A5
Pulse Oximeter

Shenzhen Hexin Zondan Medical Equipment Co., Ltd

Address:Floor 14, Block D, Dianlian Technology Building,the Crossing between South Circle Road and South Fuli Road, Guangming District, 518106 Shenzhen PEOPLE'S REPUBLIC OF CHINA
Tel: +86-755-26865970
Fax: +86-755-26860497
E-mail: intl@zondan.com
Website: www.zondan.com

Regulatory and Safety Specifications

Standard

The product is made under the ISO13485 quality system certified by TUV PS. The product has passed the CE certification.

Declaration

CE 0123 The A5 pulse oximeter is a Class IIa device and complies with the requirements of the Council Directive 93/42/EEC concerning medical devices and carries CE-marking accordingly.

Authorized EU Representative

Shanghai International Holding Corp.GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513175
Fax: 0049-40-255726

Instructions to User

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. The Manual is written for the current Pulse Oximeter. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the Manual very carefully before using this equipment. These instructions describe the operating procedures to be followed strictly, failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.

WARNING:

- **The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the individual patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man, can not stare at the light.**
- **Test can not use enamel or other makeup.**
- **Teste's fingernail can not be too long.**
- **Please peruse the relative content about the clinical restrictions and caution.**
- **This device is not intended for treatment.**
- **The Pulse Oximeter is not for diagnostic or therapeutic use.**
- **This device is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.**
- **Never use the Pulse Oximeter during MR or CT environment, in an explosive atmosphere, or on infant or neonatal patients.**
- **Never use the Pulse Oximeter in an environment of anesthetic gases.**
- **The material that the pulse oximeter contacted to body is non-toxic silica gel which meet the ISO10993 requirements, so can be safety used.**
- **Only use accessories recommended by the manufacturer. Using other kinds of accessories might cause damage or personal injury. Modification of the Pulse Oximeter could be unsafe as applicable. The degrade sensor may degrade the performance.**
- **This device is not defibrillation proof per IEC 60601-1.**
- **Inspect the sensor application site at least every 4 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to the sensor may vary due to medical status or skin condition.**
- **This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed carefully to verify normal operation.**

1 Safety

1.1 Instructions for Safe Operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User's Manual.Only the accessory that appointed or recommendatory by manufacture can be used with this device.
- This product is calibrated before leaving factory.

1.2 Warnings

- Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the teste measured by MRI and CT.
- The person who is allergic to rubber can not use this device.
- The disposal of scrap instrument and its accessories and packages (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.
- Please don't measure this device with function test paper for the device's related information.

1.3 Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high-pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60 ℃.
- As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients' SpO_2 and pulse rate, please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- Do not use the device on infant or neonatal patients.
- The product is suitable for above fifteen years to sixty years old adults (Weight should be between 15 kg to 110 kg).
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- The waveform is normalized. Please read the measured value when the waveform on screen is equably and steady-going, Here this measured value is optimal value. And the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years since the first electrified use.
- The hanging rope attached the product is made from Non- allergy material, if particular group are sensitive to the hanging rope, stop using it. In addition, pay attention to the use of the hanging rope , do not wear it around the neck avoiding cause harm to the patient.
- The instrument dose not have low-voltage alarm function, it only shows the low-voltage. please change the battery when the battery energy is used out.
- When the parameter is particularly, The instrument dose not have alarm function.Do not use the device in situations where alarms are required.
- Batteries must be removed if the device is going to be stored for more than one month, or else batteries may leak.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

2 General Description

Haemoglobin Saturation is percentage of Oxyhemoglobin (HbO2)capacity , compounded with oxygen , by all combinativable haemoglobin (Hb) obin (HbO2) capacity in blood . In other words , it is consistence of Oxyhemoglobin in blood . it is a very important ecological parameter for Respiratory circulation System . Many respiratory diseases can result in haemoglobin saturation being lowered in human blood . Moreover, the following factors can also lead to problems in oxygen supply, so that human haemoglobin saturation might be reduced: Automatic Organic Regulation Malfunction caused by Anesthesia, Intensive Postoperative Trauma, hurts resulted in by some medical examination and etc. In the situation, illnesses, such as light head, asthenia, vomitory and etc, might happen to patients and even endanger the patient's life. Therefore, it is very important to know Hemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in time.

The fingertip pulse oximeter features in small volume, low power consumption convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of hemoglobin Saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

2.1 Features

- OLED Display, four display modes.
- No key press design, auto induction for ON/OFF.
- 4-Direction Display automatically.
- Visual prompt function. Real-time spot-checks.
- Low power consumption, that can be long working by two brand new AAA batteries;
- Low voltage indicator.
- Automatic power off when no signal.
- Reliable accuracy and durability.
- Small and light weight, convenient to carry.

2.2 Product Operation Scope

This can be through the finger Pulse Oximeter to measure human blood oxygen saturation and heart rate. This product is suitable for family, clinic, oxygen bar, sports health (use before and after exercise is not recommended for use during exercise), community health and other ranges.

⚠**The product is not suitable for use in continuous supervision for patients.**

⚠**The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.3 Environment Requirements

Storage Environment
a) Temperature: -20℃~+55℃
b) Relative humidity: 10%~93%, Non-condensing
c) Atmospheric pressure: 22kPa ~ 107.4kPa

Operating Environment
a) Temperature: 0℃ ~ 40℃
b) Relative Humidity: 15%~80%, Non-condensing
c) Atmospheric pressure: 59kPa ~ 107.4kPa

3 Principle and Caution

3.1 Principle of Measurement

Principle of the oximeter is as follows: An experience formula of data process is established taking use of Lambert beer Law according to Spectrum Absorption Characteristics of reductive hemoglobin (R Hb)and Oxyhemoglobin (O2 Hb) in glow and near- infrared zones. Operation principle of the instrument is photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with capacity pulse scanning and recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LED through process in electronic circuits and microprocessor.

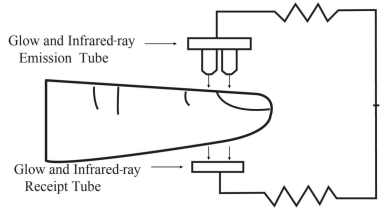


Figure 1 Operating principle

3.2 Caution

1. The finger should be placed properly (see the attached illustration of this manual, Figure 5), or else it may cause inaccurate measurement.
2. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
3. The SpO_2 sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
4. Make sure the optical path is free from any optical obstacles like rubberized fabric.
5. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
6. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
7. Testee can not use enamel or other makeup.

3.3 Clinical Restrictions

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.
3. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measure.
4. As the SpO_2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

4 Accessories

- One hanging rope (optional)
- Two batteries(optional)
- One User Manual.

5 Installation

5.1 View of the Front Panel

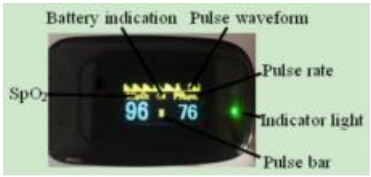


Figure 2 Front view

Figure 3 Batteries installation

Figure 4 Mounting the hanging rope

5.2 Battery

Step 1. Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.
Step 2. Replace the cover.

⚠**Please take care when you insert the batteries for the improper insertion may damage the device.**

5.3 Mounting the Hanging Rope

Step 1. Put the end of the rope through the hole.
Step 2. Put another end of the rope through the first one and then tighten it.

6 Operating Guide

1) Insert the two batteries properly to the direction, and then replace the cover.
2) Open the clip as shown in Figure 5.

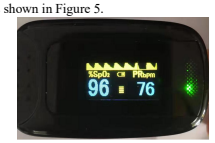


Figure 5 Put finger in position

3) Let the patient's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.After later the device exit standby mode
4) Do not shake the finger and keep the patient at ease during the process. Meanwhile, human body is not recommended in movement status.
5) Get the information directly from screen display, the display interface can automatically rotate at four directions; the direction of display interface can change atutomatictly according to the requirements of directions as shown in Figure 6 to Figure 9.

Figure 6

Figure 7

Figure 8

Figure 9

6) Indicator light: green light when pulse sound; red light when the prompt of measure data's going beyond the limits, the prompt of low-voltage, the prompt of finger's out of position.

⚠ **Fingernails and the luminescent tube should be on the same side.**

7 Repairing and Maintenance

- Please change the batteries when the low-voltage displayed on the screen.
- Please clean the surface of the device before using. Wipe the device with medical alcohol first, and then let it dry in air or clean it by dry clean fabric.
- Using the medical alcohol to disinfect the product after use, prevent from cross

infection for next time use.

- Please take out the batteries if the oximeter is not in use for a long time.
- The best storage environment of the device is -20 ℃ to 55 ℃ ambient temperature and not higher than 93% relative humidity.
- Users are advised to calibrate the device termly (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

⚠ **High-pressure sterilization cannot be used on the device.**

⚠ **Do not immerse the device in liquid.**

⚠ **It is recommended that the device should be kept in a dry environment.**

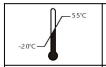
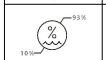
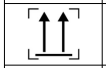
Humidity may reduce the useful life of the device, or even damage it.

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm
The device can not be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The malfunction of the device.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The display is off suddenly	1. The product will enter standby mode when no signal is in the product within 5 seconds 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

9 Key of Symbols

Symbol	Description
	Type BF
	Refer to instruction manual/booklet
--	Signal inadequacy indicator
%SpO_2	The pulse oxygen saturation(%)
PRbpm	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)
	1.No finger inserted 2. An indicator of signal inadequacy
AAA	Use AAA Battery
	Battery positive electrode
	Battery cathode
SN	Serial number
	No alarm system
	Compliance to WEEE standard
IP22	International Protection
	Manufacturer
	Date of manufacture

	Storage and Transport Temperature limitation
	Storage and Transport Humidity limitation
	Storage and Transport Atmospheric pressure limitation
	This side up
	Fragile, handle with care
	Keep dry
	Recyclable

10 Function Specification

Classification	
Classification by electric shock prevention type	Internal power supply equipment
Classification by electric shock resistance	BF type application part
Classification by operating mode	Continuous
Classification by protection against harmful ingress	IP22
Classified by safety when used with flammable anesthetic gas mixed with air or with flammable anesthetic gas mixed with oxygen or nitrous oxide	Equipment not to be used with flammable anesthetic gas mixed with air or with flammable anesthetic gas mixed with oxygen or nitrous oxide
Classification according to the disinfection and sterilization methods recommended by the manufacturer	As recommended by manufacturer
Classification by electromagnetic compatibility	Group I Class B equipment.
Display Information	**Display Mode**
The Pulse Oxygen Saturation (SpO_2)	OLED
Pulse Rate (PR)	OELD
Pulse Intensity (bar-graph)	OLED bar-graph display
Pulse wave	OLED
Parameter Specification	
SpO2 measuring range	35% ~ 99%, (the resolution is 1%).
SpO2 accuracy	90% ~ 99%: ±1%, 70% ~ 89%: ±2%, Below 70% unspecified.
Pulse rate measuring range	30 bpm ~ 240 bpm, (the resolution is 1 bpm)
Pulse rate accuracy	±1 bpm
Update frequency	around 1 second
Wavelength range	500nm ～ 1000nm
Optical sensor	Red light (wavelength is 660nm, 6.65mW) Infrared (wavelength is 940nm, 6.75mW)
Battery Requirement	1.5 V (AAA size) alkaline batteries × 2
Power consumption	Smaller than 40mA
Automatic shut-down	8 second
Indicator light	
Indicator light display, pulse and pulse tone synchronization	
Dimensions and Weight	
Dimensions	64.5(L) mm × 37.5(W) mm × 35(H) mm

Note:

A functional tester cannot be used to assess accuracy of the pulse oximeter.

The electronic pulse simulator is applied evaluation of pulse rate accuracy.

The pulse oximeter is calibrated to display functional oximetry and does not need to be calibrated during use.

Understanding the wavelength range can help clinicians to perform photodynamic therapy.

The SpO2 accuracy claimed in this manual is supported by the clinical study conducted by inducing hypoxia on healthy, non-smoking, light-to-dark skinned subjects in an independent research laboratory.

The SpO2 measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.

Since the measurement results of the pulse oximeter device conform to the statistical distribution, only about 2/3 of the measurement results fall within the ± marginal value measured by the CO-oxygen saturation meter. The oxygen volume map of the pulse oximeter has been normalized.

Appendix EMC

Note:

1. Pulse Oximeter meets the requirement of electromagnetic compatibility in IEC60601-1-2.
2. The user needs to install and use according to electromagnetism compatibility information which is attached with it.
3. Portable and mobile RF communication devices may influence pulse Oximeter performance, so pulse Oximeter should be kept away from them during using.
4. Guidance and manufacturer's declaration stated in the appendix.

Warning:

1. The user needs to install and use pulse Oximeter according to electromagnetism compatibility information which is attached with it.
2. Portable and mobile frequency communication devices may influence its performance, so it should be kept off these devices.
3. Pulse Oximeter should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Pulse Oximeter should be observed to verify normal operation in the configuration in which it will be used..

Table 1: Electromagnetic Emissions

Guidance and Declaration - Electromagnetic Emissions	
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.	
Emission test	**Compliance**
RF emissions CISPR 11	Group 1, Group B

Table 2: Electromagnetic Immunity

Guidance and Declaration - Electromagnetic Emissions		
Immunity test	**Compliance**	
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	
Radiated RF IEC 61000-4-3	80MHz- 2.7GHz	10 V/m
	380MHz- 390MHz	27 V/m
	430MHz- 470MHz	28 V/m
	704MHz- 787MHz	9 V/m
	800MHz- 960MHz	28 V/m
	1.7GHz- 1.99GHz	28 V/m
	2.4GHz- 2.57GHz	28 V/m
	5.1GHz- 5.8GHz	9 V/m

Table 3: Not Applicable

Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3), Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11), Conducted Immunity (IEC 61000-4-6)
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Warranty and Manufacturer Information

Warranty

The unit can not be repaired by users themselves. All services must be done by the engineers approved by ZONDAN. The unit is guaranteed for a period of 12 months, valid from the date of purchase. Zondan warrants that each product we sell you is free from defects in labor and materials and shall conform to its product specifications as defined in the user documentation. If the product doesn't function as warranted during the warranty period, we will repair or replace it without charge. Misuse, improper maintenance may void the warranty,

Manufacturer Information

Manufacturer: Shenzhen Hexin Zondan Medical Equipment Co., Ltd
Address: Floor 14, Block D, Dianlian Technology Building, the Crossing between South Circle Road and South Fuli Road, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA
Zip code: 518000
Tel: +86-755-26865970; +86-755-26850278
Fax: +86-755-26860497
E-mail: intl@zondan.com
Webside: www.zondan.com