Fingertip Pulse Oximeter

REF HCSM70J

This manual describes the Pulse Oximeter's operation, features, functions, specifications, usage, repair, maintenance and storage; as well as warnings and safety procedures to protect the user and equipment.

Indications For Use

The Pulse Oximeter is a non-invasive device intended to provide on-the-spot checks of saturation of arterial hemoglobin(SpO2) and the pulse rate of adults. This device is intended solely for use with sporting and aviation activities. This device is not intended for continuous monitoring and is designed for use multiple times by multiple adult individuals.

Instructions

Please read the User Manual carefully before using this product. The User Manual describes operating procedures that should be strictly followed. 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 users' negligence in following of the operation instructions. The manufacturer's warranty service does not cover such faults.
This product is designed for ongoing, multiple-user usage with an operating life of 5 years.
If you have any questions regarding to the use of this product, please call 1-800-MEDLINE.

Precautions

- Do not attempt to service the Pulse Oximeter. Only professionals with maintenance qualifications are allowed to perform device interior maintenance as necessary.
- Change the contact position between the Oximeter probe and the finger periodically if you are monitoring your SpO2 levels and pulse rate for a long time (no more than 2 hours).
- Stop use immediately if skin is damaged or the blood circulation of your finger is affected by prolonged use of the device.
- This product is not applicable to the examination of newborn babies.
- The infrared, invisible light emitted from this device is harmful to the eyes. DO NOT look at the light emitted.
- This pulse oximeter is not intended to diagnose or treat any medical condition or disease. People who need SpO2 and pulse rate measurements because of a medical condition should not use the oximeter and should consult with their physician.
- Please note the effects of degraded sensors that can degrade performance or cause other problems.
- The user is an intended operator
- Do not combine old and new batteries, different brands batteries for using.
- This is device is not intended for continuous monitoring. The sensor should not be applied to the same finger for over 2 hours.

Note: the product has no contraindications.

Warning

Explosive hazard—DO NOT use the oximeter in any area with inflammable gas such as some ignitable anesthetic agents.

- Disposal of this instrument, accessories and packaging (including battery, plastic bags, foam and paper boxes) should follow the local laws and regulations.
- Please check the device and packaging before use to make sure it contains everything on the packing list, or else the device may have the possibility of not working properly.
- DO NOT service or attempt maintenance while the device is in use.
- DO NOT attempt to modify this device.

Attention

- Handle with care, keep away from sunlight, keep dry, keep product upright, protect from freezing, avoid excessive heat.
- Keep this device away from dust, vibration, corrosive substances, explosive materials, high temperatures and moisture.
- If the oximeter gets wet, do not use it.
- When carried from a cold environment to warm or humid environment, do not use the device until condensation dissipates.
- DO NOT operate keys on front panel with sharp objects.
- High-temperature or high-pressure steam disinfection of the oximeter is not permitted. Refer to User Manual for cleaning and disinfection instructions.
- Do not immerse the oximeter in water or any liquid. When it needs cleaning, wipe its surface with a soft fabric material and medical alcohol. Do not spray any liquid directly on the device.
- Clip onto index, middle finger or thumb, making sure finger extends to the end of the measurement cavity.
- For fingers that are very thin or cold, the normal measurement of the users' SpO2 and pulse rate may be affected.
- This product is suitable for adults (Weight should be between 40kg to 110kg). Do not use the device on infants or neonates.
- The device may not work for all users. If you are unable to achieve stable readings, discontinue use.
- If some abnormal conditions appear on the screen during test process, remove device and reattach to restore normal function.
- The device lanyard is made from hypoallergenic material. If a user is sensitive to the material, please remove it. Also, do not place around neck and pay attention to its location so as not to cause harm to the user.
- The device will show when voltage is low, but does not have a low-voltage alarm function. Change the battery when voltage is low. Do not use this device in situations where an alarm is required.
- Remove the batteries if the device is going to be stored for more than one month. Otherwise, battery leakage may damage the device.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

Overview

The Pulse Oximeter is a small, convenient, portable device with low power consumption that measures: 1) pulse rate, and 2) the oxygen level in the blood. It is measured as a percentage of HbO2 found in the total Hb in the blood. It is an important biological indication for a person's respiratory condition.
To perform these two functions, a user simply puts one of their fingers into a fingertip photoelectric sensor for diagnosis. A display screen will show the measured value of oxygen saturation as well as the pulse in less than 15 seconds

Features
Small, lightweight & convenient
Simple automated operation
Battery-powered portability
Operates continuously for more than 20 hours on 2 AAA batteries
Auto shutoff when not in use
Low-battery indicator

Applications
The Pulse Oximeter can be used in measuring pulse oxygen saturation and pulse rate through the finger. It can be used at home, while traveling, at sports venues, etc. It should not be used during sports activities. Device should not be used for continuous monitoring.
The problem of incorrect readings may emerge when the user is suffering from toxicosis caused by carbon monoxide. The device is not recommended to be used under such conditions.

Product Specifications

1. Dimensions: 58mm (Width) × 32 mm (Depth) × 32.2mm (Height)
   Weight: Approx.28.5 g (without batteries)
2. Peak wavelength range of the light emitted from the probe: red light 660 nm ± 3;
   infrared light 905 nm ± 5.
3. Maximum optical output power of the probe: 1.2 mW for infrared light (905 nm).
4. Manufacturing date: see the label
   Expected service life of the device including parts and accessories: 5 years.
5. Normal working condition

Working Temperature	5°C to 40°C (41°F to 104°F)
Relative Humidity	15% to 80%, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa
Rated Voltage	DC 3.0 V

6. Default values and conditions of alert

Parameter	Value
Oxygen saturation	Upper limit: 100 Lower limit: 94
Pulse rate	Upper limit: 130 Lower limit: 50

7. Technical parameters

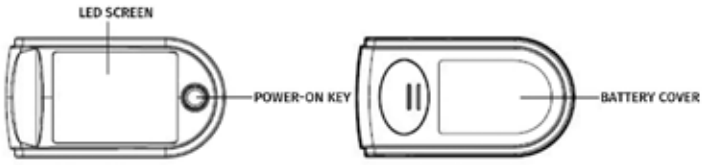
Parameter		Value
Display range	Oxygen saturation	35% to 100%
	Pulse rate	25 bpm to 250 bpm
Resolution	Oxygen saturation	1%
	Pulse rate	1 bpm
Measurement precision	Oxygen saturation	±2% (70% to 100%) | No requirement (≤ 69%)
	Pulse rate	±2 bpm
Battery	Service life	±More than 20 hours of continuous use with two AAA size batteries

8. Technical statement

- The device has no alarm system for SpO2 or pulse rate physiological alarm condition.
- When the signal detected by the pulse oximeter is inadequary or weak, the SpO2 and pulse rate readings on display are: "--" and "---".
- FUNTIONAL TESTER can not be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.
- The pulse oximeter has a specific calibration curve which is accurate for the combination of the pulse oximeter and pulse oximeter probe. If the functional tester can measure the error comes from the main part of the pulse oximeter, the accuracy of the pulse oximeter that replicates this calibration curve can be verified.
- MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel designated by the manufacturer in parts repair.

Prepare for Use

The Finger Pulse Oximeter non-invasively measures the content (oxygen saturation) of oxyhemoglobin (HbO2) in arterial blood using the optical transmittance method.
The Finger Pulse Oximeter measures the blood oxygen saturation and pulse rate of a human body via a single artery.



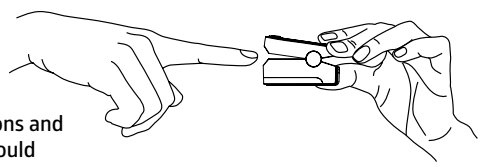
Screen Display

The following figure shows the information display on the LED screen of the Oximeter in normal detection state

Achieving Reliable Readings

Two different wavelengths of light are focused on the fingertip and nail from the top. The light signals are measured by a photosensitive element beneath the finger. Correct measurements require carefully following the guidelines below.

The finger should be placed properly (see below illustration) to achieve an accurate measurement.



- The user's fingertip should be centered and placed fully into the device receiving tube.
- The device should not be used at a location with an arterial canal, blood pressure cuff or at the site of intravenous injection.
- Make sure the optical path is free of nail decorations and polishes, treatments or any other material that would disrupt light penetration.
- Excessive ambient light may also affect measurement. This could include fluorescent lamps, red lights, infrared heaters, direct sunlight, etc.
- Strenuous activity by the user, or extreme electrical interference, may also affect the accuracy.

Clinical Restrictions

- Measurements are taken on the basis of arteriole pulse, which means that substantial pulsatin blood flow of the user is required. For those with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, reliability of the reading will decrease. The measurement will be much more sensitive to interference.
- Readings may also be inaccurate for users 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.
- Drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious errors in measurements.
- In particular, **those with anemic anoxia and toxic anoxia, may receive a good measurement number erroneously** due to the specific condition.

Operation Guide

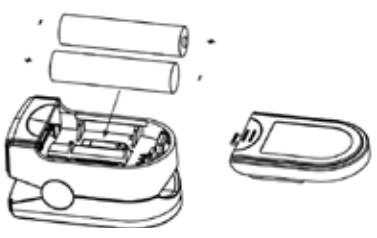
1. Squeeze device to open wide enough to clip on finger.
2. Insert user's finger, nail-side up towards the screen, into the rubber cushions and release to place on finger.
3. Press the power switch button on the front panel.
4. User should relax and not move or shake finger during testing.
5. The screen will display Pulse Rate and SpO2 within a few seconds.
6. At any point, press power button to reset reading.

Insert finger in correct position - fingernail should be facing the luminescent tube.

NOTE: The device will automatically shut down after 16 seconds of inactivity or after the user's finger is removed

Battery Installation

1. Open battery compartment.
2. Insert the two AAA size batteries, with + and – facing as indicated in the compartment.
3. Replace the cover.
   - Please take care when you insert the batteries.
     Improper insertion may damage the device.



Attaching Lanyard

1. Put one end of the strap through the hole on device.
2. Put the other end of the strap through the first one, pull it through, then tighten it.

Cleaning

Power off the instrument and remove the batteries before cleaning. Ensure that the appearance of the instrument is neat, dust-free, and dirt-free. Clean the outer surface of the instrument (including the LED screen) using 75% medical alcohol and a piece of dry soft cloth before using on a different user.
Caution: Avoid liquid flowing into the instrument during cleaning.
Caution: Do not immerse any part of the instrument into any liquid.

Disinfection

Before measurement with the instrument, wipe the rubber finger pad using a piece of dry soft cloth dipped with 75% medical alcohol. Clean the finger to be measured using the medical alcohol for disinfection purposes before and after use.
⚠ Do not disinfect the instrument by means of high-temperature/high- pressure or gas disinfection.

Maintenance

- Remove the batteries from the battery slot and properly store them if you do not plan to use the Oximeter for a long period of time.
- Check the accuracy of the oxygen saturation and pulse rate readings by using an appropriate calibration apparatus.
- Keep the transmitting and receiving windows free of obstructions before and after use.
- No service /maintenance while the equipment is in use.

Possible Problems & Resolutions

Problems	Possible Reason	Solution
The SpO2 and Pulse Rate cannot 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; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO2 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. Keep the user calm and still.
The device cannot be turned on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The device may be malfunctioning.	1. Change batteries. 2. Reinstall batteries. 3. Please contact 1-800-MEDLINE.
The display is off suddenly	1. The device will power off automatically when it gets no signal within 16 seconds. 2. The batteries are almost drained.	1. Normal. 2. Change batteries.

Product Accessories

Lanyard; Two AAA batteries; One user manual; Quick guide; Storage bag

Symbol Definitions

Symbol	Definition
	Type BF
	Caution: Please see this manual
SpO_2%	The pulse oxygen saturation (%)
PRbpm	Pulse rate (bpm)
	No SPO2 Alarm
	Consult instructions for use
	Temperature limtiation
IP22	Ingress of liquids rank
	When end users abandon this product they must send the product to the collection place for recycling
	Manufacture Date
	Humidity
	Atmospheric Pressure

Safety Type

Anti-electric-shock type: internal power supply device
Anti-electric-shock degree: Type BF applied part
Running mode: Continuous working Waterproof grade: IP22

Storage and Transportation

Packaged products should be stored in well-ventilated rooms without corrosive gas and with an ambient temperature of –10°C to +50°C, a relative humidity 10%- 93% (without condensation), and an atmospheric pressure of 50–106 kPa.

Statement

Lay responsible organization must contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and accessories as appliable.

EMC Information-Guidance and Manufacture's Declaration

1* **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
2* **WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
3* **WARNING**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ME equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines ± 0.5kV, ± 1 kV, ± 2 kV line(s) to earth	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	Not applicable
Power frequency IEC 61000-4-8 (50/60 Hz) magnetic field	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	Not applicable
Conducted RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
Radiated RF IEC 61000-4-3	Test frequency	Modulation	Maximum power	Immunity level	
	385 MHz	**Pulse Modulation: 18Hz	1.8W	27V/m	27V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2W	28V/m	28V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2W	9V/m	9V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2W	28V/m	28V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2W	28V/m	28V/m
	2450 MHz	**Pulse Modulation: 217Hz	2W	28V/m	28V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2W	9V/m	9V/m
Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. **Note**** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

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