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Pulse Oximeter

Model No.: CMS50DA

General Description

Dear User, thank you very much for purchasing our product.
Please know that in case of modifications and software upgrades, the information contained in this document is subject to change without notice.
This manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transporting, 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 sections for specific 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 measurement inaccuracies, equipment damage and personal injury.
The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring inaccuracy, personal injury and equipment damage due to user's negligence of the operating instructions. The manufacturer's warranty service does not cover such faults.
According to possible product updates, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.
This product can be used repeatedly. Its using life is 3 years.

WARNING:

- **An uncomfortable or painful feeling may appear if using the device continuously for long periods, especially for the microcirculation barrier users. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **Individual users should be more prudent with the placing process of the device. The device should not be clipped on the edema and tender tissue of the finger.**
- **The infrared light (which is invisible) emitted from the device is harmful to the eyes, so the user should not directly stare at the light.**
- **User should not use fingernail polish, press on nails, or nail embellishments while using.**
- **User's fingernail should not be too long.**
- **Please review the relative content about the restrictions and cautions.**
- **This device is not intended for treatment.**

NOTE: This oximeter is for sports or aviation use only and is NOT intended for medical use.

1 Safety

1.1 Instructions for Safe Operations

- Check the main unit's cables, transducers, and all accessories periodically to make sure that there is no visible damage that may affect user's safety. It is recommended that the device should be inspected at least once a week. If there is any obvious damage, stop using the oximeter.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to repair the device themselves. Contact Customer service if any issue arises of this nature.
- The oximeter cannot be used together with devices not specified in User's Manual.Only the accessory that is appointed or recommended by manufacture can be used with this device.
- This product has been calibrated before leaving the factory.

1.2 Warnings

- Explosive hazard—DO NOT use the oximeter in an environment with inflammable gas such as ignitable anesthetic agents.
- Someone who is allergic to rubber should not use this device.
- The disposal of scrap instrument and its accessories and packings(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 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.
- Parts of the device that are not serviced or maintained properly while in use with the user.
- Warning against servicing and maintenance while the me equipment is in use.
- No modification of this equipment is allowed.
- The probe of the device is the applied part.

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 operation immediately.
- When the device is carried from a cold environment to a warm or humid environment, please do not use it immediately.
- DO NOT operate the keys on the front panel with sharp materials.
- High temperature or high-pressure steam disinfecting of the oximeter is not permitted. Refer to User Manual in the specific section for instructions of cleaning and disinfecting.
- Do not immerge the oximeter in liquid. When the device 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 140 °F (60 °C) .
- If fingers which are too thin or too cold, it may probably affect the normal measure of the users' SpO2 and pulse rate, please clip the thick or cold finger such as thumb and middle finger deeply enough into the probe in these cases.
- Do not use the device on infant or pregnant women.
- The product is suitable for adults weighing 88.18 lb to 242.5 lb (40 kg to 110 kg).
- The device may not work for all users. If you are unable to achieve stable readings, discontinue use.
- The update period for data is less than 5 seconds, which varies according to individual pulse rates.
- The waveform normalizes. Please read the measured value when the waveform on screen is steady and forms a pattern. This is when the measured value is an optimal value. And the waveform now is standard.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The lanyard attached to the product is made from Non-allergenic material, if any groups are sensitive to the lanyard, stop using it. In addition, pay attention to the use of the lanyard, do not wear it around the neck avoiding harm to the user.
- The instrument dose not have a low-voltage alarm function, it only shows the low-voltage symbol.Please change the battery when the battery energy is low or empty.
- The instrument dose not have alarm function.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, batteries may corrode and damage the device.
- 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 used my multiple users.

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 simultaneously.
The Pulse Oximeter features include small size, low power consumption, convenient operation and being portability. It is only necessary for user to put one of his fingers into the fingertip photoelectric sensor, , and a display screen will directly show measured value of Hemoglobin Saturation.

2.1 Features

- Operation of the product is simple and convenient.
- The product is small size, light weight (total weight is about 50g including batteries) and convenient in carrying.
- Power consumption of the product is low and originally equipped with two AAA batteries that can be operated continuously for 20 hours.
- The product will automatically shut off when there is no signal from the product within 5 seconds.
- 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 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.Pulse oximeter intended for wellness use.

⚠ **The problem of overrating would emerge when the user is 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: -40°F～+140°F (-40 ℃ ~ +60 ℃)
b) Relative humidity: ≤95%
c) Atmospheric pressure: 500 hPa ~ 1060 hPa
Operating Environment
a) Temperature: 50°F～104°F (10 ℃ ~ 40 ℃)
b) Relative Humidity: ≤75%
c) Atmospheric pressure: 700 hP a~ 1060 hPa

3 Principle and Caution

3.1 Principle of Measurement

Principle of the Oximeter is as follows: An experienced 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 the measured signal can be obtained by a photosensitive element, information acquired through which will be shown on a screen through electronic circuits and a microprocessor.

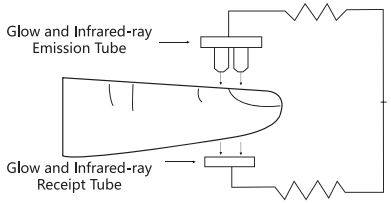

Figure 1 Operating principle

3.2 Caution

1. The finger should be placed properly (see the attached illustration of this manual, Figure 7), or else it may cause an inaccurate measurement.
2. The SpO2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position between them.
3. The SpO2 sensor should not be used at a location with a 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. This 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 of the result.
7. User should not use nail polish, fake fingernails, or nail embellishments.

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 SpO2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference and inaccurate.
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 SpO2 determination by this monitor may be inaccurate.
3. Drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also cause serious errors of SpO2 measurements.
4. As the SpO2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, please know some users with serious anemia may also report good SpO2 measurement.

4 Technical Specifications

1. **Display Format:** LCD Display;
   SpO2 Measuring Range: 0% ~ 100%;
   Pulse Rate Measuring Range: 30 bpm ~ 250 bpm;
   Pulse Wave Display: column display and the waveform display.
2. **Power Requirements:** 2×1.5 V AAA alkaline battery (or use a rechargeable battery instead), adaptable range: 2.6 V - 3.6 V.
3. **Power Consumption:** Smaller than 30 mA.
4. **Resolution:** 1% for SpO2 and 1 bpm for Pulse Rate.
5. **Measurement Accuracy:** ±2% in stage of 70% - 100% SpO2, 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 . Clinical Trial :SpO2 regression plot & Bland–Altman plot,Refer to Figure 2 & Figure 3.
6. **Measurement Performance in Weak Filling Condition:** SpO2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO2 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 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 660 nm, 6.65 mW)
   Infrared (wavelength is 880 nm, 6.75 mW)

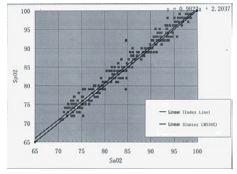
Figure 2 SpO2 regression plot

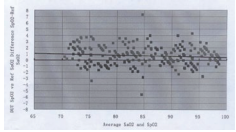
Figure 3 Bland–Altman plot

5 Accessories

- One lanyard;
- Two batteries (included)
- One User Manual.

6 Installation

6.1 View of the Front Panel

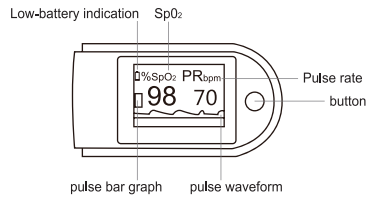

Figure 4 Front view

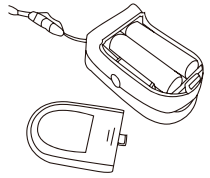
Figure 4 Battery installation

6.2 Battery

Step 1. Refer to Figure 5. and insert the two AAA size batteries properly in the right direction.
Step 2. Put back the cover.

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

6.3 Mounting the Lanyard

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.

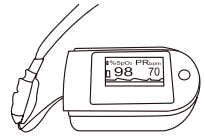
Figure 6 Mounting the lanyard

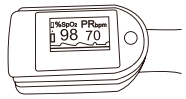
Figure 7 Put finger in position

7 Operating Guide

1. Insert the two batteries properly with correct polarity, and then replace .the cover.
2. Open the clip as shown in Figure 7.
3. Put the user's finger into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
4. Press the switch button once on front panel.
5. Do not shake your finger and the user should stay at ease during the process. Meanwhile, it is not recommended in to move your body.
6. Get the information directly from the screen display.
7. The button has two functions.When the device is in standby mode, pressing the button can shut off the device; When the device is in operation status, pressing the button down can change brightness of the screen.
8. The device can change display direction according to the handling direction.

⚠ **Fingernails and the luminescent tube 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 air dry or clean it with dry clean fabric.
- Using the medical alcohol to disinfect the product after use, to prevent from cross infection for next use.
- Please take out the batteries if the oximeter is not used for a long time to avoid corrosion.
- The packaged device can be transported by ordinary conveyance or according to transport contract.The device cannot be transported mixed with toxic, harmful, or corrosive material.
- The best storage environment of the device is -40°F～+140°F (- 40ºC to 60ºC) ambient temperature and not higher than 95% relative humidity.
- Users are advised to calibrate the device termly. It also can be performed at the state-appointed agent or contact customer service.

⚠ **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 of the device, or even damage it.**

9 Troubleshooting

Trouble	Possible Reason	Solution
The SpO2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The user's SpO2 is too low to be detected.	1. Place the finger properly and try again. 2.Try again; Contact your doctor if you are unsure if the device is working and are concerned about your results.
The SpO2 and Pulse Rate are not displayed stably	1.The finger is not placed inside deep enough. The finger is shaking or the user is moving.	1. Place the finger properly and try again. 2. Have the user keep calm and try again.
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 customer service.
The display is suddenly off	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

Symobl	Description
	Type BF
	Refer to instruction manual/booklet
%SpO2	The pulse oxygen saturation(%)
PRbpm	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inaccurate measurements)
	1. No finger inserted 2. An indicator of signal inadequacy
	Battery positive electrode
	Battery negative electrode
	1.Exit standby mode. 2.Change brightness of the screen.
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
IP22	International Protection
	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 (SpO2)	LCD
Pulse Rate (PR)	LCD
Pulse Intensity (bar-graph)	LCD bar-graph display
Pulse wave	LCD
SpO2 Parameter Specification	
Measuring range	0% ~ 100%, (the resolution is 1%)
Accuracy	70% ~ 100%:±2%, Below 70% unspecified
Optical Sensor	Red light (wavelength is 660 nm) Infrared (wavelength is 880 nm)
Pulse Parameter Specification	
Measuring range	30 bpm ~ 250 bpm (the resolution is 1 bpm)
Accuracy	± 2 bpm or±2% select larger
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates stronger pulse
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 (included) or rechargeable battery (not included)	
Battery Useful Life	
Two AAA batteries can work continually for 20 hours	
Dimensions and Weight	
Dimensions	57(L) × 31(W) × 32(H) mm
Weight	About 50 g (with the batteries)

Appendix

Guidance and manufacturer's declaration-electromagnetic emission for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration –electromagnetic emission		
The CMS50DA Pulse Oximeter is intended for use in the electromagnetic environment specified below. The user of the CMS50DA Pulse Oximeter should assure that it issued in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The CMS50DA Pulse Oximeter uses RF energy only for their internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CMS50DA Pulse Oximeter is suitable for use in all establishments, 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	Not applicable	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity			
The CMS50DA Pulse Oximeter is intended for use in the electromagnetic environment specified specified below. The the user of CMS50DA Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial environment

Guidance and manufacturer's declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity			
The CMS50DA Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of CMS50DA Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Radiated RF ICE 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Portable and mobile RF communication equipment should be used no closer to any part of the CMS50DA Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **recommended separation distance** $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 80MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer andd is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80MHz and 800MHz, 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 broadcastcannot 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 CMS50DA Pulse Oximeter is used exceeds the applicable RF compliance level above, the CMS50DA Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CMS50DA Pulse Oximeter.

b.Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3V/m.

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

Recommended separation distances between portable and mobile RF communications equipment and the CMS50DA Pulse Oximeter			
The CMS50DA Pulse Oximeter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CMS50DA Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CMS50DA Pulse Oximeter 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)**		
	150KHz to 80MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	80MHz to 800MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800MHz to 2.5GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	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 distanced in meters (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 80MHz and 800MHz, 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.

项目：CMS50DA 血氧仪说明书

尺寸：285x210mm　　颜色：C=80, Y=10

材质：80g双铜

时间：2020.05.20