HS10

Handheld Pulse Oximeter
OPERATOR'S MANUAL

Product Information

Product Name: Pulse Oximeter
Product Model: HS10A, HS10A-LI
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Software Version： V1.0
Shelf life：2 years

EC REP

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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.

- Revision number: 1.1
- Release time: 2023-8

Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety. This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

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

This product is a reusable medical device.

Intended Audience

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

Illustrations

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

Conventions

Italic text is used in this manual to quote the referenced chapters or sections.

→ is used to indicate operational procedures.

[ ] is used to enclose screen texts.

Contents

1 Safety

1.1 Safety Information

DANGER

- **Indicates an imminent hazard that, if not avoided, will result in death or serious injury.**
- **Indicates a statement that there may be hazards in using different alarm presets for the same or similar devices in any signal area.**

WARNING

- **Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.**
- **Indicates a warning to the effect that probes and cables are designed for use with specific monitors.**
- **Indicates a warning statement to the effect that the responsible organization or operators needs to verify the compatibility of the monitor, probe or cables before use, or patient injury can result.**
- **Indicates a warning statement to the effect that misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.**

CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**
- **Indicates a statement to the effect that a FUNCTIONAL TESTER cannot be used to access the ACCURACY of a pulse oximeter probe or a pulse oximeter monitor.**

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**
- **The pulse oximeter is not part of the body or tissue.**

1.1.1 Dangers

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

1.1.2 Warnings

WARNINGS

- **Before putting the system into operation, verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **To avoid explosion hazard, do not use the equipment in the presence of flammable anesthetics, vapors or liquids.**
- **Do not open the equipment housings; electric shock hazard may exist. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**
- **Do not rely exclusively on the audible notice system for personnel monitoring. Adjustment of notice volume to a low level or off may result in a hazard to the personnel. Remember that notice settings should be customized according to different or personnel situations and always keeping the personnel under close surveillance is the most reliable way for safe**

personnel monitoring.

- **The physiological data and notice messages displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by personnel.**
- **No modification of this equipment is allowed.**
- **The maximum temperature that the applied part can achieve is 42.2℃ at an environmental temperature of 40℃.**
- **The continuous test time of one part shall not exceed 2 hours, and the test part shall be replaced.**
- **Applied part having contact with the patient for a time "t", 10 min ≤ t≤2 hours.**
- **Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.**
- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **Use only accessories specified in this manual. Using other accessories may cause damage to the pulse oximeter.**
- **Disposable accessories are designed for single-person use only. Reuse of them may cause a risk of contamination and affect the measurement accuracy**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **The SpO2 sensor mentioned in this chapter meet the bio-compatibility requirements and complies with ISO 10993-1, ISO 10993-5 and ISO10993-10 standards.**
- **It should change the measurement part per 2 hours when user continuing using for detecting.**
- **The measured value is best when the pulse rate waveform is smooth and stable after normalization. Data update period: ≤3 pulse rate cycles, ＜ 30s.**
- **FUNCTIONAL TESTER cannot be used to assess the ACCURACY of a PULSE OXIMETER .**
- **The nature of Reminder signals is continue to turning on for 1s. And the intervals between Reminder signals is turn on 1 seconds and turn off 4 second. One cycle has 5 seconds.**

1.1.3 Cautions

CAUTIONS

- **To ensure safety, use only parts and accessories specified in this manual.**
- **At the end of its shelf life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the equipment, please contact us.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**

1.1.4 Notes

NOTES

- **Put the equipment in a location where you can easily see the screen and access the operating controls.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**
- **The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.**
- **This manual and the pictures on the color box are schematic diagrams, and the product is subject to the actual product.**

1.2 Equipment Symbols

	Direct Current(DC)(Only for lithium)
	Attention: Consult accompanying documents (this manual).
	Auxiliary output connector
	Notification silence button
SET	Setting button
	Power button
	Up button
	Down button
	Manufacturer
	Date of manufacture
SN	Serial number
	Type BF applied part, defibrillation protected
EC REP	European community representative
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste.
	Power supply connector (Only for lithium)
	Safety Class II equipment (Only for lithium)

	Charging indicator light (Only for lithium)
	Medical device
	This item is compliant with **REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.**

2 The Basics

2.1 Introduction

2.1.1 Intended Use

Monitoring of functional arterial oxygen saturation (SpO2) and pulse rate.

WARNING

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

2.1.2 Intended Operator

The intended operator of the pulse oximeter are clinical professionals or under their guidance. It must only be uesed by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it .

2.1.3 Intended Patient Population

The Pulse Oximeter is intended for adult, adolescent, child, infant and neonatus patients.

2.1.4 Medical Condition

The Pulse Oximeter is intended to be used in hospitals and clinics.

2.1.5 Essential Performance

1.Pulse rate.

2.Blood oxygen saturation concentration.

WARNING

- **Blood oxygen and pulse rate inaccurate measurement probably may lead to the doctors do false diagnosis.**

2.1.6 Contraindications

Do not use oximeter in a magnetic resonance (MR or CT)environment.

2.1.7 Components

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

2.1.8 Operator Position

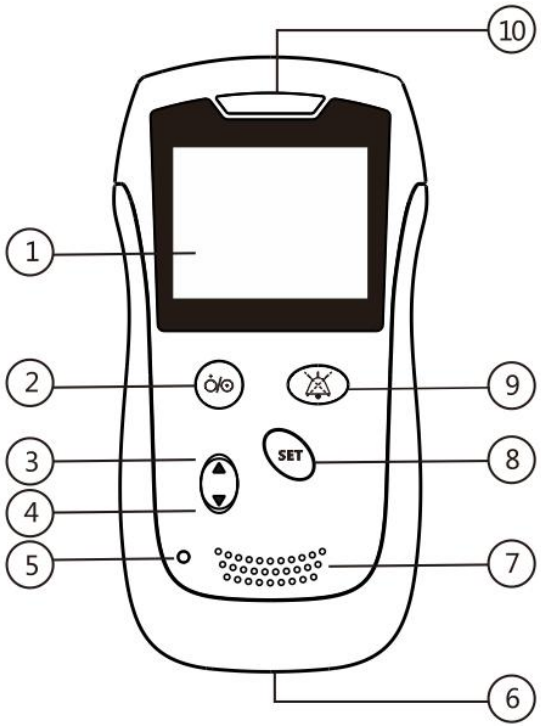
This device is a handheld portable pulse oximeter. Generally, the operator should use it within half a meter from the device.

2.1.9 Validation

Generally, after operator turn on the device , and the beep will continue to turn on for 1 second prove that it is working normally .

2.2 Main Unit

2.2.1 Front View



1. Display screen

2. Power button

- Press this button to turn the pulse oximeter on after the batteries are installed.
- Press and hold it for 2 seconds to turn off the pulse oximeter.
- Press this button for 1 second, the menu screen can quickly return to measurement interface.

3. Up button

- Press this button to change the value of select menu item or raise the beat volume.

4. Down button

- Press this button to change the value of select menu item or lower the beat volume.

5. Power Indicating Lamp(Only for lithium)

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

- Green: The lithium battery of the device has been fully charged when the power adapter is connected to the device;
- Yellow: The lithium battery of the device is being charged when the power adapter is connected to the device;
- Off: The device configured with the lithium battery is not connected to the power adapter.

6. Power Supply Connector(Only for lithium)

It is used to connect the AC adapter.

7. Speaker

8. Setting button

Press this button to enter the main menu.

9. Notice Silence Button

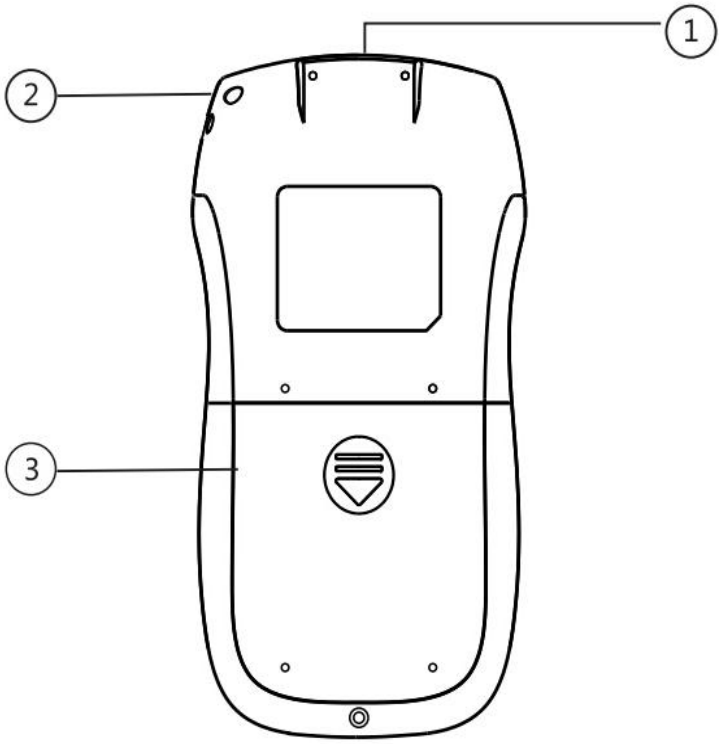
Press this button to pause or reactivate the notice sound.

10. Notice indicating lamp

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

- **High level notices**: the lamp quickly flashes red.
- **Medium level notices**: the lamp slowly flashes yellow.

2.2.2 Rear View and Right View



1. Sensor connector

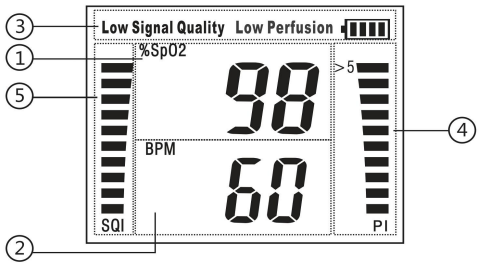
It is used to connect an SpO_2 sensor to measure the oxygen saturation .

2. Cord hole

3. Battery door

2.3 Display Views

The following figures show the layout of the normal screen.:



1. SpO_2 area.
2. PR area
3. Notice Information area

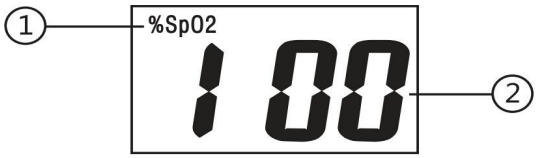
4. Perfusion Index

The Perfusion Index provides an indication of the percentage of pulsiatile signal to non pulsatile signal. The bar is highest when the quality of the perfused site is best.

5. Signal Quality Index / Pulse Bar

The Signal Quality Index provides an indication of the quality of the acquired signal as well as the timing of the pulse. A green vertical LED bar rises and falls with the pulse, where the height of the bar indicates the quality of the signal.

2.3.1 SpO_2 Area



1. SpO_2 label and unit

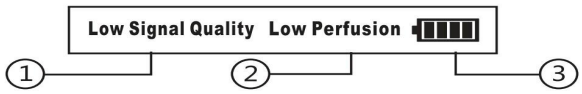
2. Oxygen saturation reading

2.3.2 PR Area

1. PR label and unit

5. Pulse rate reading

2.3.3 Information Area



1. Low Signal Quality notice

2. Low Perfusion notice

3. Battery level

3 Getting Started

3.1 Unpacking and Checking

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

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

NOTE

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

WARNING

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

3.2 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual. When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

WARNING

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

3.3 Power On the Pulse Oximeter

1. Before use, check whether there is any mechanical damage on the pulse oximeter.
2. Install the alkaline batteries or the lithium ion battery and ensure that the batteries have sufficient power.
3. Plug the SpO_2 extension cable into the multifunctional connector.
4. Press the Power button. The pulse oximeter enters the main screen.

WARNING

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

3.4 Power Off the Pulse Oximeter

Power off the pulse oximeter:

1. Confirm that the person monitoring is finished.
2. Disconnect the SpO_2 extension cable from the pulse oximeter.
3. Press and hold the Power button for 2 seconds to shut down the device.

4 Basic Operations

4.1 Adjusting the Pulse Volume

To adjust the pulse volume:

1. Press button [SET]→[VOL]

2. Pressing the Up/Down button, set to a value between 0 and 10.

NOTE

- **0 means the volume is turned off, and 10 is the maximum volume. Increase/decrease the volume by pressing the Up/Down button in the case that no menu is opened. During SpO2 monitoring,the pitch of the pulse tone changes as the patient's oxygen saturation level changes. The pitch of the tone rises as the oxygen saturation level increases and falls as the oxygen saturation level decreases.**

3. Press the the power button for 1 seconds, the menu screen can quickly return to normal operation display.

4.2 Selecting Patient Type

WARNING

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

To admit a patient:

1. Press button [SET]→[PA].

2. Pressing the Up/Down button, select patient type value: ADU(adult), PED(pediatric), NEO(neonate).

3. Press the power button for 1 second, the menu screen can quickly return to normal operation display.

4.3 Setting Alarm Limit

4.3.1 Setting PR High Alarm Limit

To adjust the PR high alarm limit:

1.Press the [SET] button to jump to the [BPM H].

2.Press the [Up] button and repeat 21 times.

3.Press the [Up]/[Down] button,set a value between (low limit + 1) and 250.

4.Press [SET] button quit the PR Alarm High setting.

5.Press the Power button for 1 second, the menu screen will quickly return to the measurement interface.

4.3.2 Setting PR Low Alarm Limit

To adjust the PR low alarm limit:

1.Press the [SET] button to jump to the [BPM L].

2.Press the [Up] button and repeart 21 times.

3.Press the [Up]/[Down] button,set a value between 25 and (high limit - 1).

4.Press [SET] button quit the PR Alarm Low setting.

5.Press the Power button for 1 second, the menu screen will quickly return to the measurement interface.

4.3.3 Setting SPO_2 High Alarm Limit

To adjust the SpO2 high alarm limit:

No SpO2 high alarm limit.

4.3.4 Setting SPO_2 Low Alarm Limit

To adjust the SpO2 low alarm limit:

1.Press the [SET] button to jump to the [%SPO2 L].

2.Press the [Up] button and repeart 21 times.

3.Press the [Up]/[Down] button,set a value between 88 and (high limit - 1).

4.Press [SET] button quit the SPO2 Alarm Low setting.

5.Press the Power button for 1 second, the menu screen will quickly return to the measurement interface.

5 Notices

Notices triggered by a vital sign that appears abnormal or by technical problems of the Pulse Oximeter, are presented to the user by visual and audible notice indications.

5.1 Notice Categories

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

1. Physiological notices

Physiological notices, also called patient status notices, are triggered by a monitored parameter value that violates set notice limits or an abnormal patient condition.

2. Technical notices

Technical notices, also called system status notices, are triggered by a device malfunction or a patient data distortion due to improper operation or system problems.

3. Prompt messages

In fact, prompt messages are not notice messages, which are displayed in the technical notice area. Apart from the physiological and technical messages, the pulse oximeter will show some messages which indicate the system status.

5.2 Notice Levels

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

1. High level notices

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

2. Medium level notices

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

5.3 Notice Indicators

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

- Notice lamp
- Notice tone
- Notice message

The notice lamp,tone and messages will be indicated differently according to different notice levels.

5.3.1 Notice Lamp

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

- High level notices: the lamp quickly flashes red.
- Medium level notices the lamp slowly flashes yellow.

5.3.2 Notice Tones

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

- High level notices: triple + double + triple + double beep

- Medium level notices: triple beep.

5.3.3 Notice Messages

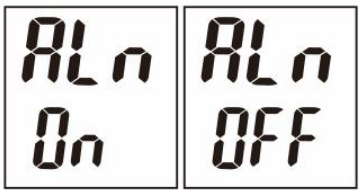
When an notice occurs, an notice message will appear in the technical or physiological notice area.

NOTE

When multiple notices of different levels occur simultaneously, the pulse oximeter will select the notice of the highest level and give visual and audible notice indications accordingly.

5.4 Notice Tone Configuration

5.4.1 Switch ON/OFF Notice Volume



To switch ON/OFF notice volume:

1.Press the [SET] button to jump to the [Aln].

2.Press the [Up] button and repeat 21 times.

3.Press the [Up]/[Down] button, and set to a status: ON or OFF

4.Press the Power button for 1 second, the menu screen will quickly return to the measurement interface.

WARNING

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

5.4.2 Pausing the Notice Tones

To pause the notice tones, press the key for 1 second.

In this case:

- The audible notice is paused, but the key remains lit and the notice messages remain displayed
- The remaining notice pause time is 60 seconds

5.5 When an Notice Occurs

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

1. Check the patient's condition.

2. Confirm the notice parameter or notice category.

3. Identify the source of the notice.

4. Take proper action to eliminate the notice condition.

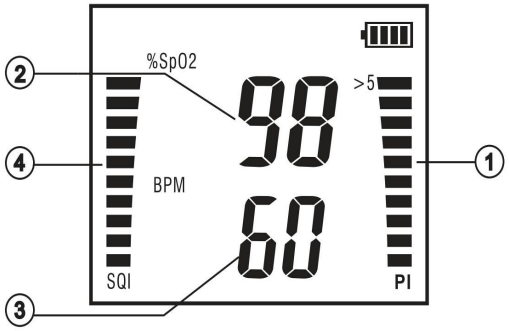
5. Make sure the notice condition is corrected.

For troubleshooting specific notices, see appendix ***D Notice Messages***.

6 Measuring SpO2

6.1 Introduction

SpO_2 measuring is a non-invasive technique used to measure the amount of oxygenated haemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light emitted by a red and infrared light-emitting diodes passes through the tissue and is converted into electrical signals by a photodiode. This device is calibrated to display functional oxygen saturation.



The Pulse Oximeter provides:

1. **PI:** The signal perfusion Index.
2. **Oxygen saturation of arterial blood (SpO_2)**: It is the percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
3. **Pulse rate (PR)**: It is the pulsations per minute derived from the Pleth wave.
4. **Pulse bar & SQI** : The number of segments indicates the pulse strength and signal quality

6.2 Safety

WARNINGS

- **Use only SpO_2 sensors specified in this manual. Follow the SpO_2 sensor's instructions for use and adhere to all warnings and cautions.**
- **Check the SpO_2 sensor and its package for any sign of damage before use. Do not use the sensor if any damage is detected.**
- **When a trend toward deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the person's condition.**
- **Do not use the pulse oximeter and the SpO_2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.**
- **Reusable sensor must be moved to new site at least every four hours. Because individual skin condition affects the ability of skin to tolerate sensor placement, it may be necessary to change the sensor site more frequently with some patients. If skin integrity changes, move the sensor to another site.**
- **Do not apply tape to secure the sensor in place or to tape it shut; venous pulsations may lead to inaccurate saturation measurements.**
- **As with electrosurgical unit, carefully route patient cabling to avoid entanglement.**
- **Do not use the SpO_2 sensor on a limb with an intravenous infusion or arterial catheter in place.**
- **Do not use the SpO_2 sensor on a limb where the NIBP cuff is applied. This may result in inaccurate SpO_2 reading due to blocked blood flow during cuff inflation.**

6.3 Applying the Sensor

1. Select an appropriate SpO_2 sensor according to the person category and weight.

2. Apply the SpO_2 sensor to the patient.

3. Connect the SpO_2 extension cable to the pulse oximeter.

4. This equipment is recommended to use ACCARE Disposable SpO2 Sensor or Reusable SpO2 Sensor(see Annex C).Operator needs to verify the compatibility of the monitor, sensor and cable before use, or patient injury can result; misapplication of a sensor with excessive pressure for prolonged periods can induce pressure injury.

6.4 Settings

6.4.1 Setting Patient Type

Please see to the "4.2 Selecting Patient Type"

6.4.2 Adjusting the Notice Limits

Please see to the "4.3 Setting Alarm Limit"

6.4.3 Setting VOL

Press button [SET]→[VOL], then pressing the Up/Down button to set the expected Pulse Beat volume.

6.5 Measurement Limitations

If you doubt the SpO_2 measurements, check the personnel or person's vital signs first. Then check the pulse oximeter and SpO2 sensor.

The following factors may influence the accuracy of measurements:

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

7 Battery

7.1 Overview

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

NOTE

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

WARNING

- **Keep the batteries out of children's reach.**
- **Use only batteries specified in this manual.**

7.2 Installing the Batteries

7.2.1 Opening the Battery Door

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

7.2.2 Installing the Alkaline Batteries

1. Insert the AA alkaline batteries in the battery compartment, aligning the + on each battery with the + shown inside the battery compartment.

2. Close the battery door and push it upwards.

Caution

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

7.2.3 Charging the Lithium Batteries

To charge the lithium battery.

1. Connect the plug of AC adaptor to the power supply connector of the pulse oximeter.

2. Plug the AC adaptor cord into the AC mains.

WARNINGS

- **Do not use the charger stand when the alkaline batteries is depleted or no battery is installed.**
- **Monitoring a patient while the battery is being charged is not recommended.**

7.3 Checking The Lithium Battery

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

1. Disconnect the pulse oximeter from the patient and stop all monitoring and measuring procedures.

2. Place the pulse oximeter in the Charger stand and connect the AC mains.Allow the battery to be charged uninterruptedly for above 2 hours.

3. Disconnect AC mains and allow the pulse oximeter to run on the battery until shuts off.

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

NOTES

- **Lithium batteries can be recharged 200 times and have a lifespan of approximately 2 years. Improper use of batteries may lead to shortened battery life. It is recommended to replace the lithium battery every 2 years or when the charging frequency exceeds 200 times.**
- **The built-in lithium battery of the device must be replaced by authorized maintenance personnel from our company. Do not replace it on your own.**
- **The operating time of a lithium battery depends on the configuration and operation of the pulse oximeter.**

7.4 Disposing Of The Batteries

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

WARNINGS

- **Do not disassemble the battery, throw it into fire, or short-circuit it, as it may cause accidental injury.**
- **Replacing lithium batteries by personnel without sufficient training may lead to battery burning, explosion, or leakage, which may cause accidental injury.**

8 Maintenance and Cleaning

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods. We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.

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

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

WARNING

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

CAUTION

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

NOTE

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

8.1 Safety Checks

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

Follow these guidelines when inspecting the equipment:

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

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

8.2 Cleaning

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

Recommended cleaning agents are:

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

- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

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

8.3 Disinfecting

Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter before disinfecting it. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants to wiping equipment.

CAUTION

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

8.4 Disposal

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

Follow local disposal and recycling laws for the oximeter and its components,including the battery,packaging waste.

9 Accessories

NO	Item	Quantity	Remark
1	Reusable Pulse Oximeter Sensor For : Adult, Adolescent, Child, Infant and Neonatus Patients	1	
2	Protective cover（optional）	1	
3	Alkaline "AA" size, 1.5-volt batteries	3	only for alkaline equipment
4	Lithium battery	1	only for lithium equipment
5	Charging Cable	1	

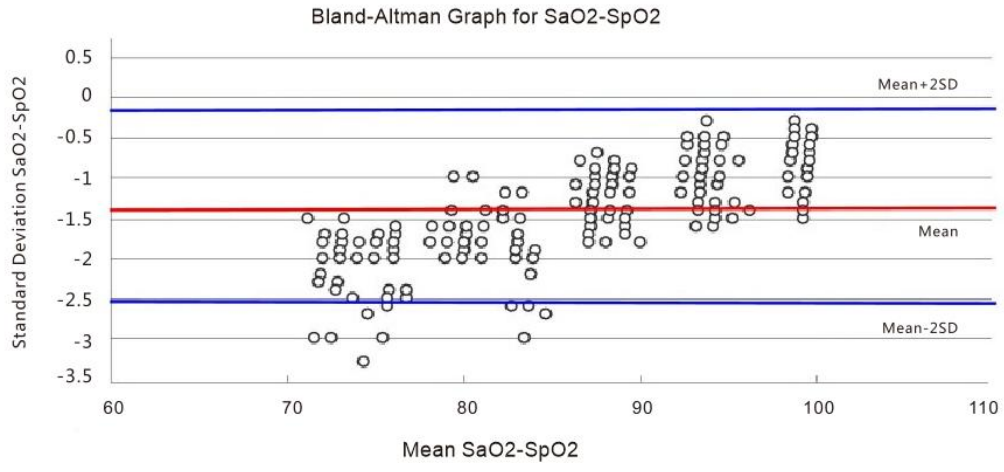
10 Clinical study summary

This Pulse oximeter has completed the clinical study in Xiangya Third Hospital of Central South University. The study included 12 subjects - 8 women and 4 men. Subjects are healthy, 22-28 years old, and their skin color includes Medium, Medium dark, dark and light.

The below table shows statistic conclusion of an invasive controlled desaturation study which guided by"ISO 80601-2-61,Annex EE,Guideline for evaluating and documenting SpO2 accuracy in human subjects". The statistic result displayed the accuracy distribution between the range of 70%~100%, which maybe helpful to user.

Bias Analysis / SpO2-Pulse Oximeter	SaO2-Radiometer ABL800 FLEX-CO-Oximeter			
	70-80 (%)	80-90 (%)	90-100 (%)	70-100 (%)
Mean Bias(Bs)	0.40	0.59	0.74	0.25
Precision(Sres)	1.23	1.62	1.35	1.39
Accuracy(Arms)	1.07	1.45	1.67	1.38

The below is the Bland-Altman graphical plot of samples from invasive controlled desaturation study.



A Product Specifications

Safety specifications (classified according to IEC60601-1)	
Type of protection against	Internally powered equipment
Degree of protection against electric shock	Type BF – Applied part
Degree of protection against hazards of explosion	Ordinary equipment, not protected
Degree of protection against ingress of liquid	IPX2
Equipment type	Handheld
Mode of operation	Continuous
Shelf life	2 years

Physical specifications	
Width × Height × Depth	72x142x31
Max. weight	< 200g (just Equipment)

Environmental specifications	Operating conditions	Storage conditions
Temperature (ºC)	0 to 40	-20 to 60
Relative humidity (non-condensing)	15% to 95%	10% to 95%
Atmospheric pressure(kPa)	70 to 106	50 to 107.4

Charger stand	
Input voltage	100 to 240 VAC, 50/60Hz, 0.2A
Output voltage	5 V DC
Output current	1 A
Output power	5 W
WARNINGS	The power adapter must meet the requirements of IEC60601-1 standard.

Alkaline batteries	
Quantity	3
Specification	1.5 V, AA
Run time	9 hours with SpO2 monitored continuously,audio indicators off and backlight brightness setto minimum using new, full power batteries at ambient temperature 25C.
Shutdown delay	Max. 10 minutes after the low battery notice first occurs.

Lithium batteries	
Quantity	1
Rated voltage	3.7 V
Run time	12 hours with SpO2 monitored continuously, audio indicators off and backlight brightness set to minimum using a new, full charged batterty at ambient temperature 25℃.
Charge time	3 hours to 90% 6 hours to 100%

Shutdown delay	Max. 10 minutes after the low battery notice first occurs.

Hardware specifications	
Display	Color LCD, 2.3"
Power indicating lamp	lighting green and yellow
Loudspeaker	Gives audible notice (45 to 85dB) and button tone; Supports multi-level volume
Notice indicating lamp	lighting red and yellow
Sensor connector	9-pin type D connector
Wavelength range	660-905nm
Output power	<18mW

SpO_2	
Measurement range	70 to 100%
Resolution	1%
Accuracy	70 to 100%: ±2% 0% to 69%: unspecified.
Refresh period	1s
Averaging time	8s
Displayed range	0% to 100%

PR	
Measurement range	25 to 250bpm
Resolution	1 bpm
Accuracy	±3 bpm
Refresh period	1s
Averaging time	8s
Displayed range	25 to 250bpm

Notice limit specifications		
Notice limits	**Range (%)**	**Step (%)**
SpO_2 high limit	/	1
SpO_2 low limit	88	
Notice limits	**Range (bpm)**	**Step (bpm)**
PR high limit	(low limit +1) to 250	1
PR low limit	25 to (high limit -1)	
Delay time of alarm signal	1s	

B EMC

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

Transmission power：0dBm

Wireless frequency range：2402MHz~2480MHz

Hereby, [Hunan Accurate Bio-Medical Technology Co., Ltd.], declares that this [HS10A，HS10A-LI] is in compliance with the essential requirements and other relevant provisions of RE Directive 2014/53/EU. A copy of the full DoC is attached.

CAUTION

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

Guidance and manufacturer′s declaration － electromagneticemission － for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer′s declaration - Electromagnetic Emissions		
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment - guidance**
Radio frequency (RF) emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radio frequency (RF) emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those indirectly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration － electromagnetic immunity － for all EQUIPMENT and SYSTEMS

Guidance and manufacturer′s declaration － electromagnetic immunity			
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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	±2 kV power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±1 kV signal input/output 100 kHz repetition frequency	N/A
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	N/A	
Voltage dips, short interruptions	N/A	N/A	N/A

and voltage variations on power supply input lines IEC 61000-4-11			
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY

Guidance and manufacturer´s declaration - Electromagnetic Immunity		
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity tests	**IEC 60601 test level**	**Compliance level**
Conduced RF IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2 Hz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 2 Hz
Electromagnetic environment - guidance		
Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: $d=[\frac{3.5}{V1}]\sqrt{P}$ $d=[\frac{3.5}{E1}]\sqrt{P}$ 80 to 800MHz $d=[\frac{7}{E1}]\sqrt{P}$ 800M to 2.7GHz 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 , should be less than the compliance level in each frequency rang b. Interference may occur in the vicinity of equipment marked with the following symbol: 		
Note 1: At 80 MHz to 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. **a:** The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz,21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHZ. **b:** The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges. **c:** 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 HS10A is used exceeds the applicable RF compliance level above, the HS10A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. **d:** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

Recommended separation distances between portable and mobileRF communications equipment and the EQUIPMENT or SYSTEM

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and The device			
The device is suitable for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.			
Rated Maximum Output power of Transmitter (W)	**Separation Distance (m) Corresponding to Frequency of Transmitter**		
	150k to 80MHz	80M to 800MHz	800M to 2.7GHz

	$d=[\frac{3.5}{V1}]\sqrt{P}$	$d=[\frac{3.5}{E1}]\sqrt{P}$	$d=[\frac{7}{E1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

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 to 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.

Guidance and manufacturer's declaration - electromagnetic Immunity				
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	**Test Frequency**	**Modulation**	**IEC 60601-1-2 Test Level (A/m)**	**Compliance level (A/m)**
	30 kHz	CW	8	8
	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 M Hz	Pulse modulation 50 kHz	7,5	7,5

Recommended separation distances between RF wireless communications equipment								
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 RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.								
	Frequency MHz	**Maximum Power W**	**Distance**	**Band (MHz)**	**Service**	**Modulation**	**IEC 60601-1-2 Test Level (V/m)**	**Compliance level (V/m)**
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	1.8	0.3	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	2	0.3	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	0.2	0.3	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745							
	780							
	810	2	0.3	800 – 960	GSM 800/900, TETRA 800,	Pulse modulation	28	28
	870							

	930				iDEN 820, CDMA 850, LTE Band 5	18 Hz		
	1720 1845 1970	2	0.3	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	2450	2	0.3	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240 5500 5785	2	0.3	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9

Electromagnetic environment - guidance

RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

$E = \frac{6}{d}\sqrt{P}$

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey , should be less than the compliance level in each frequency rang b.Interference may occur in the vicinity of equipment marked with the following symbol：

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNINGS

- **This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.**
- **The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.**

C Factory Defaults

C.1 System Setup

System Setup	
Patient /Person Type	Adult, Adolescent, Child, Infant and neonatus
Screen Display Mode	Normal(Measurement Mode)

Beat Volume	5
Auto shutdown	Unallowed
Notice	On
notification silence button	60s

C.2 SpO2 Setup

Spo2 Settings	**Adult**	**Pediatric**	**Neonate**
Spo2 High Limit	/	/	/
Spo2 Low Limit	88	88	88
PR Settings	**Adult**	**Pediatric**	**Neonate**
PR High Limit	120	160	200
PR Low Limit	50	75	100
Sensitivity	**Med**		

D Notice Messages

This section lists only the most important physiological and technical notice messages. In the tables below, "H" means high, "M" means medium. The "Cause and actions" column gives recommendations to instruct you to troubleshoot the problems. If the problem persists, contact your service personnel.

D.1 Physiological Notice Messages

Notice	Notice Message	Notice Level	Cause and actions
SpO2 Too Low	SPO2 reading will flash. Notice lamp is red and flashing.	H	A measurement has risen above the high notice limit or fallen below the low notice limit. Check the personnel or person's condition and check if the personnel or person category and notice limit settings are correct.
PR Too High	PR reading will flash. Notice lamp is red and flashing.	H	
PR Too Low	PR reading will flash. Notice lamp is red and flashing.	H	
No Pulse	PR and SPO2 reading is " - - ". Notice lamp is red and flashing.	H	The pulse signal was too weak to be analyzed. Check the personnel person's condition, SpO_2 sensor and measurement site.
Low Perfusion	Notice lamp is flashing yellow. The screen will show "Low Perfusion"	M	The pulse signal was weak and please pay attention the personnel or person's condition.
Low signal Quality	Notice lamp is yellow and flashing. The screen will show "Low Signal Quality"	M	The pulse signal was too weak , Check the personnel or person's condition, SpO_2 sensor and measurement site.

D.2 Technical Notice Messages

Notice	Notice Message	Notice Level	Cause and actions
Sensor Off	Notice lamp is yellow and flashing. The screen will show "OFF"	M	The SpO2 sensor detached the person or the pulse oximeter, or there was a fault with the SpO2 sensor, or an unspecified SpO2 sensor was used. Check that the sensor application site and the sensor type are correct, and make sure that the sensor is undamaged. Reconnect the sensor if the sensor is disconnected or use a new sensor if the sensor is damaged, for example, sensor line is broken.

E SpO2 Sensor Model

E.1 Disposable SpO2 Sensor

Adult(finger)/Neonate(foot)	
Foam Adhensive SpO2 Sensor	AF543-01,AF543-01X

E.2 Reusable SpO2 Sensor

Adult	
Soft tip SpO2 Sensor	A403S-01,A410S-01
Finger Clip SpO2 Sensor	A403-01,A410-01

F Symbols and Abbreviations

F.1 Units

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

F.2 Symbols

– minus

– negative

% percent

/ per; divide; or

+ plus

= equal to

< less than

> greater than

≤ less than or equal to

≥ greater than or equal to

± plus or minus

× multiply

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F.3 Abbreviations

CISPR International Special Committee on Radio Interference

EEC European Economic Community

EMC Electromagnetic Compatibility

ID Identification

IEC International Electrotechnical Commission

LCD Liquid Crystal Display

LED Light Emitting Diode

MDD Medical Device Directive

PC Personal Computer

PR Pulse Rate

RF Radio Frequency

SpO2 Arterial Oxygen Saturation from Pulse Oximeter