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.

Product usage period: 2 years

Version of Manual: V1.0
Issue date: 2023--8

Product Information

Product Name: Pulse Oximeter
Product Model: WS20A
Software Version： V1.0

Manufacturer: Hunan Accurate Bio-Medical Technology Co., Ltd.
Address: Accurate Industrial Park, No.108, Zhixian Road,
Xuelian Community, Xueshi Street of Yuelu District, 410208 Changsha, Hunan Province, PEOPLE'S REPUBLIC OF China
Tel: +86 731-85598539

CE 0123

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.

1.1.1DANGER

This product does not involve any information about danger levels.

1.1.2WARNING

- 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.
- 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 SpO_2 probe supplied by the manufacturer; use of a SpO_2 probe from other source could result in performance degradation or damage of the device or cause safety risks.
- Do not use the SpO_2 probe supplied by the manufacturer in conjunction with other equipment; otherwise, safety risks could be caused.
- 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 SpO_2 probe or

oximeter.

- The computer connected with the oximeter for file transfer should conform to IEC 60950-1.
- 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.
- The temperature of the enclosure such as the button and LCD display can reach 44.4 degrees . The internal temperature of the shell near the battery can reach 47.1 degrees .So don't touch buttons and screens for more than 10 minutes.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the f ollowing two conditions: (1) this device may not cause harmful interference, an d (2) this device must accept any interference received, including interference t hat may cause undesired operation.
- Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

  -Reorient or relocate the receiving antenna.

  -Increase the separation between the equipment and receiver.

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

  -Consult the dealer or an experienced radio/TV technician for help.
- This transmitter must not be co-located or operating in conjunction with any other

antenna or transmitter. The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

1.1.3CAUTION

- 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 O_2 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 SpO_2 probe, or use of incorrect SpO_2 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.

1.1.4NOTE

⚠ 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 SpO_2 probe at the same position of fingertip too long within 24h.

1.2 Device Symbols

Symbol	Meaning	Symbol	Meaning
	Notice. See the accompanying documents (this User Manual)		Keep away from 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		Date of manufacture
	Protect the package from rain		The packaging box contains fragile items. Handle with care
	The symbol indicates that the device should be sent to the special agencies according to local regulation for separate collection after its useful life		Non-ionizing radiation
	Use-by date		Temperature limit
	No alarm system	IP22	Degree of protection against liquid ingress
	Caution, consult accompanying documents	EC REP	Authorized representative
CE 0123	This item is compliant with **REGULATION (EU) 2017/745 OF THE**	MD	Medical device

	EUROPEAN PARLIAMENT AND OF THE COUNCIL.		
UDI	Unique device identifier		Stacking layer limit

2. Overview

2.1 Introduction

2.1.1 Scope of Application

The product is intended for monitoring of user's SpO_2 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.
- The Pulse Oximeter is not suitable for use under hypoperfusion and exercise conditions.

2.1.2 Intended Use

The Pulse Oximeter is intended to measure functional arterial oxygen saturation (SpO2) and pulse rate of patients in Home Health Care and Medical Facility.

2.1.3 Intended operator

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.

2.1.4 Intended Patient Population

The Pulse Oximeter is intended for adult patients.The patient's finger thickness should between 8 to 25.4 mm.

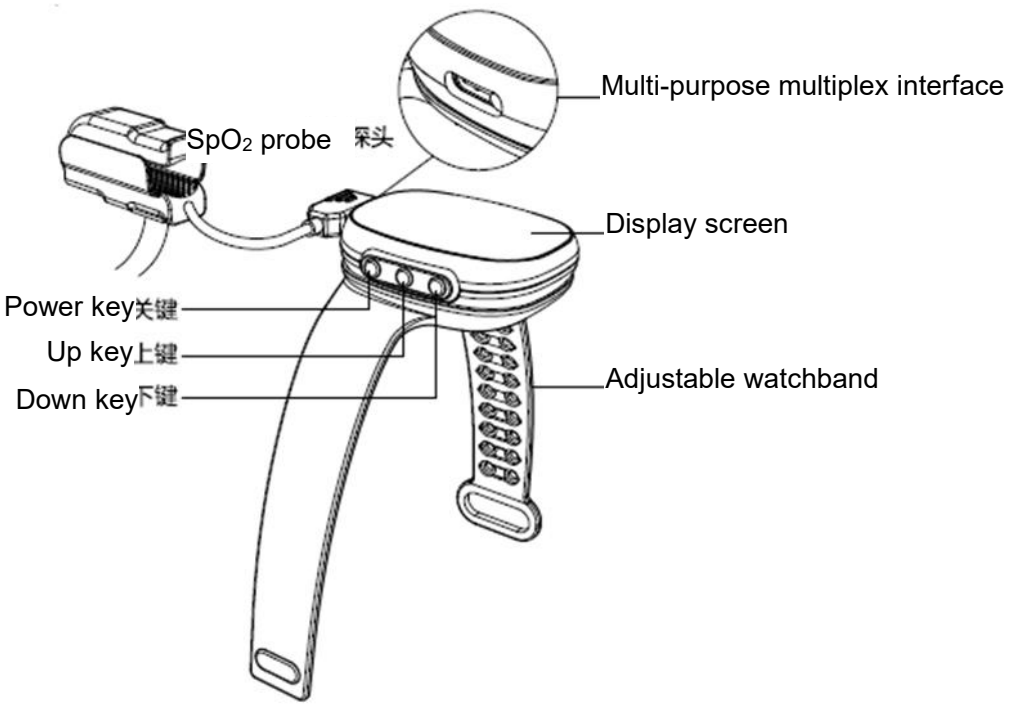
2.1.5 Medical Condition

The Pulse Oximeter is intended to be used in hospital,clinical institution, helthcare community. We recommend index finger, middle finger and ring finger are suitable position for monitor.

2.1.6 Contraindications

None

2.2 Appearance



1. Display screen

Display the SpO_2 and SpO_2 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 SpO_2 probe.
6. Watchband
7. SpO_2 probe (model: A401-201)

2.3 Product Function List

	WS20A
Display screen	✓
SpO_2	✓
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 startup, 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 Shutdown

Please shut down the oximeter according to the following steps:

1. Confirm that the measurement is to be ended.
2. Disconnect the SpO_2 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 Sex
  1. Press the Confirm key to confirm the selection of Sex;
  2. Press the Up/Down key for selection;
  3. Press the Confirm key to confirm the modification and return to other menu for selection.

- SpO2 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 low limit for SpO_2 reminder
  1. Press the Up/Down key to set the range of lower limit for SpO_2 reminder: 70%~94%;
  2. Press the Confirm key to confirm the modification and return to other menu for selection.

- PR 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 high 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 low 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.

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 → Main menu → Setting → Time;
  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 → Main menu → Setting → 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 → Main menu → Setting → Light 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.

- Factory
  1. Measurement interface → Press the Confirm key to enter the interface → Main menu → Setting → Factory;
  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;

4.3 Review

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

4.4 Report

After the device continuously monitors SpO_2 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 SpO_2 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

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

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 SpO_2 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

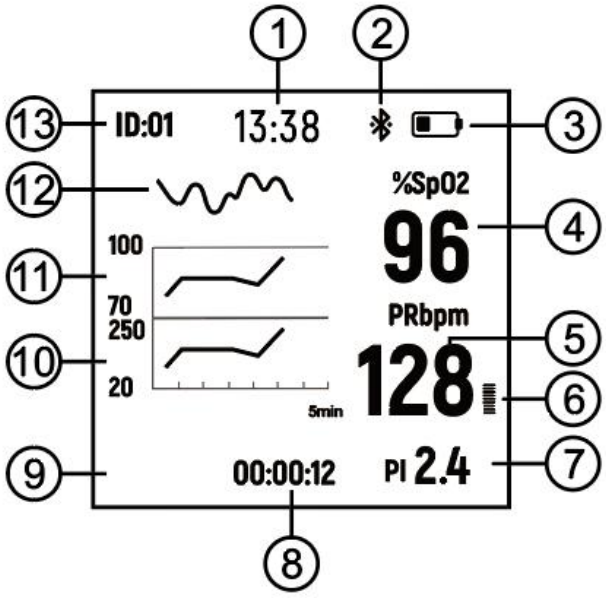
- When the probe is not inserted after the SpO_2 main unit is turned on, the state indication is “No Senser”;

- When the probe is inserted after the SpO_2 main unit is turned on, the state indication is “Testing...”.

5. SpO_2 Measurement and Information

5.1 Overview

Continuous non-invasive pulse SpO_2 oximetry is employed for SpO_2 measurement. It measures the luminous flux of light of specific wavelength emitted by the luminous light source of SpO_2 probe after absorption by oxyhemoglobin in the patient's tissue and arrival at the photoelectric detector, thus to obtain SpO_2 and PR. This oximeter has been calibrated to display functional SpO_2.



The oximeter provides:

1. Time
2. Bluetooth connection state
3. Battery level
4. SpO_2: 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. SpO_2 measurement trend graph
12. Pulse wave
13. ID: User's ID code (where applicable)

Statement: All waveforms displayed have been normalized.

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 SpO_2 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, er ythrosis, 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 SpO_2 probe.
- Do not place the SpO_2 probe on a limb with any arterial duct or intravenous line.
- Do not place the SpO_2 probe and the BP cuff on the same limb since blood flow occlusion during BP measurement will affect the SpO_2 reading.

5.3 Measurement Steps

1. Clean the measuring position, such as colored nail polish.
2. Place the SpO_2 probe at the measuring position.
3. Connect the main unit and SpO_2 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 SpO_2 main unit and the SpO_2 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 SpO_2 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 IEC 60601-1 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).
- 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.

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 SpO_2 probe.

⚠ CAUTION

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

7.1 Check

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 abr asion, 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 SpO_2 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 SpO_2 probe is damaged. Please contact the manufacturer to replace the probe with one of the same model.
SpO_2 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.

9 Clinical summary

The pulse oximeter has completed clinical research at Sir Run Run Shaw Hospital (SRRSH), affiliated with the Zhejiang University School of Medicine. The study included 13 subjects -10 women and 3 men. Participants are in good health and aged 22-30 years.

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	About 60g (just equipment)

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 than 8h (under the conditions of long-time measurement, screen off and no measurement abnormality)

Hardware specification	
Display screen	TFT
Multi-purpose multiplex interface	One multiplex interface for charging/SpO_2 probe
Watchband	1

Environmental specification	Operation	Storage
Temperature (℃)	+5~+40	-20~+60
Relative humidity	10~90%	10~90%

(non-condensing)		
Atmospheric pressure (kPa)	70kpa~106kpa	50kpa~107.4kpa

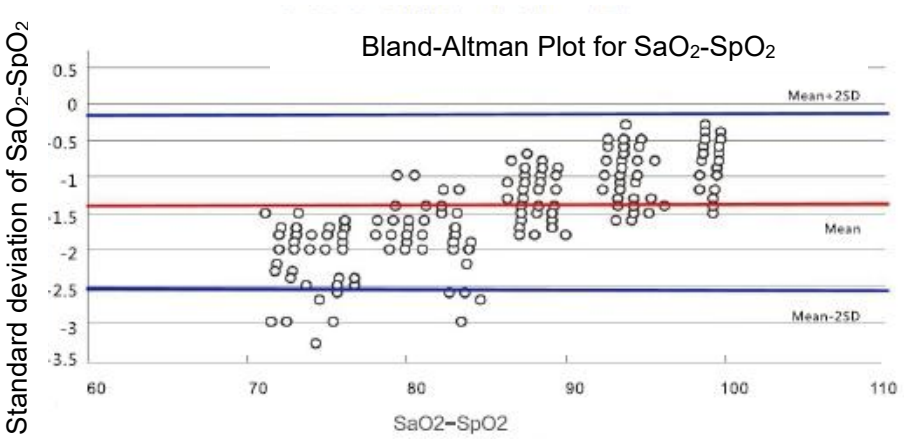
Performance parameters			
SpO_2		PR	
Measurement range	70 ~100%	Measurement range	25~250 bpm
Resolution	1%	Resolution	1bpm
Accuracy	70~100%: ±2% 0~69%:unspecified.	Accuracy	±3bpm .
Refresh Period	1s	Refresh Period	1s
Averaging Time	8s	Averaging Time	8s
displayed range	0%~100%	displayed range	25~250 bpm

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 SpO_2 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 / SpO_2-Oximeter	SaO_2-Radiometer ABL800 FLEX-CO-Oximeter					
	100-70(%)	100-97(%)	96-92(%)	91-85(%)	84-78(%)	77-70(%)
Mean deviation (Bs)	2.67	1.73	2.45	3.39	3.58	2.90
Precision (Bs)	2.41	1.51	1.53	2.55	2.34	3.98
Accuracy (Arms)	3.63	2.25	2.88	4.20	4.24	4.81

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


Bland-Altman Plot for SaO2-SpO2
Standard deviation of SaO2-SpO2
0.5
0
-0.5
-1
-1.5
-2
-2.5
-3
-3.5
60
70
80
90
100
110
Mean+2SD
Mean
Mean-2SD
SaO2-SpO2

B. Network Security

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

- B.1 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.2 Software Update

Update the instructions in the accompanying documents after independent registration.

C. EMC

The device meets the requirements of IEC 60601-1-2
Transmission power：<10 dBm
Wireless frequency range：2402MHz~2480MHz
Hereby, [Hunan Accurate Bio-Medical Technology Co., Ltd.], declares that this [WS20A] 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.

⚠ NOTE

- 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.

Appendix

Guidance and 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 B	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 61000-3-3	Not applicable	

Guidance and Declaration - Electromagnetic Immunity			
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of the device should 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 and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	N/A
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	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.
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2 Hz	3 V 0,15 MHz – 80 MHz 6 V in ISM band and Amateur radio band between 0,15 MHz and 80 MHz 80 % AM at 2 Hz	
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 2 Hz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 2 Hz	
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity		
The device is suitable for use in the electromagnetic environment specified below. The customer or the user of 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 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa
Radiated RF IEC 61000-4-3	10 V/m 80M to 2.7GHz	10 V/m
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 symbol 		
Note 1: From 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: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device. b: Over the frequency range from 150kHz to 80MHz, field strengths should be less than 3V/m.		

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 $d=[\frac{3.5}{V1}]\sqrt{P}$	80M to 800MHz $d=[\frac{3.5}{E1}]\sqrt{P}$	800M to 2.7GHz $d=[\frac{7}{E1}]\sqrt{P}$
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 at a maximum output power not listed above, the separation distance can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: From 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.			

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 kHz	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
	710 745 780	0.2	0.3	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	810 870 930	2	0.3	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	1720 1845 1970	2	0.3	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,	Pulse modulation 217 Hz	28	28

					4, 25; UMTS			
	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	2	0.3	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500							
	5785							

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.

D. Default Factory Settings

D.1 Measurement Setup

Intended population	Adult
SpO_2 low reminder	90
Upper limit for PR reminder	120
Lower limit for PR reminder	40

E. Product and Accessories

No.	Item	Quantity
1	Main unit	1
2	SpO_2 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 SpO_2 probe has a six-month warranty period.