Instruction Manual

Oxi - Q
Finger type
Pulse Oximeter

No. AE-xx

1. General Description

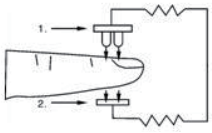
Haemoglobin Saturation is percentage of Oxyhemoglobin (HbO_2) capacity, compounded with oxygen, by all combinativable haemoglobin (Hb) obin (HbO_2) capacity in blood. In other words, it is consistence of Oxyhemoglobin in blood. It is a very important ecological parameter for Respiratory circulation System. Many respiratory diseases can result in haemoglobin Saturation being lowered in human blood. Moreover, the following factors can also lead to problems in oxygen supply, so that human haemoglobin saturation might be reduced: Automatic Organic Regulation Malfunction caused by Anesthesia, Intensive Postoperative Trauma, hurts resulted in by some medical examination and etc. In the situation, illnesses, such as light head, asthenia, vomitory and etc, might happen to patients and even endanger the patient's life. Therefore, it is very important to know Hemoglobin saturation of patient timely in clinical medical aspects. So that doctors can find problems in time. The Finger type Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a finger type photoelectric sensor for diagnosis, and a display screen will directly show measured value of hemoglobin Saturation. It has been proved in clinical experiments that it features in rather high precise and repeatability.

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 (O_2 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 SpO_2 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. SpO_2 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 SpO_2 readings.

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

4. Product Properties

1. Easy to use.
2. Small dimension, light in weight (total weight is about 55g including batteries) and convenient for portable.
3. Lower power consumption; originally-equipped equipped two AAA batteries can last to 30 hours.
4. Low voltage warning will be indicated in visual window when battery voltage is too low and normal application of the Oximeter might be influenced.
5. No signal can be tested, device will power off automatically in 8 seconds.

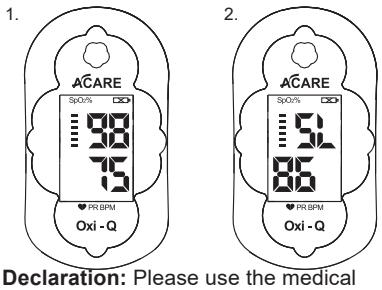
5. Product Operation Scope

The finger type 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.

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

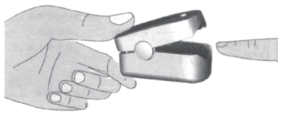
6. Operation Instructions

1. Installing two AAA batteries into battery cassette before closing its cover.
2. Open the clamp shown as in the picture below
3. Put one of your fingers into rubber hole of the Oximeter (it is better to let your finger touch the bottom.) before releasing the clamp
4. Press the switch button for one time on front panel.
5. Do not rock your finger when starting test. Recommend you do not move your body at the same time.
6. Read correspondent data from display screen.
7. Two display modes

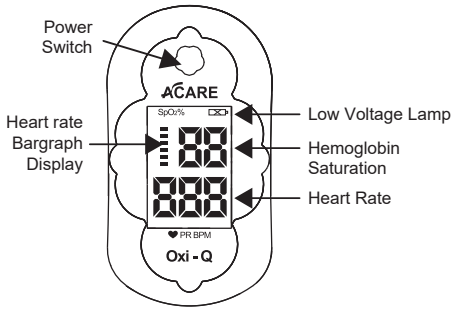


Declaration: Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test sensor using alcohol before and after operation. (The rubber inside of the Oximeter is medical rubber, which has no toxin, and no harmful to the skin of human being).

When you put finger into the Oximeter, your nail surface must be upward.



7. Brief Description of Front Panel



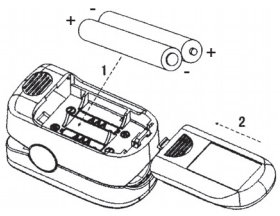
The length of the bargraph indicates the intensity of the pulse.

8. Product Accessories

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

9. Battery Installation

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 likely to damage the device bracket.

Please remove the battery if the Oximeter will not be used for long time.

10. Hang Lace Installation

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. Maintenance and Storage

1. Replace the batteries timely when low voltage indicator is on.
2. Clean surface of the finger type Oximeter before it is used in diagnosis for patients.
3. Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.
4. It is better to preserve the product in a place where ambient temperatures range from -20°C to 55°C and ≤ 93% humidity.
5. It is recommended that the product be kept in a dry place. A damp ambient might affect its lifetime and even might damage the product.
6. Please follow the articles of the local government to deal with run-out-of battery.

12. Calibrating the Pulse Oximeter

1. The functional tester cannot be used to assess the accuracy of the oximeter
2. 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.
3. The test methods used to establish the SpO_2 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.

13. Detailed descriptions of product functions

1. Display Type: LED display
2. SpO_2 :
   Measurement range: 70%~99%
   Accuracy: ±2% on the stage of 70%~99%
   0%~69% no definition
3. Pulse Rate:
   Measure range: 30~235 BPM
   Accuracy: 30~99BPM, ±2 bpm ;
   100~235bpm, ±2 %
   Pulse Intensity: Bargraph Indication
4. Power Requirements: Two AAA 1.5V Alkaline Batteries
   Power consumption: less than 25mA
   Low power indication:
   Battery Life: Two AAA 1.5V, 600mAh alkaline batteries could be continuously operated as long as 30 hours.
5. Dimension:
   Length: 62mm
   Width: 34mm
   Height: 38mm
   Weight: 55g (including 2 batteries)
6. Environment Requirements:
   Operation Temperature: 5 ~ 40°C
   Storage Temperature: -20 ~ 55°C
   Ambient Humidity: ≤80% no condensation in operation
   ≤93% no condensation in storage
7. Declaration: EMC of this product comply with IEC60601-1-1-2 standard.
8. 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%.
9. Interference Resistance Capacity aginst Ambient Light: Device work normally when mixed noise produced by BIO-TEK INDEX Pulse Oximeter tester.

14. Possible Problems and Resolutions

Problems	Possible reason	Solution
SpO_2 or PR can not be showed normally	1. Finger is not plugged correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1.Retry by plugging the finger 2. 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	1. Finger might not be plugged deep enough 2. Finger is trembling or patient's body is in movement status	1. Retry by plugging the finger 2. Try not to move
The Oximeter can not be powered on	1. Power of batteries might be inadequate or not be there at all 2. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact with local customer service centre
Indication lamps are suddenly off	1. The product is automatically powered off when no signal is detected longer than 8 seconds 2. Power quantity of the batteries is started being inadequate	1. Normal 2. Replace the batteries
"Error3" or "Error4" displayed on screen	1 .Low power 2. Receiving tube being shielded or damaged together with broken connector. 3. Mechanical misplace for receive-emissi on tube 4. Amp circuit malfunction.	1. Change new battery 2. Please contact with local customer service center 3. Please contact with local customer service center 4. Please contact with local customer service center
"Error6"	Err6 means the screen is failure.	Please contact local customer service center.
"Error7" displayed on screen	1. Low power 2. Emission tube damaged. 3. Current control circuit malfunction.	1. Please change battery 2. Please contact with local customer service center 3. Please contact with local customer service center

15. Guidance and manufacture's declaration - electronmagnetic emissions - for all Equipmnet and Systems

The Pulse Oximeter is intended for use in the 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	Electromagnetic environment-guidance
RF emissions **CISPR 11**	Group 1	The Pulse Oximeter uses RF energy only for its internal function. Therefor, its RF emissionslare very low and are not likely to cause any interference in nearby electronic equipment.
RF emission **CISPR 11**	Class B	The 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 use for domestic purposes.

17. Symbol Definitions

Symbol	Definition
	The equipment type is BF
	Refer to user manual before application
	No SpO_2 alarm
% SpO_2	Hemoglobin saturation
PR BPM	Heart rate (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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