Pulse Oximeter
USER MANUAL

A5/MAN-002 V2.5

Shenzhen Hexin Zondan Medical Equipment Co.,Ltd

Product Information

Model: A5

Product Name: Pulse Oximeter

Manufacturer Date: See product label

Company Name:

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, Shenzhen, CHINA

Tel: +86-0755-26865970、26850278

Fax: +86-0755-26860497

Post Code:518067

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 A5 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

Shanghai International Holding Corp.GmbH (Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Tel: 0049-40-2513175

Fax: 0049-40-255726

1．Product Operation Scope

The fingertip Oximeter can be used to measure human Haemoglobin saturation and heart rate through finger .The product is suitable for use in family hospital (including clinical use in internist /surgery, Anaesthesia, paediatrics, intensive care and etc.) Oxygen Club, social medical organizations, physical care in sports (It can be used before or after sports. Operation in sport procedure is not recommended) and etc.The product is not suitable to monitor patient continuously.

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: A5

Name: Fairy A5

5. Features

5.1 Two Color OLED Display, four display modes.
5.2 No key press design, auto induction for ON/OFF.
5.3 4-Direction Display automatically.
5.4 Visual alarm function. Real-time spot-checks.
5.5 Low Power consumption. 50 hours continuous to work.
5.6 Low Perfusion ≤0.4%.
5.7 Low voltage indicator.
5.8 Automatic power off when no signal.
5.9 Reliable accuracy and durability.
5.10 Small and light weight, convenient to carry.

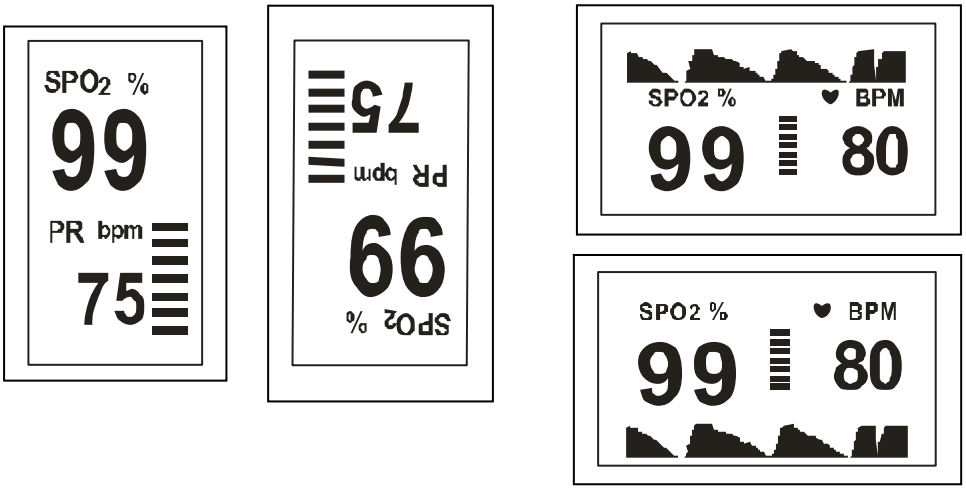
6. Operation Instructions

6.1 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.
6.1.3 Press the switch button once on front panel.
6.1.4 Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status.
6.1.5 Read correspondent date from display screen.

6.2 Display Description of Fairy A5

The display interface of Fairy A5 can automatically rotate at four directions; the direction of display interface can change automatically according to the requirements of detections. Total 4 types of display interface at 4 directions, shown as below:



6.3 A5 Operation Instructions

No keypress design employed for model A5, just put your finger(stretched fully)into the rubber hole and snail upwards, then after two seconds, the device will operate automatically to monitor the SPO2 value.

6.4 Low power alarm

Fairy A5: when battery power is at lowest level, the battery capacity indicates symbol of "▭"in OLED, remind users of replacement of battery.

6.5 Pulse rate alarm and SpO2 alarm

Alarming Default Value:

Pulse Rate: Upper Limit: 110BPM Lower Limit: 50BPM

SpO2＜85%

When device are under operation conditions, within scope of 50bpm~110bpm (PR), the indicator is in green, if PR value is out of those scope the indicator will be in red. If the SpO2 value is lower than 85%, the indicator will be in red.

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. Technical Specifications:

7.1 Display type: OLED two color display

OLED two color display, 1.04 inch

7.2 SPO2 measurement range: 35%-99%, PR measurement range: 30-240BPM.

7.3 Resolution: ±1% for SPO2, ±1BPM for Pulse Rate.

7.4 Accuracy: ±1%（90%-99%）

±2% (70%-89%), unspecified(≤70%) for SPO2.

7.5 Alarming Default Value:

Pulse Rate: Upper Limit: 110BPM Lower Limit: 50BPM

SpO2:＜85%

7.6 Low Perfusion ≤0.4%.

7.7 Power: two of 1.5V (AAA size) alkaline batteries.

7.8 Power consumption: A5＜30mA.

7.9 Automatic power-off: the product will automatically be powered off when no signal is in the product for longer than 8 seconds. (A5)

7.10 Operation Environment

Operation Temperature: 5℃~40℃

Humidity: 30%~80%

Air Pressure: 70kPa~106kPa

7.11 Anti-natural light interference ability: Under the natural light interference conditions, the

SPO2 value and pulse rate detecting value compliance to the aforesaid standards.
7.12 Anti-power interference ability: under the power interference conditions, the SPO2 value and pulse rate detecting value compliance to the aforesaid standards.
7.13 Dimension:
L 64.5mmX W 37.5mm X H 35mm

8．Classification:

Anti-electric Shock Type: Internally powered equipment
Anti-electric Shock Degree：Type BF equipment
EMC：type B class I

9．Precautions for use

9.1 Do not use the pulse oximeter in an MRI or CT environment
9.2 Explosion hazard：Do not use the pulse oximeter in an explosive atmosphere.
9.3 The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
9.4 Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity lf the patient.
9.5 Before use, carefully read the manual.
9.6 Do not use the pulse oxineter in situations where alarms are required .The device has no alarms.
9.7 Prolonged use or the patient’s condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status and correct alignment at least every 4 hours.
9.8 SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example)it necessary.
9.9 High -frequency electrosurgical interference and defibrillators.
9.10 Placement of a sensor on an extremity with a blood pressure cuff arterial catheter, or intravascular line
9.11 The patient has hypotension severe vasoconstriction severe anemia or hypothermia.
9.12 The patient is in cardiac arrest or is in shock.
9.13 Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

10．Repair and Maintenance

10.1 Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.
10.2 No flammable substance, overtop or lower temperature and humidity existed in operation conditions.
10.3 When the device is dabbled or there is hydraulic set existed, stop operating.
10.4 When lower power capacity light in red please replace the battery right away.
10.5 Please clean the surface before applying for detection.
10.6 Please take out the battery when device is not used for a period of time.
10.7 Please disposure the battery according to the local statute.
10.8 If there is dust or dirt on surface, 75% density of medical alcohol can be used to clean the surface. Please use dry fabric with little alcohol to avoid alcohol permeates into the device.

10.9 The transportation and storage conditions are:
Temperature: -20℃~60℃; Humidity : 10%~95%。

11. Trouble Shooting

Trouble	Possible Reason	Solution
The SpO2 And Pulse Rate Display instable	1.The finger is not 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 insert properly 3.The device's malfunction	1.Change batteries 2.Re-install 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

12. Accessory

AAA battery----------2 pcs
Hang String----------1 pc
User Manual ----------1 pc

13. Warranty and Manufacturer Information

13.1 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,

13.2 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,Shenzhen,China
Zip code: 518000
Tel: +86-755-26865970; +86-755-26850278
Fax: +86-755-26860497
E-mail: intl@zondan.com
Webside: www.zondan.com