Spengler

VITALIMATE MINI

User Manual

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CE 0123

Instructions

Product Name: Vital Signs Monitor
Model:SM50 REF : MON001, MON002

Intended Use: The monitor is for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Monitored parameters include: NIBP, SpO_2, TEMP. Additionally, the monitor is intended for use in transport situations within a healthcare facility.

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Responsibility of the Manufacturer

The manufacturer only considers itself responsible for any effect on safety, reliability and performance of the equipment if:
Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by the manufacturer, and
The electrical installation of the relevant room complies with national standards, and
The instrument is used in accordance with the instructions for use.

Contents

1 Safety Guidance

1.1 Safety Guidance

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

⚠ Warning

A **Warning** advises against certain actions or situations that could result in personal injury or death.

⚠ Note

A **Note** provides useful information regarding a function or a procedure.

1.1.1 Warning

⚠ Warning

- Before using the device, the equipment, patient cable and sensors etc. should be checked. Replacement should be taken if there is any evident defect or signs of aging which may impair the safety or performance.
- To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.Never adapt a grounded plug to fit an ungrounded outlet by removing the ground prong or ground clip.
- Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.
- Electric shock hazard. Covers should be removed only by qualified service personnel. There are no user-serviceable parts inside.
- Do not rely exclusively on the auditory alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.
- The packaging is to be disposed of according to local or hospital’s regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.

- Continuous power to the monitor shall be guaranteed. Data measured (including trend data, review data, alarm events and so on) could be lost when the monitor is powered down in the process of monitoring.

2 Overview

2.1 Intended Use

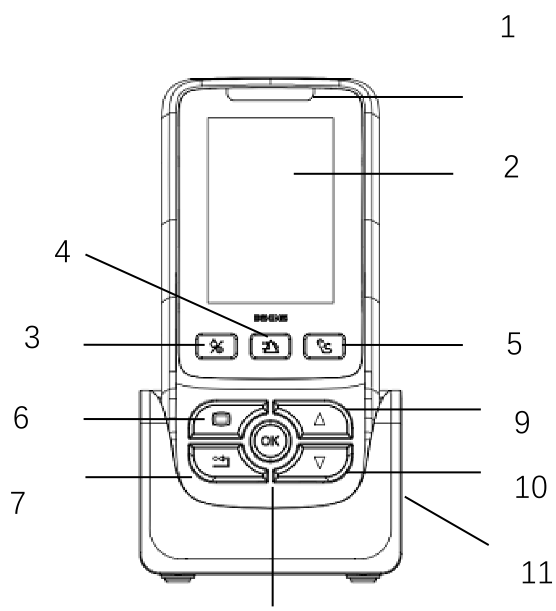
The monitor is for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates in healthcare environments. Monitored parameters include: SpO_2, NIBP and TEMP. Additionally, the monitor is intended for use in transport situations within a healthcare facility.

2.2 Product Structure and Composition

The monitor is mainly composed of host, battery, display screen and accessories.

2.3 Host

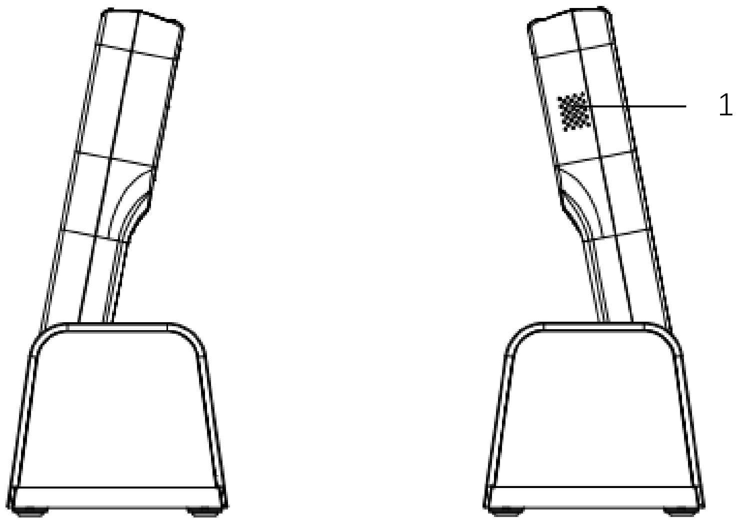
2.3.1 Front View



8

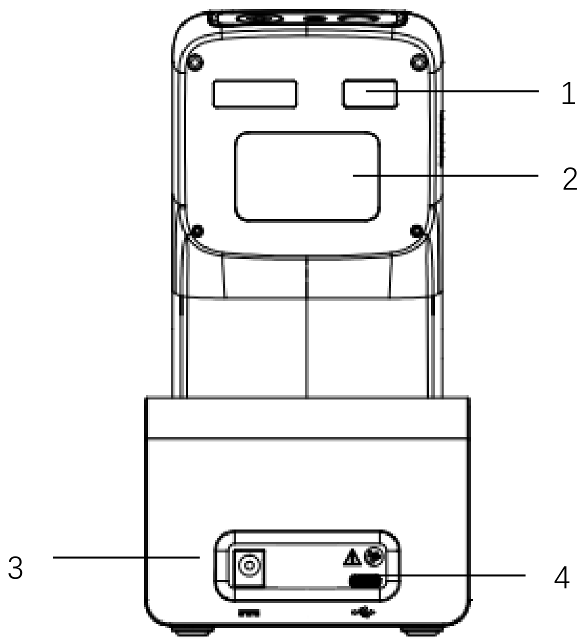
1.Alarm Indicator 2.Display screen 3.On/off key 4.Alarm reset key
5.NIBP key 6.Menu key 7.Return key 8.OK key
9.Up key 10.Down key 11.Dock

2.3.2 Side View



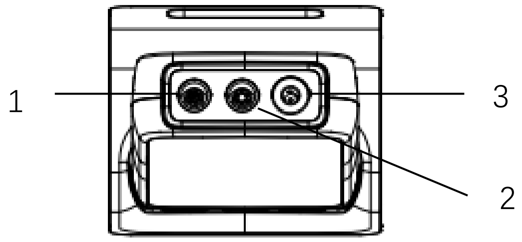
1.Speaker For alarm tones, pulse tones and so forth.

2.3.3 Rear View



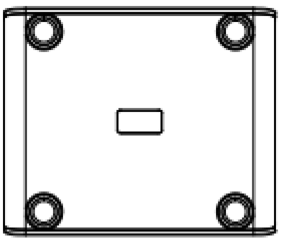
1.Serial number 2.Rating plate 3.AC power input 4.TypeC interface

2.3.4 Top View



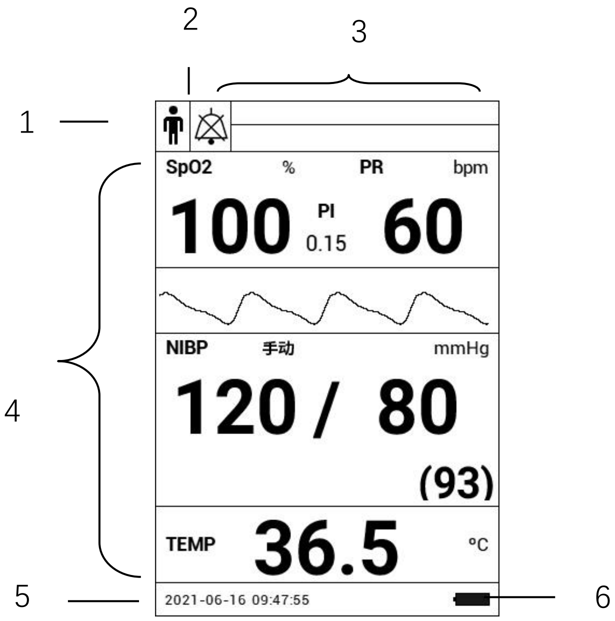
1.Temp interface 2.SpO_2 interface 3.NIBP interface

2.3.5 Bottom View



2.4 Screen Display

The interfaces in this manual are for reference only.



1. Patient information

Click here to view patient information and create new patients.

2. Alarms status icon

The icons on the interface and their meanings are as follows:

- ◆ indicates alarm reset;
- ◆ indicates audio alarm turned off;
- ◆  indicates alarm paused;
- ◆  indicates alarm turned off.

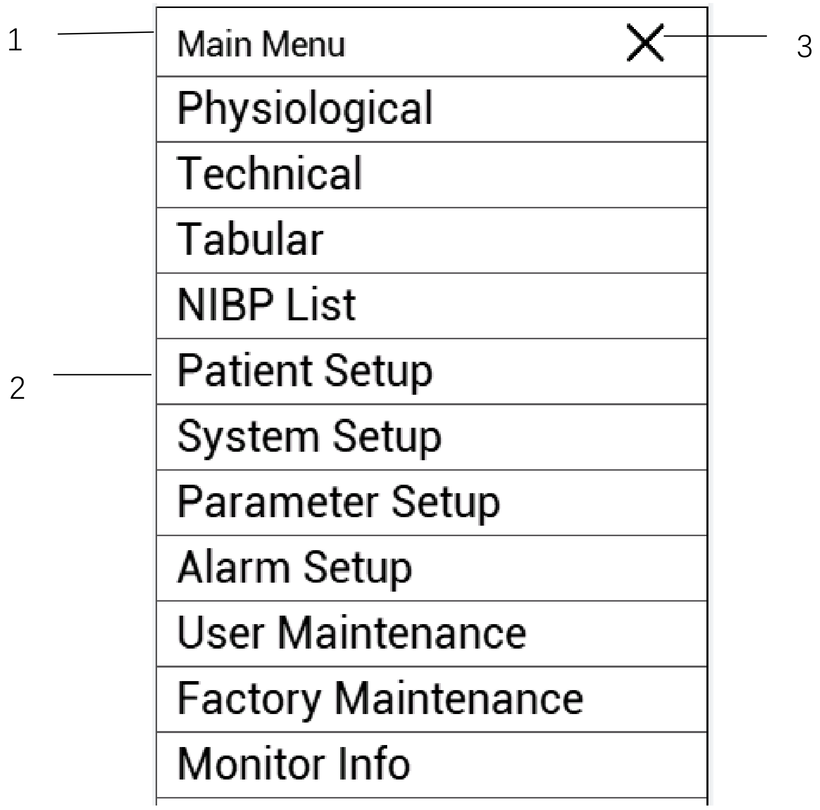
3. Alarms information area

Alarm information area is divided into two parts. The upper and lower layer displays technical alarm information, and physiological alarm information, respectively. When different level alarms occur at the same time, alarm sound and alarm indicator prompt the highest level alarm, alarm messages display in turn.

4. Parameters data and waveform areaAlarms status icon
5. Date and time
6. Battery status icon

2.5 Menu Layout

The interfaces in this manual are for reference only.



1. The menu contains the following basic elements: Menu title Summary of the menu
2. Main display area: Select the main display to enter the corresponding submenu.
3. Key: Exit the current menu and save the settings.

3 Basic Operation

3.1 On/Off

3.1.1 Power on

During startup, the monitor will perform self-test of alarm system. Press the key on the front panel, the startup screen is displayed, and the monitor enters the normal monitoring interface.

3.1.2 Power off

Long press to turn off the monitor.

3.2 General Settings

You can set the language, volume, brightness, time, unit, and view the monitoring information.

3.2.1 System Setup

3.2.1.1 Screen Light

Select → 【System Setup】→【Screen Light】

You can set brightness（100% 75% 50% 25%）

3.2.1.2 Alarm Volume

Select → 【System Setup】→【Alarm Volume】

You can set alarm volume（0-9）

3.2.1.3 Key Volume

Select → 【System Setup】→【Key Volume】

You can set Key Volume（0-9）

3.2.1.4 Pulse Volume

Select → 【System Setup】→【Pulse Volume】

You can set Pulse Volume（0-9）

3.2.2 Set language

Select → 【user maintenance】enter Password 2017) → Language selection

4 Managing patients

4.1 Admitting/Creating a Patient

To admit/create a Patient, you may: Select → 【patient Setup】

⚠ Note

●In monitor mode, creating new patient and updating patient will clear the history data in the monitor associated with the patient.

4.2 Review

Select →【Tabular】 or 【NIBP List】to review trend data.

4.3 Clear Data

Select →【User Maintenance】, then type the correct password **2017** into the displayed interface select【Data】to enter data window.

5 Alarm

5.1 Alarm Category

According to the type of alarms, the monitor provides physiological alarms and technical alarms.

5.2 Alarm Levels

In terms of severity, the device's alarm levels can be classified into three categories: high level alarms, medium level alarms and low level alarms.

1. High level alarms

A high level alarm intensively warns the operator of a high priority alarm condition which requires immediate operator response. Failure to respond to the cause of the alarm condition is likely to result in death or irreversible injury of the patient.

2. Medium level alarms

A medium level alarm warns the operator of a medium priority alarm condition which requires prompt operator response. Failure to respond to the cause of the alarm condition is likely to result in reversible injury of the patient.

3. Low level alarms

A low level alarm reminds the operator of a low priority alarm condition which requires response. And the response time for a low priority alarm condition can be greater than that for a medium priority alarm condition. Failure to respond to the cause of the alarm condition is likely to result in discomfort or reversible minor injury of the patient.

The high/medium/low-level alarms are indicated by the system in following different ways:

Alarm level	Prompt
High	Mode is "DO-DO-DO--------DO-DO",which is triggered once every 8-10 seconds. The alarm indicator flashes in red,with frequency of 1.4 Hz ~2.8 Hz. The alarm message flashes with red background, and the symbol***is displayed at the alarm area.
Medium	Mode is "DO-DO-DO",which is triggered once every 23-25 seconds. The alarm indicator flashes in yellow, with frequency of 0.4 Hz ~0.8 Hz. The alarm message flashes with yellow background, and the symbol**is displayed at the alarm area.
Low	Mode is "DO-",which is triggered once every 24-26 seconds. The alarm indicator is constantly yellow. The alarm message flashes with yellow background, and the symbol*is displayed at the alarm area.

The parameter area has two flash methods to prompt alarms: background flash and text flash. User can click respective parameter area to enter parameter setup menu:

1.Text Flash: text flashes with frequency of 1Hz.

2.Background flash: background flashes with frequency of 1Hz.

⚠ Note

●When different level alarms occur at the same time, alarm sound and alarm indicator prompt the highest level alarm, alarm messages display in turn.

5.3 Setting Alarm Options

Select →【User Maintenance】, then type the correct password **2017** into the displayed interface. You can set Alarm Volume, Alarm Pause Time and other related parameters.

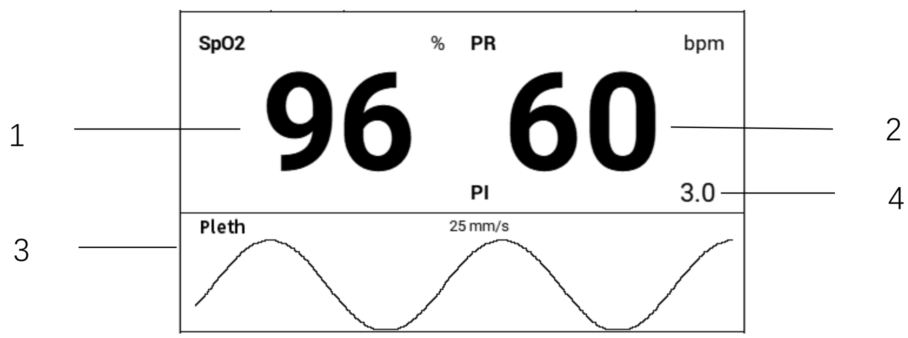
6 Monitoring SpO_2

6.1 Overview

Using the photoelectric technology, it is able to continuously monitor oxygen saturation without collecting blood samples. A finger probe is used in this monitor, and the probe is put on the finger when in use. Two light-emitting diodes (LEDs) placed side by side fixed on the upper wall of the probe emits red light at 660 nm and infrared light at 905 nm. A photodetector fixed on the lower wall converts the red light and infrared light transmitted through the arteries of the finger into electrical signals. The pulsation law of the photoelectric signal is consistent with heart beating. Therefore, PR can be determined by the detected repeated signals.

SpO_2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO_2 measuring unit. SpO_2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood.

The following illustration shows the components of the SpO_2 numeric pane.



1. SpO_2: The percentage of oxygenated hemoglobin in total hemoglobin.
2. Pulse Rate (PR): The number of detected pulses per minute obtained from the plethysmographic waveform.

3. Plethography waveform (Pleth): Non-normalized blood oxygen waveform.

4. Perfusion index (PI): The percentage of pulsation and non-pulsation caused by changes in arterial blood flow in the blood oxygen signal. PI reflects the strength of the blood oxygen signal and partly indicates the signal quality. PI>1, optimal; 0.3<PI<1, acceptable; PI<0.3, a weak perfusion. PI<0.3 needs to adjust the probe or select a more suitable perfusion site. If a continuous weak perfusion exists, it needs to verify the saturation condition using other methods.

6.2 Safety Information

⚠ Warning

- Use only specified sensors and cables, otherwise patient injury can result. Follow the sensor's instructions for use; adhere to all warnings and cautions.
- An oximeter should be used to analyze the blood sample of patients with the tendency to hypoxia, thus fully mastering the disease condition.
- Do not use the monitor or SpO_2 sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The monitor may affect the MRI image, and the MRI unit may affect the accuracy of the monitor's measurements.
- Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours. More frequent examinations may be required for different patients.
- High oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do NOT set the high alarm limit to 100%, which is equivalent to switching the alarm off.
- Make sure that the sensor is the appropriate size. The sensor should not fall off, nor should it be too tight.
- For neonatal patients, place all sensor connectors and adapter cable connectors outside the incubator. The humidity in the incubator can cause inaccurate measurements.

6.3 Measuring SpO_2 Clean the application site, such as colored nail polish.

Attach the sensor to the appropriate site of the patient finger. Plug the connector of the sensor extension cable into the SpO_2 socket.

6.4 SpO_2 Settings

■Select →【Parameter Setup】to open the SpO_2 menu, you can set Average Time、Wave Speed 、Wave Mode.

■Select →【Alarm Setup】, set the parameter alarm limits in pop-up window.

6.5 Influencing Factors of Measurement

If the accuracy of measurement does not seem reasonable, first check the patient's vital signs by alternative means then check the monitor and SpO_2 sensor. Inaccurate measurements can be caused by:

■High levels of ambient light sources, such as surgical lights.To avoid this problem, cover the application site with opaque material.

■Excessive patient movement and vibration

■Dysfunctional hemoglobins

■Low perfusion

■Venous pulsations

■Electromagnetic interference

■intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements

■Injected dyes such as methylene blue

■Incorrect sensor application

■Placement of the sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line

7 Monitoring NIBP

7.1 Overview

This monitor uses the oscillometric method for measuring NIBP. Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish. The monitor measures Systolic, Diastolic, and Mean arterial blood pressure by acquiring pressure pulses through a series of controlled deflation steps of an inflated cuff.

7.2 Safety Information

⚠ Warning

- Continual NBP measurements can cause injury to the patient being monitored. Use clinical judgement to decide whether to perform frequent blood pressure measurements on patients.
- Before starting a measurement, verify that you have selected a setting appropriate for your patient (adult or child).
- Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
- Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.
- Do not place the cuff on an extremity being used for intravenous infusion or any area where circulation is compromised or has the potential to be compromised.
- Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
- If an NIBP measurement is suspect, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.

7.3 Measurement Limitations

Measurements are impossible with pulse rate extremes of less than 40 bpm orgreater than 240 bpm), or if the patient is on a heart-lung machine.
The measurement may be inaccurate or impossible in the following situations:

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

7.4 Measurement Methods

There are three methods of measuring NIBP: Manual, loop (5 mn), Continual (Interval time : 1/2/3/4/5/10/30/60/90/120/180/240/480 mn)

Select →【Parameter Setup】 to open NIBP Setup menu, then select 【Interval】to set.

7.5 Measuring NIBP

7.5.1 Measurement Preparations

1. Switch on the monitor.
2. Select the appropriate patient type.
3. Connect the hose to the NIBP input connector.
4. Select the appropriate size cuff to the patient (About the cuff size selection, please refer to Section *NIBP accessories*), The width of the cuff is either approximately 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb.
5. Apply the blood pressure cuff to the patient's arm, and make sure that the symbol "Φ" is over the artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremity.
6. Connect the cuff to the air tubing. Do not compress the hose or restrict the pressure.

⚠ Note

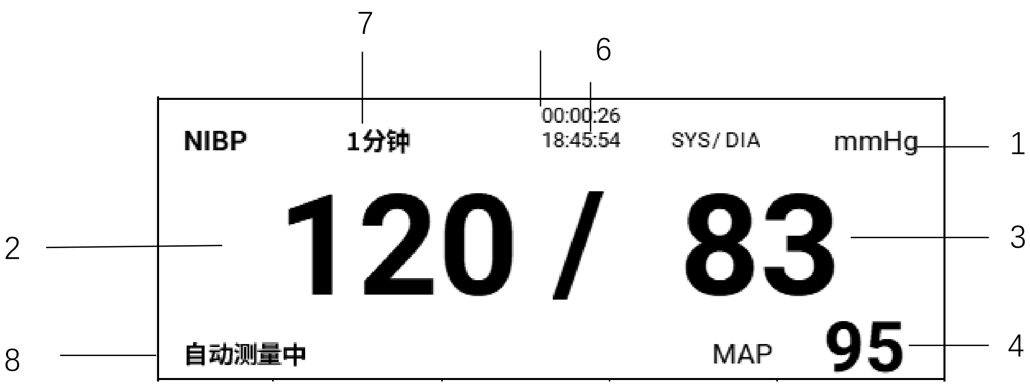
●Setting only the patient type may not be correct, it also needs to set the weight. Setting the weight is very critical, and incorrect setting may lead to failure to measure.

7.5.2 Starting/Stopping an NIBP Measurement

Press the shortcut key at the bottom of the main screen to begin the measurement. Press the shortcut key again to stop the measurement or NIBP Continual measurement.

7.6 NIBP Numeric Panes

The following illustration shows the components of the NIBP numeric panes.



1. Units of pressure, mmHg or kpa
2. Systolic value
3. Diastolic value
4. Mean value
5. Time of last measurement
6. Time from next auto measurement
7. Auto measuring interval
8. Measure mode

7.7 NIBP Settings

■Select →【Parameter Setup】 to open NIBP Setup menu, you can set Sensitivity、unit、measuring interval.

■Select → 【Alarm Setup】, set the parameter alarm limits in pop-up window.

7.7.1 Changing the NIBP Units of Measurement

In 【Parameter Setup】 menu, you can set 【NIBP Unit】 to 【mmHg】 or 【kPa】.

7.7.2 Setting measuring Interval

In 【Parameter Setup】 menu, you can set 【Interval】:

■【Manual】: The monitor performs NIBP measurement in manual mode.

■【1min】, 【2min】, ...: Continually repeated measurements, the measurement will run as specified interval.

■【Loop】: The measurement will run consecutively in five minutes.

7.7.3 Configuring the Initial Inflation Pressure

You can manually set the initial inflation pressure of the cuff: open 【Parameter Setup】 menu, select proper value of cuff pressure in 【Initial Pressure】. To change the initial inflation pressure.

The range of initial inflation pressure values is as follows:

Patient Type	Defaultvalue(mmHg/kPa)	Selectable value in NIBP menu (mmHg/kPa)
Adult	160/21.3	150-180/20.0-24.0
Pediatric	140/18.6	140/18.6

8 Monitoring TEMP

8.1 Overview

TEMP only displays the temperature value in the parameter area at the bottom of the screen without a waveform.

8.2 Safety Information

⚠ Warning

●Use only the specified probes for your monitor. The use of any other probe cover may produce temperature measurement errors or result in inaccurate readings.

●After the measurement is completed, please wash hands to greatly reduce the risk of cross-contamination and hospital infection.

⚠ Note

●Patient actions may interfere with accurate temperature readings.

●Improper use of the probe may cause discomfort to the patient and affect the measurement results

8.3 TEMP Settings

■Select →【Parameter Setup】, set 【TEMP Unit】 to 【℃】or【℉】.

■Select →【Alarm Setup】, set the parameter alarm limits in pop-up window.

8.4 Temperature Measurement

The steps for body temperature measurement are as follows:

1. Ensure the TEMP sensor has been inserted into the interface of the monitor.
2. Place the probe in the appropriate site on the patient.
3. Start TEMP measurement. Securely hold the probe in place until the temperature is displayed.

9 Battery

9.1 Overview

This monitor can run on battery power, which ensures its uninterrupted operation even when AC power supply is interrupted. The battery recharges whenever the monitor is connected to the AC power source. During monitoring, if the AC power is interrupted, the monitor will take power from the internal battery. If the monitor is powered by battery, the monitor will switch off automatically before the battery is completely depleted.

⚠ Note

●To ensure that the battery is sufficiently charged, keep the monitor plugged in to AC power when it is not in use.

●When power is lost for 30 seconds, the ALARM SETTINGS prior to the power loss shall be restored automatically.

Battery status symbols on the screen indicate battery status:

■ The battery works normally, and indicates the battery power remaining.

■ The battery is low and needs to recharge.

■ The battery is almost depleted and needs to recharge immediately, otherwise the monitor will shut down automatically.

When the battery charge is low,【Battery Low】message appears at the alarm area, the alarm indicator flashes and an alarm tone sounds.

When the battery charge is almost depleted, 【System will shutdown】 message appears at the alarm area, the alarm indicator flashes and an alarm tone sounds.

9.2 Charging the Battery

Any time the monitor is connected to AC power, the battery is being charged. When charging the battery, the green LED lights when the AC power source is connected. Also, the battery indicator indicates the current status of the battery.

9.3 Maintaining the Battery

Batteries should be conditioned regularly to maintain their useful life.

Remove the batteries from the monitor if they are not used for a longer period of time. And recharge the batteries at a minimum of every 6 months when they are stored.

Discharge the battery completely once every month.

⚠ Warning

●The service life of the battery depends on the service frequency and time. The service life of the battery is about three years if the battery is well maintained and stored. The service life of the battery may shorten if it is used inappropriately.

9.3.1 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as recommended here can help to slow down this process.

1. Disconnect the patient from the monitor and stop all monitoring and measurement.
2. Switch the monitor power on and charge the battery for more than 6 hours continuously.
3. Disconnect monitor from mains power and let the monitor run until there is no battery power left and the monitor shuts off.Respiratory Gas Monitor User Manual Using Battery.
4. The running time of the battery reflects the battery performance.

If the running time is obviously less than the specified time in the specification, please change the battery or contact the service personnel.

⚠ Warning

●Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the monitor.

9.4 Recycling the Battery

When the battery no longer holds a charge, it should be replaced., Please contact the service personnel to change it. Dispose of used batteries 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.

⚠ Warning

Do not disassemble the battery put them into fire or cause them to short circuit. They may ignite, explode or leak, causing personal injury.

10 Maintenance

10.1 Care and Cleaning

Use only the SINOHERO-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

10.1.1 General Guidelines

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute cleaning agents according to the manufacturer’s instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).

⚠ Warning

- If you spill liquid on the equipment or accessories, or they are accidentally immersed in liquid, contact your service personnel or SINOHERO service engineer.
- The MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.
- The service life of the monitor is about five years.

10.1.2 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination, then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

10.1.2.1 Cleaning the Monitor

To clean the monitor:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain.
3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Dry the monitor in a ventilated and cool place.

⚠ Warning

- Before cleaning the monitor, make sure that the monitor is switched off and disconnected from the power line.

10.1.2.2 Cleaning the Cables and External Power Supply

To clean the cables and external power supply:

1. Dampen a soft cloth with the cleaning solution.
2. Wring any excess moisture from the cloth and gently clean the cables and external power supply.
3. Clean the areas again with a damp cloth moistened with water only.
4. Wipe off residual moisture with a dry cloth.
5. Leave the cables to air dry.

10.1.3 Disinfection

For devices or accessories that have been in contact mucosal surface, High Level disinfection must occur, for all other accessories, low level disinfection is appropriate. Clean the monitor and reusable accessories before they are disinfected.

The validated disinfectants for cleaning the monitor and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

10.1.3.1 Disinfecting the Monitor

To disinfect the monitor:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.
3. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
5. Dry the monitor for at least 30 minutes in a ventilated and cool place.

⚠ Warning

- Before Disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

10.1.3.2 Disinfecting the Cables and External Power Supply

To disinfect the cables and external power supply:

2. Dampen a soft cloth with the disinfectant solution.
3. Wring any excess moisture from the cloth and gently clean the cables.
4. Clean the areas again with a damp cloth moistened with water only.
5. Leave the cables to air dry for at least 30 minutes.

10.2 Inspecting

The overall check of the monitor, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

- If the environment condition and power supply meet requirement.

- If the power supply cord has damage and insulativity meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- Battery performance
- If all functions are in good conditions.
- If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please don’t use the monitor and contact local Customer

11 Accessories

⚠ Warning

●Use only SINOHERO-approved accessories. Using non-SINOHERO-approved accessories may compromise device functionality and system performance and cause a potential hazard.

●Do not use the accessory if you see signs of damage.

●When connecting and using accessories, avoid contacting the conductive parts of accessories or the device.

11.1 SpO_2 Accessories

Accessories	Part Number	Type	Manufacturer (Parts to be purchased)
SpO_2 Sensor	30110-000060 Adult	Reusable	Shenzhen Solaris Medical Technology. Inc.
	30110-000040 Adult/Neonate	Reusable	

11.2 NIBP Accessories

Accessories	Limb Circumference	Bladder Width	Part Number	Type	Manufacturer (Parts to be purchased)
NIBP Hose	/	/	30122-000010	Reusable	Shenzhen SINOHERO Biomedical

					Technology Co., Ltd
NIBP Reusable Cuff adult	27cm~35cm	14.2 cm	30120-000020	Reusable	Shenzhen Yong Kang Da Electronic Technology Co., Ltd
NIBP Reusable Cuff large adult	34cm~43cm			Reusable	Shenzhen Yong Kang Da Electronic Technology Co., Ltd
NIBP Reusable Cuff child	18cm~26cm			Reusable	Shenzhen Yong Kang Da ElectronicTechnology Co., Ltd
NIBP Reusable Cuff neonat	10cm~19cm			Reusable	Shenzhen Yong Kang Da ElectronicTechnology Co., Ltd

11.3 TEMP Accessories

Accessories	**Part Number**	**Type**
temperature probe	30140-000030	Reusable

Appendix A Product Specification

A.1 Classification

Parameter	Specification
Anti-electroshock type	Class I equipment and internal powered equipment
Anti-electroshock degree	BF
Ingress Protection	IPX1
Suitability for use in an OXYGEN RICH ENVIRONMENT	Not Suitable
Mode of Operation	Continuous

A.2 Physical Specifications

A.2.1 Display

Parameter	Specification
Screen Type	TFT-AM LCD display
Screen Size	3.5" LCD

A.2.2 Environment Specification

Parameter	Specification
Temperature	
Working	5℃～ 40℃
Transport and Storage	-20℃～ +55℃
Humidity	
Working	15%~80%, non-condensing
Transport and Storage	10%~93%, non-condensing
Altitude	
Working	80kPa～107.4kPa (800hPa～1074hPa）
Transport and Storage	22kPa～107.4kPa (220hPa～1074hPa）

⚠ Note

●The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

●When the monitor and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

A.2.3 Electrical Specifications

Parameter	Specification
External Power Supply	100 - 240 VAC line voltage, 50/60 Hz
Internal Battery	Lithium ion, 3.7V/4000mAh。
	Battery Operating Time (new, fully-charged battery): 12 hours.
	Charging time: 8 hours; the monitor is on.

A.3 SpO_2 Specifications

Parameter	Specification
SpO_2 Measurement Range	0% ～ 100%
SpO_2 Accuracy	± 2%(70% ～ 100%)
	Undefined (0% ～ 69%)
Pulse Rate	
Measurement Range	25bpm ～ 254bpm
Adjustable Range of Alarm Limits	0 ～ 100%
Resolution	1bpm
Data Update Period	approximately 1s
Pulse Rate Accuracy	±2 bpm
Red LED Wavelength	660nm
IR LED Wavelength	905 nm
Maximum Optical Output Power	150 mW，for all specified sensors

⚠ Note

●The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed) .

● Data averaging and other signal processing on the transmitted and displayed data values of SpO_2 and pulse rate is controllable by the user-selectable SpO_2 Response Mode: Slow (20 seconds), Normal (10 seconds) and Fast (5 seconds). Depending on the magnitude of difference between the alarm limit and the displayed value, the alarm signal generation delay may be from 1 second to the value of the response time (5, 10, or 20 seconds). Because pulse oximeter equipment measurements are statistically distributed, only approximately two-thirds of pulse oximeter equipment measurements can be expected to fall within the ± Arms value measured by a CO-oximeter.

A.4 NIBP Specifications

Parameter	Specification
Technique	Oscillometry
Measuring Type	SYS,DIA,MAP
Unit	mmHg or kPa
Mode	Manual,Auto, Continuous
Adult Measurement Range	
R Systolic	30 mmHg ～ 270mmHg (4.0kPa～36.0kPa)
Diastolic	10 mmHg ～ 220mmHg (1.3kPa ～29.3kPa)
MAP	20 mmHg ～ 230mmHg (2.7kPa～30.7kPa)
Pediatric Measurement Range	

Systolic	30 mmHg ～200mmHg (4.0kPa ～26.7kPa)
Diastolic	10 mmHg ～ 165mmHg (1.3 kPa～22.0kPa)
MAP	20 mmHg ～165mmHg (2.7kPa～22.0kPa)
Accuracy	Maximum Mean Error : ± 5 mmHg (± 0.67 kPa) Maximum Standard Deviation : 8 mmHg (1.067 kPa).
Adjustable Range of Alarm Limits	Consistent with the display range
Resolution	1mmhg or 0.1kpa
Alarm Delay	<10s
Cuff Pressure Measuring Range	0 mmHg ～ 300 mmHg (0 kPa～ 40.0kPa)
Resolution	0.133 kPa（1 mmHg）
PR	
Measurement Range	40 bpm ~ 240 bpm
Accuracy	± 2% or ± 2 BPM, whichever is greater

A.5 TEMP Specifications

Parameter	Specification
Measurement Range	0℃～50℃（32.0℉～122.0℉）
Unit	℃ or℉
Accuracy	±0.1 °C
Adjustable Range of Alarm Limits	Consistent with the display range
Alarm delay	<10s
Minimum time to display TEMP	10S
Data Update Period	1S

B EMC Information

- Guidance and Manufacture's Declaration

B.1 Electromagnetic Emissions

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

⚠ Note

- The EMISSIONS characteristics of the monitor make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) iM3 might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

B.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that they are used in such an environment.

Immunity test	IEC/EN 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 floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+ 1 kV differential mode +2 kV common mode	+ 1 kV +2 kV	In the event of reduced performance, it may be necessary to operate the patient monitor from a filtered power connection or battery power (no electrical connection to the AC mains while monitoring).
Surge IEC 61000-4-5	+ 1 kV differential mode + 2 kV common mode	+ 1 kV + 2 kV	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0,5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5 sec	< 5% UT 40% UT 70% UT < 5% UT	
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

B.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity

<table>
<tr><td colspan="4">The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that they are used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC/EN 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
0.15 to 80 MHz
Outside ISM bands</td><td>3 V rms</td><td rowspan="5">Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
150KHz to 80MHz
80 MHz to 800 MHz
800 MHz to 2.7 GHz
d=6 /E at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer).
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 to 2500 MHz</td><td>3 V/m</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
</table>

			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m. Respiration measurement may be subject to interference at 900 - 1100 kHz and 70 - 80 MHz at less than 3 V/M field strength.			

B.4 Recommended Separation Distances

<table>
<tr><td colspan="4">Recommended separation distances between
portable and mobile RF communications equipment and the monitor</td></tr>
<tr><td colspan="4">The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><td rowspan="2">Rated maximum output power of transmitter
(W)</td><td colspan="3">Separation distance according to frequency of transmitter(m)</td></tr>
<tr><td>150kHz～80MHz
d=1.2$\sqrt{p}$</td><td>80MHz～800MHz
d=1.2$\sqrt{p}$</td><td>80MHz～800MHz
d=1.2$\sqrt{p}$</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.23</td></tr>
<tr><td>0.1</td><td>0.38</td><td>0.38</td><td>0.73</td></tr>
<tr><td>1</td><td>1.2</td><td>1.2</td><td>2.3</td></tr>
<tr><td>10</td><td>3.8</td><td>3.8</td><td>7.3</td></tr>
<tr><td>100</td><td>12</td><td>12</td><td>23</td></tr>
<tr><td colspan="4">For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1 At 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.</td></tr>
</table>

Appendix C Alarm Information

C.1 Physiological Alarm Information

The following table contains an alphabetical listing of physiological alarm messages.

Alarm Message	Priority	Cause
SpO_2 Too High	User-selectable	SpO_2 measuring value has exceeded the high alarm limit.
SpO_2 Too Low	User-selectable	SpO_2 measuring value has dropped below the low alarm limit.
No Pulse	High	The signal of the measurement site is too weak due to insufficient blood supply and environmental factors, so the monitor can‘t detect the pulse signal.
PR Too High	User-selectable	PR measuring value has exceeded the high alarm limit.
PR Too Low	User-selectable	PR measuring value has dropped below the low alarm limit.
Sys Too High	User-selectable	Sys measuring value has exceeded the high alarm limit.
Sys Too Low	User-selectable	Sys measuring value has dropped below the low alarm limit.
Map Too High	User-selectable	Map measuring value has exceeded the high alarm limit.
Map Too Low	User-selectable	Map measuring value has dropped below the low alarm limit.
Dia Too High	User-selectable	Dia measuring value has exceeded the high alarm limit.
Dia Too Low	User-selectable	Dia measuring value has dropped below the low alarm limit.
Temp Too High	User-selectable	Measuring value of TEMP has exceeded the high alarm limit.
Temp Too Low	User-selectable	Measuring value of TEMP has dropped below the low alarm limit.

C.2 Technical Alarm Information

Alarm Message	Priority	Cause	Action Taken
SpO_2			

SpO_2 Communication Stop	High	SpO_2 module failure or communication failure	Restart the monitor, if failure persists, stop using measuring function of SpO_2 module, and notify manufacturer's service staff.
SpO_2 No Sensor Connected	Low	SpO_2 sensor cable is disconnected from the monitor.	Make sure the monitor and sensor are well connected, reconnect the sensor.
SpO_2 Sensor Off	Low	SpO_2 sensor may be disconnected from the patient measuring site.	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the monitor and cables are well connected.
SpO_2 Search Timeout	Low	Measuring time has exceeded the specified time.	Change the measurement site, if problem exists, please notify manufacturer's service staff.
NIBP			
NIBP Communication Stop	High	NIBP module failure or communication failure	Restart the monitor, if failure persists, stop using measuring function of NIBP module, and notify manufacturer's service staff.
NIBP selfcheck error	Low	Sensor or other hardware errors.	If failure persists, stop using measuring function of NIBP module and notify manufacturer's service staff.
NIBP air pressure error	Low	Abnormal atmospheric pressure of the environment. Please confirm that	Check atmospheric pressure of the environment. Restart the monitor, if

		the environment is qualified for the monitor and the presence of any special reasons that affect the environmental pressure.	problem exists,please notify manufacturer's service staff.
Cuff type error	Low	The cuff type used isn't consistent with the patient type.	Confirm the patient type and change the cuff. Properly wrap the cuff. If failure persists, please notify manufacturer's service staff.
Cuff loose or no cuff	Low	Cuff is not properly wrapped or no cuff is connected.	
Cuff leak	Low		
Cuff position error	Low		
NIBP over range	Low	Maybe the patient blood pressure value is beyond the measurement range.	
NIBP over pressure	Low	Pressure has exceeded the specified upper safety limit.	
NIBP system error	Low	NIBP is not calibrated.	
NIBP signal saturated	Low	Signal noise is too large or pulse rate is not regular due to the patient movement.	Make sure that the patient under monitoring is motionless.
NIBP excessive motion	Low		
TEMP			
TEMP Sensor Off	Low	TEMP sensor is not connected to the TEMP module.	Connect the sensor and the monitor well, and measure again.
Battery			
Battery Low	Medium	Battery Low	Please charge the battery.
System will shutdown	High	The battery is almost depleted	

C.3 Prompts

Message	Cause

SpO2 Pulse Search	SpO2 module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
Measurement timeout	No measuring result after the module entering Predict state for 30 s.

D Terms

Abbr	English Full Name/Description
AC	Alternating current
Adu	Adult
AG	Anaesthetic Gas
CE	Communauté Européenne
CO_2	Carbon dioxide
DC	Direct current
EEC	European Economic Community
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
ID	Identification
IEC	International Electrotechnical Commission
ISO	Isoflurane
IEEE	Institute of Electrical and Electronic Engineers
IP	Internet protocol
LED	Light emitting diode
MDD	Medical Device Directive
MetHb	Methemoglobin
MRI	Magnetic resonance imaging
N_2O	nitrous oxide
O_2	Oxygen
P	Power
Pleth	Plethysmogram
PR	Pulse rate
Sev	Sevoflurane
R	Right
RA	Right arm
SpO_2	Arterial oxygen saturation from pulse oximetry
USB	Universal serial bus

TABLE DE SYMBOLES / *WARNING SIGNS AND SYMBOLS USED / SÍMBOLOS UTILIZADOS*	
	Fabricant / Manufacturer / Fabricante
	Date de Fabrication / Date of manufacture / Fecha de fabricación
	Importé par / Imported by / Importado por
	Distribué par / Distributed by / Distribuido por
CE	Le produit est conforme aux exigences du Règlement (UE) 2017/745 sur les dispositifs médicaux The product complies with the requirements of Regulation (EU) 2017/745 on medical devices El producto cumple con los requisitos de Reglamento (UE) 2017/745 sobre productos sanitarios
EU REP	Mandataire européen / European representative / Representante europeo
REF	Numéro de la référence / Reference number / Número de referencia
LOT	Numéro de lot / Batch Number / Número de lot
#	Numéro de modèle / Model number / Número de modelo
	Manuel d'utilisation à consulter OBLIGATOIREMENT Instructions for use, MUST be consulted Instrucciones de uso, DEBE consultarse
	Equipements de type BF / BF type equipment / Equipo de tipo BF
	Jetez le produit usagé au point de collecte pour le recyclage conformément aux réglementations locales Discard the used product to the recycling collection point according to local regulations Desechar el producto usado para su reciclado punto de recogida según la normativa local
	Attention / Caution / Atención
MD	Dispositif médical / Medical Device / Dispositivo médico
UDI	Numéro d'identification UDI / UDI identification number / Número de identificación del UDI
SN	Numéro de série / Serial Number / Número de serie

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