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Wrist Oximeter 75044

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ACCARE

User Manual

WS Series
Pulse Oximeter

Please read the manual carefully before use

Introduction

Thank you for your purchase of our pulse oximeter (“oximeter”). Prior to use of the product, please read the content of this manual carefully to ensure proper use of the product. After reading, please keep this manual properly for future reference.

Hunan Accurate Bio-Medical Technology Co., Ltd. (“Accurate”) owns the intellectual property rights associated with this User Manual and the product described herein.

Version of Manual: V1.0
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Software Name: Control Software for WS Series Pulse Oximeter
Software Release No.: V1.0

PRODUCT INFORMATION

Product Name: Pulse Oximeter
Product Model: WS20A、WS20A1、WS20B、WS10A、WS10B
Scope of Application: The product is intended for monitoring of user’s SpO2 and PR in hospitals and at home.
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Foreword

Introduction

- This manual introduces in detail the use and functions of the product as well as how to operate it. Prior to use of the product, please carefully read and understand the content of this manual to ensure proper use of the product and safety of user.
- This manual introduces the product having the most complete configurations. Therefore, some content hereof may not apply to the product you have purchased. If you have any question, please feel free to contact us.
- Please keep this manual near the product for easy and prompt access when needed.

Illustrations

All illustrations provided herein are for reference only. The settings or data as can be seen in the illustrations may differ from those actually shown on the product.

Conventions

- Bold and italic: Represents chapters quoted.
- [Character]: Represents character strings in the software.
- →: Represents operating steps.

Contents

1.Safety

1.1 Safety Information

⚠ DANGER

● Indicates an imminently hazardous situation, which, if not avoided, could result in death, serious injury or property damage.

⚠ WARNING

● Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in death or serious injury or property damage.

⚠ CAUTION

● Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage.

▲ NOTE

● Emphasizes important precautions and provides instructions or explanations for better use of the product.

1.1.1 DANGER

This product does not involve any information about danger levels.

1.1.2 WARNING

● Prior to use, please first check the oximeter; do not use it if any abnormality is found. If it is found that the device works abnormally during use, please stop using it immediately.

● In order to avoid fire or explosion, do not use the device in an environment with anesthetic agent or other inflammables or explosives.

● Do not open the housing of the device. In case of any problem, please contact your dealer or the manufacturer.

● The patient's safety should be guaranteed when the device is used in conjunction with electrosurgical equipment.

● During defibrillation, do not come into contact with the patient; otherwise, serious injury or death could be caused.

● Please carefully place the power cord and the cables of various

accessories to prevent the patient from getting wound or suffocated, entanglement of the cables, or electrical interference.

- Only use the SpO2 probe supplied by the manufacturer; use of a SpO2 probe from other source could result in performance degradation or damage of the device or cause safety risks.
- Do not use the SpO2 probe supplied by the manufacturer in conjunction with other equipment; otherwise, safety risks could be caused.Operator needs to verify the compatibility of the monitor, probe and cable before use, or patient injury can result. misapplication of a probe with excessive pressure for prolonged periods can induce pressure injury.
- This device is not suitable for neonate or infant patients or people weighing less than 30KG.
- This device is just auxiliary equipment for clinical diagnosis; the physiological parameters and waveforms it displays are only for reference by doctors, which cannot be directly used as a basis for clinical treatment.
- A functional tester cannot be used to assess the accuracy of the SpO2 probe or oximeter.
- The computer connected with the oximeter for file transfer should carry the CCC mark or conform to IEC 60950-1.

1.1.3 CAUTION

- For the sake of user's safety, please use accessories specified in this manual.
- For scrapping and disposal of the oximeter and its package, please observe the local laws and regulations.
- The oximeter could be subjected to interference by other equipment even if such equipment conforms to the requirements of applicable national standard on emission.
- Please properly install or carry the device to avoid damage due to drop, collision, strong oscillation or other mechanical forces.
- This device is used to measure the O2 content in blood; the

following factors could degrade the measurement performance and accuracy of the oximeter:

1)Strong interference by light (e.g., fluorescent light, dual ruby light, infrared heater, operating light, direct sunlight) in the application environment will affect the measurement accuracy.

2)Water vapor and mist in the device.

3)The size of finger measured is out of range.

4)Weak pulse.

5)Venous pulse.

6)The shock, anemia, hypothermia or application of vasoconstrictors may reduce the arterial blood flow to a non-measurable level.

7)Stain exists in blood vessels.

8)Concentration of the non-functional hemoglobin, like COHb or MetHb.

9)Dysfunction of important indices of hemoglobin (e.g., carboxyhemoglobin and methemoglobin).

10)Arrhythmia.

11)External light radiation.

12)Intense activity of user, interference from electrosurgical equipment.

13)Existence of certain stains, such as methylene blue and indigo carmine.

14)Improper position of SpO2 probe, or use of incorrect SpO2 probe.

15)Not suitable for user with arrhythmia, heart failure, hypoperfusion (PI＜0.3), finger shivering, etc.

16)The finger is too thin or too cold.

1.1.4 NOTE

⚠ NOTE

- Please install the device at a position where observation, operation and maintenance can be easily carried out.
- The software for this device has been developed in accordance with the requirements of IEC 60601-1-4 to minimize the probability of risks caused by program error.

- Do not attempt to open the housing for repair. If the product is damaged and needs repair, it can be repaired by qualified service Personnel designated by the manufacturer. The manufacturer may provide the service personnel with the Service Manual which contains information necessary for repair such as circuit diagram, component list, legend and correction rules.
- It is not suggested to place the SpO2 probe at the same position of fingertip too long within 24h.

1.2 Device Symbols

Symbols	Meaning	Symbols	Meaning
	Notice. See the accompanying documents (this User Manual)		The transport package cannot be directly exposed to sunlight
	Power/Confirm key		This side up during transport or placement
	Up key		Type BF equipment
	Down key		The device belongs to Class II equipment
	Manufacturer		Manufacturing date
	Protect the package from rain		The packaging box contains fragile items. Handle with care
	Useful life	SN	Serial number
	No alarm system	IP22	Degree of protection against liquid ingress
	Caution, consult accompanying documents		Non-ionizing radiation
	The symbol indicates that the device should be sent to the special agencies according to local regulation for separate collection after its useful life	CE 0123	This item is compliant with Medical Device Directive 93/42/EEC

2.Overview

2.1 Introduction

2.1.1 Scope of Application

The product is intended for monitoring of user's SpO2 and PR in hospitals and at home.

⚠ WARNING

● The oximeter should be used by or under the guidance of medical workers. When using the device at home, user should carefully read the User Manual before use and where necessary, consult the doctor, dealer or manufacturer.Human contact part of the equipment meet the bio-compatibility requirements and complies with ISO 10993-1, ISO 10993-5 and ISO10993-10 standards.

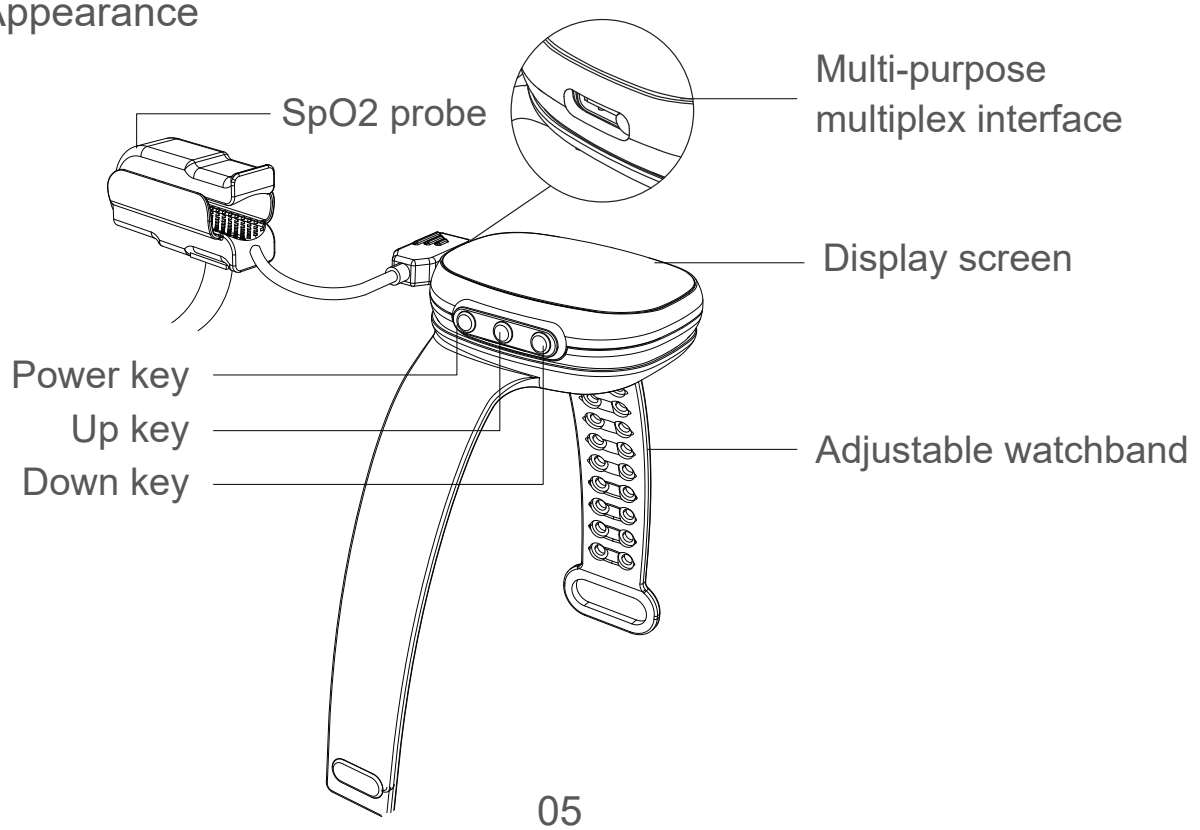
▲ NOTE

● The oximeter can be used in hospitals or for home care.

2.1.2 Contraindications

None

2.2 Appearance



1.Display screen

Display the SpO2 and SpO2 measurement trend graph; PR value, PR measurement trend graph, pulse intensity bar chart, perfusion index (PI) value, pulse wave, operating state of main unit, measurement duration, user ID, battery level, and time.

2. Power/Confirm key

- Power: Press this key to start the oximeter.
- In Menu mode, it serves as the Confirm key.

3. Up key

This key has different functions in different situations. Press this key to move the cursor upward, increase the value of a menu item, etc.

4. Down key

This key has different functions in different situations. Press this key to move the cursor downward, reduce the value of a menu item, etc.

5. Multi-purpose multiplex interface

Connect the charging cable or SpO2 probe.

6. Watchband

7. SpO2 probe (model: A401-201)

2.3 Product Function List

	WS20A	WS20A1	WS10A	WS20B	WS10B
Display screen	√	√	√	√	√
SpO2	√	√	√	√	√
PR	√	√	√	√	√
Pulse wave	√	√	√	√	√
Battery level display	√	√	√	√	√
Rechargeable	√	√	√	√	√
Bluetooth	√	√	√	/	/
Storage	√	√	/	√	/

※“√” represents that the device has this function;

“ / ” represents that the device does not have this function.

3.Preparation before Use

3.1 Unpacking Inspection

Please check the packing box carefully before opening it. Please get in touch with the carrier immediately if any damage is found. Properly open the packing box; carefully take the device and other components out of the packaging box, and count them item by item according to the Packing List. Check whether the device has any mechanical damage and whether all articles are complete. If you have any question, please contact us immediately.

▲ NOTE

● Please properly keep the packaging box and packaging materials for use in future transport or storage.

⚠ WARNING

● Please keep the packaging materials out of the reach of children. Please observe the local regulations or the hospital's waste disposal rules when disposing of packaging materials.

● The device may be contaminated with microorganisms during storage, transport and use. Please confirm the package is complete prior to use, and do not use the device if any damage is found.

3.2 Environmental Requirements

The operating environment for this device must conform to the environmental requirements specified in this manual. When the device is moved from one environment to another, condensation of the device could occur due to difference in temperature or humidity. In such case, the device can be used only after condensation disappears.

⚠ WARNING

● Please make sure the device works under the specified environmental conditions; otherwise, the technical specifications stated herein will not be achieved, and unforeseeable consequences such as device damage may take place.

● If the oximeter is damaged or cannot work normally, it should not be used for patient monitoring. Please contact the service personnel or our Company immediately.

3.3 Start up

1.Prior to start up, please check whether the oximeter has any mechanical damage.

2. Make sure the remaining battery capacity is adequate.

3. Press the Power key to enter the main interface.

3.4 Shut down

Please shut down the oximeter according to the following steps:

1. Confirm that the measurement is to be ended.

2. Disconnect the SpO2 probe from the oximeter.

3. Place the main unit of oximeter still for a while (time can be set under Menu Setup); then the oximeter will shut down automatically.

4.Basic Operations

4.1 User Setup

Measurement interface → Press the Confirm key to enter the interface → Main interface → Press the Up/Down key to select a user menu, and press the Confirm key to enter the user menu interface.

- Set User ID

1. Press the Confirm key to confirm the selection of User ID;

2. Press the Up/Down key for selection;

3. Press the Confirm key to confirm the modification and return to other menu for selection.

- Set Age

1. Press the Confirm key to confirm the selection of Age;

2. Press the Up/Down key for selection;

3. Press the Confirm key to confirm the modification and return to other menu for selection.

- Set Gender

1. Press the Confirm key to confirm the selection of Gender;

2. Press the Up/Down key for selection;

3. Press the Confirm key to confirm the modification and return to other menu for selection.

- Set Intended Population

1.Press the Confirm key to confirm the selection of Intended Population;
2. Press the Up/Down key for selection;
3. Press the Confirm key to confirm the modification and return to other menu for selection.

- Reminder ON/OFF

1. Press the Confirm key to confirm the selection of Reminder;
2. Press the Up/Down key to select ON/OFF;
3. Press the Confirm key to confirm the modification and return to other menu for selection.

- Set upper limit for PR reminder

1. Press the Confirm key to confirm the start of setting;
2. Press the Up/Down key to set the range of upper limit for PR reminder: (lower limit + 1bpm)~250bpm;
3. Press the Confirm key to confirm the modification and return to other menu for selection.

- Set lower limit for PR reminder

1. Press the Confirm key to confirm the start of setting;
2. Press the Up/Down key to set the range of lower limit for PR reminder: 25bpm~(upper limit - 1bpm);
3. Press the Confirm key to confirm the modification and return to other menu for selection.

- Set lower limit for SpO2 reminder

1. Press the Up/Down key to set the range of lower limit for SpO2 reminder: (upper limit - 1%)99%~76%;
2. Press the Confirm key to confirm the modification and return to other menu for selection.

Remark: When the Reminder function is set to ON, if the value measured by the pulse oximeter is beyond the reminder setting range and this state lasts for some time, the measured value will flicker automatically and meanwhile the vibration function will be turned on. You can press any key to end this state.

4.2 System Setup

- Time Setup (disabled when the main unit is inserted with a probe)

1. Measurement interface → Press the Confirm key to enter the interface → Squared menu → System Setup → Time Setup;
2. Press the Up/Down key to select the setting item, and press the Confirm key to confirm the selection;
3. After selecting the item, press the Up/Down key to change the value, and press the Confirm key to confirm the modification.

- Backlight Brightness

1. Measurement interface → Press the Confirm key to enter the interface → Squared menu → System Setup → Backlight Brightness;
2. Press the Confirm key to confirm the selection; press the Up/Down key to select the level, and press the Confirm key to confirm the modification.

- Backlight Time

1. Measurement interface → Press the Confirm key to enter the interface → Squared menu → System Setup → Backlight Time;
2. Press the Confirm key to confirm the selection; press the Up/Down key to select the option, and press the Confirm key to confirm the modification;
3. “10s” represents that backlight will be turned off automatically in 10s after stop of operation; other options can be explained similarly.

4.3 Review

1. Measurement interface → Press the Confirm key to enter the interface → Squared menu → Review;
2. Display abnormality data in the measurement process.

4.4 Report

After the device continuously monitors SpO2 and PR for some time, the software will automatically generate a report according to the measured data for view by user. For example, the device can provide long-time monitoring during sleep, and the software will summarize and generate a sleep report according to the measured SpO2 and PR for user to view

and know the measured results.

Note: The report is for reference only and cannot be used as a basis for treatment.

4.5 Battery Level Detection

The device automatically monitors the battery level, and displays and updates it on the display screen. When the battery level is displayed as  , please charge the battery timely.

4.6 Transmission via Bluetooth (applicable for WS20A and WS10A)

Turn on Bluetooth on your smart phone; launch the specific application to connect the device so that you can upload data via Bluetooth.

▲ Note: This device only support Bluetooth Protocol 4.0 and higher version.

4.7 Data Transmission (applicable for WS20A and WS20B)

In USB mode, the PC can correctly display data files saved during measurement, and such files can be copied to the PC.

4.8 Measurement Duration

Turn on the SpO2 main unit and connect the probe; insert your finger into the probe and start measurement. The main interface displays 00:00:00; when a value is obtained, it will update the measurement time in real time. Unplug the probe, the measurement time will continue accruing until the main unit can no longer receive detection data, and then it will stop automatically.

4.9 Main Unit State Indication

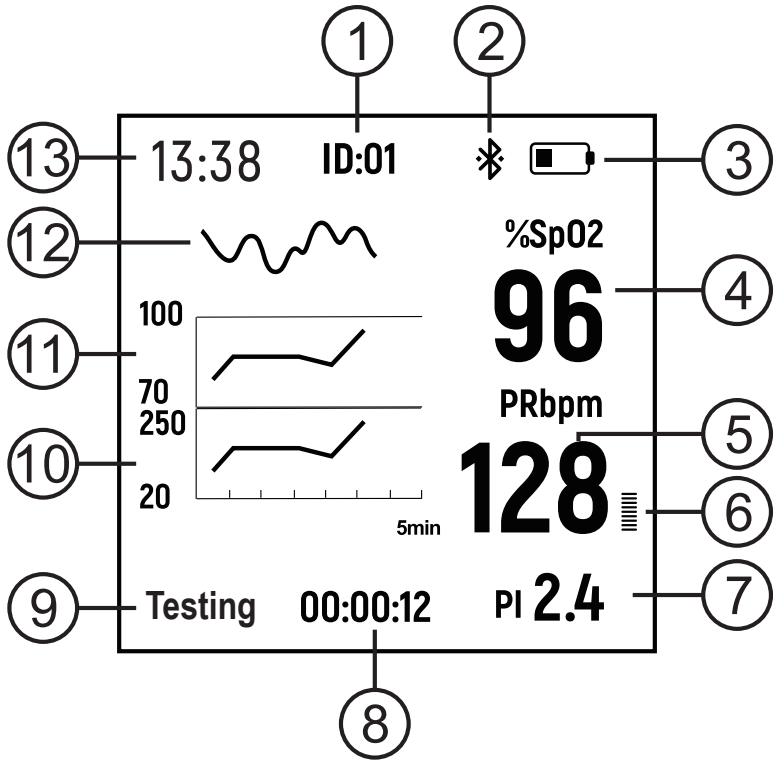
■ When the probe is not inserted after the SpO2 main unit is turned on, the state indication is “Please insert the probe for measurement”;

■ When the probe is inserted after the SpO2 main unit is turned on, the state indication is “Measuring...”.

5.SpO2 Measurement and Information

5.1 Overview

Continuous non-invasive pulse SpO2 oximetry is employed for SpO2 measurement. It measures the luminous flux of light of specific wavelength emitted by the luminous light source of SpO2 probe after absorption by oxyhemoglobin in the patient's tissue and arrival at the photoelectric detector, thus to obtain SpO2 and PR. This oximeter has been calibrated to display functional SpO2.



The oximeter provides:

1. ID: User's ID code (where applicable).
2. Bluetooth connection state
3. Battery level
4. SpO2: The percentage of oxyhemoglobin in total hemoglobin.
5. PR: The detected number of pulses per minute.

6. Bar chart: The amplitude of bar chart represents the level of pulse strength.
7. PI: Perfusion index.
8. Measurement duration: Records the duration of measurement.
9. Main unit operating state: The current state of the main unit.
10. PR measurement trend graph
11. SpO2 measurement trend graph
12. Pulse wave
13. Time
Statement: All waveforms displayed have been normalized. The device is not suitable for motion state or weak PI state.

5.2 Safety Information

⚠ WARNING

- When the patient has the hypoxia tendency, the blood sample should be analyzed so as to completely know the patient's condition.
- Avoid using the oximeter when MRI equipment is used; otherwise, the induced current may cause severe burn to the patient.
- During long-time continuous monitoring, the position where the SpO2 probe is fitted should be checked every two hours; also, the probe should be properly moved in case of any skin change or every four hours. Some patients may require more frequent examinations, such as patients with skin allergy. This is because long-time continuous monitoring may increase the possibility of unforeseeable skin changes, such as allergy, erythrosis, blistering or pressure necrosis.
- It is suggested to change the wearing position every 2-3h; if the patient feels uncomfortable or suffers allergy, stop using the device immediately and where necessary, seek medical advice.
- The cable of electrosurgical equipment should not be entangled with the cable of SpO2 probe.
- Do not place the SpO2 probe on a limb with any arterial duct or intravenous line.
- Do not place the SpO2 probe and the BP cuff on the same limb

since blood flow occlusion during BP measurement will affect the SpO2 reading.

5.3 Measurement Steps

1. Clean the measuring position, such as colored nail polish.
2. Place the SpO2 probe at the measuring position.
3. Connect the main unit and SpO2 probe.
4. Generally measured data can be read from the screen in 10s.

5.4 Factors Affecting Measurement

If you have any doubt about the accuracy of the measured result, please first use other method to check the patient's vital signs, and then check the SpO2 main unit and the SpO2 probe. See 1.1.3 for factors that could affect the measurement accuracy:

▲ Note: When signal is incomplete (signal noise is too high, signal quality becomes poorer or signal disappears), the SpO2 and PR values will become invalid, and the main unit screen will display the component as "--".

6.Battery

6.1 Overview

The oximeter is powered by the internal rechargeable lithium battery.

WARNING

- To charge the battery, please use a power adapter (DC5V output voltage and 500mA current) conforming to the safety requirements in IEC60950 and the electromagnetic compatibility requirements in IEC 60601-1-2
- It is forbidden to use the device during charging.
- Do not disassemble the battery, place it in fire, or short-circuit it.

Combustion, explosion or leakage of the battery could cause injury.

6.1.1 Lithium Battery Charging

Operation steps:

1. Connect the charging cable to the multi-purpose multiplex interface of the oximeter;
2. Connect the other end of the charging cable to the charger;
3. Disconnect the adapter after full charging.

▲ NOTE

- The service life of lithium battery depends on the time and frequency of use. If the lithium battery is maintained and stored properly, its service life is subject to the general standard for batteries and the warranty standard. If the lithium battery is used improperly, its service life could be shortened. The voltage supply time of the battery depends on the device configuration and operation.
- When the multi-purpose multiplex interface is used as the signal port, it can only connected with equipment having no external voltage risk (conforming to IEC 60601-1-1).

7.Maintenance and Cleaning

Only use materials and methods listed in this chapter for cleaning or disinfection of the device.

For any damage or accident arising from use of other materials or methods, the Company will not provide any warranty. The Company will not assume any liability for the effectiveness of listed chemicals or methods when they are used as infection control means. For infection control methods, please consult the Infection Prevention Department or an epidemiologist in your hospital.

Please keep the device and its parts and accessories dustless. In order to avoid damage of the device, please observe the following requirements:

- Never soak the device in any liquid.
- Never pour any liquid onto the device or its accessories.
- Never allow any liquid to flow into the housing.
- Never use abrasive materials (e.g., steel wool or silver polish) or strong solvents (e.g., acetone or detergents containing acetone).

⚠ WARNING

- Before cleaning the device, please power it off and disconnect the charging cable and SpO2 probe.

⚠ CAUTION

- If any liquid is poured onto the device or its accessories by accident, please contact the service personnel or our Company immediately.

7.1Check

Before initial use or after repair or upgrade of the oximeter, a comprehensive check should be performed by qualified service personnel to ensure normal operation and working of the oximeter. Items for checking should include:

- The environment and power supply conform to relevant requirements.
- The device and its accessories have no mechanical damage.
- The power cord has no abrasion, and the insulating property is good.
- Specified accessories are used.
- The battery performance is good.
- The device is in good working state.

If any damage or abnormality is found, please stop using the oximeter and contact the hospital’s medical engineer or our service personnel.

7.2 Cleaning and Disinfection

1. When dust or stain exists on the surface of the oximeter, 75% medicinal alcohol can be used for wiping. During wiping, please use a dry cloth to dip with small amounts of alcohol, and do not allow alcohol to drop or flow into the device.

2. Air-dry the device or use a dry, clean cloth to wipe the surface.
Recommended period: After each use of the device.

⚠ WARNING: Do not use high-temperature and high-pressure gas to disinfect the device.

7.3 Scrapping

To avoid contaminating the environment or other equipment or infecting other people, please disinfect and purify the device and its accessories according to applicable national laws or regulations before scrapping, and also observe the local regulations on scrapping of medical wastes. Packages should be scrapped according to applicable national laws or regulations.

8.Troubleshooting

Problem	Possible Cause	Solution
Failure to enter the measurement interface	1.The battery level is inadequate; 2.The oximeter is damaged; 3.The SpO2 probe is damaged.	1.Charge the battery; 2.Short press the Power key; if the oximeter cannot be turned on, it indicates the oximeter is damaged. Please contact the local customer service center; 3.If the oximeter can be turned on, it indicates the SpO2 probe is damaged. Please contact the manufacturer to replace the probe with one of the same model..
SpO2 or PR displayed is instable	1.The probe is not properly clamped to the finger; 2.The fingernail is too long.	1.Properly clamp the probe to the finger; 2.Cut the fingernail.

A.Product Specifications

Type	Wavelength	Power
RED	660±6nm	1.8mW
IR	905±10nm	2.0mW
The range of emission wavelength is 600~1000nm; information on the wavelength range could be especially useful for clinical physicians.		

Safety specification (classification according to IEC 60601-1)	
Type of protection against electrical shock	Class II device powered by an internal electrical power source
Rating of protection against electrical shock	Type BF
Rating of protection against explosion	Ordinary device without providing explosion protection
Rating of protection against liquid ingress	IP22
Rating of movement	Wrist-type
Working mode	Continuous

Physical specification	
Width × Height × Thickness	47×55×17 mm
Max. weight	<300g (full-configuration)

Hardware specification	
Display screen	TFT
Multi-purpose multiplex interface	One multiplex interface for charging/SpO2 probe
Watchband	1

Lithium battery	
Quantity	1
Specification	3.7V
Battery capacity	500mAh
Voltage supply time	When the device performs measurement continuously after the lithium battery is fully charged, the working time should not be less than8h (under the conditions of long-time measurement, screen off and no measurement abnormality)

Environmental specification	Operation	
Temperature（°C）	+5~+40	-20~+60
Relative humidity (non-condensing)	≤80%	≤80%
Atmospheric pressure (kPa)	70kpa~106kpa	70kpa~106kpa

Performance parameters			
SpO2		PR	
Measurement range	35% ~100%	Measurement range	25~250 bpm
Resolution	1%	Resolution	1bpm
Accuracy	80~100%: ±2% 70~79%: ±3% <70%: Not defined	Accuracy	±3bpm or ±2%, whichever is greater.
Refresh Period	1s	Refresh Period	1s
Averaging Time	8s	Averaging Time	8s
displayed range	0%~100%	displayed range	25~250 bpm

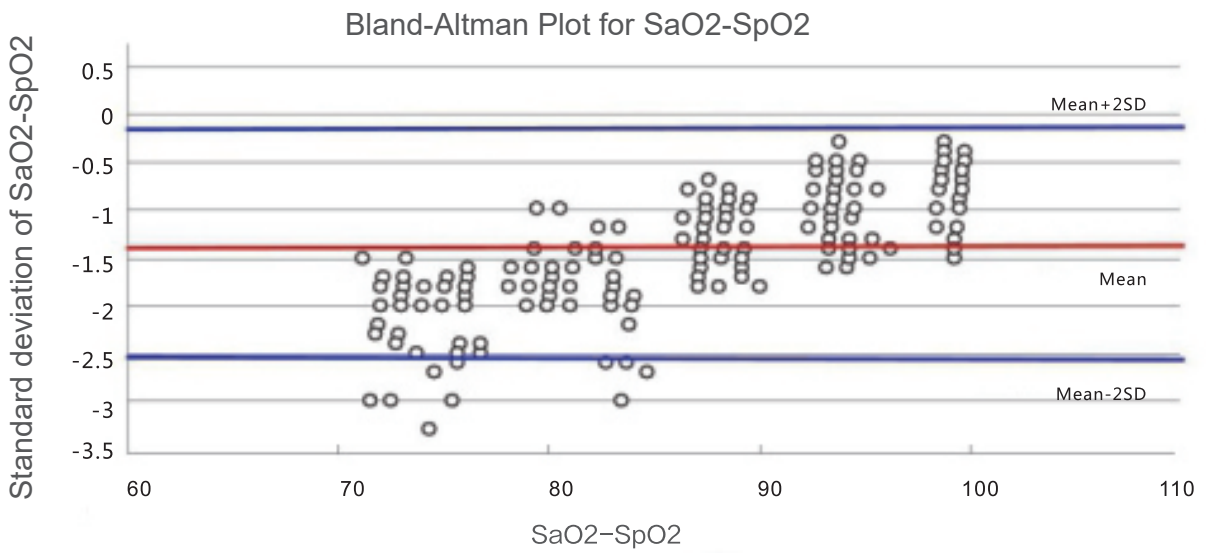
The pulse rate waveform has been normalized.The measured value is best when the pulse rate waveform is smooth and stable. Data update period: ≤3 pulse rate cycles, ＜ 30s.

Technical Description

The table below shows the statistical conclusion of the study on invasive controlled desaturation according to Annex EE “Guideline for evaluating and documenting SpO2 accuracy in human objects” of ISO 80601-2-61. The statistical result shows the accuracy distribution within the range of 70%~100%, which is helpful for user.

Deviation Analysis / SpO2-Oximeter	SaO2-Radiometer ABL800 FLEX-CO-Oximeter			
	70-80(%)	80-90(%)	70-100(%)	70-100(%)
Mean deviation (Bs)	1.94	1.45	0.89	1.4
Accuracy (Bs)	2	1.55	0.98	1.53
Accuracy (Arms)	1.98	1.53	0.96	1.52

Below shows the Bland-Altman plot of sample for study on invasive controlled desaturation.



B. Network Security

The WS Series Pulse Oximeter is available with USB port or Bluetooth function (except on WS10B). The management software is described as follows:

● B.1 PC management software for the pulse oximeter: The operating environment is a PC installed with WIN7/WIN10 OS or higher compatible version as well as Anti-virus software.

Minimum hardware configuration requirements:

CPU: 1GHz or faster; memory: 1GB or larger; hard disk: >20GB; graphics: >128MB; USB2.0 port or higher. There is no requirement on network environment.

● B.2 The mobile phone management software for the pulse oximeter: The operating environment is a mobile phone installed with Android 8.0 OS or higher compatible version.

Minimum hardware configuration requirements:

CPU: 1GHz or faster; memory: 1GB or larger; Bluetooth: 4.0 or higher. There is no requirement on network environment.

● B.3 Data port and storage format

1) Data communication between the PC and the main unit of pulse oximeter is realized via USB port; data on the main unit are stored in the SQLite database on the PC. After the main unit is used to perform measurement, connect the PC and the pulse oximeter via USB cable; the main unit of pulse oximeter can be mapped as a removable disk. After opening the removable disk, you can see the files saved during measurement. With the specified PC management software, you can open files, save measured data to the SQLite database on the PC and view data. You cannot directly read and open files with other software.

2) Data communication between the mobile phone and the main unit of pulse oximeter is realized via Bluetooth port; data on the main unit are stored in the SQLite database on the mobile phone. At the end of measurement, you can use the specified mobile phone management software to synchronize measured data to your mobile phone via the Bluetooth function; data will be stored to the SQLite database on the mobile phone.

3) You can use the username and password to log into the PC

management software and the mobile phone management software for the pulse oximeter; user types include Super Admin, Admin and Ordinary User.

- Super Admin: Create and delete the Admin account and Ordinary User account; view operating parameters and measured results.
- Admin: Create and delete the Ordinary User account; set and view operating parameters; view measured results.
- Ordinary User: View operating parameters and measured results.

※ Ordinary User needs to enter the password to log into the management software, and cannot directly open data files without password or management software, thus to avoid unauthorized data leakage.

C. EMC

Electromagnetic compatibility

⚠ NOTE

- The pulse oximeter complies with the applicable EMC requirements in IEC 60601-1-2.
- Please follow the EMC instructions in the accompanying documents to install and use the pulse oximeter.
- Portable and mobile RF communication equipment may affect the performance of the pulse oximeter. To protect the pulse oximeter against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.
- Refer to the attached guide and manufacturer’s statement.

⚠ WARNING

- The device should not be used close to or in a stack with other devices. If such use is required, please observe the device to ensure its normal operation in the current configuration.
- Use of accessories or cables other than those sold as spare parts for internal components by the manufacturer of the device may increase the electromagnetic emission or reduce the electromagnetic immunity of the device.

Guidance and Manufacturer's Statement - Electromagnetic Emissions		
The pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment:		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The pulse oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class B	The pulse oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Statement - Electromagnetic Immunity			
The pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment:			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	N/A

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Surge IEC 61000-4-5	± 1 kV line to line ± 2 kV line to ground	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5% UT (> 95% dip in UT) for 5s	N/A	N/A
Power frequency magnetic field (50Hz/60Hz) IEC 61000-4-8	3A/m	3A/m, 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Notice: UT is the AC mains voltage prior to application of the test level.			

Guide and Manufacturer's Statement – Electromagnetic Immunity		
The pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment:		
Immunity test	IEC 60601 test level	Compliance level
RF conduction IEC 61000-4-6 RF radiation IEC 61000-4-3	3Vrms 150kHz~80MHz 3Vrms 150kHz~80MHz	N/A 3V/m
Electromagnetic Environment – Guide		
Do not get any working portable and mobile RF communication equipment closer to any part of this product (including its cables) than the recommended separation distance, which is calculated using the following formula subject to the transmitter's frequency. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz~800MHz $d = 2.3\sqrt{P}$ 800MHz~2.5GHz		

In the above formula:
P – the transmitter's maximum rated output power (W) learnt from the transmitter manufacturer;
d – the recommended separation distance (m)b.
The field intensity of fixed RF transmitters is measured by surveyingc the electromagnetic field and should be lower than the compliance level in either frequency ranged.
This product may cause interference to the nearby equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency band applies.
Note 2: The above guide may not be applicable to all cases, because electromagnetic transmissions are influenced by buildings, objects and the absorption and reflection by human bodies.

a The field intensity of fixed transmitters, like radio (cellular/cordless) phone, mobile radio ground station, amateur radio, AM and FM radio and television broadcast, cannot be predicted accurately in theory. To assess the electromagnetic environment of fixed RF transmitters, try to survey the electromagnetic field. If the measured field intensity of this product is higher than the above applicable compliance RF level, observe and verify whether this product works properly. If any performance anomaly is observed, it may be necessary to take additional measures, for example, adjusting the direction or location of the product.
b The field intensity should be lower than 3V/m in 150kHz~80MHz range.

Recommended separation distances between portable and mobile RF communications equipment and the pulse oximeter

The pulse oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product as recommended below, according to the maximum output power rating of the communications equipment.

Maximum output power rating of transmitter (W)	150 kHz～80 MHz $d = 1.2\sqrt{P}$	80MHz～800 MHz $d = 1.2\sqrt{P}$	800 MHz～2.5 GHz $d = 2.3\sqrt{P}$
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' maximum rated output power not listed above, the recommended separation distance "d" in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where "P" is the transmitter maximum rated output power in watts (W) provided by the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the higher frequency band applies. Note 2: The above guide may not be applicable to all cases, because electromagnetic transmissions are influenced by buildings, objects and the absorption and reflection by human bodies.

D. Default Factory Settings

D.1 Measurement Setup

Intended population	Adult
SpO2 low reminder	88
Upper limit for PR reminder	120
Lower limit for PR reminder	40

E. Product and Accessories

No.	Item	Quantity
1	Main unit	1
2	SpO2 probe	1
3	User Manual	1
4	Charging cable	1

※ The main unit of oximeter is provided with a two-year warranty period starting from the date of purchase, and the SpO2 probe has a six-month warranty period.