SALTER®
SINCE 1760

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OxyWatch®
Fingertip Pulse Oximeter

General description
Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO2 level.

Measurement principle
Principle of the oximeter is as follows: The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 905 nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

Diagram of operation principle

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

Precautions for use
1. Before use, carefully read the manual.
2. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit (ESU).
3. The fingertip pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO2 measurement.
4. Do not use the fingertip pulse oximeter in an MRI or CT environment.
5. Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms. It is not for continuous monitoring.
6. Do not use the fingertip pulse oximeter in an explosive atmosphere.
7. The fingertip 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.
8. In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
9. Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
10. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
11. This equipment complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
12. Portable and mobile RF communications equipment can affect medical electrical equipment
13. This equipment is not intended for use during patient transport outside the healthcare facility.
14. This equipment should not be used adjacent to or stacked with other equipment.
15. It may be unsafe to:
    - use accessories, detachable parts and materials not described in the instructions for use
    - interconnect this equipment with other equipment not described in the instructions for use
    - disassemble, repair or modify the equipment
16. These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
17. When the signal is not stable, the reading may be inaccurate. Please do not reference.

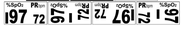
Contraindication
It is not for continuous monitoring.

Inaccurate measurements may be caused by
1. Significant levels of dysfunctional hemoglobin (such as carboxyl - hemoglobin or methemoglobin).
2. Intravascular dyes such as indocyanine green or methylene blue.
3. High ambient light. Shield the sensor area if necessary.
4. Excessive patient movement.
5. High-frequency electrosurgical interference and defibrillators.
6. Venous pulsations.
7. Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8. The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
9. The patient is in cardiac arrest or is in shock.
10. Fingernail polish or false fingernails.
11. Weak pulse quality (low perfusion).
12. Fingernail polish or flase fingernails, tattooes and dyes
13. Measurements of oxygen saturation levels in people with darker skin pigment may be over estimated

Product features
1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. Dual color OLED displays SpO2, PR, PI (Perfusion Index), Pulse bar, and waveform.
4. 7 display modes.
5. Level 1-10 adjustable brightness.
6. 2pcs AAA-size alkaline batteries; real-time battery status indication.
7. Weak or unstable signal prompt provides more accurate measurements.
8. The device automatically shuts off after no operation in 8 seconds when "finger out" displays.
9. Multiple-patient reusability.

Intended use
The Fingertip Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homecare.

Operations
1. Install two AAA batteries according to the Battery Installation instructions.
2. Place one of your fingers into the rubber opening of the Pulse Oximeter.
3. Press the switch button one time on front panel to turn the pulse oximeter on.
4. Keep your hands still for the reading. Do not shake your finger during the test.
   It is recommended that you do not move yo
   body while taking a reading.
5. Read the data from the display screen.
6. The display modes are as follows:



Notes:
1. Short press the power button to
   switch the display modes.
2. Long press the power button to
   adjust the brightness of the
   oximeter. There are 10 levels of brightness. The default is level four.
3. Take out your finger, the screen displays "FingerOut". It means the measurement ending.

Reading yo

Notes:
1. The pulse bar less than 30 % indicates signal inadequacy and the displayed SpO2 or pulse rate value is potentially incorrect.
2. If the screen display "?", it means the signal is unstable, please keep your hands still and retry.
3. PI means Perfusion Index.

Battery Installation

1. Slide the battery door cover horizontally along the arrow shown as the picture.
2. Install two AAA batteries into the battery compartment. Match the plus (+) and minus (–) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.
3. Close the battery door.

Notes: Please remove the batteries if the pulse oximeter will not be used for long periods of time
Please replace the battery when the power indicator starting flickering.

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.
3. Please notice that the lanyard which is tied to the oximeter may cause strangulation due to excessive length.

Maintenance and storage
1. Replace the batteries in a timely manner when low voltage lamp is lighted.
2. Clean surface of the fingertip oximeter before it is used in diagnosis for patients.
3. Remove the batteries if the oximeter is not operated for a long time.
4. It is best to store the product in –25 °C ~ +70 °C and ≤ 93 % humidity.
5. Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
6. Dispose of battery properly; follow any applicable local battery disposal laws.

Cleaning and disinfecting the fingertip pulse oximeter
- Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70 % isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.
- Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.
- The fingertip pulse oximeter requires no routine calibration or maintenance other than replacement of batteries.
- The applied parts touching the patients' body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.
- Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter before disinfecting it.

CAUTION: Never use EtO or formaldehyde for disinfection.
The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Stop using and contact your local service centre if one of the following cases occurs:
- An error in the Possible Problems and solutions is displayed on screen.
- The oximeter cannot be powered on in any case and not the reasons of battery.
- There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.

Specifications
- Display Type: OLED display
- SpO2
  - Display range: 0 %~100 %
  - Measurement range: 70 %~100 %
  - Accuracy: 70 %~100 %±2 %;0 %~69 % no definition.
  - Resolution: 1 %
- **Pulse rate**
  - Display range: 30 bpm~250 bpm
  - Measure range: 30 bpm~250 bpm
  - Accuracy: 30bpm~99 bpm, ±2 bpm; 100 bpm~250 bpm, ±2 %
  - Resolution: 1 bpm
- **Perfusion index**
  - Display range: 0.1 %~20 %
  - Measure range: 0.2~20.0 %
  - Accuracy: 0.2 %~1.0 %, ±0.2 digits; 1.1 %~20.0 %, ±20 %
  - Resolution: 0.1 %

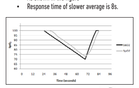
Probe LED specifications

	Wavelength	Radiant Power
RED	660 ± 3 nm	3.2 mw
IR	905 ± 10nm	2.4 mw

Power requirements
- Two AAA alkaline Batteries
- Power consumption: Less than 40mA
- Battery Life: Two AAA 1.5V, 1200mAh alkaline batteries could be continuously operated as long as 24 hours.

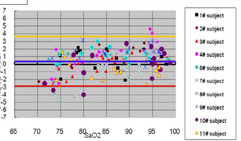
Environment requirements
- Operation Temperature: 5 °C ~ 40 °C
- Storage Temperature: -25 °C ~ +70 °C
- Ambient Humidity: 15 % ~ 93 % no condensation in operation; ≤ 93 % no condensation in storage/transport
- Atmosphere pressure: 70 kPa ~ 106 kPa

Equipment response time
- As shown in the figure
- Response time of slower average is 8s.



ARMS value analysis statement

Item	90-100	80-<90	70-<80
#pts	78	66	63
Bias	1.02	0.40	-0.48
ARMS	1.66	1.46	1.93



Classification
- According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;
- According to the degree of protection against electric shock: TYPE BF APPLIED PART, (The application part is rubber inside of the Pulse Oximeter);
- According to the degree of protection against ingress of dust and water: IP22
- According to the mode of operation: CONTINUOUS OPERATION

Clinical study summary
The following details are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot of data is shown as following:

Possible problems and solutions

Problems	Possible reason	Solution
SpO2 or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's SpO2 value is too low to be measured	1. Retry by inserting the finger 2. There is excessive illumination 3. Try some more times. If you can make sure no problem exists in the product, please go to a hospital timely for exact diagnosis.
SpO2 or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Excessive patient movement	1. Retry by inserting the finger 2. Be calmness
The oximeter cannot be powered on	1. No battery or low power of battery 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. The battery power is too low to work	1. Normal 2. Replace the batteries
"Error3" or "Error4" is displayed on screen	1. Err 3 means red emission LED is damaged 2. Err 4 means infra-red emission LED is damaged	1. Check the red emission LED 2. Check the infra-red emission LED
"Error6"	Err 6 means screen failure	Please contact the local customer service centre
"Error7" is displayed on screen	Err 7 means all the emission LED or reception diode is damaged.	Please contact with local customer service centre

Symbol definitions

Symbol	Definition	Symbol	Definition
	Type BF applied part		Attention
	Follow instructions for use	%SpO2	Oxygen saturation
PR bpm	Pulse rate (BPM)		Lower power indication
SpO2	No SpO2 Alarm	SN	Serial No.
	Storage temperature and relative humidity	IP22	The degree of protection against ingress of dust and water
	Date of manufacture		Manufacturer's information
EC REP	Authorised representative in the European community	CE 0123	European Union approval
	Conformity to WEEE Directive	?	Indicates the signal is not stable

Box contents
1. Fingertip pulse oximeter
2. One Lanyard
3. Two AAA batteries
4. One instruction manual

Notes: The illustrations used in this manual may differ slightly from the appearance of the actual product.
The specifications are subject to change without prior notice.

If this product does not reach you in an acceptable condition please contact our Customer Services Department by **www.salterhousewares.com.au**.
Please have your delivery note to hand as details from it will be required.

If you wish to return this product please return it to the retailer from where it was purchased with your receipt (subject to their terms and conditions).

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