AccuMed

User Manual

Instructions to User

Thank you very much for purchasing our product!
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.
Due to continual re-inovation, the products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.
This product is medical device, and can be used repeatedly.

WARNING:

- **An uncomfortable or painful feeling may develop 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 inspection in the measured part. The device cannot be placed 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, cannot stare at the light.**
- **Testee cannot use enamel or other makeups.**
- **Testee's fingernail should not be too long.**
- **Please peruse the relative content about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

1 Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for the respiration.
Many respiratory diseases will cause the body's SpO_2 to decrease, while the body automatic adjustment disorder caused by the anesthesia, big surgery trauma, and some of the damage caused by medical examination, are likely to lead to patient's oxygen supply problems and reduce the body's SpO_2, resulting in patient dizziness, weakness, vomiting and other symptoms. Severe cases will threaten life. So knowing the patient's SpO_2 in time will help doctor which has great significance in clinical medical area.
The Pulse Oximeter features a small size, low power consumption, convenient operation, and portability. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis. A display screen will directly show measured value of Hemoglobin Saturation.

1.1 Features

- Simple and convenient operation.
- The product is small in size, light in weight, and convenient to carry.
- Low power consumption.

1.2 Major Applications and Scope of Application

The product is applicable for use in family, hospital, oxygen bar, community medical treatment and sport health care (it is advised to be used before and after sports and it is not suggested to be used in the process of sport),etc.

⚠ **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 is caused by carbon monoxide. The device is not recommended to be used under this circumstance.**

1.3 Environment Requirements

Storage Environment

a) Temperature: -40ºC~+60ºC
b) Relative humidity: ≤95%
c) Atmospheric pressure: 500hPa~1060hPa

Operating Environment

a) Temperature: 10ºC~40ºC
b) Relative Humidity: ≤75%
c) Atmospheric pressure: 700hPa~1060hPa

1.4 Safety

1.4.1 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. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using it.
- 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 accessories that are recommended by the manufacture can be used with this device.
- This product has been calibrated before leaving the factory.

1.4.2 Warnings

- Explosive hazard—DO NOT use the oximeter in environment with flammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the testee is undergoing a MRI or CT.
- The person who is allergic to the rope cannot use this device.
- The person who is allergic to rubber cannot use this device.
- The disposal of scrap instrument and its accessories and packing (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 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.

1.4.3 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 60ºC.
- 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 infants or neonatal patients.
- The product is suitable for children above four years old and adults (Weight should be between 15kg to 110kg).
- The device may not work for all patients. If you are unable to achieve stable readings, please stop using.
- 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 the 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 life span of three years since the first electrified use.
- The hanging rope attached the product is made from Non-allergy material. If a particular group is 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 to avoid causing harm to the patient.
- The instrument doesn't have a low-voltage alarm function. It only shows the low-voltage. Please change the battery when the battery is dead.
- The device doesn't have an alarm for exceeding a limit. 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 Principle of Measurement

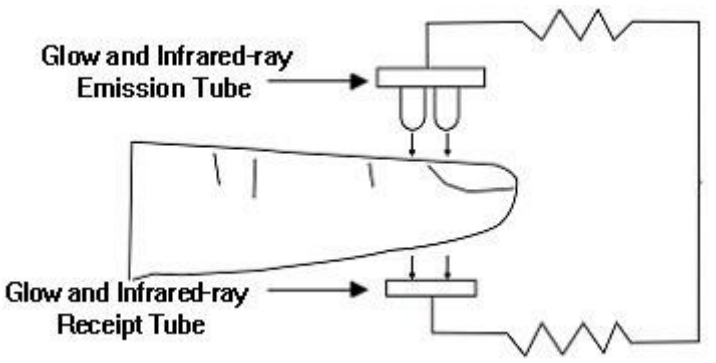

Figure 1 Operating principle

Principle of the Oximeter is as follows: An experience formula of the data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights 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 screen through treatment in electronic circuits and microprocessor.

3 Technical Specifications

3.1 Main Performance

1) SpO_2 value display.
2) Pulse rate value, bar-graph display.
3) Pulse waveform display.
4) Low battery indication: When the voltage is too low to work, the battery capacity indication appears.
5) Automatically power off function: The product will automatically be powered off when there is no signal within 5 seconds.
6) Display format can be changed.

3.2 Main Parameters

1) **SpO_2 Measuring**
   Range:0%~100%
   Accuracy: ±2% in stage of 70%-100% SpO_2, and meaningless when stage being smaller than 70%
2) **Pulse Rate Measuring**
   Range: 30 bpm - 250 bpm
   Accuracy:±2 bpm or±2% (select larger)
3) **Resolution:** 1% for SpO_2 and 1 bpm for Pulse Rate.
4) **Resistance to surrounding light:** The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.
5) **Working voltage:** DC 2.6V~3.6V.

4 Installation

4.1 View of the Front Panel

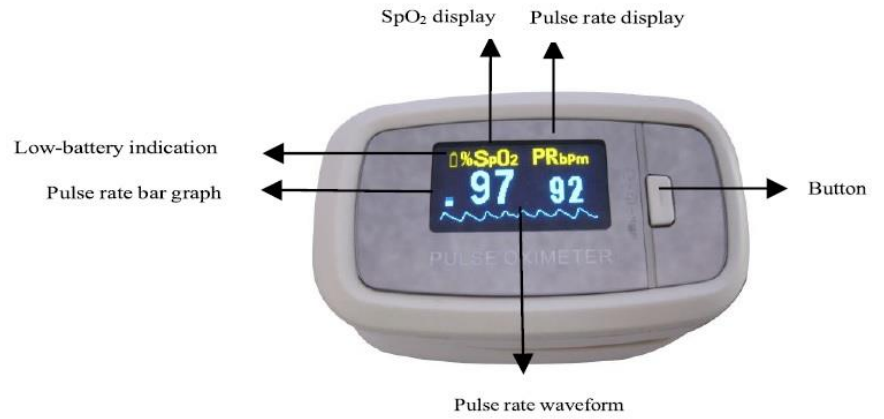

Figure 2 Front view

4.2 Battery Installation

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

⚠ **Please take care with the batteries as improper insertion may damage the device.**

Figure 3 Batteries installation

4.3 Mounting the Hanging Rope

Figure 4 Mounting the hanging rope

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

4.4 Accessories

1) A hanging rope;
2) Two batteries (optional);
3) A User Manual.

5 Operating Guide

5.1 Operation Method

1) Insert the two batteries in the proper direction, and then replace the cover.

⚠ **Please take care with the batteries as improper insertion may damage the device.**

2) Open the clip as shown in Figure 6.
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.
   a. Press the switch button once on front panel.
   b. Do not shake the finger and keep the patient calm during the measuring process. It is recommended that the patient be resting and no moving.
4) Get the information directly from screen display.
5) In operational state, lightly press this button to change the direction of the screen.
6) In operational state, long press this button can change brightness of the screen.

⚠ **Fingernails and the screen should be on the same side.**

Figure 6 Put the finger in position

5.2 Caution

1) Before use, please fully check the device to make sure that it can work correctly.
2) The finger should be placed properly (see the attached illustration in this manual Figure 6), or else it may cause inaccurate measurement.
3) The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
4) The SpO_2 sensor should not be used on a limb tied with arterial canal, blood pressure cuff, or receiving intravenous injection.
5) Make sure the optical path is free from any optical obstacles like rubberized fabric or else it may cause inaccurate SpO_2 and pulse rate.
6) Excessive ambient light may affect the measuring result. This includes fluorescent lamps, dual ruby lights, infrared heaters, direct sunlight, etc.
7) Strenuous action of the testee or extreme electrosurgical interference may also affect the accuracy.
8) Testee cannot use enamel or other makeup.
9) After use, please refer to respective chapters about cleaning and disinfection for details.

5.3 Clinical Restrictions

1) As the measurement is taken on the basis of arteriole pulse, substantial pulsating blood flow in the 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 the judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 measurement.

6 Maintenance ,Transportation and Storage

6.1 Cleaning and Disinfecting

After cleaning the device, wipe the surface of device with ethanol and self-air dry (or clean with a clean, dry cloth).

6.2 Maintenance

- Before using, please refer to respective chapters about cleaning and disinfection for details.
- Please change the batteries when the low-voltage is displayed on the screen.
- Please take out the batteries if the oximeter is not in use for a long time.
- Users are advised to calibrate the device periodically (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.**

6.3 Transportation and Storage

- The device cannot be transported mixed with toxic, harmful, or corrosive material.
- The best storage environment of the device is -40ºC to 60ºC ambient temperature and no higher than 95% relative humidity and in a room with no corrosive material and good ventilation.

7 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate cannot 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 cannot be turned on	1. Low battery or no battery. 2. The batteries are not inserted properly. 3. The device is malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The display is off suddenly	1. The device will power off automatically when there is no signal within 5 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

8 Key of Symbols

Symbol	Description
⚠	Warning – See User Manual
%SpO_2	The pulse oxygen saturation (%)
PRbpm	Pulse rate (bpm)
▭	The battery voltage is low (replace the battery to avoid inexact measure)
+	Battery anode
−	Battery cathode
– ⏻ – ↻	Power key/function key
IP22	International Protection

9 Function Specification

Display Information	**Display Mode**
The Pulse Oxygen Saturation(SpO_2)	Two numbers OLED display
Pulse Rate(PR)	Three numbers OLED display
Pulse Intensity (bar-graph)	OLED bar-graph display
SpO_2 Parameter Specification	
Measuring range	0%~100%, (the resolution is 1%).
Accuracy	70%~100%: ±2%, Below 70% unspecified.
Pulse Parameter Specification	
Measuring range	30bpm~250 bpm (the resolution is 1 bpm)
Accuracy	±2bpm or ±2% select larger
Safety type	Internally powered equipment type: BF applied part
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
Battery Useful Life	
1.5V,600mAh (AAA size) alkaline batteries × 2 can work continually for 32 hours	
Dimensions and Weight	
Dimensions	61(L) × 36(W) × 32(H) mm
Weight	About 60g (with the batteries)