CONCORD HEALTH SUPPLY, INC.

Pulse Oximeter

85301/85302

User Manual

Concord Health Supply, Inc.

Off: 888-970-2999 Fax: 888-970-8999 www.ConcordHealthSupply.com

 Issue date: February 01, 2016

Instructions to User

Dear Users, thank you very much for purchasing our product.

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, 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.

The specific products you received may not be exactly as described in this User Manual. If you have any questions regarding to the use of this product, please call us at 888-970-2999 M-F from 8:00 AM to 5:00 PM CST

WARNING:

- **The uncomfortable or painful feeling may appear if using the device ceaselessly. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the individual user there should be a more prudent inspecting in the placing process. The device can not be clipped on swollen or 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.**
- **User can not use fingernail polish, fake nails or other makeup.**
- **User fingernails can not be too long.**
- **Please peruse the relative content about the clinical restrictions and cautions.**
- **This device is not intended for treatment.**

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 users 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 flammable gas such as some ignitable anesthetic agents.
- The person who is allergic to rubber can not use this device
- The disposal of scrap instrument and its accessories and packing(including battery, plastic bags, foam 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.

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 immersed 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.
- For fingers which are too thin or too cold, improved readings can be achieved by placing on a thick finger such as thumb and middle finger .
- Do not use the device on infant or neonatal users.
- The product is suitable for children above four years old and adults (Weight should be between 15kg/ 33lbs to 110kg/243lbs).
- The device may not work for all users. If you are unable to achieve stable readings, discontinue use.
- The data refresh is less than 5 seconds.
- The waveform is normalized. Please read the measured value when the waveform on screen is steady-going, 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 instrument shows the low-voltage indicator when the battery is low requiring a battery replacement.
- 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.

1.4 Indication for Use

The Pulse Oximeter is a non-invasive device intended for the spot-check of saturation of arterial hemoglobin(SpO2) and the pulse rate of adult in home use environments.This device is not intended for continuous monitoring.The device can be multi-used. Solely for use with sporting and aviation activities.

2 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 respiration. For the purpose of measuring the SpO_2 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 small size, low power consumption, convenient operation and being portable. It is only necessary for users to put one finger into the device to quickly get a reading.

2.1 Features

- Operation of the product is simple and convenient.
- The product is small in volume, light in weight (total weight is about 50 g including batteries) and convenient to carry.
- Power consumption of the product is low and the two originally equipped AAA batteries can be operated continuously for 20 hours.
- The product will enter standby mode when no signal is in the product within 5 seconds.
- Display direction can be changed automatically,easy to view.

2.2 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure human Hemoglobin Saturation and pulse rate through finger, and indicate the pulse intensity by the bar-display.

⚠**The product is not suitable for use in continuous monitoring of home users**

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

2.3 Environment Requirements

Storage Environment

a) Temperature: -40℃~+60℃

b) Relative humidity: ≤95%

c) Atmospheric pressure: 500hPa~1060hPa

Operating Environment

a) Temperature: 10℃~40℃

b) Relative Humidity: ≤75%

c) Atmospheric pressure: 700hPa~1060hPa

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 (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.

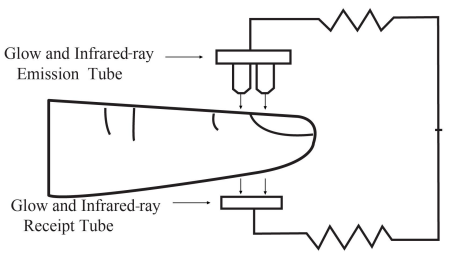

Figure 1 Operating principle

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 etc.
6. Strenuous action of the subject or extreme electro interference may also affect the accuracy.
7. User can not use fingernail polish, fake nails 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 users with serious anemia may also report good SpO_2 measurement.

4 Technical Specifications

1) **Display Format:** OLED Display;
   SpO_2 Measuring Range: 0% ~ 100%;
   Pulse Rate Measuring Range: 30bpm ~ 250 bpm;
   Pulse Wave Display: columniation display and the waveform display.
   PI Measuring Range: 0 ~ 20%
2) **Power Requirements:** 2×1.5V AAA alkaline battery (or using the rechargeable battery instead), adaptable range: 2.6V~3.6V.
3) **Power Consumption:** less than 80mA.
4) **Resolution:** 1% for SpO_2 , 1 bpm for Pulse Rate and 0.1% for PI.
5) **Measurement Accuracy:** ±2% in stage of 70%-100% SpO_2, and meaningless when stage being smaller than 70%. ±2 bpm during the pulse rate range of 30-99 bpm and ±2% during the pulse rate range of 100~250 bpm.
6) **Measurement Performance in Weak Filling Condition:** SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ± 2 bpm during the pulse rate range of 30~99 bpm and ±2% during the pulse rate range of 100~250 bpm .
7) **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%.
8) It is equipped with a function switch. The product will enter standby mode when no signal is in the product within 5 seconds.
9) **Optical Sensor**
   Red light (wavelength is 660nm, 6.65mW)
   Infrared (wavelength is 880nm, 6.75mW)

⚠

wavelength range.

5 Accessories

- One lanyard ;
- Two batteries,carrying case and rubber boot cover
- One User Manual.

6 Installation

6.1 View of the Front Panel

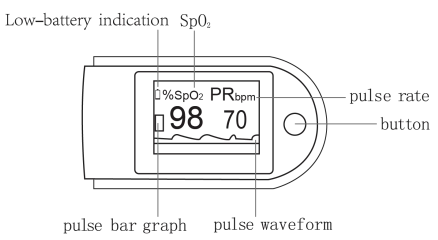

Figure 2 Front view

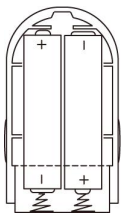

Figure 3 Batteries installation

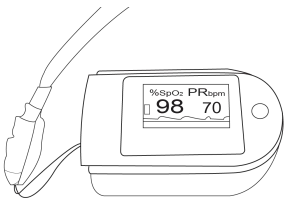

Figure 4 Mounting the hanging rope

6.2 Battery

Step 1. Refer to Figure 3 and insert the two AAA size batteries according to the diagram on the unit.

Step 2. Install the battery compartment cover, shown as Figure 5 by sliding the cover back onto the unit. Follow the tabs on the inside of the cover.

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

6.3 Mounting the Lanyard

Step 1. Put the end of the lanyard through the hole.

Step 2. Put another end of the lanyard through the first one and then tighten it.

7 Operating Guide

1) Insert the two batteries in the proper direction as shown on the diagram on the bottom of the unit, and then replace the cover.
2) Open the clip as shown in Figure 5.

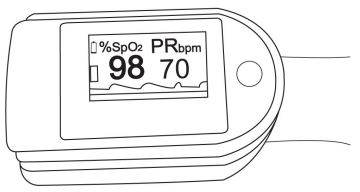

Figure 5 Put finger in position

3) Insert the users finger into the opening of the unit, resting the finger onto the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
4) Press the power button once on front panel.
5) Minimize motion of the finger during the reading. Movement is not recommended while taking a reading.
6) Get the information directly from screen display.
7) The button has two functions.When the device is in standby mode, pressing the button can exit it; When the device is in operation status, pressing the button shortly can enter into menus; In the state of alarm, press the button long can pause alarm for 60s.

Pressing the button once when the device is in operation status, can enter into the menu settings(in the Figure 6, Figure 7, Figure 8, Figure 9 interface, press the button once to move the drop-down icon, holding the button down on each menu option will allow you to turn on/off the pulse sound alarm, enter the next menu to change the up and down limit of pulse rate and SpO_2, and select the direction of the up and down limit.)

Figure 6 Menu interface

Figure 7 Alarm setting interface

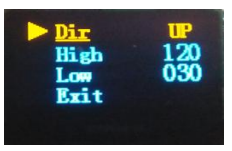

Figure 8 PR alarm limits setting interface

Figure 9 SpO_2 alarm limits setting interface

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

8 Repairing and Maintenance

- Please change the batteries when the 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 air dry or clean it with a dry clean towel.
- Using the medical alcohol to disinfect the product after use, prevents cross infection for next use.
- Please remove the batteries if the oximeter is not in use for a long time.
- The best storage environment of the device is - 40ºC/32ºF to 60ºC/140ºF ambient temperature and not higher than 95% relative humidity.

⚠ **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.**

9 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 user'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 user is moving.	1. Place the finger properly and try again. 2. Have the user keep still
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.

10 Key of Symbols

Symbol	Description
	Type BF
	Refer to instruction manual/booklet
%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)
	An indicator of signal inadequacy
	battery positive electrode
	battery cathode
	1.Exit standby mode. 2.Can enter into menus
	Alarm indication
	Pulse sound indication
SN	Serial number
	WEEE (2002/96/EC)
IP22	International Protection
	Manufacture Date

11 Function Specification

Display Information	**Display Mode**
The Pulse Oxygen Saturation (SpO_2)	OLED
Pulse Rate (PR)	OLED
Pulse Intensity (bar-graph)	OLED bar-graph display
Pulse wave	OLED
SpO_2 Parameter Specification	
Measuring range	0%~100%, (the resolution is 1%).
Accuracy	70%~100%:±2%, Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660nm) Infrared (wavelength is 880nm)
Pulse Parameter Specification	
Measuring range	30bpm~250bpm (the resolution is 1 bpm)
Accuracy	±2bpm or±2% select larger
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
Battery Useful Life	
Two batteries can work continually for 20 hours	
Dimensions and Weight	
Dimensions	60(L) × 30.5(W) × 32.5(H) mm
Weight	About 50g (with the batteries)

2.782.027(CHS)ESS/1.1
1.4.01.34.280
2018.05