PM-60

Pulse Oximeter

Operator’s Manual

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- the electrical installation of the relevant room complies with the applicable national and local requirements;and
- the product is used in accordance with the instructions for use.

WARNING

- **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.**

NOTE

- **This equipment must be operated by skilled/trained clinical professionals.**

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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.

Contents

1 Safety

1.1 Safety Information

 **DANGER**

- **Indicates an imminent hazard that, if not avoided, will result in death or serious injury.**

 **WARNING**

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

 **CAUTION**

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

NOTE

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

1.1.1 Dangers

There are no dangers that refer to the product in general. Specific “Danger” statements may be given in the respective sections of this manual.

1.1.2 Warnings

WARNINGS

- **This equipment is used to one patient at a time.**
- **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.**
- **Use and store the equipment in specified environmental condition. The equipment and accessesories may not meet the performance specification due to aging, stored or used outside the specified temperature and humidity range.**
- **Ensure that the patient monitor is supplied with continuous electric power during work. Sudden power failure leads to the loss of patient data.**
- **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.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**

1.1.3 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.

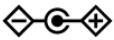
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**

1.1.4 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.**
- **During normal use, the operator is expected to face the front of the equipment.**

1.2 Equipment Symbols

	Direct Current (DC)
	Caution
	Refer to instruction manual/booklet
	Input/Output
	AUDIO PAUSED
	Battery door locked/unlocked
	Power supply connector
	Left/Right button
	Power ON/OFF (for a part of the equipment)
	Up button
	Down button
	Date of manufacture
	Manufacturer
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Serial number
	Safety Class II equipment

	DEFIBRILLATION-PROOF TYPE BF APPLIED PART
	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive. Note: The product complies with the Council Directive 2011/65/EU.
	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.

2 The Basics

2.1 Introduction

2.1.1 Intended Use

The pulse oximeter is intended for continuously monitoring, spot checking, displaying, storing and transferring oxygen saturation and pulse rate of single adult, pediatric and neonatal patients in hospitals, emergency treatment, patient 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

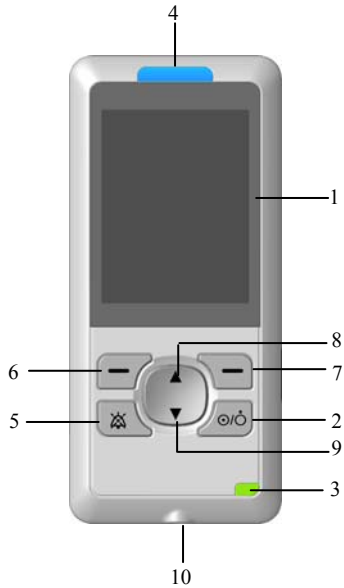
None.

2.1.3 Components

This pulse oximeter consists of a main unit and an SpO_2 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.

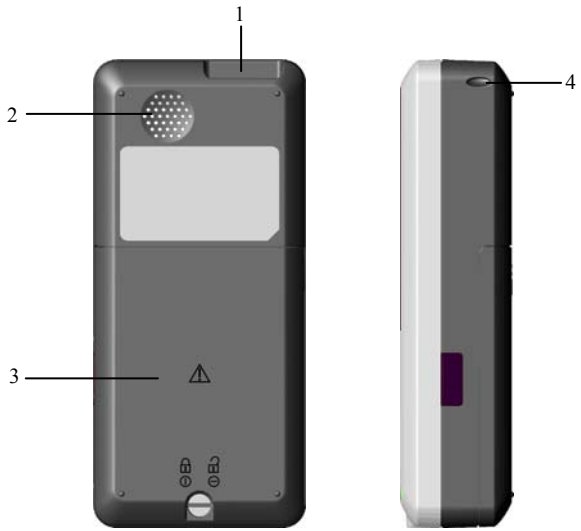
9. Down button

   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



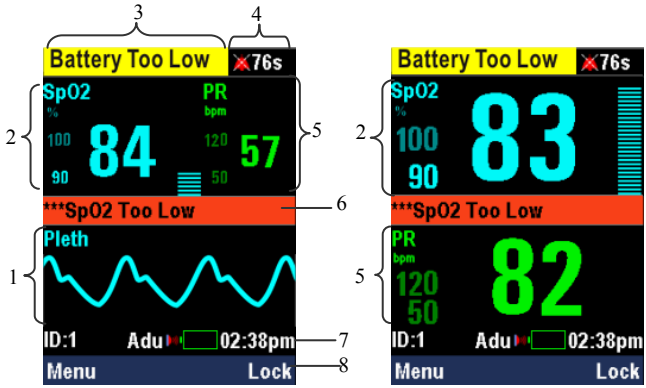
1. Multifunctional connector

   It is used to connect an SpO_2 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

2.3 Display Views

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



Wave screen **Normal screen**

1. Waveform Area

   This area displays Pleth waveform (Pleth). The label of this waveform is shown at the top left corner.

2. SpO_2 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

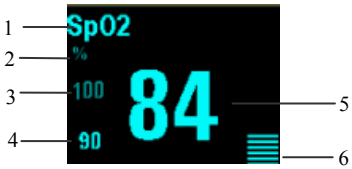
   This area shows physiological alarm messages. When multiple alarms come, they will be displayed circularly.

7. Information area

8. QuickKeys area

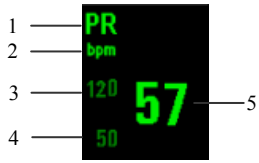
   This area contains QuickKeys that give you fast access to functions.

2.3.1 SpO2 Area



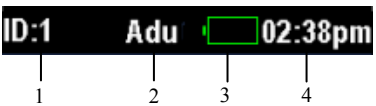
1. SpO_2 label
2. SpO_2 unit
3. SpO_2 high alarm limit
4. SpO_2 low alarm limit
5. Oxygen saturation reading
6. Pleth bar

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. Battery symbol
4. 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 SpO_2 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 SpO_2 extension cable from the pulse oximeter.
3. Press and hold the Power button for 2 seconds.

FOR YOUR NOTES

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 SpO_2 sensor to the patient. After valid SpO_2 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 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 SpO_2 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 excetp 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 techinical alarm.

4.10.2 Exiting the Standby Mode

In the standby mode, if the SpO_2 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 SpO_2 signal are detected for 5 minutes in the standby mode.
   - [**Unallowed**]: The pulse oximeter will not shut down if no button operation and SpO_2 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. SpO_2 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.

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. in which 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 theSpO_2 sensor falls off before a valid SpO_2 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 SpO_2 sensor falls off before an effective SpO_2 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:

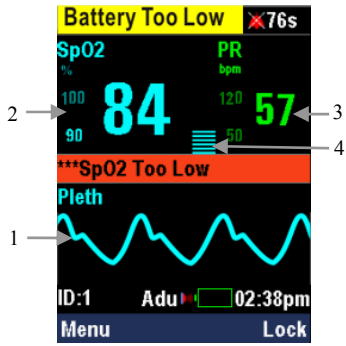
1. Check the patient's condition.
2. Confirm the alarming parameter or alarm category.
3. Identify the source of the alarm.
4. Take proper action to eliminate the alarm condition.
5. Make sure the alarm condition is corrected.

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

6 Measuring SpO_2

6.1 Introduction

SpO_2 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 (SpO_2): 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 SpO_2 sensors specified in this manual. Follow the SpO_2 sensor's instructions for use and adhere to all warnings and cautions.**
- **Check the SpO_2 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 SpO_2 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 SpO_2 sensor on a limb with an intravenous infusion or arterial catheter in place.**
- **Do not use the SpO_2 sensor on a limb where the NIBP cuff is applied. This may result in inaccurate SpO_2 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℃. This may lead to skin burn.**

6.3 Applying the Sensor

1. Select an appropriate SpO_2 sensor according to the patient category and weight.
2. Remove colored nail polish from the application site.
3. Apply the SpO_2 sensor to the patient.
4. Connect the SpO_2 extension cable to the pulse oximeter.

6.4 Changing SpO_2 Settings

6.4.1 Switching On/Off SpO2 and PR Alarms

1. Select [**Menu**]→[**Alarm Setup**].
2. Select SpO_2 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 SpO_2 or PR area.

6.4.2 Setting Alarm Level

1. Select [**Menu**]→[**System**]→[**Maintenance >>**]→enter required password.
2. Select [**Alarm >>**]→[**Alarm Level>>**].
3. Set [**SpO2 Alm Lev**] to [**High**] or [**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 SpO_2 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 SpO_2 or PR measurement is lower than the low alarm limit, the "SpO2 Too Low" or "PR Too Low" alarm will be triggered.

When an SpO_2 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 SpO_2 Sensitivity

The SpO_2 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 SpO_2 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 SpO_2 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 unmeaurable 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.

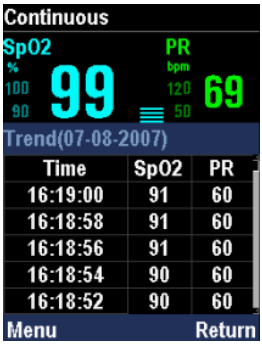
7.2 Reviewing Trend Data

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**].



In the trend window, SpO_2 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

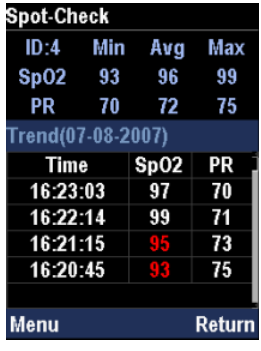
- Press the Up or Down button to page up or down, or press and hold the Up or Down button for 1 second to speed paging up or down.
- Press the Left button to enter the [**Trend Setup**] menu. In the [**Trend Setup**] menu, you can
  - Adjust [**Interval**]: The minimum interval is 2 seconds.

- 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**].



In the trend window, SpO_2 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 paitent.
- 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 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.

FOR YOUR NOTES

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 can place the pulse oximeter in the Charger stand and connect the AC mains. In this case, the pulse oximeter will give prompt message [**Battery Type Err**] if the alkaline batteries are used. You must pay close attention to the power supply to the pulse oximeter and replace the alkaline batteries or charge the lithium ion battery as soon as interruption of patient monitoring is permissible.

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 recommended.

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.**

8.2 Installing the Batteries

8.2.1 Opening the Battery Door

1. Remove the pulse oximeter from the Charger stand and disconnect the SpO_2 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

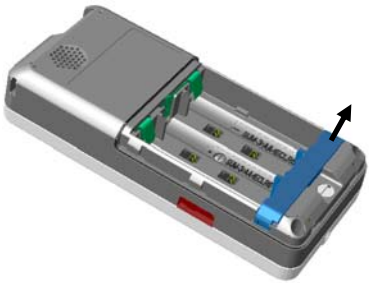
1. Insert the AA alkaline batteries in the battery compartment, aligning the + on each battery with the + shown inside the battery compartment.
2. Close the battery door and push it upwards.
3. Tighten the screw that secures the battery door to the pulse oximeter.

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.**
- **Monitoring a patient while the battery is being charged is not recommended.**

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

- **Do not disassemble batteries, 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.**
- **No modification of this equipment is allowed.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.**
- **The safety checks or maintenance involving any disassembly of the equipment should be performed by professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **The responsible hospital or institution shall carry out all cleaning and disinfection procedure specified in this chapter.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the service personnel.**

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 abnormity, 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:

- 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%, Perform® classic concentrate OXY ($KHSO_4$ solution).

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 SpO_2 sensor, follow local regulations regarding disposal of hospital waste.

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 SpO_2 sensor mentioned in this chapter meet the bio-compatibility requirements and complies with ISO 10993-1, ISO 10993-5 and ISO 10993-10 standards.**

SpO_2 Sensor

Type	Model	Applicable patient	Wavelength*	PN
Single patient use	520A	Adult (finger clip)	660 nm 905 nm	520A-30-64101
	520P	Pediatric (finger clip)		520P-30-64201
	520I	Infant (toe sensor)		520I-30-64301
	520N	Neonate (foot sensor)		520N-30-64401
Reusable	512E	Adult (finger clip)	660 nm 905 nm	512E-30-90390
	512F			512F-30-28263
	512G	Pediatric (finger clip)		512G-30-90607
	512H			512H-30-79061
	DS-100A	Adult (finger clip)	660 nm 890 nm	9000-10-05161
	OXI-P/I	Pediatric/Infant (finger clip)		9000-10-07308
	OXI-A/N	Adult/Neonate (finger clip)		9000-10-07336
	ES-3212-9	Pediatric (ear clip)	/	0010-10-12392
	518B	Adult (multi-site sensor) Neonate (multi-site sensor)	660 nm 905 nm	518B-30-72107

* The maximum optical output power of SpO_2 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	0852-21-77412
Carrying case	0852-10-77701
Charger stand	0000-10-11263
PC Communication cable	0850-20-30725
Lithium ion battery(LI11S001A)	M05-010004-08
Mounting clamp	0852-30-77537

FOR YOU NOTES

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	56×124×30 mm
Max. weight	< 300g (full configuration, including the batteries)

Environmental specifications	Operating conditions	Storage conditions
Temperature (ºC)	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
Maximum 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

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℃.
Shutdown delay	Min. 5 minutes after the low battery alarm first occurs.

Lithium ion battery(LI11S001A)	
Quantity	1
Rated voltage	3.7V
Capacity	1800 mAh
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℃.
Charge time	2 hours to 90% 3.5 hours to 100%
Shutdown delay	Min. 5 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

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, SpO2 and PR value, measurement time	

Measurement specifications	
SpO_2	
Measurement validation: The SpO2 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% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonatal mode) 70 to 100%: ±3% (measured with motion) 0% to 69%: Unspecified
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 (measured without motion) ±5 bpm (measured with motion)
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: 2014.

⚠WARNING

- **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.**
- **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.**
- **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.**
- **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.**
- **This device is intended for use in professional healthcare facility EMC environment and home healthcare EMC environment only. 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.

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 test	**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 B	The device is suitable for use in all establishments, including domestic establishments 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.

NOTE

- **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.**
- **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.**

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**

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	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15kV air	±8 kV contact ±15kV 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	±2 kV for	±2 kV for	Mains power quality

transient/burst IEC 61000-4-4	power supply lines ±1 kV for input/output lines (length greater than 3 m)	power supply lines ±1 kV for input/output lines (length greater than 3 m)	should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycle	0 % U_T for 0,5 cycle 0 % U_T for 1 cycle and 70 % U_T for 25/30 cycles 0 % U_T for 250/300 cycle	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.
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz	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 A.C. 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	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted disturbances 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 from the equation applicable to
	6 Vrms in ISM bands and	6 Vrms	

IEC61000-4-6	amateur radio bands[a] between 0,15 MHz and 80 MHz		the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3.5}{V}\right]\sqrt{P}$ 150k to 80 MHz
Radiated RF EM fields IEC61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m	$d = \left[\frac{3.5}{E}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E}\right]\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[b], should be less than the compliance level in each frequency range[c].
	20V/m 80 MHz to 2.5 GHz (ISO80601-2-61)	20 V/m	
Proximity fields from RF wireless communications equipment IEC6100	27 V/m 380–390 MHz	27 V/m	
	28 V/m 430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz	28 V/m	

0-4-3	9 V/m 704–787 MHz, 5100–5800 MHz	9 V/m	Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] 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.

[b] 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.

[c] Over the frequency ranges 150 kHz to 80 MHz, field strengths should be

less than 3V/m.

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 Transmitter Watts (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	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 $d = \left[\frac{7}{E}\right]\sqrt{P}$
0.01	0.12	0.035	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.11	2.21
100	12	3.5	7

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.

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
Reminder Tone	×	Off
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 SpO_2 Setup

SpO2 Settings	A	Adult	Pediatric	Neonate
SpO2 High Limit	√	100	100	95
SpO2 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.

E Symbols and Abbreviations

E.1 Units

A	ampere
bpm	beats per minute
ºC	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

FOR YOUR NOTES

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