Handheld Pulse Oximeter
Model: AH-M1
Instruction Manual

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Ver.1.0

Product Information

- Product Model: AH-M1
- Product Name: Handheld pulse oximeter
- Manufacturer: Acare Technology Co., Ltd.
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Revision History

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

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CE mark

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Statement

Manufacturer's Responsibility

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

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

About this manual

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

This manual is based on the maximum potential configuration of the product, and therefore some contents may not apply to your device. If you have any questions, 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 referred to when needed.

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

Key:

- ***Bold Italic*** text is used in this manual to quote the referenced chapter or sections.
- 【 】is used to signify text as it appears on the product screen.
- → is used to indicate operational procedures.

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.

Contents

Chapter 1 General Introduction

1.1 Intended Use

The AH-M1 handheld pulse oximeter is intended for continuously monitoring or spot checking peripheral oxygen saturation (SpO_2) and pulse rate (PR) for adult, pediatric or neonatal patients.

This device can be used in institutions or units with health care capability. This includes outpatient departments, emergency rooms and departments of internal medicine in hospitals, ordinary departments in clinics, nursing hospitals and community medical institutions. It may also be used in the home.

1.2 Main Unit

1.2.1 Front View

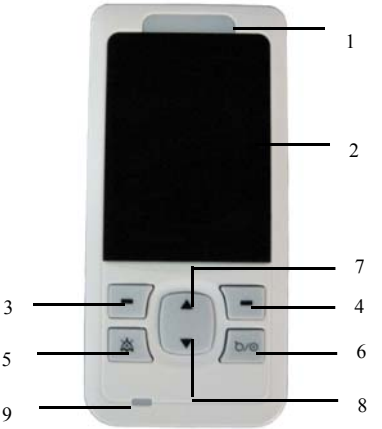

Fig 1-1 Front view of the oximeter

1 Alarm indication lamp

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

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

flashing.

2 Display screen

3 Left button

Press this button to:

- Enter the main menu under the monitoring screen.
- Select the highlighted menu item under the menu screen.

4 Right button

Press this button to:

- Switch the screen display between large numeric mode and SpO_2 waveform mode under the monitoring screen.
- Exit current menu under the menu screen.

5 Alarm pause button

Pressing this button:

- Will not work when the alarm volume is off.
- Can pause the alarm for 120 seconds when the alarm volume is on.
- Changes the alarm message to prompt message when “Sensor off” alarm is activated.
- Note: the alarm can-not be permanently switched

off.

6 Power button

After the batteries are installed:

- Press this button to turn on the oximeter.
- Press and hold it for 2 seconds to turn the oximeter off.

7 Up button

Press this button to:

- Raise the volume of the heart beat displayed
- Move the cursor upwards or increase the value of a selected menu item under the menu screen.

8 Down button

Press this button to:

- Lower the volume of the heart beat displayed
- Move the cursor downwards or decrease the value of a selected menu item.

9 Battery charging indicating lamp

- Lights orange when the battery is being charged.
- Will show no light when the battery is fully charged or not being charged.

1.2.2 Rear View

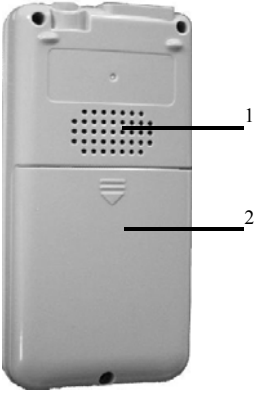

Fig 1-2 Rear view of the oximeter

1. Speaker
2. Battery door

1.2.3 Side View

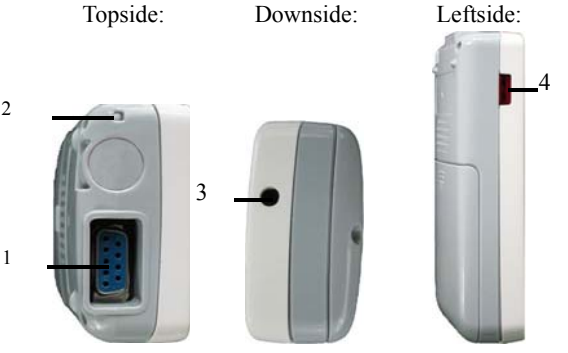

Fig 1-3 Side view of the oximeter

1. SpO_2 probe connector
2. Cord hold
3. Power supply connector

   Used to connect the charger stand.
4. Infrared port

   A port through which a personal computer can communicate with the product, to export data in real time.

1.3 Display Views

This device features an automatic display rotation (gravity activated), which allows vertical and horizontal positioning of the screen, to maximize space utilization and visibility.

1.3.1 Large Numeric Display Mode

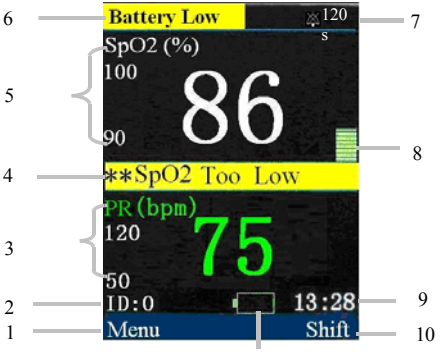

Fig 1-4 Big numerics display mode

1. Menu: Directly after startup,【**Menu**】shown here， is the function controlled by the left hand button. When

appropriate, press the left button to enter 【**Menu**】.

2. Patient ID No.: When 【**Continuous**】 is selected for work mode, the patient ID is set at 0 at all times; when 【**Spot-Check**】 is selected, the ID will display a number between 1 and 99.
3. PR parameter area: Current pulse rate (PR) value and its high and low alarm limits are displayed in this area.
4. Physiological alarm area: Current physiological alarm information is displayed in this area.
5. SpO_2 parameter area: Current SpO_2 value and its high and low alarm limits are displayed in this area.
6. Technical alarm and prompt information area: Current technical alarm and prompt information is shown in this area.
7. Alarm status area: Alarm status symbols and alarm pause time are displayed in this area.
8. Pleth bar: Pulse intensity is indicated by the number of stacked blocks visible.
9. System time: Current time is shown in the area.
10. Shift: Directly after startup, 【**Shift**】shown here is the function controlled by the right hand button. Press the right hand button to shift between different display

modes.

11. Battery symbol: This symbol indicates the remaining quantity of electrical charge in the batteries.

1.3.2 SpO_2 Waveform Display Mode

Fig 1-5 SpO_2 waveform display mode

1. SpO_2 waveform area: The waveform shown in this area illustrates the current SpO_2 volume curve of the patient being monitored.
2. SpO_2 parameter area: Current SpO_2 value and its upper and lower alarm limits are displayed in this area.
3. PR parameter area: Current PR value and its upper and lower alarm limits are displayed in this area.

Chapter 2 Safety

2.1 Safety Information

Warning:

- **Explosion hazard: Do not use the oximeter in the presence of flammable anesthetics mixed with air, oxygen, or hydrogen.**
- **Do not use the product in the presence of high power appliances such as high voltage cables, X-ray machines, ultrasound equipment or a defibrillator.**
- **Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.**
- **The device is not designed for use in a sterile field**
- **The oximeter should be handled with care so as to avoid it getting knocked or falling.**

Warning:

- **Do not use this device during defibrillation.**
- **When the device is in use, ensure that the batteries have sufficient charge remaining; otherwise start-up abnormalities may occur or the measurement data may be inaccurate.**
- **Patients must not wear nail varnish while using the pulse oximeter as this will lead to unreliable SpO_2 measurements.**
- **Measurements and pulse signals can be affected by certain environmental conditions, errors in applying the sensor, and certain patient conditions. See the appropriate sections of this manual for specific safety information.**
- **The use of accessories, sensors, and cables other than those specified may result in increased emission, low anti-disturbance and/or may lead to the oximeter producing invalid readings. It is advisable to check the oximeter at least once a month.**

Caution: In order to obtain accurate results, the oximeter should be used in a quiet and comfortable environment.

2.2 Explanation of Symbols

Symbol	Symbol Note
	Type BF applied part, defibrillation protected
	Attention: Consult accompanying documents (this manual).
	Direct Current（DC）
IPX1	Degree of protection against ingress of liquid
	Alarm volume off
	Alarm volume pause
	parameter alarm off

Symbol	Symbol Note
	Beep volume off
	Power supply connector
	Left/right button
	Up button
	Down button
	Date of manufacture
	Manufacturer
	CE mark
SN	Serial number
	Power button
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.

Chapter 3 Basic Operations

3.1 Unpacking and Checking

Open the package. Take out the oximeter and its accessories. The following parts are provided in the package:

Parts	Standard	Optional	Quantity
SpO_2 probes (DB9 plugs)	√		1
User's manual	√		this manual
Lithium battery	√		1
AC-DC adapter	√		1
Battery charger stand	√		1
Protective cover	√		1
Clip with lanyard	√		1
QuickStart	√		1
CDROM	√		1
Check list	√		1
Alkaline battery		√	3

3.2 Getting Started

1. Before using the oximeter to take measurements for the first time, carry out the following checks on the oximeter and all connected modules:

   ——Check for any mechanical damage;

   — — Check for correct connection between of all the external cables and accessories.

2. Insert batteries into the battery compartment. Make sure that the battery has sufficient power. When using rechargeable batteries for the first time, you must charge them,first, following the instructions given in the ***Battery*** chapter.

Warning:

- **If the oximeter is mechanically damaged, or if it is not working properly, do not use it on a patient for any monitoring procedure. Contact your service personnel.**
- To avoid the risk of explosions, do not use the oximeter in the presence of flammable anesthetics, vapors or liquids.

3.3 Starting the oximeter

Press the button to turn on the oximeter. The alarm indication lamp should flash, and then stop. The system should give a beep and enter the main screen. After starting the oximeter you can change the settings for more convenient use, as shown in ***section 3.4***.

3.4 General Setup

Press the Left button to enter 【 **Menu** 】, then select【**General Setup**】to enter the general setup menu shown as follows. You can set parameters for the following functions: .

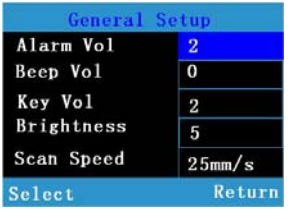

Fig 3-1 General setup window

3.4.1 Beep Volume Setup

Press the Left button to select the item, then adjust its value using the Up or Down button. You can select from 0 to 4. A sign will be shown at the bottom of the monitoring

screen when the beep volume is off.

3.4.2 Key Volume Setup

Press the Left button to select the item, then adjust the value using the Up or Down button. You can select from 0 to 4.

3.4.3 Adjust the Screen Brightness

Press the Left button to select the item, then adjust the value using the Up or Down button. You can select from 1 to 5. Selecting the minimum brightness can save power.

Caution: If the oximeter is used outdoors, or if the ambient light is strong, set the screen brightness to a higher level.

3.4.4 Scan Speed Setup

Press the Left button to select the item, then adjust its value using the Up or Down button. You can select from 12.5mm/s to 25mm/s.

3.5 Date and Time Setup

After starting up, set the date and time of your oximeter. Operations are as follows:

1 Select【**Menu**】→【**System**】 to enter the System menu, as shown below:

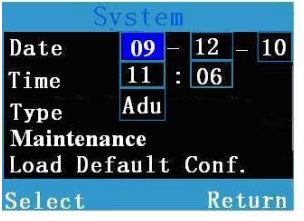

Fig 3-2 System setup window

2 Select the year, month and day to the right of 【**Date**】, and set them to the current date at your location.

3 Select the hour and minute to the right of 【**Time**】, and set them to the current time at your location.

3.6 Selecting the Work Mode

The oximeter is designed to operate in two modes: continuous monitoring and spot-checking. The work mode

that is currently selected will be displayed in the technical alarm area. You can choose the oximeter's work mode through the following steps:

1. Select【**System**】→【**Maintenance**】, at which point a window will pop up and ask for your password. Input the password and select【**OK**】to enter the maintenance window shown as follows:

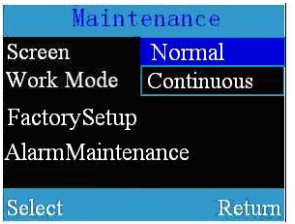

Fig 3-3 Maintenance window

2. Select【Work Mode】, and then set the oximeter's work mode to【Continuous】or【Spot-Check】.

3.6.1 Continuous Monitoring Mode

The continuous monitoring mode is intended for long-term monitoring of a patient. This mode is normally selected when the patient is in hospital or under transport., The

default patient ID given by the system is 0. When the oximeter's memory reaches full capacity, the oldest stored data will be deleted.

3.6.2 Spot-checking Mode

Spot-checking mode is intended for short-term, on-site measurement. This mode is normally selected to check up on the condition of a patient by doctors making rounds of a ward. The patient ID will automatically increase from 1 to 99 with each patient. Details are as follows:

Apply the SpO_2 sensor to the patient. After valid SpO_2 signals are detected,

1. The patient ID flashes and after 8 seconds will automatically increase by 1 number to admit a new patient.
2. Pressing the Left hand button when the current patient ID is flashing, will make the patient ID stop flashing and the ID number will remain unchanged. The new patient will not be admitted and further measurements will be stored under the current patient ID.
3. When the storage of patient measuring data reaches its limit, the patient ID will be reset to 1 and new data will

replace the information stored under the first patient ID.

3.7 Selecting Patient Type

To select the patient type,

1. Select【**Menu**】→【**System**】→【**Type**】.
2. Set【**Type**】to【**Adu**】, Adult【**Ped**】Pediatric or 【**Neo**】Neonate.

3.8 Entering/Exiting the Demo Mode

To enter the demo mode:

1. Select【**Menu**】→【**System**】→【**Maintenance**】→ enter the required password.
2. Set【**Screen**】to【**Demo**】and the message【**Demo Mode**】will appear in the technical alarm area.

To exit the demo mode:

1. Select【**Menu**】→【**System**】→【**Maintenance**】→ enter the required password.
2. Set【**Screen**】to【**Normal**】.

Caution: The Demo mode is for demonstration purpose only. Do not enter the Demo Mode when a patient is being monitored, to avoid mistaking simulated data for the patient's actual data. This

could result in improper patient monitoring and delayed treatment.

3.9 Changing the Language

Select【**Menu**】→【**System**】→【**Maintenance**】, enter the required password. Select 【 **Factory Setup** 】 to set 【**Language** 】.

3.10 Checking the Version

Select【**Menu**】→【**System**】→【**Maintenance**】, enter the required password. Select 【**Factory Setup**】 to check the version of the oximeter.

3.11 Restoring the Factory Configuration

If you have made changes to the system's configuration and want to restore the original factory settings, follow this procedure:

1. Select【**Menu**】→【**System**】.
2. Select【**Load Default Conf.**】. A pop up window will appear, asking you to confirm that you want

to return to the original configuration., Select【**OK**】to restore the factory configuration.

3.12 Shutting off the Oximeter

To turn off the oximeter, follow the steps below:

1. Confirm that patient monitoring is complete.
2. Disconnect the SpO_2 sensors form the oximeter.
3. Press the power button and hold it for 2 seconds to turn off the oximeter.

Caution: Under the Spot-check mode, if the oximeter is not in use and there has been no button operation for more than 5 minutes, the oximeter will shut down automatically.

Chapter 4 Alarm

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

Note: The oximeter generates all audible and visual alarms through a speaker, a visual alarm lamp and the screen.

4.1 Alarm Categories

The oximeter's alarms fall into three categories:

1.Physiological alarms

Physiological alarms are triggered when a monitored parameter moves outside of set alarm limits, or by an abnormal patient condition. Physiological alarm messages are displayed in the physiological alarm area.

2.Technical alarms

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

3.Prompt messages

Prompt messages are not alarm messages. The pulse oximeter will sometimes show messages updating the user on the system status, separate from the physiological and technical alarm messages,. Prompt messages are displayed in the technical alarm area.

4.2 Alarm Levels

1. The oximeter's physiological alarms fall into three categories of increasing severity: low level alarms, medium level alarms, and high level alarms.

   - High level alarms

   Indicate that the patient is in a life-threatening situation and emergency treatment is required.

   - Medium level alarms

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

- Low level alarms

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

2. The oximeter's technical alarms can be classified into two categories of severity: medium level alarms and low level alarms.

Caution: The technical alarms cannot be changed by the user.

4.3 Alarm Indicators

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

- Alarm tone: The speaker on the rear panel of the oximeter will sound the alarm in different tones, according to the severity of the alarm.
- Alarm lamp: The alarm lamp on the front of the oximeter will flash a different color and speed, according to the severity of the alarm.

- Alarm message: Alarm messages are displayed on the front screen.
- Flashing numeric: The monitored parameter that has been breached to cause the alarm to sound will flash.

Caution: Alarm lamp, alarm tone and alarm messages will vary according to the level of severity of the alarm.

4.3.1 Alarm tone

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

Alarm level	Audible prompt
High	"DO-DO-DO------DO-DO, DO-DO-DO------DO-DO"
Medium	"DO-DO-DO"
Low	"DO-"

4.3.2 Alarm Lamp

When an alarm occurs, the severity is indicated on the alarm lamp in the following visual ways:

Alarm level	Visual prompt
High	Alarm lamp flashes in red at 2 Hz
Medium	Alarm lamp flashes in yellow at 0.5 Hz.
Low	Alarm lamp is yellow but does not flash.

Caution:

- **When multiple alarms of different levels occur at the same time, the oximeter will select the highest warning level and give the highest visual and audible alarm indications.**
- **When multiple alarms occur at the same time, the alarm messages will be displayed in the alarm area in turn.**

4.3.3 Alarm Message

When an alarm occurs, the alarm message will be displayed in the alarm area.

- The system uses the following alarm symbols to match the level of physiological alarm messages:
  High level alarms: ***
  Medium level alarms: **
  Low level alarms: *
- The system uses the following background colors to indicate different messages and match the alarm level:
  High level alarms: red
  Medium level alarms: yellow
  Low level alarms: yellow

4.3.4 Flashing Numeric

When a physiological alarm occurs, the flashing numeric indicates the parameter that has been breached

4.4 Alarm Status Symbol

 Indicates that the alarm sound is turned off.

 Indicates that the alarm sound is paused.

 Indicates that individual measurement alarms are turned off.

4.5 Alarm Tone Configuration

4.5.1 Setting the minimum Alarm Volume

1. Select【**Menu**】→【**System**】→【**Maintenance**】→enter the required password.
2. Select【**Min.Al.Vol**】and then select a value between 0 and 4.

4.5.2 Changing the Alarm Volume

1. Select【**Menu**】→【**General Setup**】.
2. Select【**Alarm Vol**】and then select a value between X and 4. X is the minimum volume. The value of X depends on the setting of the minimum alarm volume.

4.6 Pausing the Alarm Tones

Press the alarm pause button  to keep the alarm paused for 120 seconds. An alarm paused symbol will indicate that the alarm is paused, and the pause time will be displayed in the alarm status area.

- When the audible alarm is paused, 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.
- Pressing the key will restart the audible alarm.

The audible alarm automatically starts again once the alarm pause period expires.

4.7 Shutting off the Alarm Volume

Set the【**Min.Al.Vol**】and【**Alarm Vol**】to 0 to shut off the alarm volume. This symbol will show in the alarm status area:

The alarm lamp and alarm messages remain active even when the alarm volume is off. The audible alarm is reactivated automatically when:

- The factory configuration is selected.
- The alarm volume is set to a nonzero value.

When a factory configuration is selected, the alarm volume of the 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 oximeter will give no audible alarm tones even if a new alarm occurs. Any decision to switch off the alarm sound should be made with extreme caution.**
- **Users should not rely exclusively on the audible alarm system for patient monitoring. Adjusting the alarm volume to a low level may result in a hazard to the patient. Always keep the patient under close surveillance.**

4.8 When an Alarm Occurs

Note: When an alarm occurs, always check the patient's condition first.

Check which alarm message has appeared on the screen. This is necessary to identify the alarm and the appropriate action to be taken.

1. Check the patient's condition.

2. Identify which parameters have set off the alarm, and identify the alarm category.
3. Identify the cause of the alarm.
4. Silence the alarm, if necessary.
5. When the cause of the alarm has been identified and addressed, check that the alarm system is working properly.

Alarm messages for individual parameters can be found in ***Appendix D Alarm message***.

Chapter 5 Measuring SpO2

5.1 Introduction

The measurement of oxygen saturation of arterial blood (also known as peripheral oxygen saturation, usually shortened to SpO_2) relies on the principles of light spectra and volume tracing. An LED in the oximeter emits light rays through the body, wherever the probe is used, e.g. through the finger, at two different specific wavelengths. Each of these is selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin in the blood. An optical receptor measures the changes in the light intensity after the light passes through the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.

$$SpO_2\,\% = \frac{\text{oxygenated hemoglobin}}{\text{oxyhemoglobin + deoxyhemoglobin}} \times 100\%$$

5.2 Safety Information

Warning:

- **Only use the SpO_2 sensors specified in this manual. Follow the SpO_2 sensor instructions for use and adhere to all warnings and cautions.**
- **When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter for a full diagnosis of the patient's condition.**
- **Do not use the oximeter and the SpO_2 sensor during magnetic resonance imaging (MRI). The induced current could cause burns to the patient.**
- **Prolonged continuous monitoring may increase the risk of unexpected changes in skin characteristics of the patient, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.**

Warning:

- **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 discarding a disposable or broken SpO_2 probe, please observe all local, state, and federal regulations relating to the disposal of this products or similar products.**

Caution: In cases where it is necessary to add a clip to fix the fingertip sensor, clip the cable and not the sensor itself. Please note that the sensor cable should not be pulled with force.

Note:

- **The pleth wave is not equal to the intensity of PR signal.**
- **The oximeter does not provide an automatic self-check alarm signal; the operator should use an SpO2 simulator or use the oximeter on themselves to check the oximeter is working correctly.**

5.3 Monitoring Procedure

1. Selecting the SpO_2 Sensor

Depending on the patient category, weight and application site, you can select a different SpO_2 sensor as required.

2. Connecting the SpO_2 Sensor

Plug the SpO_2 sensor cable into the SpO_2 connector on the oximeter.

3. Applying the SpO_2 Sensor to the patient

Clean the application site, removing barriers such as colored nail polish, and apply the sensor to the patient.

Warning:

- **Do not use the SpO_2 sensor on a limb where a NIBP cuff has been applied. This may result in inaccurate SpO_2 readings during cuff inflation.**
- **Do not attempt to monitor SpO_2 levels on a finger that has been painted with nail polish, as this may result in unreliable measurements.**
- **When attaching a finger sensor to a patient, make sure that the patient's nail faces the light window inside the sensor.**

5.4 SpO_2 Display

- **Parameter Display**

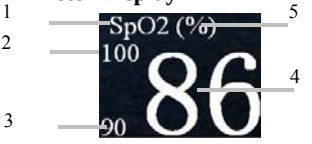

Fig 5-1 SpO_2 parameter

1. SpO_2 label 2. High alarm limit of SpO_2 3. Low alarm limit of SpO_2 4. SpO_2 value 5. SpO_2 unit

- **Waveform Display**

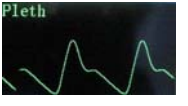

Fig 5-2 SpO2 waveform

5.5 PR Display

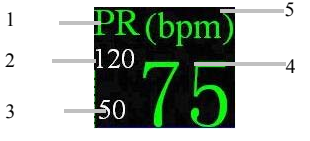

Fig 5-3 PR parameter

1. PR label 2. High alarm limit of PR 3. Low alarm limit of PR 4. PR value 5. PR unit

5.6 SpO_2 Alarm Setup

5.6.1 Switching On/Off SpO_2 Alarm

1. Select【**Menu**】→【**Alarm Setup**】.
2. Set the【**Alarm**】of SpO_2 to【**Off**】to shut off SpO_2 alarm. When the alarm of SpO_2 is off, this sign  will be in the visible SpO2 parameter display area:

5.6.2 Setting the Alarm Level

1. Select【**Menu**】→【**Alarm Setup**】.
2. Set the【**Alarm**】of SpO_2 to【**Med**】or【**High**】.

5.6.3 Adjusting the Alarm Limit

1. Select【**Menu**】→【**Alarm Setup**】.
2. Adjust【**High**】:If an SpO_2 measurement is higher than the high alarm limit, the "SpO2 Too High" alarm will be triggered.
3. Adjust【**Low**】:If an SpO_2 measurement is lower than the low alarm limit, the "SpO2 Too Low" alarm will be triggered.

5.6.4 Altering the Desaturation Limit

When the oximeter records an SpO_2 value that is lower than the lower saturation limit, a high physiological alarm will be triggered. The desaturation limit may be reset is as follows:

1. Select【**Menu**】→【**System**】→【**Maintenance**】, and a pop up window will appear, requiring a password.
2. Input the password and select 【 **OK** 】 to enter the maintenance window. Select【**Desat Lim.**】, and then set its value through the Up and Down button.

5.7 PR Alarm Setup

5.7.1 Switching PR Alarm On/Off

1. Select【**Menu**】→【**Alarm Setup**】.
2. Set the【**Alarm**】of PR to【**Off**】to shut off PR alarm. When the PR alarm is, off, this symbol will be in the visible PR parameter display area:

5.7.2 Setting the Alarm Level

1. Select【**Menu**】→【**Alarm Setup**】.
2. Set the【**Alarm**】of PR to【**Med**】or【**High**】.

5.7.3 Adjusting the Alarm Limit

1. Select【**Menu**】→【**Alarm Setup**】.
2. Adjust【**High**】: If a PR measurement is higher than the high alarm limit, the "PR Too High" alarm will be triggered.
3. Adjust【**Low**】: If a PR measurement is lower than the low alarm limit, the "PR Too Low" alarm will be triggered.

Chapter 6 Reviewing

6.1 Introduction

Select【**Menu**】→【**Trend**】to enter the trend reviewing window. You can review previously stored SpO_2 and PR data in this window.

6.2 Reviewing Screen

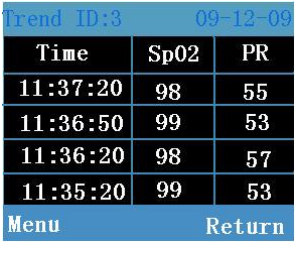

Fig 6-1 SpO_2/PR reviewing window

The above screen shows the SpO_2/PR reviewing window. You can review SpO_2/PR values measured at different time intervals in this window. When SpO_2or PR values are over the alarm limit that has been set, their values will appear in red. If the trend data spreads across more than one page, you can turn pages by using the Up or Down button.

6.3 Reviewing Setup

After entering the reviewing window, press the left button to enter the【**Trend Setup**】window, as shown below:

Fig 6-2 Trend Setup

In the window you can set【**Interval**】,【**Select ID**】,【**Delete Selected** 】,【**Delete All**】and【**Export Trend**】:

- Interval： The time interval between recordings can be adjusted to take regular readings within the range of 2 seconds to 30 minutes.
- Select ID：This selects the desired patient ID No. The user may change ID Nos. to browse the trend data of corresponding patients.
- Delete Selected：This deletes the stored trend data of the selected ID No.

- Delete All：This deletes all trend data from every stored ID No.
- Export Trend：This allows the user to send trend data from a selected ID No to a computer. Before this can be done, the relevant computer software must be opened, and the infrared interfaces of the instrument and the computer must be aligned.

Chapter 7 Battery

7.1 Introduction

The oximeter is designed to operate on three 1.5V alkaline AA batteries or one piece Li-ION rechargeable battery. Under normal circumstances, no special battery maintenance is necessary.

When alkaline batteries or the Li-ION battery are used, the battery icon indicates the battery status as follows:

1.  Indicates that the power of the battery is full;
2.  Indicates that the power of the battery has 3 grids left (3/4 full) ;
3.  Indicates that the power of the battery has 2 grids left (half full) ;
4.  Indicates that the power of the battery has 1 grid left (1/4 full) ;
5.  Indicates that the battery is almost depleted.

The battery power supply can only last for a certain period of time. If the voltage of batteries is too low, a "Battery

Low" alarm will be triggered. If alkaline AA batteries are used, please change them at timely intervals. If the Li-ION rechargeable battery is used, please insert the oximeter to the battery charger and connect the charger to a commercial power supply to charge the battery. The oximeter will switch off automatically 10 minutes after the first "Battery Low" alarm is given.

Caution: Remove the batteries prior to shipping, or if the oximeter is not likely to be used for an extended period of time.

Warning:

- **Use only batteries specified in this manual.**
- **Keep the batteries out of the reach of children.**
- **When the oximeter is not in use for a long time, the batteries should be removed. Dispose of used batteries in accordance with local ordinances and regulations.**

7.2 Installing Batteries

The battery compartment is at the back of the device; follow the steps below to install or change the batteries.

7.2.1 Opening the Battery Door

1. Turn the oximeter off first.
2. Use a screw driver to remove the screw that secures the battery door to the oximeter.

Fig 7-1 Loose the screw

3. Press the battery door, pushing it downwards to remove the battery door.

Fig 7-2 Push the battery door

7.2.2 Installing the Alkaline Battery

1. Insert the AA alkaline batteries into 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. Use a screw driver to tighten the screw that secures the battery door to the pulse oximeter.

Caution: Check the batteries periodically for corrosion. Replace batteries if corrosion is present, otherwise damage to the oximeter may occur.

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

7.2.3 Installing the Lithium-Ion Battery

1. Insert the lithium ion battery in the battery compartment, following shown as follows:

Press the battery in

Fig 7-3 Install the Li battery

2. Close the battery door and push it upwards.

3. Tighten the screw that secures the battery door to the pulse oximeter.

Warning: Disconnect the oximeter from the patient and stop all monitoring before charging the battery.

7.3 Charging Lithium Ion Battery

Only Lithium-Ion rechargeable battery can be recharged by the charger stand with this pulse oximeter.

Fig 7-4 Charging device

To charge the Lithium Ion battery:

1. Place the oximeter in the charger stand.
2. Connect the AC-DC adapter and plug the adapter into the AC mains.
3. The indicating lamp on the battery charger and the indicating lamp on the oximeter will light up, to show that the battery is charging.

4. When the indicating lamp on the oximeter turns off, the battery is fully charged.

7.4 Optimizing Battery Performance

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

To optimize a battery, follow this procedure:

1. Disconnect the oximeter from the patient and stop all monitoring and measuring procedures.
2. Place the battery in need of optimizing into the battery compartment of the oximeter.
3. Place the oximeter in the charger stand and connect it to the AC mains. Allow the battery to charge uninterrupted for more than 4 hours.

4. Disconnect the oximeter from the AC mains and allow the oximeter to run on the battery until it shuts off.
5. Replace the oximeter in the charger stand and connect it to the AC mains. Allow the battery to charge uninterrupted for more than 4 hours.
6. The optimization of the battery is complete.

7.5 Checking the Lithium-Ion Battery

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

1. Disconnect the oximeter from the patient and stop all monitoring and measuring procedures.
2. Place the oximeter in the charger stand and connect it to the AC mains. Allow the battery to charge uninterrupted for more than 4 hours.
3. Disconnect the oximeter from the AC mains and allow the oximeter to run on the battery until it shuts off. Make a note of how long this takes.
4. The operating time of a battery directly reflects its performance.

Caution:

- **The service life of battery depends on the length and frequency of use. Lithium-Ion batteries can generally be charged and discharged 300 times.**
- **The operating time of a battery depends on the configuration and operation of the pulse oximeter.**

7.6 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, dispose of them in fire, or cause them to short circuit. They may leak, ignite, or explode, causing personal injury.

Chapter 8 Maintenance and Cleaning

8.1 Introduction

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

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

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

Warning: For optimal performance, product service should be performed only by qualified service personnel.

Caution: If you spill liquid onto the equipment or accessories, contact your service personnel or Acare.

8.2 Annual Safety Checks

Note: To ensure the ongoing performance and safety of your equipment, the device must be checked after 1 year of use. Use professional technology engineers to check the device.

Clean the plug connected to the power cord at least once a year. Too much dust on the plug may cause a fire.

The following safety checks and tests should be performed at least every 12 months by a qualified person with adequate training, knowledge, and practical experience.

The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the following tests, the device must be repaired.

① Inspect the equipment and accessories for mechanical and functional damage.

② Inspect the relevant safety labels for legibility.

③ Verify that the device functions properly, as described in the instructions for use.

④ Test the earth leakage current, according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 500μA, SFC: 1000μA.

⑤ Test the enclosure leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 100μA, SFC: 500μA.

⑥ Test the patient leakage current (normal operation) according IEC 60601-1:1988 + A1:1991 + A2:1995:
Limit: type BF: for a.c.: 100μA, for d.c.: 100μA.

⑦ Test the patient leakage current under single fault condition according to IEC 60601-1:1988 + A1:1991 + A2:1995:
Limit: type BF: for a.c.: 5mA, for d.c.: 5mA.

⑧ Test the patient leakage current Mains voltage on applied part: According IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: type BF: for a.c.: 5mA.

Warning: Do not attempt to service the device yourself, take it to an authorized representative or manufacturer.

8.3 Cleaning the Oximeter

1. Common detergent and non-corrosive disinfectant used in hospitals can be used to clean the oximeter; be aware that many kinds of detergents must be diluted prior to utilization. Use cleaning fluids according to the instruction of the detergent manufacturer.
2. Avoid the use of alcohols, amino or acetonyl detergents when cleaning the oximeter.
3. The oximeter case and screen must be kept free of dust. It can be wiped with a lint-free soft cloth or a sponge soaked in detergent. While cleaning the oximeter, be careful not to spill liquid onto the instrument, and do not

allow any liquid to spill inside the oximeter. When wiping the side panel of the oximeter, be especially careful to keep liquid away from the cable and the outlet.

4. Do not use abrasive materials such as wire brushes or metal brighteners when cleaning the oximeter, as they will damage the panel and the oximeter screen.
5. Do not submerge the oximeter in liquid.
6. If the cable or plug accidentally gets wet, rinse them with distilled or deionized water and dry them in an environment with a temperature between 40˚C and 80 ˚C for at least one hour.

8.4 Cleaning SpO_2 Sensor

1. The casing of the sensor and light tube can be cleaned with a swab, or a non-velvet soft cloth dipped in medical alcohol.
2. The sensor cable can be cleaned or sterilized with hydrogen peroxide 3%, or isopropyl alcohol 70%.
3. Never put the oximeter in a high-pressure container, and never put the sensor directly in liquid.

Warning: Do not reuse or disinfect disposable SpO_2 sensors.

8.5 Disposal

Dispose of the oximeter in accordance with local environment and waste disposal laws and regulations. For the disposal of SpO_2 sensors, follow local regulations regarding the disposal of hospital waste.

Chapter 9 Accessories

Nellcor SpO_2 sensor

Type	Model	Patient Category
Disposable	ASDNR-A1	Adult finger (patient size>30kg)
	ASDNR-P2	Pediatric foot/hand (patient size 10-50kg)
	ASDNR-N3	Adult finger or neonatal foot/hand (patient size >40 kg or <3 kg)
Reusable	ASANR-D3	Adult
	ASYNR-D3	Adult / neonatal
	ASPNR-D3	Pediatric / neonatal

Appendix A Product Specifications

A.1 Safety Specifications

SFDA classification	II
CE classification	IIb
Type of protection against electric shock	II, with external power internal power device
Degree of protection against electric shock	BF
Degree of protection against hazards of explosion	Ordinary equipment, without protection against hazards of explosion
Degree of protection against ingress of liquid	IPX1
Equipment type	Handheld

A.2 Physical Specifications

Mainframe weight	＜200g
Mainframe size	58.5mm(W)×123mm(H)×28mm(D)
Charger weight	＜100g
Charger size	96mm(W)×66mm(H)×78mm(D)

AC-DC adapter weight	＜200g
AC-DC adapter size	41.5mm(W)×90mm(H)×32mm(D)

A.3 Environmental Specifications

Temperature	Operating: 0℃ to +40℃；
	Storage: -20℃ to +50℃；
Atmospheric pressure	Operating: 860hPa to 1060hPa；
	Storage: 500hPa to 1060hPa；
Humidity	Operating: 15% to 85% (non condensing)
	Storage: 10% to 93% (non condensing)

A.4 Charging Specifications

A.4.1 AC-DC Adapter (Optional)

Input	100～240VAC，50/60Hz
Output	5V，1.5A

A.4.2 Battery Specification

Standard	
Type	Lithium ion rechargeable battery
Size	50mm×46.5 mm×13.5mm

Weight	50g
Quantity	1
Rated voltage	3.7 VDC
Capacity	1600 mAh
Run time	＞14 hours With SpO_2 monitored continuously, Audio indicators off and backlight brightness set to minimum and using new, full power batteries at ambient temperature 25℃.
Charge time	3 hours to 90% 4 hours to 100%
Shutdown delay	10min（After the first "low battery" alarm）
Optional	
Type	1.5V, AA alkaline battery
Capacity	2000mAh
Quantity	3
Run time	>14 hours With SpO_2 monitored continuously, Audio indicators off and backlight brightness set to minimum and using new, full power batteries at ambient temperature 25℃.
Shutdown delay	10 min (After the first "low battery" alarm)

A.5 Hardware Specifications

A.5.1 Display

Type	OLED
Size（diagonal）	2.4 inch
Resolution	320×240 pixels

A.5.2 Indicating LED

Mainframe LED	
Alarm indicating lamp	1 (Yellow/Red）
Battery charging indicating lamp	1 (Orange) When charged, it lights orange. When fully charged or not charged, it does not light.
Charger LED	
AC power indicating lamp	1 (Green) When connecting to the AC-DC adapter, it lights green; When disconnecting from the AC-DC adapter, it does not light.

A.5.3 Audio Indicating

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

A.5.4 Buttons

Quantity	6
Functions	Power button, Up button, Down button, Left button, Right button, and Alarm pause button.

A.5.5 Sensors

Wavelength	Pulse oximetry sensors contain LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 905 nm. The total optical output power of the sensor LEDs is less than 15 mW. This information may be useful to clinicians, such as those performing photodynamic therapy.

A.6 Data Storage

The changing trends of SpO_2 and PR data will be shown in the oximeter:

Displaying way	Trend tabular
Trend interval	2 seconds to 30 minutes
Trend parameter	PR，SpO_2
Trend data	Spot-check: ID from 1 to 99, 300 groups can be stored for each ID. Continuous: ID is 0, 60000 groups can be stored.

A.7 Measurement Specifications

A.7.1 Digital SpO2

SpO_2	
Technic	Digital SpO_2 technic
Range	0~100%
Resolution	1%
Accuracy	70% to 100%: ±2% 0% to 69%: unspecified
Refreshing rate	<13 seconds
Pitch Tone	with
PR	
Range	25 bpm to 250 bpm
Resolution	1 bpm
Accuracy	±2% or ±1 bpm, whichever is the greater
Refreshing rate	<13 seconds

A.7.2 Nellcor SpO2

SpO_2	
Range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2%（adult/pediatric） 70% to 100%: ±3%（neonate） 70% to 100%: ±2%（low perfusion） 0% to 69%, unspecified
Refreshing rate	7s
Pitch Tone	with
PR	
Range	25 bpm to 250 bpm
Resolution	1 bpm
Accuracy	± 3 bpm
Refreshing rate	7s

A.7.3 Alarm Limit Specifications

Alarm limits	**Range (%)**	**Step (%)**
SpO_2 high limit	(low limit +1) to 100	1
SpO_2 low limit	Desat to (high limit -1)	

Alarm limits	Range (bpm)	Step (bpm)
PR high limit	(low limit +1) to 250	1
PR low limit	20 to (high limit -1)	

Appendix B EMC

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should make certain that they are in such an environment when operating it.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Radio frequency (RF) emissions CISPR 11</td><td>Group 1</td><td>The device only uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>Radio frequency RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions IEC 61000-3-3</td><td>N/A</td></tr>
</table>

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 make certain that they are in such an environment when operating it.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst (EFT) IEC 61000-4-4	N/A	N/A	N/A
Surge IEC 61000-4-5	N/A	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic The power frequency of 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 device should make certain that they are in such an environment when operating it.

Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m

Electromagnetic environment - guidance

Portable and mobile RF communications equipment should not be used closer to any part of the device, including cables, than the recommended separation distance. This is calculated from the equation applicable to the frequency of the transmitter.

$$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$$

$$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$$

80 MHz to 800 MHz

$$d = \left[\frac{7}{E_1}\right]\sqrt{P}$$

800 MHz to 2.5 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[a], should be less than the compliance level in each frequency range[b].

Interference may occur in the vicinity of equipment marked with the following symbol:

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the SL-F SL Series Anti-decubitus Mattress

The device is intended for use in an electromagnetic environment in which radiated RF disturbances 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 communications equipment.

Rated maximum output power of	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz

transmitter (W)	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	1.2	0.12	0.23
0.1	3.8	0.38	0.73
1	12	1.2	2.3
10	38	3.8	7.3
100	120	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

Appendix C Factory Defaults

This section lists the most important factory default settings. These settings can be adjusted and you can load the factory defaults if you need.

C.1 Alarm Setup

Alarm Setup	Factory Default
Alarm Vol	2
SpO_2 Alarm Level	Med
PR Alarm Level	Med

C.2 System Setup

System Setup	Factory Default
Beep Vol	2
Key Vol	2
Brightness	3
Scan Speed	25mm/s

C.3 SpO_2 Setup

SpO_2 Setup	Adult	Pediatric	Neonate
SpO2 High Limit	100	100	95
SpO2 Low Limit	90	90	90
PR Setup	Adult	Pediatric	Neonate
PR High Limit	120	160	200
PR Low Limit	50	75	100

C.4 Trend Setup

Trend Setup	Factory Default
Interval	30s

Appendix D Alarm Message

This section lists some important alarm message. In the tables below, "*" means the alarm level is user-adjustable.

D.1 Physiological alarm

Messages	Cause	Level
SpO_2 Too High*	A measurement has risen above the high alarm limit or fallen below the low alarm limit.	Medium
SpO_2 Too Low*		
SpO_2 Desat	SpO_2 measurement has fallen below the SpO_2 desat limit.	High
PR Too High*	A measurement has risen above the high alarm limit or fallen below the low alarm limit.	Medium
PR Too Low*		
No Pulse	The pulse signal was too weak to be analyzed.	High

D.2 Technical alarm

Messages	Cause	Level
Sensor Off	The SpO_2 sensor detached the patient or the oximeter.	Medium
Battery Low	The battery power is low.	Medium
SpO_2 Low Perf	The signal detected is weak.	Medium

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