

Instruction Manual

Children Finger type Pulse Oximeter

No. AE-CX

1. Product Intended Use

Intended Use:

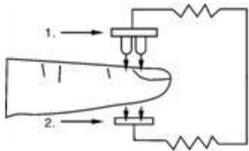
Fingertip Pulse Oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult and pediatric patient at home, and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). Not for continuously monitoring.

The requires no routine calibration or maintenance other than replacement of batteries.

2. Measurement principle

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 (R Hb) and Oxyhemoglobin (O₂ Hb) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) 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 two groups of LEDs through process in electronic circuits and microprocessor.

Diagram of Operation Principle



1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube

3. Precautions for use

1. Do not use the pulse oximeter in an MRI or CT environment.
2. Do not use the pulse oximeter in situations where alarms are required. The device has no alarms.
3. Explosion hazard: Do not use the pulse oximeter in an explosive atmosphere.
4. The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
5. Check the pulse oximeter sensor application site frequently to determine the positioning of the sensor and circulation and skin sensitivity of the patient.
6. Do not stretch the adhesive tape while applying the pulse oximeter sensor. This may cause inaccurate read the manual.
7. Before use, carefully read the manual.
8. The pulse oximeter has no SpO₂ alarms; it is not for continuous monitoring, as indicated by the symbol.
9. Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 4 hours.
10. Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid may cause inaccurate readings.
11. Significant levels of dysfunctional hemoglobins (such as carbonxy-hemoglobin or methemoglobin)

12. Intravascular dyes such as indocyanine green or methylene blue.
13. SpO₂ measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
14. Excessive patient movement
15. High-frequency electrosurgical interference and defibrillators
16. Venous pulsations
17. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
18. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
19. The patient is in cardiac arrest or is in shock
20. Fingernail polish of false finernails may cause inaccurate SpO₂ readings.

Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

4. Product Properties

1. Operation of the product is simple and convenient
2. The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying.
3. Power consumption of the product is low and the two originally-equipped two AAA batteries can be operated continuously for 30 hours.
4. Low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the oximeter might be influenced.
5. The product will automatically be powered off when no signal is in the product for longer than 8 seconds.

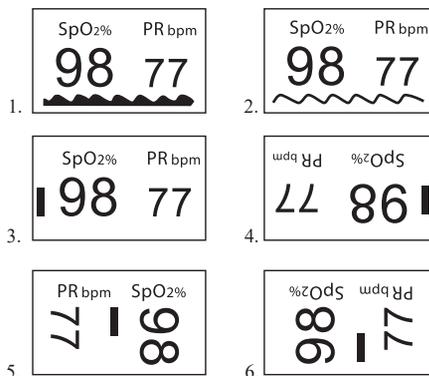
5. Product Operation Scope

The finger type pulse oximeter can be used to measure human Haemoglobin Saturation and heart rate through finger. The product is suitable for use in family, hospital (including clinical use in internist/surgery, Anaesthesia, paediatrics, intensive care and etc.) Oxygen Club, social medical organizations, physical care in sports (It can be used before or after sports. Operation in sport procedure is not recommended) and etc. The product is not suitable to monitor patient continuously.

6. Operation Instructions

1. Install two AAA batteries into battery cassette before covering its cover.
2. Nip the clamp as diagram.
3. Plug one of fingers into rubber hole of the Oximeter (it is best to plug the finger thoroughly) before releasing the clamp.
4. Press the switch once on front panel.
5. Your finger do not tremble during the Oximeter is working. Your body is not recommended in moving status.
6. Read correspondent datum from display screen.
7. Six display modes

After turn on the oximeter, each time you press the power switch, the oximeter will switch to another display mode. There are 6 display modes shown as follows:

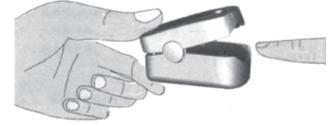


When you press the power switch for a long time (more than one second), the brightness of the oximeter will be changed by degrees, there are 10 levels on brightness; the default level is level four.

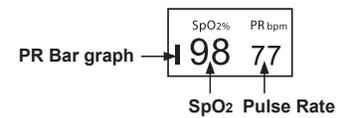
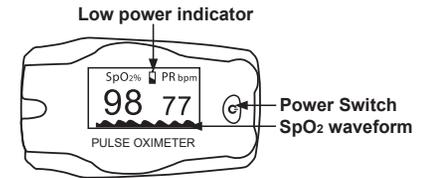
Declaration: Please use the medical alcohol to clean the rubber touching the finger inside of

Oximeter, and clean the test finger using alcohol before an after each test. (The rubber inside os the Oximeter belongs medical rubber, which has no toxin, and no harmful to the skin of human being).

When your finger is plugged into the Oximeter, your nail surface must be upward.



7. Brief Description of Front Panel



It is apparent the heart rate bargraph display corresponds with pulse rate.

8. Product Accessories

1. One hang lace
2. Two batteries
3. One User manual
4. One Silicone case

9. Battery Installations

1. Put the two AAA batteries into battery cassette in correct polarities.
2. Push the battery cover horizontally along the arrow shown as below:



Notes: Battery polarities must be correctly installed. Otherwise, damage might be caused to device.

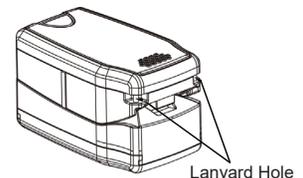
Please put or remove batteries in right order, or is likely to damage the device bracket. Please remove the battery if the Oximeter will not be used for long time.

10. Hang Lace Installations

1. Thread thinner end of the hang lace through the hanging hole.
2. Thread thicker end of the lace through the threaded end before pulling it tightly.

11. Using the Lanyard

1. Thread thinner end of the lanyard through the hanging hole.
2. Thread thicker end of the lanyard through the threaded end before pulling it tightly.



Warnings!

1. Keep the oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.
2. Do not hang the lanyard from the device's electrical wire.

12. Maintenance and Storage

1. Replace the batteries timely when low voltage lamp is lighted.
2. Clean surface of the finger type Oximeter before it is used in diagnosis for patients

- Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.
- It is best to preserve the product in a place where ambient temperatures range from -20°C to 55°C and ≤ 93% humidity.
- It is recommended that the product should be kept in a dry environment anytime. A wet ambient might affect its lifetime and even might damage the product.
- Please follow the law of the local government to deal with used battery.

Cleaning the Oximeter

Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter with a soft cloth dampened with 70% isopropyl alcohol, and clean the test finger using alcohol before and after each test. Do not pour or spray and liquids onto the Oximeter, and do not allow any liquid to enter any openings in the device. Allow the Oximeter to dry thoroughly before reusing.

13. Calibrating the pulse oximeter

- The functional tester cannot be used to assess the accuracy of the oximeter.
- Index 2 that made by Bioteck company is a function tester. Set Tech to 1. R curve to 2, then user can use this particular calibration curve to measure the oximeter.
- The test methods used to establish the SpO₂ accuracy is clinical testing. The oximeter used to measure the arterial haemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-oximeter.

14. Detailed descriptions of product functions

- Display Type: OLED display
- SpO₂ :
Measurement range: 70%~99%
Accuracy: ±3% on the stage of 70%~99%
0%~69% no definition
- Pulse Rate:
Measure range: 30~235 BPM
Accuracy: 30~99BPM, ±2 bpm ;
100~235bpm, ±2 %
Pulse Intensity: Bargraph Indication
- Power Requirements: Two AAA 1.5V Alkaline Batteries
Power consumption: less than 30mA
Low power indication: 
Battery Life: Two AAA 1.5V, 800mAh alkaline batteries could be continuously operated as long as 30 hours.
- Dimension:
Length: 50mm
Width: 28mm
Height: 28mm
Weight: 25g(without batteries)
- Environment Requirements:
Operation Temperature: 5 ~ 40°C
Storage Temperature: -20 ~ 55°C
Ambient Humidity: ≤80% no condensation in operation
≤93% no condensation in storage
- Declaration: EMC of this product comply with IEC60601-1-1-2 standard.
- Measurement Performance in Weak Filling Condition: required the test equipment (BIO-TEK INDEX Pulse Oximeter tester) the pulse wave is available without failure when the simulation pulse wave amplitude is at 6%.
- Interference Resistance Capacity against Ambient Light: Device work normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

16. Possible Problems and Resolutions

| Problems | Possible reason | Solution |
|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| SpO ₂ or PR can not be showed normally | <ol style="list-style-type: none"> Finger is not plugged correctly Patient's Oxyhemoglobin value is too low to be measured | <ol style="list-style-type: none"> Retry by plugging the finger Try some more times, If you can make sure about no problem existing in the product. Please go to a hospital timely for exact diagnosis |
| SpO ₂ or PR is showed unstably | <ol style="list-style-type: none"> Finger might not be plugged deep enough Finger is trembling or patient's body is in movement status | <ol style="list-style-type: none"> Retry by plugging the finger Try not to move |
| The Oximeter can not be powered on | <ol style="list-style-type: none"> Power of batteries might be inadequate or not be there at all Batteries might be installed incorrectly The Oximeter might be damaged | <ol style="list-style-type: none"> Please replace batteries Please reinstall the batteries Please contact with local customer service centre |
| Indication lamps are suddenly off | <ol style="list-style-type: none"> The product is automatically powered off when no signal is detected longer than 8 seconds Power quantity of the batteries is started being inadequate | <ol style="list-style-type: none"> Normal Replace the batteries |
| "Error3" or "Error4" displayed on screen | <ol style="list-style-type: none"> Low power Receiving tube being shielded or damaged together with broken connector. Mechanical misplace for receive-emission on tube Amp circuit malfunction. | <ol style="list-style-type: none"> Change new battery Please contact with local customer service center Please contact with local customer service center Please contact with local customer service center |
| "Error6" | Err6 means the screen is failure. | Please contact local customer service center. |
| "Error7" displayed on screen | <ol style="list-style-type: none"> Low power Emission tube damaged. Current control circuit malfunction. | <ol style="list-style-type: none"> Please change battery Please contact with local customer service center Please contact with local customer service center |

15. Declaration

Guidance and Manufacture's declaration – electromagnetic emissions - For all EQUIPMENT and SYSTEMS

| Guidance and Manufacture's declaration – electromagnetic environment specified below. The customer of the user of the Pulse Oximeter should assure that it is used in such and environment. | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Emission test | Compliance | Emission test Compliance Electromagnetic Environment – guidance | |
| RF emissions CISPR 11 | Group 1 | The pulse Oximeter uses RF energy only for very low and are not likely to cause interference in nearby electronic equipment. | |
| RF emission CISPR 11 | Class B | The pulse Oximeter is suitable for use in all establishment, 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 emissions IEC 61000-3-2 | Not Applicable | | |

Guidance and Manufacture's declaration – electromagnetic immunity- For all EQUIPMENT and SYSTEMS

| Immunity test Compliance | 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 Pulse Oximeter including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance |

| | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | | $d = \left[\frac{3.5}{F_1} \right] \sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{F_1} \right] \sqrt{P}$ 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, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with 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 structures, objects and people. | | |
| A Field strengths from fixed transmitters, such as base station 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 Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Pulse Oximeter. B Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m | | |

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEMS - For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

| Recommended separation distances between portable and mobile RF communications equipment and Pulse Oximeter | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|-------------------------------------------------------------------|
| The Pulse Oximeter is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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) | |
| | 80 MHz to 800 MHz $d = \left[\frac{3.5}{F_1} \right] \sqrt{P}$ | 800 MHz to 2.5 GHz $d = \left[\frac{7}{F_1} \right] \sqrt{P}$ |
| 0.0 | 0.1167 | 0.2334 |
| 0.1 | 0.3689 | 0.7378 |
| 1 | 1.1667 | 2.3334 |
| 10 | 3.6893 | 7.3786 |
| 100 | 11.6667 | 23.3334 |

16. Symbol Definitions

| Symbol | Definition |
|---------------------------------------------------------------------------------------|-------------------------------------------|
|  | The equipment type is BF |
|  | Refer to user manual before application |
|  | No for continuous monitoring |
| % SpO ₂ | Hemoglobin saturation |
|  | BPM |
|  | Low power indication |
| SN | Serial No. (Attached inside of the unit) |

Notes: Please remove the battery when product will not be in used for period of time.




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