Pulse Oximeter

85101/85102
User Manual

Concord Health Supply, Inc.

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Issue date: February 01, 2016

Instructions to User

Thank you very much for purchasing a Concord Pulse Oximeter.

This Manual describes the Pulse Oximeter's features and requirements, 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. Please read and follow the User Manual carefully before using this product. Failure to follow the User Manual may cause measuring abnormality, equipment damage 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 improper use. The specific products you received may not be exactly as described in this User Manual. This product can be used repeatedly. If you have any questions regarding to the use of this product, please call us at 888-970-2999 Monday-Friday from 8:00 AM to 5:00 PM Central Time.

WARNING:

- **Uncomfortable or painful feelings can occur when using this product continuously. Typically, the sensor should not be applied to the s same finger for over 2 hours.**
- **The device should not be clipped on swollen, damaged or tender tissue.**
- **The infrared light is harmful to eyes, do not stare at the light part of the SpO2 probe, the infrared is invisible.**
- **Use of Fingernail polish, fake nails or other makeup can cause the oximeter not to get a reading or get unreliable readings.**
- **The fingernails of the User should not be too long, preventing insertion of the finger into the oximeter.**
- **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 user's safety and monitoring performance. It is recommended that the device should be inspected once a week at least. Please stop using the device if there is obvious damage.
- ● Necessary maintenance must be performed by qualified technicians only. Users are not permitted to open or maintain it by themselves.
- ● This product is calibrated before leaving factory
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1.2 Warnings

- ● Explosive hazard—DO NOT use the oximeter in environment with flammable gas such as some ignitable gases.
- ● The person who is allergic to rubber cannot use this device.
- ● Disposal of oximeter, accessories and packing should follow local laws and regulations.
- ● No modification of this equipment is allowed.
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1.3 Precautions

- 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 moved from cold environment to warm or humid environment, please allow a few minutes to acclimate.
- DO NOT operate the button on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted.
- Do not have the oximeter immersed in liquid. When it needs cleaning, please wipe its surface with medical alcohol.
- 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 or middle finger in the oximeter.
- Do not use the device on infant or neonatal users.
- The product is suitable for pediatric and adults (Weight should be between 15kg/ 33lbs to 110kg/243lbs).
- The data refresh is less than 5 seconds, If abnormal results appear on the screen during testing process, pull out the finger and reinsert to restore normal use.
- The device 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.

1.4.Indication for Use

The Pulse Oximeter is a non-invasive device intended for the spot-checking of saturation of arterial hemoglobin(SpO2) and the pulse rate of adult in home use environments. This device is not intended for continuous monitoring. Intended for use with sporting and aviation activities. Intended to monitor heart rate during exercise.

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. 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 a user to put one finger into the device to quickly get a reading.

2.1 Features

- Operation of the product is simple and convenient.
- Power consumption of the product is low and two AAA batteries can be operated continuously for about 24 hours.
- The product will automatically be powered off when no signal is received after 5 seconds.
- Low-battery indicator

2.2 Major Applications and Scope of Application

The Pulse Oximeter can be used for measuring oxygen saturation and pulse rate through the finger.

⚠ **Do not use if suffering from toxicosis caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.3 Environment Requirements

Storage Environment

a) Temperature :- 40ºC/32ºF to 60ºC/140ºF
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 (HbO2) 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.

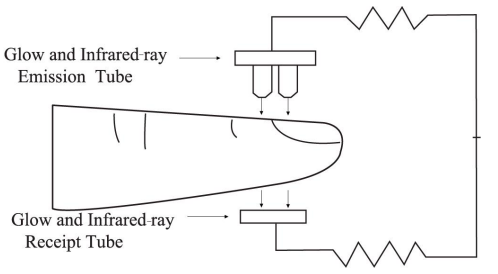

Figure 1. Operating Principle

3.2 Caution

1. The finger should be placed properly (see the attached illustration of this manual ,Figure 7), 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 and etc.
6. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
7. User can not use enamel or other makeup.

3.3 Clinical Restrictions

1. 1. As the measurement is taken on the basis of arteriole pulse, substantial pulsating blood flow is required. For a subject with a weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 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 problems, the SpO2 determination by this monitor may be inaccurate.
3. Drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor for errors in SpO2 measurement.
4. As the SpO2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some users with serious anemia may also report good SpO2 measurement.

4 Technical Specifications

1) **Display Format:** Digital tube Display;
   SpO_2 Measuring Range: 0% - 100%;
   Pulse Rate Measuring Range: 30 bpm - 250 bpm;
   Pulse Intensity Display: columniation display
2) **Power Requirements:** 2 ×1.5V AAA alkaline battery, adaptable range: 2.6V-3.6V.
3) **Power Consumption:** Less than 25 mA.
4) **Resolution:** 1% for SpO_2 and 1 bpm for Pulse Rate.
5) **Measurement Accuracy:** ±2% in stage of 70%-100% SpO_2, and meaningless when stage being smaller than 70%. ±2 bpm or±2% (select larger) for Pulse Rate. Clinical Trial :SpO_2 regression plot & Bland–Altman plot,Refer to Figure 2 & Figure 3.
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 or ±2% (select larger).
7) **Resistance to surrounding light:** The deviation between the value measured in the condition of man-made light, indoor natural light and that of darkroom is less than ±1%.
8) It is equipped with a automatic switch function. The Oximeter can be powered off when the finger is off the oximeter within 5 seconds.
9) **Optical Sensor**
   Red light (wavelength is 660nm, 6.65mW)
   Infrared (wavelength is 880nm, 6.75mW)

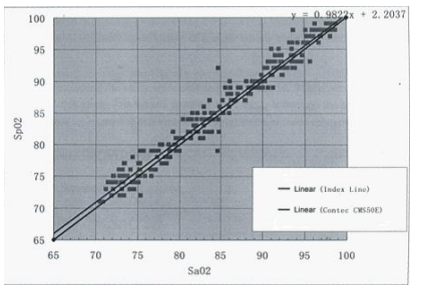

Figure 2 SpO_2 regression plot

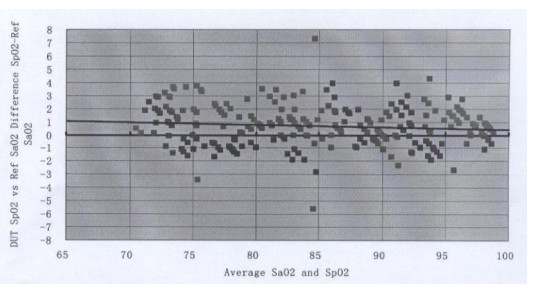

Figure 3 Bland–Altman plot

5 Accessories

- One Lanyard
- Two batteries, carrying case and rubber boot coverOne User Manual.

6 Installation

6.1 View of the Front Panel

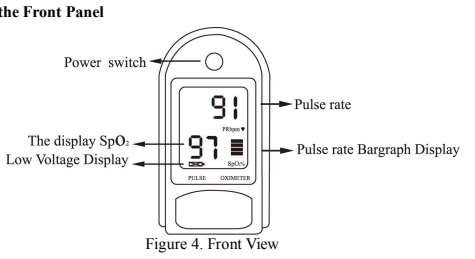

Figure 4. Front View

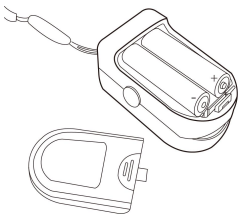

Figure 5. Batteries Installation

6.2 Battery

Step 1. Refer to Figure 5. and insert the two AAA size batteries according to the diagram on the unit.

Step 2. Install the battery compartment cover, 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 Installing 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.

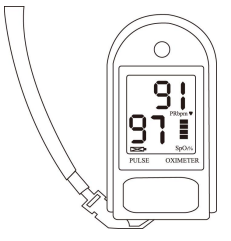

Figure 6. Mounting the hanging rope

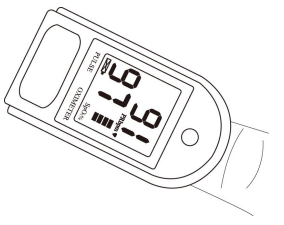

Figure 7. Put finger in position

7 Operating Instructions

7.1 Insert the two batteries in the proper direction as shown on the diagram on the bottom of the unit, and then put the cover.
7.2 Open the clip as shown in Figure 7.
7.3 Place finger onto the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
7.4 Press the power button once on front panel to turn the unit on.
7.5 Minimize motion of the finger during the reading. Movement is not recommended while taking a reading.
7.6 Get the information directly from screen display.
7.7 When the device is powered on, press power button once and the device will reset itself.

⚠ **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 from 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 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.
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. Let the user reduce motion.
The device can not be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. Malfunction of the device.	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 it gets no signal 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)
	1. no finger inserted 2. An indicator of signal inadequacy
	battery positive electrode
	battery negative electrode
	Power switch
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
IP22	Ingress of liquids rank
	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
EC REP	EUROPEAN REPRESENTATIVE
	Manufacturer
	Manufacture Date
	Storage and Transport Temperature limitation
	Storage and Transport Humidity limitation
	Storage and Transport Atmospheric pressure limitation
	This side UP
	Fragile, handle with care
	Keep dry
	Recyclable

11 Function Specification

Display Information	Display Mode
The Pulse Oxygen Saturation(SpO_2)	Digital
Pulse Rate(BPM)	Digital
Pulse Intensity (bar-graph)	Digital bar-graph display
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 24 hours	
Dimensions and Weight	
Dimensions	57(L) × 31(W) × 32(H) mm
Weight	About 50g (with the batteries)

Appendix: Electromagnetism Compatibility

Guidance and manufacture's declaration – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The *85101/85102* is intended for use in the electromagnetic environment specified below. The customer of the user of the *85101/85102* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *85101/85102* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The *85101/85102* is suitable for use in a home environment, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *85101/85102* is intended for use in the electromagnetic environment specified below. The customer or the user of *85101/85102* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 KV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	N/A	Mains power quality should be that of a typical commercial environment.
Surge IEC 61000-4-5	±1 kV differential mode	N/A	Mains power quality should be that of a typical commercial environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	N/A	Mains power quality should be that of a typical commercial environment. If the user of the *85101/85102* requires continued operation during power mains interruptions, it is recommended that the *85101/85102* be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC-61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields sould be at levels characteristic of a typical location in a typical commercial environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The *85101/85102* is intended for use in the electromagnetic environment specified below. The customer or the user of *85101/85102* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the *85101/85102*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the is used exceeds the applicable RF compliance level above, the *85101/85102* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *85101/85102*			
The *85101/85102* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *85101/85102* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *85101/85102* as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.39**	**0.37**	**0.74**
1	**1.17**	**1.17**	**2.33**
10	**3.69**	**3.69**	**7.38**
100	**11.67**	**11.67**	**23.33**
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meter's (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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