Pulse Oximeter
USER MANUAL

A3/MAN-002 V2.4

Shenzhen Hexin Zondan Medical Equipment Co.,Ltd

Product Information

Model: A3

Product Name: Pulse Oximeter

Manufacturer Date: See product label

Company Name:

Manufacturer: Shenzhen Hexin Zondan Medical Equipment Co.,Ltd

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Edition

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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 A3 pulse oximeter is a Class II device and complies with the requirements of the Council Directive 93/42/EEC concerning medical devices and carries CE-marking accordingly.

Authorized EU Representative

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1. Product Operation Scope

This Pulse Oximeter is a kind of innovated medical detection device with non-invasive and continuous features for artery SPO2 and PR detection. It is portable and easy to measure the SPO2 and PR value quickly and precisely.

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. It's for ages from 15 to 60 years old patients. This product is not suitable for monitoring the patient's prolonged use.

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.

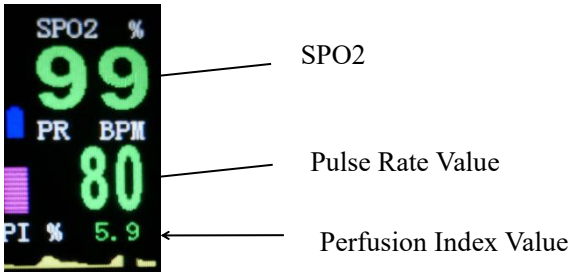
3. Measurement principle

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.

4. Appearance introduction

Model No. A3

Display screen



5. Features

5.1 TFT display, 4 display interface, figure and Oxygen volume chart display together on interface;

5.2 Adjust the display interface direction manually, according to the patient observation data needs;

5.3 Audible alarm function;

5.4 Low Power consumption. 50 hours continuous to work.

5.5 Low Perfusion ≤0.4%.

5.6 An alarm will show on display when low voltage happens;

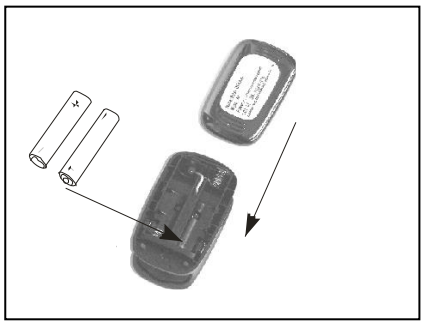
5.7 Automatic power off when no signal in 8 s

5.8 Small and light weight, convenient to carry.

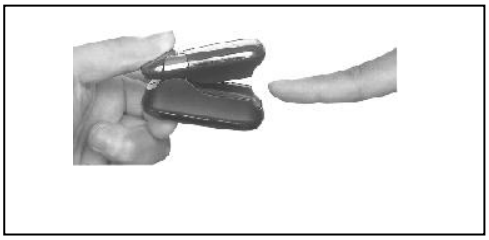
6. Operation Instructions

6.1 The product Operation Instructions

6.1.1 Installing two AAA batteries into battery cassette in correct polarities and cover it.



6.1.2 Plug one of fingers into rubber hole of the Oximeter (it is best to plug the finger thoroughly) nail surface upward, then releasing the clamp.



6.1.2.1 Press the switch button once on front panel.

6.1.2.2 Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status.

6.12.3 Read correspondent date from display screen.

6.2 Operation Instructions

6.2.1 Display Description （4 interface diagrams）

Interface 1

Interface 2

Interface 3

Interface 4

6.2.2 A3 button operating instructions:

6.2.2.1 Put into two AAA batteries according to the instructions, the A3 will turn on automatically and display interface 1; then put into finger for measuring, if there is finger for detection and without operation, it power off automatically in 8s.

6.2.2.2 When there is battery, but the Pulse Oximeter power off, press the button, it will be opened.

6.2.2.3 During the measurement (there is a measurement signal and figure), press the button shortly, the interface can turns from interface 1 to interface 4 circularly.

6.2.2.4 Short Press the button during the measurement; it can turn to settings menu interface.

6.3 Low power alarm

When the battery power appears low, the battery power indicate for empty on OLED, reminding the user to replace the battery; (the battery capacity indicates symbol of “▭”in OLED to remind user to replace battery.)

6.4 Pulse rate and SPO2 alarm

When a certain physiological parameter of the patient exceeds the set alarm high and low range, a physiological alarm is triggered, and the parameter in the parameter area will change color, reminding the user to pay attention to the measurement parameter.

The font color of SPO2 parameter values within the range of 85-99 is green, and the font color of parameter values outside the range is orange;

If the PR parameter value is within the range of 50-160, the font color is green, and the parameter value outside the range is orange;

Declaration: Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using medical alcohol before and after each test.(The rubber inside of the Oximeter belongs medical rubber, which has no toxin, and no harmful to the skin of human being).

When your finger is plugged into the Oximeter, you nail surface must be upward.

7. Product Classification

Product classification information of pulse oximeter is shown in Table 1.

Table 1 Product Classificatio

Classification basis	Safety classification
Classification by electric shock prevention type	Internal power supply equipment, general portable without defibrillation protection Belt equipment
Classification by electric shock resistance	BF type application part
Classification by operating mode	Continuously running equipment.
Classification by protection against harmful ingress	IPX1
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	Disinfection and sterilization equipment recommended by the manufacturer.
Classification By management category	Class Ⅱ
Classification by electromagnetic compatibility	Group I Class B equipment.

8.Power Specification

Table 2 Power Specification

Parameter	Specification
Fuse	466series, 0.5A 6.3V
Battery	d.c. 3V AAA(×2)
	When the battery is almost exhausted, the pulse oximeter will automatically shut down

9.Technical Specification

The data update period, data averaging, and other signal processing have an effect on the display and transmission of SpO2 and pulse rate. According to the alarm limit and the difference between the displayed values, the delay time for generating the alarm signal is 1 second. ~ 20 seconds. The maximum alarm state delay time is 4 seconds, and the maximum alarm signal is generated.

The delay time is 20 seconds, the average alarm state delay time is 2 seconds, and the average alarm

signal delay is10 seconds. The statistics of each decentralized state conform to the statistical analysis. If you have any questions, please contact Hexin Zhongdian Company.

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.

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

Table 3 Pulse oximeter specification

Parameter	**Specification**
SpO_2 measurement range	35% ～ 99%
SpO_2 measurement accuracy [1]	90%-99%, accuracy: ±1%; 70%-89%, accuracy±2%; ≤70%, no specified
Pulse Rate Measurement range	30 bpm ～240 bpm
Pulse Rate measurement accuracy	±1 bpm
SpO2 value and refresh rate of pulse rate	around 1 second
Pulse Rate Volume	Non-modulated
Wavelength range2	500nm ～ 1000nm
Maximum luminous power	150 mW
PR Display	Digital
Screen	TFT display "0.96" inch
Power consumption	150mW in normal measurement; 0.2uA in shutdown state;

1. Controlled blood oxygen monitoring in healthy, non-smoking adult volunteers to obtain sensor accuracy (according to EN ISO9919). These SpO2 readings have been compared with the CO-oxygen saturation meter measurement results of arterial blood standards. In order to represent the general population, at least 10 subjects (male and female) with different skin colors were collected to verify the accuracy of SpO2. Functional testing equipment cannot be used to evaluate the accuracy of pulse oximeters and the accuracy of blood oxygen sensors.

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

10.Physical Specification

The physical specifications of the host are shown in Table 4.

Table 4 The physical specification of the host

Table 4 The physical specification of the host

Parameter	A3
Size(mm)	63×41×31

11. Environment Specification

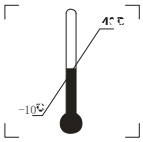
The environmental specifications of the pulse oximeter are shown in Table

Table 5 The environmental specifications of the pulse oximeter

Parameter	Specification
Operating Temperature	0℃ ～ 40℃
Storage and transportation Temperature	-20℃ ～ +55℃
Relative humidity in operation	15%~80%,Non-condensing
Relative humidity during storage and transportation	10%~93%, Non-condensing
Operating atmospheric pressure	59 kPa ～ 107.4 kPa
Atmospheric pressure during storage and transportation	22 kPa ～ 107.4 kPa

12． Logo Description

Signs	Notes on the signs
	Type BF Applied Part
	Attention, see instruction for use!
	Date of manufacture
	The carton should be lift in the right way of upward during transportation

	The goods is fragile, please handle with care
	Keep moisture off the packing carton
	Storage temperature should be marked clear on the carton
	Prohibition of free throw

13. Troubleshooting

Trouble	Possible Reason	Solution
The SpO2and Pulse Rate display instable	1. The finger is not places inside 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 turn on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device's malfunction.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The indicator light is off suddenly	1. The device will power off automatically when it gets no signal for 8 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

14. Accessory

AAA battery----------2 pcs（optional）
Hang String----------1 pc
User Manual ----------1 pc

15. Warranty and Manufacturer Information

15.1 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,

15.2 Manufacturer Information

Manufacturer: Shenzhen Hexin Zondan Medical Equipment Co., Ltd

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