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. In case of modifications and software upgrades, the information contained in this manual is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter’s features and requirements, main sections: introductions, functions for transportation, usage, operation, maintenance, repair, 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 User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause malfunction and human injury. The manufacturer is not responsible for the safety, reliability, and performance issues and any monitoring abnormality, human injury, and equipment damage due to users’ negligence of the operating instructions. The manufacturer’s warranty service does not cover such faults.

Due to continual improvement, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely apologize for this.

This product is a medical device, which can be used repeatedly.

WARNING:

◆ An uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the elderly, young, and weak individuals. It is recommended that the sensor should not be applied to the same finger for over 2 hours.

◆ For the special patients, there should be a more prudent inspecting in the placing process.

◆ The device cannot 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 should not stare at the light.

◆ Testee’s fingertip cannot be too long.

◆ Please note the correlation between the clinical restrictions and caution.

◆ This device is not intended for treatment.

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1. Specification

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 accessories that are recommended by the manufacturer can be used with this device.

◆ This product is calibrated before leaving the factory.

1.2 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 and CT.

◆ People who are allergic to rubber cannot use this device.

◆ The disposal of scrap instruments, its accessories, and packing (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

◆ Please check, if the working 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 temperatures, and moisture.

◆ If the oximeter gets wet, please stop using it.

◆ When it is carried from cold environment to a 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 related chapter for instructions on cleaning and disinfection.

◆ Do not have the oximeter immersed in liquid. When it needs cleaning, please wipe its surface with medical alcohol on soft material. Do not spray any liquid on the device directly.

◆ Do not clean the device with water, the temperature is higher than 20ºC.

◆ As to the fingers which are too thin or too cold, it would probably affect the normal measure of the patients’ SpO2 and pulse rate. Please clip a thin 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, discontinue use.

◆ The update period of data is less than 5 seconds, which is changeable according to different individual’s circumstances.

◆ If some abnormal conditions appear on the screen during test process, pull out the finger and reinstruct to restore normal use.

◆ The device has normal life span of three years since the first electricity used.

◆ The hanging rope attached the product is made from non- allergic material. If particular groups are sensible 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 does not have a 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 specific, the instrument does not have an alarm function. Do not use the device in situations where alarms are required.

◆ Batteries must not be replaced if the device is going to be stored for more than one month, or else batteries may leak.

◆ A reliable circuit connects the two parts of the device. Do not twist or pull on the connection.

2. Overview

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so called the O2 concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO2 more easily and accurately, our company developed the Pulse Oximeter. At the same time, the device can measure the pulse rate.

The Pulse Oximeter features in small size, low power consumption, convenient operation, and portability. It is only necessary for patients to put one of his fingers into a finger photodetector sensor for diagnosis, and a display screen will directly show the measured value of Hemoglobin Saturation.

2.1 Classification:

Class III (MDD93/42/EEC IX Rule 10)

2.2 Features

◆ Operation of the product is simple and convenient.

◆ The product is small in size, light in weight (total weight is about 50g including batteries) and convenient in carrying.

◆ Power consumption of the product is low and the two originally equipped AAA batteries can be operated continuously for 24 hours.

◆ The product will automatically be powered off when no signal is in the product in the within 5 seconds.

◆ Low battery indicator as battery icon will flash when the battery is low.

2.3 Major applications and scope of application

The Pulse Oximeter can be used to measure the percentage of human Hemoglobin Saturation and pulse rate through finger, and indicate the pulse intensity by the bar-display. The product is suitable for use in family, hospital (ordinary sickroom), Oxygen Bar, social medical organizations, and also the measure of saturation of oxygen and pulse rate.

The product is not suitable for use in continuous supervision for patients. If the patient’s condition of suffering would emerge when the patient is suffering from intoxication which is caused by carbon monoxide. The device is not recommended to be used under this circumstance.

2.4 Environment requirements

Storage Environment

a) Temperature: -40ºC - +60ºC

b) Relative humidity: ≤95%

c) Atmospheric pressure: 500hPa-1050hPa

Operating Environment

a) Temperature: 10ºC - 40ºC

b) Relative Humidity: ≤75%

c) Atmospheric pressure: 700hPa-1050hPa

3 Principle

3.1 Principle of measurement

Principle of the Oximeter is as follows: An experience formula of data processing is taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO) in glow & near-infrared zones. Operation principle of the instrument is: Photocurrent generated by the oximeter is detected in accordance with Capacitive Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused on the same point. The signal transmission through photodetector finger-tip 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 a microprocessor.

4 Technical

4.1 Display Format: Digital tube Display;

SpO2 Measuring Range: 0% - 100%;

Pulse Rate Measuring Range: 30 bpm - 250 bpm;

Pulse Intensity Display: columnar display;

4.2 Measuring Requirements:

a) The SpO2 can be measured in the range of normal normal range: 2.6% - 3.6%.

b) Power Consumption: Lower than 25 mA.

c) Resolution: 1% for SpO2 and 1 bpm for Pulse Rate.

4.3 Measuring Accuracy:

≥ 95% for SpO2, and 2% for Pulse Rate, and meaningful when stage being smaller than 70%. 12 rpm or 2% (select larger) for Pulse Rate.

4.4 Measurement Performance in Weak Filling Condition:

SpO2 and pulse rate can be shown correctly, when pulse-filling rate is ≥ 44%, pulse rate error is ± 2 bpm or ± 2% (select larger).

4.5 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 2%.

4.6 It is equipped with a function switch. The Oximeter can be powered off in case no finger is detected for 5 seconds.

5 Accessories

◆ One hanging rope;

◆ Two batteries (optional);

◆ One User Manual.
6 Installation

6.1 View of the front panel

- Power switch
- Pulse rate
- The display Split
- Low Voltage Display
- Pulse rate Bar graph display

Figure 2. Front View

6.2 Battery
Step 1. Refer to Figure 3 and insert the two AAA size batteries in the right direction.
Step 2. Replace the cover.
⚠️ Please take care when you insert the batteries as improper insertion may damage the device.

Figure 3. Batteries Installation

6.3 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.

Figure 4. Mounting the hanging rope

7 Operating Guide
7.1 Insert the two batteries in the correct direction, and then replace the cover.
7.2 Open the clip as shown in Figure 5.

Figure 5. Put finger in position

7.3 Put the patient’s finger into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
7.4 Press the switch button once on front panel.
7.5 Do not shake the finger and keep the patient at ease during the process. It is not recommended for the patient to be moving.
7.6 Get the information directly from screen display.
7.7 In boot-strap state, press button, and the device is reset.
⚠️ Fingernail and screen should be on the same side.

8 Repairing and Maintenance
- Please change the batteries when low-voltage is 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 with dry clean fabric.
- Use the medical alcohol to disinfect the product after use to prevent cross infection the next time it is used.
- Please take out the batteries if the oximeter is not in use for a long period of time.
- The best storage environment of the device is -40°C to 60°C ambient temperature and no higher than 95% relative humidity.
- Users are advised to calibrate the device periodically (or according to the calibrating program of hospital). It also can be performed by 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 life span of the device, or even damage it.

9 Troubleshooting

<table>
<thead>
<tr>
<th>Trouble</th>
<th>Possible Reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The SpO2 and Pulse Rate cannot be displayed normally</td>
<td>1. The finger is not properly positioned. 2. The patient’s SpO2 is too low to be detected.</td>
<td>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 correctly.</td>
</tr>
<tr>
<td>The SpO2 and Pulse Rate are not displayed stably</td>
<td>1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving.</td>
<td>1. Place the finger properly and try again. 2. Keep the patient calm and at rest.</td>
</tr>
<tr>
<td>The device cannot be turned on</td>
<td>1. The batteries are dead or almost dead. 2. The batteries are not inserted properly. 3. The device is defective.</td>
<td>1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.</td>
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