Handheld Pulse Oximeter
Model: AH-TX Series
(AH-TA)
(AH-TB)
Instruction Manual

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Ver.1.0

Product Information

- Product Model: AH-TX Series
- Product Name: Handheld pulse oximeter
- Manufacturer: Acare Technology Co., Ltd.
- After Service Contact Information:
  Address: 6F.-3, No.24, Wuquan 2st Rd., Xinzhuang Dist., New Taipei City 242, Taiwan
  TEL: +886-2-2298-8170
  FAX: +886-2-2298-8560
  Email: service@acaretech.com

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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EC Representative Name:

COMPAŇIA EUROPEA DE PROSUCTOS MEDICOS, S.L.

(MEDIPRO)

Villapark Business Park, Av Quitapesares 8, Building 8, Villaviciosa de Odon (Madrid) 28670, Spain

Statement

The contents of this manual are subject to amendment without notification.

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 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.

Note: The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle.

Compliance regulations

This product complies with the relevant medical equipment regulations as follows:

- ✓ IEC 60601-1 (Edition 3.1)
- ✓ IEC 60601-1-2 (4th Ed.)
- ✓ IEC 60601-1-8
- ✓ ISO 80601-2-61
- ✓ EN 301489-1
- ✓ EN 301489-17
- ✓ FCC Part15B
- ✓ FCC Part15C
- ✓ NCC (Taiwan Only)

Contents

Chapter 1 General Introduction

1.1 Intended Use

The AH-TX handheld pulse oximeter is intended for continuously monitoring or spot checking peripheral oxygen saturation (SpO2) and pulse rate (PR) for adult, pediatric or neonatal patients.

This device can be used in professional 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.

1.2 Main Unit

1.2.1 Front & Rear View

Fig 1-1 Front & rear view of the oximeter

1. Display screen
   - The Display screen is a 4.3 inch TFT LCD with touch

function. Users can operate all functions through the touch interface.

2. Speaker
3. Battery case

1.2.2 Side View

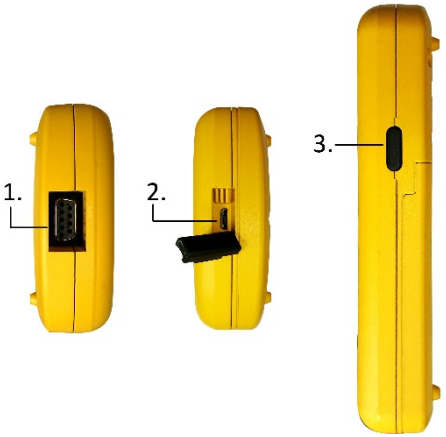


Fig 1-3 Side view of the oximeter

1.3 Display Views

1. SpO2 probe connector
2. Charger connector / Data download connector
3. Power button

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

1.3.1 Large Numeric Display Mode

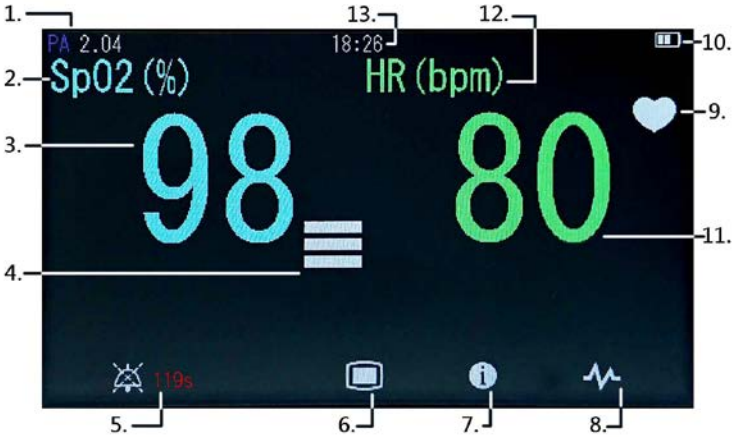


Fig 1-4 Big numeric display mode

1. PA: It is show the pulse amplitude, similar the PI.
2. SpO_2 (%): Display the SpO_2 unit.
3. SpO_2 parameter area: Current SpO_2 value and its high and low alarm are displayed in this area.
4. Plath bar: Pulse intensity is indicated by the number of stacked blocks visible.
5. Alarm status area: Alarm status symbols and alarm pause time are displayed in this area.
6. 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】**.
7. Information: It's show the manufacturer information.
8. PPG wave: It's show the PPG waveform while press the symbol.
9. Heart icon: It will flash with the heartbeat.
10. Battery symbol: This symbol indicates the remaining quantity of

electrical charge in the batteries.

11. HR parameter area: Current heart rate (HR) value and its high and low alarm are displayed in this area.
12. HR(bpm): Display the heart rate unit.
13. System time: Current time is shown in the area.

1.3.2 SpO2 Waveform Display Mode

Fig 1-5 SpO2 waveform display mode

1. SpO2 parameter area: Current SpO2 value and its upper and lower alarm are displayed in this area.
2. PPG waveform area: The waveform shown in this area illustrates the current PPG curve of the patient being monitored.
3. PR parameter area: Current PR value and its upper and lower alarm are displayed in this area.

Chapter 2 Safety

2.1 Safety Information

 **Warning:**

- **Explosion hazard: Do not use the oximeter in an environment with flammable gases.**
- **Do not use the product in the presence of high power appliances such as high voltage cables, X-ray machines, ultrasound equipment or 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.**
- **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 probe, and certain patient conditions. See the appropriate sections of this manual for specific safety information.**
- **The physiological data and alarm messages displayed on the**

monitor are for reference only and cannot be directly used for diagnostic interpretation.

- **The use of accessories, probes, 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.**
- **Do not use to measure the patient while charging the battery.**
- **The battery should only be replaced by a service technician with a screwdriver and keep the hands dry.**
- **Inserting a specific type of battery that is not supplied by the manufacturer or replacement of lithium batteries by inadequately trained personnel could result damage to device.**
- **Do not open the monitor housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by manufacturer only.**

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

2.2 Explanation of Interface Symbols

Symbol	Symbol Note
	Alarm volume pause
	Menu button
	Wave enable/disenable
	Home button, back to the main page

Symbol	Symbol Note
	Increase/Up button
	Decrease/Down button
	Back to previous page
	Next page
	Previous page
	Battery indicator
	Battery in charge
	Bluetooth connection indicator (AH-TB only)
	Cancel selection
	Conform selection
	Information button, show the manufacturer information

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	Quantity
SpO_2 probes	√	1
User's manual	√	1
AC-DC Class II adapter (MPU15-102)	√	1

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. Make sure that the battery has sufficient power. For the first time use, you must charge the battery, 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 power button to turn on the pulse oximeter, the startup screen appears and show the software version at the bottom right. Enter the main screen, the alarm indication should light up and system should give a beep. After starting the oximeter you can change the settings for more convenient use, as shown in section 3.4. Enter the main screen, the alarm indication should light up and system should give a beep. 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 menu button to enter【Menu】, then select【System Setup】to enter the system setup menu shown as follows. You can set parameters for the following functions:

Fig 3-1 Menu window

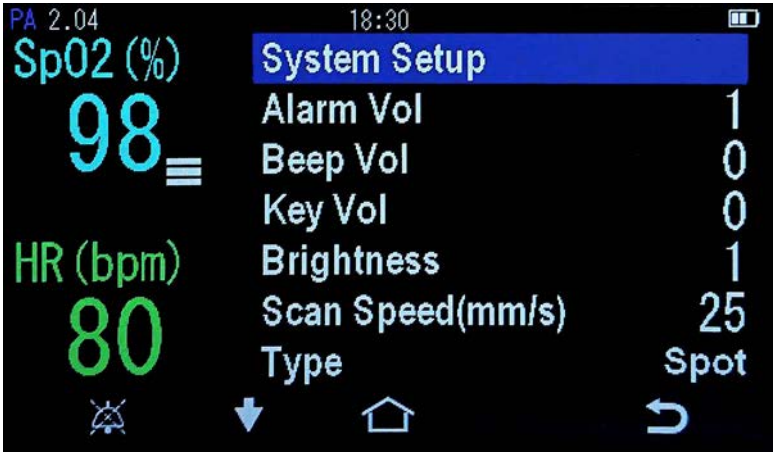


Fig 3-2(a) System setup window

Fig 3-2(b) System setup window

3.4.1 Alarm Volume Setup

Press the **Alarm Vol** to select the item, then adjust its value using the "  " or "  " icon. You can select from 1 to 5. The volume will be minimum when select is 1.

3.4.2 Beep Volume Setup

Press the **Beep Vol** to select the item, then adjust its value using the "  " or "  " icon. You can select from 0 to 4. The volume will off when select is 0.

3.4.3 Key Volume Setup

Press the **Key Vol** to select the item, then adjust the value using the "  " or "  " icon. You can select from 0 to 4. The volume will off when select is 0.

3.4.4 Adjust the Screen Brightness

Press the **Brightness** to select the item, then adjust the value using the "  " or "  " icon. 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.

If the user to turn off the physiological alarms totally, which may cause the emergency event of the patient not be discovered in time. When the alarm is completely turned off, this device should be used accompanied by the professionals.

3.4.5 Scan Speed Setup

Press the **Scan Speed** to select the item, then adjust its value using the "  " or "  " icon. You can select from 12mm/s or 25mm/s.

3.4.6 Date Setup

Press the **Year / Month / Day** to select the item, then adjust its value using the "  " or "  " icon.

3.4.7 Time Setup

Press the **Hour / Minute** to select the item, then adjust its value using the "  " or "  " icon.

3.4.8 Language Setup

Press the **Language** to select the item, then adjust the language type using the "  " or "  " icon.

3.5 Selecting the Work Type

The oximeter is designed to operate in two types: continuous monitoring and spot-checking. You can choose the oximeter's work type through the following steps:

1. Select【System Setup】→【Type】, then adjust the type using the "  " or "  " icon.
   - Spot: Work in spot check type, only record the measurement data after removing the probe from your finger.
   - 10sec, 30sec, 1min, 5min, 10min, 30min: Work in continuous type, every 10sec or 30sec or 1min or 5min or 10min or 30min record the measurement data.

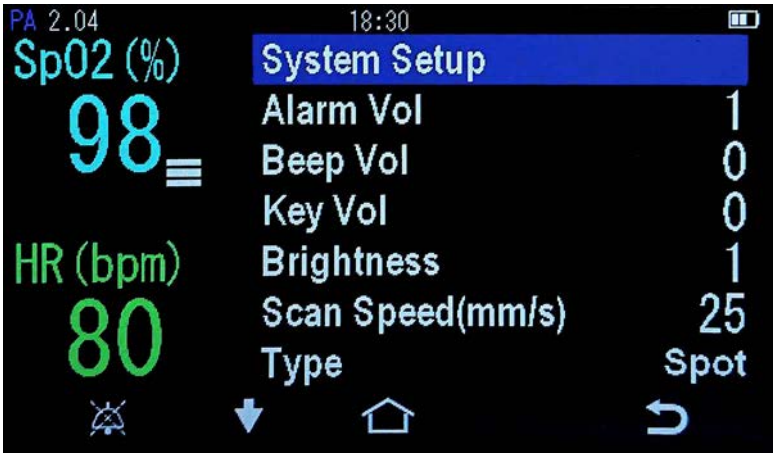


Fig 3-3 Type select window

3.5.1 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. When the oximeter's memory reaches full capacity, it will stay in the last column.

Caution: Users should periodically clear the data manually.

3.5.2 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.

3.6 Selecting Patient Type

To select the different patient type can set the different alarm limit value.

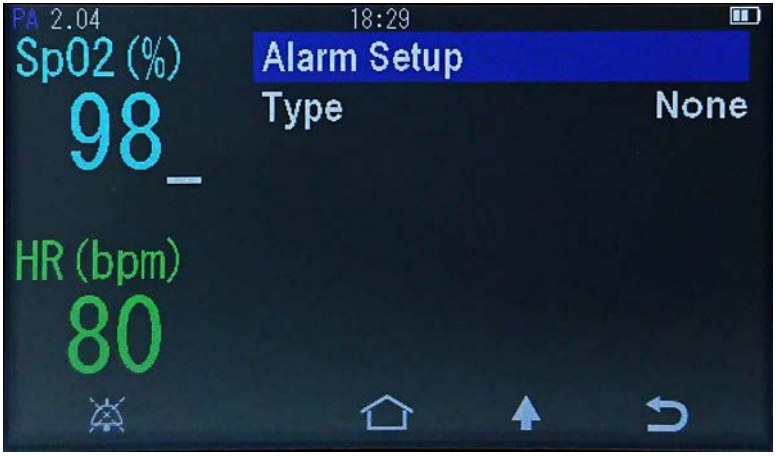


Fig 3-3 Patient Type select window

1. Select【Menu】→【Alarm Setup】→【 Next page】→【Type】.
2. Using the “ ” or “ “ icon set the【Type】to【Adu】Adult, 【Ped】Pediatric or【Neo】Neonate. The default is【None】.

3.7 Load Default Configuration

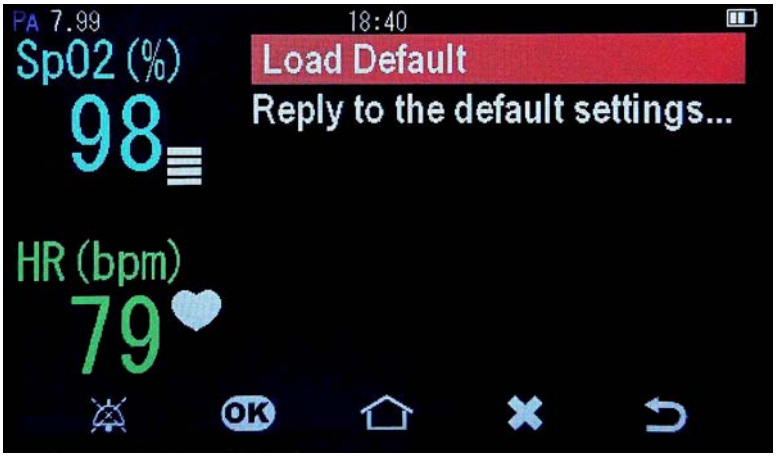


Fig 3-3 Load Default window

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

1. Select【Menu】→【Load Default】.
2. A window will appear, asking you to confirm that you want to return to the original configuration. Select【OK】to restore the factory configuration. If not, press the【✖】or【↩】to back to the previous page , also can press the【⌂】 to back the main page.

3.8 Shutting off the Oximeter

To shut off the oximeter, follow the steps below:

1. Confirm that patient monitoring is complete.
2. Disconnect the SpO2 probe form the oximeter.
3. Press the power button to turn off the oximeter.

 **Caution: If the oximeter is not in use and there has been no button operation for more than 1 minutes, the oximeter will shut down automatically.**

Chapter 4 Alarm

The oximeter generates all audible and visual alarms through a speaker and visual alarm on the screen.

"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.

4.1 Alarm Categories

The oximeter's alarms fall into two categories:

1. Physiological alarms

   A physiological alarm is triggered when the monitored parameter exceeds the set alarm limit or the patient condition is abnormal.

2. Technical alarms

   A technical alarm is triggered a device malfunction or incorrect operation of the oximeter or system problems.

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

4.2 Alarm Level

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.

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 message: Alarm messages are displayed on the front screen.

 Caution: Alarm tone and alarm messages will 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-DO”

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 respective alarm area.**
- **Test the alarm system when turning on the device:**
  1. **Do not insert your finger into the probe while turning on the device in order to enter and test the alarm sound.**
  2. **By adjusting the SpO2 and HR settings to an abnormal value to enter and test the alarm system, you can check for visual and audible alarms.**

4.3.2 Alarm Background color

When an alarm occurs, the alarm levels are indicated in the following different visual ways:

Alarm level	Visual prompt
High(!!!)	Red background color flashes in red with 2.5 Hz.
Medium(!!)	Yellow background color flashes in yellow with 0.5 Hz.
Low(!)	Yellow background color lights on in yellow without flashing.

4.3.3 Alarm Message

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

- The system uses the following symbols to match the alarm 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

4.4 Pausing the Alarm Tones

Press the alarm pause icon "  " to keep the alarm paused for 120 seconds and the pause time will be displayed in red numeric.

- When the audible alarm is paused, the alarm background color remains lit, and the alarm message remains displayed.
- Pressing the "  " icon again will restart the audible alarm.

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

Warning:

- ~~**When the alarm sound is switched off, the monitor will give no audible alarm tones even if a new alarm occurs. Therefore, the user should be very carefully about whether to switch off the alarm sound or not.**~~**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.

- **General personnel should not arbitrarily modify the alarm conditions, and only those who have professional knowledge or relevant training can adjust the alarm setting.**

4.5 When an Alarm Occurs

Warning:

- **When an alarm occurs, you should always check the patient's condition first.**
- **Do not setting alarm limits to extreme values that can render the alarm system useless.**

Check the alarm message appeared on screen. It is needed to identify the alarm and action appropriately, according to the cause of the alarm.

1. Check the patient's condition.
2. Identify alarming parameter and alarm category.
3. Identify the cause of the alarm.
4. Silence the alarm, if necessary.
5. When cause of alarm has been over, check that the alarm system is working properly.

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

4.6 Alarm Delay

The alarm condition delay and alarm signal generation delay is under 0.5 sencond.

Chapter 5 Measuring SpO2

5.1 Introduction

The measurement of oxygen saturation of arterial blood (also known as peripheral oxygen saturation, usually shortened to SpO2) 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.

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

5.2 Safety Information

Warning:

- **Only use the SpO_2 probes specified in this manual. Follow the SpO_2 probe 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 probe 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 probe site every two hours and move the probe if the skin quality changes. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the probe site more frequently.**
- **Check the SpO_2 probe and its package for any sign of damage before use. Do not use the probe 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.**
- **If using a disposable probe, do not reuse it on different patients.**

Caution: In cases where it is necessary to add a clip to fix the fingertip probe, clip the cable and not the probe itself. Please note that the probe 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 SpO2 Probe**

   Depending on the patient category, weight and application site, you can select a different SpO2 probe as required.

2. **Connecting the SpO2 Probe**

   Plug the SpO2 probe cable into the SpO2 connector on the oximeter.

3. **Applying the SpO2 Probe to the patient**

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

 **Warning:**

- **Do not use the SpO_2 c 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.**

5.4 Parameter Display

Fig 5-1 Parameter and PPG Waveform

1. SpO2 parameter area: Current SpO2 value and its upper and lower alarm are displayed in this area. The data average is done with an average of ten data and the data update by every second.
2. PPG waveform area: The waveform shown in this area illustrates the current PPG curve of the patient being monitored.
3. PR parameter area: Current PR value and its upper and lower alarm are displayed in this area. The data average is done with an average of ten data and the data update by every second.

5.5 SpO2 Alarm Setup

~~1. Select【Menu】→【Alarm Setup】.~~

~~2. Set the【SpO2 Level】to【Off】to shut off SpO2 alarm.~~

5.5.1 Setting the Alarm Levels

1. Select【Menu】→【Alarm Setup】.
2. Set the【SpO2 Level】to 【Med】or【High】.

5.5.2 Adjusting the Alarm Limit

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

5.6 HR Alarm Setup

5.6.1 Setting the Alarm Level

1. Select【Menu】→【Alarm Setup】.
2. Set the【HR Level】to 【Low】or【Med】or【High】.

5.6.2 Adjusting the Alarm Limit

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

Chapter 6 Reviewing

6.1 Introduction

Select【Menu】→【Trend】→【Report】to enter the trend reviewing window. You can review previously stored SpO2 and HR data in this window.

Fig 6-1 SpO2/HR reviewing window

6.2 Reviewing Screen

The above screen shows the SpO2/HR reviewing window. You can review SpO2/PR values measured at different time intervals in this window. If the report data spreads across more than one page, you can turn pages by using the 【 Next page】or 【 Previous page】.

6.3 Delete Record

Users can delete single data or delete all data at once, as shown below:

6.3.1 Delete single data

Select【Menu】→【Trend】→【Report】to enter the trend reviewing

window. The user can click on any column then the delete icon and cancel icon will appear at the bottom. If you want to delete the data, press the "  " icon, if not, press the "  " or "  " icon to back.

Fig 6-2 Single data delete window

6.3.2 Export data

Select【Menu】→【Trend】→【Export】to enter the data export mode.

- Connection the PC or NB through a USB cable.
- Use the "SpO2Reader" software to download the record data.

Fig 6-3 Data export window

The screen will display "Data exporting..." in the data transfer process, and "Completed" will be displayed after the transfer is completed.

Fig 6-3 Data export completed window

6.3.3 Delete all data

If you want to delete all the data, please follow the steps as below:

Select【Menu】→【Trend】→【Delete all】to enter the “Delete all” window. If you want to delete all records, press the “OK” to delete all records data. If not, press the “✖” or “↩” icon to back.

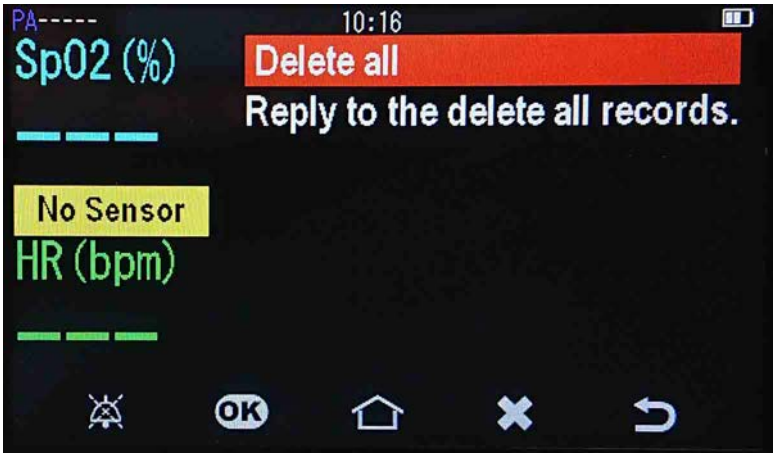


Fig 6-3 Delete all data windowc

The window will show the “Completed” when data deleted.

Chapter 7 Data transmission

7.1 Wired transmission

7.1.1 USB cable

Users can download data through the general USB cable.

Select【Menu】→【Trend】→【Export】to enter the data export mode.

- Connection the PC or NB through a general USB cable.
- Use the “SpO2Reader” software to download the record data.

Fig 7-1 Connection PC or NB by a USB cable

7.2 Wireless transmission (AH-TB only)

7.2.1 Bluetooth Low Energy

Users can also wirelessly transmit data via Bluetooth.

AH-TB provides a Bluetooth Low Energy(V4.2) wireless transmission interface that allows you to develop your own software or mobile app to receive data.

Chapter 8 Battery

8.1 Introduction

The oximeter is designed to operate on a Li-ION rechargeable battery. Under normal circumstances, no special battery maintenance is necessary.

The battery status as follows:

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

Under normal conditions, the battery can be used for about 14 hours. If the battery is too low, it will trigger a low battery warning and show the Low Battery icon ” 

” on screen. In this case, please connect the charger to charge the battery.

Warning:

- **Do not attempt to replace the battery yourself, take it to an authorized representative or manufacturer.**
- **Use only batteries specified in this manual.**
- **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.

- **If removed the battery from oximeter, keep the batteries out of the reach of children.**

8.2 Charging Lithium Ion Battery

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

To charge the Lithium Ion battery:

1. Take out the adapter(MPU15-102) provided by the manufacturer.
2. Open the silicone protective plug.
3. Connect the AC-DC adapter and plug the adapter into the AC mains.
4. The indicating icon on the oximeter will light up, to show that the battery is charging.
5. When the battery charge icon on the oximeter become to battery full icon, the battery is fully charged.

Fig 8-1 Open the silicone protective plug

Fig 8-2 Connect the AC-DC adapter

Warning:

- **Disconnect the oximeter from the patient and stop all monitoring before charging the battery.**
- **Please use the adapter provided by the original manufacturer to charge. If you use an adapter that is not supplied form the original manufacturer, it may cause damage to the product.**
- **When using this adapter for charging, please ensure that there is enough space in the AC socket installation area to install or remove the AC power cord, and avoid obstacles in the vicinity of the AC power cord to affect the power cord installation.**
- **The user can disconnect the power by unplugging the AC power cord.**

8.3 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. Plug the adapter into the oximeter 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.**

8.4 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 9 Maintenance and Cleaning

9.1 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.**
- **For optimal performance, product service should be performed only by qualified service personnels.**
- **Do not serviced or maintained while in use with the patient.**

 **Caution:**

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

9.2 Maintenance

Note: In order to ensure the performance and safety of the equipment, it is recommended to do regular inspection and maintenance, at least must be checked after 1 year of use. Check the equipment through a professional technical engineer.

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.

- Inspect the equipment and accessories for mechanical and functional damage.
- Inspect the relevant safety labels for legibility.
- Verify that the device functions properly, as described in the instructions for use.

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

9.3 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.

9.4 Cleaning SpO2 Probe

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

never put the probe directly in liquid.

 **Warning: Do not reuse or disinfect disposable SpO2 probe.**

9.5 Disposal

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

Chapter 10 Accessories of Probe

Nellcor compete SpO_2 probe (Applied parts)

Type	Model	Patient Category
Disposable  Single patient use only	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-D1	Adult
	ASANR-D3	
	ASWNR-D1	Adult / Neonatal
	ASWNR-D3	
	ASYNR-D1	Neonatal
	ASYNR-D3	
	ASWNR-D3	Adult / Neonatal
	ASPNR-D1	Pediatric / Neonatal
	ASPNR-D3	Pediatric / Neonatal
	ASSNR-D1	Adult
	ASSNR-D3	
	ASVNR-D1	Adult / Pediatric / Neonatal
	ASVNR-D3	

Chapter 11 Symbol Definitions

	Refer to user manual before application		Manufacturer information
	Keep away from sunlight		Date of Manufacture
 (YYYY-MM)	Use by date		Dispose the waste according to the national law.
	Do not use if package damaged.		Type BF Applied Part.
CE 2460	CE mark	SN	Serial number
	Attention: Consult accompanying documents (this manual).	IP22	Degree of protection against ingress of dust and liquid.
	Single patient use only		Contains no Latex
	FCC certification mark		NCC certification mark
	This side up		Handle With Care
	Fragile		Keep dry
	Keep away from heat		Direct Current（DC）

Appendix A Product Specifications

A.1 Safety Specifications

SFDA classification	II
CE classification	IIb
Type of protection against electric shock	II, with 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	IP22
Equipment type	Handheld

A.2 Physical Specifications

Mainframe weight	＜320g
Mainframe size	84mm(W)×165mm(H)×26mm(D)
AC-DC adapter weight	＜150g
AC-DC adapter size	43.5mm(W)×60mm(H)×40.2mm(D)

A.3 Environmental Specifications

Temperature	Operating: 0℃ to +35℃；

	Storage/Transportation: -20℃ to +70℃；
Atmospheric pressure	Operating: 860hPa to 1060hPa；
	Storage: 500hPa to 1060hPa；
Humidity	Operating: 10% to 95% (non-condensing)
	Storage/Transportation: 10% to 95% (non-condensing)

A.4 Charging Specifications

A.4.1 AC-DC Adapter (MPU15-102)

Sinpro Electronics Co. Ltd	MPU15-102
Input	100～240VAC，50/60Hz
Output	5V ，2.4A

A.4.2 Battery Specification

Standard	
Type	NCA596080 Lithium-ion rechargeable battery
Size	5.85mm×60 mm×80mm
Weight	67g
Quantity	1
Rated Voltage	3.6 VDC
Rated Capacity	3950 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%

A.5 Hardware Specifications

A.5.1 Display

Type	TFT LCD
Size（diagonal）	4.3 inch
Resolution	480×272 pixels

A.5.2 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 sound pressure	60~90 dB, Testing place is 1 meter from the tone.

A.5.3 Button

Quantity	1
Functions	Power button.

A.5.4 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. This information may be useful to clinicians, such as those performing photodynamic therapy.

A.5.5 Bluetooth L.E Specifications

Specifications
BGM121/BGM123 SiP Module with a standard 2.14 dBi dipole antenna.
Bluetooth 4.2 Low Energy compliant.
The BGM121/BGM123 has Bluetooth, CE, partial FCC, ISED Canada and Japan certifications
The BGM121/BGM123 Bluetooth Declaration ID is: D033250.
FCC ID: QOQBGM12LMA
ISED: 5123A-BGM12LMA
Japan certification number 209-J00226.
NCC ID: CCAB19LP1110T9

A.6 Specifications

A.6.1 Digital SpO2

SpO_2	
Technic	Digital SpO_2 technic
Range	0~100%
Resolution	1%
Oxygen Saturation Declared Accuracy Range	70 – 100% SpO2 ±2 digits, Below 70% unspecified
Low Perfusion Oxygen Saturation Declared Accuracy Range	70 – 100% SpO2 ±3 digits, Below 70% unspecified
Refreshing rate	1 second
Pitch Tone	with
Heart Rate	
Range	25 bpm to 250 bpm
Resolution	1 bpm
Pulse Rate Declared Accuracy Range	25–250 bpm ±2bpm or ±2% (select larger)
Low Perfusion Pulse Rate Declared Accuracy Range	25–250 bpm ±3bpm or ±2% (select larger)
Refreshing rate	1 second

A.6.2 Alarm Limit Specifications

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

SpO_2 low limit	85% to (high limit -1)	
Alarm limits	**Range (bpm)**	**Step (bpm)**
PR high limit	(low limit +1) to 250	1
PR low limit	25 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</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</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	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst (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	N/A	N/A	N/A

IEC 61000-4-11			
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	Separation distance according to frequency of

output power of transmitter(W)	150 kHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.1.1 Alarm Setup

Alarm Setup	Factory Default
SpO_2 Alarm Level	High
PR Alarm Level	Medium

C.1.2 Alarm Type 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.3 System Setup

System Setup	Factory Default
Alarm Volume	1
Beep Volume	0
Key Volume	0
Brightness	1
Scan Speed	25mm/s

C.4 Work Type Setup

Work Type Setup	Factory Default
Interval	10s

Hint: The “Work Type” is mean the work is in the spot check mode or

continues mode.

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.	High Medium
SpO_2 too Low*		
PR too High*	A measurement has risen above the high alarm limit or fallen below the low alarm limit.	High Medium Low
PR too Low*		
No Pulse	The signal was too weak or poor to be analyzed.	High
Low Perf	The signal detected is weak.	Medium

D.2 Technical alarm

Messages	Cause	Level
No Sensor	The SpO_2 probe detached the oximeter.	Medium
No Finger	The SpO_2 probe detached the patient.	Medium
LowBatt	The battery power is low.	Medium

D.3 Symbols on marking

Symbol	Title (informative)	Description for ALARM SYSTEMS (normative)
No Sensor	The SpO_2 probe detached the oximeter.	Medium
No Finger	The SpO_2 probe detached the patient.	Medium
LowBatt	The battery power is low.	Medium

國家通訊傳播委員會(NCC)警告

根據「低功率電波輻射性電機管理辦法」第十條：

製造、輸入或販賣低功率射頻電機者，應於低功率射頻電機使用說明書內加印第十二條及第十四條之規定內容。

根據「低功率電波輻射性電機管理辦法」第十二條：

經型式認證合格之低功率射頻電機，非經許可，公司、商號或使用者均不得擅自變更頻率、加大功率或變更原設計之特性及功能。

根據「低功率電波輻射性電機管理辦法」第十四條：

低功率射頻電機之使用不得影響飛航安全及干擾合法通信；經發現有干擾現象時，應立即停用，並改善至無干擾時方得繼續使用。

前項合法通信，指依電信法規定作業之無線電通信。

低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之干擾。

FCC Warning

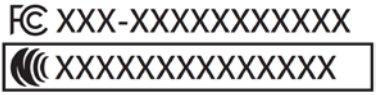
1. This device complies with part 15 of the fcc rules. Operationis subject to the following two conditions: (1) this device maynot cause harmful interference, and (2) this device mustaccept any interference received, including interference thatmay cause undesired operation.
2. NOTE: the grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.
3. Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

   —Reorient or relocate the receiving antenna.

   —Increase the separation between the equipment and receiver.

   —Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

   —Consult the dealer or an experienced radio/TV technician for help.



Acare Technology Co., Ltd.

Address: 6F.-6, No.5, Wuquan 1st Rd., Xinzhuang Dist., New Taipei City 242, Taiwan

TEL : +886-2-2298-8170
FAX : +886-2-2298-8560
Email: info@acaretech.com
Website: http://www.acaretech.com