**to **【Within a week】****【 Within a month】****【 Within half a year】** or **【All】** .
- b Select **【Lookup】** on the right to enter **【History Review】** menu.

## Caution

- 
- **No matter where the current cursor is in the Data Manage dialog box, the successful scanning result by using a barcode scanner will fill in the Lookup ID Record automatically. The ID will be replaced instead of accumulating when repeated scanning occurs.**
-

# Chapter 11 Recording

## 11.1 Recorder

This monitor uses the thermal recorder which supports various record type. It can output the patient information, measurement data, review data and two waveforms at most.



## 11.2 Recording Type

The records can be divided into the following types according to trigger modes:

1. Real-time record of manual startup;
2. The circular record of automatic startup of the recording meter in line with the given time interval;
3. The alarm record triggered by out-of-limit parameter and so on;
4. Record started by manual operation and related to special function.

## 11.3 Starting/Stopping Recording

Through the following methods, you can start and stop recording:

- Press the button  on the front panel of monitor to start real time recording.
- Press the button  again to stop recording.

## 11.4 Setting Recorder

Select  to enter **【Recorder Setup】** menu.

### 11.4.1 Setting Cycle Record

1. Enter **【Recorder Setup】** menu through the above methods.
2. Set **【Cycle Record】** to **【5 Min】** , **【10 Min】** , **【30 Min】** , **【1 H】** or **【2 H】** .

### 11.4.2 Setting Cycle Record Time

You can set a certain time interval, and the recorder will automatically start recording in line with the given time interval.

1. Enter **【Recorder Setup】** menu through the above methods.



2. Set **【Cycle Record Time】** to **【5 Sec】** , **【10 Sec】** or **【30 Sec】** .

### 11.4.3 Setting Alarm Record

1. Enter **【Recorder Setup】** menu through the above methods.
2. Set **【Alarm Record】** to **【On】** or **【Off】** .

### 11.4.4 Setting Alarm Record Time

1. Enter **【Recorder Setup】** menu through the above methods.
2. Set **【Alarm Record Time】** to **【5 Sec】** , **【10 Sec】** or **【30 Sec】** .

### Caution

- 
- **The contents recorded will be covered by the new one when the contents of the log reach its capacity.**
- 

### 11.4.5 Setting Gridding

1. Enter **【Recorder Setup】** menu through the above methods.
2. Set **【Open Grid】** to **【On】** or **【Off】** .

### 11.4.6 Setting Recorder Speed

1. Enter **【Recorder Setup】** menu through the above methods.
2. Set **【Recorder Speed】** to **【6.25 mm/s】** , **【12.5 mm/s】** **【25 mm/s】** or **【50 mm/s】** .

## 11.5 Installing Recording Paper

If the record paper runs out, please install the record paper as the following step:

1. Press both sides of the recorder door with one hand and pull outwards to open the recorder door.
2. Put the recording paper into the recorder with the thermal side, which is smoother up.
3. Close the door of the recorder, and pull some recording paper outside of the paper out port.

## Caution

---

- **Must use the thermo-sensitive record paper; otherwise, it will lead to recording failure, bad-quality record or damage of thermo-sensitive printing head.**
  - **Do not pull out the recording paper during recorder printing; otherwise, the recording meter may be damaged.**
  - **Unless for paper replacement or fault remedy, do not keep the recorder door open.**
- 

## 11.6 Clearing Jam Paper

While the sound of recorder operation or printing of recording meter is abnormal, please first check whether there is paper jam in the recording meter.

If so, please clear it as per following steps:

1. Open the recorder door;
2. Pull out the recording paper, and cut off the wrinkle part;
3. Load recording paper once again and close the recording meter door.

## 11.7 Cleaning Recorder

After long-time service, some paper scrap and impurity will accumulate on the printing head, and affect printing quality as well as the service life of printing head and roll shaft. The recorder can be cleaned according to the following methods:

1. Before cleaning, the measures such as wearing anti-static wrist strap shall be adopted to avoid the damage to recording meter resulting from static;
2. Open the recorder door and pull out recording paper;
3. Use a tampon with some alcohol to sweep slightly the surface of thermo-sensitive parts of printing head;
4. After the alcohol entirely vaporizes, load recording paper once again and close the recorder's door.

## Caution

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




- **Don't use any article that can damage the thermo-sensitive parts of recorder during cleaning.**
  - **Don't heavily press the printing head of recorder.**
-

# Chapter 12 Battery

## 12.1 Introduction

The monitor can be fitted with rechargeable battery to ensure its continuous work after the failure of alternating current power supply, and it needs no special maintenance under the normal condition. While the monitor connecting with alternating current power, no matter whether the monitor is operating or not, the battery always can be charged. In the case of sudden power off, the monitor will automatically get power supply from battery without interruption of monitoring work.

Indicative message under the screen will display battery states:

-  The icon indicates that the battery is fully charged.
-  The icon indicates that the battery is four grids left.
-  The icon indicates that the battery is three grids left.
-  The icon indicates that the battery is two grids left.
-  The icon indicates that the battery is one grid left.
-  The icon indicates that the battery is almost depleted and need to be charged immediately.

### Warning

---

- **Use only batteries specified in this manual.**
  - **Keep the batteries out of children's reach.**
- 

### Caution

---

- **Remove the batteries prior to shipping or if the monitor is not likely to be used for an extended period.**
-

## 12.2 Installing a Battery

The battery compartment is in the bottom part of the monitor, please refer to the following steps when installing or charging the batteries.

1. Turn off power of the monitor, and disconnect the power wire and other connected wires.
2. Open the battery door towards the direction labeled on it.
3. Take out the old battery.
4. Insert the new battery towards the direction labeled.
5. Close the battery door.

## 12.3 Optimizing Battery Performance

A battery needs at least two optimizing cycles when it is put into use for the first time. A battery cycle is one complete, uninterrupted charge of the battery, followed by a complete, uninterrupted discharge of the battery. A battery should be conditioned regularly to maintain its useful life. Condition a battery once when it is used or stored for two months, or when its run time becomes noticeably shorter.

To optimize a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the battery in need of optimizing into the battery compartment to the monitor.
3. Place the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
4. Remove the AC mains and allow the monitor to run from the battery until it shuts off.
5. Replace the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
6. The optimizing of the battery is over.

## 12.4 Checking Battery Performance

The performance of a battery may deteriorate over time. To check the performance of a battery, follow this procedure:

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

2. Place the monitor in the charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 6 hours.
3. Disconnect AC mains and allow the monitor to run on the battery until it shuts off.
4. The operating time of a battery reflects its performance directly.

### **Caution**

- 
- **The operating time of a battery depends on the configuration and operation of the monitor. NIBP measurement, SpO<sub>2</sub> measurement and using of recorder will deplete the battery faster than other parameters' measurement.**
- 

## **12.5 Disposing Batteries**

Batteries that are damaged or depleted should be replaced and discarded properly. Dispose of used batteries according to local regulations.

### **Caution**

- 
- **The service life of battery depends on the service time and frequency. This monitor battery can be charged and discharged for 300 times generally.**
- 

### **Warning**

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

## Chapter 13 Maintenance and Cleaning

### 13.1 Introduction

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

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

#### Warning

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

#### Caution

- 
- **If you spill liquid onto the equipment or accessories, contact your service personnel or us.**
- 

### 13.2 Cleaning of Monitor

1. Common detergent and non-corrosive disinfectant used in hospital can be applied to clean monitor, however you must be aware that many kinds of detergents must be diluted prior to utilization, and please use it according to the instruction of detergent manufacturer.
2. Avoid the use of alcohols, amino or acetonyl detergent.
3. The enclosure and screen of monitor shall be free of dust, and they can be

wiped with lint-free soft cloth or sponge soaked in detergent. While cleaning, be careful and do not spill liquid onto the instrument and keep any liquid out of it. When wiping the side panel of monitor, you must be especially careful to keep water out of all kinds of cable and outlet on the panel.

4. Do not use abrasive material including wire brush or metal brightener during cleaning because this material will damage the panel and monitor screen.
5. Do not submerge the monitor in liquid.
6. While cable or plug of attachment accidentally gets wet, please rinse it with distilled water or deionized water and dry it in the environment of temperature 40°C to 80°C for at least one hour.

## 13.3 Cleaning and Sterilizing of Accessories

### 13.3.1 SpO<sub>2</sub> Sensor

The recommended disinfectant include isopropyl alcohol 70%, 10% decolourant solution can be used for sterilization at lower standard. Don't use undiluted decolourant (5%~5.25% sodium hypochlorite) or other non-recommended disinfectant in order to avoid damage to sensor.

#### Attention

- 
- **Do not sterilize sensor by ray, steam or epoxy ethane.**
  - **Do not directly submerge sensor in liquid.**
  - **To avoid long-time harm to sensor, it is suggested that sterilization to the product be conducted only when necessary according to the regulation of your hospital.**
- 

### 13.3.2 NIBP Cuff

1. Please regularly clean the product;
2. Remove cuff from connector and pull out airbag from sheath;
3. Submerge clean and soft medical gauze pad or other soft cleaning tools into fresh water or neutral soapy water, and wring out surplus water from the submerged gauze then wipe airbag and pipe;
4. Wash the cuff sheath in the clean neutral soapy water;
5. After the sheath and airbag intensive drying, enclose airbag with cuff sheath and put into operation.

## Attention

---

- **Excessive or frequent cleaning may damage airbag, so don't clean airbag unless necessary.**
  - **Do not dry airbag and sheath in high temperature.**
  - **If higher sterilization level is required, please choose disposal cuff.**
  - **One disposal cuff can only be used for one patient.**
  - **Carefully keep water and cleaning solution out of the connecting parts of cuff and monitor.**
- 

### 13.3.3 CO2 Sensor and Reusable Airway Adapter

- The outside of the module or sensor may be cleaned and disinfected by wiping with 70% isopropyl alcohol, a 10% bleach solution, or mild soap. After cleaning, wipe with a clean, water-dampened cloth to rinse. Dry before use.
- Reusable airway adapters may be cleaned by rinsing in a warm soapy solution, followed by soaking in a liquid disinfectant such as 70% isopropyl alcohol, a 10% bleach solution, Cidex® or System 1® (refer to the disinfectant manufacturer's instructions for use). Adapters should then be rinsed with sterile water and dried.
- Reusable airway adapters may also be pasteurized or autoclaved. Autoclave at 121°C (250°F) for 20 minutes, unwrapped.
- Before reusing the adapter, ensure the windows are dry and residue-free, and that the adapter has not been damaged during handling or by the cleaning process.

### 13.3.4 Temp probe

The recommended disinfectant is isopropyl alcohol 70%. Don't use undiluted decolourant (5%~5.25% sodium hypochlorite) or other non-recommended disinfectant in order to avoid damage to sensor.

Please clean the probe lens as the following steps:

1. Use the pily stick or soft cloth bedewed with water or alcohol to wipe the lens gently. Do not pot the probe in the water or other liquid.
2. Dry the lens for over 30 min before cover the new earcap, and avoid solarizing directly while the temperature is beyond 10°C~40°C.



## Attention

---

- **Do not sterilize sensor by ray, steam or epoxy ethane.**
  - **Do not directly submerge sensor in liquid.**
  - **To avoid long-time harm to sensor, it is suggested that sterilization to the product be conducted only when necessary according to the regulation of your hospital.**
  - **Please change the earcap after each use to ensure the veracity and avoid cross infecting.**
- 

## Note

---

- **The electric schematic and element list can only be offered to the eligible service center or personnel.**
-

## Chapter 14 Accessories

### Warning

- Use only accessories specified in this manual. Using other accessories may cause damage to the monitor.
- Disposable accessories are designed for single-patient use only. Reuse of them may cause a risk of contamination and affect the measurement accuracy.
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.

### 14.1 SpO<sub>2</sub>

#### 1. Nellcor SpO<sub>2</sub>

Type	Model	Patient category
Disposable	MAX-N	Adult finger or neonatal foot/hand (patient size >40 kg or <3 kg)
	MAX-A	Adult finger (patient size >30kg)
	MAX-P	Pediatric foot/hand (patient size 10-50kg)
	MAX-I	Infant foot/hand (patient size 3-20kg)
Reusable	DS-100A	Adult finger
	OXI-A/N	Adult / neonatal
	OXI-P/I	Pediatric / infant

#### 2. BLT SpO<sub>2</sub>

Type	Patient category	PN
Reusable	Adult finger	15-100-0013
	Pediatric finger	15-100-0014
	Neonatal foot/hand	15-100-0015

- **SpO<sub>2</sub> Extension cable**

Accessories	PN
Extension cable	15-031-0016

### 3. Masimo SpO<sub>2</sub> Sensor

Type	Model / PN	Patient category
Reusable	DCI / 2501	Adult finger
	DCIP / 2502	Pediatric finger
Disposable	Neo / 2514	Infant foot/hand

- **Masimo SpO<sub>2</sub> Extension cable**

Accessories	Model / PN
Extension cable	2525

## 14.2 NIBP

- **Disposable cuffs**

Model	Patient category	Limb circumference (cm)
15-100-0104	Neonatal	3-5.5
15-100-0105		4-8
15-100-0106		6-11
15-100-0107		7-13

- **Reusable cuffs**

Patient category	Limb circumference (cm)	PN
Adult	25-35	15-100-0118
Adult thigh	44-53	15-100-0142
Large adult	33-47	15-100-0120
Pediatric	18-26	15-100-0121
Infant	6-11	15-100-0122

### 14.3 CO<sub>2</sub> (LoFlo)

Accessories	PN
LoFlo CO <sub>2</sub> sensor	16-100-0016
Airway adapter (adult)	15-100-0045
CO <sub>2</sub> nasal cannula (adult)	15-100-0044
CO <sub>2</sub> nasal cannule (pediatric)	15-100-0048
CO <sub>2</sub> nasal cannule (infant)	15-100-0049
Extension cable	15-031-0010

### 14.4 Temp

Accessories	Model
Earcap (Disposable)	Probe Cover - 038
Fast temp electronic thermometer	F3000-2
Fast temp probe cover	F3000-3

### 14.5 Barcode scanner

Accessories	Model
Barcode scanner	FG2100

## Appendix A Product Specifications

### A.1 Safety Specifications

#### A.1.1 Classification

Classification of Protection against electric shock	I
Degree of protection against electric shock	SpO <sub>2</sub> , NIBP, Temp :CF CO <sub>2</sub> :BF
Degree of protection against hazards of explosion	Not suitable
Degree of protection against ingress of liquid	IPX1
Mode of operation	Continuous

**Note:**

I: Class I, internally and externally powered equipment.

CF: Type CF applied part

BF: Type BF applied part

Not suitable: Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

#### A.1.2 Environmental Specifications

Temperature	Operating	(5~40)°C
	Transportation and Storage	(-20~+55) °C
Humidity	Operating	15%~85% (noncondensing)
	Transportation and Storage	10%~93% (non-condensing)
Atmospheric Pressure	Operating	(700~1060) hPa
	Transportation and Storage	(500~1060) hPa

### A.1.3 Power Specifications

Input voltage	AC (100-240) V, (50/60) Hz
Input power	70VA
Fuse	T1.6AL/250V, 2-Φ5×20mm

### A.2 Physical Specifications

Part	Weight (kg)	Size (W×H×D) (mm)
Mainframe	About 2.5 (Including a lithium battery)	<160×130×260
Temp module	About 0.16 (Including the connecting wire)	153×40.5×60

### A.3 Hardware Specifications

#### A.3.1 Display

Type	Color TFT LCD
Size (diagonal)	7 inch
Resolution	234×480 pixels
Anti-glare screen	With
LCD switch	With
<b>Temp module</b>	
Type	black and white LCD
Size	1.2 inch

#### A.3.2 Recorder

Type	Thermal dot array
Paper width	50 mm
Recording width	40 mm
Recording speed	25 mm/s
Recording waveform	double tracks

### A.3.3 Battery

Type	Rechargeable lithium ion battery
Model	LB-08
Size	105mm×78mm×20mm
Weight	<360 g
Quantity	1
Rated voltage	11.1 VDC
Capability	4000 mAh
Operating time	8 hours Using a new and fully charged battery at 25°C ambient temperature, connecting SpO <sub>2</sub> sensor and NIBP work on AUTO mode for 15 minutes interval.
Charge time	6h to 100% (Standby)
Turn off delay	5 min -15 min after the low battery alarm first occurs.
Indicator of battery capability	With

### A.3.4 Mainframe LED

Physiological alarm indicating lamp	1 (Yellow/Red)
Technical alarm indicating lamp	1(Cyan/ Yellow)
Power indicating lamp	1(Green/Orange) Green: When powered with AC, it lights green while turn on and off the monitor. Orange: When powered with battery, it lights orange only while turn on the monitor.
Battery charging indicating lamp	1 (Orange)

### A.3.5 Audio indicating

Speaker	Gives audible alarm, QRS tone; Supports Pitch Tone and multi-level volume; Alarm tones meet the requirement of IEC 60601-1-8.
Alarm pressure	45 dB to 85 dB. Testing place is 1 meter from the tone.

### A.3.6 Input device

Function button	5, NIBP, record, suspend/silence, screen switch and power switch
Knob	With
Barcode scanner	Optional
<b>Temp module</b>	
Button	1, START

### A.3.7 Connectors

Center computer connector	RJ-45, 10M/100M, TCP/IP
Serial port	RS232 serial port
Nurse call	Nurse call connector
Equipotential grounding point	1
USB connector	Barcode scanner or other USB devices supported by monitor
SD card connector	reserved connector
Wireless network	reserved connector
Temp module connector	Temp probe connector

### A.3.8 Signal Output

<b>Nurse call output</b>	
Drive mode	Relay
Electric specification	$\leq 60W, \leq 2A, \leq 36VDC, \leq 25VAC$
Isolated voltage	1500VAC
Signal type	N.C., N.O.

### A.3.9 Data Storage

<b>Clinic Mode</b>	
Patient quantity	1000
Recording number	16000
Single patient clinic record number	(1-16000)



Monitor Mode	
Patient quantity	1
Trend data	3 kinds of resolution: 1Min, 5Min, 10Min. 1Min: can store 96 hours 5 Min: can store 480 hours 10 Min: can store 960 hours
Alarm events	1000
NIBP measurement record	5000

## A.4 Measurement Specifications

### A.4.1 SpO<sub>2</sub>

- Digital SpO<sub>2</sub> module

Measurement technic	Digital SpO <sub>2</sub> technic
Monitoring parameters	SpO <sub>2</sub> and PR
SpO <sub>2</sub> Measurement range Resolution Accuracy	(0~100) % 1% ±2% (70~100)% SpO <sub>2</sub> (0~69) % unspecified
PR Measurement range Resolution Accuracy	(25~255) bpm 1 bpm ±1% or ± 1 bpm, whichever is the greater
Resisting low perfusion ability	With powerful ability of resisting low perfusion, PR amplitude can reach to 0.2% with value of SpO <sub>2</sub> displaying
SpO <sub>2</sub> alarm range	(0~100) %, high/low limit can be adjusted continuously
PR alarm range	(0~300) bpm, high/low limit can be adjusted continuously
Recovery time after defibrillation	≤10 s.
Update time	1s

● **Nellcor SpO<sub>2</sub> module**

Measurement technic	Nellcor SpO <sub>2</sub> technic
Monitoring parameters	SpO <sub>2</sub> and PR
SpO <sub>2</sub> Measurement range Resolution Accuracy	(0~100)% 1% ± 2% ((70~100)% SpO <sub>2</sub> ) (adult) ± 3% ((70~100)% SpO <sub>2</sub> ) (neonate) unspecified (0~69)%
PR Measurement range Resolution Accuracy	(20~300) bpm 1 bpm ±1% or ± 1 bpm, whichever is the greater
SpO <sub>2</sub> alarm range	(0~100)%, high/low limit can be adjusted continuously
PR alarm range	(0~300) bpm, high/low limit can be adjusted continuously
Recovery time after defibrillation	≤10 s.
Update time	1s

● **Masimo SpO<sub>2</sub> module**

Measurement range	0%~100%
Resolution	1%
Accuracy	70%~100%: ±2% (Adult/Pediatric, non-motion conditions) 70%~100%: ±3% (Neonate, non-motion conditions) 70% to 100%: ±3% (motion conditions) 0%~69%, undefined
Average time	2s-4s, 4s-6s, 8s, 10s, 12s, 14s, 16s
Recovery time after defibrillation	≤10 s.
SpO <sub>2</sub> alarm range	(0~100)%, high/low limit can be adjusted continuously
Update time	1s
<b>PR</b>	
Measurement range	25 bpm~240 bpm
Accuracy	±3 bpm (non-motion conditions) ±5 bpm (motion conditions)
Resolution	1 bpm

<b>SpCO</b>	
Measurement range	0% to 100%
Accuracy	0% to 40%: $\pm 3\%$ (non-motion conditions) >40%, unspecified
<b>SpMet</b>	
Measurement range	0% to 100%
Accuracy	0% to 15%: $\pm 1\%$ (non-motion conditions) >15%, unspecified
<b>PI</b>	
Measurement range	0.05% to 20%
<b>SpHb</b>	
Measurement range	0 g/dl to 25 g/dl
Accuracy	8 g/dl to 17 g/dl: $\pm 1$ g/dl (non-motion conditions) <8 g/dl or >17 g/dl, unspecified
<b>SpOC</b>	
Measurement range	0 ml/dl to 35 ml/dl

**Note 1:** The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation, which encompasses 68% of the population

## A.4.2 NIBP

Measurement way	Automatic oscillometry		
Measurement range	Adult	Sys	(30~270) mmHg
		Dia	(10~220) mmHg
		Map	(20~235) mmHg
	Pediatric	Sys	(30~235) mmHg
		Dia	(10~220) mmHg
		Map	(20~225) mmHg
	Neonatal	Sys	(30~135) mmHg
		Dia	(10~110) mmHg
		Map	(20~125) mmHg
Cuff pressure range	(0~300) mmHg		

Resolution	1 mmHg	
Pressure accuracy	Static: $\pm 3$ mmHg Clinic: Average error: $\pm 5$ mmHg, standard deviation: $\leq 8$ mmHg	
Unit	mmHg, kPa	
PR range	(40~240) bpm	
Recovery time after defibrillation	$\leq 10$ s.	
PR Resolution	1bpm	
Cuff auto deflation	The cuff will deflate automatically when power is off or time of measurement is beyond 120 seconds (90 seconds for neonate) or the cuff pressure is beyond the overpressure protection set by software and hardware.	
Measurement time	Normally, it is 20s to 45s (depending on HR and moving interference typically)	
Overpressure protection		
Adult	(297 $\pm$ 3) mmHg	
Pediatric	(252 $\pm$ 3) mmHg	
Neonatal	(147 $\pm$ 3) mmHg	
Alarm range	Sys	(0~300) mmHg, high/low limit can be adjusted continuously
	Dia	(0~300) mmHg, high/low limit can be adjusted continuously
	Map	(0~300) mmHg, high/low limit can be adjusted continuously

### A.4.3 CO<sub>2</sub> (LoFlo)

- **Microflow CO<sub>2</sub> module**

Measurement way	Infrared spectrum
Measurement mode	microflow
Warm up time	Capnogram displayed in less than 15 s, at an ambient temperature of 25°C, full specifications within 2 minutes.
Measurement range	(0~19.7) % (0~150 mmHg)
Resolution	0.1% or 1mmHg
Stability	Short term drift: $\pm 0.8$ mmHg over four hours Long term drift: Accuracy specification will be maintained over a 120 hour period.

Unit	%, mmHg, kPa	
Recovery time after defibrillation	≤ 10 s.	
Accuracy ( 760mmHg, temperature is 25℃)	0 mmHg to 40 mmHg, ±2 mmHg 41 mmHg to 70 mmHg, ±5% of reading 71 mmHg to 100 mmHg, ±8% of reading 101 mmHg to 150 mmHg, ±10% of reading (when RR >80 rpm, all the range is ±12% of reading) Gas temperature at 25℃	
Total system response time	<3s	
10% to 90% rise time	<0.2s	
Sample rate	100 samples/s	
ETCO2 Calculation	Method: Peak of the expired CO2 waveform Selections: 1 breath, 10 second, 20 second	
Alarm range	0%~20.0%(0mmHg~152mmHg) , high/low limit can be adjusted continuously.	
Alarm accuracy	±0.1% or ±1mmHg	
<b>The effects on CO2 measuring values caused by the interfering gases</b>		
<b>Gas or vapour</b>	<b>Gas level</b>	
Nitrous oxide	60 <sup>a</sup>	Dry and Saturated Gas 0-40mmHg: ± 1mmHg additional error 41-70mmHg: ± 2.5% additional error 71-100mmHg: ± 4% additional error 101-150mmHg: ± 5% additional error  Desflurane: The presence of desfluane in the exhaled breath at concentrations greater than 5% will positively bias Carbon Dioxide values by up to an additional 3mmHg at 38mmHg.  Xenon: The presence of Xenon in the exhaled breath will negatively bias Carbon Dioxide values by up to an additional 5mmHg at 38mmHg.
Halothane	4 <sup>a</sup>	
Enflurane	5 <sup>a</sup>	
Isoflurane	5 <sup>a</sup>	
Sevoflurane	5 <sup>a</sup>	
Xenon	80 <sup>b</sup>	
Helium	50 <sup>c</sup>	
Metered dose inhaler propellants	excluded	
Desflurane	15 <sup>a</sup>	
Ethanol	0.1%vol	
Isopropanol	0.1%vol	
Acetone	0.1%vol	
Methane	1.0%vol	

Test GAS LEVEL shall be  $\pm 20\%$  of the specified level.

<sup>a</sup> If intended for use with inhalation halogenated agents.

<sup>b</sup> If intended for use with Xenon.

<sup>c</sup> If intended for use with Helium

● **awRR**

Measurement range	0 rpm~150 rpm
Measurement accuracy	0 rpm~70 rpm: $\pm 1$ rpm; 71 rpm~120 rpm: $\pm 2$ rpm; 121 rpm~150 rpm: $\pm 3$ rpm.
Alarm range and accuracy	Range: 0rpm~150rpm, high/low limit can be adjusted continuously. Accuracy: $\pm 1$ rpm

## A.4.4 Temp

### A.4.4.1 Infrared ear Temp

Ambient temperature	10°C~40°C
Measurement range	34.0°C~43.0°C
Measurement part	Ear cavity
Unit	°C, °F
Resolution	0.1°C/°F
Accuracy	Between 35.0°C~42.0°C: $\leq \pm 0.2$ °C
	Beyond 35.0°C~42.0°C: $\leq \pm 0.3$ °C
clinical repeat accuracy	$\leq \pm 0.3$ °C
Measurement time	$\leq 0.8$ s
Measurement interval time	12s
Recovery time after defibrillation	$\leq 10$ s.
Standby time	40s
Memory storage	10
Temp probe alarm	The measured value is beyond the range: Alarm occurs when the value is lower than 34.0°C or higher than 43.0°C.
	The ambient temp is beyond the range: Alarm occurs when the ambient temp is lower than 10.0°C or higher than 40.0°C.
	Fever alarm: Alarm occurs when the measured value is higher than 37.5°C and lower than 43.0°C.

### A.4.4.2 Fast Temp

Sensor type	Thermosensitive sensor
Measurement range	30.0°C~43.0°C (86°F ~ 109.4°F)
Measurement part	Oral, Axillary
Measurement modes	Fast modes, Monitor modes and Cold modes
Unit	°C, °F
Resolution	0.1°C/°F
Accuracy	Oral Fast mode: $\pm 0.2^{\circ}\text{C}$ Axillary Fast mode: $\pm 0.1^{\circ}\text{C}$ Monitor mode ,Cold mode: $\pm 0.1^{\circ}\text{C}$ (the accuracy must be tested in constant temperature water tank)
Update time	Every 1s
Preheat time	About 800 ms
Self-checking	Every 3s
Alarm range	30.0~43.0°C, up-low range can be adjustable
Alarm indication	Sound and light alarm, three alarm level, alarm message display with flashing words.
Recovery time after defibrillation	$\leq 10$ s.
Transient response time in Monitor mode	<30s
minimum measuring time in monitor mode	100s

## Appendix B Factory Defaults

### B.1 Patient messages

Patient messages	Factory Defaults
Type	Adult

### B.2 Alarm

Alarm setup	Factory defaults
ALM Volume	2
Alarm paused time	2min

### B.3 Interface Setup

Interface setup	Factory defaults
Brightness	3

### B.4 SpO<sub>2</sub>

#### B.4.1 General Setups

SpO <sub>2</sub> setup	Adult	Pediatric	Neonatal
Alarm switch	On		
Alarm Level	Medium		
Alarm Print	Off		
Average Time	8s		
High alarm limit of SpO <sub>2</sub>	100%	100%	95%
Low alarm limit of SpO <sub>2</sub>	90%	90%	85%
Desat Limit	85%		
<b>Pleth</b>			
Wave Speed	25mm/s		
Color	Yellow		



## B.4.2 Special Setups (Masimo)

SpO <sub>2</sub> setup	Factory defaults
Sensitivity Mode	Normal
Fast Sat Mode	off
Smart Tone Mode	off
Waveform Mode	Resp.out
Alarm Delay	off
SpHb Mode	Arterial
SpHb Average Time	Long
SpHb Precision	0.1
SpHb Unit	g/dL

## B.5 NIBP

NIBP setup	Adult	Pediatric	Neonatal
Alarm switch	On		
Alarm Level	Medium		
Alarm Print	Off		
High alarm limit of Sys	160 mmHg	120 mmHg	90 mmHg
Low alarm limit of Sys	90 mmHg	70 mmHg	40 mmHg
High alarm limit of Map	110 mmHg	90 mmHg	70 mmHg
Low alarm limit of Map	60 mmHg	50 mmHg	25 mmHg
High alarm limit of Dia	90 mmHg	70 mmHg	60 mmHg
Low alarm limit of Dia	50 mmHg	40 mmHg	20 mmHg
Measure Mode	Manual		
Unit	mmHg		
Interval	15 min		
Color	red		
Venipuncture Press	60 mmHg	40 mmHg	30 mmHg
Inflation	170 mmHg	130 mmHg	100 mmHg

## B.6 CO<sub>2</sub> (LoFlo)

CO <sub>2</sub> setup	Adult	Pediatric	Neonatal
Alarm switch	On		
Alarm Level	Medium		
Alarm Print	Off		
Limit Display	Off		
Unit	mmHg		
High alarm limit of EtCO <sub>2</sub>	50 mmHg	50 mmHg	45 mmHg
Low alarm limit of EtCO <sub>2</sub>	20 mmHg	20 mmHg	30 mmHg
High alarm limit of FiCO <sub>2</sub>	4 mmHg	4 mmHg	4 mmHg
High alarm limit of awRR	30 rpm	30 rpm	100 rpm
Low alarm limit of awRR	8 rpm	8 rpm	30 rpm
Scale	61mmHg		
Wave Speed	12.5 mm/s		
Color	White		
Apnea alarm time	20s		

## B.7 Temp

Temp setup	Factory defaults
Alarm switch	On
Alarm Level	Medium
Unit	°C
High alarm limit of Temp	39°C
Low alarm limit of Temp	36°C

## Appendix C Alarm Messages

### C.1 Physiological alarm Messages

The third line in the cable is “Alarm level” of factory default, the ones with “\*” mean that the level can be changed by users.

#### ● SpO<sub>2</sub>

Alarm messages	Cause	Level
SpO <sub>2</sub> High	SpO <sub>2</sub> measuring value is above the high alarm limit	Medium *
SpO <sub>2</sub> Low	SpO <sub>2</sub> measuring value is below the low alarm limit	
SpO <sub>2</sub> Desat	SpO <sub>2</sub> measuring value is too low.	High
PR High	PR measuring value is above the high alarm limit	Medium *
PR Low	PR measuring value is below the low alarm limit	
SpO <sub>2</sub> No Pulse	SpO <sub>2</sub> signal is predominantly invalid and therefore cannot be analyzed	High

#### ● NIBP

Alarm messages	Cause	Level
NIBP Sys High	NIBP Sys measuring value is above high alarm limit	Medium *
NIBP Sys Low	NIBP Sys measuring value is below low alarm limit	
NIBP Dia High	NIBP Dia measuring value is above high alarm limit	
NIBP Dia Low	NIBP Dia measuring value is below low alarm limit	
NIBP Map High	NIBP Map measuring value is above high alarm limit	
NIBP Map Low	NIBP Map measuring value is below low alarm limit	

● **CO<sub>2</sub>**

Alarm messages	Cause	Level
EtCO <sub>2</sub> High	EtCO <sub>2</sub> measuring value is above high alarm limit.	Medium *
EtCO <sub>2</sub> Low	EtCO <sub>2</sub> measuring value is below low alarm limit.	
FiCO <sub>2</sub> High	FiCO <sub>2</sub> measuring value is above high alarm limit.	
awRR High	awRR measuring value is above high alarm limit.	
awRR Low	awRR measuring value is above high alarm limit.	
CO <sub>2</sub> Apnea	No breath is detected in the set period.	High

● **Temp**

Alarm messages	Cause	Level
Temp High	Temp measuring value is above high alarm limit.	Medium *
Temp Low	Temp measuring value is below low alarm limit.	

## C.2 Technical alarm Messages

● **System**

Alarm messages	Cause	Level
Battery Failure	Battery failure or no battery.	Low
Battery Low	Voltage of battery is too low.	Medium
SD Write Protected	SD memory card is write-protect.	Low
SD Unknown part	The inserted SD card is unrecognized.	Low
SD Write Error	SD card is miswriting.	Medium
SD No Space	SD card has no space.	
Flash No Space	Interior flash has no space.	
Recorder Error	No paper in the recorder when recording or the recorder door is open or recorder is absent.	Low

● **SpO<sub>2</sub>**

Alarm messages	Cause	Level
SpO <sub>2</sub> Sensor off	SpO <sub>2</sub> sensor may be disconnected from the patient or the monitor	Medium
SpO <sub>2</sub> sensor error	SpO <sub>2</sub> sensor failure	Low
SpO <sub>2</sub> signal weak	SpO <sub>2</sub> signal is weak.	

● **Masimo SpO<sub>2</sub> module**

Alarm messages	Cause	Level
SpO <sub>2</sub> No cable	No cable connected	Low
SpO <sub>2</sub> Replace cable	Cable life expired; Cable is defective	
SpO <sub>2</sub> Incompatible cable	Cable is incompatible	
SpO <sub>2</sub> Unrecognized cable	Cable is unrecognized	
SpO <sub>2</sub> No sensor	No sensor connected	
SpO <sub>2</sub> Replace sensor	Sensor life expired; Sensor is defective	
SpO <sub>2</sub> Invalid sensor	Sensor is incompatible; Sensor is unrecognized	
SpO <sub>2</sub> No tape	No tape	
SpO <sub>2</sub> Replace tape	Tape life expired Tape is defective	
SpO <sub>2</sub> Invalid tape	Tape is incompatible; Tape is unrecognized	
SpO <sub>2</sub> Sensor Calibrating	Sensor is calibrating	
SpO <sub>2</sub> Sensor off	Sensor may be disconnected from patient	
SpO <sub>2</sub> Pulse search	Searching pulse	
SpO <sub>2</sub> Interference	Interference detected	
SpO <sub>2</sub> Low perfusion	Low perfusion index	
SpO <sub>2</sub> Demo Mode	The monitor is at demo mode	
SpO <sub>2</sub> Check sensor	Check sensor is connecting	
SpO <sub>2</sub> Low SIQ	SpO <sub>2</sub> Signal IQ is low	
SpO <sub>2</sub> Low PR SIQ	PR Signal IQ is low	
SpO <sub>2</sub> Low PI SIQ	PI confidence is low	
SpO <sub>2</sub> Low SpCO SIQ	SpCO Signal IQ is low	
SpO <sub>2</sub> Low SpMet SIQ	SpMet Signal IQ is low	
SpO <sub>2</sub> Low SpHb SIQ	SpHb Signal IQ is low	
SpO <sub>2</sub> Low SpOC SIQ	SpOC Signal IQ is low	

SpO2 Low PVI SIQ	PVI Signal IQ is low	
SpO2 Board Failure	SpO2 board is failure	
SpO2 Failure	SpO2 module is failure	
SpO2 Communication Error	SpO2 communication is error	
SpO2 Enter Programming Mode	SpO2 is entering programming mode	
SpO2 Weak signal	SpO2 signal is weak	
SpO2 PR Over 239bpm	SpO2 PR is over 239bpm	

● **NIBP**

Alarm messages	Cause	Level
Self-test Failed	Transducer or other hardware failure.	Low
Loose Cuff	1. Cuff is completely unwrapped. 2. The cuff is not connected. 3. Adult cuff used in neonate mode.	
Air Leak	Air leak in pneumatics, hose, or cuff.	
Air Pressure Error	Unable to maintain stable cuff pressure, e.g. kinked hose.	
Weak Signal	Very weak patient signal due to a loosely wrapped cuff. The pulse of patient is too weak.	
Range Exceeded	Measurement range exceeds module specification.	
Excessive Motion	1. Too many retries due to interference of motion artifact. 2. Signal is too noisy during measurement, e.g. patient has severe tremor. 3. Irregular pulse rate, e.g. arrhythmia.	
Overpressure Sensed	Cuff pressure exceeds the specified high safety limit. Could be due to rapid squeezing or bumping of cuff.	
Signal Saturated	Large motion artifact that saturates the BP amplifier's amplitude handling capability.	
Pneumatic Leak	Module reports Air Leakage failure while in the Pneumatic Test mode.	
System Failure	Module occurs abnormal processor event.	
Time Out	Measurement took more than 120 seconds in adult, 90 seconds in neonate mode.	
Cuff Type Err	Neonate cuff is used in adult mode.	

● **CO<sub>2</sub>**

Alarm messages	Cause	Level
CO <sub>2</sub> sensor off	CO <sub>2</sub> sensor is off patient or off the monitor.	Low
Check airway adapter	CO <sub>2</sub> airway adapter is disconnected with CO <sub>2</sub> sensor.	
CO <sub>2</sub> measurement over range	CO <sub>2</sub> measurement is over range and need verify zero.	Low
Zero Required	Sensor or module is not initialized.	
Check CO <sub>2</sub> Sampling Line	Sampling tube is occluded or damaged; Sampling tube is kinked or pinched; Exhaust tube is blocked.	
CO <sub>2</sub> sensor error	CO <sub>2</sub> sensor is error.	
Sensor no initialized	Sensor or module is not initialized.	

● **Temp**

**Infrared ear temp**

Alarm messages	Cause	Level
Temp Sensorerror1	The temp sensor is error.	Low
Temp Sensorerror2	The temp sensor is error.	
Temp Over range Up	The measurement value is higher than 43°C.	
Temp Over range Down	The measurement value is lower than 34°C.	
Temp Environment Over range Up	The ambient temp is higher than 40°C.	
Temp Environment Over range Down	The ambient temp is lower than 10°C.	
Temp Disconnect	The temp probe is disconnected.	

**Fast temp measurement**

Alarm messages	Cause	Level
Fast temp module error	Fast temp module breakdown	middle
Fast temp sensor disconnection	The temp sensor is not installed.	middle

Temp over range Up	The ambient temp is higher than 43°C.	Low
Temp over range Down	The ambient temp is lower than 30°C.	Low

### C.3 Prompt Messages

- **System**

Messages	Cause	Level
Recording	Recorder is in printing operation.	No level

- **SpO<sub>2</sub>**

Messages	Cause	Level
Search pulse	SpO <sub>2</sub> module is searching for pulse.	No level
Motion interference	Patient movement is too much.	

- **NIBP**

Messages	Cause	Level
Software Overpress	NIBP is testing Software Over-Pressure.	No level
Hardware Overpress	NIBP is testing Hardware Over-Pressure.	
Manometer	NIBP is testing Manometer.	No level
Air Leakage Testing	NIBP is testing Air Leakage.	
Venipuncture	NIBP is in venipuncture.	

- **CO<sub>2</sub>**

Messages	Cause	Level
Zero in Progress	Zeroing is in progress.	No level
CO <sub>2</sub> Sensor Warm Up	Module is warming up.	



## Appendix D Instructions on Environmental Aspects

### D.1 Instructions for minimizing environmental impact during normal use.

➤ **Instructions on how to install the monitor in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;**

Try to keep the integrity of the non-disposable packing material and put away the packing materials for future use or put into the specified location where complying with the rules and regulations of the local and the hospital. Avoid overusing the cleaning reagents and other substances. For the reusable accessories, clean it with specified reagent and put away, and for the disposable one, deal with it in a collective way and put into the specified location where complying with the rules and regulations of the local and the hospital. If not specified, please follow the rules and regulations of the local and the hospital.

➤ **Instructions on how to use and maintain the monitor in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;**

Use the specified accessories and cleaning and disinfection reagent to avoid harm to the machine and accessories and reduction of the service life. Use the medical device strictly following the instruction manual. And for maintaining the medical device, always dilute according to the manufacturer's instructions or use lowest possible concentration. Never use bleach. Do not mix disinfecting solutions (such as bleach and ammonia) as this may result in hazardous or poisonous gases or liquids. When there is a need to maintain, please follow the instruction for use of follow the rules and regulations of the hospital.

➤ **Consumption during NORMAL USE (e.g. energy, consumable materials/parts, disposables, water, gasses, chemicals/reagents etc.);**

During normal use of this device, it will consume electricity (alternate current and direct current-battery). The disposable electrode is also consumed and shall be disposed following the rules. For cleaning or disinfection for the cables and machine, the water and ethanol or isopropanol will be used and the waste liquid shall be thrown following the rules.

- **Emissions during NORMAL USE (e.g. WASTE water, WASTE consumable materials, acoustic, energy, heat, gasses, vapours, particulates, HAZARDOUS SUBSTANCES and other WASTE);**

During normal use, it is expected there will be some consumption of the medical device. To avoid unnecessary consumption such as acoustic energy, heat, gases, hazardous substances, etc, it's recommended that on the premise of normal operation, turn down the volume of alarm so that much interference will not be exerted to the environment. Also turn off the unused module in time to reduce the unnecessary heat emission and electricity consumption.

- **Information on the location within the monitor of HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials.**

The battery is located on the back of the machine. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

## **D.2 Information for end of life management.**

- **The location of components and parts within the monitor that contain stored energy or pose other hazards that can result in an unacceptable risk to disassembles or others and methods for controlling such risks.**

The battery is located on the back of the machine. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

- **The identity and location of hazardous substances requiring special handling and treatments.**

The battery is located on the back of the machine. Capacitors may contain stored energy or may pose other hazards, assembled on the PCB boards within the device.

- **Disassembly instructions sufficient for the safe removal of these hazardous substances including radioactive sources and induced radioactive materials within the monitor.**

For other hazards that may result in unacceptable risk, the main concern is the handing with battery, risk of fire, explosion, or burns. Do not crush, puncture, disassemble or short circuit the battery. Do not dispose of the battery in an environment whose temperature is above 60°C (140°F). Store the battery in the

20°C (-4°F) to 60°C(140°F) environment. Use the specified charger only. Read instructions for use. Maximum recommended ambient is 45°C (125°F) dispose of used batteries promptly and in an environmentally-responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements.

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

# Appendix E Guidance and Manufacturer's Declaration of EMC

## Guidance and manufacturer's declaration – electromagnetic emissions -for all EQUIPMENT and SYSTEMS


Guidance and manufacture's declaration – electromagnetic emission		
The <i>monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>monitor</i> should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>monitor</i> 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 <i>monitor</i> is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

## Guidance and manufacturer's declaration – electromagnetic immunity -for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The <i>monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of <i>monitor</i> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> )	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> )	Mains power quality should be that of a typical commercial or hospital

<p>voltage variations on power supply input lines IEC 61000-4-11</p>	<p>for 0.5 cycle 40% <math>U_T</math> (60% dip in <math>U_T</math>) for 5 cycles 70% <math>U_T</math> (30% dip in <math>U_T</math>) for 25 cycles &lt;5% <math>U_T</math> (&gt;95% dip in <math>U_T</math>) for 5 sec</p>	<p>for 0.5 cycle 40% <math>U_T</math> (60% dip in <math>U_T</math>) for 5 cycles 70% <math>U_T</math> (30% dip in <math>U_T</math>) for 25 cycles &lt;5% <math>U_T</math> (&gt;95% dip in <math>U_T</math>) for 5 sec</p>	<p>environment. If the user of the <i>monitor</i> requires continued operation during power mains interruptions, it is recommended that the <i>monitor</i> be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50Hz) magnetic field IEC 61000-4-8</p>	<p>3A/m</p>	<p>3A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE <math>U_T</math> is the a.c. mains voltage prior to application of the test level.</p>			

**Guidance and manufacturer's declaration – electromagnetic immunity  
–for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

<b>Guidance and manufacture's declaration – electromagnetic immunity</b>			
The <i>monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of <i>monitor</i> should assure that it is used in such an environment.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Conducted RF IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>rms</sub>	Portable and mobile RF communications equipment should be used no closer to any part of the <i>monitor</i> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b> $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz  $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz  Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:  
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the <i>monitor</i> is used exceeds the applicable RF compliance level above, the <i>monitor</i> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <i>monitor</i>			
<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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

Recommended separation distances between portable and mobile RF communications equipment and the V6monitor			
The <i>monitor</i> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <i>monitor</i> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <i>monitor</i> as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

**Warning**

- **This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.**
- **Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.**

**Caution**

- **This unit has been thoroughly tested and inspected to assure proper performance and operation!**
- **This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used**

# LIMITED WARRANTY

Your Dynarex Product is warrantied to be free of defects in materials and workmanship for two (2) years on the unit, and six (6) months on the connected accessories included with the unit from the original date of purchase. This item was built to exacting standards and carefully inspected prior to shipment. This Limited Lifetime Warranty is an expression of our confidence in the materials and workmanship of our products and our assurance to the consumer of years of dependable service.

The Warranty shall not apply under the following conditions:

- Problems arising from normal wear
- Problems arising from failure to adhere to the product instructions
- Problems arising from misuse, negligence, accident or improper operation, maintenance or storage
- Problems arising from modifications or unauthorized repairs, parts or attachments

- Products where the serial number has been removed or defaced
- Problems with non-durable components, such as rubber accessories, casters, and grips, which are subject to normal wear and need periodic replacement

Dynarex shall not be liable for any consequential or incidental damages whatsoever. Dynarex shall repair or replace defective products at its option. The foregoing warranty is exclusive and in lieu of other express warranties, if any, including the implied warranties of merchantability and fitness of a particular purpose. The remedy for any violation of the implied warranty shall be limited to repair or replacement of the defective product pursuant to the terms contained herein.

If you have a question about your Dynarex device or this warranty, please contact an authorized Dynarex dealer.



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