VS 9/VS 9A/VS 9C VS 8/VS 8A/VS 8C

**Vital Signs Monitor** 

**Operator's Manual** 



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- the product is used in accordance with the instructions for use.

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- This equipment must be operated by skilled/trained clinical professionals.
- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

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# **Preface**

# **Manual Purpose**

The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

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

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

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

### **Intended Audience**

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

### Illustrations

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

## **Conventions**

- Italic text is used in this manual to quote the referenced manuals, chapters, sections and formulas.
- **Bold text** is used to indicate the screen texts and names of hard keys.
- $\rightarrow$  is used to indicate operational procedures.

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# 1 Safety

# 1.1 Safety Information

### WARNING

 Indicates a potential hazard or unsafe practice that, if not avoided, could 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.

## 1.1.1 Warnings

### WARNING

- This equipment is used for single patient at a time.
- To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.
- The equipment is not intended to be used within the Magnetic Resonance (MR) environment.
- Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.
- Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.

- To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if possible.
- Do not use the multiple portable socket outlets (MPSO) or AC mains extension cords. Insure that the sum of the individual ground leakage currents does not exceed the allowable limits.
- Do not touch the patient and live parts simultaneously. Otherwise patient injury may result.
- Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.
- Do not open the equipment housings. All servicing and future upgrades must be carried out by trained and authorized personnel.
- Do not rely exclusively on the audible alarm system for patient monitoring. Turning the alarm volume to a low level or off may result in a hazard to the patient. Remember that alarm settings should be customized according to patient situations. Always keep the patient under close surveillance.
- Physiological data and alarm messages provided by the monitor should not be used as the sole basis for diagnosis or therapy decisions. They must be used in conjunction with clinical signs and symptoms. Misinterpretation of the measured values or other parameters can endanger the patient.
- Do not place the equipment or accessories in any position that might cause it to fall on the patient.
- Do not start or operate the equipment unless the setup was verified to be correct.
- To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to reduce risk of entanglement by patients or personnel.
- The equipment should not be used as the sole basis for medical decisions. It
  must be used in conjunction with clinical signs and symptom. If any
  measurement seems questionable, first check the patient's vital signs by
  alternate means and then check the equipment for proper functioning.
- The software equipment copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.

### 1.1.2 Cautions

### CAUTION

Use only parts and accessories specified in this manual.

- Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure may cause data loss.
- Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment 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.
- Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.
- Dry the equipment immediately in case of rain or water spray.
- Some settings are password protected and can only be changed by authorized personnel. Contact your department manager or biomedical engineering department for the passwords used at your facility.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Dispose of the package material as per the applicable waste control regulations. Keep it out of children's reach.
- At the end of its service life, the equipment, 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 equipment, please contact us.

### 1.1.3 Notes

### NOTE

- Put the equipment in a location where you can easily view and operate the equipment.
- The equipment use a mains plug as isolation means to the mains power. Do not locate the equipment in a place difficult to operate the mains plug.
- The typical operator's position is in front of the monitor.
- The software was developed in compliance with IEC62304. The possibility of hazards arising from software errors is minimized.
- This manual describes all features and options. Your equipment may not have all of them.
- Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.

# 1.2 Equipment Symbols

Some symbols may not appear on your equipment.

$\triangle$	Caution	SN	Serial number
	Refer to instruction manual/ booklet	W	Date of manufacture
===	Direct current	~	Alternating current
-+	Battery indicator	<b>↔</b>	Input/output
•	USB connector	$\triangle$	Equipotentiality
1 <u>V</u>	DEFIBRILLATION-PROOF TYPE BF APPLIED PART	-  <b> </b>	DEFIBRILLATION-PROOF TYPE CF APPLIED PART
	Gas inlet	$\qquad \qquad \longrightarrow$	Gas outlet
5	Graphical record	<b>%</b>	Alarm Reset
<b>%</b>	NIBP Start/Stop key	<b>†</b> +	Admit patient
(h)	Stand-by	몶	Computer network
$\wedge$	General warning sign	1	Temperature limit

<b>€</b>	Atmospheric pressure limitations	<b>Ø</b>	Humidity limitations		
11	This way up	<b>*</b>	Keep away from rain		
T	Fragile, handle with care	ÌXÍ⊠■	Stacking limit by number		
$((\mathbf{r}))$	Non-ionizing electromagnetic radiation		Plastic identification symbol		
	Dispose of in accordance to your country's requirements	EC REP	Authorized representative in the European Community		
	Manufacturer	MD	Medical Device		
<b>C</b> € <sub>0123</sub>	The product bears CE mark indicating its conformity with the provisions of the REGULATION (EU) 2017/745 on medical devices and fulfills the general safety and performance requirements of Annex I of this regulation.  Note: The product complies with the Council Directive 2011/65/EU.				
TrueBP™	TrueBP is Mindray's new non-invasive blood pressure measurement algorithm using linear inflation technology, which can measure the blood pressure quickly and comfortably during cuff inflation.				
TrueResp™	TrueResp is Mindray's new respiration algorithm using pulse wave amplitude variation from $\mbox{SpO}_2.$				

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# **2** Equipment Introduction

### 2.1 Intended Use

The VS 9/VS 9A/VS 9C/VS 8/VS 8A/VS 8C Vital Signs Monitors are intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters including Temperature (Temp), Pulse Oxygen Saturation (SpO $_2$ ), Pulse Rate (PR), Respiration Rate (RR), Non-invasive Blood Pressure (NIBP), Carbon Dioxide (CO $_2$ ). All the parameters can be monitored on single adult, pediatric, and neonatal patients.

The monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use. VS 9/VS 9A/VS 9C/VS 8/VS 8A/VS 8C Vital Signs Monitors are not intended for helicopter transport, hospital ambulance, or home use.

### **NOTE**

 According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed due to the risk management report.

# 2.2 Intended Users

The VS Series Monitors are to be used in healthcare facilities by clinical professionals or under their guidance. They should only be used by persons who have received adequate training in their use.

# 2.3 Intended patient population

The VS 8/VS 8A/VS 8C/VS 9/VS 9A/VS 9C Vital Signs Monitors are applicable for single adult, pediatric, and neonatal patients.

## 2.4 Intended Medical conditions

The VS Series Monitors are expected to be used in medical institutions, and its application fields include: emergency care, internal medicine and surgical care, neonatal care, elderly care, Ambulance Surgical Center, postoperative recovery, Physician Office.

The VS Series Monitors are not intended for helicopter transport, hospital ambulance, or home use.

## 2.5 Contra-indications

None.

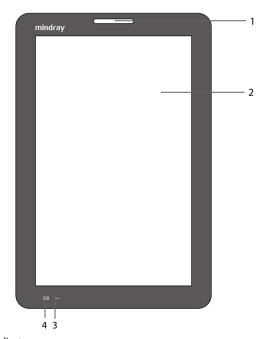
# 2.6 Applied Parts

The applied parts of the monitor are:

- SpO<sub>2</sub> sensor
- Temp probe
- NIBP cuff
- CO<sub>2</sub> sampling line/nasal sampling cannula

### 2.7 Main Unit

# 2.7.1 Front View (VS 9 Series)

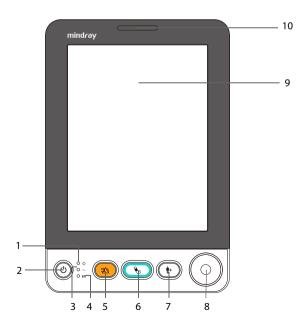


1. Alarm indicator

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

- High priority alarm: the lamp quickly flashes red.
- Medium priority alarm: the lamp slowly flashes yellow.
- Low priority alarm: the lamp is cyan without flashing.
- 2. Display screen
- 3. AC power indicator
  - On: indicates that the monitor is connected to the AC power.
  - Off: indicates that the monitor is not connected to the AC power.
- 4. Battery LED
  - Green: the battery is fully charged.
  - ◆ Yellow: the battery is being charged.
  - Flashing green: the monitor runs on battery power.
  - ◆ Flashing yellow: the battery malfunctions.
  - Off: no battery is installed, or the AC mains is not connected when the monitor is powered off.

### 2.7.2 Front View (VS 8 Series)



#### Power on/off indicator

- On: indicates that the monitor is on or on Standby.
- Off: indicates that the monitor is off.

### 2. Power switch

- Press this key to turn the monitor on.
- When the monitor is on, if no measurement is being performed, press this key to enter standby mode.
- When the monitor is on, press and hold this key for above 3 seconds to turn the monitor off.

#### 3. AC power indicator

- On: indicates that the monitor is connected to the AC power.
- Off: indicates that the monitor is not connected to the AC power.

### 4. Battery LED

- Green: the battery is fully charged.
- Yellow: the battery is being charged.
- ◆ Flashing green: the monitor runs on battery power.
- Off: no battery is installed, or the AC mains is not connected when the monitor is powered off.

#### 5. Alarm Reset/Pause key

- Press this key to reset the alarm system.
- Press and hold this key for more than 2 seconds to pause or resume alarms.

### 6. NIBP Start/Stop key

Press to start or stop NIBP measurement.

#### 7. Admit patient key

Press this key to admit a new patient.

#### 8. Knob

- Rotate the knob clockwise or counterclockwise to switch to another screen element.
- Press the knob to select one item, such as accessing a menu or confirming the selection.

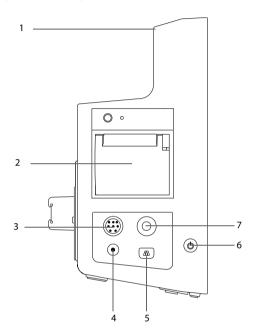
### 9. Display screen

#### 10. Alarm indicator

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

- High priority alarm: the lamp quickly flashes red.
- ◆ Medium priority alarm: the lamp slowly flashes yellow.
- ◆ Low priority alarm: the lamp is cyan without flashing.

### 2.7.3 Side View (VS 9 Series)

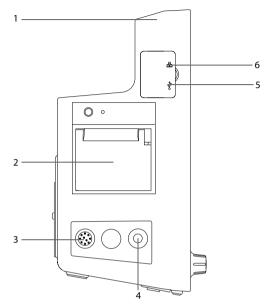


- 1. Handle
- 2. Recorder
- 3.  $SpO_2$  cable connector
- 4. CO<sub>2</sub> gas outlet
- 5. CO<sub>2</sub> sampling line connector
- 6. Power switch
  - Press this key to turn the monitor on.
  - When the monitor is on, if no measurement is being performed, press this key to enter standby mode.
  - When the monitor is on, press and hold this key for above 3 seconds to turn the monitor off.

An indicator is built in this switch. It turns on when the monitor is on and turns off when the monitor is off.

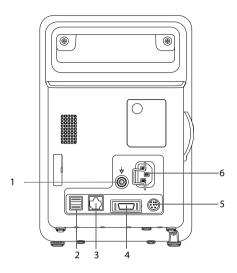
### 7. NIBP cuff connector

# 2.7.4 Side View (VS 8 Series)



- 1. Handle
- 2. Recorder
- 3. SpO<sub>2</sub> cable connector
- 4. NIBP cuff connector
- 5. USB connector
- 6. Network connector

# 2.7.5 Rear View (VS 9 Series)

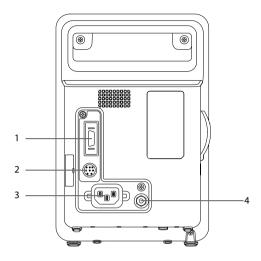


### 1. Equipotential grounding terminal

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

- 2. USB connector
- 3. Network connector
- 4. Multi-function connector
- 5. External battery connector
- 6. AC power input

# 2.7.6 Rear View (VS 8 Series)



- 1. Multi-function connector
- 2. Connector for an external battery
- 3. AC power input
- 4. Equipotential grounding terminal

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

# **3** Getting Started

# 3.1 Equipment Preparation Safety Information

### WARNING

- Use only installation accessories specified by Mindray.
- The equipment software copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
- Connect only approved devices to this equipment. Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact Mindray.
- The monitor and parameter monitoring accessories are suitable for use within the patient environment. For other equipment and accessories connected to the monitor, consult corresponding manufacturers for the suitability within the patient environment.
- If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturer or an expert in the field. A determination must be made that the proposed combination will not negatively affect the devices themselves or the patient's safety.
- If the accuracy of any value displayed on the monitor, central station, or printed on a report is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.

### **CAUTION**

- The equipment should be installed by authorized Mindray personnel.
- When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.

- Before use, verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.
- Avoid rude handling during transport.
- Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

### NOTE

- Put the equipment in a location where you can easily view and operate the equipment.
- Keep this manual in the vicinity of the equipment so that it can be conveniently referenced when needed.
- Save the packing case and packaging material as they can be used if the equipment must be reshipped.

# 3.2 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or us.

If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact us in case of any problem.

### NOTE

 If your monitor contains the internal CO<sub>2</sub> module, connect the CO<sub>2</sub> adapter to the CO<sub>2</sub> receptacle soon after you unpack the monitor to avoid losing the CO<sub>2</sub> adapter.

### 3.3 Environmental Requirements

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

The environment where the equipment is used shall be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances. Moreover, to maintain good ventilation, the equipment shall be at least 2 inches (5cm) away from around the cabinet.

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

### **CAUTION**

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

## 3.4 Setting Up the Equipment

Observance of this manual is a prerequisite for proper product performance and correct operation. It ensures patient and operator safety.

### 3.4.1 Installing a Battery

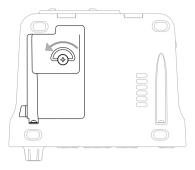
It is recommended to always install a fully charged battery in the monitor to ensure normal monitoring in case of accidental power failure.

Follow this procedure:

- VS 9 series monitors:
- 1. Make sure the monitor is off and disconnected with any cable.
- 2. Lay the monitor down to expose the bottom of the monitor.
- 3. Open the battery compartment door.



- 4. Turn the latch aside.
- 5. Insert the battery into the battery compartment with the battery terminal inwards.
- 6. Turn the latch back to the middle and close the battery door.
- VS 8 series monitors:
- 1. Make sure the monitor is off and disconnected with any cable.
- 2. Lay the monitor down to expose the bottom of the monitor.
- 3. Open the battery compartment door.



- 4. If a 2500 mAh battery is used, put a battery support into the battery compartment. If a 5000 mAh battery is used, the support is not needed.
- Insert the battery into the battery compartment with the battery terminal outwards. Then connect the battery to the connectors on the left of the battery compartment.
- 6. Close the battery door.

### 3.4.2 Connecting the AC Mains

Before connecting the equipment to the AC mains, check that the voltage and frequency ratings of the power line are the same as those indicated on the monitor.

To connect the monitor to the AC power source, follow this procedure:

- Connect the monitor to the female end of the power cord, and the male end of the power cord to a wall AC outlet.
- 2. Check that the external power supply indicator is on.

The external power supply indicator lies in the lower right corner of the display. When the AC mains is not connected, the external power supply indicator is off. When AC mains is connected, the external power supply indicator is illuminated in green.

### WARNING

- Always use the accompanying power cord delivered with the monitor.
- Before connecting the equipment to the AC mains, check that the voltage and frequency ratings of the power line are the same as those indicated on the monitor.
- Use the cable retainer to secure the power cord to prevent it from falling off.
- Use the battery if the integrity of the protective earth conductor or the protective earthing system in the installation is in doubt.

### 3.4.3 Connecting a Barcode Reader

The monitor supports both linear (1D) barcode reader and two-dimension (2D) barcode reader. The barcode reader is connected to the monitor via the USB connector.

## 3.4.4 Connecting a Digital Scale

You can connect a HEALTH O METER 600KL-BT scale via the USB connector to obtain the height, weight, and BMI data of a patient.

## 3.5 Turning on the Monitor

Before turning on the monitor, perform the following inspections:

- Check the monitor for any mechanical damage. Make sure that all external cables, plug-ins and accessories are properly connected.
- Connect the monitor to the AC power source. Make sure the battery power is sufficient if the monitor is powered by the battery.
- 3. Press the power switch to turn on the monitor.

The monitor automatically performs a self test at startup. Check that the alarm tone is heard and the alarm lamp illuminates, one after the other, in red, yellow, and cyan. This indicates that the visible and audible alarm indicators function correctly.

### **CAUTION**

 Check that visual and auditory alarm signals are presented correctly when the equipment is powered on. Do not use the patient monitor for any monitoring procedure on a patient if you suspect it is not working properly, or if it is mechanically damaged. Contact your service personnel or us.

## 3.6 Start Wizard

When the monitor is started for the first time, a start wizard is launched to help set up your monitor. You can:

- $\blacksquare$  Set the system language: select a language from the list and then select  $\rightarrow$ .
- $\blacksquare$  Set the Temp type: select the Temp module of your monitor and then select  $\rightarrow$ .
- Select Import Configuration if a preferred configuration has been exported and saved in a USB drive. For details, refer to 5.5.2 Importing a Configuration.
- Select Create New Configuration to:
  - Set the system time: for details of the settings, see 3.9.7 Setting the Date and Time.
  - Set parameter units: for details of the settings, see 3.9.8 Setting Parameter Units.

Set the department of your monitor: the default configurations are department-oriented. Select a department and then select  $\rightarrow$ .

After completing the above settings, you can select:

- **Restart to use**: the monitor restarts and enters normal working mode.
- Advanced Settings: you can continue to set the network and workflow. For more information about workflow setting, refer to 3.9.2 Setting the Workflow.
- **Export Configuration**: you can export the current configuration to a USB drive. Before selecting this option, connect a USB drive to the USB connector first. For details, refer to 5.5.1 Exporting a Configuration.

### **Operation and Navigation** 3.7

Everything you need to operate the monitor is on its screen. Almost every element on the screen is interactive. Screen elements include parameter values, waveforms, quick keys, information fields, alarms fields and menus. Often you can access the same element in different ways. For example, you can access a parameter menu by selecting corresponding numeric area or waveform area, or by selecting the **Main Menu** guick key → from the **Parameters** column select **Setup**.

### 3.7.1 Using the Touchscreen

For monitors configured with touchscreen, you can touch the screen or swipe across the screen with your fingers to operate the monitor.

#### 3.7.1.1 Tapping the screen or Swiping across the Screen

- Tapping the screen
  - To select an item from menus or lists, or select a quick key, tap on it with your finger.
  - To enter a parameter menu, tap corresponding numeric area or waveform area. For example, select the NIBP area to enter the NIBP menu.
- Swiping across the screen with a single finger:
  - To scroll through a list and a menu, swipe up and down.
  - To show more pages of a screen, such as the Main Menu screen, swipe left or right to switch between the two setup pages.

#### 3.7.1.2 **Locking the Touchscreen**

To avoid misuse, you can temporarily disable the touchscreen. To do so, hold and press the Main Menu quick key and slide as directed by the arrow. When the touchscreen is

locked, the **Main Menu** quick key changes to 🔒 .



The touchscreen lock period is configurable. To do so, follow this procedure:

1. Select the **Main Menu** guick key  $\rightarrow$  from the **Display** column select **Display**.

### Set Screen Lock Duration.

- 1 min, 30 sec, 20 sec or 10 sec: a countdown clock is displayed after the touchscreen is locked. The touchscreen is enabled when the preset time is reached.
- **Permanent**: the touchscreen can only be enabled manually.

If you need to manually enable the touchscreen:

- 1. Tap anywhere on the touchscreen.
- 2. Press < and slide it to the for position.

### **CAUTION**

- Check that the touchscreen is not damaged or broken. If there is any sign of damage, stop using the monitor and contact the service personnel.
- Wipe off the water on the touchscreen in case of rain or water spray.

### 3.7.2 Using the Knob (For VS 8 Series)

VS 8 series monitors, configured with touchscreen or not, provide a navigation knob and four hardkeys. For detailed descriptions, refer to 2.7.2 Front View (VS 8 Series).

## 3.7.3 Using the On-Screen Keyboard

The on-screen keyboard enables you to enter information:

- Enter the information by selecting one character after another.
- Select the Backspace key ← to delete single characters or select × to delete the entire entry.
- Select the Caps Lock key to access uppercase letters.
- Select to show the password that has been input.

## 3.7.4 Using the Barcode Reader

The monitor supports both linear (1D) barcode reader and two-dimension (2D) barcode reader. The barcode reader is connected to the monitor through the USB connector.

If you are using the Mindray custom 2D barcode reader (Model HS-1R or HS-1M), before using the it for the first time, clear old data formats and configure the barcode reader.

Before configuring the Mindray custom barcode reader, clear old data formats. To do so, follow this procedure:

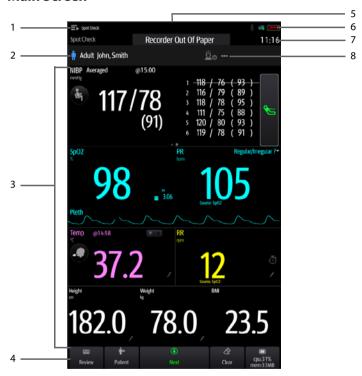
- 1. Scan the engineering barcode to clear the previous data format.
- 2. Scan the 2D engineering barcode which contains your hospital's data format.

### NOTE

 Contact the scanner manufacturer or Mindray to obtain the engineering barcodes for clearing data formats and containing the hospital's data format.

## 3.8 Screen Display

### 3.8.1 Main Screen

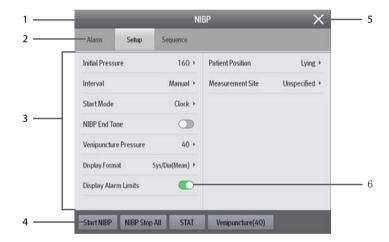


- Workflow area: displays the current workflow. Select this area and you can switch to another workflow.
- Patient information area: displays patient information, including patient ID, name, gender and so on. The displayed patient information is configurable. Selecting this area enters the Patient Management menu.
- 3. Parameter area: displays parameter values, waveforms, alarms and so on. Selecting a parameter area to display the corresponding parameter menu.

- Quick key area: displays quick keys. These keys may vary according to the workflow settings.
- 5. Alarm information area: displays physiological alarms on the above, and prompt messages and technical alarms at the bottom.
- System status information area: displays symbols indicating the battery status, network status, blue tooth status etc.
- 7. System time: displays the current system time.
- 8. Clinician information: displays login information of clinician. Select this area to log in or out.

### 3.8.2 Menus

All menus have similar style and structure, see the figure below:



- 1. Menu heading
- 2. Tabs: enters submenus
- 3. Main body area: includes menu items and options.
- 4. Operation buttons
- 5. Exit button: closes the current menu page.
- 6. Switch:
  - Green: the switch is on.
  - Gray: the switch is off.

## 3.8.3 Quick Keys

The monitor provides quick keys for you to quickly access some functions. The quick key area is located at the bottom of the screen. These keys may vary according to the workflow settings.

The following table shows available quick keys.

Symbol	Label	Function	Symbol	Label	Function
<b>==</b>	Review	Enters the Review menu.	<b>*</b> +	Patient	Displays the patient list.
<b>-</b>	Save	Saves the input information.	<b>⊘</b>	Clear	Clears all input information.
	Main Menu	Enters the main unit.		More	Shows more quick keys.
•	Next	Shows the next screen.	•	Back	Shows the previous screen.
溪	Alarm Pause	Pauses the physiological alarms.	<b>***</b>	Alarm Reset	Resets the alarm system.
0	Targeted Goal	Enters the <b>Targeted Goal</b> screen.			

## 3.8.4 On-screen Symbols

The following table lists the on-screen symbols:

Symbol	Description	Symbol	Description
Ť	Adult, male (blue)	• <b>@</b> =	Adult, female (pink)
<b>†</b>	Pediatric, male (blue)	#	Pediatric, female (pink)

Symbol	Description	Symbol	Description
<b>047</b>	Neonate, male (blue)	047	Neonate, female (pink)
<b>□</b>	Wired network is connected.	×	Wired network is not connected.
	All alarms are paused.	X	Individual physiological alarms are turned off or the monitor is in the alarm off status
潋	Audible alarm tones are paused.	<b>₹</b> ()	Alarms are acknowledged and the alarm is reset.
×	Audible alarm tones are turned off.		CMS is connected. Press this button to select another available CMS, if any.
<b>⊗</b>	Wireless network is connected. The solid part indicates network signal strength. Press this button to select another available network, if any.	<b>≈</b>	Wireless network cannot be connected.
*	Bluetooth device is connected.	*	Bluetooth function is enabled.

## 3.9 Configuring Your Monitor

Before putting your monitor in use, other preferential settings can be made to ease your operations.

## 3.9.1 Setting Device Location

To better locate and manage your monitor, you can set the location information. Follow this procedure:

### Set Location.

 Fixed: the Patient Management menu displays Bed No and Room No, but you cannot change them. If your monitor is installed at a fixed position, or you do not need to frequently change the room number and bed number, set **Location** to **Fixed**.

 Unfixed: you can change Bed No and Room No from the Patient Management menu.

### NOTE

- If Location is set to Unfixed, Bed No and Room No are cleared each time you discharge a patient.
- 3. Input the Monitor Name, Facility, Department, Room No, Bed No.

### 3.9.2 Setting the Workflow

Workflow is a configuration user-definable basing on daily tasks to simplify the use of the monitor.

You can set the screen layout to select parameters displayed on the main screen and their positions.

You can also make preferential settings for each parameter. For workflows under **Continuous Monitoring**, you can change alarm settings.

Every time you switch to a workflow, the pre-defined settings are loaded.

### 3.9.2.1 Accessing the Workflow Setup Menu

Access the **Workflow Setup** menu in the following ways:

- Select the **Main Menu** quick key → from the **Configuration** column select **Workflow** → input the required password → select 

   .
- Select the Main Menu quick key → from the Configuration column select Manage → input the required password → select
  → Workflow Setup.

In the **Workflow Setup** menu, the currently set workflows are listed under the work modes. You can:

- Select to change the current workflow settings.
- Select 🗊 to add a copy of the current workflow.
- Select to delete a workflow.
- Select Add Workflow to create a new workflow.

### NOTE

You can save up to 10 workflows.

### 3.9.2.2 Setting the Screen Layout

To set the parameters and their positions to be displayed on the screen, follow this procedure:

- 1. In the **Workflow Setup** menu, select on the right of the workflow to be set.
- 2. Select an area, and then from the popup list select the parameter to be displayed.
  - You can set up to 3 pages of screens and each page displays up to 4 rows of parameters, corresponding to the parameter areas displayed on the main screen.
  - Select to lock or unlock the first parameter of the first page. If locked, a is displayed and this parameter is displayed as the first parameter of each page.
  - Select to change the current row to a two-tile display area. The previously selected parameter will be changed to Off.
  - Select \_\_\_\_\_ to change the current row to an undivided display area. The
    previously selected parameters will be changed to Off.

### 3.9.2.3 Changing Parameter Settings

After setting the screen layout, you can make preferential settings for each parameter on the monitor. To access the **Parameters Setup** menu, in the **Edit Workflow** menu, select **Parameters Setup**.

The settings under the tabs might be different for different departments and work modes. For details, see the table below:

Tab	Menu Item	Description	Work Mode
NIBP	NIBP End Tone	If enabled, a reminder tone is issued at the completion of NIBP measurement.	Both
	Display Format	Selects the type and sequence of displayed NIBP readings.	Both
	Initial Pressure (Neo)	Sets the initial cuff inflation pressure for neonatal patients.	Both
	Measurements	Sets the number of measurement that can be performed in Manual NIBP Measurement. For details, see 11.7.1 Performing Manual Measurement.	Spot Check
	Interval	Sets the interval between two auto NIBP measurement.	Continuous Monitoring
	Start Mode	Defines how NIBP auto mode works. For details, see 11.8.3 Selecting NIBP Start Modenot a task.	Continuous Monitoring
	Display Alarm Limits	Sets whether to display the alarm limits of diastolic NIBP and mean NIBP.	Continuous Monitoring
	Patient Position	Sets the patient position for NIBP measurement.	Both

Tab	Menu Item	Description	Work Mode
NIBP	Measurement Site	Sets the measurement site for NIBP measurement.	Both
	Sequence	Sets the duration and interval of NIBP measurement sequences.	Continuous Monitoring
	Orthostatic BP Measurement	Selects whether to enable Orthostatic BP measurement.	Spot Check
	Lying Duration	Sets the time before starting lying BP measurement. Available only when Orthostatic BP Measurement is enabled.	
	Standing BP Measurement Interval	Sets the interval for automatic standing BP measurement. Available only when Orthostatic BP Measurement is enabled.	
	Maximum Standing BP Measurements	Sets the number of automatic standing BP measurement. Available only when Orthostatic BP Measurement is enabled.	
	BP Averaging	Selects whether to enable BP averaging. Available only when <b>Department</b> is set to <b>Physician Office</b> .	Spot Check
	Number of Measurements	Sets the number of measurement to be performed in a group of BP measurements for averaging. Available only when Department is set to Physician Office.	
	Discard First Group of Readings	Selects whether to include the first group of readings in the averaging calculation. Available only when <b>Department</b> is set to <b>Physician Office</b> .	
	Delay Before Starting Measurement	Sets the time to wait before starting the first measurement. Available only when Department is set to Physician Office.	
	Time Between Readings	Sets the time to wait before starting the rest automatic BP measurement. Available only when <b>Department</b> is set to <b>Physician Office</b> .	

Tab	Menu Item	Description	Work Mode
SpO2 Sensitivity		For Masimo SpO <sub>2</sub> modules, see 8.6.4 Setting $SpO_2$ Sensitivity (for Masimo SpO <sub>2</sub> ). For Mindray SpO <sub>2</sub> modules, see 8.6.8 Changing the Sensitivity (for Mindray SpO <sub>2</sub> ).	Both
	Display PI	Sets whether to display PI in the SpO <sub>2</sub> parameter area.	
	Speed	Sets the sweep speed of Pleth waveforms.	
	NIBP Simul	Switch on for patients performing $\mathrm{SpO}_2$ and NIBP monitoring on the same limb. The $\mathrm{SpO}_2$ alarm status is locked until the NIBP measurement ends.	Continuous Monitoring
PR	Pulse Volume	Sets the pulse volume.	Both
	Irr. PR Switch	Selects whether to enable the Irregular PR function. If enabled, you can mark the pulse as regular or irregular on the PR screen.	Spot Check
Temp	Measurement Site (Manual)	Sets the default measurement site for Temp measurement.	Both
RR	Timer Reminder Interval	Sets the interval of reminder tone for the timer used for manual RR. For details, see 13.5.5 Setting Timer Interval.	Both
	Apnea Delay (Adult)/(Ped)/ (Neo)	Sets the delay for giving an Apnea alarm.	Continuous Monitoring

Tab	Menu Item	Description	Work Mode
CO2	Auto Standby	The CO <sub>2</sub> module automatically enters standby mode after the configured period of time is no breath is detected since the last detected breath.	Continuous Monitoring
	BTPS Compensation	Enables or disables the BTPS (body temperature and pressure, saturated) compensation.	
	O2 Compensation	Sets the default concentration of interfering	
	N2O Compensation	gas.	
	AG Compensation		
	Speed	Sets the speed of CO <sub>2</sub> waveform.	
	CO2 Scale	Sets the scale of CO <sub>2</sub> waveform.	
	Waveform Type	Sets the type of CO <sub>2</sub> waveform.	
Pain	Default Method	Sets the default pain scale for scoring.	Both
	Pain Score Setup	See 18.9.5 The Pain Score Tab.	
EWS	Default Adult Score	Sets the default scoring protocol for adult patients.	Spot Check
	Default Ped Score	Sets the default scoring protocol for pediatric patients.	
	Default Neo Score	Sets the default scoring protocol for neonatal patients.	

Tab	Menu Item	Description	Work Mode	
EWS(Ad ult)	Score	Sets the default scoring protocol for adult patients.	Continuous Monitoring	
	Auto Scoring	Selects the condition to start auto scoring. If none of the options is checked, auto scoring is switched off. For details, see  15.1.4.2 Enabling Auto Scoring.		
	Interval	Sets the auto scoring interval. For details, see 15.1.4.3 Setting Auto Scoring Interval.		
	Auto Refresh Scores	Selects whether to enable the auto refreshing score function. For details, see 15.1.5.2 Auto Refreshing Scores.		
	Alarm	Selects whether to enable EWS alarms. For		
	EWS Score	details, see 15.1.5 EWS Alarm.		
	3 in single parameter			
EWS(Pe	Score	/	Continuous	
d)/(Neo)	Auto Scoring	Selects the condition to start auto scoring. If none of the options is checked, auto scoring is switched off. For details, see 15.1.4.2 Enabling Auto Scoring.	Monitoring	
	Interval	Sets the auto scoring interval. For details, see 15.1.4.3 Setting Auto Scoring Interval.		
Manual Input	/	Selects the parameters and their position to be displayed in the <b>Manual Input</b> list.	Both	
	Parameter Library	See 17.9.4 The Manual Input Tab.	Both	
Paramet	NIBP	White	Both	
er Color	SpO2	Blue	Both	
	Temp	White	Both	
	CO2	Yellow	Continuous Monitoring	
	RR	Yellow	Both	

## 3.9.2.4 Changing Alarm Settings

For workflows under **Continuous Monitoring**, you can enable or disable an alarm, and set the alarm limits and priorities of physiological alarms of each parameter.

Follow this procedure:

- 1. After setting the screen layout, in the **Edit Workflow** menu, select **Alarm Setup**.
- Select Adult, Ped, and Neo tabs to set the alarms for adult, pediatric and neonatal patients.

### **NOTE**

SpO2 Desat and Apnea alarms cannot be disabled by default.

## 3.9.3 Adjusting Screen Brightness

To adjust the screen brightness, follow this procedure:

- 1. Select the **Main Menu** quick key → from the **Device** column select **Display**.
- 2. If you are using the AC power, set **Brightness**. If you are using the battery to run the monitor, set **Brightness On Battery**. You can set the brightness to 1 to 10, in which 10 is the brightest, and 1 is the least bright.

If the monitor operates on battery power, you can set a less bright screen to prolong the operating time of the battery. When the monitor enters Standby mode, the screen will change to the least brightness automatically.

## 3.9.4 Adjusting the Volume

To adjust the volume, follow this procedure:

- 1. Select the **Main Menu** quick key → from the **Device** column select **Volume**.

## 3.9.5 Changing Measurement Colors

You can set the color of measurement values and waveforms for each parameter. To do so, follow this procedure:

- Select Main Menu quick key 

  from the Parameters column select Parameter
  Color. The Current tab is displayed.
- 2. Set the colors of the currently monitoring measurement values and waveforms.

## 3.9.6 Setting System Language

To change the language setting, follow this procedure:

- 2. Select **Language**, and from the popup list, select the target language.

## 3.9.7 Setting the Date and Time

To set the system time, follow this procedure:

- 1. Select the **Main Menu** quick key → from the **System** column select **Time**.
- Set Date and Time.
- 3. Set Date Format to yyyy-mm-dd, mm-dd-yyyy, or dd-mm-yyyy, in which:
  - ◆ **vvvv** indicates the year.
  - mm indicates the month.
  - ◆ dd indicates the day.
- 4. If you want to use the 12-hour mode, switch off **24-Hour Time**.
- If you want to use daylight savings time, switch on **Daylight Savings Time**. You
  can manually switch on or off the daylight savings time only when the auto
  daylight savings time function is disabled. For more information, see 18.11 The
  Time Settings.

### **CAUTION**

 Changing the date and time affects the storage of trends and events and may result in loss of data.

### **NOTE**

 If your monitor is connected to a central monitoring system (CMS) or hospital clinical system (HIS), the date and time are automatically taken from the CMS.
 In this case, you cannot change the date and time from your monitor.

## 3.9.8 Setting Parameter Units

To set the units, follow this procedure:

- 2. Select a parameter, and from the popup list, select the unit to be used.

Below is a list of the units you can set:

Parameter	Options	Default
Height Unit	cm, inch	cm
Weight Unit	kg, lb	kg
Glucose Unit	mg/dl, mmol/L	mg/dl

Parameter	Options	Default
I/O Fluid Unit	ml, L	ml
CO2 Unit	mmHg, kPa, %	mmHg
Temp Unit	°C, °F	°C
Pressure Unit	mmHg, kPa	mmHg

### 3.9.9 Checking Software Licenses

To run the following functions in your monitor, software licenses are required:

- Orthostatic BP measurement
- Vitalslink
- Network Connectivity
- MI DAP
- SpO2 Calc RR

To check the licenses, select the **Main Menu** quick key  $\rightarrow$  select **License**  $\rightarrow$  **Local**.

To install the licenses, follow this procedure:

- 1. Connect the USB drive with the licenses in to the monitor's USB connector.
- 2. Select the **Main Menu** quick key  $\rightarrow$  select **License**  $\rightarrow$  select **External**.
- Select Install.

## 3.10 Start Working

## 3.10.1 Selecting a Work Mode

The monitor provides spot check mode and continuous monitoring mode. It works based on the workflow you selected.

### 3.10.1.1 Continuous Monitoring Mode

The continuous monitoring mode is used for long-term patient monitoring. To switch to monitoring mode, select the workflow area and select a workflow under **Continuous Monitoring**.

## 3.10.1.2 Spot Check Mode

The spot check mode is intended for on-spot measurement in a short period. To switch to spot check mode, select the workflow area and select a workflow under **Spot Check**.

In spot check mode, physiological alarm system is disabled.

There will be no physiological alarm related indications.

- The alarm setup menus will not be displayed.
- Alarm limits cannot be set.

Different features between continuous monitoring mode and spot check mode:

Functions	Continuous Monitoring mode	Spot check mode
Configure and use Sat-Seconds (Nellcor)	Yes	No
Access Alarm Setup tab	Yes	No
Access <b>Events</b> tab	Yes	No
Access <b>Graphic Trends</b> tab	Yes	No
Auto data updating with the central monitoring system	Yes	No
BP Averaging	No	Yes
Orthostatic BP measurement	No	Yes
Measure CO <sub>2</sub> (VS 9 series)	Yes	No
SpO <sub>2</sub> sourced RR (Mindray SpO <sub>2</sub> module)	No	Yes

### 3.10.1.3 Standby Mode

You can temperately stop patient monitoring without switching off the monitor by entering the standby mode. In standby mode, the monitor behaves as follows:

- Stops all parameter measurement.
- Disables all the alarms and prompt messages, except for the battery low alarm.
- Turns screen brightness to the dimmest after entering the standby mode.

You can switch the monitor to standby mode manually, or set **Auto Enter Standby** for the monitor to enter standby mode automatically.

To switch the monitor to standby mode:

- Press the power switch, or select the Main Menu quick key → from the Patient Management column select Standby.
- If the monitor is in Continuous Monitoring mode, select a location in the drop down list to define where the patient is when the monitor enters the standby mode. If the monitor is in Spot Check mode, skip this step.
- 3. Select **OK**.

To set Auto Enter Standby:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select
   \_\_\_\_\_\_.
- Select the Standby tab, switch on Auto Enter Standby, and set the Auto Enter Standby Time.

After setting, the monitor enters standby mode automatically if no operation is detected after the **Auto Enter Standby Time**.

### WARNING

 Pay attention to the potential risk of placing the monitor to standby. In the standby mode, the monitor stops all parameter measurement and disable all the alarm indications, except for the battery low alarm.

If the monitor enters standby mode in **Continuous Monitoring** mode, you can:

- Change the patient location from the standby screen.
- Select **Discharge Patient** on the standby screen to discharge a patient.
- Select **Resume monitor** on the standby screen to exit the standby mode.

If the monitor enters standby mode in **Spot Check** mode, you can select anywhere on the touchscreen to exit the standby mode.

## 3.10.2 Inputting Patient Information

It is recommended to input the patient information correctly before monitoring. Follow this procedure:

- 1. Select patient information area and the Patient Management menu is displayed.
- 2. Input the **Patient ID**, name, date of birth, **Patient Category**, and **Gender**.
- Select OK.

## 3.10.3 Accessing Parameter Setup Menus

Each parameter has a setup menu in which you can adjust the alarm and parameter settings. You can enter a parameter setup menu by using the following methods:

- In **Continuous Monitoring** mode, select the parameter area to display a parameter setup menu.
- In **Spot Check** mode, select the **Main Menu** quick key → from the **Parameters** column select **Setup** → select the desired parameter.

## 3.10.4 Checking the Alarm Settings

For patients under continuous monitoring, make sure the alarm limits are appropriate for the currently admitted patient. To check the alarm limits, in **Continuous Monitoring** 

mode, select the **Main Menu** quick key  $\rightarrow$  from the **Alarm** column select **Limits**. Change them if necessary.

## 3.11 Stopping a Parameter Measurement

To stop monitoring a parameter, follow this procedure:

- 1. Remove corresponding sensors from the patient.
- 2. Disconnect the sensor from the patient cable.
- 3. Disconnect the patient cable from the parameter connector.
- 4. If you are using the disposable sensor, discard it.

## 3.12 Turning Off the Monitor

Before turn off the monitor, perform the following check:

- 1. Ensure that the monitoring of the patient has been completed.
- 2. Disconnect the cables and sensors from the patient.
- 3. Make sure to save or clear the patient monitoring data as required.

To turn off the monitor, press and hold the power switch for 3 seconds.

Turning off the monitor does not disconnect the monitor from the AC mains. To completely disconnect the power supply, unplug the power cord.

### CAUTION

 Press and hold the power switch for 10 seconds to forcibly shut down the monitor if it could not be shut down normally. This may cause loss of patient data.

### **NOTE**

In case of a temporary power failure, if the power is restored within 30
minutes, monitoring will resume with all active settings unchanged; if the
monitor is without power for more than 30 minutes, the monitor behaves the
same as it is normally turned off.

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## **Managing Patients**

The monitor provides patient management functions. On the monitor, you can admit and discharge a patient, and edit, review, import, and export patient information.

## 4.1 Admitting a Patient

## 4.1.1 Automatically Admitting a Patient

The monitor admits a new patient automatically when started for the first time or after a patient is discharged. For automatically admitted patient, you need to input and save the patient information so the measurements and other physiological data could be correctly saved to the patient.

Always inputs patient information as soon as the patient is admitted. For more information, see 4.2.2 Editing Patient Information for details.

### WARNING

 The setting of patient category always contain a default value, regardless of whether the patient is admitted or not. Check if the setting is correct for your patient.

## 4.1.2 Manually Admitting a Patient

You can admit a patient from **ADT Database** (if available) and **Local Patient List**. You can also admit a new patient. Follow this procedure:

- 1. Select **Patient** quick key.
- Select a patient from the list and then select **Admit** to admit a patient. Or, select **Add New** to admit a new patient.
- 3. Check or modify the information of the patient. Select **OK**.

### **WARNING**

 Before admitting a patient, make sure the data for the current patient is properly edited and saved. Failure to do so can lead to data being attributed to the wrong patient.

## 4.2 Managing Patient Information

## 4.2.1 Entering the Patient Management Menu

Use any of the following methods to enter the **Patient Management** menu:

- Select the patient information area at the top left corner of the screen.
- Select the Main Menu quick key → from the Patient Management column select Patient Management.

### 4.2.2 Editing Patient Information

Edit patient information after a patient has been admitted, or when patient information is incomplete, or when you want to change patient information.

To edit patient information, follow this procedure:

- 1. Enter the **Patient Management** menu. For more information, see *4.2.1 Entering* the Patient Management Menu.
- 2. Edit patient information as required.

If you connect a barcode reader with your monitor, you can scan the patient's barcode to enter the patient's information.

Input the **Patient ID** or **Visit Number** of a patient, other information will automatically fill in if the patient is in the **Local Patient List** or **ADT Database** (if the monitor is connected with the Admit-Discharge-Transfer (ADT) server through the eGateway).

### NOTE

 The monitor will reload the configuration if you changed the patient category.

## 4.3 Discharging a Patient

The monitor discharges a patient in the following situations:

- After a patient is manually admitted, the previous patient is automatically discharged.
- In Spot Check mode, a patient is discharged if the monitor is powered off or workflow is switched.
- For patients under **Continuous Monitoring** mode, you can let the monitor automatically discharge after the monitor has been switched off for a period of time. The configuration of this function is password protected. For more information, see 18.3.3 The Discharge Tab.
- If the monitor has not detected certain patient vital signs (SpO<sub>2</sub>, PR, RR, NIBP) for 30 minutes, you will be prompted whether to start monitoring a new patient if any of the above vital signs are detected again.

When a patient is discharged, all patient data, including patient information, trend data, and physiological alarm information is deleted from the monitor. The technical alarms is reset, and monitor settings returns to their defaults.

### NOTE

Discharging a patient deletes all history data from the monitor.

### 4.3.1 Manually Discharging a Patient

Patients under **Continuous Monitoring** mode can be discharged manually. Follow this procedure:

- 1. Make sure all the patient data needed is properly saved.
- 2. Select the patient information area at the top left corner of the screen.
- 3. Select **Discharge Patient**.

## 4.3.2 Auto Discharging a Patient after Monitor Power Off

For patients under **Continuous Monitoring** mode, you can set the monitor to automatically discharge a patient upon startup after being switched off for a period of time. Follow this procedure:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select
- 2. Select the **Patient Management** tab→ select the **Discharge** tab.
- Select a time for Auto Discharge When Power Off. The monitor will automatically
  discharge the patient at next startup after being switched off for the selected
  period of time. The default is Never. That is to say the monitor will not discharge a
  patient upon startup no matter for how long the monitor has been switched off.

## 4.3.3 Changing Patient Management Settings

You can define which items can be displayed and edited from the **Patient Management** menu. To do so, follow this procedure:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select .
- 2. Select the **Patient Management** tab.
- 3. Select the fields you want to display in the **Patient Management** menu.
- 4. If necessary, select the customized fields and input names for these fields.

### NOTE

 If the monitor is connected with the CMS, the patient information items and customized fields are loaded from the CMS.

### 4.3.4 Setting Monitor Information

To set monitor information, follow this procedure:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select .
- Select the **Device Location** tab.
- 3. Input monitor name, facility name and department name.

## 4.3.5 Setting Patient Location

To set patient location, follow this procedure:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select
- 2. Select the **Patient Management** tab.
- Select the Location tab.
- 4. Input patient location as desired.

## 4.4 Deleting Patient Data

To delete the data of discharged patients, follow this procedure:

- 1. Select the **Patient** quick key.
- 2. Select **Select Patient**. From the patient list select desired patients.
- Select **Delete**.

# **5** Managing Configurations

## 5.1 Configuration Introduction

When performing measurement or continuously monitoring on a patient, the clinical professional often needs to adjust the monitor's settings according to the patient's condition. The collection of all these settings is called a configuration. The system configuration items can be classified as: parameter configuration items, conventional configuration items, and user maintenance items. Allowing you to configure the monitor more efficiently, the monitor provides different sets of configurations to accommodate the varying patient categories and departments. You can change some settings from a certain set of configuration and then save the changed configuration as a user configuration.

The default configurations provided for your monitor are department-oriented. You can choose any of the following department:

- Wards
- **■** Emergency Department
- Physician Office
- Ambulatory Surgery Center

### WARNING

 The configuration management function is password protected. The configuration management tasks must be performed by clinical professionals.

## 5.2 Changing the Department

If the current department configuration is not the one you want to view, you can change the department by following this procedure:  $\frac{1}{2} \int_{-\infty}^{\infty} \frac{1}{2} \int_{-$ 

- Select the Main Menu quick key → from the Configuration column select Manage → input the required password → select
- Select Department Type.
- 3. Select a department.
- Select OK.

### **CAUTION**

Changing the department will delete all current user configurations.

## 5.3 Setting Default Patient Category

To set the default patient category when admitting a new patient, follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Manage → input the required password → select
- 2. Set Default Patient Category.

## 5.4 Setting Workflows

For details, refer to 3.9.2 Setting the Workflow.

## 5.5 Transferring a Configuration

When installing several monitors with identical user configurations, it is not necessary to set each unit separately. Use a USB drive to transfer the configuration from monitor to monitor.

## 5.5.1 Exporting a Configuration

To export the current monitor's configuration, follow this procedure:

- 1. Connect a USB drive to the monitor's USB port.
- 3. Select Export Configuration.
- 4. Select the workflows and **User Maintenance Settings** to export.
- Select Export.

## 5.5.2 Importing a Configuration

To import the configuration from the USB drive to the monitor, follow this procedure:

- 1. Connect the USB drive to the monitor's USB connector.
- Select the Main Menu quick key → from the Configuration column select Manage → input the required password → select
- 3. Select Import Configuration.
- 4. Select the workflows and **User Maintenance Settings** to import.
- Select Import.

## 5.6 Modifying Configuration Password

To modify the configuration password, follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Manage → input the required password → select
- 2. Select Modify Password.
- 3. Respectively input the old password and new password.
- Select OK.

## 5.7 Restoring the Latest Configuration Automatically

During operation, you may make changes to some settings. However, these changes may not be saved as user configuration. To prevent the changes from losing in case of a sudden power failure, the equipment stores the configuration in real time. The saved configuration is the latest configuration.

In case of a temporary power failure, if the power is restored within 30 minutes, monitoring will resume with all active settings unchanged; if the monitor is without power for more than 30 minutes, the monitor behaves the same as it is normally turned off.

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# **6** Networked Monitoring

### 6.1 Network Introduction

You can connect the monitor to the central monitoring system (CMS), and eGateway through wired LAN or wireless LAN.

## 6.2 Network Safety Information

### CAUTION

- Wireless network designing, deploying, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.
- Always set the wireless network according to local wireless regulations.
- Using 5G frequency band is recommended whenever possible. There are more interference sources in 2.4G frequency band.
- Private APs and wireless routers are not allowed. These devices may cause radio interference and result in monitor and CMS data loss.
- Data communication must be performed within a closed network or within a virtually isolated network provided by a hospital for all network functions.
   The hospital is responsible for ensuring the security of the virtually isolated network.
- WPA2-PSK and WPA2-Enterprise verification and encryption should be used
  if possible. Otherwise, the equipment may not be able to work or patient
  information may be divulged. WPA2-Enterprise and a long password are
  recommended.
- Keep network authentication information, for example password, safe, protecting the network from being accessed by unauthorized users.
- Do not connect non-medical devices to the monitor network.
- If wireless network signal is poor, there may be a risk of CMS data loss.
- RF interference may result in wireless network disconnection.
- Maximum number of monitors connected to a single AP is 16. Too many monitors connected to the same AP may result in network disconnection.
- Disconnecting from the network may result in CMS data loss and function failure. Check the patient in case of network disconnection and solve the network problem as soon as possible.

 Ensure that the monitor IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.

## 6.3 Connecting the Monitor to the CMS

You can connect the monitor to the BeneVision CMS. When connected to the CMS, the system provides the following function.

- The monitor can transmit parameter values, waveforms, alarm settings (if the monitor is working in **Continuous Monitoring** mode), and events to the CMS. From the CMS, you can check the patient's data and alarms (if any).
- When the monitor is working in Continuous Monitoring mode, patient information, alarm settings, and alarm status can be synchronized between the monitor and the CMS.
- You can start or stop NIBP measurement from the CMS.
- In case of network disconnection, the monitor can transmit the offline data to the CMS when network is reconnected.

For more information on the CMS, see the operator's manual of corresponding central monitoring system.

To select a CMS, select the system status information area at the top right corner of the main screen. Select the desired CMS from the popup CMS list.

### NOTE

 You can select CMS only when the Select CMS switch is on. For more information, refer to 18.16.5 The Transfer Setup Tab.

## 6.4 Connecting the eGateway

You can connect the monitor to the eGateway to implement interaction between the monitor and external devices. When connected to the eGateway, the system provides the following functions:

- The monitor can transmit parameter values, waveforms, alarm settings (if the monitor is working in **Continuous Monitoring** mode), and events to the eGateway.
- Clock can be synchronized between the monitor and the eGateway.

## 6.5 MLDAP

MLDAP refers to Mindray LDAP (Lightweight Directory Access Protocol). It is an independent process which can be installed on eGateway or other application server (Windows). MLDAP provides user identity and authentication.

The MLDAP server is connected with the hospital LDAP server. All monitoring devices are connected to the MLDAP server to implement identity and authentication for the following operations:

- Changing alarm settings
- Accessing the Maintenance menu

For details about the settings, see 18.16.8 The MLDAP Tab.

## 6.6 Connecting the Wireless Network

You can add up to five wireless networks for the monitor. If connecting the current wireless network fails, the monitor automatically connects other wireless networks in the order when they were added.

To manually switch the wireless network, from the system status information area on the top right corner of the screen select  $\bigcirc$ , and select the desired wireless network.

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# **7** Alarms

### 7.1 Alarm Introduction

This chapter describes alarm functions and alarm settings. Physiological alarms are available only when the monitor is in **Continuous Monitoring** mode.

## 7.2 Alarm Safety Information

### WARNING

- A potential hazard can exist if different alarm presets and default configuration settings are used for the same or similar equipment in the same care area, for example an intensive care unit or cardiac operating room.
- If your monitor is connected to the central monitoring system (CMS), alarms
  can be presented and controlled remotely. Remote suspension, inhibition, or
  reset of monitor alarms via the CMS may cause a potential hazard. For more
  information, see the operator's manuals of the CMS.
- The monitors in your care area may each have different alarm settings to suit different patients. Always check that the alarm settings are appropriate for your patient before start monitoring. Always make sure that necessary alarm limits are active and set according to the patient's clinical condition.
- Setting alarm limits to extreme values may cause the alarm system to become ineffective. For example, high oxygen levels may predispose a premature infant to retrolental fibroplasia. If this is a consideration do not set the SpO<sub>2</sub> high alarm limit to 100%, which is equivalent to switching the alarm off.
- When the alarm sound is switched off, the monitor gives no alarm tones even if a new alarm occurs. Be careful about whether to switch off the alarm sound or not. When the alarms are off or while alarm audio is paused either temporarily or indefinitely, observe the patient frequently.
- When monitoring patients that are not continuously attended by a clinical operator, properly configure the alarm system and adjust alarm settings as per the patient's condition.
- Do not rely exclusively on the audible alarm system for monitoring.
   Adjustment of alarm volume to a low level may result in a hazard to the patient. Always make sure that the audio alarm volume level is adequate in your care environment. Always keep the patient under close surveillance.

## 7.3 Understanding the Alarms

## 7.3.1 Alarm Categories

The monitor has two different types of alarms: physiological alarms and technical alarms.

- Physiological alarms are triggered by patient measurement exceeding the parameter limits, or by an abnormal patient conditions.
- Technical alarms are triggered by an electrical, mechanical, or other monitor failure, or by failure of a sensors or components. Technical alarm conditions may also be caused when an algorithm cannot classify or interpret the available data.

Apart from the physiological and technical alarms, the monitor can also prompt some messages telling the system status or patient status.

### 7.3.2 Alarm Priorities

By severity, the alarms are classified into the following priority levels:

- High priority alarms: indicates a life threatening situation or a severe device malfunction. High priority alarms require an immediate response.
- Medium priority alarms: indicates abnormal vital signs or a device malfunction. Medium priority alarms require a prompt response.
- Low priority alarms: indicates a discomfort condition, a device malfunction, or an improper operation. Low priority alarms require you to be aware of this condition.
- Messages: provides additional information on the patient or the equipment.

### 7.3.3 Alarm Indicators

When an alarm occurs, the monitor indicates it to you through visual or audible alarm indications. For more information, see the following table.

Alarm Indicator	High Priority Alarm	Medium Priority Alarm	Low Priority Alarm	Message
Alarm lamp	Red Flashing frequency: 1.4 - 2.8 Hz Duty cycle: 20 - 60% on	Yellow Flashing frequency: 0.4 - 0.8 Hz Duty cycle: 20 - 60% on	Cyan No flashing Duty cycle: 100% on	None

Alarm Indicator		High Priority Alarm	Medium Priority Alarm	Low Priority Alarm	Message
Audible tone pattern	ISO	Repeat pattern of triple + double + triple + double beeps	Repeat pattern of triple beeps	Single beep	None
	Mode 1	Repeat pattern of high-pitched single beep	Repeat pattern of double beeps	Low-pitched single beep	None
	Mode 2	Repeat pattern of high-pitched triple beeps	Repeat pattern of double beeps	Low-pitched single beep	None
Alarm message <sup>1</sup>		White text inside a red box	Black text inside a yellow box	Black text inside a cyan box	White text
Alarm priority indicator <sup>2</sup>		***	**	*	None
Parameter value		White text inside a flashing red box	Black text inside a flashing yellow box	Black text inside a flashing cyan box	None

<sup>1:</sup> Alarm messages are displayed in the alarm information area at the top of the screen. You can select the alarm messages to show the alarm list.

#### NOTE

- When multiple alarms of different priority levels occur simultaneously, the monitor select the alarm of the highest priority to light the alarm lamp and issue the alarm tone.
- When multiple alarms of different priority levels occur simultaneously and should be displayed in the same area, the monitor only displays the messages of the highest priority alarm.
- When multiple alarms of the same priority levels occur simultaneously alarm messages are displayed circularly.
- Apnea, and SpO<sub>2</sub> Desat are exclusive high priority alarms. When these alarms occur, the monitor only displays messages of exclusive alarms. Other high priority alarms will not be displayed. When multiple exclusive alarms occur simultaneously, alarm messages are displayed circularly.

<sup>&</sup>lt;sup>2</sup>: The indicator shows in front of corresponding alarm message.

## 7.3.4 Alarm Status Symbols

Apart from the alarm indicators as described in **7.3.3** Alarm Indicators, the monitor uses the following symbols to indicate the alarm status:

Alarm pause: indicates that all the alarms are paused.

Alarm off: indicates that individual measurement alarms are turned off or

the system is in the alarm off status.

Audio pause: indicates that audible alarm tones are paused.

Audio off: indicates that audible alarm tones are turned off.

Alarm reset: indicates that alarms are acknowledged and the alarm system is

reset.

## 7.4 Checking Alarm List

To check the alarm list, follow this procedure:

1. Select the technical alarm area to check the **Technical Alarms**.

2. Select the physiological alarm area to check the **Physiological Alarms**.

# 7.5 Accessing On-screen Help for Technical Alarms (AlarmSight)

In the technical alarm list, alarm messages followed by **Detail** include help messages or pictures to help you identify the problem. This function is called AlarmSight. To access AlarmSight, follow this procedure:

- 1. Select the technical alarm area to check the **Technical Alarms** list.
- 2. From the alarm list select **Detail** on the right of the desired alarm.

## 7.6 Changing Alarm Settings

From the **Alarm** column of the main menu select desired buttons to set alarm properties.

## 7.6.1 Setting Parameter Alarm Properties (Continuous Monitoring Mode)

For workflows under **Continuous Monitoring**, you can set the alarm properties of physiological alarms of each parameter. Every time you switch to a workflow, the alarm settings of the workflow are loaded. For details, see 3.9.2.4 Changing Alarm Settings.

You can also change the parameter alarm properties based on the condition of the current patient. To do so, follow this procedure:

- Select the Main Menu quick key → from the Alarm column select Limits. Enter the password if required.
- 2. Select a parameter tab and set alarm properties as desired.

You can also change the alarm properties of individual parameter from corresponding parameter menu.

The alarm settings of workflow override the alarm settings under **Limits** menu and parameter menus. Every time you discharge a patient or switch to another workflow, the workflow settings are loaded.

#### WARNING

 When monitoring patients that are not continuously attended by a clinical operator, properly configure the alarm system and adjust alarm settings as per the patient's condition.

## 7.6.2 Setting Alarm Tone Properties

## 7.6.2.1 Changing the Alarm Volume

To change the alarm volume, follow this procedure:

- 1. Select the **Main Menu** quick key → from the **Alarm** column select **Setup.**
- 2. Set **Alarm Volume**. The optional alarm volume is between X to 10, in which X is the minimum volume, depending on the setting of minimum alarm volume, and 10 is the maximum volume.
- 3. Select **High Alarm Volume** to set the volume of the high priority alarm.
- 4. Select **Reminder Volume** to set the volume of the reminder tone.

#### NOTE

- When the alarm volume is set to 0, the alarm sound is turned off and the audio off symbol appears on the screen.
- You cannot set the volume of high priority alarms if Alarm Volume is set to 0.

### 7.6.2.2 Setting the Interval between Alarm Sounds

If you choose the ISO pattern, you can change the interval between alarm tones. To change the interval between alarm tones, follow this procedure:

- Select the Alarm tab → Audio tab.
- 3. Set High Alarm Interval, Med Alarm Interval, and Low Alarm Interval:

Item	Range	Default
High Alarm Interval	3 s to 15 s	10 s
Med Alarm Interval	3 s to 30 s	20 s
Med Alarm Interval	16 s to 30 s	20 s

#### 7.6.2.3 Other Password Protected Audio Alarm Settings

The following alarm settings are password protected:

- Minimum alarm volume
- Alarm sound pattern
- Alarm sound escalation switch and delay

For more information, see 18.6.1 The Audio Tab.

## 7.6.3 Setting the Alarm Delay Time

For continuously measured parameters, you can set the alarm delay time. If the alarm condition is resolved within the delay time, the monitor does not present the alarm.

This setting is password protected. For more information, see 18.6.5 The Other Tab.

The setting of **Alarm Delay** is not applied to the apnea alarms. You can set **Apnea Delay** separately.

#### WARNING

 The alarm delay time can be set to 15 sec at most. Changing this setting to an inappropriate level may result in a hazard to the patient.

## 7.6.4 Setting the Apnea Delay Time

To set the apnea delay time, follow this procedure:

- 1. Select the **Main Menu** quick key → from the **Alarm** column select **Setup.**
- 2. Select **Apnea Delay** to set the apnea delay time.

## 7.6.5 Restoring the Default Alarm Settings

To reset all alarm settings to the defaults, follow this procedure:

1. Select the **Main Menu** quick key → from the **Alarm** column select **Setup.** 

- 2. Select the Limits tab.
- 3. On the **Limits** page, select **Defaults** at the bottom.

## 7.6.6 Setting the CMS and eGateway Disconnection Alarm

You can choose whether to issue an alarm when the monitor is not connected or disconnected from the CMS/eGateway, and set the priority of these alarms.

This setting is password protected. For details, see 18.6.5 The Other Tab.

## 7.6.7 Setting the Switch of the SpO<sub>2</sub> Desat Alarm Off

You can choose whether switching off the SpO2 Desat alarm is permissible or not. This setting is password protected. For more information, see 18.6.5 The Other Tab.

#### WARNING

If you switch off the SpO2 Desat alarm, the monitor will not alarm when the
patient's SpO<sub>2</sub> is extremely low. This may result in a hazard to the patient.
Always keep the patient under close surveillance.

## 7.6.8 Setting the Switch of the Apnea Alarm Off

You can choose whether switching off the apnea alarm is permissible or not. This setting is password protected. For more information, see 18.6.5 The Other Tab.

#### WARNING

 If you switch off the apnea alarm, the monitor will not issue the apnea alarm in case that apnea happens. This may result in a hazard to the patient. Keep the patient under close surveillance.

## 7.7 Pausing Alarms/Pausing Alarm Tones

## 7.7.1 Defining the Pause Function

You can either pause alarms or pause alarm tones. This depends on the pause setting. This setting is password protected. For more information, see 18.6.2 The Pause/Reset Tab.

## 7.7.2 Pausing Alarms

If the pause function is designated as pausing alarms, pressing the **Alarm Pause** quick key can temporarily disable alarm indicators. When alarms are paused, the following rules are followed:

- No physiological alarm will be presented.
- For technical alarms, alarm sounds are paused, but alarm lamps and alarm messages remain presented.
- The remaining alarm pause time is displayed in the physiological alarm information area.
- The alarm pause symbol is displayed in the system information area.

When the alarm pause time expires, the alarm paused status is automatically deactivated. You can also cancel the alarm paused status by pressing the **Alarm Pause** quick key.

The following alarm pause and alarm reset settings are password protected.

- Alarm pause time
- Priorities of paused alarms
- Alarm reset setting
- Reminder tone settings

For more information, see 18.6.2 The Pause/Reset Tab.

### 7.7.2.1 Setting the Alarm Pause Time

The alarm pause time can be set to 1 min, 2 min, 3 min, or Permanent. The default alarm pause time is 2 min.

This function is password protected. For more information, see 18.6.2 The Pause/Reset Tab.

#### 7.7.2.2 Prolonging the Alarm Pause Time

You can temporarily prolong the alarm pause time after the monitor enters the alarm paused status. This function is password protected. For more information, see 18.6.2 The Pause/Reset Tab.

## **NOTE**

- Prolonging alarm pause time does not affect the setting of alarm pause time.
- You can not prolong the pause time if the Pause Time is set to Permanent.

## 7.7.2.3 Selecting the Priority of Paused Alarms

You can select alarms of what priority can be paused. This function is password protected. For more information, see 18.6.2 The Pause/Reset Tab.

#### 7.7.2.4 Switching Off All Alarms

If **Pause Time** is set to **Permanent** (see 18.6.2 The Pause/Reset Tab), pressing the **Alarm Pause** quick key permanently switches off all alarms. The alarm off status has the following features:

- Physiological alarms are switched off. The alarm lamp does not flash and alarm sound is not issued.
- Alarm sound of technical alarms is switched off, but alarm lamp flashes and alarm messages are presented.
- The message **Alarm Off** with red background is displayed in the physiological alarm information area.
- The alarm off symbol is displayed in the system status information area.

To exit the alarm off status, press the **Alarm Pause** quick key again.

#### WARNING

• Pausing or switching off alarms may result in a hazard to the patient.

## 7.7.3 Pausing Alarm Sound

If the pause function is defined as **Audio Pause**, pressing the **Audio Pause** key pauses alarm tone. When alarm tones are paused, the following rules are followed:

- The sound of all physiological alarms and technical alarms are switched off.
- The remaining audio pause time is displayed in the physiological alarm information area.
- The audio pause symbol is displayed in the system information area.

When the audio pause time expires, the audio paused status is automatically deactivated. You can also cancel the audio paused status by pressing the **Audio Pause** quick key.

#### 7.7.3.1 Setting the Alarm Tone Pause Time

The alarm tone pause time can be set to 1 min, 2 min, 3 min, or Permanent. The default audio pause time is two minutes.

This function is password protected. For more information, see 18.6.2 The Pause/Reset Tab.

#### 7.7.3.2 Prolonging the Alarm Tone Pause Time

You can temporarily prolong the alarm tone pause time after the monitor enters the alarm tone paused status. This function is password protected. For more information, see 18.6.2 The Pause/Reset Tab.

#### **NOTE**

 Prolonging alarm pause time does not affect the setting of alarm tone pause time.

#### 7.7.3.3 Setting the Priority of Audio Paused Alarms

You can select alarm sound of what priority can be paused. This function is password protected. For more information, see 18.6.2 The Pause/Reset Tab.

#### 7.7.3.4 Switching Off Alarm Sound

If **Pause Time** is set to **Permanent**, pressing the **Audio Pause** quick key permanently switches off all alarm sound. The audio off status has the following features:

- Alarm sound of both physiological alarms and technical alarms is switched off.
- The audio off symbol is displayed in the system information area.
- The Audio Off message is displayed in the physiological alarm information area with a red background.

To exit the audio off status, press the **Audio Pause** guick key again.

#### WARNING

Pausing or switching off alarm sound may result in a hazard to the patient.

## 7.8 Resetting Alarms

Pressing the **Alarm Reset** quick key to acknowledge the ongoing alarms and reset the alarm system. When the alarm system is reset, the alarm reset symbol displays in the system status information area for alarm symbols.

#### NOTE

 If a new alarm is triggered after the alarm system is reset, the alarm reset icon will disappear and the alarm light and alarm tone will be reactivated.

## 7.8.1 Resetting Physiological Alarms

Physiological alarms give different alarm indicators when the alarm system is reset:

- The alarm sound is silenced.
- A √ appears before the alarm message, indicating that the alarm is acknowledged.
- The color of the parameter numeric background corresponds with the alarm priority, but the parameter numeric does not flash.

## 7.8.2 Resetting Technical Alarms

Technical alarms give different alarm indicators when the alarm system is reset:

- Some technical alarms are cleared. The monitor gives no alarm indications.
- Some technical alarms are changed to the prompt messages.
- For some technical alarms, the alarm is silenced and a  $\sqrt{}$  appears before the alarm message, indicating that the alarm is acknowledged.

For details about the indications of technical alarms when the alarm system is reset, see *D Alarm Messages*.

## 7.8.3 Setting Alarm Light Status on Alarm Reset

When the alarm system is reset, the monitor presents the alarm light by default, but you can switch off the alarm light. This function is password protected. For more information, see 18.6.2 The Pause/Reset Tab.

## 7.9 Latching Alarms

The latching setting for physiological alarms defines how alarm indicators behave if you do not reset the alarms.

- If you do not "latch" physiological alarms, their alarm indications disappear when the alarm condition ends.
- If you "latch" physiological alarms, all visual and audible alarm indications remains until you reset the alarms. For latched alarms the time when the alarm is last triggered is displayed behind the alarm message.

You can separately latch visual indications or simultaneously latch the visual and the audible indications.

- When visual indications are latched, visual indications, including alarm lamp, alarm message and its background remains when the alarm condition ends and the time when the alarm last triggered is displayed behind the alarm message.
- When audible indications are latched, the monitor issues alarm sounds when the alarm condition ends.

The alarm latch settings is password protected.

#### NOTE

- Changing alarm priority may affect the latching status of corresponding alarm. Determine if you need to reset the alarm latching status if you changed the alarm priority.
- When the alarm system is reset, latched physiological alarms are cleared.

## 7.10 Nurse Call

The monitor provides a nurse call connector to output nurse call signal when a userdefined alarm occurs. To obtain nurse call signal, use the nurse call cable to connect the hospital nurse call system with the monitor's nurse call connector.

Alarms are indicated on the nurse call device only when the following conditions are met:

- The nurse call system is enabled.
- A user-defined alarm occurs.
- Alarms are not paused or reset.

This function is password protected. For more information, see 18.6.4 The Nurse Call Tab.

### WARNING

Do not rely exclusively on the nurse call system for alarm notification.
 Remember that the most reliable alarm notification combines audible and visual alarm indications with the patient's clinical condition.

## 7.11 Testing Alarms

The monitor automatically performs a selftest at startup. Check that an alarm tone is heard, and the alarm lamp illuminates, one after the other, in red, yellow, and cyan. This indicates that the visible and alarm indicators function correctly.

To further test individual measurement alarms, perform measurement on yourself or using a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

## 7.12 Actions When an Alarm Occurs

When an alarm occurs, observe the following steps and take proper actions:

- 1. Check the patient's condition.
- 2. Confirm the alarming parameter or alarm category.
- 3. Identify the source of the alarm.
- 4. Take proper action to eliminate the alarm condition.
- 5. Make sure the alarm condition is corrected.

For more information, see **D** Alarm Messages.

# 8 Monitoring Pulse Oxygen Saturation (SpO<sub>2</sub>)

## 8.1 SpO<sub>2</sub> Introduction

Pulse Oxygen Saturation ( $\mathrm{SpO}_2$ ) monitoring is a non-invasive technique used to measure the amount of oxygenated haemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the emitter side of the probe is partly absorbed when it passes through the monitored tissue. The amount of transmitted light is detected in the detector side of the probe. When the pulsative part of the light signal is examined, the amount of light absorbed by the haemoglobin is measured and the pulse oxygen saturation can be calculated. This device is calibrated to display functional oxygen saturation.

SpO<sub>2</sub> monitoring is intended for adult, pediatric and neonatal patients.

The following types of SpO<sub>2</sub> can be configured for the monitor:

- Mindray SpO<sub>2</sub>: the connector is blue and no logo is on the monitor.
- Nellcor SpO<sub>2</sub>: the connector is grey and the logo of Nellcor is on the monitor.
- Masimo SpO<sub>2</sub>: the connector is purple and the logo of Masimo SET is on the monitor.

#### NOTE

- The SpO<sub>2</sub> extension cable should be compatible with the SpO<sub>2</sub> connectors.
   For example, you can only connect the Mindray SpO<sub>2</sub> extension cable to the Mindray SpO<sub>2</sub> connectors.
- A functional tester or SpO<sub>2</sub> simulator can be used to determine the pulse rate accuracy.
- A functional tester or SpO<sub>2</sub> simulator cannot be used to assess the SpO<sub>2</sub> accuracy.

## 8.2 SpO<sub>2</sub> Safety Information

#### WARNING

- When a trend toward patient deoxygenation is indicated, analyze the blood samples with a laboratory co-oximeter to completely understand the patient's condition.
- Do not use SpO<sub>2</sub> sensors during magnetic resonance imaging (MRI). Induced current could potentially causes burns. The sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Prolonged continuous monitoring may increase the risk of undesirable 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. Change the application site every four hours. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.
- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- Setting alarm limits to extreme values may cause the alarm system to become ineffective. For example, 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 off the alarm.
- SpO<sub>2</sub> is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- To protect from electric shock, always remove the sensor before bathing the patient.
- The pulse oximetry function of the bedside monitor should not be used for apnea monitoring.
- The pulse oximetry function of the bedside monitor should not be used for arrhythmia analysis.

#### **CAUTION**

- Change the application site or replace the sensor and/or patient cable when a
  persistent SpO2 Low Signal Quality message is displayed on the equipment.
  These messages may indicate that patient monitoring time is exhausted on
  the patient cable or sensor.
- Replace the cable or sensor when a "SpO2 Sensor Off", "SpO2 No Sensor", or "SpO2 Low Signal Quality" message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.
- Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
- 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.
- Do not place the pulse oximeter where the controls can be changed by the patient.
- If using patient monitor during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.

### **NOTE**

- Additional information specific to the Masimo sensors compatible with the equipment, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Masimo cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

## 8.3 SpO<sub>2</sub> Measurement Limitations

The following factors may influence the accuracy of SpO<sub>2</sub> measurement:

- Patient physiological characteristics:
  - ◆ Cardiac arrest

- Hypotension
- Darkly pigmented skin
- ♦ Shock
- Severe vasoconstriction
- ♦ Hypothermia
- Severe anemia
- Ventricular septal defects (VSDs)
- Venous pulsations
- Poor perfusion
- Dysfunctional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
- ◆ Elevated levels of bilirubin
- Vasospastic disease, such as Raynaud's, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.

#### Interfering substances:

- Intravascular dyes (such as indocyanine green, methylene blue, indigo carmine, etc.)
- Dyes in the measure site, such as nail polish.

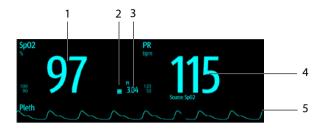
#### Environmental conditions:

- ◆ Excessive ambient light
- Electrosurgery equipment
- ◆ Defibrillation (may cause inaccurate reading for a short amount of time)
- Excessive patient/sensor motion
- Electromagnetic field
- Arterial catheters and intra-aortic balloon

#### Others

- Inappropriate positioning of the SpO<sub>2</sub> sensor, or use of incorrect SpO<sub>2</sub> sensor
- Cuff or arterial blood pressure measurement device on the same limb as the SpO<sub>2</sub> sensor.

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



- Oxygen saturation of arterial blood (SpO<sub>2</sub>): percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
- 2 Perfusion indicator: the pulsatile portion of the measured signal caused by arterial pulsation.
- Perfusion index (PI): gives the numerical value for the pulsatile portion of the measured signal caused by arterial pulsation. PI is an indicator of the pulsatile strength. You can also use it to assess the SpO<sub>2</sub> signal strength.
  - · Above 1 is optimal.
  - Between 0.3 and 1 is acceptable. The PI is displayed with a yellow background.
  - Below 0.3 indicates low perfusion. The PI is displayed with a red background and the SpO<sub>2</sub> value is outlined. Reposition the SpO<sub>2</sub> sensor or find a better site. If low perfusion persists, choose another method to measure oxygen saturation if possible.
- 4 Pulse rate (derived from the pleth wave): detected pulsations per minute.
- 5 Pleth waveform (Pleth): visual indication of patient's pulse. The waveform is not normalized.

## **NOTE**

- PI is only available for Mindray SpO<sub>2</sub> and Masimo SpO<sub>2</sub>.
- If the measurement fails, or measurement is not taken, "--" is displayed.
- Outlined numerics indicate that the measurement may not be reliable. So these values are not recommended for reference.

## 8.5 Preparing for SpO<sub>2</sub> Monitoring

To prepare to monitor SpO<sub>2</sub>, follow this procedure:

- Select an appropriate sensor according to the module type, patient category, weight, and measurement site.
- 2. Clean the contact surface of the reusable sensor.
- Remove colored nail polish, earrings, or other extraneous matter from the application site.
- 4. Apply the sensor to the patient according to the instruction for use of the sensor.
- 5. Select an appropriate extension cable according to the connector type and plug the cable into the SpO<sub>2</sub> connector.
- Connect the sensor to the extension cable.

#### **CAUTION**

- Do not apply sensor too tightly as this results in venous pulsation which may severely obstruct circulation and lead to inaccurate measurements.
- At elevated ambient temperatures be careful with measurement sites that are not well perfused, because this can cause burns after prolonged application.
- Avoid placing the sensor on extremities with an arterial catheter, an NBP cuff or an intravascular venous infusion line.
- For neonatal patients, make sure that all sensor connectors and adapter cable connectors are outside the incubator. The humid atmosphere inside can cause inaccurate measurements.

## 8.6 Changing the SpO<sub>2</sub> Settings

#### **NOTE**

 Alarm related settings are available only when the monitoring is in Continuous Monitoring mode.

## 8.6.1 Changing the SpO<sub>2</sub> Alarm Settings

In **Continuous Monitoring** mode, you can change the  ${\rm SpO_2}$  alarm settings. Follow this procedure:

- 1. Select the SpO<sub>2</sub> numeric area or waveform area to enter the **SpO2** menu.
- 2. Select the Alarm tab.
- 3. Enter the password if required.
- 4. Set the alarm properties of SpO<sub>2</sub> and SpO<sub>2</sub> Desat.

#### **NOTE**

- The desat alarm is a high level alarm notifying you of potentially life threatening drops in oxygen saturation. When the SpO2 value is below the desat alarm limit and desat alarm switch is set on, the message "SpO2 Desat" is displayed.
- You can switch off the SpO2 Desat alarm only when SpO2 Desat Alarm Off is enabled. For more information, see section 7.6.7 Setting the Switch of the SpO<sub>2</sub> Desat Alarm Off.

## 8.6.2 Nellcor Sat-Seconds<sup>TM</sup> Alarm Management

With traditional alarm management, high and low alarm limits are set for monitoring oxygen saturation. During monitoring, once an alarm limit is violated, an audible alarm immediately sounds. When the patient  ${\rm SpO}_2$  fluctuates near an alarm limit, the alarm sounds each time the limit is violated. Such frequent alarms can be distracting. Nellcor's Sat-Seconds alarm management technique is used to reduce these nuisance alarms.

The Sat-Seconds feature is available with the Nellcor  $\mathrm{SpO}_2$  to decrease the likelihood of false alarms caused by motion artifacts. With Sat-Seconds alarm management, high and low alarm limits are set in the same way as those with traditional alarm management. A Sat-Seconds limit is also set. The Sat-Seconds limit controls the amount of time that  $\mathrm{SpO}_2$  saturation may be outside the set limits before an alarm sounds.

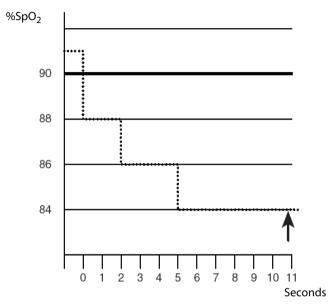
The method of calculation is as follows: the percentage points of the  $SpO_2$  saturation falling outside the alarm limit is multiplied by the number of seconds remaining outside the limit. This can be stated as the equation:

Sat-Seconds = Points × Seconds

Only when the Sat-Seconds limit is reached, the monitor gives a Sat-Seconds alarm. For example, the figure below demonstrates the alarm response time with a Sat-Seconds limit set at 50 and a low  ${\rm SpO_2}$  limit set at 90%. In this example, the patient  ${\rm SpO_2}$  drops to 88% (2 points) and remains there for 2 seconds. Then it drops to 86% (4 points) for 3 seconds, and then to 84% (6 points) for 6 seconds. The resulting Sat-Seconds are:

% SpO <sub>2</sub>	Seconds	Sat-Seconds
2×	2=	4
4×	3=	12
6×	6=	36
Total Sat-Seconds=		52

After approximately 10.9 seconds, a Sat-Second alarm would sound, because the limit of 50 Sat-Seconds would have been exceeded.



Saturation levels may fluctuate rather than remaining steady for a period of several seconds. Often, the patient  ${\rm SpO}_2$  may fluctuate above and below an alarm limit, reentering the non-alarm range several times. During such fluctuation, the monitor integrates the number of  ${\rm SpO}_2$  points, both positive and negative, until either the Sat-Seconds limit is reached, or the patient  ${\rm SpO}_2$  re-enters the non-alarm range and remains there.

#### **NOTE**

The SpO<sub>2</sub> Too Low or SpO<sub>2</sub> Too High alarm is presented in the case that SpO<sub>2</sub> value violates the alarm limits for 3 times within one minute even if the setting of Sat-Seconds is not reached.

## 8.6.3 Setting the Nellcor SpO<sub>2</sub> Sat-Seconds

In **Continuous Monitoring** mode, you can set the Sat-Seconds. Follow this procedure:

- 1. Select the SpO<sub>2</sub> numeric area or waveform area to enter the **SpO2** menu.
- Select the Alarm tab.
- Set Sat-Seconds.

## 8.6.4 Setting SpO<sub>2</sub> Sensitivity (for Masimo SpO<sub>2</sub>)

For Masimo SpO<sub>2</sub>, selects the **Sensitivity** as per signal quality and patient motion.

Normal sensitivity is the recommended for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as the intensive care unit (ICU).

Adaptive Probe Off Detection (APOD) sensitivity is the recommended sensitivity mode where there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.

Maximum sensitivity is recommended for use on patients with weak signals (e.g. high ambient noise and/or patients with very low perfusion) and for use during procedures or when clinician and patient contact is continuous such as in higher acuity settings.

To set SpO<sub>2</sub> sensitivity, follow this procedure:

- In Continuous Monitoring mode, select the SpO<sub>2</sub> numeric area or waveform area to enter the SpO2 menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select SpO2.
- 2. Select the **Setup** tab.
- Set Sensitivity to Maximum, Normal, or APOD.

#### **CAUTION**

- When using the Maximum Sensitivity setting, performance of "Sensor Off" detection may be compromised. If the equipment and the sensor becomes detached from the patient, the potential for false readings may occur due to environmental noise such as light, and vibration.
- Changing workflows may result in Masimo SpO<sub>2</sub> being set to Maximum sensitivity mode on power up or after admitting a new patient. Maximum sensitivity is recommended for use during procedures or when clinician and patient contact is continuous, such as in higher acuity settings. Maximum sensitivity is not recommended for care areas where patients are not monitored visually as "Sensor Off" detection may be compromised.

## 8.6.5 Enabling FastSAT (for Masimo SpO<sub>2</sub>)

FastSAT enables rapid tracking of arterial oxygen saturation changes as may be required in urgent situations. When FastSAT is switched on, the averaging algorithm evaluates all the SpO<sub>2</sub> values and provides an averaged SpO<sub>2</sub> value that is a better representation of the patient's current oxygen saturation status.

The reliability of FastSAT is dependent on the setting for the averaging time and the input signal. FastSAT is disabled by default. To enable FastSAT, follow this procedure:

- In Continuous Monitoring mode, select the SpO<sub>2</sub> numeric area or waveform area to enter the SpO2 menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select SpO2.
- 2. Select the **Setup** tab.
- Switch on Fast SAT.

## 8.6.6 Displaying SIQ (for Masimo SpO<sub>2</sub>)

The signal quality indicator (SIQ) displays below the Pleth waveform. The SIQ is conveyed by vertical bars. The height of the bar provides an assessment of the confidence in the displayed  ${\rm SpO_2}$  value. The  ${\rm SpO_2}$  SIQ can also be used to identify the occurrence of a patient 's pulse.

The following picture shows the SpO<sub>2</sub> SIQ:



Signal quality indicator (SIQ)

To show SpO<sub>2</sub> SIQ, follow this procedure:

- In Continuous Monitoring mode, select the SpO<sub>2</sub> numeric area or waveform area to enter the SpO2 menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select SpO2.
- 2. Select the **Setup**tab.
- 3. Switch on **Display SIQ**.

## 8.6.7 Changing Averaging Time (for Masimo SpO<sub>2</sub>)

The  $SpO_2$  value displayed on the monitor screen is the average of data collected within a specific time. The shorter the averaging time is, the quicker the monitor responds to changes in the patient's oxygen saturation level. Contrarily, the longer the averaging time is, the slower the monitor responds to changes in the patient's oxygen saturation level, but the  $SpO_2$  measurement is more stable. For critically ill patients, selecting a shorter averaging time will help with understanding the patient's state.

To set the averaging time, follow this procedure:

- In Continuous Monitoring mode, select the SpO<sub>2</sub> numeric area or waveform area to enter the SpO2 menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select SpO2.
- 2. Select the **Setup** tab.

Set Averaging.

## 8.6.8 Changing the Sensitivity (for Mindray SpO<sub>2</sub>)

The  $SpO_2$  value displayed on the monitor screen is the average of data collected within a specific time. The shorter the averaging time is, the quicker the monitor responds to changes in the patient's oxygen saturation level. Contrarily, the longer the averaging time is, the slower the monitor responds to changes in the patient's oxygen saturation level, but the  $SpO_2$  measurement is more stable. For critically ill patients, selecting shorter averaging time will help understanding the patient's state.

To set the averaging time, follow this procedure:

- In Continuous Monitoring mode, select the SpO<sub>2</sub> numeric area or waveform area to enter the SpO2 menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select SpO2.
- 2. Select the **Setup** tab.
- 3. Set the Sensitivity.

## 8.6.9 Showing/Hiding PI

You can set whether to display PI in the  ${\rm SpO_2}$  parameter area. To do so, follow this procedure:

- In Continuous Monitoring mode, select the SpO<sub>2</sub> numeric area or waveform area to enter the SpO2 menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select SpO2.
- Select the Setup tab.
- 3. Switch on or off **Display Pl.**

## **NOTE**

This function is only available for Mindray SpO<sub>2</sub> and Masimo SpO<sub>2</sub>.

## 8.6.10 Monitoring SpO<sub>2</sub> and NIBP Simultaneously

When monitoring  $SpO_2$  and NIBP on the same limb simultaneously, you can switch on NIBP Simul to lock the  $SpO_2$  alarm status until the NIBP measurement ends. If you switch off NIBP Simul, low perfusion caused by NIBP measurement may lead to inaccurate  $SpO_2$  readings and therefore cause false physiological alarms.

In Continuous Monitoring mode, you can set the NIBP Simul. Follow this procedure:

- 1. Select the SpO<sub>2</sub> numeric area or waveform area to enter the **SpO2** menu.
- Select the Alarm tab.
- Set NIBP Simul.

## 8.6.11 Changing the Sweep Speed of the Pleth Wave

To set the sweep speed of Pleth waveforms, follow this procedure:

- In Continuous Monitoring mode, select the SpO<sub>2</sub> numeric area or waveform area to enter the SpO2 menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select SpO2.
- 2. Select the **Setup** tab.
- Set Speed.

## 8.6.12 Setting the Alarm Priority for SpO2 Sensor Off Alarm

The level for **SpO2 Sensor Off** alarm under **Continuous Monitoring** mode can be set. Follow this procedure:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select .
- Select the Alarm tab → select the Other tab.
- 3. Set SpO2 Sensor Off.

## 8.6.13 Setting the SpO<sub>2</sub> Tone Mode

The monitor adjusts the QRS tone (pitch tone) according to the  $SpO_2$  values. To set the  $SpO_2$  tone mode, follow this procedure:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select .
- Select the Other tab.
- Set SpO2 Tone.

#### **CAUTION**

 The same SpO<sub>2</sub> tone mode shall be used for the same monitors in a single area.

## 8.7 SpO<sub>2</sub> Troubleshooting

This section lists the problems that might occur. If you encounter the problems when using the equipment or accessories, check the table below before requesting for services. If the problem persists, contact your service personnel.

#### **NOTE**

For the physiological and technical alarm messages, see D Alarm Messages.

Problem	Solution
Do not see SpO <sub>2</sub> numeric area or waveform area on the main screen	Check that the SpO <sub>2</sub> is set to display in the <b>Edit Workflow</b> menu. For more information, see 3.9.2.2 Setting the Screen Layout.
Dashes "" display in place of numerics.	<ol> <li>Check that the cable connections of SpO<sub>2</sub> sensor and the extension cable are tight. Replace the SpO<sub>2</sub> sensor or the extension cable if needed.</li> <li>Reconnect the SpO<sub>2</sub> sensor if the alarm SpO2 Sensor Off appears.</li> <li>Check the PI value. If the PI value is too low, adjust the SpO<sub>2</sub> sensor, or apply the sensor to the site with better perfusion.</li> <li>Move the sensor to the place with weaker light, or cover the sensor with shade cloth if the alarm SpO2 Sensor Off appears.</li> </ol>
Low amplitude SpO <sub>2</sub> signal	<ol> <li>The SpO<sub>2</sub> sensor and NIBP cuff are placed on the same limb.</li> <li>Change a monitoring site if necessary.</li> <li>Check the PI value. If the PI value is too low. Adjust the SpO<sub>2</sub> sensor, or apply the sensor to the site with better perfusion.</li> <li>Check the sensor and its application site.</li> </ol>
SpO <sub>2</sub> value is inaccurate	<ol> <li>Check the patient's vital signs.</li> <li>Check for conditions that may cause inaccurate SpO<sub>2</sub> readings.</li> <li>For more information, see 8.3 SpO<sub>2</sub> Measurement Limitations.</li> <li>Check the monitor, the SpO<sub>2</sub> sensor for proper functioning.</li> </ol>

## 8.8 Nellcor Information



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This device may be covered by one or more of the following US patents and foreign equivalents: 5,485,847, 5,676,141, 5,743,263, 6,035,223, 6,226,539, 6,411,833, 6,463,310, 6,591,123, 6,708,049, 7,016,715, 7,039,538, 7,120,479, 7,120,480, 7,142,142, 7,162,288, 7,190,985, 7,194,293, 7,209,774, 7,212,847, 7,400,919.

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# **9** Monitoring PR

## 9.1 PR Introduction

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart. The pulse value can be from  ${\rm SpO}_2$  or NIBP. The PR parameter area displays its source.

## 9.2 PR Display



- 1. PR unit
- 2. PR high limit
- 3. PR low limit
- 4. PR Source: it can be sourced from SpO<sub>2</sub> or NIBP, with SpO<sub>2</sub> taking precedence.
- 5. Pulse rate (PR): detected pulsations per minute.
- 6. In **Spot Check** mode, select this area to mark the pulse as regular or irregular. It can be switched on or off. For details, see *9.3.3 Enabling Irregular PR*.

#### **NOTE**

 A functional tester or SpO<sub>2</sub> simulator can be used to determine the pulse rate accuracy.

## 9.3 Changing the PR Settings

## 9.3.1 Changing the PR Alarm Settings

In **Continuous Monitoring** mode, you can change the PR alarm settings. Follow this procedure:

1. Select the PR numeric area to enter the **PR** menu.

- Select the PR Alarm tab.
- 3. Set the alarm properties of PR.

## 9.3.2 Changing the Pulse Volume

To change the pulse volume, follow this procedure:

- In Continuous Monitoring mode, select the PR numeric area to enter the PR menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select PR.
- 2. Select **PR Setup** tab.
- 3. Set the **Pulse Volume** to an appropriate level.

## 9.3.3 Enabling Irregular PR

To enable the Irregular PR function, follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select 

  .
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select Parameters Setup  $\rightarrow$  PR.
- 4. Switch on Irr. PR Switch.

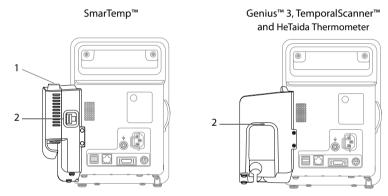
# **10** Measuring Temperature (Temp)

## 10.1 Temp Introduction

The monitor can measure temperature with any one of the following temperature modules:

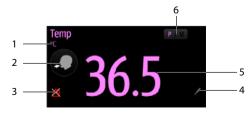
- Mindray SmarTemp<sup>™</sup> module
- Convidien Genius<sup>™</sup> 3 tethered tympanic thermometer
- Exergen TemporalScanner<sup>™</sup> thermometer
- HeTaida Thermometer

Below is a view of monitors configured with the above modules:



- Probe well
- 2. Connector for thermometers or Temp sensors

## 10.2 Temp Display



1. Temp unit

- Measurement site: displays the current measurement site. You can select this area
  to select another measurement site.
- 3. Alarm off symbol if Temp alarm is off; alarm limit if Temp alarm is on
- 4. Select this area to manually input a measured Temp value
- 5. Temp reading
- Measurement mode (for SmarTemp only): displays the current mode, where "P" stands for **Predictive** and "M" stands for "**Monitor**". You can select this area to switch to another mode.

## 10.3 Monitoring Temp with SmarTemp™ Module

The SmarTemp™ Temp module is intended for monitoring oral, axillary and rectal temperature of adult and pediatric patients and axillary temperature of neonatal patients.

Temperature can be measured in either **Predictive** mode or **Monitor** mode. The default is **Predictive** mode.

#### WARNING

- Do not take oral temperature on the infant (0-3 years).
- Do not take rectal temperature on the neonate (0-28 days).
- Use only the specified temperature probe and probe cover. Using other probe or probe cover, or not using probe cover may cause damage to the monitor or failure to meet the declared specifications in this manual.
- The temperature probe cover is disposable. Re-use of probe cover may result in patient cross-contamination.
- Use disposable probe covers for temperature measurement. Failure to use a probe cover can cause inaccurate temperature readings, and patient crosscontamination.
- Check the disposable probe cover for damage before using. Never use any probe cover for temperature measurement in case of damage or contamination.
- Be careful to avoid damaging the temperature probe. Place the temperature probe in the probe well if not in use.
- Prior to taking a temperature, instruct the patient not to bite down on the probe, as patient injury and damage to the probe may result.
- In the rectal mode, incorrect probe placement may result in bowel perforation.
- Wash hands after temperature is taken. This will significantly reduce the risk of cross contamination and nosocomial contamination.

- Ensure that probe covers are disposed of according to local regulations or hospital's requirements.
- Accuracy verification of the temperature module is required every two years or according to your hospital's policy. Please contact our Customer Service if accuracy verification is needed.

#### NOTE

- Patient actions may interfere with oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum, brushing teeth, smoking, or performing strenuous activities may affect temperature readings for up to 20 minutes after the activity has ended.
- In the axillary mode, the probe shall directly contact with patient's skin.
   Measuring through patient's clothes or long-term exposure of patient's armpit to the air may result in inaccurate temperature reading.
- Choose appropriate probe according to patient type and measurement site.
   Using the incorrect probe may cause patient's discomfort and inaccurate measurements.
- Improper use of probe may also cause patient's discomfort and inaccurate measurements.

## 10.3.1 Measuring Temp

#### 10.3.1.1 Selecting Measuring Site

The temperature module can be configured with 2 types of temperature probe:

Туре	Color	Patient Category	Measurement Site
Oral/axillary	Red	Adult, pediatric	Oral, axillary
		Neonate	Axillary
Rectal	Blue	Adult, pediatric	Rectal

The blue oral/axillary probe shall only be used with blue probe well, while the red rectal probe shall only be used with red well.

Be sure to select correct probe according to the measurement site.

For adult and pediatric patients, when oral/axillary probe is used, the measurement site will automatically be set to **Oral**. You can change the site in **Temp** area.

For neonatal patients, when oral/axillary probe is used, the measurement site will automatically be set to **Axillary**. The measurement site cannot be changed.

#### 10.3.1.2 Taking a Temperature in Predictive Mode

- 1. Verify that the probe is placed in the probe well.
- 2. Verify that the temperature measurement type and site are correct.
- Unplug the probe from the probe well and the measurement mode changes to Predictive automatically.
- 4. Insert it into a cover in the probe cover pack and press the probe handle down firmly until the cover engages with the probe.

The temperature module starts to warm up when the probe is taken out. The message "Temp Warming Up" displays in Temp parameter area. The warming up time is about 2 seconds in room temperature. The monitor issues two beeps and provides the message "Temp Prediction Ready" on the screen when warm-up is complete. Then you can place the probe at measurement site.

- Place the probe at measurement site and wait till the measurement stabilizes.
   When the dynamic symbol appears, it indicates that the monitor starts to take the measurement.
  - When taking an oral temperature, apply the probe under the patient's tongue from either side of the mouth. Verify that the probe reaches the rear sublingual pocket. Have the patient close his/her lips to hold the probe. Hold the probe in place. Make sure that the probe contacts with the patient's oral tissue throughout the measurement.
  - When taking an axillary temperature, lift the patient's arm to expose the entire armpit. Apply the probe as high as possible in the armpit. Check that the probe tip is completely surrounded by the axillary tissue. Lower the patient's arm so that it is tightly placed at the patient side. Keep the patient's arm and the probe in place throughout the measurement.
  - When taking a rectal temperature, separate patient's buttocks with one hand, and the probe 1.5 cm inside the rectum with the other hand. For pediatric patient, depth of insertion shall be less. Tilt the probe so that it always contacts with patient's tissue. Lubricant can be used in rectal mode.

The monitor will give a beep as the temperature measurement is complete. The temperature reading displays continuously until the probe is taken out from the probe well.

 Withdraw the probe. Press firmly the ejection button on the top of the probe to eject the probe cover. Replace the probe into the probe well.

In **Predictive** mode, the monitor automatically enters **Monitor** mode in the following cases:

- Accurate temperature is not reached.
- Neither measurement is taken nor is the probe replaced in the probe well in 60 seconds after the probe is withdrawn from the well.

The temperature type automatically changes to Predictive mode when the probe returns to the probe well.

#### **NOTE**

- In Predictive mode, temperature probe shall be placed to the measurement site as soon as probe warmup is complete; otherwise, inaccurate temperature reading may result.
- In Predictive mode, if the probe has a high temperature due to the environmental temperature or other causes, cool the probe and then measure the patient's temperature.

#### 10.3.1.3 Taking a Temperature in Monitor Mode

To measure a temperature in the Monitor mode,

- 1. Verify that the probe is placed in the probe well.
- 2. Verify that the temperature measurement type and site are correct.
- 3. Select P/M on the screen to set the measurement mode to **Monitor**.
- Unplug the probe from the probe well and insert it into a cover in the probe cover pack. Press the probe handle down firmly until the cover engages with the probe.
- 5. Place the probe to the measurement site and then start measuring. Refer to Step 4 in 10.3.1.2 Taking a Temperature in Predictive Mode for how to place a probe.
- 6. Withdraw the probe. Press firmly the ejection button on the top of the probe to eject the probe cover. Replace the probe into the probe well.

#### NOTE

 In Monitor mode, record the measured value prior to taking away the probe from measurement site. The monitor will automatically stop measuring temperature after 10 minutes from the start of the measurement.

## 10.3.2 Disinfecting Temperature Probe

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

To disinfect the temperature probe:

- 1. Disconnect the temperature probe from Temp connector.
- Disinfect the probe with a soft cloth dampened with the recommended disinfectant.
- Wipe off all the remaining disinfectants from the probe with a soft cloth dampen with water.
- 4. Dry the probe in a cool place.

#### WARNING

- Perform the decontamination or cleaning process with the monitor powered down and power cord removed.
- The used soft cloth shall be properly disposed of.

## 10.4 Monitoring Temp with Genius™ 3 Tethered Tympanic Thermometer

The Genius™ 3 tethered tympanic thermometer is a fast, accurate, and convenient clinical instrument for measuring patient temperatures. The Genius™ 3 thermometer is an ear canal thermometer with measurement site equivalence modes including oral and rectal equivalent temperatures.

The thermometer is powered by the monitor.

Refer to the *Genius 3 Tethered Tympanic Thermometer Operator's Manual* for additional information.

## 10.4.1 Safety Information

## **WARNING**

No alarm is provided for the temperature measurement.

## **CAUTION**

 Used probe covers must be treated as infectious biological waste and disposed of in accordance with current medical practices and local regulations.

#### 10.4.2 Thermometer Buttons

Button	Name	Functions
	Eject button	Press the eject button to eject the probe cover from the probe.
<b>%</b> ₅	°C/°F button	When a temperature is in the display, you may press and hold the °C/°F button to toggle between degrees Celsius and degrees Fahrenheit.

(1)	Timer button	Press and hold the timer button to enter the timer mode. Press again to start the timer.
	Scan button	When the thermometer is on, press the scan button to initiate a temperature measurement.  When the thermometer is off, press the scan button to turn on the device.

## 10.4.3 Equivalence Mode Temperature

The thermometer can measure the ear temperature and acquire the equivalence temperature.

A patient's temperature at the site of mouth or rectum would be slightly different from the ear temperature. The thermometer compensates for the average difference in temperature at each of these sites by adjusting the displayed temperature.

A checker/calibrator is available for this device. The device should be checked if it is dropped or if it is stored at less than -25 °C or above 55 °C.

#### **NOTE**

 Only the authorized personnel can adjust the data for Genius3 thermometer equivalence modes.

Equivalence Mode	Description
Oral	The temperature is adjusted to display an oral temperature equivalent.  Oral Mode = Ear Mode -0.09 °C
Rectal	The temperature is adjusted to display a rectal temperature equivalent.  Rectal Mode = Ear Mode + 0.56 °C

## 10.4.4 Taking a Temperature

To take a temperature, follow this procedure:

- 1. When the monitor starts, remove the thermometer from the cradle.
- 2. Inspect the probe tip and make sure that the probe tip is clean. If it is soiled, clean it with a lens wipe or lint free swab.
- Press the scan button to verify functionality and mode selection on the LCD screen.
- 4. Install a probe cover by firmly inserting the probe tip into a probe cover. Make sure that the probe cover is fully seated.

- 5. Place the probe in the ear canal.
- 6. Once positioned lightly in the ear canal, press and release the scan button.
- Remove the probe from the ear as soon as the triple beep is heard. The temperature and probe eject icon display on the LCD screen.
- 8. Press the eject button to eject the probe cover.
- 9. Replace the thermometer to the cradle.

#### NOTE

- Always wait at least two minutes before taking another measurement in the same ear.
- Do not configure the thermometer during the start-up of the monitor.
   Otherwise, the thermometer data may conflict with the data that displays on the monitor.

## 10.4.5 Troubleshooting

Message/Issue	Cause	Solution
Temp comm abnormal	The communication between the monitor and thermometer is abnormal.	Eject and re-install the probe cover. And then measure the temperature again.
The measurement site displayed on the monitor conflicts with that on the thermometer.	During the monitor start- up, the thermometer has the probe cover installed. This causes the abnormal start-up of the thermometer.	Keep the monitor power on and wait till the thermometer automatically switches off, and then press the Scan button on the thermometer.

## 10.4.6 Cleaning and Disinfecting the Tympanic Thermometer

Refer to the Genius 3 tethered tympanic thermometer operator's manual for cleaning and disinfection information.

## 10.5 Monitoring Temp with Exergen TemporalScanner™ Thermometer

The Temporal Scanner™ thermometer measures the temperature of the skin over the temporal artery. Operation is based on measuring the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery.

The TemporalScanner™ is a handheld infrared thermometer used by medical professionals for the intermittent measurement of human body temperature of people of all ages, by scanning the forehead skin over the temporal artery.

## 10.5.1 Safety Information

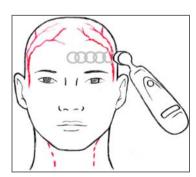
#### **WARNING**

- Use this product only for its intended use as described in this manual.
- Keep the TemporalScanner™ away from electromagnet interference.
- Do not take temperature over scar tissue, open sores or abrasions.
- The thermometer is not shockproof. Do not drop it or expose it to electrical shocks.
- Do not use this thermometer if it is not working properly, if it has been exposed to temperature extremes, damaged, been subject to electrical shocks or immersed in water.
- There are no parts that you can service yourself except for the battery, which
  you should replace when low by following the instructions in this manual. For
  service, repair, or adjustments, return your thermometer to Mindray.
- No modification of this equipment is allowed.
- Never drop or insert any object into any opening, unless stated in this manual.
- If your thermometer is not used regularly, remove the battery to prevent possible damage due to chemical leakage.
- Follow the battery manufacturer's recommendations or your hospital policy for the disposal of used batteries.

## 10.5.2 Taking a Temperature with the TemporalScanner™

## 10.5.2.1 Understanding the Measurement sites

Recommended measurement sites are: temperature at the temporal artery area or temperature behind the ear.





Alternate sites when temporal artery or behind ear are unavailable:

- Femoral artery: slowly slide the probe across groin.
- Lateral thoracic artery: slowly scan side-to-side in the area, midway between the axilla and the nipple.

#### 10.5.2.2 Taking a Temperature on an Infant

To take a temperature on an infant, follow this procedure:

- 1. Place probe flush on center of forehead and depress button. Keeping button depressed, slowly slide probe mid-line across forehead to the hair line.
- Release button remove from head and read measurement.

#### **NOTE**

- The preferred site is the temporal artery area. Unless visibly diaphoretic, one measurement here is typically all that is required.
- If the temporal artery is covered, then the area behind the ear, if exposed, can be an alternate site.
- Measure straight across the forehead and not down side of face.
- Brush the hair aside if covering the area to be measured. Measurement site must be exposed.

#### 10.5.2.3 Taking a Temperature on an Adult

To take a temperature on an adult, follow this procedure:

- Slide across forehead. Place probe flush on center of forehead and depress button. Keeping button depressed slowly slide probe mid-line across forehead to the hair line.
- Slide behind ear. Keeping button depressed, lift probe from forehead, touch behind ear halfway down the mastoid process and slide down to the soft depression behind the earlobe.
- Release button and read measurement.

#### NOTE

 Measure only the up-side on a patient in a lateral position. The down-side will be insulated preventing the heat from dissipating, resulting in falsely high readings.

- Think of a sweatband. Measure straight across the forehead and not down the side of the face. At mid-line, the temporal artery is about 2 mm below the surface, but can go deeply below the surface on the side of the face.
- Measure exposed skin. Brush the hair and bangs aside if covering the area to be measured.

## 10.5.3 Understanding the TemporalScanner™ Thermometer LED Display

The following chart summarizes the conditions that may occur while the TemporalScanner™ is in use, and the associated indications:

Condition	Display	Solution/Range
High Target	Н	>110 °F(43 °C)
Low Target	LO	<61 °F(16 °C)
High Ambient	HI A	>104 °F (40 °C)
Low Ambient	LO A	<60 °F (16 °C)
Low Battery	bAtt	/
No or Very Low Battery	blank display	/
Processing Error	Err	Restart. Return to Mindray for repair if error message persists.
Scanning (Normal Operation)		1

#### 10.5.4 Fahrenheit or Celsius Conversion

The TemporalScanner $^{\text{m}}$  can be used in either °F or °C. To convert from one scale to the other, the only tools necessary are a paper clip and the tip of a small screwdriver.

To convert to Fahrenheit or Celsius:

- Bend one leg of a paper clip and insert it into the hole in the side of the plastic housing.
- 2. Push to release the battery cover, and then remove the battery.
- 3. Slide the switch to left (Celsius) or right (Fahrenheit) with the tip of a screwdriver.
- 4. Replace battery and cover.

#### **NOTE**

 After converting to Fahrenheit, the readings on TemporalScanner™ and the monitor might be slightly different. The readings on TemporalScanner™ would be more accurate.

## 10.5.5 Replacing the Battery

To replace the battery, follow this procedure:

- Bend one leg of a paper clip and insert it into the pinhole in the side of the plastic housing.
- 2. Push to release the battery cover, and then remove the battery.
- 3. Replace the battery into the compartment.
- 4. Reinstall the battery cover.

## 10.5.6 Troubleshooting

Message/Issue	Cause	Solution
Abnormally low Temperature	Dirty Lens	Clean lens of scanner every two weeks.
	Releasing the button before finished measuring	Release the button after finished measuring.
	Measuring when an ice pack or wet compress is on the forehead	Remove ice pack or wet compress, wait 2 minutes, and re-take temperature.
	Measuring a completely diaphoretic patient	Complete diaphoresis includes diaphoresis of area behind the ear and suggests that the temperature is rapidly dropping. Use an alternative method of temperature measurement in these cases until the patient is dry and the temporal artery measurement can be repeated.
	Improperly scanning down the side of the face	Scan straight across forehead. The temporal artery is closest to skin in that area.
Abnormally high temperature	Anything covering the area to be measured would insulate and prevent heat from dissipating, resulting in false high readings.	Confirm measurement site has not recently been in contact with heat insulators such as hats, blankets, and hair. Scan the area not covered or wait about 30 seconds for the previously covered area to equilibrate to the environment.

## 10.5.7 Cleaning the TemporalScanner™ Thermometer

#### WARNING

- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).
- Never immerse any part of the product in liquids or allow liquid to enter the interior.
- When cleaning or disinfecting the product, avoid pouring any liquid on the thermometer.

You should clean the product as per your hospital's regulations after each use. Sterilization is not allowed for the product.

#### Cleaning the case

The TemporalScanner™ case can be wiped down using a cloth dampened with 70% isopropyl alcohol. The industrial grade housing and design of the electronic components allow for completely safe cleaning with 70% isopropyl alcohol but should not be immersed in fluid or autoclaved.

#### ■ Cleaning the sensor lens

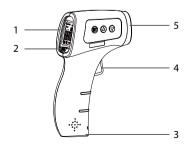
Dirt, greasy films or moisture on the lens will interfere with the passage of infrared heat and affect the accuracy of the product.

Clean the lens every two weeks with a cotton swab dipped in alcohol. Use only light force for cleaning, to avoid damaging the lens. Water can be used to remove any residual film left by the alcohol. Do not use bleach or other cleaning solutions on the sensor lens.

## 10.6 Monitoring Temp with HeTaida Thermometer

The HeTaida thermometer is a non-contact infrared thermometer that measures temporal temperature. It is applicable for adult, pediatric and neonatal patients. The thermometer connects with the monitor through the connector on the back.

#### 10.6.1 Overview of HeTaida Thermometer



- 1. Screen: displays the Temp readings and measurement mode
- 2. Mode button: sets the measurement mode to Forehead or Body
- 3. Battery compartment: installs two AAA batteries
- Start Measurement button: press it to turn the thermometer on and perform a Temp measurement
- 5. Infrared sensor window: detects the temperature

## 10.6.2 Taking a Temperature with HeTaida Thermometer

To take a temperature with Hetaida Thermometer, follow this procedure:

- Set the thermometer to Forehead mode.
- 2. Point the infrared sensor window to the forehead of a patient.
- Press the Start Measurement button and read measurement.

## 10.7 Manually Inputting Temp

You can manually input a Temp value and save the data for future reference.

Follow this procedure:

- Select in the Temp area. For monitors configured with Mindray SmarTemp™ module, to input Temp value in **Continuous Monitoring** mode, press and hold in the Temp area.
- Select a **Temp Measurement Site**. The options displayed in the menu is configurable. For details, refer to 18.9.3 The Temp Tab.
- 3. Input a measured Temp value.
- 4. Select the **Save** quick key to save the data.

# 1 1 Measuring Noninvasive Blood Pressure (NIBP)

## 11.1 NIBP Introduction

The monitor uses the oscillometric method for measuring the non-invasive blood pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. The oscillometric device uses a blood pressure cuff to sense these oscillations that appear as tiny pulsations in cuff pressure.

Two algorithms can be used on the monitor:

- Inflation: at the inflation stage, the device effects a slow inflation of a cuff while simultaneously detects oscillations. As soon as systolic pressure is determined, the cuff is deflated. The oscillations appeared during inflation increase in amplitude to a peak amplitude (which approximates to the mean pressure) with increasing cuff pressure and then decrease in amplitude. If the measurement fails at the inflation stage, the device will automatically continue the measurement at deflation stage.
- Deflation: the device measures 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 oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

NIBP measurement adopting inflation algorithm is intended for adult and pediatric patients, and NIBP measurement adopting deflation algorithm is intended for adult, pediatric, and neonatal patients.

#### **NOTE**

- Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the limits prescribed by the American National Standard: manual, electronic, or automated sphygmomanometers.
- NIBP measurement can be performed during electro-surgery and discharge of defibrillator.

## 11.2 NIBP Safety Information

#### WARNING

- Be sure to select the correct patient category setting for your patient before NIBP measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise, it may present a safety hazard.
- Do not measure NIBP on patients with sickle-cell disease or on the limb where skin damage has occurred or is expected.
- If your monitor is using inflation algorithm, select cuffs with the TrueBP™ symbol. Using other cuffs may lead to incorrect or failed measurements.
- Use clinical judgment to determine whether to perform frequent unattended blood pressure measurement on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- 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.
- Do not apply cuff on the arm on the side of a mastectomy or lymph node clearance.
- Continuous cuff pressure due to connection tubing kinking may cause blood flow interference, and resulting in harmful injury to the patient.
- NIBP reading can be affected by the measurement site, the position of the
  patient, exercise, or the patient's physiologic condition. If you doubt the NIBP
  measurements, determine the patient's vital signs by alternative means, and
  then verify that the monitor is working correctly.
- Devices that exert pressure on tissue have been associated with purpura, ischemia, and neuropathy. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site or stop the blood pressure measurement immediately. Check more frequently when making automatic or STAT measurement. Auto NIBP measurement with one and two minute intervals is not recommended for extended periods of time.
- NIBP diagnostic significance must be decided by the physician.

#### **CAUTION**

- Using IABP may cause NIBP, including PR, measurements inaccurate or failed.
- Only use parts and accessories specified in this manual. Follow the instructions for use and adhere to all warnings and cautions.

Accuracy of NIBP measurement depends on using a cuff of proper size. It is
essential to measure limb circumference and choose a cuff with proper size.

## 11.3 NIBP Measurement Limitations

Measurement is impossible with heart rate extremes of less than 30 bpm or greater than 300 bpm, or if the patient is on a heart-lung machine. The measurement may be inaccurate or impossible in the following situations:

- Regular arterial pressure pulses are hard to detect
- With excessive and continuous patient movement such as shivering or convulsions
- With cardiac arrhythmias
- With rapid blood pressure changes
- With severe shock or hypothermia that reduces blood flow to the peripheries
- On an edematous extremity.

#### NOTE

 The effectiveness of this sphygmomanometer has not been established in pregnant, including pre-eclamptic patients.

## 11.4 Measurement Modes

In **Spot Check** mode, there are three NIBP measurement modes:

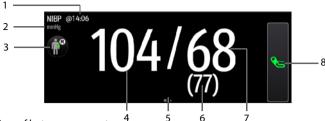
- Manual: measurement on demand.
- BP (Blood Pressure) Averaging: see 11.9 BP Averaging.
- Orthostatic BP measurement: see 11.10 Orthostatic BP Measurement.

In **Continuous Monitoring** mode, there are four NIBP measurement modes:

- Manual: measurement on demand.
- Auto: repeated measurement at set interval or an interval synchronized with the real time clock.
- STAT: continually rapid series of measurement over a five minute period.
- Sequence: continually automatic measurement at set durations and intervals.

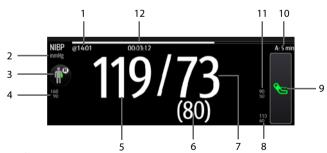
## 11.5 NIBP Display

Below is an example of NIBP screen in **Spot Check** mode:



- 1. Time of last measurement
- 2. NIBP unit
- 3. Select this area to set the patient position and measurement site
- 4. Systolic pressure
- 5. Another measurement mode is available:
  - If the department is set to Physician Office, swipe on the NIBP area to the left or right to switch to BP averaging screen. For details, see 11.9 BP Averaging.
  - If orthostatic BP measurement is enabled, swipe on the NIBP area to the left or right to switch to orthostatic BP measurement screen. For details, see 11.10 Orthostatic BP Measurement.
- Mean pressure (displayed after measurement completed) or cuff pressure (displayed during the measurement)
- 7. Diastolic pressure
- 8. Start/Stop NIBP measurement

Below is an example of NIBP screen in **Continuous Monitoring** mode:



- 1. Time of last measurement
- 2. NIBP unit
- 3. Select this area to set the patient position and measurement site
- 4. Systolic pressure alarm limits
- 5. Systolic pressure

- Mean pressure (displayed after measurement completed) or cuff pressure (displayed during the measurement)
- 7. Diastolic pressure
- 8. Mean pressure alarm limits
- 9. Start/Stop NIBP measurement
- 10. Sequence information (for Sequence mode): the capital letter indicates the current phase and the time indicates the current measurement interval
- 11. Diastolic pressure alarm limits
- 12. Time to the next measurement (for Auto mode and Sequence mode)

The display of pressure values can be configured. For details, see 11.8.5 Setting the NIBP Display Format.

#### **NOTE**

- If the measurement fails, "XX" is displayed; if measurement is not taken, "--" is displayed.
- Outlined numerics indicate that the measurement is old and exceeds the set time. So these values are not recommended for reference.

## 11.6 Preparing for NIBP Measurement

## 11.6.1 Preparing the Patient for NIBP Measurement

In normal use, perform NIBP measurement on a patient who is in the following position:

- Comfortably seated
- Leas uncrossed
- Feet flat on the floor
- Back, arm and feet supported

For patients taking orthostatic BP measurement, refer to 11.10 Orthostatic BP Measurement.

#### **NOTE**

- It is recommended that the patient calms down and relaxes as much as
  possible before performing the measurement and that the patient do not
  talk during the measurement.
- It is recommended to have the patient sit quietly for several minutes before taking the measurement.
- For known hypertensive patients, you need to set initial cuff pressure to a higher value to reduce the measurement time.

- The operator should not touch the cuff or tubing during NIBP measurement.
- Other factors that have been shown to result in an overestimation of blood pressure are labored breathing, full bladder, pain etc.

## 11.6.2 Placing the NIBP Cuff

To place the NIBP cuff, follow this procedure:

- Verify that the patient category setting is correct. If not, enter the Patient Management menu to change patient category. For more information, see 4.2.2 Editing Patient Information.
- 2. Connect the air tubing to the NIBP connector on the monitor.
- Select an appropriate cuff for the patient, and then wrap it around the limb directly over the patient's skin as follows:
  - a If your monitor is using inflation algorithm, select cuffs with the *TrueBP*™ symbol. Using other cuff may lead to incorrect or failed measurements.
  - b Determine the patient's limb circumference.
  - c Select an appropriate cuff by referring to the limb circumference marked on the cuff. The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the length of the upper arm or the thigh. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb.
  - d Apply the cuff to the patient's upper arm or leg and make sure the Φ marking on the cuff matches the artery location. The cuff should fit snugly, but with enough room for two fingers to be placed between the cuff and the patient's arm (on adults), and loosely on neonates with little or no air present within the cuff. Otherwise it may cause discoloration and ischemia of the extremities. Make sure that the cuff index line falls within the range markings on the cuff.
  - e Middle of the cuff should be at the level of the right atrium of the heart. If it is not, you must use the measurement correction formula to correct the measurement. For more information, see 11.8.9 Correcting the NIBP Measurements.
- Connect the cuff to the air tubing. Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.

#### CAUTION

- A wrong cuff size and a folded or twisted bladder can cause inaccurate measurements.
- Do not touch or apply external pressure against the cuff and air tubing during NIBP measurement. This may cause inaccurate blood pressure values.

 Use care when placing the cuff on an extremity used for monitoring other patient parameters.

## 11.7 Performing Measurement

This section describes the procedure to start manual, auto, STAT, and sequence measurement. For BP Averaging, see 11.9 BP Averaging. For Orthostatic BP measurement, see 11.10 Orthostatic BP Measurement.

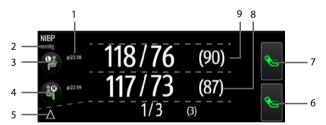
## 11.7.1 Performing Manual Measurement

To perform manual measurement, follow this procedure:

- Prepare the patient and place the cuff as instructed in 11.6 Preparing for NIBP Measurement.
- 2. Select ( to set the patient position and measurement site.
- Select \( \start\) to start the measurement.

In **Spot Check** mode, you can perform two times of measurement as a group for clinical evaluation. For setting of measurement times, see *11.8.8 Setting Measurement Times*.

Below is an example of NIBP screen if Measurements is set to Twice:



- 1. Time of last measurement
- 2. NIBP unit
- 3. Patient position and site of the first measurement
- 4. Patient position and site of the second measurement
- Differences between the two groups of measurements: displayed in the form of Sys/Dia (Mean)
- 6. Start/Stop the second measurement
- 7. Start/Stop the first measurement
- 8. Values of the second measurement: displayed in the form of Sys/Dia (Mean)
- 9. Values of the first measurement: displayed in the form of Sys/Dia (Mean)

## 11.7.2 Performing Auto Measurement

To perform auto measurement, follow this procedure:

- Prepare the patient and place the cuff as instructed in 11.6 Preparing for NIBP Measurement.
- 2. Select a workflow under **Continuous Monitoring**.
- 3. Select ( to set the patient position and measurement site.
- 4. Select the NIBP numeric area to enter the **NIBP** menu.
- 5. Set **Interval** to an appropriate duration.
- 6. Set Start Mode to Interval or Clock.
  - Clock: after the first measurement, the monitor automatically synchronizes NIBP automatic measurement with the real time clock. For example, if Interval is set to 20 min, and you start NIBP auto measurement at 14: 03, the next measurement will be taken at 14: 20, and then at 14:40, 15:00, and so on.
  - ◆ Interval: after the first measurement, the monitor automatically repeats measurement at set interval. For example, if Interval is set to 20 min, and you start NIBP auto measurement at 14:03, the next measurement will be taken at 14:23, and then at 14:43, 15:03, and so on.
- 7. Select Start NIBP.

## 11.7.3 Performing STAT Measurement

To perform STAT measurement, follow this procedure:

- Prepare the patient and place the cuff as instructed in 11.6 Preparing for NIBP Measurement.
- 2. Select a workflow under **Continuous Monitoring**.
- 3. Select ( to set the patient position and measurement site.
- 4. Select the NIBP numeric area to enter the **NIBP** menu.
- Select STAT.

## 11.7.4 Performing Sequence Measurement

To perform sequence measurement, follow this procedure:

- Prepare the patient and place the cuff as instructed in 11.6 Preparing for NIBP Measurement.
- 2. Select a workflow under **Continuous Monitoring**.
- 3. Select ( to set the patient position and measurement site.
- 4. Select the NIBP numeric area to enter the **NIBP** menu.
- Select Sequence tab to set the duration and interval of phases in the sequence. For details, see 11.8.4 Setting NIBP Sequence.
- 6. Select **Setup** tab, set **Interval** to **Sequence**.

- Set Start Mode to Interval.
- 8. Select Start NIBP.

## 11.8 Changing NIBP Settings

## 11.8.1 Setting the NIBP Alarm Properties

In **Continuous Monitoring** mode, you can set the NIBP alarm properties. Follow this procedure:

- 1. Select the NIBP numeric area to enter the **NIBP** menu.
- 2 Select the Alarm tab
- 3. Enter the password if required.
- 4. Set alarm properties as desired.

## 11.8.2 Setting the NIBP Interval

For auto NIBP measurement, you need to set the interval between two times of NIBP measurement. In **Continuous Monitoring** mode, you can set the NIBP interval. Follow this procedure:

- 1. Select the NIBP numeric area to enter the **NIBP** menu  $\rightarrow$  **Setup** tab.
- 2. Set Interval. Selecting Manual switches to manual mode.

## 11.8.3 Enabling the NIBP End Tone

The monitor can issue a reminder tone at the completion of NIBP measurement. The NIBP End Tone is off by default. You can switch on the NIBP tone in workflow setup menu. After setting, every time you switch to the workflow, **NIBP End Tone** is switched on.

You can also switch on the NIBP end tone in the **NIBP** menu, follow this procedure:

- In Continuous Monitoring mode, select the NIBP numeric area to enter the NIBP menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select NIBP.
- Switch on NIBP End Tone.

## 11.8.4 Setting NIBP Sequence

NIBP sequence measurement can have up to five phases: A, B, C, D, and E. You can individually set the duration and interval of each phase.

In **Continuous Monitoring** mode, you can set NIBP sequence. Follow this procedure:

- 1. Select the NIBP numeric area to enter the **NIBP** menu.
- 2. Select the **Sequence** tab.
- 3. Set **Duration** and **Interval** of each phase.

## 11.8.5 Setting the NIBP Display Format

To set the NIBP display format, follow this procedure:

- In Continuous Monitoring mode, select the NIBP numeric area to enter the NIBP menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select NIBP.
- 2. Select the **Setup** tab.
- 3. Set Display Format.

## 11.8.6 Setting the NIBP Alarm Limits Display Switch

In **Continuous Monitoring** mode, you can set whether to display the alarm limits of diastolic NIBP and mean NIBP. Follow this procedure:

- Select the NIBP numeric area to enter the NIBP menu.
- 2. Select the **Setup** tab.
- 3. Switch on or off **Display Alarm Limits.**

## 11.8.7 Selecting NIBP Measurement Algorithm

You can change the NIBP measurement algorithm adopted on your monitor. Follow this procedure:

- 2. Under the **NIBP** tab, set **NIBP Measurement Algorithm** to:
  - Inflation: the monitor measures blood pressure during cuff inflation. If succeeded, this measurement is completed. If the measurement fails at the inflation stage, the monitor will automatically continue the measurement at deflation stage.
  - ◆ **Deflation**: the monitor measures blood pressure during cuff deflation.

Affected by measurement factors or patient's physiological conditions, inflation algorithm might fail, be incorrect, or unavailable. Then the monitor automatically continues to perform the NIBP measurement at deflation stage. The measurement factors or patient's physiological conditions include:

- Excessive patient movement
- Using cuffs with no TrueBP<sup>™</sup> symbol
- Using cuffs of inappropriate size
- Cuffs being too tight or loose
- Using well-worn cuffs
- Patient blood pressure being too low
- Patient pulse rate being too low

- Patient having frequent arrhythmia
- Weak patient pulse

#### NOTE

 The monitor always performs NIBP measurement at deflation stage if Patient Category is Neo.

## 11.8.8 Setting Measurement Times

To set the measurement times, follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select Parameters Setup.
- Under NIBP tab, set Measurements to Twice.

## 11.8.9 Correcting the NIBP Measurements

The middle of the cuff should be at the level of right atrium. If the limb is not at the heart level, you need to correct the measurement:

- Add 0.75 mmHg (0.10 kPa) to the displayed value for each centimetre higher.
- Deduct 0.75 mmHg (0.10 kPa) to the displayed value for each centimeter lower.

## 11.9 BP Averaging

In BP averaging mode, a group of BP measurement is performed on a patient automatically. At the completion of measurement, a group of averaged BP readings is displayed.

## 11.9.1 Enabling BP Averaging

BP averaging is available only when the **Department** is set to **Physician Office** and the monitor is working in **Spot Check** mode.

To change the department, see 5.2 Changing the Department.

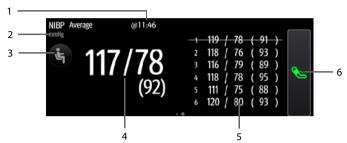
To enable BP averaging, follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select **Parameters Setup**  $\rightarrow$  the **NIBP** tab.

4. Under Average, enable BP Averaging.

## 11.9.2 BP Averaging Display

The following figure shows the BP averaging screen.



- Time of last measurement
- 2. NIBP unit
- 3. Select this area to set the patient position and measurement site
- 4. Averaged blood pressure: displayed in the form of Sys/Dia (Mean)
- 5. Measurements used for averaging: if the first group of measurements is displayed with a strikethrough, it is excluded in the averaging. For details, see 11.9.4.4 Excluding the First Group of Readings in the Calculation.
- 6. Start NIBP measurement

## 11.9.3 Performing BP Averaging

Follow this procedure:

- Prepare the patient and place the NIBP cuff as instructed in 11.6 Preparing for NIBP Measurement.
- 2. Swipe on the NIBP area to the left or right to switch to BP averaging screen.
- 3. Select (so set the patient position and measurement site.
- 4. Select \( \subseteq \text{ to start the first measurement.} \)
  - The monitor starts the first measurement immediately or after the set delay.
     For details, see 11.9.4.1 Setting the Delay before Starting the First Measurement.
  - After the first measurement, the monitor automatically takes several times
    of BP measurement (see 11.9.4.2 Setting the Number of Measurement) at the
    set interval (see 11.9.4.3 Setting Time between Readings).
- At the completion of automatic measurement, select Return to check the readings of each measurement and the averaged BP values.

## 11.9.4 Changing BP Averaging Settings

#### 11.9.4.1 Setting the Delay before Starting the First Measurement

Follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select **Parameters Setup**  $\rightarrow$  the **NIBP** tab.
- 4. Under Average, set Delay Before Starting Measurement.

#### 11.9.4.2 Setting the Number of Measurement

Follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select 

  J.
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select **Parameters Setup**  $\rightarrow$  the **NIBP** tab.
- 4. Under Average, set Number of Measurements.

#### 11.9.4.3 Setting Time between Readings

You can set the time duration between the starts of two consecutive measurement. Follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select 

  J.
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select **Parameters Setup**  $\rightarrow$  the **NIBP** tab.
- 4. Under Average, set Time Between Readings.

#### 11.9.4.4 Excluding the First Group of Readings in the Calculation

You can choose to exclude the first group of readings in the averaging calculation. Follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select 

  J.
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.

- 3. Select **Parameters Setup**  $\rightarrow$  the **NIBP** tab.
- 4. Under Average, enable Discard First Group of Readings.

#### 11.10 Orthostatic BP Measurement

Orthostatic blood pressure is important for the assessment of fall risks. On the monitor, you can measure the lying and standing blood pressure of a patient, and check the differences for clinical evaluation. Orthostatic BP measurement is only applicable for adult patient.

A license is required for the orthostatic BP measurement function. To check the license, see 3.9.9 Checking Software Licenses.

## 11.10.1 Enabling Orthostatic BP Measurement

Orthostatic BP measurement is available only when the monitor is working in **Spot Check** mode.

To enable Orthostatic BP measurement, follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select 

  .
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select **Parameters Setup**  $\rightarrow$  the **NIBP** tab.
- 4. Under Orthostatic BP Measurement, enable Orthostatic BP Measurement.

## 11.10.2 Orthostatic BP Measurement Display

The following figure shows the orthostatic BP measurement screen.



- 1. NIBP unit
- 2. Lying blood pressure: displayed in the form of Sys/Dia (Mean)
- Standing blood pressure: displayed in the form of Sys/Dia (Mean). The lowest values measured are used in contrasting.
- 4. Differences between the lying blood pressure and lowest standing blood pressure

- 5. Evaluation result based on the set criteria:
  - Negative: the differences are within the acceptable range as per the set criteria.
  - Positive: the differences are out of the acceptable range as per the set criteria

For details, see 11.10.4.5 Setting Orthostatic BP Evaluation Criterion.

- Start/Stop standing blood pressure measurement before measurement and clear data after measurement
- 7. Start/Stop lying blood pressure measurement
- 8. Add patient symptoms for result evaluation

## 11.10.3 Performing Orthostatic BP Measurement

Follow this procedure:

- 1. Place the NIBP cuff as instructed in 11.6.2 Placing the NIBP Cuff.
- Swipe on the NIBP area to the left or right to switch to the orthostatic BP measurement screen.
- 4. After the lying BP measurement is completed, ask the patient to stand up. Within 1 minute, select on the bottom. The monitor automatically takes several times of standing BP measurement, depending on your setting of Standing BP Measurement Interval and Maximum Standing BP Measurements. For details, see 11.10.4.2 Setting Standing BP Measurement Interval and 11.10.4.3 Setting the Times of Standing BP Measurement.
- Select symptoms if necessary. The list of symptoms are configurable. For details, see 11.10.4.4 Setting Orthostatic BP Symptoms.
- Upon completion of measurement, the evaluation result is displayed in the NIBP area. Select Negative or Positive to check for details.

## 11.10.4 Changing Orthostatic BP Measurement Settings

#### 11.10.4.1 Setting the Lying Duration of Patient

Follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.

- Select Parameters Setup → the NIBP tab.
- 4. Under Orthostatic BP Measurement, set Lying Duration.

#### 11.10.4.2 Setting Standing BP Measurement Interval

Follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select 

  J.
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select **Parameters Setup**  $\rightarrow$  the **NIBP** tab.
- 4. Under Orthostatic BP Measurement, set Standing BP Measurement Interval.

#### 11.10.4.3 Setting the Times of Standing BP Measurement

Follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select 

  J.
- Select on the right of the workflow to be set. Make sure the workflow is under Spot Check.
- 3. Select **Parameters Setup**  $\rightarrow$  the **NIBP** tab.
- Under Orthostatic BP Measurement, set Maximum Standing BP Measurements.

#### 11.10.4.4 Setting Orthostatic BP Symptoms

Follow this procedure:

- 2. Under **Orthostatic BP Symptoms**, select to edit a symptom. You can also select **Add Symptom** to create a new symptom and then select to edit it.

#### NOTE

You can set up to ten symptoms.

#### 11.10.4.5 Setting Orthostatic BP Evaluation Criterion

You can set criteria for evaluation of the pressure differences. A negative/positive result displays on the screen at the completion of the measurement.

Follow this procedure:

- In Spot Check mode, select the Main Menu quick key → from the System column select Maintenance → input the required password → select → Module.
- Under Evaluation Criterion, select to edit an existing criterion or Add Criterion to create a new one
- Set the Parameter, Type, Threshold, and select With Symptoms to set whether to include symptoms in the criterion.
- Select Save.

## 11.11 Assisting Venous Puncture

You can use the NIBP cuff to cause sub-diastolic pressure to block the venous blood vessel and therefore help venous puncture. To assist venous puncture, follow this procedure:

- In Continuous Monitoring mode, select the NIBP numeric area to enter the NIBP menu. In Spot Check mode, select the Main Menu quick key → from the Parameters column select Setup → select NIBP.
- 2. Set Venipuncture Pressure.
- 3. Select **Venipuncture** at the bottom of the menu.
- 4. Puncture vein and draw blood sample.
- Select the Venipuncture again to deflate the cuff. If you do not deflate the cuff, the cuff automatically deflates after a period of time (170 seconds for adult and pediatric patient, 85 seconds for neonatal patient).

During venous puncture, pay attention to the cuff pressure and the remaining time displayed in the NIBP numerics area.

#### NOTE

This function is not available on VS 9A and VS 8A monitors.

## 11.12 NIBP Maintenance

## 11.12.1 NIBP Leakage Test

The NIBP leakage test checks the integrity of the system and of the valve. The NIBP leakage test should be performed once every two years or when you doubt the NIBP measurements. The NIBP leakage test should be performed by Mindray-qualified service personnel only.

## 11.12.2 NIBP Accuracy Test

The NIBP accuracy test should be performed once every two years or when you doubt the NIBP measurements. The NIBP accuracy test should be performed by Mindray-qualified service personnel only.

## 11.13 NIBP Troubleshooting

For more information, see **D Alarm Messages**.

# 12 Monitoring CO<sub>2</sub>

#### 12.1 Overview

 ${\rm CO_2}$  monitoring is a continuous, non-invasive technique for determining the concentration of  ${\rm CO_2}$  in the patient's airway by measuring the absorption of infrared (IR) light of specific wavelengths.  ${\rm CO_2}$  has its own absorption characteristic and the amount of light passing the gas probe depends on the concentration of the measured  ${\rm CO_2}$ . When a specific band of IR light passes through respiratory gas samples, some of the IR light will be absorbed by the  ${\rm CO_2}$  molecules. The amount of IR light transmitted after it has been passed through the respiratory gas sample is measured with a photodetector. From the amount of IR light measured, the concentration of  ${\rm CO_2}$  is calculated.

The CO<sub>2</sub> measurement is to monitor the patient's respiratory status.

CO<sub>2</sub> monitoring is intended for adult, pediatric and neonatal patients.

CO<sub>2</sub> monitoring is for VS 9 series only.

CO<sub>2</sub> measurement is available when the monitor is in **Continuous Monitoring** mode.

## 12.2 Safety

#### WARNING

- Remove the airway sampling line from the patient's airway while nebulized medications are being delivered.
- Leakage in the breathing or sampling system may cause the displayed EtCO<sub>2</sub>
  values to be significantly low. Always make sure that all components are
  securely connected.
- EtCO<sub>2</sub> values measured from the CO<sub>2</sub> module may differ from those of from the blood gas analysis.
- Route all tubing away from the patient's throat to avoid strangulation.
- Inspect the airway for a tight connection and make proper settings before attaching it to the patient.
- Squeezing or bending the sampling line during the CO<sub>2</sub> measurement may cause inaccurate CO<sub>2</sub> reading or no reading.

## 12.3 Measurement Limitations

The following factors may influence the measurement accuracy:

- Leaks or internal venting of sampled gas
- Mechanical shock
- Cyclic pressure up to 10 kPa (100 cmH<sub>2</sub>O)
- Other sources of interference, if any

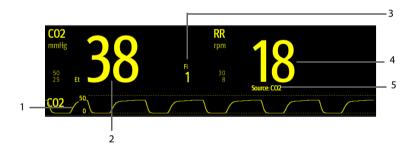
Measurement accuracy may be affected by the breath rate and inspiration/expiration ratio (I: E ratio) as follow:

- EtCO<sub>2</sub> value is within specification for breath rate  $\leq$  60 bpm and I/E ratio  $\leq$  1:1;
- EtCO<sub>2</sub> value is within specification for breath rate  $\leq$  30 bpm and I/E ratio  $\leq$  2:1.

Measurement accuracy is unspecified for breath rate larger than 60 bpm.

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

The  ${\rm CO_2}$  numeric and waveform areas provide  ${\rm FiCO_2}$  measurement,  ${\rm EtCO_2}$  measurement, RR measurement and a  ${\rm CO_2}$  waveform.



- 1. CO<sub>2</sub> waveform
- 2. End tidal CO<sub>2</sub> value (EtCO<sub>2</sub>)
- 3. Fraction of inspired CO<sub>2</sub> (FiCO<sub>2</sub>)
- 4. RR (Respiration Rate)
- 5. RR source: indicates the source of the current RR value

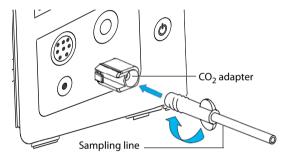
## 12.5 Measuring CO<sub>2</sub>

#### **CAUTION**

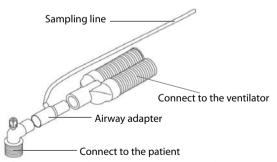
- Eliminate the exhausted gas before performing the measurement.
- Connect an exhaust tube to the gas outlet connector of the monitor to vent the calibration gases to a scavenging system.
- Check that the alarm limit settings are appropriate before taking measurement.

To measure CO<sub>2</sub>, follow this procedure:

- 1. Select an appropriate sampling line according to the patient category.
- 2. Connect the sampling line to the  $CO_2$  adapter that is installed on the monitor.



- 3. Connect the other end of the sampling line to the patient.
  - For intubated patients requiring an airway adapter, install the airway adapter between the patient circuit and the ventilator Y-piece.



 For non-intubated patients, place the nasal cannula onto the patient as shown in the figure below.



4. Connect the  ${\rm CO_2}$  gas outlet to the scavenging system with an exhaust tube.

CO<sub>2</sub> can be measured after the start-up is complete.

#### **NOTE**

- When sample gas of 37 °C, sample flowrate of 50 ml/min, room temperature of 23 °C, 100% RH, the sampling line with a general type should be replaced once at most every 8 hours, and the sampling line with a humidified type should be replaced once at most every 72 hours.
- If not necessary, do not disconnect the CO<sub>2</sub> adapter from the equipment after the first installation. This reduces the risk of the CO<sub>2</sub> adapter becoming lost or damaged.

## 12.6 Automatic CO<sub>2</sub> Module Zeroing

The CO<sub>2</sub> module performs zero calibration automatically when needed.

#### NOTE

The CO<sub>2</sub> module temporally stops measuring during zeroing.

## 12.7 Changing CO<sub>2</sub> Settings

## 12.7.1 Changing CO<sub>2</sub> Alarm Settings

In  ${\bf Continuous\ Monitoring\ }$  mode, you can change the  ${\bf CO_2\ }$  alarm settings. Follow this procedure:

- 1. Select the CO<sub>2</sub> numeric area or waveform area to enter the **CO2** menu.
- Select Alarm tab.
- 3. Set the following alarm properties:
  - Switch on or switch off the alarms.
  - Adjust the alarm limits and alarm priority.

## 12.7.2 Setting the CO<sub>2</sub> Waveform

In  ${\bf Continuous\ Monitoring\ mode}$ , you can set the  ${\bf CO_2\ waveform}$ . Follow this procedure:

- 1. Select the CO<sub>2</sub> numeric area or waveform area to enter the **CO2** menu.
- Select Setup tab.
- 3. Set **Waveform Type**, **Speed** and **CO2 Scale** of the CO<sub>2</sub> waveform.
  - ◆ Select **Waveform Type** and toggle between **Draw** and **Fill**.

**Draw**: The CO<sub>2</sub> wave is displayed as a curved line.

**Fill**: The  $CO_2$  wave is displayed as a filled area.

- Select Speed and then select the appropriate setting. The faster the wave sweeps, the wider the wave is.
- Select CO2 Scale and then change the size of the CO<sub>2</sub> waveform.

## 12.7.3 Entering the Standby Mode

In **Continuous Monitoring** mode, you can set the  ${\rm CO}_2$  module to one of the following modes according to the module status:

- Select **Measure** mode when you use the CO<sub>2</sub> module for monitoring.
- Select Standby mode when you does not use the CO<sub>2</sub> module to prolong the service life of the CO<sub>2</sub> module.

The default operating mode is Measure. If you are not using the  $CO_2$  module, you can proceed as follows to enter the Standby mode:

- 1. Select the CO<sub>2</sub> numeric area or waveform area to enter the **CO2** menu.
- 2. Select **Setup** tab.
- 3. Set Operating Mode to Standby.

## 12.7.4 Setting the Auto Standby

The monitor enters the standby mode automatically after the configured period of time if no breath is detected since the last detected breath.

To set the auto standby, follow this procedure:

- 1. Select the CO<sub>2</sub> parameter area or waveform area to enter the **CO2** menu.
- 2. Select **Setup** tab.
- Set Auto Standby.

## 12.7.5 Setting Humidity Compensation

The  $\mathrm{CO}_2$  modules is configured to compensate  $\mathrm{CO}_2$  readings for either Body Temperature and Pressure, Saturated Gas (BTPS), to account for humidity in the patient's breath, or Ambient Temperature and Pressure, Dry Gas (ATPD).

- $\blacksquare \quad \text{ATPD: } P_{co2}(mmHg) = CO_2(vol\%) \times P_{amb}/100$
- BTPS:  $P_{co2}(mmHg) = CO_2(vol\%) \times (P_{amb} 47)/100$

Where,  $P_{co~2}$  = partial pressure, vol~% = CO<sub>2</sub> concentration,  $P_{amb}$  = ambient pressure, and unit is mmHg.

To set the humidity compensation, follow this procedure:

- 1. Select the CO<sub>2</sub> numeric area or waveform area to enter the **CO2** menu.
- 2. Select **Setup** tab.
- 3. Set BTPS Compensation to On or Off.

## 12.7.6 Setting Gas Compensation

The presence of interfering gas affects the  $CO_2$  measurement. To get the best possible measuring result, it is needed to set the gas compensation. The configured concentration of the interfering gas should be in accordance with its actual proportion.

#### WARNING

 Make sure to use the appropriate compensations. Inappropriate compensations may cause inaccurate measurement values and result in misdiagnosis.

To set the gas compensation, follow this procedure:

- 1. Select the CO<sub>2</sub> numeric area or waveform area to enter the **CO2** menu.
- 2. Select **Setup** tab.
- Set the O<sub>2</sub>, N<sub>2</sub>O and AG compensation according to the actual amount of the respective gas in the ventilation gas mixture.

#### 12.7.7 Automatic Barometric Pressure

The CO<sub>2</sub> module has the function of automatic barometric pressure compensation.

## 12.7.8 Calibrating the CO<sub>2</sub> Module

A calibration should be performed once a year or when the readings go far beyond the range. To calibrate the  $CO_2$  module, contact your service personnel.

#### **CAUTION**

Connect the gas outlet to the scavenging system when calibrating the CO<sub>2</sub> module.

# **13** Monitoring Respiration

## 13.1 Resp Safety Information

#### WARNING

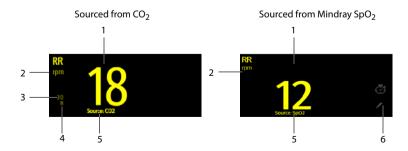
- The respiration measurement does not recognize the cause of apneas. It only
  indicates an alarm if no breath is detected when a pre-adjusted time has
  elapsed since the last detected breath. Therefore, it cannot be used for
  diagnostic purpose.
- If operating under conditions according to the EMC Standard IEC 60601-1-2 (Radiated Immunity 3V/m), field strengths above 3V/m may cause erroneous measurements at various frequencies. Therefore, it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.

#### **CAUTION**

- Only use parts and accessories specified in this manual.
- Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.

## 13.2 RR Display

The RR parameter area displays its source.



1. RR: Respiration rate per minute

- 2. RR unit
- 3. RR high limit
- 4. RR low limit
- 5. RR Source: it can be SpO<sub>2</sub>, CO<sub>2</sub> or Manual.
- Select to input RR manually: displays only in Spot Check mode, or when CO<sub>2</sub> is not configured.

## 13.3 Measurement Limitations of SpO2-Sourced RR

The following factors may influence the accuracy of RR measurement sourcing from  $SpO_2$ :

- Low perfusion
- Excessive motion on the measurement site
- Arhythmia
- RR signal too weak to be detected in the pleth waveform

## 13.4 Manually Inputting RR Value

To manually input an RR value, follow this procedure:

- 1. Select in the Resp area. A 60s timer is displayed and starts counting seconds.
- 2. Count the total number of Resp of the patient in the past minute.
- 3. Input the number and select .
- 4. Select the **Save** quick key to save the data.

## 13.5 Changing the RR Settings

## 13.5.1 Enabling SpO<sub>2</sub> Source for RR Measurement

In **Spot Check** mode, you can enable the SpO<sub>2</sub> source. Follow this procedure:

- Select Module → Other.
- 3. Switch SpO2 Calc RR on.

## 13.5.2 Enabling RR Alarms

In Continuous Monitoring mode, you can enable the RR alarm. Follow this procedure:

- 1. Select the CO<sub>2</sub> numeric area or waveform area to enter the **CO2** menu.
- Select Alarm tab.

Switch on RR.

## 13.5.3 Setting RR Alarms

In **Continuous Monitoring** mode, you can set the RR alarm limits. Follow this procedure:

- 1. Select the CO<sub>2</sub> numeric area or waveform area to enter the **CO2** menu.
- Select Alarm tab.
- 3. Set the high and low limits and the priority in the **RR** row.

## 13.5.4 Setting the Apnea Alarm Delay

The monitor will alarm if the patient has stopped breathing for longer than the preset Apnea time.

In **Continuous Monitoring** mode, you can set the Apnea delay time, follow this procedure:

- 1. Select the CO<sub>2</sub> numeric area or waveform area to enter the **CO2 Setup** menu.
- 2. Select **Apnea Delay** and then select the appropriate setting.

## 13.5.5 Setting Timer Interval

A timer is provided when manually inputting RR value. A reminder is given at a set interval to assist in counting of Resp number. To set the timer reminding interval for manual RR, follow this procedure:

- 2. Select on the right of the workflow to be set.
- Select Parameters Setup → RR tab.
- Set Timer Reminder Interval as needed.

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# **14** Manual Parameters

The monitor supports inputting physiological information of a patient manually for clinical evaluation and record. The information can be saved for future reviewing, printing, or sending to other devices.

## 14.1 Manual Input Parameters

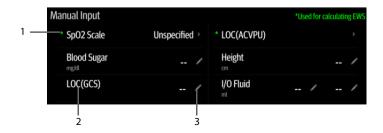
Below is a list of manual parameters provided by default:

- Blood Sugar
- Height
- Weight
- FiO<sub>2</sub>
- O<sub>2</sub> Flow Rate
- I/O Fluid
- LOC (GCS)
- LOC (AVPU)
- O2 Source
- LOC (ACVPU)
- Supp. O<sub>2</sub>

You can also add new types of parameters to the list. For details, refer to 14.4.2 Adding a New Parameter.

## 14.2 The Manual Input Display

The following figure shows the manual input area. Your display may be configured to look different.



- (1) \* symbol: indicates the parameter can be used for EWS calculation.
- (2) Parameter name
- (3) Parameter setup area: select to input a value, show the options, or a setup menu.

If you need to change the parameters to be displayed or their sequence in the list, refer to 14.4.1 Changing the Display of Manual Parameters.

## 14.3 Inputting/Editing Parameter Information

Follow this procedure:

- 1. Select a parameter in the list, and input the information as instructed below:
  - : input a value with the popup on-screen keyboard, or set the parameter in the displayed menu.
  - : select an option from the popup list.
  - ◆ The range or options of the parameters are shown below:

Parameter	Range
Blood Sugar	1.0 mg/dl -720.0 mg/dl (0.06 mmol/L -40.00 mmol/L)
Height	20.0 cm - 300.0 cm
Weight	0.1 kg -499.0 kg
FiO <sub>2</sub>	21% ~100%
O <sub>2</sub> Flow Rate	0.1 L/min -20.0 L/min
I/O Fluid	1-10000 ml 0.001 - 10.000 L
LOC (GCS)	3-15
LOC (AVPU)	Alert, Reacting to voice, Reacting to pain, Unresponsive
O <sub>2</sub> Source	Room Air, Aerosol Mask, Bi PAP, C PAP, Face Mask, Mask, Bnasal Cannula, Nonrebreather, Partial Rebreather, T-piece, Trach Collar, Ventilator, Venturi Mask, Oxymizer
LOC (ACVPU)	Alert, Confusion, Reacting to voice, Reacting to pain, Unresponsive
Supp. O <sub>2</sub>	Yes, No

2. Select the **Save** quick key to save the data.

#### NOTE

 The input information can be reviewed, printed or sent to other devices only after being saved. If not saved, the information may be lost after a patient is discharged or workflow is switched.

## 14.4 Changing Manual Input Settings

#### 14.4.1 Changing the Display of Manual Parameters

To change the parameters to be displayed or their sequence in the list, follow this procedure:

- Select the Main Menu quick key → from the Configuration column select Workflow → input the required password → select ◄.
- 2. Select the on the right of the workflow to be set. Select an area and from the popup list, select **Manual Param**.
- Select Parameters Setup → Manual Input tab. Then select an item and from the popup list, select the parameter to be displayed.
- 4. Return to the main screen and switch workflows for the setting to take effect.

#### 14.4.2 Adding a New Parameter

If you need to add other manual parameters to the **Manual Input** list, follow this procedure:

- 2. Select **Module** → **Manual Input** tab, and then select **Add**.
- Select Name and input the name of the new parameter with the on-screen keyboard.
- 4. Set **Type** to **Numeric** or **Text**.

#### NOTE

- The type of a parameter cannot be changed after saving.
- For Numeric type, continue to set the Unit and Resolution of the parameter. For
  Text type, you need to set the options to be selected. At least 2 options need to be
  set. If needed, you can select Add to set more options.
- 6. Select Save.

After saving the setting, you can follow the procedure in 14.4.1 Changing the Display of Manual Parameters to add the new parameter to the Manual Input list displayed on the screen.

# **15**Clinical Assistive Applications (CAA)

The Clinical Assistive Applications (CAA) function integrates some commonly used clinical guidelines and tools into the monitor. It puts the currently monitoring parameter measurements together and provides comprehensive analysis results.

CAA is not intended to replace the competent judgment of a clinician. It must be used in conjunction with observation of clinical signs and symptoms.

## 15.1 Early Warning Score (EWS)

The Early Warning Scores (EWS) can help you recognize the early sign of deterioration in patients based on vital signs and clinical observations. Depending on the score calculated, appropriate recommendations are displayed.

The monitor supports the following scores:

- MEWS (Modified Early Warning Score)
- NEWS (National Early Warning Score)
- NEWS2 (National Early Warning Score 2)
- Custom Score

There are two types of scoring tools:

- Total score: A subscore is given for each parameter based on the measured or entered value. When all the required parameters are entered or measured, the subscores are added together to calculate the total early warning score. Each subscore has a color coding to indicate associated level of risk, When the total score is outside of the thresholds, actions are recommended. MEWS, NEWS and NEWS2 can give total scores.
- IPS (individual parameter score): A color-coded score is given for each parameter based on the measured or entered value. Each parameter has upper and lower thresholds. When an individual parameter measured or entered is outside of the thresholds, actions are recommended.

Custom Score is based on user-defined parameters. It can be a total score or an IPS, depending on the configuation.

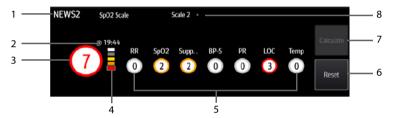
MEWS, NEWS and NEWS2 are intended for adult patients only. The patient category applied to the Custom Score is defined by Mindray Clinical Score Configuration Tool. For more information, see *Mindray Clinical Scoring Config Tool Instruction for Use (P/N: 046-007126-00)*.

#### WARNING

- EWS should not be used as the sole basis for diagnosis or therapy decisions. It
  is not intended to replace the competent judgment of a clinician. The EWS
  scores and recommended actions must be used in conjunction with
  observation of clinical signs and symptoms.
- MEWS and NEWS are not applicable to pregnant woman, COPD (Chronic Obstructive Pulmonary Disease) patients and patients under 16 years old.
   NEWS2 is not applicable to pregnant woman and patients under 16 years old.

## 15.1.1 The EWS Display

The following figure shows the EWS screen.



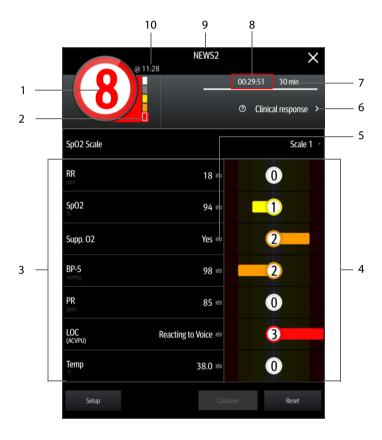
- 1. EWS protocol label
- 2. The current scoring time
- Total score. The color of the circle indicates the level of risk. For IPS, no score is displayed. Only level of risk is shown: white means normal and red indicates alert.
- Risk level indicator. The level of risk increases from top down. The current level is enclosed by a white square frame. For IPS, this indicator does not display.
- 5. Subscore area: displays the subscore of each parameter.
- Reset (available in Continuous Monitoring mode): select this button to clear the previous score.
- Calculate (available in Continuous Monitoring mode): select this button to calculate the total score. It is available when all parameter values used for scoring are obtained automatically.
- SpO<sub>2</sub> scale (for NEWS2 only): displays the current SpO<sub>2</sub> scale used for scoring. Select this area to change to another scale.

#### 15.1.2 Accessing the EWS Screen

Access the **EWS** window in any of the following ways:

- Select the **EWS** parameter area
- $\blacksquare$  Select the **Main Menu** quick key  $\rightarrow$  from the **CAA** column select **EWS**.

Take NEWS2 as an example, the EWS screen is shown as follows. Your screen may be slightly different due to the configuration.



- Total score. The color of the circle indicates the level of risk. For IPS, no numeric score is displayed. Only level of risk is shown: white means normal and red indicates alert by default.
- Risk level indicator. The level of risk increases from top down. The current level is enclosed by a white frame. For IPS, this indicator does not display.
- 3. Parameter area: display the value of each parameter.

- 4. Subscore area: display the subscore of each parameter.
- 5. Keyboard symbol: indicates that the value is manually entered.
- 6. Selecting this button to see the clinical response to the current score.
- 7. Scoring interval (available in **Continuous Monitoring** mode)
- 8. Scoring countdown (available in **Continuous Monitoring** mode): time to the next scoring.
- 9. EWS protocol label
- 10. The scoring time (available in **Continuous Monitoring** mode)

### 15.1.3 EWS Scoring in Spot Check Mode

In Spot Check mode, EWS scoring is performed automatically.

After a parameter value is obtained, the monitor calculates the subscore of the parameter. If all parameters required for EWS scoring are obtained, the monitor calculates the total score automatically.

If any of the parameter value changes, the subscore and total score are recalculated accordingly.

#### NOTE

Observe the parameter and score changes and save the data timely.

## 15.1.4 EWS Scoring in Continuous Monitoring Mode

#### 15.1.4.1 Performing EWS Scoring

To perform scoring, follow this procedure:

- Select Reset to clear the previous score and update values of currently monitored parameters and relevant subscores.
- 2. For NEWS2, set the **SpO2 Scale**.
  - ◆ **Scale 1**: for patient without hypercapnic respiratory failure.
  - Scale 2: for patients with a prescribed oxygen saturation requirement of 88– 92% (for example, in patients with hypercapnic respiratory failure).
- 3. Measure or manually enter other required parameters and observations.
- 4. Select **Calculate** to get the total score.
- If Score Confirmation is enabled, select Confirm to save current scoring, or select Cancel to give up current scoring. Refer to section 15.1.6.2 Setting the Score Confirmation Switch for more information.

#### **NOTE**

- The decision to use Scale 2 of the SpO2 Scale should be made by a competent clinical decision maker and should be recorded in the patient's clinical notes.
- Before calculating the score, select Reset to clear the previous score.
- You can get the score only when all required parameters have been measured or entered.

#### 15.1.4.2 Enabling Auto Scoring

In **Continuous Monitoring** mode, the monitor automatically starts scoring at the preset interval. To enable auto scoring, follow this procedure:

- 1. From the EWS page select **Setup**.
- 2. Set Auto Scoring:
  - Interval: the monitor automatically starts scoring at the preset interval.
  - NIBP: the monitor automatically starts scoring at the completion of each NIBP measurement.
  - Alarm: the monitor automatically starts scoring when an alarm occurs to the parameter for scoring.
  - If no option is selected, the monitor does not initiate auto scoring.

#### 15.1.4.3 Setting Auto Scoring Interval

In **Continuous Monitoring** mode, you can set the auto scoring interval. Follow this procedure:

- 1. From the EWS page select **Setup**.
- Set Interval:
  - By Score: the monitor automatically starts scoring as per the interval selected for corresponding total score.
  - 5 min 24 hrs: If Auto Scoring is set to Interval, the monitor automatically starts scoring as per the selected interval. If Auto Scoring is not set to Interval, the countdown timer of manual scoring is selected.
  - Off: the monitor does not automatically start scoring.

#### 15.1.5 EWS Alarm

When working under **Continuous Monitoring** mode, if alarms are enabled, the monitor can automatically give alarms and refreshes the score.

#### 15.1.5.1 Setting the EWS Alarm

In **Continuous Monitoring** mode, if **Alarm** is enabled, the monitor can automatically give alarms in the following cases:

- The total score exceeds the configured threshold
- The score of auto obtained parameter is 3.

To configure the EWS alarm, follow this procedure:

- 1. From the EWS page select **Setup**.
- 2. Select the Alarm tab.
- 3. Turn on the Alarm switch.
- Set the alarm switches for the single parameters listed in the 3 in single parameter area.
- 5. Set the alarm switch and threshold of the total score in the **EWS Score** area.

#### 15.1.5.2 Auto Refreshing Scores

If **Auto Refresh Scores** is enabled, the monitor can automatically refresh the total score in the following cases:

- The total score reaches the configured threshold, or falls from the configured threshold to a lower score.
- The score of auto obtained parameter reaches 3, or falls from 3 to a lower score.

To enable the auto refreshing score function, follow this procedure:

- 1. From the EWS page select **Setup**.
- 2. Select the Alarm tab.
- Turn on the Auto Refresh Scores switch.

## 15.1.6 Changing EWS Settings

#### 15.1.6.1 Changing the Scoring Protocol

The monitor is configured with a default scoring protocol. To change the scoring protocol, follow this procedure:

- 1. From the EWS page select **Setup**.
- Set Score.

#### 15.1.6.2 Setting the Score Confirmation Switch

In **Continuous Monitoring** mode, you can select if confirmation is required before saving score. Follow this procedure:

- 1. From the EWS screen select **Setup**.
- Set Score Confirmation switch.
  - Off: the monitor automatically saves the scoring result after the scoring is completed.

 On: you need to confirm that whether the scoring result is saved or not after the scoring is completed.

#### 15.1.6.3 Setting the Manual Data Timeout

The manually input parameter data become invalid after a preset time. To set the timeout period for the input data, follow this procedure:

- 1. From the EWS screen select **Setup**.
- From the Manual Data Timeout area, select a desired parameter and set its timeout period.

#### **NOTE**

 If the data is expired and not updated, the monitor displays the corresponding parameter score in outline font, and gives a timeout alarm.

#### 15.1.6.4 Selecting the Default Scoring Tool

To set the default scoring tool for different patient catalog, follow this procedure:

- Select the CAA tab → select EWS tab.
- From the Select Default Score area, set Default Adult Score, Default Ped Score, and Default Neo Score.

## 15.1.7 Viewing History Scores

To view the history scores, follow this procedure:

- 1. Select the **Review** quick key  $\rightarrow$  select **Scoring Review** tab.
- Select PID and from the popup list select the ID of which the scores are to be viewed.
- 3. Select Filter and choose a protocol if needed.
- 4. Select a record and then select **Detail**.

#### 15.1.7.1 Managing the Scoring Tools

To manage the scoring tool, follow this procedure:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select .
- 2. Select the **CAA** tab  $\rightarrow$  select **EWS** tab.
- 3. Select Manage Score.
  - Delete local scoring tools: from the Local page, delete the unnecessary scoring tools.

 Import the desired scoring tools to the monitor: connect a USB drive to the monitor's USB port. From the **USB Drive** page, select the scoring tools on the USB drive, and then select **Import**.

### **NOTE**

- The monitor provide MEWS, NEWS, and NEWS2 by default. You cannot delete them.
- For details about how to import scoring tools, refer to Mindray Clinical Scoring Config Tool Instruction for Use (P/N: 046-007126-00).

## 15.2 Glasgow Coma Scale (GCS)

The Glasgow Coma Scale (GCS) function is based on 1974\_Lancet\_Teasdale Assessment of Coma and Impaired Consciousness-A Practical Scale. Three aspects of behavior are independently measured: eye opening, verbal response, and motor response. The scores are added together to indicate that patient's level of consciousness.

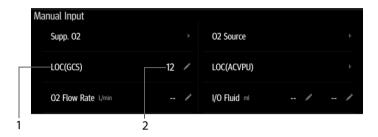
GCS is intended for adults and pediatric patients.

#### CAUTION

- GCS is intended as an adjunct in patient assessment and must be used in conjunction with observation of clinical signs and symptoms.
- GCS is not applied to patients that are sedated, muscularly relaxed, with artificial airway, drunk, or in status epilepsies.
- GCS is not applied to deaf people and patients having language barrier or with mental disorder.
- When applied to children younger than five years old or elder people who are slow, the GCS score might be low.

## 15.2.1 GCS Display

The GCS value displays in the Manual Input list, as shown below:

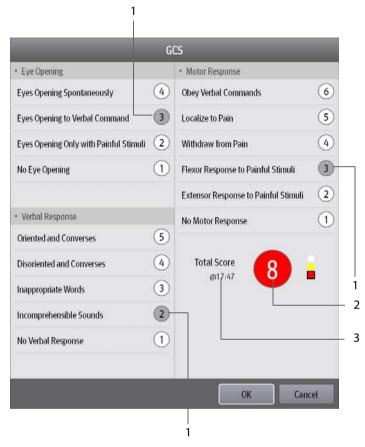


- 1 GCS label
- 2 GCS value: total score. Select this area to enter the GCS menu.

Your display may look slightly different. If GCS is not displayed, you can follow the procedure in 14.4.1 Changing the Display of Manual Parameters to add GCS to the list.

## 15.2.2 Accessing the GCS Menu

Select the GCS value to enter the GCS menu.



- 1 Subscores
- 2 Total score and level of consciousness. The color of the circle indicates the level of risk.
- 3 Scoring time

## 15.2.3 Performing GCS Scoring

To perform scoring, follow this procedure:

- From the Eye Opening area, Verbal Response area, and Motor Response area, respectively select an item that represents the patient's status.
- 2. Select **OK** to accept the total score.
- 3. Select the **Save** guick key to save GCS scoring.

The following table lists the default score range and color of relevant consciousness level.

Level	Range	Color	Description
Mild	13 to15	White	The brain function is normal or mildly damaged.
Moderate	9 to 12	Yellow	The brain function is suffered from moderate to severe damage.
Severe	3 to 8	Red	Can be brain death or remain vegetative.

## 15.2.4 Setting Threshold for Each Consciousness Level

You can configure the threshold of each consciousness level. To do so, follow this procedure:

- Select the CAA tab → select the GCS tab.
- 3. Set high limit and low limit for each level.

## 15.2.5 Reviewing GCS Data

If the GCS data is correctly saved, you can review the GSC data following this procedure:

- 1. Select the **Review** quick key  $\rightarrow$  select **Scoring Review** tab.
- 2. Select a record from the list, and then select **Detail**.
- 3. Check the LOC(GCS) value.

## 15.3 Pain Score

The monitor provides pain score functions to help assess a patient's pain. The following scales are provided by default:

- VAS-cm: a visual analog scale of 0 to 10 cm.
- VAS-mm: a visual analog scale of 0 to 100 mm.
- NRS: a numeric rating scale, using numbers to rate the pain.
- VRS-5: a verbal rating scale of 0 to 5.

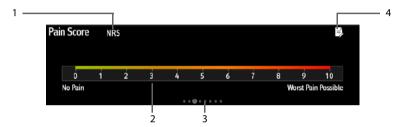
- FPS-R: face pain scale revised.
- FLACC: stands for face, legs, activity, crying, and consolability.

You can also add custom pain scores to the list. For details, refer to 15.3.3 Adding a Custom Pain Scale.

Pain Score is applicable for adult, pediatric, and neonatal patients.

#### 15.3.1 The Pain Score Display

The following figure shows the pain score screen. Your display may be configured to look different.



- (1) The name of currently used pain scale
- Scoring area: selecting this area to select a value or an option from the popup list for total scoring.
- (3) Indicating the number of pain scales currently selectable
- (4) Adding pain description

## 15.3.2 Performing Pain Score

Follow this procedure:

- 1. Swipe on the **Pain Score** screen to the left or right to select a pain scale.
- 2. Set the pain description if needed.
- 3. Tap the scoring area to select a value or an option for scoring.
- 4. Select the **Save** guick key to save the data.

## 15.3.3 Adding a Custom Pain Scale

You can set up to 2 custom pain scales on the monitor. Follow this procedure:

- Select the Main Menu quick key → from the System column select Maintenance
   → input the required password → select
- 2. Select **Module** → **Pain Score** tab.

- Under Custom Pain Score Method, select corresponding area to edit the name of your scale, and change the upper limit of scoring value.
- Enable Display on the right of the pain score for it to be displayed on the Pain Score screen.

#### 15.3.4 Adding a Pain Description

You can add up to 15 descriptions on the monitor. Follow this procedure:

- 2. Select Module → Pain Score tab, and then select Add Description.
- 3. Select **Name** and input the name of the description with the on-screen keyboard.
- 4. Set **Type** to **Numeric** or **Text**.

#### NOTE

- The type of a description cannot be changed after saving.
- For Numeric type, continue to set the Unit and Resolution of the parameter. For Text type, you need to set the options to be selected. At least 2 options need to be set. If needed, you can select Add to set more options.
- Select Save.

## 15.4 Targeted Goal

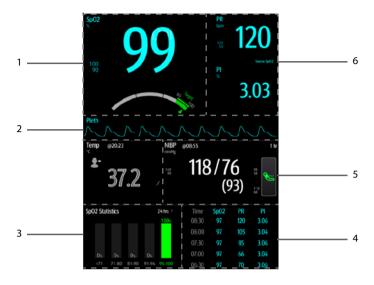
For patients under continuous monitoring, if you are concerned with specific parameters and their trends, you can use the **Targeted Goal** screen. The **Targeted Goal** screen focuses on the target parameter and displays parameter measurements in big numerics. You can easily identify whether parameter target is reached via a dashboard and review the statistics of the target parameter by sections.

The **Targeted Goal** screen displays parameter measurements and waveforms of SpO<sub>2</sub>, PI, PR, NIBP, and Temp. The measurements of these parameters displays in big numerics.

## 15.4.1 Entering the Targeted Goal Screen

To enter the **Targeted Goal** screen, in **Continuous Monitoring** mode, select **Targeted Goal** quick key.

### 15.4.2 The Display of the Targeted Goal Screen



- Target parameter area: displays the SpO<sub>2</sub> measurement in big numerics, as well as its target range, and alarm limits.
  - ◆ The dashboard shows the target range in green.
  - $\ \, \bullet \ \,$  The  $\triangle$  pointer below the dashboard indicates the current measurement value.
- 2. Target parameter waveform area: displays the SpO<sub>2</sub> waveform.
- 3. Target parameter statistics area: displays the  $SpO_2$  statistics by sections.
- Parameter trends area: displays trends of the target parameter and secondary parameters.
- 5. Other parameter area: displays parameter measurements and alarm limits of parameters other than the target parameter and secondary parameters.
- Secondary parameters area: displays parameter measurement of PR and PI in big numerics, as well as parameter sources and alarm limits.

## 15.4.3 Operating the Targeted Goal Screen

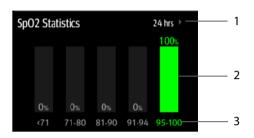
You can access parameter setup and trends review from the **Targeted Goal** screen.

- Select the parameter trends area to enter the Tabular Trends review page.
- Select the target parameter statistics area to enter the parameter statistics setup menu. Set the range of each section and the target section.

 Select the desired waveform area, parameter numeric area, or dashboard to enter corresponding parameter setup menu.

#### 15.4.3.1 SpO<sub>2</sub> Statistics Display

The following figure shows the SpO<sub>2</sub> statistics area:



- 1 Duration of SpO<sub>2</sub> statistics
- 2 Results of SpO<sub>2</sub> statistics
- 3 Sections for statistics: The section in green indicates the target range.

#### 15.4.3.2 Selecting the Range of each SpO<sub>2</sub> Section and the Target Section

To define the SpO<sub>2</sub> range of each section, follow this procedure:

- 1. Select the SpO<sub>2</sub> statistics area.
- 2. Select a value on the left of the scale.
- 3. Use the keyboard on the right to change the value.
- Drag the section label on the right of the scale up or down to select a target section. The target section is highlighted in green in the SpO<sub>2</sub> statistics area.

#### 15.4.3.3 Selecting the SpO<sub>2</sub> Statistics Length

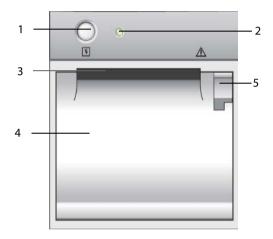
The Duration of  $SpO_2$  statistics is configurable. From the  $SpO_2$  statistics area, select the duration to redefine the length of  $SpO_2$  statistics.

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# 16 Recording

## 16.1 Recorder

The thermal recorder records patient information, measurement data, and up to two waveforms. The monitor can be configured with a built-in recorder.



- 1. Start/Stop key: press to start a recording or stop the current recording.
- 2. Module status indicator
  - On: when the recorder works correctly.
  - Off: when the monitor is switched off.
  - ◆ Flashes: if an error occurred to the recorder.
- 3. Paper outlet
- Recorder door
- 5. Latch: pull it backward to open the recorder door.

## 16.2 Starting Recordings

Recordings can be started manually.

In **Continuous Monitoring** mode, to start a recording, you can either:

■ Press the | | hardkey on the front of the recorder.

■ Select **§** on the current page.

In **Spot Check** mode, to start a recording:

- 1. Select the **Save** quick key.
- 2. Select S on the current page.

## 16.3 Stopping Recordings

Recordings can be stopped manually or automatically.

## 16.3.1 Stopping Recordings Manually

To manually stop a recording, choose either of the following method:

- Press the S hardkey again.
- Select the Main Menu quick key → from the Device column select Record Setup, and then select Clear All Record Tasks.

### 16.3.2 Stopping Recordings Automatically

Recordings stop automatically in the following conditions:

- The recording is completed.
- The recorder runs out of paper.
- The recorder has an alarm condition.

## 16.4 Recording Related Flags

You can find the following flags on the recording reports:

- For automatically stopped recordings, there are two columns of asterisks "\*" at the end of the report.
- For manually or abnormally stopped recordings, there is one column of asterisks "\*" at the end of the report.

## 16.5 Setting the Recorder

To set the recorder, follow this procedure:

- 1. Select the **Main Menu** quick key → from the **Device** column select **Record Setup**.
- 2. In the **Record Setup** menu, select the desired waveform for **Waveform 1** and **Waveform 2** in turn. The recorder can record up to 2 waveforms at a time.
- 3. Select **Recording Duration** to set the duration of real-time recording.
- 4. Select **Recorder Paper Speed** to set the speed for recording waveforms.

## 16.6 Loading Paper

To load paper, follow this procedure:

- 1. Use the latch at the upper right of the recorder door to pull the door open.
- 2. Insert a new roll into the compartment as shown below. Feed the paper through and pull some paper out from the top of the roller.
- 3. Close the recorder door.



### **CAUTION**

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

## 16.7 Removing Paper Jam

If the recorder works incorrectly or produces unusual sounds, check if there is a paper jam first. If a paper jam is detected, follow this procedure to remove it:

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

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# 17<sub>Review</sub>

## 17.1 Review Overview

Trends are patient data collected over time and displayed in graphic, tabular, or other forms to give you a picture of how your patient's condition is developing. You can also review the events, scores, and so on.

# 17.2 Review Page

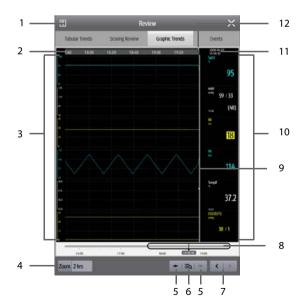
The **Review** page contains tabs to display trend data in tabular, graphic, or other forms.

## 17.2.1 Accessing the Review Page

To enter the review page, select the **Review** quick key.

## 17.2.2 Example Review Page

The review pages have similar structure. We take the graphic trends review page as an example.



- 1. Record button: select it to output patient information and data through the recorder.
- 2. Current window time line: indicates the time length of the current window.
- 3. Waveform area: displays trend curves. The color of trend curves is consistent with the color of parameter labels.
- 4. Zoom: select the time duration of data to be viewed on one screen.
- 5. or : goes to the previous or next event.
- isQ: displays events in a chronological order. The most recent event is displayed at the top. The number of asterisk symbols before an event matches alarm priority.
- 7. < or > : moves the cursor backward or forward
- 8. Dragging the slider left or right enables you to locate the trend data at a specific time and also refreshes data in current window accordingly.
- 9. Cursor
- Numeric area: displays numeric values at the cursor indicated time. The background color of numeric values matches the alarm priority.
- Event area: displays the event of the cursor time. Selecting the event access the event list. If there is no event at the cursor time, the cursor time is displayed.
- 12. Event type indicator: different color blocks match different types of events:
  - Red: high priority alarm event
  - Yellow: medium priority alarm event
  - ◆ Cyan: low priority alarm event
  - ♦ White: operation-related event

## 17.2.3 Reviewing the Tabular Trends

The Tabular Trends review page displays trend data in a tabular form. You can select a patient and trends of a certain period or type to be viewed. Follow this procedure:

- 1. Select the **Review** quick key  $\rightarrow$  select **Tabular Trends** tab.
- Set the filtering condition to PID, Name, or Visit No. Then select the information of the patient to be viewed.
- 3. Set **Filter** to a period of time (30 seconds to 3 hours selectable), a parameter (Temp, Scoring etc.) or type of data (**Manually Saved** for example).
- 4. Select a record to be viewed and select **Detail** to check more information.

## 17.2.4 Reviewing Scores

The Scoring Review page displays scores in a tabular form. You can select a patient and a certain scoring protocol to be viewed. Follow this procedure:

- 1. Select the **Review** quick key  $\rightarrow$  select **Scoring Review** tab.
- Set the filtering condition to PID, Name, or Visit No.. Then select the information of the patient to be viewed.
- Set Filter to MEWS, NEWS or NEWS2.
- 4. Select a record to be viewed and select **Detail** to check more information.

#### 17.2.5 Reviewing the Graphics Trends

The Graphic Trends review page displays trend data in a graphic form. To review the **Graphic Trends**, follow this procedure:

- 1. Select the **Review** guick key  $\rightarrow$  select **Graphic Trends** tab.
- 2. Select **Zoom** to set the period of data to be displayed on one screen.
- 3. Move the slider to the left or right to browse more trend data.

## 17.2.6 Reviewing Events

The monitor stores events in real time, including technical alarm events, physiological alarm events, and operational events. When an event occurs, all the measurement numerics and three event-related waveforms 16 seconds before and after the event is stored.

#### **NOTE**

- A total loss of power has no impact on the events stored.
- Alarms are saved as events and will be maintained if the equipment is powered down. The time of equipment power down is not recorded as an event and cannot be reviewed.
- Earlier events will be overwritten by later ones if the capacity is reached.

#### 17.2.6.1 Viewing the Events Page

To enter the events review page, select **Review** guick key  $\rightarrow$  select **Events** tab.

The **Events** page displays event list. Events are displayed in descending chronological order. The most recent event is displayed at the top. The number of asterisk symbols before an event indicate alarm priorities. Different color blocks are displayed on the left of each event to indicate different event types.

- Red: high priority alarm event
- Yellow: medium priority alarm event
- Cyan: low priority alarm event
- White: operation-related event

You can view operation events not related to parameters, such as system time change.

The number of asterisk symbols before and event matches alarm priorities as follows:

- \*\*\*: high priority alarm
- \*\*: medium priority alarm
- \*: low priority alarm

#### NOTE

 Pausing or switching off alarms will not be recorded as events. The time of these operations will not be recorded in the system log.

#### 17.2.6.2 Viewing Event Details

To view waveforms and parameter values at the event time, follow this procedure:

- 1. Select **Review** quick key → select **Events** tab.
- 2. Select an event to be viewed, and then select **Detail**.

On the **Detail** page, you can also view the details of other events by either:

- selecting **=Q** and then the desired event.
- selecting or to view the previous or next event.

# **18**User Maintenance Settings

User maintenance enables you to customize your equipment to best meet your needs. Accessing the **Maintenance** menu is password protected.

This chapter describes the settings and functions in the **Maintenance** menu.

#### **CAUTION**

The maintenance settings can only be changed by authorized personnel.
 Contact your department manager or biomedical engineering department for the passwords used at your facility.

## 18.1 Accessing the Maintenance Menu

To perform user maintenance, follow this procedure:

- Select desired tab.

## 18.2 The Device Location Settings

Menu Item	Default Setting	Function
Monitor Name	/	/
Facility		
Department		
Room No		
Bed No		
Location	Fixed	Fixed: the Patient Management menu displays Bed No and Room No, but you cannot change them.
		Unfixed: you can change Bed No and Room No from the Patient Management menu.

Menu Item	Default Setting	Function	
Auto Obtain Bed No.	Off	The setting is available if <b>Location</b> is set to <b>Unfixed</b> .	

#### **NOTE**

 If Location is set to Unfixed, Bed No and Room No are cleared each time you discharge a patient.

# 18.3 The Patient Management Settings

#### 18.3.1 The Patient Field Tab

Menu Item	Default Setting	Function	
Required	1	Selects which items can be displayed	
Optional	Patient ID, Age (GA: Neo)	Management menu.	
Primary Screen Display Full Name	On	Selects whether patient name is displayed in the patient information area on the primary display.	
Default Admit Patient Method	ADT Database	Selects the default list from which to admit a patient. The tab will be displayed after selecting the <b>Patient</b> quick key, if available.	
Patient Verification	Off	If enabled, only patients from local or ADT database can be admitted.	

#### **NOTE**

 If the monitor is connected with the CMS, the patient information items and customized fields are loaded from the CMS.

## 18.3.2 The ADT Query Tab

Menu Item	Default Setting	Function	
ADT Query	Patient ID, Patient Name	Selects which criteria can be used to search patients in the ADT server	

## 18.3.3 The Discharge Tab

Menu Item Default Setting		Function		
Auto Discharge Patient If Powered Off In Continous Monitoring Mode	Never	Automatically discharges the patient when the monitor is turned off for the designated period of time.  Never: not discharge a patient no matter for how long the monitor has been switched off.		
Auto Delete Patient Auto Data if Discharged		Automatically deletes patient data when the patient is discharged.		
Clear All Patient / Data		Deletes all patient information and data. Clearing patient data will discharge the current patient.		

## 18.3.4 The Location Tab

Menu Item	Default Setting	Function	
Location 1 - Location 10	/	Selects where the patient goes after patient monitoring stops.	

# 18.4 The Authorization Setup Tab

# 18.4.1 The Clinician Login Tab

Menu Item	Default Setting	Function	
Clinician Login	No Verification	Defines whether verification or authentication is required for clinician login.	
Automatic Logout Time	10 min	Sets the time for the monitor to log out the clinician information	
Imprivata Domain	/	Sets the Imprivata domain.	

# 18.4.2 The Authorization Setup Tab

Section	Menu Item	Default Setting	Function
Maintenance	Maintenance Password monitor's Map Password Maintenance Password National Pass		Selects the password for accessing the monitor's Maintenance menu.  Local Password: the monitor's password for accessing the Maintenance menu is required.  Clinician Authentication: the user name and password saved in the MLDAP server are required.
	Modify Local Password	/	Changes the monitor's password for accessing the <b>Maintenance</b> menu.
Clinic	Alarm Setup	No Password	Selects the password for changing alarm settings.  No Password: changing alarm settings is not password protected.
			Local Password: changing alarm switch, alarm limit, and alarm priority is password protected. The monitor's password for changing alarm settings is required.
			Clinician Authentication: changing alarm switch, alarm limit, and alarm priority is password protected. The account and password in the MLDAP are required.
	View Discharged Patients	No Password	Selects whether password or clinician login is needed to view discharged patients.  No Password: no password is required to view patient list.
			Clinician Login: patient list can be viewed only after clinician login succeeds.
	Retention Time	20 sec	Selects timeout period of the MLDAP password for accessing the <b>Maintenance</b> menu, alarm settings and arrhythmia settings.  If there is no operation after the specified timeout period is reached, you need to re-enter the password.

Section	Menu Item	Default Setting	Function
Clinic	Modify Local Password	/	Changes the monitor's password for accessing alarm settings.

# 18.5 The Save&Send Tab

Section	Menu Item	Default Setting	Function
Save Options	Confirm Before Saving	On	Selects whether confirmation is needed before saving physiological data.
	Clinician And Patient info. Required	Off	Selects whether clinician and patient information is required before saving physiological data.
	Send After Saving	Off	Selects whether to automatically send the data after saving.
	Record After Saving	Off	Selects whether to automatically start recording after saving.
	Log Out After Saving	Off	Selects whether to automatically log out after saving.
	Discharge Patient After Saving	On	Selects whether to automatically discharge the patient after saving in <b>Spot Check</b> mode.
	Auto Save After NIBP Measurement	Off	Selects whether to save the data after NIBP measurement is performed.

Section	Menu Item	Default Setting	Function
Send Options	nd Options Clinician Required		Selects whether clinician login is needed before sending data.
	Clinician Match Required	Off	Selects whether data can be sent if clinician information does not match with the information in database.
	Clear Sent Data After Sending	Off	Selects whether to clear data after sending.
/	Auto Clear Local Patient List	Off	Selects whether to clear the patient information and physiological data after sending.

## 18.6 The Alarm Tab

## 18.6.1 The Audio Tab

Menu Item	Default Setting	Function
Minimum Alarm Volume	2	/
Alarm Sound	ISO	Defines the alarm tone pattern to distinguish the pulse tone and keystroke tone by frequency.
High Alarm Interval	10 sec	Defines the interval between alarm tones for
Med Alarm Interval	20 sec	the ISO mode.
Low Alarm Interval	20 sec	

Menu Item	Default Setting	Function
Auto Increase Volume	2 Steps	2 Steps: if an alarm is not reset within the designated delay time after the alarm occurs, the alarm volume automatically increases by two levels.
		1 Step: if an alarm is not reset within the designated delay time after the alarm occurs, the alarm volume automatically increases by one level.
		Off: if an alarm is not reset within the designated delay time after the alarm occurs, the volume of the alarm tone does not change.
Increase Volume Delay	20 sec	Defines the delay time of alarm volume escalation
Defaults	/	Restores default settings on current page.

## **NOTE**

- The alarm volume escalation function is not applied to the latched alarms.
- When your monitor is connected to the CMS and Minimum Alarm Volume is set to 0, Minimum Alarm Volume automatically changes to 2 if the CMS is disconnected.

#### 18.6.2 The Pause/Reset Tab

Section	Menu Item	Default Setting	Function
Pause	Pause	Alarm Pause	<ul><li>Selects the pause function.</li><li>Alarm Pause: pauses alarms.</li><li>Audio Pause: pauses alarm tones.</li></ul>
	Pause Time	2 min	Selects the alarm pause time. The alarm pause time can be set to 1 min, 2 min, 3 min, or Permanent.

Section	Menu Item	Default Setting	Function
Pause	Pause Priority	All	Selects alarms of what priority can be paused.  All: pressing the Alarm Pause quick key pauses all alarms.  Med & Low: pressing the Alarm Pause quick key pauses alarms of medium and low priority. The high priority alarms will not be paused.  Disable: the Alarm Pause quick key is
	D 5 :	0,11	disabled.
	Pause 5 min	Off	Selects how long the alarm can be paused if switched on.
	Pause 10 min	Off	
	Pause 15 min	Off	
Alarm Reset	Alarm Light	On When Reset	On When Reset: when the alarm system is reset, the alarm tones of the current alarms are switched off, but the alarm lamp remains flashing.
			Off When Reset: when the alarm system is reset, both the alarm tone and alarm lamp of the current alarms are switched off.
Reminder Tone	Alarm Reset Reminder	On	Selects the reminder tone rule when the alarm volume is set to zero, or the alarm is reset or switched off.  On: the monitor issues reminder tones at a designated interval.
			Re-alarm: if the alarm condition persists the alarms marked with " √ " will be regenerated after the designated reminder tone interval.
			Off: the monitor does not issue reminder tones at a designated interval.  The alarms marked with "√" will be silenced.
	Alarm Off Reminder	On	Selects whether to issue reminder tones when alarm is switched off.

Section	Menu Item	Default Setting	Function
Reminder Tone	Reminder Interval	5 min	10 min: the monitor issues reminder tones every 10 minutes.
			5 min: the monitor issues reminder tones every five minutes.
			3 min: the monitor issues reminder tones every three minutes.
			2 min: the monitor issues reminder tones every two minutes.
			1 min: the monitor issues reminder tones every one minute.

## 18.6.3 The Latching Tab

Menu Iter	n	Default Setting	Function
High, Med,	Visible	Unselected	Selects alarm latching rules:  • If <b>Visible</b> is selected, you can separately
Low	Audible		latch visual alarm signal.
			<ul> <li>If Audible is selected, you can latch both audible and visual alarm signals.</li> </ul>
		<ul> <li>Selecting alarms of lower priority simultaneously latches higher priority alarms.</li> </ul>	

## 18.6.4 The Nurse Call Tab

Menu Item	Default Setting	Function	
Signal Type	Continuous	Pulse: the nurse call signal is a pulse signal and each pulse lasts one second. When multiple alarms simultaneously occur, only one pulse signal is outputted. If an alarm occurs but the previous one is not cleared, a new pulse signal will also be outputted.	
		Continuous: the nurse call signal lasts until the alarm ends. That is to say the duration of a nurse call signal is equal to that of the alarm condition.	
Contact Type	Normally Open	Selects the work mode of the nurse call relay	

Menu Item	Default Setting	Function	
Alarm Priority	High Only	Selects the priority of alarms sent to the nurse call system	
Alarm Type	Physiological Only	Selects the type of alarms sent to the nurse call system.	

## 18.6.5 The Other Tab

Section	Menu Item	Default Setting	Function
Alarm Priority	SpO2 Sensor Off	Low	Selects the alarm level for $\ensuremath{SpO}_2$ sensor off alarm.
	CMS/eGW Disconnected	Low	Selects the priority of the CMS and eGateway disconnection alarm. This setting is available only in Continuous Monitoring mode.
Alarm Delay	Alarm Delay	6 sec	1 sec - 15 sec for continuously measured parameters, the monitor does not present the alarm if the alarm condition is resolved within the delay time.      Off: an alarm is always presented.
			The setting of <b>Alarm Delay</b> is not applied to the apnea alarms.
Other	SPO2 Desat Alarm Off	Disable	Selects whether the SpO <sub>2</sub> Desat alarm can be switched off.  • <b>Disable</b> : the SpO <sub>2</sub> Desat alarm cannot be switched off.  • <b>Enable</b> : the SpO <sub>2</sub> Desat alarm can be
	Apnea Alarm Off	Disable	switched off.  Selects whether the apnea alarm can be switched off.  Disable: the apnea alarm cannot be switched off.  Enable: the apnea alarm can be switched off.

Section	Menu Item	Default Setting	Function
Other	CMS/eGW Disconnected Alarm	Off	Selects whether an alarm is issued when the monitor is not connected or disconnected from the CMS/eGateway.  Off: the "Offline" alarm is not presented when the monitor is not connected or disconnected from the CMS/eGateway.

# **18.7** The Standby Settings

Menu Item Default Setting		Function	
Prompt On Standby Screen	/	Sets the prompt message to be displayed on the Standby screen.	
Auto Enter Standby	On	If enabled, the monitor enters Standby mode automatically if no operation is detected for the time set below.	
Auto Enter Standby Time	10 min	Sets the time for the monitor to automatically enter Standby mode.	
Black Screen On Standby	Off	If enabled, the screen turns black after entering Standby mode.	

# 18.8 The CAA Settings

## 18.8.1 The EWS Tab

Menu Item		Default Setting	Function
Default Adult Score		NEWS2	Selects the default scoring tool for different
Default Pec	l Score	/	patient category.
Default Ned	Score	1	
Manage Score	Local	/	<b>Delete</b> : deletes the selected scoring tools. The monitor provide MEWS and NEWS by default. You cannot delete them.
	USB Drive	/	<b>Import</b> : imports the desired scoring tools to the monitor.

## 18.8.2 The GCS Tab

Menu Item		Default Setting	Function
Mild	High	15	Selects the threshold and color of
	Low	13	each consciousness level.
	Color	White	
Moderate	High	12	
	Low	9	
	Color	Yellow	
Severe	High	8	
	Low	3	
	Color	Red	

# 18.9 The Module Settings

## 18.9.1 The NIBP Tab

Menu Item Default Setting		Function	
NIBP Measurement Algorithm	Inflation	Selects the algorithm for NIBP measurement.  Inflation: The monitor performs NIBP measurement during cuff inflation. If measurement fails, it will continue the measurement in deflation stage. This algorithm is applicable only for adult patients.  Deflation: The monitor performs NIBP measurement during cuff deflation.	
		measurement during curr denation.	
NIBP Accuracy Test /		To perform a NIBP accuracy test.	
NIBP Leakage Test /		To perform a NIBP leakage test.	
Cuff /		Shows the cuff pressure during NIBP accuracy and leakage tests.	

Menu Item	Default Setting	Function
Orthostatic BP Symptoms Disturbance/ Light- Headedness/ Feeling of Weakness/ Vagueness/ Palpitation/Pallor		Edits the provided symptoms. Available only when the monitor is in <b>Spot Check</b> mode.
	Add Symptom	To add new symptoms. Available only when the monitor is in <b>Spot Check</b> mode.
Add Criterion	/	Sets the evaluation criterion for orthostatic BP results. Available only when the monitor is in <b>Spot Check</b> mode.

# 18.9.2 The CO2 Tab

Menu Item	Default Setting	Function
CO2(%)	5.0	Sets the concentration of calibration gas. A range of 3.0 to 7.0 is selectable. Click <b>Calibrate</b> to start CO <sub>2</sub> calibration.
Zero Recovery For 30s	On	On: After the zero calibration is completed, the $CO_2$ module reacquires the $CO_2$ readings. During the reacquisition period, "Zero Recovering" is displayed in the $CO_2$ numeric area.  Off: After the zero calibration is completed, the $CO_2$ module reacquires the $CO_2$ readings. During the reacquisition period, "Zero Recovering" is not displayed in the $CO_2$ numeric area.
Zero	/	Select this button to start zeroing the CO <sub>2</sub> module.
Defaults	/	Restores default CO <sub>2</sub> settings.

# 18.9.3 The Temp Tab

Menu Item	Default Setting	Function
Temp	/	Selects the type of Temp module.
Temp Measurement Site	Ear/Temporal / Oral/Axillary	Sets the options displayed in the <b>Measurement Site</b> menu.

## 18.9.4 The Manual Input Tab

This menu lists the manual parameters currently supported on the monitor. You can also add other parameters to the list. For details, refer to 14.4.2 Adding a New Parameter.

#### 18.9.5 The Pain Score Tab

Menu Item	Default Setting	Function	
Pain Score Method VAS-cm/VAS-mm/NRS/VRS-5/FPS-R/FLACC		Enables or disables the pain scales.	
Custom Pain Score Method	Custom 1/ Custom 2	Sets custom pain scales and selects whether to display them.	
Add Description	/	Adds descriptions for pain assessment.	

#### 18.9.6 The Other Tab

Menu Item	Default Setting	Function	
NIBP Timeout	15 min	Sets the time for a NIBP value to be displayed as outlined.	
Temp Timeout	30 min	Sets the time for a Temp value to be displayed as outlined.	
Outline Font for Suspected Values	On	Selects whether unreliable SpO <sub>2</sub> measurements are displayed in outline font. This prevents unreliable measurements from being misinterpreted as normal measurements.	
SpO2 Calc RR	On	If enabled, the RR value can be sourced from ${\rm SpO}_2$ . This function requires a license.	

# 18.10 The Unit Settings

Menu Item	Default Setting	Description
Height Unit	cm	Selects measurement unit for each
Weight Unit	kg	parameter.
Glucose Unit	mg/dl	
I/O Fluid Unit	ml	
CO2 Unit	mmHg	
Temp Unit	°C	
Pressure Unit	mmHg	

# **18.11 The Time Settings**

# 18.11.1 The Time Synchronization Tab

Section	Menu Item	Default Setting	Description
/	Time Zone		Selects the current time zone.
NTP Server	Start NTP Time Sync	Off	On: enables synchronizing the monitor time with the NTP server time.
	Interval	1 hr	Select the time interval for synchronizing the monitor time with the NTP server time.
	Time Server Address	0.0.0.0	The domain name of the time server.
	Time Server	/	The IP address of the time server.
	Connection Status	/	Shows the status of connection with the NTP server.
	Network Test	/	Tests whether the NTP server is properly connected.

# 18.11.2 The Daylight Savings Time Tab

Section	Default Setting	Description
Auto Daylight Savings Time	Off	<b>On</b> : auto starts the daylight savings time.

## 18.12 The Version Tab

Tab	Default Setting	Function
Version	/	Displays system software version, module hardware and software version, and firmware version.

# 18.13 The Battery Information Settings

Tab	Default Setting	Function
Battery1	/	Displays battery information.
Battery2	/	

# **18.14 The Scanner Settings**

## 18.14.1 The Scanner Info. Tab

Section	Menu Item	Default Setting	Description
/	Data Parse Mode	JADAK	Sets the data parse mode. JADAK, Local, and DLL are selectable.
	Data Encoding Type	UTF8	Sets the data encoding type. Keyboard Code, UTF8, and Unicode are selectable.

Section	Menu Item	Default Setting	Description
Patient	Prefix	/	Sets the prefix for patient barcode.
Barcode	Postfix	/	Sets the postfix for patient barcode.
	Remove Prefix/Suffix	Off	Sets whether to remove the set prefix or postfix.
	Content Fill to	Patient ID	Selects a destination to fill the scanned information.
Clinician	Prefix	/	Sets the prefix for clinician barcode.
Barcode -	Postfix	/	Sets the postfix for clinician barcode.
	Remove Prefix/Suffix	Off	Sets whether to remove the set prefix or postfix.

## 18.14.2 The JADAK Barcode Tab

Menu Item	Default Setting	Function
Patient Category	1	Sets the information of JADAK
Gender	1	barcode.
Age	1	
Month	/	

# 18.14.3 The Identify Scanner Tab (for the non-Mindray Custom 2D Barcode Reader)

Tab	Default Setting	Function
Identify Scanner	/	When you are using barcode readers other than HS-1R or HS-1M, you should select the barcode reader from the USB device list, so that the monitor can identify the barcode reader. From the USB device list, select the barcode reader you are using.

# 18.14.4 The Field Tab (for the Mindray Custom 2D Barcode Reader)

Menu Item	Default Setting	Function
Patient ID/First Name/Last Name/ Patient Category/Gender/DOB	Selected	Selects desired patient information to be output by the barcode reader.
Visit Number/Room No/Bed No/ Age/Department/Custom Field 1 - Custom Field 4	Unselected	the parcode reader.

# 18.15 The Record Settings

Tab	Default Setting	Function
Report Layout	Patient Name/Patient ID/Patient Category/ Visit Number/Gender/ Bed No/DOB/Room No	Sets the information to be included in the reports, and positions of the information

# 18.16 The Network Setup Settings

## 18.16.1 The Network Type Tab

Menu Item	Default Setting	Function
Monitor	Auto (if WLAN is available on your monitor) LAN1 IP (if WLAN is not available on your monitor)	Selects the type of network to be used. <b>Auto:</b> the monitor automatically identify your network type.

## 18.16.2 The LAN1 IP Tab

Menu Item	Default Setting	Function
Obtain IP Address Automatically	On	Automatically gets the IP address.
Use the Following Address	Off	IP Address, Subnet Mask, and Gateway are required.
Obtain DNS address automatically	On	Automatically gets the DNS address

Menu Item	Default Setting	Function
Using the Following DNS Address	Off	IP addresses of <b>Preferred DNS Server</b> and <b>Alternate DNS Server</b> are required.

## 18.16.3 The WLAN Tab

Menu Item		Default Setting	Function	
Available Netwo	Available Network List		/	Lists the available network currently detected.
Add WLAN	WLAN		/	Sets the Name, SSID, Security Method, and Password of the wireless network.
	WLAN IF	)	/	See 18.16.4 The WLAN IP Tab.
	WLAN Setup	WLAN Band	Auto	<b>Auto</b> : automatically identifies the WLAN band.
		2.4G Channel	All	Selects the type of 2.4G channels.
		5G Channel	All	Selects the type of 5G channels.
Certificate Management	Local		/	<b>Delete</b> : delete the selected certifications.
	USB Drive		/	Select certifications you want to import from the USB memory, and then select <b>Import</b> : import the desired certifications from the USB memory.

## 18.16.4 The WLAN IP Tab

Menu Item	Default Setting	Function
Obtain IP Address Automatically	On	Selects whether to enable the function of automatically getting the IP address.
Use the Following Address	Off	Selects whether inputting the <b>IP Address</b> , <b>Subnet Mask</b> , and <b>Gateway</b> is required.

Menu Item Default Setting		Function
Obtain DNS address On automatically		Selects whether to enable the function of automatically getting the DNS address.
Using the Following Off DNS Address		Selects whether inputting the IP address of Preferred DNS Server and Alternate DNS Server is required.

# 18.16.5 The Transfer Setup Tab

Menu Item		Default Setting	Function
/	Send Data	Central Station	Selects a destination to send selected data.
Central Station	Select CMS	On	Selects whether to enable the CMS selection function for your monitor.
Setup	Add Central Station	/	Inputs the name, department, and server address of the CMS. You can add up to 30 CMSs for monitor.
eGate	Server Address	/	Input the server address or IP address
way Setup	IP Address	0.0.0.0	of eGateway.
	Network Test	/	Tests whether the eGateway server is properly connected.
Data +	Server Address	/	Inputs the name or IP address for the
Wavef orms	Destination IP	0.0.0.0	server receiving the realtime data and waveform.
	Port	0	/
	Send Data	Off	
	Send Waveforms	Off	
	Data Interval	30 sec	
	Connection Status	Disconnected	

Menu Ite	em	Default Setting	Function
Alarms	Server Address	/	Inputs the name or IP address for the
	Destination IP	0.0.0.0	server receiving the alarm data.
	Port	0	1
	Send Alarms	Off	
	Connection Status	Disconnected	
		•	You can send the realtime data, e hospital servers via HL7 protocol.
ADT	Server Address	192.168.0.100	Input the host name or IP address of
	IP Address	192.168.0.100	the ADT gateway.
	Port	3502	Input the port of the ADT gateway.
	ADT Query	Off	Selects whether patient information can be loaded to the monitor from the ADT server.
	Network Test	/	Tests whether the ADT server is properly connected.

The ADT (admit-discharge-transfer) gateway is normally deployed in the eGateway. You can obtain patient information from the hospital ADT server through the ADT gateway.

#### 18.16.6 The Device Discover Tab

Multicast helps device discovery between monitors and between monitors and CMS. Devices in the same multicast group can be mutually discovered.

Menu Item	Default Setting	Function
Multicast TTL	1	/
Multicast Address	225.0.0.8	
Master Server Address	/	/
Master Server IP Address	0.0.0.0	
Connected Status	Disconnected	

Menu Item	Default Setting	Function
Network Test	/	Tests whether the master server is properly connected.

## 18.16.7 The QoS Tab

Menu Item	Default Setting	Function
QoS Level For Realtime Monitoring	0	Selects the service quality of network connection for realtime monitoring, for example parameter measurements and waveforms, alarms, and so on
QoS Level For Others	0	Selects the service quality of network connection for non-realtime monitoring, for example history data, printing, and as on.

# 18.16.8 The MLDAP Tab

Menu Item	Default Setting	Function
Server Address	/	Inputs the name or IP address for the MLDAP
IP Address	0.0.0.0	server.
Port	6665	/
Network Test	/	Tests whether the monitor is properly connected with the MLDAP server.

## 18.16.9 The VitalsLink Tab

Section	Menu Item	Default Setting	Description
/	Enable	Off	Selects whether to enable VitalsLink connection. This function requires a license.
	Automatically Logout after	10 min	Sets the time to log out automatically.

Section	Menu Item	Default Setting	Description
General Connectivity	Master Server Address	/	Sets the connection information.
	Context Root	/	
	Organization ID	/	
	Local CSI	Off	
Security	Auth Type	Basic	Sets the security information.
	User Name	/	
	User Password	/	
	Tenant Type	None	
	Tenant Value	/	
	Transport Protocol	НТТР	
Barcode Format Configuration	Data Encoding Type	UTF8	Sets the data encoding type.
Import Aliases		/	To import Aliases.
Import Bearer		/	To import Bearer.
Import Certificate		/	To import certificate.
Import CSI		/	To import CSI.

# 18.17 The Bluetooth Tab

Menu Item	Default Setting	Function
Enable	Off	<ul> <li>On: the bluetooth function is enabled, and the monitor can be found by other bluetooth devices.</li> <li>Off: the bluetooth function is disabled.</li> </ul>
Auto Unpair On Disconnection	10 minNone	Sets the time of unpairing after the monitor and bluetooth device being connected.
Paired Device	/	Lists the devices that has paired with the monitor.

# 18.18 The Other Tab

Menu Item	Default Setting	Function
Barometric Pressure	760 mmHg	Sets the barometric pressure.
SpO2 Tone	Mode 1	Selects the SpO <sub>2</sub> tone. The same SpO <sub>2</sub> tone mode should be used for monitors in the same area.
Clear CMS IP at startup	On	/
Language	/	1
Parameter Output Setup	/	Configures DIAP protocol parameters to realize communications between the monitor and third party devices.
Export Patient Data	/	To export the patient data to a USB drive.
Browse System Log	/	To browse the system log.
Export System Log	/	To export the system log to a USB drive.
Modify Password	/	To modify maintenance password.

# 19<sub>Battery</sub>

#### 19.1 Overview

This monitor is designed to operate on battery power when the mains power is not available. The monitor uses mains power as primary power source. In case of mains power failure, the monitor automatically runs on the battery power.

# 19.2 Battery Safety Information

#### WARNING

- Keep batteries out of children's reach.
- Use only specified battery. Use of a different battery may present a risk of fire or explosion.
- Keep the batteries in their original package until you are ready to use them.
- Do not expose batteries to liquid.
- Do not crush, drop or puncture the battery. Mechanical abuse can lead to internal damage and internal short circuits. If a battery has been dropped or banged against a hard surface, whether damage is externally visible or not, remove the battery from use and dispose of it properly.
- If the battery shows signs of damage or signs of leakage, replace it immediately.
- The battery should be charged only in this monitor.
- Extremely high ambient temperature may cause battery overheat protection, resulting in monitor shutdown.
- The lithium-ion battery has a service life of three years. Replace your battery when it reaches the end of its service life. Failure to replace the battery may cause serious damage to your equipment from battery overheating.
- Do not open batteries, heat batteries above 60 °C, incinerate batteries, or short battery terminals. They may ignite, explode, leak or heat up, causing personal injury.

#### **CAUTION**

 Remove the battery before shipping the monitor or if it will not be used for an extended period of time.

#### NOTE

 It is recommended to always install a fully charged battery in the monitor to ensure normal monitoring in case of accidental power failure.

## 19.3 Battery Indications

The battery LED, on-screen battery symbols, and related alarm messages indicate the battery status.

#### 19.3.1 Battery LED

The battery LED is on the left bottom of the front panel of the monitor. For details, see 2.7.1 Front View (VS 9 Series) and 2.7.2 Front View (VS 8 Series).

#### 19.3.2 Battery Symbols

The on-screen battery symbols indicate the battery status as follows:

- For VS 9 series:
  - • 17.1h indicates that the battery power is sufficient. The green portion represents the remaining charge and the numerics in the middle indicates the estimated run time of the battery.
  - 10.5h indicates that the battery power is low and needs to be charged. The
    red portion represents the remaining charge and the numerics in the middle
    indicates the estimated run time of the battery.
  - indicates that the battery is almost depleted and needs to be charged immediately. Otherwise, the monitor will soon automatically shut down.
  - indicates that no battery is installed or the battery fails.
  - ◆ 17.8h indicates that the battery is being charged. An extra lightning symbol is displayed and the green portion is animated. When a battery is charged on a new monitor for the first time, the estimated run time will not be displayed. Instead, a percentage indicating the current charge is displayed on the right of the battery symbol.

#### ■ For VS 8 series:

- indicates that the battery power is sufficient. The green portion represents the remaining charge.
- indicates that the battery power is low and needs to be charged. The red portion represents the remaining charge.

- Indicates that the battery is almost depleted and needs to be charged immediately. Otherwise, the monitor will soon automatically shut down.
- indicates that no battery is installed or the battery fails.
- indicates that the battery is being charged. An extra lightning symbol is displayed and the green portion is animated.

#### CAUTION

• The numerics on the battery symbol are estimated remaining battery run time. The accuracy of the remaining time is greatly affected by the working condition of the monitor and status of the battery. Do not rely exclusively on this for operation time estimation in clinical applications.

#### 19.3.3 Battery-related Alarms

Refer to **D.2.7 Power Supply Technical Alarm Messages**.

## 19.4 Replacing the Battery (for VS 9 Series)

For VS 9 series, to replace the battery, follow this procedure:

- 1. Turn off the monitor. Disconnect the power cable and other cables.
- 2. Lay the monitor down to expose the bottom of the monitor.
- 3. Open the battery compartment door.

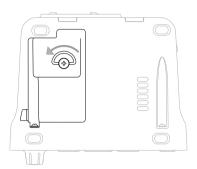


- 4. Turn the latch aside.
- Take out the old battery. Then insert the new battery into the battery compartment with the battery terminal inwards.
- 6. Turn the latch back to the middle and close the battery door.

## 19.5 Replacing the Battery (For VS 8 Series)

For VS 8 series, to replace the battery, follow this procedure:

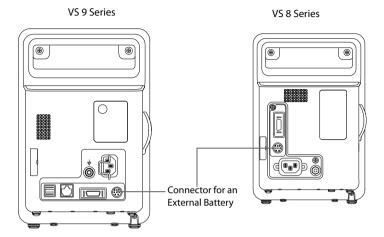
- 1. Turn off the monitor. Disconnect the power cable and other cables.
- 2. Lay the monitor down to expose the bottom of the monitor.
- 3. Open the battery compartment door.



- 4. Disconnect the old battery from the connectors on the left of the battery compartment and take out the old battery.
- 5. If a 2500 mAh battery is used, put a battery support into the battery compartment. If a 5000 mAh battery is used, the support is not needed.
- Insert the new battery into the battery compartment with the battery terminal outwards. Then connect the battery to the connectors on the left of the battery compartment.
- 7. Close the battery door.

## 19.6 Connecting an External Battery

You can connect an external battery to the monitor via the connector on the back.



The external battery is charged whenever the monitor is connected to an AC power source regardless of whether or not the monitor is currently on.

# 19.7 Charging a Battery

The battery is charged whenever the monitor is connected to an AC power source regardless of whether or not the monitor is currently on. When battery is charging, the AC power indicator and battery indicator are both on.

## 19.8 Maintaining the Battery

## 19.8.1 Conditioning the Battery

The performance of a rechargeable battery deteriorates over time. You should condition the batteries every three months.

If the battery is not conditioned for a prolonged time, its charge indication may not be accurate and you may wrongly evaluate the remaining battery runtime.

To condition a battery, follow this procedure:

- Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
- 2. Turn the monitor off. Install the battery to be conditioned.
- 3. Connect the monitor to AC power. Allow the battery to be charged uninterrupted till it is fully charged.
- 4. Remove AC power and allow the monitor to run from the battery until it shuts off.

5. Connect the monitor to AC power. Fully charge the battery again for use or charge it to 40 – 60% for storage.

#### **NOTE**

- Do not use the monitor to monitor the patient during battery conditioning.
- Do not interrupt battery conditioning.

#### 19.8.2 Checking Battery Performance

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

You should check the battery performance every three months or if you doubt that the battery may fail.

See steps 1 to 5 of 19.8.1 Conditioning the Battery to check battery performance. The operating time of the battery reflects their performance directly. If the operating time of a battery is noticeably shorter than that stated in the specifications, the battery may reach its service life or malfunction. If the battery performance meets the requirement, fully charge the battery again for use or charge it to 40-60% for storage.

#### NOTE

Battery operating time depends on equipment configuration and operation.
 For example, high display brightness or measuring NIBP repeatedly will shorten the battery operating time.

## 19.9 Storing Batteries

When storing batteries, make sure that the battery terminals do not come into contact with metallic objects. If batteries are stored for an extended period of time, place the batteries in a cool place with a partial charge of 40% to 60% capacity.

Condition the stored batteries every three months. For more information, see 19.8.1 Conditioning the Battery.

#### NOTE

- Remove the battery from the equipment if the equipment is not used for a prolonged time (for example, several weeks). Otherwise the battery may overdischarge.
- Storing batteries at high temperature for an extended period of time will significantly shorten their life expectancy.

 Storing batteries in a cool place can slow the aging process. Ideally the batteries should be stored at 15 °C.

## 19.10 Recycling Batteries

Discard a battery in the following situations:

- The battery has visual signs of damage.
- The battery fails.
- The battery is aged and its runtime significantly less than the specification.
- The battery service life is reached.

Properly dispose of batteries according to local regulations.

#### WARNING

 Do not open batteries, heat batteries above 60 °C, incinerate batteries, or short the battery terminals. They may ignite, explode, leak or heat up, causing personal injury. This page intentionally left blank.

# **20** Care and Cleaning

## 20.1 Care and Cleaning Introduction

In this chapter we only describe cleaning and disinfection of the monitor (not including the cradle of Convidien Genius™ 3tethered tympanic thermometer), and certain accessories. For the cleaning and disinfection of the other reusable parameter accessories, refer to their instructions for use.

# 20.2 Care and Cleaning Safety Information

#### WARNING

- Use only Mindray approved cleaners, disinfectants and methods listed in this chapter to clean or disinfect your equipment or accessories. Warranty does not cover damage caused by unapproved substances or methods.
- Do not mix disinfecting solutions, as hazardous gases may result.
- We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's infection control officer or epidemiologist.
- Be sure to turn off the system and disconnect all power cables from the outlets before cleaning the equipment.
- The responsible hospital or institution shall carry out all cleaning and disinfection procedures specified in this chapter.

#### **CAUTION**

- Never immerse any part of the equipment or accessories in liquids or allow liquid to enter the interior.
- Any contact of cleaners or disinfectants with connectors or metal parts may cause corrosion.
- Do not pour or spray any liquid directly on the equipment or accessories or permit fluid to seep into connections or openings.
- If you spill liquid on the equipment or accessories, disconnect the power supply, dry the equipment, and contact your service personnel.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

- Dilute and use the cleaners or disinfectants according to the manufacturer's instructions.
- Check the equipment after cleaning and disinfecting. If there is any sign of damage, remove it from use.

# 20.3 Cleaning and Disinfecting the Main Unit

#### 20.3.1 Cleaning the Main Unit

Clean the monitor on a regular basis. Before cleaning, consult your hospital's regulations.

To clean the monitor, follow this procedure:

- 1. Dampen a soft lint-free cloth with water or ethanol (70%).
- 2. Wring excess liquid from the cloth.
- 3. Wipe the display screen of the monitor.
- Wipe the external surface of the main unit with the damp cloth, avoiding the connectors and metal parts.
- 5. Dry the surface with a clean cloth. Allow the equipment and mounting kits air dry in a ventilated and cool place.

#### **CAUTION**

- During the cleaning procedure, disable the touch operation by switching off the monitor or locking the touchscreen.
- Any contact of cleaners or disinfectants with connectors or metal parts may cause corrosion.

## 20.3.2 Disinfecting the Main Unit

Disinfect the monitor as required in your hospital's servicing schedule. Cleaning the monitor before disinfecting is recommended. Always dilute and use disinfectants according to the manufacturer's instructions.

#### 20.3.3 Approved Cleaning and Disinfecting Agents for Main Unit

The following table lists approved cleaning and disinfecting agents:

Product Name	Product Type	Manufacturer
Alpet® D2 Surface Sanitizing Wipes	Wipes	BEST SANITIZERS INC™.

Product Name	Product Type	Manufacturer
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Wipes	Clorox professional products company
Clorox Healthcare® Bleach Germicidal Wipes	Wipes	Clorox professional products company
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes	Wipes	Clorox professional products company
Diversey Oxivir® TB Wipes	Wipes	Diversey Inc
Metrex CaviCide1™	Liquid, spray	METERX® RESEARCH
Metrex CaviWipes™	Wipes	METERX® RESEARCH
PDI Sani-Cloth® AF3 Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® Bleach Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® HB Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® Plus Germicidal Disposable Cloth	Wipes	PDI Inc.
PDI Super Sani-Cloth® Germicidal Disposable Wipe	Wipes	PDI Inc.
Virex® II 256 (1:256)	Liquid	Diversey Inc
Virex® TB	Liquid, spray	Diversey Inc
HEALTH ESSENCE Disinfecting Effervescent Tablets	Tablets	Beijing ChangJiangMai Medical Science Technology Co. Ltd.
HEALTH ESSENCE Surface Disinfectant	Liquid, spray	Beijing ChangJiangMai Medical Science Technology Co. Ltd.
Health Essence Bis-QACs Disinfectant	Liquid	Beijing ChangJiangMai Medical Science Technology Co. Ltd.
DIAN'ERKANG® Surface Wipes	Wipes	Shanghai Likang Disinfectant Hi- Tech Co., Ltd.
DIAN'ERKANG® Surface Disinfectant	Liquid	Shanghai Likang Disinfectant Hi- Tech Co., Ltd.

Product Name Product Type		Manufacturer	
DIAN'ERKANG® Disinfection Spray	Liquid, spray	Shanghai Likang Disinfectant Hi- Tech Co., Ltd.	
Clinell® Universal Wipes	Wipes	GAMA Healthcare Ltd	
Clinell ® Sporicidal Wipes	Wipes	GAMA Healthcare Ltd	
Tristel Duo™	Liquid, spray	Tristel solutions Limited	
Tristel Jet	Liquid, spray	Tristel solutions Limited	
Tristel Fuse For Surfaces, 196ppm	Liquid	Tristel solutions Limited	
Surfanios Premium, 0.25%	Liquid	ANIOS LABORATORIES	
Surfa 'safe	Liquid, spray	ANIOS LABORATORIES	
Wip' Anios EXCEL	Wipes	ANIOS LABORATORIES	
Aniosurf ND premium, 0.25%	Liquid	ANIOS LABORATORIES	
Mikrobac® Tissues	Wipes	BODE Chemie GmbH	
Cleanisept® Wipes	Wipes	Dr. Schumacher GmbH	
mikrozid® PAA Wipes	Wipes	Schülke & Mayr GmbH	
mikrozid® Sensitive Wipes	Wipes	Schülke & Mayr GmbH	
Ecolab Incidin® OxyWipe S.	Wipes	Ecolab Deutschland GmbH	
Glutaraldehyde, 2%	Liquid	/	
Ethanol, 70%	Liquid	/	
Isopropanol, 70%	Liquid	1	
*Sodium hypochlorite bleach, 0.5%	Liquid	/	
Hydrogen peroxide, 3%	Liquid	1	
Rely+On™ Virkon® High Level surface Disinfectant, 1%	Powder	Antec International Ltd	
1-Propanol, 50%	Liquid	1	

Product Name	Product Type	Manufacturer
Descosept® forte	Liquid	Dr. Schumacher GmbH
Descosept® AF	Liquid	Dr. Schumacher GmbH
Dismozon® plus, 0.4%	Powder	BODE Chemie GmbH
mikrozid® AF Wipes	Wipes	Schülke & Mayr GmbH
Terralin® Liquid	Liquid	Schülke & Mayr GmbH
Perform® Classic Concentrate OXY, 0.5%	Powder	Schülke & Mayr GmbH
S-7 hospital grade disinfectant surface wipes	Wipes	ANAERON
Neutral detergent wipes	Wipes	RAYNARD Health
Premier disinfectant wips	Wipes	RAYNARD Health
V-wipes	Wipes	Whiteley Medical

# 20.4 Cleaning and Disinfecting the Accessories

For the NIBP air hose and  ${\rm SpO}_2$  cable, you should clean and disinfect them using the cleaners and disinfectants and methods listed in this section. For other accessories, you should consult the instructions delivered with the accessories.

#### **CAUTION**

- Fluids entering the NIBP air hose can damage the equipment. When cleaning or disinfecting the NIBP air hose, prevent liquid from entering the hose.
- Periodically inspect the NIBP air hose and connector for signs of wear or deterioration after cleaning or disinfecting the NIBP air hose. Replace the NIBP air hose if you detect a leak. Dispose of damaged NIBP air hose according to local laws for disposal of hospital waster.
- Never immerse or soak the accessories in any liquid.
- Never clean or disinfect the connectors and metal parts.
- Use only Mindray approved cleaners and disinfectants and methods listed in this section to clean or disinfect the accessories. Warranty does not cover damage caused by unapproved substances or methods.
- To avoid long term damage, the accessories should be disinfected only when necessary as determined by your hospital's policy.

# 20.4.1 Cleaning and Disinfecting Agents for the NIBP Air Hose

The following table lists approved cleaning and disinfecting agents for the NIBP air hoses:

Product Name	Product Type	Manufacturer
Alpet® D2 Surface Sanitizing Wipes	Wipes	BEST SANITIZERS INC™.
CIDEXR OPA	Liquid	Gilag GmbH International Advanced Sterilization products
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Wipes	Clorox professional products company
Metrex CaviCide1™	Liquid, spray	METERX® RESEARCH
Metrex CaviWipes™	Wipes	METERX® RESEARCH
PDI Sani-Cloth® AF3 Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® Plus Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Super Sani-Cloth® Germicidal Disposable Wipe	Wipes	PDI Inc.
Virex® TB	Liquid, spray	Diversey Inc
Clinell® Universal Wipes	Wipes	GAMA Healthcare Ltd
Surfa 'safe	Liquid, spray	ANIOS LABORATORIES
Aniosurf ND premium, 0.25%	Liquid	ANIOS LABORATORIES
mikrozid® Tissues	Wipes	Schülke & Mayr GmbH
Glutaraldehyde, 2%	Liquid	/
Ethanol, 70%	Liquid	/
Isopropanol, 70%	Liquid	/
Rely+On™ Virkon® High Level surface Disinfectant, 1%	Powder	Antec International Ltd
1-Propanol, 50%	Liquid	/

# 20.4.2 Cleaning and Disinfecting Agents for the SpO<sub>2</sub> Cable

The following table lists approved cleaning and disinfecting agents for the Masimo cables:

Product Name	Product Type	Manufacturer
Isopropanol, 70%	Liquid	1

The following table lists approved disinfectants for the Nellcor  ${\rm SpO_2}$  cables:

Product Name	Product Type	Manufacturer
CIDEXR OPA	Liquid	Gilag GmbH International Advanced Sterilization products
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Wipes	Clorox professional products company
Clorox Healthcare® Bleach Germicidal Wipes	Wipes	Clorox professional products company
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes	Wipes	Clorox professional products company
Diversey Oxivir® TB Wipes	Wipes	Diversey Inc
PDI Super Sani-Cloth® Germicidal Disposable Wipe	Wipes	PDI Inc.
Virex® TB	Liquid, spray	Diversey Inc
Glutaraldehyde, 2%	Liquid	/
Ethanol, 70%	Liquid	/
Isopropanol, 70%	Liquid	/
Sodium hypochlorite bleach, 0.5%	Liquid	/
Hydrogen peroxide, 3%	Liquid	/
Rely+On™ Virkon® High Level surface Disinfectant, 1%	Powder	Antec International Ltd
1-Propanol, 50%	Liquid	/

#### 20.4.3 Cleaning the Accessories

You should clean the accessories (NIBP air hose, and  ${\rm SpO_2}$  cable) on a regular basis. Before cleaning the accessories, consult your hospital's regulations for cleaning the accessories.

To clean the accessories (NIBP air hose and SpO<sub>2</sub> cable), follow this procedure:

- 1. Clean the accessories with a soft cloth moistened with water or ethanol (70%).
- 2. Wipe off all the cleaner residue with a dry cloth.
- 3. Allow the accessories to air dry.

## 20.4.4 Disinfecting the Accessories

We recommend that the accessories (NIBP air hose and SpO<sub>2</sub> cable) should be disinfected only when necessary as determined by your hospital's policy. Cleaning the accessories before disinfecting is recommended.

#### 20.5 Sterilization

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

# 20.6 Impact of Improper Cleaning

Using cleaners other than those recommended may have the following impact:

- Product discoloration
- Metal part corrosion
- Brittle and breaking wires, connectors, and equipment housing
- Reduced cable and leadwire life
- Overall system performance degradation
- Equipment malfunction or failure

# **21** Maintenance

#### 21.1 Maintenance Introduction

Regular maintenance is essential to ensure that the equipment functions properly. This chapter contains information on periodic testing and maintenance.

# 21.2 Maintenance Safety Information

#### WARNING

- To avoid electric shock, stop using the monitor if you find the housing of the monitor has signs of broken. Contact the service personnel for help in that case.
- Failure on the part of the responsible individual hospital or institution using this equipment to implement a recommended maintenance schedule may cause undue equipment failure and possible health hazards.
- No modification of this equipment is allowed.
- This equipment contains no user serviceable parts.
- Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.
- The safety checks or maintenance involving any disassembly of the equipment should be performed by professional service personnel.
   Otherwise, undue equipment failure and possible health hazards could result.
- Do not open batteries, heat batteries to above 60 °C, incinerate batteries, or short the battery terminals. Batteries may ignite, explode, leak or heat up, causing personal injury.
- Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for servicing if necessary.
- The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.

#### **CAUTION**

- The equipment and accessories shall not be served or maintained while in use with a patient.
- If you discover a problem with any of the equipment, contact your service personnel or Mindray.
- Use and store the equipment within the specified temperature, humidity, and altitude ranges.
- When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.
- At the end of its service life, the equipment, 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 equipment, please contact Mindray.

#### **NOTE**

 If needed, contact the manufacture for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.

# 21.3 Maintenance and Testing Schedule

Follow the maintenance and testing schedule or local regulations to perform testing and maintenance. Make sure to clean and disinfect the equipment before taking any tests and maintenance

The following table lists the maintenance and testing schedule:

Test/Maintenance Item	Recommended Frequency	
Performance Tests		
Visual inspection	Every day, before first use.	
Measurement module performance test and calibration	<ol> <li>If you suspect that the measurement values are incorrect.</li> <li>Follow any repairs or replacement of relevant module.</li> <li>Once a year for CO<sub>2</sub> tests.</li> <li>Once every two years for other parameter module performance tests.</li> </ol>	

Test/Maintenance Item		Recommended Frequency		
Performanc	Performance Tests			
Nurse call test		If you suspect that the nurse call function does not work properly.		
Electrical Sa	fety Tests			
Electrical safe	Electrical safety tests Once every two years.			
Other Tests	Other Tests			
Power-on tes	st	Before use.		
Recorder check		When the recorder is used for the first time.     Follow any repair or replacement of the recorder.		
Battery Functionality check test		When first installed.     When battery is replaced.		
	Performance test	Every three months or if the battery runtime reduced significantly.		

# 21.4 Checking Version Information

You may be asked for information on monitor and module version.

To view system software version information, select the **Main Menu** quick key  $\rightarrow$  from the **System** column select **Version**.

You can also view more version information by following this procedure

- 2. Select the **Version** tab.

You can check system software version, module hardware and software version, and firmware version.

# 21.5 Testing Methods and Procedures

Except the following maintenance tasks, all other test and maintenance tasks should be performed by Mindray-qualified service personnel only.

- Regular check, including visual inspection and power-on test
- Recorder test
- Battery check

If your monitor needs a safety test and performance test, contact the service personnel.

#### 21.5.1 Performing Visual Inspection

Visually inspect the equipment before its first used every day. If you find any signs of damage, remove your monitor from use and contact the service personnel.

Verify that the equipment meets the following requirements:

- Environment and power supply specifications are met.
- The monitor housing and display screen are free from cracks or other damages
- The power cord is not damaged and the insulation is in good condition.
- Connectors, plugs, and cables are not damaged and kinked.
- Power cord and patient cables are securely connected with the equipment.

#### 21.5.2 Performing Power-on Test

The monitor automatically performs a selftest at startup. Check the following items for the power-on test:

- The equipment powers on properly.
- The alarm system works properly.
- The monitor displays properly.

#### 21.5.3 Testing the Recorder

To test the recorder, follow this procedure:

- 1. Start a recording task to print waveforms and reports.
- 2. Check that the recorder functions correctly.
- 3. Check that the printout is clear without missing dots.

## 21.5.4 Checking the Battery

For information on battery check, see 19.8.2 Checking Battery Performance.

## 21.6 Disposing of the Monitor

Dispose of the monitor and its accessories when its service life is reached. Follow local regulations regarding the disposal of such product.

#### WARNING

 For disposal of parts and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

# **22** Accessories

The accessory material that contacts the patients or other staff has undertaken the biocompatibility test and is verified to be in compliance with ISO 10993-1.

For details about the accessories, refer to the instructions for use provided with the accessory.

#### WARNING

- Use accessories specified in this chapter. Using other accessories may cause damage to the equipment or not meet the claimed specifications.
- Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.

#### **CAUTION**

- The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
- Use the accessories before the expiry date if their expiry date is indicated.
- The disposable accessories shall be disposed of according to hospital's regulations.

## 22.1 SpO<sub>2</sub> Accessories

Wavelength emited by the sensors is between 600 nm and 1000 nm.

The maximum photic output consumption of the sensor is less than 18 mW.

The information about the wavelength range and maximum photic output consumption can be especially useful to clinicians (for example, when photodynamic therapy is performed).

# 22.1.1 SpO<sub>2</sub> Extension Cable

Module type	Remarks	Part No.	Usage	Applicable patient
Mindray SpO <sub>2</sub>	7 pins, 2.5 m	0010-20-42710	Reusable	/
Module	7 pins, 1.2 m	040-001443-00	Reusable	/
Masimo SpO <sub>2</sub>	8 pins, 2.1 m	040-000332-00	Reusable	/
Module	8pin masimo Cable(RD SET)	040-005973-00	Reusable	/
Nellcor SpO <sub>2</sub> Module	8 pins, 2.5 m	0010-20-42712	Reusable	/

# 22.1.2 Mindray SpO<sub>2</sub> Sensors

Model	Patient Category	Part No.	Applicable patient	Application site
520A	Disposable SpO <sub>2</sub> Sensor	009-005087-00	Adult	Finger
520P	Disposable SpO <sub>2</sub> Sensor	009-005088-00	Pediatric	Finger
5201	Disposable SpO <sub>2</sub> Sensor	009-005089-00	Infant	Toe
520N	Disposable SpO <sub>2</sub> Sensor	009-005090-00	Neonate	Foot
			Adult	Finger
521A	Disposable SpO <sub>2</sub> Sensor	009-005091-00	Adult	Finger
521P	Disposable SpO <sub>2</sub> Sensor	009-005092-00	Pediatric	Finger
5211	Disposable SpO <sub>2</sub> Sensor	009-005093-00	Infant	Toe
521N	Disposable SpO <sub>2</sub> Sensor	009-005094-00	Neonate	Foot
/	Disposable bandage, for 518C SpO <sub>2</sub> Sensor	115-004895-00	Neonate	/
518B	Reusable SpO <sub>2</sub> Sensor	518B-30-72107	Neonate	Foot
518BLH	Reusable SpO <sub>2</sub> Sensor	115-020887-00	Neonate	Foot
518BLH	Reusable SpO <sub>2</sub> Sensor	115-050154-00	Neonate	Foot
518C	Disposable SpO <sub>2</sub> Sensor	040-000330-00	Neonate	Foot
513A	Reusable SpO <sub>2</sub> Sensor	115-033848-00	Adult, pediatric	Ear
512E	Reusable SpO <sub>2</sub> Sensor	512E-30-90390	Adult	Finger

Model	Patient Category	Part No.	Applicable patient	Application site
512F	Reusable SpO <sub>2</sub> Sensor	512F-30-28263	Adult	Finger
512FLH	Reusable SpO <sub>2</sub> Sensor	115-012807-00	Adult	Finger
512G	Reusable SpO <sub>2</sub> Sensor	512G-30-90607	Pediatric	Finger
512H	Reusable SpO <sub>2</sub> Sensor	512H-30-79061	Pediatric	Finger

# 22.1.3 Masimo SpO<sub>2</sub> Sensors

Model	Patient Category	Part No.	Applicable patient	Application site
LNCS DCI	Masimo P/N:1863	0010-10-42600	Adult	Finger
4050	Adult, RD SET DCI	040-003376-00	(>30kg)	Finger

<sup>\*</sup>If you need to purchase Masimo sensors, please contact Masimo.

# 22.1.4 Nellcor SpO<sub>2</sub> Sensors

Model	Patient Category	Part No.	Applicable patient	Application site
MAXAI	Disposable SpO <sub>2</sub> Sensor	0010-10-12202	Adult (>30 kg)	Finger
MAXPI	Disposable SpO <sub>2</sub> Sensor	0010-10-12203	Pediatric (10 to 50 kg)	Finger
MAXII	Disposable SpO <sub>2</sub> Sensor 0010-10-12204	Infant (3 to 20 kg)	Toe	
MAXNI	Disposable SpO <sub>2</sub> Sensor	0010-10-12205	Neonate (<3 kg), Adult (>40 kg)	Foot Finger
DS100A	Reusable SpO <sub>2</sub> Sensor	9000-10-05161	Adult	Finger
D-YS	Reusable SpO <sub>2</sub> Sensor	0010-10-12476	Adult, Pediatric, Infant, Neonate (>1 kg)	foot (1-3 kg), toe (3-15 kg), or finger (>15 kg)
OXI-P/I	Reusable SpO <sub>2</sub> Sensor	9000-10-07308	Pediatric, infant	Finger
OXI-A/N	Reusable SpO <sub>2</sub> Sensor	9000-10-07336	Adult, neonate	Finger, foot

# 22.2 NIBP Accessories

### 22.2.1 NIBP Hoses

Model	Usage	Patient Category	Part No.
CM1903	Reusable	Adult, pediatric, neonate	6200-30-09688/115- 012522-00
CM1908			040-002712-00

# 22.2.2 Reusable NIBP Cuffs

Model	Patient Category	Measurement Site	Limb Circumference (cm)	Part No.
CM1200	Small Infant	Arm	7 to 13	115-002480-00
CM1201	Infant		10 to 19	0010-30-12157
CM1202	Pediatric		18 to 26	0010-30-12158
CM1203	Adult		24 to 35	0010-30-12159
CM1204	Large adult		33 to 47	0010-30-12160
CM1205	Adult	Thigh	44 to 66	0010-30-12161
CM1300	Small infant	Arm	7 to 13	040-000968-00
CM1301	Infant		10 to 19	040-000973-00
CM1302	Pediatric		18 to 26	040-000978-00
CM1303	Adult		24 to 35	040-000983-00
CM1304	Large adult		33 to 47	040-000988-00
CM1305	Adult	Thigh	46 to 66	040-000993-00
CM1306	Adult	Arm	25 to 35	115-015930-00
CM1307	Large adult		33 to 47	115-015931-00

# 22.2.3 Disposable NIBP Cuffs

Model	Patient Category	Measurement Site	Limb Circumference (cm)	Part No.
CM1500A	Neonate	Arm	3.1 to 5.7	125-000046-00
CM1500B			4.3 to 8.0	125-000047-00
CM1500C			5.8 to 10.9	125-000048-00
CM1500D			7.1 to 13.1	125-000049-00
CM1500E			8 to 15	125-000050-00
CM1501	Infant		10 to 19	001B-30-70697
CM1502	Pediatric		18 to 26	001B-30-70698
CM1503	Adult		24 to 35	001B-30-70699
CM1504	Large adult		33 to 47	001B-30-70700
CM1505	Adult	Thigh	46 to 66	001B-30-70701
CM1506	Adult	Arm	25 to 35	115-016969-00
CM1507	Large adult		33 to 47	115-016970-00
CM1500A	Neonate	Arm	3.1 to 5.7	125-000051-00
CM1500B			4.3 to 8.0	125-000052-00
CM1500C			5.8 to 10.9	125-000053-00
CM1500D			7.1 to 13.1	125-000054-00
CM1500E			8 to 15	125-000055-00
CM1501	Infant		10 to 19	001B-30-70682
CM1502	Pediatric		18 to 26	001B-30-70683
CM1503	Adult		24 to 35	001B-30-70684
CM1504	Large adult		33 to 47	001B-30-70685
CM1505	Adult	Thigh	46 to 66	001B-30-70686
CM1506	Adult	Arm	25 to 35	115-015940-00
CM1507	Large adult		33 to 47	115-015941-00

# **22.3** Temp Accessories

# 22.3.1 SmarTemp™ Accessories

**Probe Well** 

Model	Usage	Description	Part No.
MR491	Reusable	Blue, oral/axillary	M09A-20-62062
MR492		Red, Rectal	M09A-20-62062-51

### **Temp Probes**

Model	Description	Patient Category	Measurement Site	Part No.
MR431	Reusable,	Adult, Pediatric, Neonate	Oral/Axillary	6006-30-39598
MR432	box	Adult, Pediatric	Rectal	6006-30-39599
MR431	Reusable,	Adult, Pediatric, Neonate	Oral/Axillary	6006-30-39600
MR432	package	Adult, Pediatric	Rectal	6606-30-39601

### Probe Cover

Model	Usage	Patient Category	Description	Part No.
ST-001	Disposable	Adult, Pediatric,	Cover, 20 pcs/pack	M09A-20-62124
		Neonate	Cover, 200 pcs/pack	M09A-30-62126
			Cover, 2000 pcs/pack	M09A-30-62128

# 22.3.2 Genius™ 3 Tympanic Thermometer Accessories

### Tympanic Thermometer

Model	Usage	Description	Part No.
303075	Reusable	Tethered tympanic thermometer	115-038397-00

#### **Probe Cover**

Model	Usage	Patient Category	Description	Part No.
303030	Disposable	Adult, Pediatric, Neonate	Cover, 96 pcs/case	100-000200-00

# 22.3.3 Exergen TemporalScanner™ Thermometer Accessories

Model	Usage	Description	Model	Part No.
124237- AF-MR	Reusable	Exergen temporal scanner thermometer	TAT-5000S- RS232	040-003273-00

# 22.3.4 HeTaida Thermometer

Model	Usage	Description	Part No.
HTD8808C	Reusable	Non-contact Infrared Thermometer	100-000446-00

# 22.4 CO<sub>2</sub> Accessories

Model	Part No.	Description	Applicable patient
XS04620	0010-10-42560	Disposable airway sampling line	Adult/Pediatric
XS04624	0010-10-42561	Disposable airway sampling line, humidified	Adult/Pediatric
006324	0010-10-42562	Disposable airway sampling line, humidified	Neonatal
007768	0010-10-42563	Disposable airway sampling line, long	Adult/Pediatric
007737	0010-10-42564	Disposable airway sampling line, long, humidified	Adult/Pediatric
007738	0010-10-42565	Disposable airway sampling line, long, humidified	Neonatal
009818	0010-10-42566	Disposable nasal sampling line	Adult
007266	0010-10-42567	Disposable nasal sampling line	Pediatric
009822	0010-10-42568	Disposable nasal sampling line, plus O <sub>2</sub>	Adult
007269	0010-10-42569	Disposable nasal sampling line, plus O <sub>2</sub>	Pediatric
009826	0010-10-42570	Disposable nasal sampling line, long, plus O <sub>2</sub>	Adult
007743	0010-10-42571	Disposable nasal sampling line, long, plus O <sub>2</sub>	Pediatric
008177	0010-10-42572	Disposable nasal sampling line, humidified	Adult
008179	0010-10-42574	Disposable nasal sampling line, humidified	Neonatal
008180	0010-10-42575	Disposable nasal sampling line, humidified, plus O <sub>2</sub>	Adult

Model	Part No.	Description	Applicable patient
008181	0010-10-42576	Disposable nasal sampling line, humidified, plus O <sub>2</sub>	Pediatric
008174	0010-10-42577	Disposable nasal sampling line	Adult
008175	0010-10-42578	Disposable nasal sampling line	Pediatric
MVIIHL	040-006160-00	Intubated CO <sub>2</sub> FilterLine	Neonatal/Infant
MVAIHL	040-006161-00	Intubated CO <sub>2</sub> FilterLine	Adult/Pediatric
MVAIL	040-006162-00	Intubated CO <sub>2</sub> FilterLine	Adult/Pediatric
MVIIH	040-006163-00	Intubated CO <sub>2</sub> FilterLine	Neonatal/Infant
MVAIH	040-006164-00	Intubated CO <sub>2</sub> FilterLine	Adult/Pediatric
MVAI	040-006165-00	Intubated CO <sub>2</sub> FilterLine	Adult/Pediatric
MVPN	040-006166-00	Nasal CO <sub>2</sub> FilterLine	Pediatric
MVAN	040-006167-00	Nasal CO <sub>2</sub> FilterLine	Adult
MVANH	040-006168-00	Nasal CO <sub>2</sub> FilterLine	Adult
MVA	040-006169-00	Oral-Nasal CO <sub>2</sub> FilterLine	Adult
MVP	040-006170-00	Oral-Nasal CO <sub>2</sub> FilterLine	Pediatric
MVPNOH	040-006171-00	Nasal CO <sub>2</sub> FilterLine w/O <sub>2</sub> H	Pediatric
MVAOL	040-006172-00	Oral-Nasal CO <sub>2</sub> FilterLine w/O <sub>2</sub> L	Adult
MVAO	040-006173-00	Oral-Nasal CO <sub>2</sub> FilterLine w/O <sub>2</sub>	Adult
MVANOH	040-006174-00	Nasal CO <sub>2</sub> FilterLine w/O <sub>2</sub> H	Adult
MVINH	040-006175-00	Nasal CO <sub>2</sub> FilterLine H	Neonatal/Infant
MVPO	040-006176-00	Oral-Nasal CO <sub>2</sub> FilterLine w/O <sub>2</sub>	Pediatric
MVPOL	040-006177-00	Oral-Nasal CO <sub>2</sub> FilterLine w/O <sub>2</sub> L	Pediatric
/	045-003134-00	CO <sub>2</sub> adapter	/

# 22.5 Others

PN	Description
DA8K-10-14454	Power cord, Europe
DA8K-10-14453	Power cord, UK
DA8K-10-14452	Power cord, USA
509B-10-05996	Power cord, 10 A, 250 V, 1.6 m, China
009-001075-00	Power cord, 10 A, 250 V, 3 m, Brazil
009-001791-00	Power cord, 250 V, 16 A, 3 m, South Africa
009-007190-00	Power cord, 3 m, India
009-007191-00	Power cord, 1.8 m, Switzerland
009-003116-00	Nurse Call Cable
009-003436-00	Serial Port Cable
022-000248-00	Li-ion Battery (10.8V, 5600mA, Ll23l003A, VS9)
022-000273-00	Li-ion Battery (10.95V, 5000mAh, Ll23S005A, VS 8)
022-000122-00	Li-ion Battery (10.95V, 2500mAh, Ll13S001A, VS8)
045-004267-00	Rolling stand (Standard)
045-004268-00	Rolling stand (with workbench)
045-004269-00	Rolling stand (with workbench & battery)
045-003054-00	Wall mount, standard
045-003424-00	Quick Release Tray
045-003427-00	GCXM Series 12" Bracket (with quick release kit A)
115-020575-00	Bedrail Clamp
115-008393-00	Barcode scanner kit
115-039575-00	Barcode reader, HS-1M, JADAK, 2D
115-039635-00	Barcode reader, HS-1R, JADAK, 2D

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# A Product Specifications

#### Classifications **A.1**

The equipment is classified, according to IEC60601-1:

Type of protection against electrical shock	CLASS I EQUIPMENT, equipment energized from an external and internal electrical power source.
Degree of protection against electrical shock	DEFIBRILLATION-PROOF TYPE CF AAPPLIED PART for SpO <sub>2</sub> , NIBP, and SmarTemp™ Temp  TYPE BF APPLIED PART for Genius™ 3 Temp  Type B APPLIED PART for HeTaida Thermometer  DEFIBRILLATION-PROOF TYPE BF APPLIED PART for CO <sub>2</sub> and Exergen TemporalScanner ™ Temp.
Mode of operation	Continuous
Degree of protection against harmful ingress of water	IPX2 (Protection against vertically falling water drops when ENCLOSURE tilted up to 15°)
Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE	EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTUREWITH AIR or WITH OXYGEN OR NITROUS OXIDE
Degree of mobility	Portable

#### **A.2 Environmental Specifications**

#### A.2.1 **Main Unit**

Item	Operating conditions	Storage conditions
Temperature	0 to 40 °C (without $CO_2$ ) 5 to 40 °C (with $CO_2$ )	–20 to 60 °C
Relative humidity (non- condensing)	15% to 95%	10% to 95%
Barometric	57.0 to 107.4 kPa (without CO <sub>2</sub> ) 57.3 to 105.3 kPa (with CO <sub>2</sub> )	16.0 to 107.4 kPa (without CO <sub>2</sub> ) 57.3 to 105.3 kPa (with CO <sub>2</sub> )

### A.2.2 SmarTemp™Temperature Module

Item	Operating conditions	Storage conditions
Temperature	5 °C to 40 °C	Same as the main unit
Relative humidity (non- condensing)	Same as the main unit	Same as the main unit
Barometric	Same as the main unit	Same as the main unit

# A.2.3 Genius™ 3 Temperature Module

Item	Operating conditions	Storage conditions
Temperature	16°C to 33 °C	–25 to 55 °C
Relative humidity (non- condensing)	10% to 95%	10%~95%

### A.2.4 Exergen TemporalScanner Thermometer

Item	Operating conditions	Storage conditions
Temperature	16 to 40 ℃	–20 to 50 °C
Relative humidity (non- condensing)	15% to 95%	10% to 95%
Barometric	57.0 to 107.4 kPa	16.0 to 107.4 kPa

### A.2.5 HeTaiDa Infrared Thermometer

Item	Operating conditions	Storage conditions
Temperature	16 to 35 ℃	−20 to 45 °C
Relative humidity (non- condensing)	15% to 85%	10% to 93%
Barometric	70.0 to 106.0 kPa	70.0 to 106.0 kPa

### **WARNING**

 The equipment may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges.

### **NOTE**

 The environmental specifications of unspecified parameters are the same as those of the main unit.

# **A.3** Power Supply Specifications

### A.3.1 AC Power Supply Specifications

Line voltage	100 to 240 VAC (±10%)
Current	0.9 to 0.5 A
Frequency	50/60 Hz (±3 Hz)
Fuse	T2AL-250V

# A.3.2 Battery Specifications of VS 9 Series

Battery Type	Rechargeable lithium-lon battery
Voltage	10.8 VDC
Capacity	5600 mAh
Run time	At least 8 hours when powered by a new, fully-charged battery at 25 $^{\circ}$ C ±5 $^{\circ}$ C on standard configuration (SpO <sub>2</sub> and NIBP), with SpO <sub>2</sub> sensor connected, auto NIBP measurement at an interval of 15 minutes, and screen brightness set to factory default.
	At least 5.3 hours when powered by a new, fully-charged battery at 25 °C $\pm$ 5 °C on a configuration of SpO <sub>2</sub> , NIBP, SmarTemp and Wi-Fi,
	with SpO <sub>2</sub> sensor and barcode scanner connected, auto NIBP
	measurement at an interval of 15 minutes, and screen brightness set to factory default.
	At least 4 hours when powered by a new, fully-charged battery at 25 $^{\circ}$ C $\pm 5$ $^{\circ}$ C on a configuration of SpO <sub>2</sub> , NIBP, CO <sub>2</sub> , Wi-Fi and recorder,
	with SpO <sub>2</sub> sensor connected, auto NIBP measurement and auto
	recording at an interval of 10 minutes, and screen brightness set to factory default.
Charge time	Monitor power off or standby: no more than 4 hours to 100% (at 25 $^{\circ}$ C $\pm 5$ $^{\circ}$ C).  Monitor power on: no more than 12.5 hours to 100%.
	'
Shutdown delay	At least 20 minutes (after a low battery alarm first occurs) at 25 °C $\pm$ 5 °C with SpO <sub>2</sub> sensor connected, auto NIBP measurement at an interval of 15 minutes, and brightness set to factory default.

# A.3.3 Battery Supply Specifications of VS 8 Series

Battery Type	Rechargeable lithium-lon battery
Voltage	10.95 VDC
Capacity	2500 mAh or 5000 mAh
Run time	At least 4 hours for the 2500mAh battery and at least 8 hours for the 5000mAh battery when powered by a new fully-charged battery at 25 °C $\pm$ 5 °C on standard configuration (SpO <sub>2</sub> and NIBP), with SpO <sub>2</sub> sensor connected, auto NIBP measurement at an interval of 15 minutes and screen brightness set to factory default.
Charge time	Monitor power off or standby: no more than 3 hours to 100% for the 2500mAh battery and no more than 4 hours to 100% for the 5000mAh battery (at 25 °C $\pm$ 5 °C). Monitor power on: no more than 7.5 hours to 100% for the 2500mAh battery and no more than 11.5 hours to 100% for the 5000mAh battery.
Shutdown delay	At least 20 minutes (after a low battery alarm first occurs) at 25 °C $\pm$ 5 °C with SpO $_2$ sensor connected, auto NIBP measurement at an interval of 15 minutes, and brightness set to factory default.

# A.4 Physical Specifications

Item	VS 8 series (H*W*D)	VS 9 series (H*W*D)
Size	≤252mm x 170mm x150mm	≤275mmx 185mm x 135mm
Weight	≤2.5 kg (with Mindray SpO <sub>2</sub> module, NIBP module, recorder module and a 5000 mAh battery; without capacitive screen; without accessory)	≤3.4 kg (with Mindray SpO <sub>2</sub> module, NIBP module, recorder module and a battery; without accessory)

# A.5 Hardware Specifications

# A.5.1 Display Specifications of VS 9 Series

Screen type	Color TFT LCD
Screen Size (diagonal)	10.1"
Resolution	1280×800 pixels

# A.5.2 Display Specifications of VS 8 Series

Screen type	Color TFT LCD
Screen Size (diagonal)	8"

Resolution	1024×768 pixels
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# A.5.3 Recorder Specifications

Method	Thermal dot array
Paper speed	25 mm/s

### A.5.4 LEDs

Alarm lamp	1 (three color coded: cyan, yellow and red)
Power on LED	1 (green)
AC power LED	1 (green)
Battery LED	1 (two color coded: yellow and green)

### A.5.5 Audio Indicator

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

# A.5.6 Monitor Interface Specifications

Power	1 AC power input connector
Wired network	1 RJ45 connector
USB	2 standard connectors, USB 2.0, type A
Equipotential Grounding Terminal	1
Multi-Functions Connector	1
External battery connector	1

# A.5.7 Outputs Specifications

Nurse Call Signal	
Amplitude	High level: 3.5 to 5 V, ±5%, providing a minimum of 10 mA output current  Low level: <0.5 V, receiving a minimum of 5 mA input current
Rising and falling time	≤ 1 ms
Alarm output (Network connector)	

Alarm delay time from monitor to remote	The alarm delay time form the monitor to remote equipment is ≤2 seconds, measured at the monitor's signal output connector.
equipment	

### A.5.8 Wi-Fi Technical Specifications

Standards	IEEE 802.11a/b/g/n/ac
Modulation mode	BPSK, QPSK, 16QAM, 64QAM, 256QAM
Operating frequency	2412MHz~2472MHz, 5180MHz~5320Mz, 5500MHz~5700MHz, 5745MHz~5825MHz
Wireless data rate	IEEE 802.11a: 6-54 Mbps IEEE 802.11b: 1-11 Mbps IEEE 802.11g: 6-54 Mbps IEEE 802.11n: MCS0-MCS7 IEEE 802.11ac: MCS0-MCS8
Output power	<20 dBm (CE requirements, detection mode: RMS) <30 dBm (FCC requirements, detection mode: peak power)
Working mode	Infrastructure
Data security	Standard: WPA/WPA2-PSK, WPA/WPA2-Enterprise, WPA/WPA2 CCKM EAP method: LEAP, EAP-TTLS, EAP-TLS, EAP-FAST, PEAP-MsChapV2, PEAP-GTC, PEAP-TLS Encryption: TKIP and AES

### A.5.9 Wi-Fi Performance Specifications

### **WARNING**

 All network functions of data communication are designed to operate on a private network.

#### A.5.9.1 System Capacity

Number of the monitors supported by a single AP:  $\leq 16$ 

Testing conditions are as follows:

- Each monitor can communicate with the CMS.
- Only one monitor can transmit history data.
- The weakest strength of the AP signal where the monitor is located cannot be less than -65 dBm.

#### A.5.9.2 Resistance to Wireless Interference

The distance between the interfering devices and the monitor is greater than 20 cm. A Wi-Fi interference (no greater than -85 dBm) in the same channel and a Wi-Fi interference (no greater than -50 dBm) in an adjacent channel are presented synchronously. The interfering devices include 2.4 GHz wireless devices, cellular mobile networks, microwave ovens, intercoms, cordless phones, and ESU equipment. The interfering devices do not include Wi-Fi devices.

The monitoring network must support the following requirements:

- The total delay of data transmission from the monitor to the CMS:  $\leq 2$  seconds.
- The delay for monitor-related settings configured at the CMS to be effective: ≤ 2 seconds.

#### A.5.9.3 Wi-Fi Network Stability

There is no communication data loss when the monitor moves at a speed not higher than 3.75 m/s in a 15 meter obstacle-free linear range.

16 monitors are connected to the same AP and each roams for 30 times, of which at least 3 monitors roam simultaneously. The ratio of the communication data loss on the CMS from any monitor does not exceed 0.1% over a 24-hour period.

#### A.5.9.4 Line of Sight Distance

The line of sight distance between the monitor and the AP is no less than 50 meters.

### A.5.10 Blue Tooth Specification

Protocol	Bluetooth 5
Modulation mode	GFSK
Operating frequency	2402 ~ 2480MHz
Wireless data rate	2Mbps, 1Mbps, 125kbps
Output power	≤ 8 dBm ± 4 dB
Data security	AES128

### A.5.11 Bluetooth Performance Specifications

#### WARNING

- Keep the monitor away from interference sources.
- Do not use Bluetooth nodes to perform realtime vital signs monitoring.

#### A.5.11.1 System Capacity

In a range of 10 m<sup>2</sup>, there should be no more than 3 groups of paired monitors and bluetooth nodes working simultaneously.

#### A.5.11.2 Resistance to Interference

The distance between the interfering devices and the monitor is greater than 20 cm. The interfering devices include 2.4 GHz Wi-Fi devices, bluetooth communication devices, remote controls, microwave ovens, intercoms, cellular mobile networks, and cordless phones.

The monitoring network must support the following requirements:

- The total delay of data transmission from the monitor to the bluetooth node: ≤ 6 seconds.
- The success rate for transmission of vital signs data from the monitor to the bluetooth node: > 99%.

#### A.5.11.3 Line of Sight Distance

The line of sight distance between the monitor and the bluetooth node is no less than 10 meters

# A.6 Measurement Specifications

### A.6.1 SpO<sub>2</sub> Specifications

Alarm limit	Range (%)	Step (%)
SpO <sub>2</sub> High	(low limit + 2) to 100	1
SpO <sub>2</sub> Low	Mindray, Masimo: (Desat +1) to (high limit – 2) Nellcor: (Desat+1) or 20 (whichever is greater) to (high limit – 2)	
Desat	0 to (low limit – 1)	

### A.6.1.1 Mindray SpO<sub>2</sub> Module Specifications

Standards	Meet standards of ISO 80601-2-61	
*Measurement accuracy verification: The $\mathrm{SpO}_2$ accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.		
SpO <sub>2</sub> Measurement range 0 to 100%		
PI measurement range 0.05% to 20%		
SpO <sub>2</sub> Resolution	1%	

PI Resolution	PI < 10.0: 0.01 PI ≥ 10.0: 0.1
Accuracy	70 to 100%: ±2% ABS (adult/pediatric)
	70 to 100%: ±3% ABS (neonate)
	0% to 69%: Not specified.

\*Studies were performed to validate the accuracy of Pulse Oximeter with neonatal  $SpO_2$  sensors by contrast with a CO-Oximeter. Some neonates aged from 1 day to 30 days with a gestation age of 22 weeks to full term were involved in this study. The statistical analysis of data of this study shows the accuracy (Arms) is within the stated accuracy specification. Please see the following table.

Sensor type	Totally neonates	Data	Arms
518B	97 (51 male & 46 female)	200 pairs	2.38%
520N	122 (65 male & 57 female)	200 pairs	2.88%
The Pulse Oximeter with neonatal SpO <sub>2</sub> sensors was also validated on adult subjects.			
Refreshing rate	≤1s		
Response time	< 30 s (normal perfusion, no disturbance, SpO <sub>2</sub> value sudden		

change within 70% – 100%)

### A.6.1.2 Masimo SpO<sub>2</sub> Module Specifications

Standards	meets the requirements of ISO 80601-2-61
SpO <sub>2</sub> Measurement range	1 to 100%
PI Measurement range	0.02 to 20%
SpO <sub>2</sub> Resolution	1%
PI Resolution	PI < 10.0: 0.01 PI ≥ 10.0: 0.1
Accuracy <sup>1</sup>	70% to 100%: $\pm 2\%$ ABS (without motion, adult/pediatric) 70% to 100%: $\pm 3\%$ ABS (without motion, neonate) 70% to 100%: $\pm 3\%$ ABS (with motion) 1% to 69%: Not specified.
Refreshing rate	≤1s
Response time	≤20 s (normal perfusion, no disturbance, SpO <sub>2</sub> value sudden change within 70% – 100%)
SpO <sub>2</sub> averaging time	2-4 s, 4-6 s, 8 s, 10 s, 12 s, 14 s, 16 s

Low perfusion conditions	Pulse amplitude: >0.02% Light penetration: >5%
Low perfusion SpO <sub>2</sub> accuracy <sup>2</sup>	±2%

 $<sup>^1</sup>$  The Masimo pulse oximeter with sensors have been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70% to 100% SpO $_2$  against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population. One percent was added to the accuracies for neonatal sensors to account for accuracy variation due to properties of fetal hemoglobin. The Masimo pulse oximeter with sensors has 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 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% to 100% SpO $_2$  against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

### A.6.1.3 Nellcor SpO<sub>2</sub> Module Specifications

Standards	Meet standards of ISO 80601-2-61
Measurement range	0 to 100%
Resolution	1%
Accuracy	70 to 100%: ±2% ABS (adult/pediatric) 70 to 100%: ±3% ABS (neonate) 0% to 69%: Not specified.
Refreshing rate	≤1s
Response time	≤ 30 s (normal perfusion, no disturbance, SpO <sub>2</sub> value sudden change within 70% – 100%)

<sup>\*</sup> When the  $\mathrm{SpO}_2$  sensor is applied for neonatal patients as indicated, the specified accuracy range is increased by  $\pm 1\%$ , to compensate for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.

#### Information of the Test Subjects of the Clinical Study Report

Skin color Gender	Number	Age (years)	Health	
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<sup>&</sup>lt;sup>2</sup> The Masimo pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Black	Male	1	28.2±9.19	Healthy
	Female	1		
Yellow	Male	3		
	Female	9		

### A.6.2 PR

Alarm limit	Range (bpm)	Step (bpm)
PR High	PR ≤ 40: (low limit +2) to 40 PR > 40: (low limit +5) to 300	PR ≤ 40: 1 PR > 40: 5
PR Low	PR ≤ 40: 15 to (high limit - 2) PR > 40: 40 to (high limit - 5)	

# A.6.2.1 PR from Mindray SpO<sub>2</sub> Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Response time	< 30 s (normal perfusion, no disturbance, PR value sudden change within 25 – 220 bpm)
Accuracy	±3 bpm
Refreshing rate	≤1s

# A.6.2.2 PR from Masimo SpO<sub>2</sub> Module

Measurement range	25 to 240 bpm
Resolution	1 bpm
Response time	≤ 20 s (normal perfusion, no disturbance, PR value sudden change within 25 – 220 bpm)
Accuracy	±3 bpm (without motion) ±5 bpm (with motion)
Low perfusion conditions	Pulse amplitude: >0.02% Light penetration: >5%
Low perfusion PR accuracy <sup>1</sup>	±3 bpm
Refreshing rate	≤1s

### A.6.2.3 PR from Nellcor SpO<sub>2</sub> Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Response time	≤30 s (normal perfusion, no disturbance, PR value sudden change within 25 – 250 bpm)
Accuracy	20 to 250 bpm: ±3 bpm 251 to 300 bpm: not specified
Refreshing rate	≤1s

#### A.6.2.4 PR from NIBP Module

Measurement range	30 to 300 bpm
Resolution	1 bpm
Accuracy	±3 bpm or ±3%, whichever is greater

### A.6.3 NIBP

Standards	Meet standards of IEC 80601-2-30, ISO 81060-2	
Technique	Oscillometry	
Mode of operation	Manual, Auto, STAT, Sequence,	and BP averaging
Auto mode repetition intervals	1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 hour, 1.5 hours, 2 hours, 3 hours, 4 hours, 8 hours	
STAT mode cycle time	5 min	
Typical measurement time	Adult: ≤ 15 s (Inflation algorithm, measured with CM1203/CM1303/CM1503 cuff, PR within 60 to 200 bpm and systolic pressure within 80 to 120 mmHg)	
	Pediatric: ≤ 15 s (Inflation algorithm, measured with CM1202/CM1302/CM1502 cuff, PR within 60 to 200 bpm and systolic pressure within 80 to 120 mmHg)	
Max measurement time	Adult, pediatric: 180 s	
	Neonate:	90 s
Heart rate range	30 to 300bpm	

<sup>&</sup>lt;sup>1</sup> The Masimo pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Measurement ranges		Adult	Pediatric	Neonate
(mmHg)	Systolic:	25 to 290	25 to 240	25 to 140
	Diastolic:	10 to 250	10 to 200	10 to 115
	Mean:	15 to 260	15 to 215	15 to 125
Accuracy	Max mean erro Max standard o	r: ±5 mmHg leviation: 8 mml	Hg	
Static pressure measurement range	0 mmHg to 300	) mmHg		
Static pressure measurement accuracy	±3 mmHg			
Resolution	1 mmHg			
Initial cuff inflation pressure range (mmHg) (Deflation algorithm)	Adult: Pediatric: Neonate:	80 to 280 80 to 210 60 to 140		
Default initial cuff inflation pressure (mmHg) (Deflation algorithm)	Adult: Pediatric: Neonate:	160 140 90		
Software overpressure protection	Adult: Pediatric: Neonate:	297±3 mmHg 297±3 mmHg 147±3 mmHg		
Hardware overpressure protection	Adult: Pediatric: Neonate:	≤330 mmHg ≤330 mmHg ≤165 mmHg		
Alarm limit	Range (mmHg	)		Step (mmHg)

Sys High	Adult: (low limit+5) to 290 Pediatric: (low limit+5) to 240 Neonate: (low limit+5) to 140	≤ 50: 1 > 50: 5
Sys Low	25 to (high limit-5)	
Mean High	Adult: (low limit+5) to 260 Pediatric: (low limit+5) to 215 Neonate: (low limit+5) to 125	
Mean Low	15 to (high limit-5)	
Dia High	Adult: (low limit+5) to 250 Pediatric: (low limit+5) to 200 Neonate: (low limit+5) to 115	
Dia Low	10 to (high limit-5)	

<sup>\*</sup> Measurement accuracy verification: In adult and pediatric modes, the blood pressure measurements measured with this device are in compliance with the American National Standard for Electronic or Automated Sphymomanometers (ANSI/AAMI SP10) in terms of mean error and standard deviation by comparing with intra-arterial or auscultatory measurements (depending on the configuration) in a typical patient population. For auscultatory reference, the 5<sup>th</sup> Korotkoff sound was used to determine the diastolic pressure. In neonatal mode, the blood pressure measurements measured with this device are in compliance with the American National Standard for Electronic or Automated Sphymomanometers (ANSI/AAMI SP10) in terms of mean error and standard deviation by comparing with intra-arterial measurements (depending on the configuration) in a typical patient population.

### A.6.4 Temp Specifications

### A.6.4.1 Specifications of the SmarTemp™ Temperature Module

Standards	Meets standards of ISO 80601-2-56
Technique	Thermal resistance (use thermistor to measure temperature)
Operating mode	Adjusted mode (predictive mode) Direct mode (monitor mode)
Measurement range	Monitor mode: 25 °C to 44 °C (77 °F to 111.2 °F) Predictive mode: 34 °C to 43 °C (93.2 °F to 109.4 °F)
Accuracy (Monitor mode)	25 °C to 32 °C (not including 32 °C): ±0.2 °C 32 °C to 44 °C (including 32 °C): ±0.1 °C or 77 °F to 89.6 °F (not including 89.6 °F): ±0.4 °F 89.6 °F to 111.2 °F (including 89.6 °F): ±0.2 °F

Resolution	0.1 °C	
Minimum measurement time for accurate readings	Monitor mode: <60 s Predictive mode: <20 s (typical test:< 12 s)	
Alarm limit	Range	Step
Alarm limit Temp High	(low limit +1) °C to 44 °C	<b>Step</b> 0.1 °C

### Statistical Results of Clinical Investigation Data

	Clinical BIAS ( ∆ cb)	Limits of Agreement (LA)	Clinical Repeatability (σr)
Oral	0.02	0.33	0.1
Axilla	0.06	0.38	0.13
Rectum	-0.05	0.48	0.14

### A.6.4.2 Specifications of the Genius™ 3 Tethered Tympanic Thermometer

Operating mode	Adjusted mode
Measurement range	33.0 °C to 42.0 °C (91.4 °F to 107.6 °F)
Accuracy	±0.3 °C

### A.6.4.3 Specifications of the Exergen TemporalScanner™ Thermometer

Measurement range	16.0°C to 43.0 °C
Measurement accuracy	± 0.2 °C
Resolution	0.1 °C
Battery Specifications	
Туре	Alkaline battery
Voltage	9V
Run time	Approximately one hour continuous use or 15000 readings

### A.6.4.4 Specifications of the HeTaiDa Infrared Thermometer

Measurement range	34.0°C to 42.9°C
Measurement accuracy	34.0°C to 34.9°C: ±0.3°C
	35.0°C to 42.0°C: ±0.2°C 42.1°C to 42.9°C: ±0.3°C

# A.6.5 CO<sub>2</sub> Specifications

Standard	Meet standard of ISO 80601-2-55			
Technique	Infrared absorption			
Apnea delay	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s			
Measurement range	0 to 150 mmHg			
Accuracy	Full accuracy mode: 0 to 40 mmHg: ±2mmHg 41 to 76 mmHg: ±5% of reading 77 to 99 mmHg: ±10% of reading 100 to 150mmHg: ±(3mmHg + 8% of reading) >150mmHg CO <sub>2</sub> : unspecified			
	ISO accuracy mode: Add ±2 mmHg to the full accuracy m	ode		
Accuracy drift	Meet the requirement for measurement	ent accuracy within 6 hours.		
Resolution	1 mmHg			
Sample flowrate	Connecting the Oridion sampling line: 50 ml/min			
Sample flowrate tolerance	$\pm$ 15% or $\pm$ 15 ml/min, whichever is greater.			
Start-up time	20 s (typical), 90 s (maximum)			
Response time	Measured with an Oridion sampling I sampling line) or ≤6.5 s @ 50 ml/min	(extended sampling line)		
	Measured with a DRYLINE <sup>TM</sup> PRIME sampling line: ≤5 s @ 50 ml/min			
Rise time	Measured with an Oridion sampling line: ≤250 ms @ 50 ml/min (standard sampling line) or ≤280 ms @ 50 ml/min (extended sampling line)  Measured with a DRYLINE <sup>TM</sup> PRIME sampling line: ≤200 ms @ 50 ml/			
min				
Effect of interference gases on CO <sub>2</sub> measurement				
Gas	Concentration (%)	Quantitative effect*		
N <sub>2</sub> O	≤ 60	±1 mmHg		
Hal	≤ 4			
Sev	≤ 5			
Sev	≤5 ≤5			

Des	< 15	±2 mmHg
DC3	- 13	±2

<sup>\*:</sup> means an extra error should be added in case of gas interference when CO<sub>2</sub> measurements are performed between 0 to 40 mmHg. Inaccuracy specifications are affected by the breath rate and I:E change. The end-tidal gas reading is within specification for breath rate below 15 bpm and I:E ratio smaller than 1:1 relative to the gas readings without breath.

Alarm limit	Range	Step
EtCO <sub>2</sub> High	(low limit + 2) to 99 mmHg	1 mmHg
EtCO <sub>2</sub> Low	1 to (high limit – 2) mmHg	
FiCO <sub>2</sub> High	1 to 99 mmHg	

## A.6.6 RR Specifications

Alarm limit	Range	Step (rpm)
RR High	RR $\leq$ 20 rpm: (low limit + 2) to 20 rpm RR >20 rpm: Adult, pediatric: (low limit + 5) to 100 rpm Neonate: (low limit + 5) to 150 rpm	≤ 20: 1 > 20: 5
RR Low	RR $\leq$ 20 rpm: 0 to (high limit – 2) rpm RR >20 rpm: 20 to (high limit – 5) rpm	

## A.6.6.1 RR from Mindray CO<sub>2</sub> Module

Measurement range	0 to 150 rpm
Measurement precision	<60 rpm: ±1 rpm 60 to 150 rpm: ±2 rpm
Resolution	1 rpm

### A.6.6.2 RR from Mindray SpO<sub>2</sub> Module

Measurement range	4 to 70 rpm
Measurement precision	Arms: ≤ 3rpm, mean difference [-1,1] rpm
Resolution	1 rpm
Time for first measurement	≤ 30 s
Refreshing rate	≤1 s

# A.7 Operating Environment

Host CPU	AM3358
Primary programming language	C++
Operating system	Linux 3.2.0

# **B** EMC and Radio Regulatory Compliance

### B.1 EMC

The device meets the requirements of IEC 60601-1-2: 2014.

#### **NOTE**

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.
- The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.
- Use of this device adjacent to or stacked with other device should be avoided because it could result in improper operation. If such use is necessary, this device and the other device should be observed to verify that they are operating normally.
- This device is intended for use in professional healthcare facility EMC environment. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.
- 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 this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

#### **Guidance and Declaration - Electromagnetic Emissions**

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

Emission tests	Compliance	Electromagnetic environment – guidance
Conducted and radiated RF EMISSIONS CISPR 11	Group 1	The device 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 device.
Conducted and radiated RF EMISSIONS CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic distortion IEC 61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly
Voltage fluctuations and flicker IEC 61000-3-3	Complies	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

If the device is operated within the electromagnetic environment listed in Table **Guidance and Declaration** — **Electromagnetic Immunity**, the system will remain safe and provide the following essential performance,

- Operating mode
- Accuracy
- Function
- Accessories identification
- Data stored
- Alarm
- Detect for connection

#### NOTE

- If the essential performance is lost or degraded, it may be necessary to take
  mitigation measures, such as re-orienting or relocating the ME EQUIPMENT
  or ME SYSTEM or shielding the location or stopping using the monitor and
  contact the service personnel.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in appendix B.
- Other devices may affect this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- The EMISSIONS characteristics of this device 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) this device 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 device.

#### **Guidance and Declaration - Electromagnetic Immunity**

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

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines (length greater than 3 m)	±2 kV for power supply lines ±1 kV for input/ output lines (length greater than 3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	

RATED power 30 A/m 30 A/m Power frequency magnetic frequency 50 Hz/60 Hz 50 Hz/60 Hz fields should be at levels	Voltage dips and Voltage interruptions IEC 61000-4-11	0% U <sub>T</sub> for 0.5 cycle 0% U <sub>T</sub> for 1 cycle and 70% U <sub>T</sub> for 25/ 30 cycles 0% U <sub>T</sub> for 250/300 cycles	0% U <sub>T</sub> for 0.5 cycle 0% U <sub>T</sub> for 1 cycle and 70% U <sub>T</sub> for 25/ 30 cycles 0% U <sub>T</sub> for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
magnetic fields characteristic of a typical location in a typical commercial or hospital environment.	frequency magnetic fields			fields should be at levels characteristic of a typical location in a typical commercial or hospital

Note: U<sub>T</sub> is the AC mains voltage prior to application of the test level.

#### **Guidance and Declaration - Electromagnetic Immunity**

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

Immunity test	IEC60601 test level	Complia nce level	Electromagnetic environment – guidance
Conducted disturbanc es induced by RF fields	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated
IEC61000- 4-6	6 Vrms in ISM bands and amateur radio bandsa between 0,15 MHz and 80 MHz	6 Vrms	from the equation applicable to the frequency of the transmitter. Recommended separation distance:  150k to 80 MHz $d = \left[\frac{3.5}{V}\right]\sqrt{P}$ 80 MHz to 80 0MHz
Radiated RF EM fields IEC61000- 4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	$d = \left[\frac{3.5}{E}\right] \sqrt{P}$ $800 \text{ MHz to 2.7GHz}$ $d = \left[\frac{7}{E}\right] \sqrt{P}$
Proximity fields from RF wireless communic	27 V/m 380–390 MHz	27 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the
ations equipment IEC61000- 4-3	28 V/m 430–470 MHz, 800– 960 MHz, 1700–1990 MHz, 2400– 2570 MHz	28 V/m	recommended separation distance in meters (m).  Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>b</sup> , should be less than the compliance level in each frequency range <sup>c</sup> .  Interference may occur in the vicinity of equipment marked with the following
	9 V/m 704–787 MHz, 5100– 5800 MHz	9 V/m	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> The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The

amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50.0 MHz to 54.0 MHz.

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

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

#### WARNING

 The device is configured with a wireless network connector to receive wireless signal. Other devices may interfere with this device even though they meet the requirements of CISPR.

#### Recommended Separation Distances between Portable and Mobile RF, Communications Equipment and This Equipment

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

Rated Maximum Output power of	Separation Distance According to Frequency of Transmitter (m)		
Transmitter Watts (W)	150 kHz to 80 MHz $d = \left[\frac{3.5}{V}\right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E}\right] \sqrt{P}$	800 MHz to 2.7 GHz $d = \begin{bmatrix} \frac{7}{E} \end{bmatrix} \sqrt{P}$
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
100	' <i>-</i>	' <i>-</i>	23

For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 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.

# **B.2** Radio Regulatory Compliance

# CE

The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any

interference received, including interference that may cause undesired operation.

Any changes or modifications to this equipment not expressly approved by Mindray may cause harmful radio frequency interference and void your authority to operate this equipment.

The maximum antenna gain permitted complies with the e.i.r.p. limits as stated in RSS-210.

The maximum antenna gain permitted complies with the e.i.r.p. limits specified for point-to-point operation, as stated in RSS-210.

#### WARNING

 Changes or modifications not expressly approved by the party responsible compliance could void the user's authority to operate the equipment. This page intentionally left blank.

# C Default Settings

# **C.1** Parameters Default Settings

# C.1.1 SpO2 Default Settings

Item	ltem		Default Setting
Alarm	SpO2	On/Off	On
		High	Adult and pediatric: 100% Neonate: 95%
		Low	90%
		Priority	Med
	SpO2 Desat	On/Off	On
		Low	80%
		Priority	High
	NIBP Simul		Off
Setup	Sat-Seconds (for Nellcor SpO <sub>2</sub> )		Off
	Sensitivity (for Mindray SpO <sub>2</sub> )		Med
	Sensitivity (for Masimo SpO <sub>2</sub> )  Averaging (for Masimo SpO <sub>2</sub> )  Display PI (for Mindray SpO <sub>2</sub> , Masimo SpO <sub>2</sub> )		APOD
			8 s
			On
	Speed		25 mm/sec

### C.1.2 PR

Item		Default Setting	
PR Alarm	PR	On/Off	On
		High	Adult: 120 Pediatric: 160 Neonate: 200
		Low	Adult: 50 Pediatric: 75 Neonate: 100
		Priority	Med
PR Setup	Pulse Volume		2

# C.1.3 Temp Default Settings (SmarTemp)

Item			Default Setting
Alarm	Temp	On/Off	Off
		High	38.0 °C
		Low	35.0 °C
		Priority	Med

# C.1.4 NIBP Default Settings

Item			Default Setting
Alarm	NIBP-S	On/Off	On
		High	Adult: 160 mmHg Pediatric: 120 mmHg Neonate: 90 mmHg
	Low	Adult: 90 mmHg Pediatric: 70 mmHg Neonate: 40 mmHg	
		Priority	Med

Item			Default Setting
Alarm	NIBP-D	On/Off	On
		High	Adult: 90 mmHg Pediatric: 70 mmHg Neonate: 60 mmHg
		Low	Adult: 50 mmHg Pediatric: 40 mmHg Neonate: 20 mmHg
		Priority	Med
	NIBP-M	On/Off	On
		High	Adult: 110 mmHg Pediatric: 90 mmHg Neonate: 70 mmHg
		Low	Adult: 60 mmHg Pediatric: 50 mmHg Neonate: 25 mmHg
		Priority	Med
	NIBP-S Extreme	On/Off	Off
		High	Adult: 175 mmHg Pediatric: 130 mmHg Neonate: 95 mmHg
		Low	Adult: 75 mmHg Pediatric: 60 mmHg Neonate: 35 mmHg
		Priority	High
	NIBP-D Extreme	On/Off	Off
		High	Adult: 105 mmHg Pediatric: 80 mmHg Neonate: 65 mmHg
		Low	Adult: 35 mmHg Pediatric: 30 mmHg Neonate: 15 mmHg
		Priority	High

Item			Default Setting
Alarm NIBP-M	On/Off	Off	
	Extreme	High	Adult: 125 mmHg Pediatric: 100 mmHg Neonate: 75 mmHg
		Low	Adult: 45 mmHg Pediatric: 40 mmHg Neonate: 20 mmHg
		Priority	High
Setup	Initial Pressure		Adult: 160 mmHg Pediatric: 140 mmHg Neonate: 90 mmHg
	Interval		Sequence
	Start Mode		Clock
	NIBP End Tone		Off
	Venipuncture Pressure		Auto
	Display Format		Sys/Dia(Mean)
Display Alarm L		nits	Off
	Patient Position		Lying
	Measurement Site	2	Unspecified
Sequence	Phase A	Duration	1 hr
		Interval	5 min
	Phase B	Duration	4 hrs
		Interval	15 min
	Phase C	Duration	4 hrs
		Interval	30 min
	Phase D	Duration	Continuous
		Interval	1 hr
	Phase E	Duration	Off
		Interval	1 hr

# C.1.5 CO<sub>2</sub> Default Settings

Item			Default Setting
Alarm	RR	On/Off	On
		High	Adult and pediatric: 30 rpm Neonate: 100 rpm
		Low	Adult and pediatric: 8 rpm Neonate: 30 rpm
		Priority	Med
	Apnea	On/Off	On (Locked)
		Priority	High
	EtCO <sub>2</sub>	On/Off	On
		High	Adult and pediatric: 50 mmHg Neonate: 45 mmHg
		Low	Adult and pediatric: 25mmHg Neonate: 30 mmHg
		Priority	Med
	FiCO <sub>2</sub>	On/Off	On
		High	4 mmHg
		Priority	Med
	Apnea Delay		Adult and pediatric: 20 sec Neonate: 15 sec
Setup	Operating Mode  Auto Standby  BTPS Compensation  O2 Compensation		Measure
			60 min
			Off
			21%
	N2O Compensa	ation	0%

Item		Default Setting
Setup	AG Compensation	0%
	Speed	6.25 mm/sec
	CO2 Scale	50 mmHg
	Waveform Type	Draw

## C.1.6 EWS Default Settings

Item			Default Setting
EWS	Score		NEWS2
	Score Confirmation		On
	Auto Scoring	1	Off
		Interval	By Score
			4 hrs (Score: 0)
			2 hrs (Score: 1~4)
			1 hr (Score: 5~6)
			30 min (Score: 7~20)
	Manual Data Timeout	SpO2	4 hrs
	rimeout	Supp. O2	24 hrs
		PR	1 hr
		LOC	24 hrs

Item			Default Setting
Alarm	Auto Refresh Scores		On
	Alarm		Off
	EWS Score	Priority	Med
		On/Off	On
		High	5
		Priority	High
		On/Off	On
		High	7
Alarm	3 in single	RR	Off, Med
par	parameter	SpO2	Off, Med
		BP-S	Off, Med
		PR	Off, Med
		Temp	Off, Med

# **C.2** Routine Default Settings

#### C.2.1 Alarm Default Settings

Item	Default Setting
Alarm Volume	2
High Alarm Volume	Alarm Volume+3
Reminder Volume	2
Apnea Delay	Adult and pediatric: 20 sec Neonate: 15 sec

#### **C.2.2** Parameter Color Default Settings

Item	Default Setting
SpO2	Cyan

Item	Default Setting
NIBP	White
Temp	White
RR	Yellow
CO2	Yellow

## C.2.3 Display Default Settings

Item	Default Setting
Screen Lock Duration	10 sec
Brightness	5
Brightness On Battery	5

### C.2.4 Volume Default Settings

Item	Default Setting
Alarm Volume	2
High Alarm Volume	Alarm Volume+3
Reminder Volume	2
Key Volume	2

### C.2.5 Record Setup

Item	Default Setting
Waveform 1	Off
Waveform 2	Off
Recording Duration	8 sec
Recorder Paper Speed	25 mm/sec

## **C.2.6** System Time Default Settings

Item	Default Setting
Date Format	yyyy-mm-dd
24-Hour Time	On
Daylight Savings Time	Off

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# **D** Alarm Messages

This chapter lists only the physiological and technical alarm messages. Some messages appearing on your monitor may not be included. In the "Cause and solution" column, corresponding solutions are given instructing you to troubleshoot problems. If the problem persists, contact your service personnel.

#### D.1 Physiological Alarm Messages

#### D.1.1 General Physiological Alarm Messages

Alarm messages	Default priority	Cause and solution
XX High	Med	XX value has risen above the high alarm limit or fallen
XX Low	Med	below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct.

**Note:**XX represents a measurement or parameter label, such as NIBP, RR, SpO<sub>2</sub>, CO<sub>2</sub>, PR, and so on.

#### D.1.2 SpO<sub>2</sub> Physiological Alarm Messages

Alarm message	Default priority	Cause and solution
SpO2 Desat	High	The SpO <sub>2</sub> value falls below the desaturation alarm limit. Check the patient's condition and check if the alarm limit settings are correct.

#### D.1.3 PR Physiological Alarm Messages

Alarm message	Default priority	Cause and solution
No Pulse	High	The pulse signal was so weak that the monitor cannot perform pulse analysis. Check the patient's condition, SpO <sub>2</sub> sensor and measurement site.

#### D.1.4 NIBP Physiological Alarm Messages

Alarm message	Default priority	Cause and solution
NIBP-S Extremely High/NIBP-D Extremely High/ NIBP-M Extremely High	High	The NIBP value is higher than the NIBP Extreme alarm high limit. Check the patient's condition and check if the alarm limit settings are correct.
NIBP-S Extremely Low/NIBP-D Extremely Low/ NIBP-M Extremely Low	High	The NIBP value is lower than the NIBP Extreme alarm low limit. Check the patient's condition and check if the alarm limit settings are correct.

#### D.1.5 EWS Physiological Alarm Messages

Alarm message	Default priority	Cause and solution
EWS Score > N	High/ Mediate	The total score exceeds the configured alarm limit. Check the patient condition.
XX score = 3	Mediate	The parameter score is 3. Check the patient condition.

**Note:**N represents a numeric. XX represents RR, SpO<sub>2</sub>, BP-S, BP-D, BP-M, PR, Temp, EtCO<sub>2</sub>.

## D.2 Technical Alarm Messages

This section lists technical alarms, their default priority, indication on alarm reset, and the actions that can be taken when an alarm occurs.

Technical alarms give different alarm indicators when the alarm system is reset. In this section we classify the technical alarms into three categories for easy clarification:

- A: technical alarms are cleared. The monitor gives no alarm indications.
- B: technical alarms are changed to the prompt messages.
- $\blacksquare$  C: the alarm is silenced and a  $\sqrt{}$  appears before the alarm message, indicating that the alarm is acknowledged.

In the following tables we will use A, B, and C to refer to the indications on alarm reset.

#### **D.2.1** General Technical Alarm Messages

Alarm message	Default priority	Indication on alarm reset	Cause and solution
XX Module Error	High	С	XX module does not work properly. Contact your service personnel.

 $\textbf{Note:} XX \ represents \ a \ measurement \ or \ parameter \ label, such \ as \ SpO_2, \ NIBP, CO_2, \ and \ so \ on.$ 

## D.2.2 SpO<sub>2</sub> Technical Alarm Messages

Alarm message	Default priority	Indication on alarm reset	Cause and solution
SpO2 Sensor Off	Low	В	The SpO <sub>2</sub> sensor has become detached from the patient or the module. Check the sensor connection. If the alarm persists, replace the sensor.
SpO2 No Sensor	Low	A	The SpO <sub>2</sub> extension cable is detached from the SpO <sub>2</sub> module, or the SpO <sub>2</sub> sensor is detached from the SpO <sub>2</sub> extension cable. Check the SpO <sub>2</sub> cable and the sensor connection. If the alarm persists, replace the sensor.
SpO2 Excess Light	Low	С	Ambient light is too strong. Move the sensor to a place with lower level of ambient light or cover the sensor to minimize the ambient light.
SpO2 No Pulse	Low	С	The SpO <sub>2</sub> sensor failed to obtain pulse signal. Check the patient's condition and replace the sensor application site. If the alarm persists, replace the sensor.
SpO2 Sensor Incompatible	Low	С	Incompatible or an unspecified SpO <sub>2</sub> sensor is used. Use specified sensors.

Alarm message	Default priority	Indication on alarm reset	Cause and solution
SpO2 Low Signal Quality	Low	С	1. Check the sensor and sensor position. 2. Make sure the patient is not shivering or moving. 3. The patient's pulse may be too low to be measured.
SpO2 Interference	Low	С	The SpO <sub>2</sub> signal has been interfered. Check for any possible sources of signal noise and check the patient for excessive motion.
SpO2 Sensor Error	Low	С	Replace the sensor and measure again.
SpO2 Searching Pulse	Prompt	/	SpO <sub>2</sub> is searching for pulse.
SpO2 Low Perfusion	Prompt	/	The SpO <sub>2</sub> sensor is not properly placed or the patient's perfusion index is too low.  1. Check the sensor and sensor position.  2. Reposition the sensor if necessary.
Replace SpO2 Cable	Low	С	The SpO <sub>2</sub> cable expired, cannot be recognized, or failed. Replace the SpO <sub>2</sub> cable.
	Prompt		The SpO <sub>2</sub> cable is about to expire. Replace the SpO <sub>2</sub> cable.
Incompatible SpO2 Cable	Low	С	The SpO <sub>2</sub> cable connected is not compatible with the equipment. Replace the SpO <sub>2</sub> cable.
Replace SpO2 Sensor	Low	С	The ${\rm SpO}_2$ sensor expired. Replace the ${\rm SpO}_2$ sensor.
	Prompt		The SpO <sub>2</sub> sensor is about to expire. Replace the SpO <sub>2</sub> sensor.
Check SpO2 Sensor Connection	Low	С	No $SpO_2$ sensor is connected. Connect an $SpO_2$ sensor.

Alarm message	Default priority	Indication on alarm reset	Cause and solution
SpO2 No Cable Connected	Low	С	No $SpO_2$ cable is connected. Connect an $SpO_2$ cable.

### **D.2.3** Temp Technical Alarm Messages

Alarm message	Default priority	Indication on alarm reset	Cause and solution
Cannot Take Neonatal Rectal Temp (for SmarTemp)	High	В	Rectal measurement is not applicable for neonatal patient. Select another site.
Temp No Probe (for SmarTemp)	Med	В	The Temp probe is disconnected or damaged. Reconnect the probe. If the problem persists, change for another probe.
Temp Probe Misplaced (for SmarTemp™)	Med	А	The measured value is invalid. Replace the probe and check the value.
Temp Measuring Timeout (for SmarTemp™)	Med	В	The measurement has exceeded regular measurement time. Try another measurement.
Ambient Temp Overrange (for SmarTemp™)	Low	A	The ambient temperature is too low.  Move the patient to a warmer place and take temperature measurement again if necessary.
Temp Overrange (for SmarTemp™)	Low	С	The temperature measurement exceeds the measurement range. Check the patient's condition.
Thermal Resistor Err (for SmarTemp™)	Med	С	The Temp module may fail. Take temperature measurement again. If the alarm persists, contact your service personnel.
TempIF Thermometer Error (for Genius™ 3)	High	С	The thermometer may fail. Take temperature measurement again. If the alarm persists, replace the thermometer.

Alarm message	Default priority	Indication on alarm reset	Cause and solution
TempIF Ambient Temp High (for Genius™ 3)	Low	С	The ambient temperature is too high. Move the patient to a cooler place and take temperature measurement again if necessary.
TempIF Ambient Temp Low (for Genius™ 3)	Low	С	The ambient temperature is too low. Move the patient to a warmer place and take temperature measurement again if necessary.
TempIF Overrange (for Genius™ 3)	Low	С	The temperature measurement exceeds the measurement range. Check the patient's condition.
Ambient Temp Overrange (for HeTaiDa)	Prompt	/	The ambient temperature is out of the specified range. Move the patient to a place where the temperature is within in the specified range and take temperature measurement again if necessary.
Ambient Temp Unstable (for HeTaiDa)	Prompt	/	The ambient temperature changes greatly. Move the patient to a place of stable temperature and take temperature measurement again if necessary.
Measurement Mode Unsupported (for HeTaiDa)	Prompt	/	Change the measurement mode of the thermometer to forehead.

## **D.2.4** NIBP Technical Alarm Messages

Alarm message	Default priority	Indication on alarm reset	Cause and solution
NIBP Cuff Loose	Low	A	There is a leak in the cuff or air tubing. Use a cuff of correct type based on the patient size. Apply the cuff and connect the air tubing as instructed in the manual.

Alarm message	Default priority	Indication on alarm reset	Cause and solution
NIBP Timeout	Low	A	The measurement time exceeds 120 seconds in the adult or pediatric mode, or exceeds 90 seconds in the neonatal mode, and the BP value cannot be obtained. Check the patient's condition and NIBP connections, or replace the cuff and measure again.
NIBP Cuff or Airway Leak	Low	A	Check the NIBP cuff and pump for leakages.
NIBP Airway Leak	Low	А	Airway leakage is found during the NIBP leakage test. Check the NIBP cuff and pump for leakages.
NIBP Airway Error	Low	A	The air tubing may be occluded. Check the air tubing for an occlusion or kinking. If the alarm persists, contact your service personnel.
NIBP Weak Signal	Low	A	The patient's pulse is weak or the cuff is loose. Check the patient's condition and replace the cuff application site.
NIBP Excessive Motion	Low	А	Check the patient's condition and reduce patient motion.
NIBP Cuff and Patient Mismatch	Low	A	The cuff type mismatches the patient category. Verify the patient category or replace the cuff if necessary. If patient category is correct, check that the tubing is not bent and the airway is not occluded.
NIBP Cuff Overpressure	Low	A	The NIBP airway may be occluded. Check the airway and measure again. If the alarm persists, contact your service personnel.
NIBP Overrange	Low	А	The measured NIBP value exceeds the module measurement range. Check the patient's condition.

## D.2.5 CO<sub>2</sub> Technical Alarm Messages

Alarm message	Default priority	Indication on alarm reset	Cause and solution
CO2 Module High Temp	Low	С	Ambient temperature is too high or there is a module failure.  1. Lower the operating temperature.  2. If the alarm persists, the CO <sub>2</sub> module may fail, contact your service personnel.
CO2 Zero Failed	Low	С	Try to zero the module again. If the alarm persists, contact your service personnel.
CO2 Airway Occluded	Low	С	Check if the sample line is kinked or occluded.     Replace the sample line.     If the alarm persists, contact your service personnel.
XX Overrange	Low	С	The measured value exceeds the module measurement range. Check the patient's condition.
CO2 No Adaptor	Low	В	Check the adaptor connection.

#### D.2.6 EWS Technical Alarms

Alarm message	Default priority	Indication on alarm reset	Cause and solution
EWS param XX is timeout	Low	A	The manually input parameter is timeout. Input a parameter numeric again.
EWS score needs to be confirmed	Low	A	Confirm to save or give up current score.

Note: XX represents RR, SpO2, Supp. O2, Temp, BP, Consciousness, Blood Sugar etc.

## **D.2.7** Power Supply Technical Alarm Messages

Alarm message	Default priority	Indication on alarm reset	Cause and solution	
Low Battery	Med	С	Connect the monitor to an AC power source and allow the batteries to charge.	
Critically Low Battery	High	С	Connect the monitor to an AC power source and allow the batteries to charge.	
Battery Service Required	Low	В	The battery reaches its lifetime. Replace the battery.	
Power Board Comm Error	High	С	Restart the monitor. If the alarm persists, contact your service personnel.	
Battery Error	High	С	The battery may fail. Contact your service personnel.	
Battery Charging Error	High	С	The charging circuit fails or the battery fails. Contact your service personnel.	
Battery Temperature Too High	High	С	Stop using the monitor after this alarm appears, and contact your service personnel.	
Battery Off	High	С	Restart the monitor. If the alarm persists, contact your service personnel.	
RT Clock Need Reset	High	С	Contact your service personnel.	
RT Clock Not Exist	High	С	Contact your service personnel.	

# D.2.8 Technical Alarm Messages Related to Networked Monitoring

Alarm message	Default priority	Indication on alarm reset	Cause and solution
CMS/eGW Disconnected	Low	В	The monitor is disconnected from the CMS/eGateway. Check the network connection.
WLAN IP Address Conflict	Low	С	Wireless network IP network conflicts. Check the network settings.
LAN1 IP Address Conflict	Low	С	Wired network LAN1 IP network conflicts. Check the network settings.
Fail To Get WLAN IP Address	Low	С	Unable to automatically obtain the wireless network IP address. Check the network settings.
Fail To Get LAN1 IP Address	Low	С	Unable to automatically obtain the wired network LAN1 IP address. Check the network settings.

### **D.2.9** Other System Technical Alarm Messages

Alarm message	Default priority	Indication on alarm reset	Cause and solution
Storage Error	High	С	The storage card fails or files are damaged. Restart the monitor to format the storage card. If the alarm persists, contact your service personnel.
The patient data storage space is nearly full. Please delete some discharged patients.	Med	В	Delete unnecessary earlier discharged patient.

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# E Abbreviations

AAMI Association for Advancement of Medical Instrumentation

AC alternating current

ADT Admit/Discharge/Transfer

Adu adult

AVPU Alert, Reacting to Voice, Reacting to Pain, and Unresponsive

CE Conformité Européenne

CISPR International Special Committee on Radio Interference

CMOS complementary metal oxide semiconductor

CMS central monitoring system

COPD Chronic Obstructive Pulmonary Disease

DC direct current
Dia diastolic
DPI dot per inch

EEC European Economic Community
EMC electromagnetic compatibility
EMI electromagnetic interference
EMR Electronic Medical Record
GCS Glasgow Coma Scale
IABP intra-aortic balloon pump

ID identification

I:E inspiratory time: expiratory time ratio

IEC International Electrotechnical Commission

ISO International organization for standardization

IEEE Institute of Electrical and Electronic Engineers

IP internet protocol

IPS Individual Parameter Score

LED light emitting diode
MDD Medical Device Directive

MetHb methemoglobin

MEWS Modified Early Warning Score

MRI magnetic resonance imaging

N/A not applied Neo neonate

NEWS National Early Warning Score
NIBP noninvasive blood pressure

NIBP-D NIBP-diastolic pressure

NIBP-M NIBP-mean pressure

NIBP-S NIBP-systolic pressure

P power

PD photodetector

Ped pediatric

Pleth plethysmogram

PR pulse rate

RAM random access memory
ROM read-only memory

SpO<sub>2</sub> arterial oxygen saturation from pulse oximetry

TD temperature difference

TEMP temperature

F

# **Declaration of Conformity**

Declaration of Conformity V1.0

# CE

#### **Declaration of Conformity**

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Mindray Building, Keji 12th Road South, Hi-tech Industrial

Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80

20537 Hamburg, Germany

Product: Vital Signs Monitor (Including Accessories)

Model: VS 8/VS 8A/VS 8C/VS 8 Neo/VS 9/VS 9A/VS 9C/VS 9 Neo

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2014/53/EU concerning radio equipment. All supporting documentation is retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer. Standards Applied:

⊠ EN 60601-1:2006/A1:2013	⊠ EN 60601-1-2:2015
☑ EN IEC 62311:2019	⊠ EN 301 489-1 V2.2.0
⊠ EN 301 489-17 V3.1.1	⊠ EN 301 893 V2.1.1
⊠ EN 300 328 V2.1.1	

Start of CE-Marking: 2020-12-21

Place, Date of Issue: Shenzhen, Solo 12.

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

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