

DPMTM | 2

Pulse Oximeter

Operator's Manual

mindray

Revision History

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

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- Release time: 2012-12

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WARNING

- **Federal Law (USA) restricts this device to sale by or on the order of a physician.**
-

FOR YOUR NOTES

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Manufacturer:	Mindray DS USA, Inc.
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Tel:	1.800.288.2121, 1.201.995.8000
Website:	www.mindray.com

FOR YOUR NOTES

Preface

Manual Purpose

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

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

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

Intended Audience

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

Illustrations

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

Password

Password is required to access maintenance. The password is 321.

Conventions

- *Italic* text is used in this manual to quote the referenced chapters or sections.
- [] is used to enclose screen texts.
- → is used to indicate operational procedures.

FOR YOUR NOTES

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FOR YOUR NOTES

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

WARNINGS

- **Before putting the system into operation, verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
 - **To avoid explosion hazard, do not use the equipment in the presence of flammable anesthetics, vapors or liquids.**
 - **Do not open the equipment housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**
 - **When using the equipment with electrosurgical units (ESU), make sure the patient is safe.**
 - **Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.**
 - **Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**
 - **The physiological data and alarm messages displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.**
 - **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patients or personnel.**
-

1.1.2 Cautions

CAUTIONS






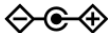











- To ensure patient safety, use only parts and accessories specified in this manual.
 - At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the equipment, please contact us.
 - 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.
 - 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.
 - Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.
-

1.1.3 Notes

NOTES



- Put the equipment in a location where you can easily see the screen and access the operating controls.
 - Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.
 - The software was developed in compliance with IEC60601-1-4. 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.
-

1.2 Equipment Symbols

	Direct Current (DC)
	Attention: Consult accompanying documents (this manual).
	Auxiliary output connector
	Audio pause
	Battery door locked/unlocked
	Power supply connector
	Left/Right button
	Power button
	Up button
	Down button
	Date of manufacture
	Manufacturer
	European community representative
	Serial number
	Safety Class II equipment
	Type BF applied part, defibrillation protected
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only.

The machine has only one of the certification labels below.

Please refer to the label attached to the machine to determine the applicable certification label.

	The presence of this label indicates the machine was certified by ETL with the statement: CONFORMS TO UL STD 60601-1 CERTIFIED TO CSA STD C22.2 NO 601.1
	Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards, only in accordance with UL 60601-1, CAN/CSA C22.2 NO.601-1, IEC 60601-1-1.

2 The Basics

2.1 Introduction

2.1.1 Intended Use

The handheld pulse oximeter is intended for continuous monitoring, spot checking of functional pulse oxygen saturation(SpO₂) and pulse rate(PR) of single adult, pediatric and neonatal patients in hospitals, out-of-hospital transport and home care.

WARNING

- **This pulse oximeter is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.**
-

2.1.2 Contraindications

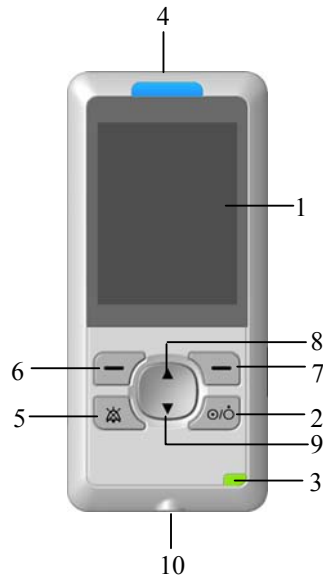
None.

2.1.3 Components

This pulse oximeter consists of a main unit and an SpO₂ sensor.

2.2 Main Unit

2.2.1 Front View



1. Display screen

2. Power button

- Press this button to turn the pulse oximeter on after the batteries are installed.

- Press and hold it for 2 seconds to turn the pulse oximeter off.

3. Power indicating lamp

It is a LED that lights green and yellow. The status of the LED is specified as follows:

- Green: when the pulse oximeter is placed in the Charger stand and the AC mains is connected, or when the battery is fully charged if a lithium battery is used.

- Yellow: when a lithium ion battery is used and is being charged.

- Off: When the AC mains is not connected.

4. Alarm indicating lamp

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

- High level alarms: the lamp quickly flashes red.

- Medium level alarms: the lamp slowly flashes yellow.

- Low level alarms: the lamp lights yellow without flashing.

5. Press this button to pause or reactivate the alarm sound.

6. Left button

Press this button to enter the main menu or select the highlighted menu item.

7. Right button

Press this button to return to the previous menu or exit the current menu. In the case that no menu is opened, you can press and hold this button for 2 seconds to lock or unlock buttons except the Power button.

8. Up button

Press this button to move the cursor upwards, increase the value of selected menu item or raise the beat volume.

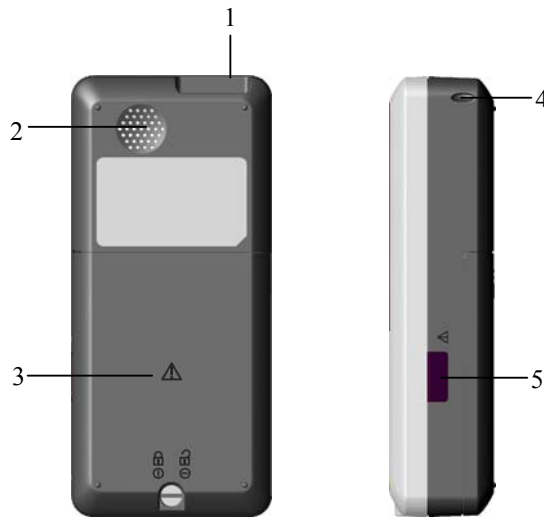
9. Down button

Press this button to move the cursor downwards, decrease the value of selected menu item or lower the beat volume.

10. Power supply connector

It is used to connect the Charger stand.

2.2.2 Rear View and Right View



1. Multifunctional connector

It is used to connect an SpO₂ sensor to measure the oxygen saturation or connect a personal computer through a PC communication cable to export the trend data.

2. Speaker

3. Battery door

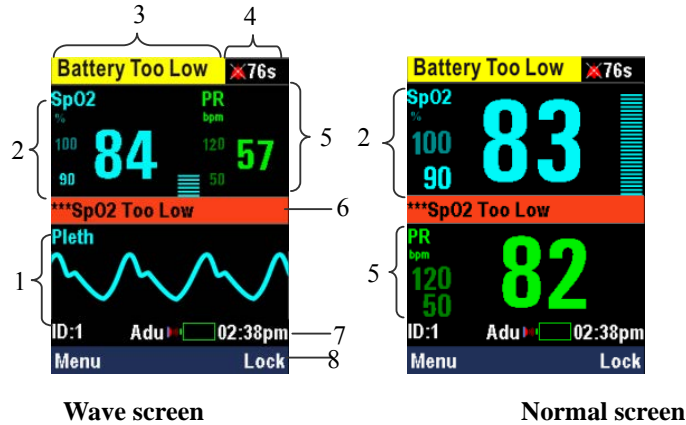
4. Cord hole



5. Infrared port

It is a port through which a personal computer is communicated to export data in real time.

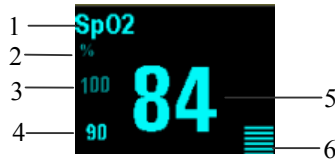
2.3 Display Views

The following figures show the layout of the wave screen and the normal screen.



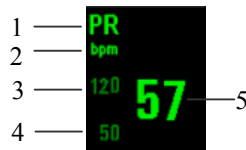
1. Waveform Area
This area displays Pleth waveform (Pleth). The label of this waveform is shown at the top left corner.
2. SpO₂ area
3. Technical alarm area
This area shows the technical alarm message, prompt message and the pulse oximeter's operating mode. When multiple messages come, they will be displayed circularly.
4. Alarm status area
 indicates that alarm sounds are paused;
 indicates that alarm sounds are turned off.
5. PR area
6. Physiological alarm area
This area shows physiological alarm messages. When multiple alarms come, they will be displayed circularly.
7. Information area
8. QuickKeys area
This area contains QuickKeys that give you fast access to functions.

2.3.1 SpO₂ Area



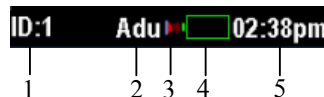
1. SpO₂ label
2. SpO₂ unit
3. SpO₂ high alarm limit
4. SpO₂ low alarm limit
5. Oxygen saturation reading
6. Pleth bar

2.3.2 PR Area



1. PR label
2. PR unit
3. PR high alarm limit
4. PR low alarm limit
5. Pulse rate reading

2.3.3 Information Area



1. Patient ID
2. Patient category
Patients are classified into three categories: adults, pediatrics and neonates.
3. Real-time data exporting symbol
This symbol appears when data is being exported in real-time through the infrared port.
4. Battery symbol
5. Real-time clock

FOR YOUR NOTES

3 Getting Started

3.1 Unpacking and Checking

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

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

NOTE

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

WARNING

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

3.2 Environmental Requirements

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

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.

WARNING

- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise the equipment may not meet the specifications claimed in this manual and unexpected consequences, e.g. damage to the equipment, could result.**
-

3.3 Starting the Pulse oximeter

1. Before use, check the pulse oximeter for mechanical damage.
2. Install the alkaline batteries or the lithium ion battery and ensure that the batteries have sufficient power.
3. Plug the SpO₂ extension cable into the multifunctional connector.
4. Press the Power button. The alarm indicating lamp flashes, and then goes out. The system gives a beep and displays the startup screen.
5. The startup screen disappears and the pulse oximeter enters the main screen.

NOTE

-
- **If the pulse oximeter has not used for a prolonged time, a technical alarm [Clock Need Set] may occurs when the pulse oximeter is started. In this case, set the clock. In the continuous monitoring mode, changing the clock may clear the trend data of this mode.**
-

WARNING

- **Do not use the pulse oximeter for patient monitoring if it is mechanically damaged or appears abnormal. Contact your service personnel or us.**
-

3.4 Shutting Off the Pulse oximeter

To shut off the pulse oximeter,

1. Confirm that the patient monitoring is finished.
2. Disconnect the SpO₂ extension cable from the pulse oximeter.
3. Press and hold the Power button for 2 seconds.

4 Basic Operations

4.1 Selecting the Work Mode

The pulse oximeter is designed to operate in the continuous monitoring and spot-checking mode. The continuous monitoring mode is intended for long-term monitoring. This mode is normally selected when the patient is in hospital or under transport. The spot-checking mode is intended for short-term on-site measurement. This mode is normally selected to check outpatient or to check inpatient when doctors make rounds of the wards.

To select the work mode,

1. Select [Menu]→[System]→[Maintenance >>]→enter required password.
2. Select [User Maintenance >>] and then select [Work Mode] to toggle between [Spot-Check] and [Continuous]. Press the Right button and follow the prompt.

The work mode is shown in the technical alarm area. When other technical alarms or prompt messages occur, the work mode and the message will be displayed circularly.

NOTE

- **The trend data of the continuous monitoring mode will be cleared if you change the continuous monitoring mode to the spot-checking mode.**
-

4.2 Admitting a Patient

WARNING

- **Be sure to select correct patient category setting for your patient before measurement. Wrong patient category may result in patient hazard due to improper alarm limits.**
-

4.2.1 Continuous Monitoring Mode

In the continuous monitoring mode, to admit a patient,

1. Select [**Menu**]→[**Patient Info.**].
2. Set up [**Patient ID**] and [**Patient Cat.**].
3. Press the Left button to confirm the settings.

If you do not change the patient ID for a new patient, the patient will not be admitted.

4.2.2 Spot-checking Mode

In the spot-checking mode, to admit a patient,

1. Select [**Menu**]→[**Patient Info.**].
2. Select [**Patient Cat.**] and toggle between [**Adu**], [**Ped**] and [**Neo**].
3. Apply the SpO₂ sensor to the patient. After valid SpO₂ signals are detected,
 - The patient ID automatically changes to 1 if the current patient ID is 0. Thus the patient is admitted.
 - The patient ID flashes and automatically increases by 1 after 8 seconds if the current patient ID is not 0. Thus the patient is admitted.

If you press the Left button when the current patient ID is flashing, the patient ID will stop flashing and remain unchanged. The patient will not be admitted and new measurements will be stored under the current patient ID.

4.3 Selecting the Screen

To select a screen to be viewed,

1. Select [**Menu**]→[**System**].
2. Select [**Screen**] and toggle between [**Normal**] and [**Wave**].

4.4 Adjust the Screen Brightness

To adjust the screen brightness,

1. Select [**Menu**]→[**General Setup**].
2. Adjust [**Brightness**]: You can set the screen brightness to a value between 1 and 10. 1 is the minimum brightness and 10 the maximum. If the pulse oximeter runs on batteries, choose a lower level brightness to save the power.

NOTE

- **If the pulse oximeter is used outdoors or the ambient light is strong, set the screen brightness to a higher level.**
-

4.5 Changing the Language

To change the pulse oximeter's operating language,

1. Select [Menu]→[System]→[Maintenance >>]→enter the required password.
2. In the [User Maintenance >>] menu, select [Language] and then choose a desired language.
3. Restart the pulse oximeter.

4.6 Setting the Clock

To set the clock,

1. Select [Menu]→[System]→[Clock >>].
2. Set [Date] and [Time].
3. Select [Format >>]. In the [Format] menu,
 - Set [Date Format] to [yyyy-mm-dd], [mm-dd-yyyy] or [dd-mm-yyyy].
 - Set [Time Format] to [24 h] or [12 h].
4. Press the Right button to return to the previous menu in the spot-checking mode, or press the Right button and follow the prompt in the continuous monitoring mode.


NOTE

- **In the continuous monitoring mode, trend data of this mode may be cleared if you change the clock.**
-

4.7 Adjusting the Volume

4.7.1 Setting the Beat Volume

To set the beat volume,

1. Select [**Menu**]→[**General Setup**].
2. Set [**Beat Vol**] to a value between 0 and 10. 0 means the beat volume is turned off, and 10 is the maximum volume. When [**Beat Vol**] is set to 0, the icon  is shown in the PR area.

You can increase/decrease the beat volume by pressing the Up/Down button in the case that no menu is opened.

During SpO₂ monitoring, the pitch of the pulse tone changes as the patient's oxygen saturation level changes. The pitch of the tone rises as the oxygen saturation level increases and falls as the oxygen saturation level decreases.

4.7.2 Setting the Key Volume

To set the key volume,

1. Select [**Menu**]→[**General Setup**].
2. Set [**Key Vol**] to a value between 0 and 10. 0 means the key volume is turned off, and 10 is the maximum volume.

4.8 Entering/Exiting the Demo Mode

To enter the demo mode:

1. Select [**Menu**]→[**System**]→[**Maintenance >>**]→enter the required password.
2. Select [**Demo**] and follow the prompt.

In the demo mode, the message [**Demo Mode**] is shown in the technical alarm area. To exit the demo mode, press the Right button to return to the screen displayed before you enter the demo mode.

WARNING

- **The Demo mode is for demonstration purpose only. To avoid that the simulated data are mistaken for the monitored patient's data, you should not enter the Demo mode during a patient is being monitored. Otherwise, improper patient monitoring and delayed treatment could result.**
-

4.9 Checking the Version

To check the version information,

1. Select [**Menu**]→[**System**]→[**Maintenance >>**]→enter the required password.
2. Select [**Version >>**].

4.10 Entering/Exiting the Standby Mode

4.10.1 Entering the Standby Mode

In the spot-checking mode, in situations where reviewing or exporting trend data is not performed, the pulse oximeter will automatically enter the standby mode if no button operation and SpO₂ signal are detected for 1 minute and no "Battery Too Low" alarm occurs.

In the standby mode,

- The backlight is turned off.
- The standby screen is displayed.
- Alarms except the "Battery too Low" alarm are disabled.

In the standby mode, if the "Battery too Low" alarm occurs, the system gives an audible alarm which is defined as follows:

- Double beep
- Alarm volume: 2
- Alarm interval: 30 seconds.

If you exit the standby mode at this time, the "Battery too Low" alarm will be given in the form of technical alarm.

4.10.2 Exiting the Standby Mode

In the standby mode, if the SpO₂ signal is detected or any button except the Power button is pressed, the pulse oximeter will automatically exit the standby mode and return to the previous mode.

4.11 Setting Auto Poweroff

In the spot-checking mode, you can select to shut off the pulse oximeter automatically:

1. Select [**Menu**]→[**System**]→[**Maintenance >>**]→enter the required password.
2. Select [**User Maintenance >>**], and then select [**Auto Quit**] to toggle between:
 - [**Allowed**]: The pulse oximeter will shut down automatically if no button operation and SpO₂ signal are detected for 5 minutes in the standby mode.
 - [**Unallowed**]: The pulse oximeter will not shut down if no button operation and SpO₂ signal are detected for 5 minutes in the standby mode.

4.12 Configuration

The pulse oximeter provides factory configuration and user configuration. The configuration is loaded and saved according to the operating mode and patient category. SpO₂ and PR alarm limits are subject to the patient category. The user configuration will be loaded first when the pulse oximeter is started. If the user configuration is not available, corresponding factory configuration will be loaded. Refer to *C* Factory Defaults.

4.12.1 Restoring the Factory Configuration

If you have changed the system's configuration and want to restore the factory configuration, follow this procedure:

1. Select [**Menu**]→[**System**].
2. Select [**Load Conf. >>**] →[**Load Factory Conf.**].

The factory configuration will be restored according to the current work mode and patient category.

4.12.2 Saving the User Configuration

You can change the pulse oximeter's settings and save the changed settings as user configuration.

To save the user configuration,

1. Select [**Menu**]→[**System**]→[**Maintenance >>**]→enter the required password.
2. Select [**User Maintenance >>**]→[**Save as User Conf.**].

The user configuration will be saved according to the current work mode and patient category.

4.12.3 Loading the User Configuration

To call the saved user configuration,

1. Select [**Menu**]→[**System**].
2. Select [**Load Conf. >>**] →[**Load User Conf.**].

The system will select an appropriate user configuration according to the current work mode and patient category. If the user configuration of this type is not available, corresponding factory configuration will be restored.

FOR YOUR NOTES

5 Alarms

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

5.1 Alarm Categories

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

1. Physiological alarms

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

2. Technical alarms

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

3. Prompt messages

As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the pulse oximeter will show some messages telling the system status. Prompt messages are displayed in the technical alarm area.

5.2 Alarm Levels

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

1. High level alarms

Indicate that the patient is in a life threatening situation and an emergency treatment is demanded.

2. Medium level alarms

Indicate that the patient's vital signs appear abnormal and an immediate treatment is required.

3. Low level alarms

Indicate that the patient's vital signs appear abnormal and an immediate treatment may be required.

The pulse oximeter's technical alarms can be classified into three categories: high level alarms, medium level alarms and low level alarms.

The levels for some technical alarms and physiological alarms are predefined before the pulse oximeter leaves the factory and cannot be changed.

5.3 Alarm Indicators

When an alarm occurs, the pulse oximeter will indicate it through the following indications:

- Alarm lamp
- Alarm tone
- Alarm message

For different alarm levels, the alarm lamp, alarm tone and alarm messages presented are different.

5.3.1 Alarm Lamp

If a technical or a physiological alarm occurs, the alarm lamp will flash. The flashing color and frequency match the alarm level as follows:

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

5.3.2 Alarm Tones

When a technical or a physiological alarm occurs, the pulse oximeter presents different alarm tone patterns to match the alarm level:

- High level alarms: triple + double + triple + double beep
- Medium level alarms: triple beep.
- Low level alarms: single beep.

5.3.3 Alarm Messages

When an alarm occurs, an alarm message will appear in the technical or physiological alarm area.

For physiological alarms, the asterisk symbols (*) before the alarm message match the alarm level as follows:

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

Additionally, the system uses different background colors for the alarm message to match the alarm level:




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

NOTE

-
- **When multiple alarms of different levels occur simultaneously, the pulse oximeter will select the alarm of the highest level and give visual and audible alarm indications accordingly. Alarm messages will be presented circularly.**
-

5.3.4 Alarm Status Symbols

Apart from the aforementioned alarm indicators, the pulse oximeter still uses the following symbols telling the alarm status:

-  indicates the alarm sound is paused.
-  indicates the alarm sound is turned off.
-  indicates individual measurement alarms are turned off.

5.4 Alarm Tone Configuration


5.4.1 Setting the Minimum Alarm Volume

1. Select [Menu]→[System]→[Maintenance >>]→enter the required password.
2. Select [Alarm >>] and then select [Min. Alm Vol]. Choose a value between 0 and 10. 0 is the minimum volume and 10 the maximum.

Minimum alarm volume decides the minimum value to be set for the alarm volume, which is not affected by user or factory default configurations. The setting of the minimum alarm volume remains unchanged when the pulse oximeter is shut down and restarted.

5.4.2 Changing the Alarm Volume

1. Select [Menu]→[General Setup].
2. Select [Alm Vlm] and then select a volume between X and 10. X is the minimum volume which depends on the setting of the minimum alarm volume, and 10 the maximum volume.

When alarm volume is set to 0, the alarm sound is turned off and a  symbol appears in the alarm status area. In the case that alarm sound is switched off, the alarm lamp remains lit and alarm message remains presented. The audible alarm is reactivated automatically when:


- The pulse oximeter is shut down and restarted;
- The factory configuration is loaded;
- The user configuration is loaded.


When a factory or user configuration is selected, the alarm volume of the pulse oximeter may be lower than the minimum alarm volume. In this case, the alarm volume is automatically adjusted according to the minimum alarm volume.


WARNING

- **When the alarm sound is switched off, the pulse oximeter will give no audible alarm tones even if a new alarm occurs. Therefore the user should be very careful about whether to switch off the alarm sound or not.**
 - **Do not rely exclusively on the audible alarm system for patient monitoring. Adjusting alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.**
-

5.4.3 Pausing the Alarm Tones

To pause the alarm tones, press the  key. In this case,

- The audible alarm is paused, but the alarm lamp remains lit and the alarm message remains displayed;
- The remaining alarm pause time is displayed in the alarm status area;
- The  symbol is displayed in the alarm status area.

Audible alarm starts again automatically after the alarm pause period expires. You can also press the  key to restart the audible alarm. The audible alarm is reactivated automatically when:

- The pulse oximeter is shut down and restarted.
- The pulse oximeter is switched to a new operating mode
- The pulse oximeter enters or exits the standby mode
- The pulse oximeter enters or exits the demo mode.

Alarm pause time can be adjusted and the default is 2 minute. To change the alarm pause time,

1. Select [**Menu**]→[**System**]→[**Maintenance >>**]→enter the required password.
2. Select [**Alarm >>**] and then set [**Audio Paused**] to an appropriate time.

5.5 Setting the Alarm Level

The levels of all technical alarms except [**Sensor Off**] are predefined before the pulse oximeter leaves the factory. To set the alarm level of [**Sensor Off**],

1. Select [**Menu**]→[**Alarm Setup**];
2. Select [**Sensor Off**] and choose a desired alarm level.

If you enter the demo mode after the [**Sensor Off**] alarm occurs, the alarm will be presented in the form of prompt message when you exit the demo mode.

In the continuous monitoring mode, the alarm level of [**Sensor Off**] can be set to [**High**], [**Med**] or [**Low**]. If the SpO₂ sensor falls off before a valid SpO₂ signal is obtained, the pulse oximeter will present [**Sensor Off**] in the form of prompt message.

In the spot-check mode, the alarm level of **[Sensor Off]** can be set to **[High]**, **[Med]**, **[Low]** or **[Off]**.

- If the **[Sensor Off]** alarm is not switched off, the pulse oximeter will present the alarm in the form of prompt message in the case that the SpO₂ sensor falls off before an effective SpO₂ signal is obtained.
- If the pulse oximeter enters the standby mode after the **[Sensor Off]** alarm occurs, it will present the alarm in the form of prompt message when the standby mode is exited.

5.6 Switching On/Off the Reminder Tone

When the alarm volume is set to 0, the pulse oximeter gives a reminder tone of two beeps every three minutes if reminder tone is switched on.

To switch on or off the reminder tone,

1. Select **[Menu]**→**[System]**→**[Maintenance >>]**→enter the required password.
2. Select **[Alarm >>]** → **[Reminder Tone]**, and toggle between **[On]** and **[Off]**.

The reminder tone is switched off by default. The setting of the reminder tone is saved even if the pulse oximeter is turned off.

5.7 When an Alarm Occurs

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

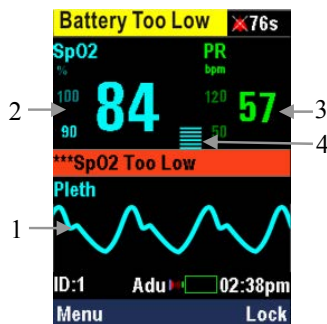
1. Check the patient's condition.
2. Confirm the alarming parameter or alarm category.
3. Identify the source of the alarm.
4. Take proper action to eliminate the alarm condition.
5. Make sure the alarm condition is corrected.

For troubleshooting specific alarms, see appendix *D* Alarm Messages.

6 Measuring SpO₂

6.1 Introduction

SpO₂ measuring 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 emitted by a red and infrared light-emitting diodes passes through the tissue and is converted into electrical signals by a photodiode. This device is calibrated to display functional oxygen saturation.



The pulse oximeter provides:

1. Pleth waveform (Pleth): The waveform is normalized.
2. Oxygen saturation of arterial blood (SpO₂): It is the percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
3. Pulse rate (PR): It is the pulsations per minute derived from the Pleth wave.
4. Pleth bar: The number of segments indicates the pulse strength.

6.2 Safety

WARNING


- Use only SpO₂ sensors specified in this manual. Follow the SpO₂ sensor's instructions for use and adhere to all warnings and cautions.
 - Check the SpO₂ sensor and its package for any sign of damage before use. Do not use the sensor if any damage is detected.
 - When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
 - Do not use the pulse oximeter and the SpO₂ sensor during magnetic resonance imaging (MRI). Induced current could cause burns.
 - 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.
 - As with electrosurgical unit, carefully route patient cabling to avoid entanglement.
 - Do not use the SpO₂ sensor on a limb with an intravenous infusion or arterial catheter in place.
 - Do not use the SpO₂ sensor on a limb where the NIBP cuff is applied. This may result in inaccurate SpO₂ reading due to blocked blood flow during cuff inflation.
 - Do not apply the equipment to a patient younger than one year old if the operating temperature is higher than 40°C. This may lead to skin burn.
-

6.3 Applying the Sensor

1. Select an appropriate SpO₂ sensor according to the patient category and weight.
2. Remove colored nail polish from the application site.
3. Apply the SpO₂ sensor to the patient.
4. Connect the SpO₂ extension cable to the pulse oximeter.

6.4 Changing SpO₂ Settings

6.4.1 Switching On/Off SpO₂ and PR Alarms

1. Select **[Menu]**→**[Alarm Setup]**.
2. Select SpO₂ or PR **[Alarm]** and toggle between:
 - **[On]**: When an alarm limit is exceeded, the pulse oximeter will give an alarm according to the defined alarm level.
 - **[Off]**: When an alarm limit is exceeded, the pulse oximeter will not give an alarm; the audible and visible alarm as well as the alarm message will be switched off and the symbol  will be shown in the SpO₂ or PR area.

6.4.2 Setting Alarm Level

1. Select **[Menu]**→**[System]**→**[Maintenance >>]**→enter required password.
2. Select **[Alarm >>]**→**[Alarm Level>>]**.
3. Select **[SpO2 Alm Lev]** and toggle between **[High]** and **[Med]**.
4. Set **[PR Alm Lev]** to **[High]**, **[Med]** or **[Low]**.

The level of the “No Pulse” alarm is configured to high and is not user adjustable.

6.4.3 Adjusting the Alarm Limits

1. Select [**Menu**]→[**Alarm Setup**].
2. Adjust [**High Limit**]: If an SpO₂ or PR measurement is higher than the high alarm limit, the “SpO₂ Too High” or “PR Too High” alarm will be triggered.
3. Adjust [**Low Limit**]: If an SpO₂ or PR measurement is lower than the low alarm limit, the “SpO₂ Too Low” or “PR Too Low” alarm will be triggered.

When an SpO₂ or PR alarm occurs, the parameter reading will flash and corresponding alarm limit will synchronously flash in the color of the parameter reading.

6.4.4 Switching On/Off the Alarm Limit Display

1. Select [**Menu**]→[**System**]→[**Maintenance >>**]→enter required password.
2. Select [**Alarm >>**].
3. Select [**Alm Limit**] and toggle between:
 - [**On**]: Alarm limits are displayed in the SpO₂ and PR area.
 - [**Off**]: Alarm limits are not displayed in the SpO₂ and PR area.

6.4.5 Setting SpO₂ Sensitivity

The SpO₂ reading is the average of data collected within a specific time. The shorter the averaging time is, the quicker the pulse oximeter responds to the changes in the patient’s oxygen saturation level. Contrarily, the longer the averaging time is, the slower the pulse oximeter responds to the changes in the patient’s oxygen saturation level, but the measurement accuracy will be improved. When a critical patient is monitored, selecting shorter averaging time will help understanding the patient’s state.

To set the SpO₂ sensitivity,

1. Select [**Menu**]→[**General Setup**].
2. Set [**Sensitivity**] to [**High**], [**Med**] or [**Low**], whose averaging time is respectively 7 seconds, 9 seconds and 11 seconds.

6.5 Measurement Limitations

If you doubt the SpO₂ measurements, check the patient's vital signs first. Then check the pulse oximeter and SpO₂ sensor. The following factors may influence the accuracy of measurements:

- Ambient light
- Physical movement (patient or imposed motion)
- Diagnostic testing
- Low perfusion
- Electromagnetic interference, such as MRI environment
- Electrosurgical units
- Dysfunctional haemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
- Presence of certain dyes, such as methylene and indigo carmine
- Inappropriate positioning of the SpO₂ sensor, or use of incorrect SpO₂
- Drop of arterial blood flow to unmeasurable level due to shock, anemia, low temperature or vasoconstrictor.

FOR YOUR NOTES

7 Data Management

7.1 Storing data

NOTE

- **The stored data will not be cleared in case of power failure or power off.**
 - **It's recommended to export the data before the memory is filled up.**
-

7.1.1 Continuous Monitoring Mode

In the continuous monitoring mode, the data, including the measurement time, oxygen saturation and pulse rate values, are stored once every 2 seconds. The pulse oximeter can store up to 96 hours of data for a single patient.

In the continuous monitoring mode,

- The initial patient ID is 1 when the pulse oximeter is used for the first time.
- The range of patient ID is 1 to 99 and you have to change the patient ID manually when a new patient is admitted.
- The patient ID remains unchanged after all data is cleared in the trend window.
- The patient ID selected before the pulse oximeter is last turned off is automatically loaded when you start the pulse oximeter.

During continuous patient monitoring,

- The measurements are stored under the current patient ID as long as the patient ID is not changed.
- If the patient ID is changed, a new patient is considered to be admitted and the new measurements will be stored under the new patient ID. The data under the old patient ID will be cleared.

When the memory is filled up, the oldest data will be overwritten by the new data.

7.1.2 Spot-checking Mode

In the spot-checking mode, the data are stored once every 30 seconds. The stored data include all the average oxygen saturation and pulse rate values measured during this period. The pulse oximeter can store up to 4000 groups of data for 99 patients.

In the spot-checking mode,

- The initial patient ID is 0 when the pulse oximeter is used for the first time.
- The range of the patient ID is 1 to 99. The patient ID will automatically increase by 1 if a new patient is admitted.
- As the patient ID reaches 99, the patient ID will turn to 1 if a new patient is admitted.
- In the trend window, the patient ID will be restored to 0 after all data is cleared.
- The patient ID set before the pulse oximeter is last turned off will be loaded automatically when the pulse oximeter is started.

During spot checking,

- The measurements are stored under the current patient ID as long as the patient ID is not changed.
- If the patient ID is changed, a new patient is considered to be admitted and the new measurements will be stored under the new patient ID. Data of the old patients will not be cleared unless the memory is filled up.

If the data are stored under multiple patient IDs, all the data under the oldest patient ID will be cleared when the memory is filled up. If the data is stored under one patient ID, the earliest data will be overwritten by the new one when the memory is filled up.

7.2 Reviewing Trend Data

The patient's history physiological data can be stored and displayed in the form of a trend table. Reviewing the trend data helps you to understand changes in the patient condition.

7.2.1 Continuous Monitoring Mode

In the continuous monitoring mode, you can perform patient monitoring with the trend window opened.

To open the trend window, select [Menu]→[Trend].

Continuous		
SpO2	PR	
%	bpm	
100	120	
90	50	
99	69	
Trend(07-08-2007)		
Time	SpO2	PR
16:19:00	91	60
16:18:58	91	60
16:18:56	91	60
16:18:54	90	60
16:18:52	90	60
Menu		Return

In the trend window, SpO₂ and PR readings beyond the alarm limits are displayed in red and the blank lines indicate that the pulse oximeter is shut off during that period.

In the trend window, you can

- Press the Up or Down button to page up or down, or press and hold the Up or Down button for 1 second to speed paging up or down.
- Press the Left button to enter the [Trend Setup] menu. In the [Trend Setup] menu, you can
 - ◆ Adjust [Interval]: The minimum interval is 2 seconds.
 - ◆ Select [Start Time >>] to set the [Date] and [Time] from which you want to review.
 - ◆ Select [Delete All] to delete all the trend data under the current patient ID.
- Press the Right button to exit the trend window.

7.2.2 Spot-checking Mode

In the spot-checking mode, the pulse oximeter will stop measuring the patient if you open the trend window. A patient cannot be admitted with the trend window opened.

To open the trend window, select **[Menu]**→**[Trend]**.

Spot-Check			
ID:4	Min	Avg	Max
SpO2	93	96	99
PR	70	72	75
Trend(07-08-2007)			
Time	SpO2	PR	
16:23:03	97	70	
16:22:14	99	71	
16:21:15	95	73	
16:20:45	93	75	
Menu		Return	

In the trend window, SpO₂ and PR readings beyond the alarm limits are displayed in red. If you have changed the system time before entering the trend window, the trend data time before the system time is changed remains unchanged.

In the trend window, you can


- Press the Up or Down button to page up or down, or press and hold the Up or Down button for 1 second to speed paging up or down.
- Press the Left button to enter the **[Trend Setup]** menu. In the **[Trend Setup]** menu, you can
 - ◆ Select **[Select ID]** to review the history data as well as the maximum, minimum and average measurements of the selected patient.
 - ◆ Select **[Delete Selected]** to delete the trend data under the selected patient ID.
 - ◆ Select **[Delete All]** to delete the trend data under all patient IDs.
- Press the Right button to exit the trend window.

7.3 Data Exporting

7.3.1 Real-time Exporting

During SpO₂ measuring, you can export the data in real-time through the infrared port. To do so, follow this procedure:

1. Select [Menu]→[System].
2. Select [RT Export] and toggle between [Start] and [Stop].

When the data is being exported in real-time, the symbol  will be shown in the information area. You can enter the trend exporting window when data is being exported in real-time. In this case, real-time data exporting will stop automatically. If you need to export the real-time data again, manually adjust [RT Export] to [Start].

The real-time data transmission protocol has the following features:

- The baud rate is 9600;
- The data frame format is one start bit plus eight data bits plus one stop bit;
- The data sending rate is 1 Hz and the packet head is F1H.

The real-time data transmission protocol has 6 bytes as listed in the table below:

Byte 1	Byte 2	Byte 3	Byte 4	Byte 5	Byte 6
Packet head	Module type code and checksum	Data			

Byte 1 is the packet head whose value is 0xF1. The structure of Byte 1 is:

Byte 1	7	6	5	4	3	2	1	0
	1	1	1	1	0	0	0	1

The structure of Byte 2 is:

Byte 2	7	6	5	4	3	2	1	0
	1	0	0	1	Checksum			

Bit 7 to 4 is the module type code; Bit 3 to 0 is the checksum which is the sum of the last 4 bits of Byte 3, Byte 4, Byte 5 and Byte 6.

The structure of Byte 3 is:

Byte 3	7	6	5	4	3	2	1	0
	0							The last 7 bits of the pulse rate value.

The structure of Byte 4 is:

Byte 4	7	6	5	4	3	2	1	0
	0	The first two bits of the pulse rate value.			SP	For future use		

SP is the pulse searching label. The value of SP is 0 or 1; 1 means the system is searching the pulse.

The structure of Byte 5 is:

Byte 5	7	6	5	4	3	2	1	0
	0	The last 7 bits of SpO2 value						

The structure of Byte 6 is:

Byte 6	7	6	5	4	3	2	1	0
	0	0	For future use	LP	NS	SO	SPL	

The value of LP is 1 or 0; 1 means low perfusion. The value of NS is 1 or 0; 1 means that SpO₂ sensor is not connected. The value of SO is 1 or 0; 1 means SpO₂ sensor is off. The value of SPL is 1 or 0; 1 means that the pulse searching time is too long.

7.3.2 Exporting Trend Data

You can export trend data through the multifunctional connector. To do so, follow this procedure:

1. Connect a personal computer to the multifunctional connector using a communication cable.
2. Select [**Menu**]→[**Trend**] to enter the trend window.
3. Press the Left button to enter the [**Trend Setup**] menu.
4. Set [**Export Port**] to [**Wire**].
5. Select [**Export Trend**] to enter the trend exporting window.

When the trend exporting window is entered, all operations except exiting the trend export window and turning off the pulse oximeter are disabled. To exit the trend exporting window, press the Right button and select [**OK**].




Refer to the PC data management system software for detailed information on trend data exporting.

8 Battery




8.1 Overview

The pulse oximeter is designed to operate on three 1.5V alkaline AA batteries or a rechargeable lithium ion battery.

When the alkaline batteries are used, the battery icon indicates the battery status as follows:

-  Indicates that the batteries work correctly. The solid portion represents the current power level of the batteries in proportion to its maximum power level..
-  Indicates that the batteries have low power level and need to be replaced.
-  Indicates that the batteries are almost depleted and need to be replaced immediately.

When a lithium ion battery is used, the battery icon indicates the battery status as follows:

-  Indicates that the battery works correctly. The solid portion represents the current charge level of the battery in proportion to its maximum charge level.
-  Indicates that the battery has low charge level and need to be charged.
-  Indicates that the battery is almost depleted and need to be charged immediately.

If the battery capacity is too low, a technical alarm will be triggered and the **[Battery Too Low]** message displayed. At this moment, replace the batteries if the alkaline batteries are used, or charge the battery if a lithium ion battery is used. Otherwise, the pulse oximeter will shut down automatically when the battery is depleted. If interrupting patient monitoring is not allowed at this moment, you need use another monitor.

You can charge the lithium ion battery using a Charger stand whether the pulse oximeter is turned on or off. However, monitoring a patient while the battery is being charged is not allowed.

NOTE

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

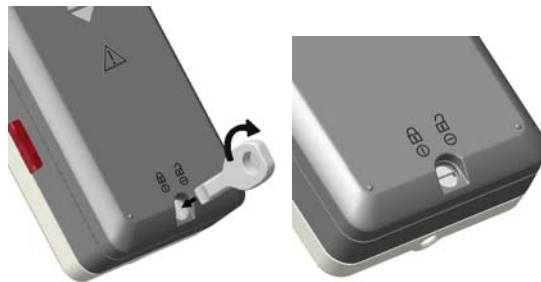
⚠ WARNING

- **Keep the batteries out of children’s reach.**
 - **Use only batteries specified in this manual. Use of another battery may present a risk of fire or explosion.**
 - **The battery used in this device may present a risk of fire or chemical burn if mistreated.**
-
-

8.2 Installing the Batteries

8.2.1 Opening the Battery Door

1. Remove the pulse oximeter from the Charger stand and disconnect the SpO₂ sensor.
2. Use the key to loose the screw that secures the battery door to the pulse oximeter.



3. Press the battery door, push it downwards and remove the battery door.



8.2.2 Installing the Alkaline Batteries

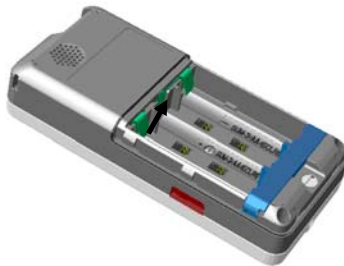
1. Insert the AA alkaline batteries in the battery compartment, aligning the + on each battery with the + shown inside the battery compartment.
2. Close the battery door and push it upwards.
3. Tighten the screw that secures the battery door to the pulse oximeter.

Caution

- **Do not run the pulse oximeter using alkaline batteries of different types or capacities at the same time.**
-

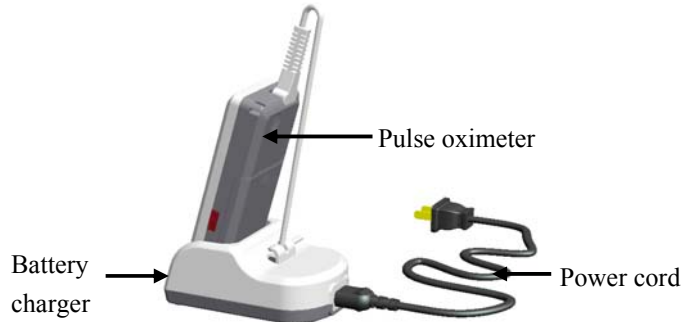
8.2.3 Installing the Lithium Ion Battery

1. Remove the battery adjusting bracket.



2. Insert the lithium ion battery in the battery compartment, aligning the + on the battery with the + shown inside the battery compartment.
3. Close the battery door and push it upwards.
4. Tighten the screw that secures the battery door to the pulse oximeter.

8.3 Charging the Lithium Ion Battery



To charge the lithium ion battery,

1. Place the pulse oximeter in the Charger stand.
2. Connect the power cord.
3. Plug the power cord into the AC mains.

WARNING

- **Do not use the charger stand when the alkaline batteries is depleted or no battery is installed.**
 - **Not use the monitor when it is charged.**
 - **Use specified charger stand when lithium ion battery is charged, Use of another charger device may present a risk.**
-

8.4 Conditioning the Lithium Ion Battery

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

To condition a lithium ion battery, follow this procedure:

1. Disconnect the pulse oximeter from the patient and stop all monitoring and measuring procedures.
2. Place the lithium ion battery in need of conditioning into the battery compartment of the pulse oximeter
3. Place the pulse oximeter in the Charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 2 hours.
4. Remove the AC mains and allow the pulse oximeter to run from the battery until it shuts off.
5. Replace the pulse oximeter in the Charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 2 hours.

Now, the battery is conditioned and the pulse oximeter can be returned to service.

8.5 Checking the Lithium Ion Battery

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

1. Disconnect the pulse oximeter from the patient and stop all monitoring and measuring procedures.
2. Place the pulse oximeter in the Charger stand and connect the AC mains. Allow the battery to be charged uninterruptedly for above 2 hours.
3. Disconnect AC mains and allow the pulse oximeter to run on the battery until it shuts off.

The operating time of a battery reflects its performance directly. If the operating time of a lithium ion battery is noticeably shorter than that stated in the specifications, replace it or contact your service personnel.

NOTE

-
- **Life expectancy of a lithium ion 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 a lithium ion battery every 3 years.**
 - **The operating time of a lithium ion battery depends on the configuration and operation of the pulse oximeter.**
-

8.6 Disposing of the Batteries

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

WARNING

- **The battery used in this device may present a risk of fire or chemical burn if mistreated.**
 - **Dispose of used battery promptly.**
 - **Do not disassemble, or heat above 60°C, or incinerate, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, or leak, causing personal injury.**
-

9 Maintenance and Cleaning

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

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

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

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

WARNING

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

CAUTION

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

NOTE

- **To clean or disinfect reusable accessories, refer to the instructions delivered with the accessories.**
-

9.1 Safety Checks

Before first use, or at least every two years, or whenever your pulse oximeter is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect all power cords for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Inspect if the alarm system functions correctly.
- Make sure that the batteries meet the performance requirements.
- Make sure that the pulse oximeter is in good working condition.

In case of any damage or abnormality, do not use the pulse oximeter. Contact your hospital's biomedical engineers or your service personnel immediately.

9.2 Cleaning

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

Recommended cleaning agents are:

- Mild soap (diluted)
- Ammonia (diluted)
- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

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

9.3 Disinfecting

Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter before disinfecting it.

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

CAUTION

- **Never use EtO or formaldehyde for disinfection.**
-

9.4 Disposal

Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations. For the disposal of SpO₂ sensor, follow local regulations regarding disposal of hospital waste.

FOR YOUR NOTES

10 Accessories

WARNING

- Use only accessories specified in this manual. Using other accessories may cause damage to the pulse oximeter.
- Disposable accessories are designed for single-patient use only. Reuse of them may cause a risk of contamination and affect the measurement accuracy
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
- The SpO₂ sensor mentioned in this chapter meet the bio-compatibility requirements and complies with ISO 10993-1, ISO 10993-5 and ISO 10993-10 standards.

SpO₂ Sensor

Type	Model	Applicable patient	Wavelength*	PN
Disposable	520A	Adult (finger clip)	660 nm	520A-30-64101
	520P	Pediatric (finger clip)	905 nm	520P-30-64201
	520I	Infant (toe sensor)		520I-30-64301
	520N	Neonate (foot sensor)		520N-30-64401
Reusable	512E	Adult (finger clip)	660 nm	512E-30-90390
	512F		905 nm	512F-30-28263
	512G	Pediatric (finger clip)		512G-30-90607
	512H			512H-30-79061
	518B	Adult (multi-site sensor) Neonate (multi-site sensor)	660 nm 905 nm	518B-30-72107

* The maximum optical output power of SpO₂ sensors is less than 18 mw. Information on wavelength range and the maximum optical output power can be especially useful to clinicians, for example, when performing photodynamic therapy.

Other Accessories

Description	PN
SpO ₂ Extension cable	0010-20-43075
Protective cover, light blue	0852-21-77412-51
Protective cover, blue	0852-21-77412-52
Protective cover, orange	0852-21-77412-53
Protective cover, yellow	0852-21-77412-54
Carrying case	0852-10-77701
Kit (One Li-on battery, one charger stand, One power cord)	0852-30-77504
Charger Stand and power cord	0852-30-77517
Data Output Software Package (includes record management software CD, PC communication cable)	0852-30-77491
Infrared adapter	0000-10-11254
PC Communication cable	0850-20-30725
Lithium ion battery	M05-010004-08
Mounting clamp	0852-30-77537

A Product Specifications

Safety specifications (classified according to IEC60601-1)		
Type of protection against electrical shock	II (Internally powered equipment)	
Degree of protection against electric shock	Type BF – Applied part (defibrillation proof)	
Degree of protection against hazards of explosion	Ordinary equipment, not protected	
Degree of protection against ingress of liquid	IPX2	
Equipment type	Handheld	
Mode of operation	Continuous	
Physical specifications		
Width × Height × Depth	56 mm×124 mm×30 mm or 2.2 in.×4.9 in.×1.2 in.	
Max. weight	< 300 g or 7.3 oz. (full configuration, including the battery)	
Environmental specifications	Operating conditions	Storage conditions
Temperature (°C)	0 to 40	-20 to 60
Relative humidity (non-condensing)	15% to 95%	10% to 95%
Atmospheric pressure (mmHg)	425 to 809	120 to 809
Max. recommended ambient temperature:	35 °C for battery charging and 45 °C for battery discharging	
Charger stand		
Input voltage	100 to 240 VAC, 50/60 Hz	
Output voltage	5 VDC	
Output current	1.2 A	
Output power	6 W	
Model	GTM91094-0605-FW	
Manufacturer	Mindray DS USA, Inc.	

Alkaline batteries	
Quantity	3
Specification	1.5 V, AA
Capacity	2000 mAh
Run time	36 hours with SpO ₂ monitored continuously, audio indicators off and backlight brightness set to minimum using new, full power batteries at ambient temperature 25°C.
Shutdown delay	Max. 10 minutes after the low battery alarm first occurs.
Lithium ion battery	
Quantity	1
Rated voltage	3.7V
Capacity	1800 mAh
Model	LI11S001A
Manufacturer	Mindray DS USA, Inc.
Run time	24 hours with SpO ₂ monitored continuously, audio indicators off and backlight brightness set to minimum using a new, fully charged battery at ambient temperature 25°C.
Charge time	2 hours to 90% 3.5 hours to 100%
Shutdown delay	Max. 10 minutes after the low battery alarm first occurs.
Hardware specifications	
Display	Color TFT, 2.4", 320×240 pixel
Power indicating lamp	1, lighting green and yellow
Loudspeaker	1; Gives audible alarm (45 to 85dB) and button tone; Supports Pitch Tone and multi-level volume; Alarm tones meet the requirement of IEC 60601-1-8.
Alarm indicating lamp	1, lighting red and yellow
Multifunctional connector	1, 9-pin type D connector
Power supply connector	1, used to connecting the Charger stand
Infrared port	1, through which a personnel computer is communicated.

Data storage			
Operating mode	Continuous monitoring	Spot-checking	
Capacity	96 hours of data	4000 data	
Resolution	2 s	30 s	
Stored data	Patient ID, patient category, SpO ₂ and PR value, measurement time		
Measurement specifications			
SpO₂			
Measurement validation: The SpO ₂ accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, and only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.			
Range	0 to 100%		
Resolution	1%		
Accuracy	70 to 100%: ±2% (in adult/pediatric mode) 70 to 100%: ±3% (in neonatal mode) * 0% to 69%: Unspecified		
*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 ₂ sensors was also validated on adult subjects.			
Refreshing rate	1 s		
Averaging time	7 s (When the sensitivity is set to High) 9 s (When the sensitivity is set to Med) 11 s (When the sensitivity is set to Low)		
PR			
Range	18 to 300 bpm		
Resolution	1 bpm		
Accuracy	± 3 bpm		
Refreshing rate	1 s		
Averaging time	7 s (When the sensitivity is set to High) 9 s (When the sensitivity is set to Med) 11 s (When the sensitivity is set to Low)		

Alarm limit specifications		
Alarm limits	Range (%)	Step (%)
SpO ₂ high limit	(low limit +1) to 100	1
SpO ₂ low limit	50 to (high limit -1)	
Alarm limits	Range (bpm)	Step (bpm)
PR high limit	(low limit +1) to 300	1
PR low limit	18 to (high limit -1)	

B EMC


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

NOTES

- **Using accessories, transducers and cables other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the patient monitoring equipment.**
 - **The device or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or its components should be observed to verify normal operation in the configuration in which it will be used.**
 - **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
 - **Other devices may affect this pulse oximeter 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.**
 - **Portable and mobile communication equipment will have impact on the performance of the pulse oximeter.**
-

Guidance and Declaration - Electromagnetic Emissions		
The device is suitable 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
Radio frequency (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 equipment. The device is suitable for use in all establishments other than domestic and those indirectly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Radio frequency (RF) emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions 61000-3-3	Compliance	

Guidance and Declaration - Electromagnetic Immunity			
The device is suitable 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	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst (EFT) IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines (>3m)	±2 kV for power supply lines ±1 kV for input/output lines (>3 m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation during power mains interruptions, it is recommended that the product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity		
The device is suitable 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	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms
Radiated RF IEC 61000-4-3	20 V/m 80M to 2.5GHz	20 V/m
Electromagnetic environment - guidance		
<p>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 from the equation applicable to the frequency of the transmitter. Recommended Separation Distance:</p> $d = \left[\frac{3.5}{3} \right] \sqrt{P}$ $d = \left[\frac{3.5}{20} \right] \sqrt{P} \quad 80 \text{ to } 800 \text{ MHz}$ $d = \left[\frac{7}{20} \right] \sqrt{P} \quad 800\text{M to } 2.5\text{GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the symbol</p> 		
<p>Note 1: From 80 MHz to 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 reorienting or relocating the device. b: Over the frequency range from 150kHz to 80MHz, field strengths should be less than 3V/m.</p>		

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and The device

The device is suitable 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 Transmitter (W)	Separation Distance (m) Corresponding to Frequency of Transmitter		
	150k to 80MHz $d = \left[\frac{3.5}{3} \right] \sqrt{P}$	80M to 800MHz $d = \left[\frac{3.5}{20} \right] \sqrt{P}$	800M to 2.5GHz $d = \left[\frac{7}{20} \right] \sqrt{P}$
0.01	0.12	0.0175	0.035
0.1	0.37	0.055	0.11
1	1.2	0.175	0.35
10	3.7	0.55	1.1
100	12	1.75	3.5

For transmitters at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: From 80 MHz to 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.

C Factory Defaults

This section lists the most important factory default settings. These settings are not user-adjustable. However, you can restore the factory default settings if necessary.

In the tables below, column “A” indicates whether this item is affected by factory configuration or user configuration.

- “√” means “Yes”: The user configuration will be loaded when the pulse oximeter is restarted; if the user configuration is not available, the factory configuration will be restored.
- “×” means “No”: The changed settings will be saved when the pulse oximeter is shut off and will be loaded when the pulse oximeter is restarted.

C.1 Alarm Setup

Alarm Setup	A	Factory Default
Alarm Volume*	√	2
Minimum Alarm Volume	×	2
Audio Pause	×	120 s
SpO2 Alarm	√	On
PR Alarm	√	On
SpO2 Alarm Level	×	Med
PR Alarm Level	×	Med
Sensor Off alarm	√	Low
Alarm Limits	×	On

* The user configuration is loaded when the pulse oximeter is shut off and restarted. If the alarm volume in this user configuration is 0 or the user configuration of this type is not available, corresponding factory default will be restored.

C.2 System Setup

System	A	Factory Default
Patient Category	×	Adu
Work Mode	×	Spot-checking
Screen	×	Normal
System Time	×	1-1-2007 00:00:00
Date Format	×	dd-mm-yyyy
Time Format	×	24 h
Language	×	English
Brightness	√	5
Key Volume	√	2
Beat Volume	√	2
Real Time Export	×	Stop
Export Trend	×	Wire
Interval	√	2 s
Auto shutdown	×	Unallowed

C.3 SpO₂ Setup

SpO ₂ Settings	A	Adult	Pediatric	Neonate
SpO ₂ High Limit	√	100	100	95
SpO ₂ Low Limit	√	90	90	90
PR Settings	A	Adult	Pediatric	Neonate
PR High Limit	√	120	160	200
PR Low Limit	√	50	75	100
Sensitivity	A	Factory Default		
In the Continuous monitoring mode	√	Med		
In the spot-checking mode	√	Med		

D Alarm Messages

This section lists only the most important physiological and technical alarm messages. Some messages appearing on your pulse oximeter may not be included.

In the tables below, column “L” indicates the default alarm level: “H” means high, “M” means medium and “L” means low; “*” means the alarm level is user-adjustable.

The “Cause and actions” column gives recommendations to instruct you to troubleshoot the problems. If the problem persists, contact your service personnel.

D.1 Physiological Alarm Messages

Alarm messages	L	Cause and actions
SpO2 Too High	M*	A measurement has risen above the high alarm limit or fallen below the low alarm limit. Check the patient’s condition and check if the patient category and alarm limit settings are correct.
SpO2 Too Low	M*	
PR Too High	M*	
PR Too Low	M*	
No Pulse	H	The pulse signal was too weak to be analyzed. Check the patient’s condition, SpO2 sensor and measurement site.

D.2 Technical Alarm Messages

Alarm messages	L	Cause and action
SpO2 Self Test Err	L	The pulse oximeter failed the power-on self-test. Restart the pulse oximeter.
SpO2 Comm Err	L	The pulse oximeter encountered a communication error. Restart the pulse oximeter.
SpO2 Comm Stop	L	An error occurred to the SpO2 module or there was a communication problem. Restart the pulse oximeter.
SpO2 Overrange	L	Measured SpO2 value is beyond the specified measurement range. Check the patient’s condition.
PR Overrange	L	Measured PR value is beyond the specified measurement range. Check the patient’s condition.

Sensor Off	L*	The SpO2 sensor detached the patient or the pulse oximeter, or there was a fault with the SpO2 sensor, or an unspecified SpO2 sensor was used. Check that the sensor application site and the sensor type are correct, and make sure that the sensor is undamaged. Reconnect the sensor if the sensor is disconnected or use a new sensor if the sensor is damaged.
No Sensor	L	
SpO2 Low Perf	L	The signal detected is weak or the signal quality is poor. Check the patient's condition. Change the sensor application site. If the problem persists, replace the sensor.
Voltage Too High	L	The system power supply fails. Restart the pulse oximeter.
Voltage Too Low	L	
Battery Too Low	M	The battery power is low. Replace the batteries if alkaline batteries are used or charge the battery if a lithium ion battery is used.
Battery Error	L	A problem occurs when the lithium ion battery is being charged. Check the battery for damage. If yes, replace the battery.
Power Comm Err	M	Communication problem occurred to the power supply part during the power-on self-test or operation. Restart the pulse oximeter.
Clock Need Set	L	The real-time clock is reset. Set the clock.
Export Failed	L	Transmission error occurs during data export. Reexport the data.

D.3 Prompt messages

Prompt messages	Cause and actions
Search Pulse	The SpO2 module is searching for the patient's pulse
ID Full	Patient ID is full. Export the data and then clear the memory.
ID Covered	Identical ID is used. Change the ID or export the data and then clear the memory.
Memory To Be Full	Insufficient memory space. Export the data and then clear the memory.
Memory Full	The memory space is full. Export the data and then clean the memory.
Data Covered	Data is covered. Export the data and then clean the memory.
Battery Type Err	Wrong battery type. Install correct battery.

E Symbols and Abbreviations

E.1 Units

A	ampere
bpm	beats per minute
°C	centigrade
g	gram
kHz	kilohertz
MHz	megahertz
GHz	Gigahertz
h	hour
Hz	hertz
k	kilo
kg	kilogram
kPa	kilopascal
m	meter, minute
M	mega
min	minute
mm	millimeters
ms	millisecond
mW	milliwatt
s	second
nm	nanometer
ppm	part per million
V	volt
μA	microampere

E.2 Symbols

–	minus
–	negative
%	percent
/	per; divide; or
+	plus
=	equal to
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
×	multiply
©	copyright

E.3 Abbreviations

CISPR	International Special Committee on Radio Interference
EEC	European Economic Community
EMC	Electromagnetic Compatibility
ID	Identification
IEC	International Electrotechnical Commission
LCD	Liquid Crystal Display
LED	Light Emitting Diode
MDD	Medical Device Directive
PC	Personal Computer
PR	Pulse Rate
RF	Radio Frequency
SpO2	Arterial Oxygen Saturation from Pulse Oximeter

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