Classic Fingertip Pulse Oximeter

PO6L

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User Manual

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Instructions to User

Thank you for purchasing the MediGenix Classic Fingertip Pulse Oximeter.
This user manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical oximeters and harmonised standards. In case of modifications and software upgrades, the information contained in this document is patient to change without notice.
The user manual describes the oximeter's features, 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 the equipment. Refer to the respective sections for details.
Please read the user manual carefully before using this oximeter. The operating procedures described below should be strictly followed. Failure to do so may cause abnormal results, 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 user negligence regarding the operation instructions. The manufacturer's warranty does not cover such faults caused by user error or negligence.
Owing to continuous oximeter development there may be slight differences between this manual and the oximeter you have received.
This is a medical oximeter, which can be used repeatedly.

WARNING:

- **An uncomfortable or painful feeling may appear if the oximeter is used continuously, especially for microcirculation barrier patients. It is recommended that the oximeter is not applied to the same finger for more than 2 hours at a time.**
- **The oximeter cannot be clipped on tender, swollen or oedema tissue.**
- **The infrared light emitted from the oximeter is harmful to the eyes, so do not stare at the light.**
- **Do not use the oximeter on fingers that have nail polish, false nails, gel nails or other makeup as this will interfere with the results.**
- **Ensure the fingernail is not too long.**
- **Please refer to the correlative literature about clinical restrictions and cautions.**
- **This oximeter is not intended for treatment.**

1 Safety

1.1 Instructions for safe operation

- Check the oximeter and accessories regularly to ensure there is no visible damage that may affect the patient's safety or monitoring performance. It is recommended that the oximeter should be inspected at least once a week. Stop using the oximeter when there is obvious damage.
- Necessary maintenance must be performed by qualified service technicians ONLY. Users are not permitted to maintain it themselves.
- The oximeter cannot be used together with oximeters not specified in this user manual.
- This oximeter is calibrated before leaving the factory.

1.2 Warning

- Explosive hazard - do NOT use the oximeter in an environment where inflammable gas such as ignitable anaesthetic agents, is present.
- Do NOT use the oximeter while the patient is being measured by MRI or a CT scan.
- Do NOT use the oximeter on patients who are allergic to rubber.
- Follow local laws and regulations when disposing of the oximeter, accessories, and packaging (including batteries, plastic bag, foam and paper boxes).
- Please check the packaging before using for the first time to ensure the oximeter and accessories are in accordance with the packing list.

1.3 Attention

- 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 the oximeter is moved from a cold environment to a warm or humid environment, please do not use it immediately but rather wait 20 minutes for the oximeter to adjust to the ambient temperature.
- Do NOT operate the button on the front panel with a sharp object.
- High temperature or high-pressure steam disinfection of the oximeter is not permitted. Refer to "Cleaning, disinfection and maintenance" in section 8 in the manual.
- Do not submerge the oximeter in liquid. When it needs cleaning, please refer to "Cleaning, disinfection and maintenance" in section 8 in the manual.
- Fingers which are too thin or too cold, are likely to affect the normal measurement of a patient's SpO_2 and pulse rate. Clip the oximeter onto a thicker finger such as the thumb or middle finger and ensure the finger is positioned deep enough into the probe for measurement to be effective.
- Do not use the oximeter on infants or neonatal patients.
- The oximeter is suitable for children over four years old and adults. Patients should weigh between 40kg and 110kg.
- The oximeter may not work for all patients. Discontinue use if you are unable to achieve stable readings.
- The data updates in less than 5 seconds and changes according to individual pulse rates.
- If abnormal conditions appear on the screen during the testing process, remove the oximeter and then reinsert the finger to restore normal use.
- The oximeter has a normal lifespan of 3 years since using for the first time.
- The lanyard attached to the oximeter is made from non-allergenic material. Discontinue using the lanyard if a patient appears sensitive to it. In addition, pay attention to the use of the lanyard and avoid wearing it around the neck so as to not cause harm.
- The oximeter does not have an abnormal reading alarm function. Do not use the oximeter in situations where alarms are required.
- Change the batteries when the low-battery icon displays on screen.
- Batteries must be removed if the oximeter is going to be stored unused for more than 1 month as batteries may leak.
- A flexible circuit connects the two parts of the oximeter. Do not twist or pull on the connection.

1.4 Indication for Use

The Fingertip Pulse Oximeter is a non-invasive oximeter intended for spot-checking oxygen saturation of arterial haemoglobin (SpO_2) and the pulse rate of adult and paediatric patients.

2 Overview

The oximeter is simple to operate, portable and uses very little battery power. It is only necessary for the patient to insert a finger into the fingertip photoelectric sensor for a diagnosis. The screen will display the measured value of Haemoglobin Saturation (SpO2) and Pulse Rate.

2.1 Classification

Class II a (MDD93/42/EEC IX Rule 10)
Class II (U.S.FDA)

2.2 Features

- Simple to operate
- Portable and lightweight (approx. 50g, including batteries) with a handy lanyard
- Low power consumption
- The oximeter will automatically power off when no signal is received in 5 seconds
- Low-battery warning indicator
- Pulse strength and rate is displayed
- SpO2 percentage is displayed

2.3 Major Applications and Scope of Application

The Classic Fingertip Pulse Oximeter is used to measure human Haemoglobin Saturation (SpO2) and pulse rate - the so-called the O_2 concentration in the blood. It is an important bio-parameter for respiration.
The oximeter is suitable for use in home and hospital environments (including clinical use in internist/surgery and intensive care).
This oximeter is NOT intended for continuous monitoring.

⚠ **The oximeter is not suitable for use in continuous supervision of patients.**
⚠ **The problem of overrating could emerge if the patient is suffering from toxicosis caused by carbon monoxide. The oximeter is not recommended to be used under this circumstance.**

2.4 Environment Requirements

Storage Environment

- Temperature: -40℃~+60℃
- Relative humidity: ≤95%
- Atmospheric pressure: 500hPa~1060hPa

Operating Environment

- Temperature: 10℃~40℃
- Relative Humidity: ≤75%
- Atmospheric pressure: 700hPa~1060hPa

3 Principle and Caution

3.1 Principle of Measurement

An experienced formula of data processing is established by making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Haemoglobin (Hb) and OxyHaemoglobin (HbO_2) in glow and near-infrared zones. The operation principle of the oximeter is: Photoelectric OxyHaemoglobin Inspection Technology which is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two light beams of different wavelengths can be focused on the human fingertip through a perspective clamp finger-type sensor. The measured signal is obtained by a photosensitive element. The information acquired is displayed on screen through the electronic circuits and microprocessor.

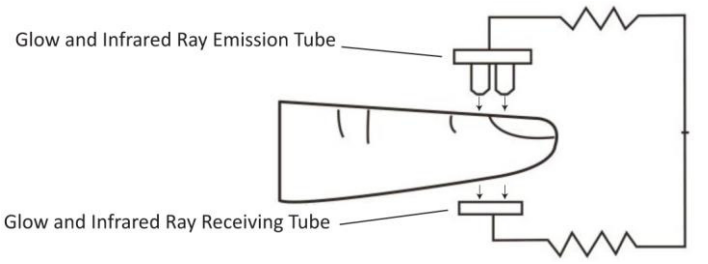

Figure 1. Operating Principle

3.2 Caution

- The finger should be placed properly (see Figure 5) or else it may cause inaccurate measurement.
- The SpO_2 sensor and photoelectric receiving tube should be arranged such that the patient's arteriole is positioned in-between them.
- Do not use the oximeter on the same limb that is receiving an intravenous injection/drip, or which is restricted due to a blood pressure cuff or a compression bandage.
- Make sure the optical path is free from any particle obstacles like rubberised fabric or dirt.
- Excessive ambient light may affect the measuring result. This includes fluorescent lamps, dual ruby light, infrared heaters, direct sunlight etc.
- Strenuous action of the patient or extreme electrosurgical interference may also affect the accuracy.
- Ensure the fingernail of the patient is clean and free of nail polish, gel covering, artificial nail etc.

3.3 Clinical Restrictions

- As the measurement is taken based on arteriole pulse, substantial pulsating blood flow of the patient is required. For a patient with a weak pulse due to shock, low ambient/body temperature, major bleeding or use of a vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
- For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), carbon monoxide Haemoglobin (COHb), methionine (ME+Hb) or Thiosalicylic Haemoglobin, and for some with icterus problem, the SpO_2 determination with this oximeter may be inaccurate.
- Drugs such as dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO_2 measures.
- As the SpO_2 value serves as a reference value for the judgement of anaemic anoxia and toxic anoxia, some patients with serious anaemia may also report good SpO_2 measurement.

4 Technical Specifications

4.1 Display Format: Digital tube Display
4.2 SpO_2 Measuring Range: 0% - 100%
4.3 Pulse Rate Measuring Range: 30 bpm - 250 bpm
4.4 Pulse Intensity Display: column display
4.5 Power Requirements: 2 ×1.5V AAA alkaline battery
4.6 Power Consumption: Less than 25 mA
4.7 Resolution: 1% for SpO_2 and 1 bpm for Pulse Rate
4.8 Measurement Accuracy: ±2% accuracy within 70%-100% SpO_2 range. Accuracy for results that are less than 70% is unspecified.
4.9 Measurement Performance in Weak Filling Condition: SpO_2 and pulse rate can be shown correctly when the pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select the larger value).
4.10 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%.
4.11 Function switch: The oximeter powers off when there is no finger in the oximeter.
4.12 Optical Sensor: Red light (wavelength is 660nm, 6.65mW); Infrared (wavelength is 880nm, 6.75mW)

5 Accessories

- 1 lanyard
- 2 AAA batteries
- 1 user manual

6 Installation

6.1 View of the Front Panel

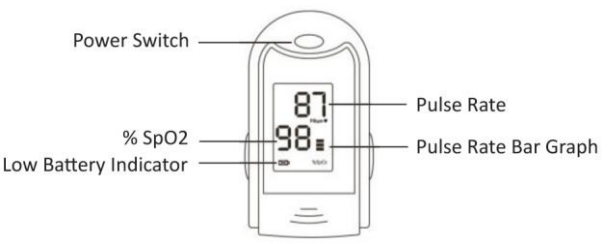

Figure 2. Front View

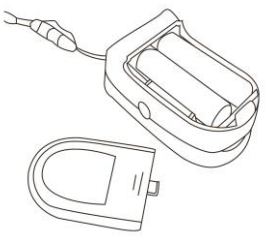

Figure 3. Battery Installation

6.2 Battery

⚠ Observe the **correct polarity** when inserting the batteries as improper insertion may damage the oximeter**.**

Step 1. Refer to Figure 3. and insert the 2 AAA batteries.
Step 2. Replace the cover.

6.3 Attaching 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 pull to tighten it.

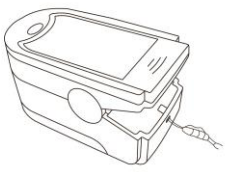

Figure 4. Attaching the lanyard

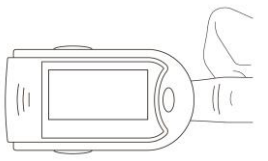

Figure 5. Correct finger positioning

7 Operating Guide

7.1 Insert the 2 batteries correctly according to the polarity and then replace the cover.
7.2 Open the clip by pressing the hinge end of the oximeter.
7.3 As shown in Figure 5. position the patient's finger on the rubber cushions of the oximeter ensuring the finger is set deep within the oximeter with the fingernail facing upwards.
7.4 Press the switch button once on front panel.
7.5 Do not shake the finger. The patient must be still during the process and should not move around.
7.6 The results will display on screen and will continuously update.
7.7 Press the button to reset the oximeter.

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

8 Cleaning, disinfection and maintenance

8.1 Change the batteries when the low battery indicator is displayed on screen.
8.2 Clean the surface of the oximeter before using it. Wipe the surface with a clean, soft cloth that has been

8.3 dampened with medical alcohol. Then let it air dry or dry it with a clean cloth. Do NOT spray any liquid directly onto the oximeter. When cleaning the oximeter with water, ensure the temperature is not higher than 60°C.
8.4 Use medical alcohol to disinfect the oximeter after use to prevent cross-contamination when using next time.
8.5 Remove the batteries if the oximeter is not going to be used for a long time.
8.6 The best storage environment for the oximeter is -40~60°C ambient temperature and less than 95% relative humidity.
8.7 Users are advised to calibrate the oximeter termly (or according to the calibrating program of hospital
8.8 ⚠ High-pressure sterilisation cannot be used on the oximeter. Do not immerse the oximeter in liquid.
It is recommended that the oximeter should be kept in a dry environment. Humidity may reduce the useful life of the oximeter, or even damage it.

9 Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate are not being displayed normally	1. The finger is incorrectly positioned. 2. The patient's SpO_2 is too low to be detected. 3. There is nail polish or false nails.	1. Position the finger correctly and try again. 2. Try again. Go to a hospital for a diagnosis if you are certain the oximeter is working all right. 3. Ensure fingernail is free of polish or false nail.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not placed deeply enough inside the oximeter. 2. The finger is shaking or the patient is moving.	1. Position the finger correctly and try again. 2. Keep the patient calm and still.
The oximeter will not turn on	1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The oximeter has malfunctioned.	1. Change batteries. 2. Reinstall batteries correctly. 3. Please contact Syringa UK Ltd.
The display is suddenly off	1. The oximeter will automatically power off in 5 seconds when it receives no signal. 2. The batteries are almost drained.	1. This is normal. 2. Change batteries.

10 Key of Symbols

Symbol	Description
	Type BF
	Refer to the user manual
SpO_2%	The pulse oxygen saturation expressed as a percentage (%)
PRbpm	Pulse rate - beats per minute (bpm)
	Low battery indicator
	No finger inserted or detected An indicator of an inadequate signal
	battery positive electrode
	battery cathode
	Power switch
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
IP22	Ingress of liquids rank
CE 0197	This item is compliant with Medical Oximeter Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
EC REP	European Representative

11 Function Specification

Display Information	Display Mode
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 (660nm wavelength) Infrared (880nm wavelength)
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 indicates the stronger pulse
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2	
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 emission		
The PO6L is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The PO6L 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 PO6L 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacture's declaration – electromagnetic immunity			
The PO6L is intended for use in the electromagnetic environment specified below. The user should ensure 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 is 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 or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	N/A	Mains power quality should be that of a typical commercial or hospital 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 or hospital environment.
Power frequency (50/60Hz) Magnetic field IEC-61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital 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			
The PO6L is intended for use in the electromagnetic environment specified below. The user should ensure 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 PO6L 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 PO6L is used exceeds the applicable RF compliance level above, the PO6L should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PO6L.

[b] If the frequency range is over 150 kHz to 80 MHz, then field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PO6L			
The PO6L is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PO6L as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance in metres (m) according to frequency of transmitter**		
	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 metres (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.			