Alcédo

Pulse Oximeter AE174 (OLED)

Date of Issue: 2019.11, Version: V1.0

Precautions

- Do not attempt to maintain the Oximeter unless you are professional engineers. Only professionals with maintenance qualification are allowed to perform interior maintenance necessary.
- Periodically change the contact position between the Oximeter probe and the finger for a measurement that lasts a long time. Adjust the position of the probe before the measurement lasts two hours, and check the integrity of skin, the blood circulation condition of the finger as well as the position of the finger.
- This product is not applicable to the examination of newborn babies.
- Seek for medical care in time if the measured value goes beyond the normal range while you are sure that the instrument does not malfunction.
- Do not directly expose your eyes to light-emitting components of the Oximeter, as that could cause harm to your eyes.
- For details about clinical limitations and contraindications, please carefully consult relevant medical literatures.

The following factors may cause disturbance to or affect the accuracy of examination:

- This product is used in an environment involving high-frequency devices, such as high-frequency electric knives and CT apparatuses.
- The probe of the Oximeter is placed on the same body part or limb as with blood pressure cuff arterial duct or intravenous injection.
- The user suffers from hypotension, severe vascular atrophy, severe anemia, or low oxygen.
- The user is in sudden cardiac arrest or shock state.
- The finger with nail polish or a fake fingernail may cause wrong readings of pulse oxygen saturation.

Warnings

Warning: Do not use the Oximeter in an environment with any flammable gases, flammable anesthetic, or other flammable substances.

Warning: Keep unit and lanyard away from children as the included lanyard may present an entanglement or choking hazard to small children. Adult supervision required; never leave children unattended with unit or lanyard

Warning: Do not throw the batteries into fire, as that could cause an explosion.

Warning: Do not attempt to charge the included batteries, as that could cause leakage, fire disaster, or even explosion. Dispose the used batteries in accordance to the local laws and regulations.

Warning: Do not use the Oximeter in an MRI or CT environment.

Warning: Do not operate the Oximeter if it is wet. Avoid moving the oximeter from a cold to a hot and humid environment.

Warning: Install the batteries properly before powering on the Oximeter for normal use. Please remove the batteries if you are not planning to use the Oximeter for a long time.

Warning: Close the battery cover when the instrument is in use.

Warning: The patient is an intended operator.

Warning: Do not modify the device and use the device for other purposes.

Warning: The Functional tester cannot be used to evaluate the accuracy of pulse oximetry probes or pulse oximetry monitors.

Product Accessories

1.One lanyard;
2.Carrying case;
2.Two AAA batteries;
3.One user manual;
4.One quick start guide

Symbol Conventions

Symbol	Description
	Type BF applied part
	Caution: Please see this manual.
%SpO2	Symbol of oxygen saturation.
bpmPR	Symbol of pulse rate.
	No SpO_2 alarms.
	Consult the instructions for use.
IP22	The degree of protection against harmful ingress of water and particulate matter.
	When end users abandon this product, they must send the product to the collection place for recycling.

Overview

Oxygen saturation is the percentage of oxyhemoglobin (HbO2) that is combined with oxygen against all combinable hemoglobin (Hb). It is an important physiological parameter involved in respiration and circulation. The oxygen saturation of arterial blood in a normal human body is 98%. Oxygen saturation is an important indicator of the oxygen condition in the human body. In general, the normal values of oxygen saturation shall not be lower than 94%. If the measured value of oxygen saturation is lower than 94%, an insufficient supply of oxygen is considered.

The pulse rate is the number of pulse beats per minute. Normally, the pulse rate is consistent with the heart rate. In general, the pulse rate of every people is 60 to 90 beats per minute.

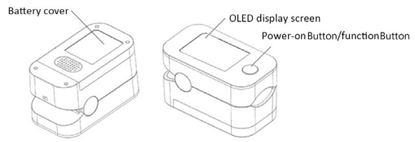
The Perfusion Index (PI) usually reflects the limb perfusion status of an examined patient, and shows the detection precision of the instrument as well; that is, examination can still be performed even in the low or weak perfusion condition. The PI of a normal human body is 3% or greater.

Working Principles, Expected Usage, and Applicable Scope

Based on full digital technology, the Finger Pulse Oximeter non-invasively measures the actual content (oxygen saturation) of oxyhemoglobin (HbO2) in arterial blood using the optical transmittance method.

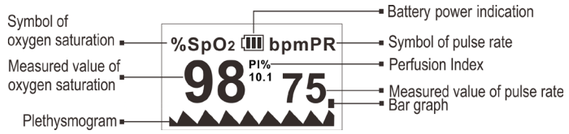
The Finger Pulse Oximeter measures the blood oxygen saturation and pulse rate of a human body via finger artery. It is applicable to a wide range of fields, such as families, oxygen bars, and sports & health. Use this instrument for measurement before or after sports. You are not advised to use this instrument during sports activities.

Appearance of the structure



Screen Display

The following figure shows the information display on the OLED screen of the Oximeter in normal detection state:



Power-On button/Functional button Operations

Press and release the button to turn on, hold the button for about one second. The Oximeter shows a parameter setting interface. Press or hold the button to perform corresponding operations. Hold it to set an item, or press it to switch an option. Press means no more than 0.5 seconds, while Hold means more than 0.5 seconds.

Alert Sound Setting

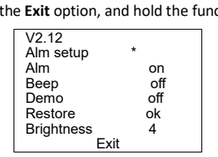
Hold the functional button while the Oximeter is in powered-on state. Parameter setting interface 1 is displayed, as shown in the following figure. Move "*" to the corresponding option, and hold the functional button to set **Alm** to **on** and set **Beep** to **off**. When **Alm** is set to **on** and the measured values of the blood oxygen saturation and pulse rate go beyond the upper limit or lower limit, the Oximeter gives off an alert sound. When **Alm** is set to **off** and the measured values go beyond the limit, the Oximeter will not give any alert sound. When **Beep** is set to **on**, a tick will be heard along with pulse beats during pulse rate measurement. When **Beep** is set to **off**, no sound will be output along with pulse beats during pulse rate measurement. While the "*" symbol stays on the **Restore** option, hold the functional button to restore factory settings.

Brightness Setting

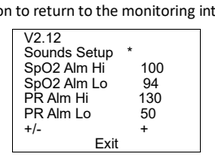
On parameter interface 1, press the functional button to select the **Brightness** option and then hold the functional button to set the brightness to a value ranging from 1 to 5. The greater the value, the greater the brightness of the screen.

Alert Range Setting

On parameter interface 2, press the functional button to switch between options. On this interface, you can set the upper limit and lower limit of **SpO2 Alm** and **PR Alm**. While the "*" symbol stays on the **+/-** option, hold the functional button to set the option to **+** or **-**. In **+** mode, select the corresponding option and hold the functional button to increment the upper or lower limit; in **-** mode, hold the functional button to decrement the upper or lower limit. Move "*" to the **Exit** option, and hold the functional button to return to the monitoring interface.



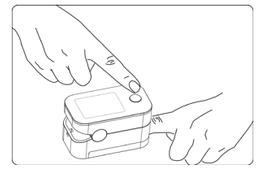
Interface 1



Interface 2

Operation Guide

Stick one finger completely into the measuring parts of the Oximeter, keep the fingernail surface upward, and release the clip. Then press the power button to power on the Oximeter.

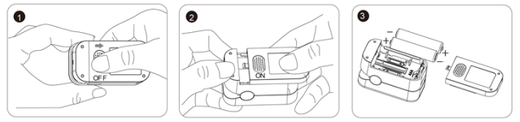


⚠ If you do not yet completely insert your finger into the cavity, the measurement result may be inaccurate.

⚠ Do not vibrate your finger during measurement. Preferably, ensure that your body does not move. After the readings become stable, read the measured values of oxygen saturation and the pulse rate on the screen.

NOTE: The Oximeter will automatically shut down 10 seconds later after your finger leaves away.

⚠ Replace the batteries when the battery capacity is insufficient and the symbol （▭） flickers on the screen. Open the battery cover with your fingers, you can replace the batteries according to the correct battery polarity.



Cleaning

Power off the instrument and remove the batteries before cleaning. Ensure that the appearance of the instrument is neat, dust-free, and dirt-free. Clean the outer surface of the instrument (including the OLED screen) using 75% medical alcohol and a piece of dry soft cloth.

Caution: Avoid liquid flowing into the instrument during cleaning.

Caution: Do not immerse any part of the instrument into any liquid.

Disinfection

Before measurement with the instrument, wipe the rubber finger pad using a piece of dry soft cloth dipped with 75% medical alcohol. Clean the finger to be measured using the medical alcohol for disinfection purposes before and after use.

⚠ Do not disinfect the instrument by means of high-temperature /high-pressure or gas disinfection.

Maintenance

- Remove the batteries from the battery slot and properly store them if you do not plan to use the Oximeter for a long period of time.
- Avoid using the Oximeter in an environment with inflammable gases or using it in an environment where the temperature or humidity is excessively high or low.
- Check the accuracy of the oxygen saturation and pulse rate readings by using an appropriate calibration apparatus.

Technical Specifications

1. Dimensions: 58.2 mm (Width) × 32.2 mm (Depth) × 32.0 mm (Height)
   Weight: 51.5 g (without batteries)
2. Peak wavelength range of the light emitted from the probe: red light 660 nm ± 3; infrared light 905 nm ± 5.
3. Maximum optical output power of the probe: 1.2 mW for infrared light (905 nm).
4. Manufacturing date: see the label
5. Normal working condition

Working Temperature	5°C to 40°C (41°F to 104°F)
Relative Humidity	15% to 80%, non-condensing
Atmospheric Pressure	70 kPa to 106 kPa
Rated Voltage	DC 3.0 V

6. Default values and conditions of alert

Parameter	Value
Oxygen saturation	Upper limit: 100 Lower limit: 94
Pulse rate	Upper limit: 130 Lower limit: 50
Alert condition	When the alert switch is on and the actual measured value goes beyond the preset alert parameter range, the Oximeter gives an alert sound.

7. Technical parameters

Parameter		Value
Display range	Oxygen saturation	35% to 100%
	Pulse rate	25 bpm to 250 bpm
Resolution	Oxygen saturation	1%
	Pulse rate	1 bpm
Measurement precision	Oxygen saturation	±2% (70% to 100%) No requirement (≤ 69%)
	Pulse rate	±2 bpm
Alert range	Oxygen saturation	Upper limit: 50% to 100% Lower limit: 50% to 100%
	Pulse rate	Upper limit: 25 bpm to 250 bpm Lower limit: 25 bpm to 250 bpm
Alert error	Oxygen saturation	± 1% of the preset value
	Pulse rate	The greater of ±10% of the preset value and ±5 bpm
PI	Weak PI	Min. 0.3%

Safety Type

Anti-electric-shock type: internal power supply device
Anti-electric-shock degree: Type BF applied part
Running mode: continuous working
Waterproof grade: IP22

Storage and Transportation

Temperature : –10°C - 50°C(14°F-122°F)
Relative humidity : 10%-93% (no condensation)
Atmospheric pressure : 50kPa–106 kPa.

After-sale Service

After-sale service unit: Nature Major Inc.
Address: 315 W 36th Street, New York, NY 10018
E-mail：info@alcedohealth.com
Website: www.alcedohealth.com

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and manufacturer’s declaration - electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The devuce device use 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 emissions CISPR11	Class B	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ Ficker emissionsIEC61000-3-3	Not applicable	

Guidance and manufacturer’s declaration — electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood , concrete or ceramic tile. If floors 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 ± 1 kV Input/ output line	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Surge IEC 61000-4-5	± 1 kV Differential mode voltage ± 2 kV	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
	Common mode voltage		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture’s declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of device 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 Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Blood Pressure Monitor.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [Vi] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	/	0.12	0.23
0.1	/	0.38	0.73
1	/	1.2	2.3
10	/	3.8	7.3
100	/	12	23

For transmitters rated at a maximum output power not listed above, There commended 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) accordable to the transmitter manufacturer.
NOTEI At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.

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