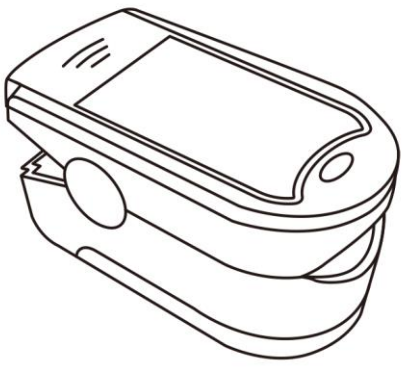
kinetik WELLBEING

CE 0197

Pulse Oximeter

UserManual

PO6L



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Instructions to User

Thank you for purchasing the Kinetik Wellbeing Finger Pulse Oximeter.

This Manual is written and compiled in accordance with the council directive MDD93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed carefully. Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is not responsible for the safety, reliability, performance and any monitoring abnormality, human injury, and equipment damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, 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 is medical device, which can be used repeatedly.

WARNING:

- **Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the special patients, there should be a more prudent inspection in the placing process. The device cannot be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so users and service engineers should not stare at the light.**
- **Users cannot use enamel or other makeup.**
- **Users fingernail cannot be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **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 patient's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by qualified service engineers only. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User's Manual. Only accessories that are appointed or recommend by manufacturer can be used with this device.
- This product is calibrated during production.

1.2 Warnings

- Explosive hazard—DO NOT use the oximeter in an environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the user is being measured by MRI and CT.
- If allergic to rubber do not use this device.
- The disposal of scrap instrument and accessories (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 there is a possibility that the device will work abnormally.
- Please don't measure this device with function test paper for the device's related information.

1.3 Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When taken from a cold environment to warm or humid environment, please do not use immediately.
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high-pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection.
- Do not immerge the oximeter in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.
- If fingers are too thin or too cold, this may affect the normal measure of the patients' SpO_2 and pulse rate, please use a thicker finger such as the thumb and middle finger deeply enough into the probe.
- Do not use the device on infant or neonatal patients.
- The product is suitable for children above four years old and adults (Weight should be between 15kg to 110kg).
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years since the first electrified use.
- The hanging rope attached the product is made from Non- allergy material, if you are sensitive to the hanging rope, stop using it. In addition, pay attention to the use of the hanging rope, do not wear around the neck to avoid any harm.
- The instrument does not have a low-voltage alarm function, it only shows the low-voltage. Please change batteries when they run out.
- The instrument does 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, or else batteries may leak.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

1.4 Indication for Use

The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). This device is not intended for continuous monitoring.

2 Overview

The pulse oxygen saturation is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood. It is an important bio-parameter for respiration. For the purpose of measuring the SpO_2 more easily and accurately, Kinetik Wellbeing have developed this Pulse Oximeter. This device can also measure the pulse rate simultaneously.

The Pulse Oximeter includes features such as; low power consumption, convenient operation, small and being portable. It is only necessary for users to put one of their fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of Hemoglobin Saturation.

2.1 Classification:

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

2.2 Features

- Operation of the product is simple and convenient.
- The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying.
- Power consumption of the product is low, and the two originally equipped AAA batteries can be operated continuously for 24 hours.
- The product will automatically power off when no signal is in the product within 5 seconds.
- Low-battery indicator as battery icon flash manner.

2.3 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure human Hemoglobin Saturation and pulse rate through the finger and indicate the pulse intensity by the bar-display. The product is suitable for use in family, Oxygen bars, social medical organizations and also the measure of saturation oxygen and pulse rate.

⚠ **The product is not suitable for use in continuous supervision for patients.**

⚠ **The problem of overrating would emerge if the patient is suffering from toxicosis caused by carbon monoxide, the device is not recommended to be used under this circumstance.**

2.4 Environment Requirements

Storage Environment
a) Temperature: -40℃~+60℃
b) Relative humidity: ≤95%
c) Atmospheric pressure :500hPa~1060hPa

Operating Environment
a) Temperature: :10℃~40℃
b) Relative Humidity :≤75%
c) Atmospheric pressure:700hPa~1060hPa

3 Principle and Caution

3.1 Principle of Measurement

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert-Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

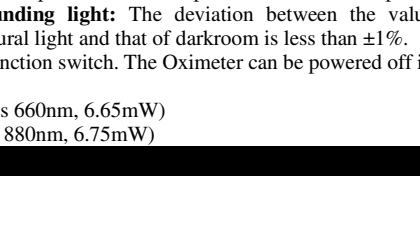

Figure 1. Operating Principle

3.2 Caution

1. The finger should be placed properly (see the attached illustration of this manual, Figure 5), or else it may cause inaccurate measurement.
2. The SpO_2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in correct position.
3. The SpO_2 sensor should not be used at a location or limb that is tied with arterial canal or blood pressure cuff or receiving intravenous injection.
4. Make sure the optical path is free from any optical obstacles like rubberized fabric.
5. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight etc.
6. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.
7. Users cannot use enamel or other makeup.

3.3 Clinical Restrictions

1. As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO_2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this monitor may be inaccurate.
3. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also cause serious error of SpO_2 measurement.
4. As the SpO_2 value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO_2 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:** Smaller 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.
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 or indoor natural light and that of darkroom is less than ±1%.
8) It is equipped with a function switch. The Oximeter can be powered off in case no finger is the
9) **Optical Sensor**
Red light (wavelength is 660nm, 6.65mW)
Infrared (wavelength is 880nm, 6.75mW)

5 Accessories

- One hanging rope.
- Two batteries.
- One User Manual.

6 Installation

6.1 View of the Front Panel

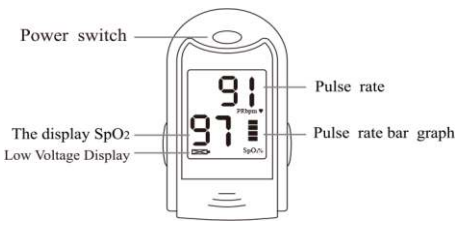

Figure 2. Front View

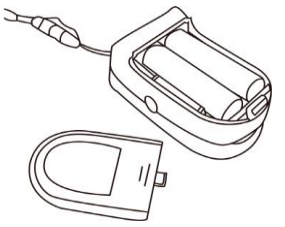

Figure 3. Batteries Installation

6.2 Battery

Step 1. Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.
Step 2. Replace the cover.

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

6.3 Mounting the Hanging Rope

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.

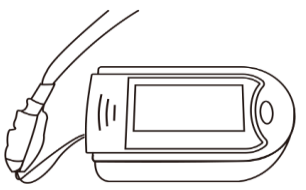

Figure 4. Mounting the hanging rope

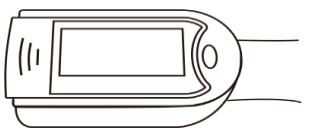

Figure 5. Put finger in position

7 Operating Guide

7.1 Insert the two batteries properly to the direction, and then replace the cover.
7.2 Open the clip as shown in Figure 5.
7.3 Let the patient's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
7.4 Press the switch button once on front panel.
7.5 Do not shake the finger and keep the patient at ease during the process. Measurement is not recommended if moving.
7.6 Get the information directly from screen display.
7.7 In boot-strap state, press button, and the device is reset.

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

8 Repairing and Maintenance

- Please change the batteries when the low voltage symbol 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 dry in air or clean it by dry clean fabric.
- Use 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 in use for a long time.
- The best storage environment of the device is - 40ºC to 60ºC ambient temperature and not higher than 95% relative humidity.
- Users are advised to calibrate the device termly (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

⚠ **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 is not displaying normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works correctly.
The SpO_2 and Pulse Rate displayed is not stable	1. The finger is not placed inside deep enough. 2. The finger is shaking, or the patient is moving.	1. Place the finger properly and try again. 2. Ensure the patient is calm.
The device is not turning 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 Kinetik Wellbeing.
The display suddenly turned off	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 cathode
	Power switch
SN	Serial number
	Alarm inhibit
	WEEE (2002/96/EC)
IP22	Ingress of liquids rank
CE0197	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

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 indicates a stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 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 *PO6L* is intended for use in the electromagnetic environment specified below. The customer of the user of the *PO6L* should assure that it is used in such and 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 – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *PO6L* is intended for use in the electromagnetic environment specified below. The customer or the user of *PO6L* 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 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. If the user of the *PO6L* requires continued operation during power mains interruptions, it is recommended that the *PO6L* 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 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

Guidance and manufacture's declaration – electromagnetic immunity			
The *PO6L* is intended for use in the electromagnetic environment specified below. The customer or the user of *PO6L* 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 *PO6L*, 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 *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] 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 *PO6L*			
The *PO6L* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *PO6L* 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 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 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 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.			