

Fingertip Pulse Oximeter User Manual



Product Model:
AS-301

Product Features

The product is easy to operation, small in volume, light in weight, convenient in carrying, and adopted the low consumption design, with strong resistance to ambient light interference ability. 2pcs AAA batteries can be continuously used for 12 hours, and battery voltage can be indicated. The product is suitable for use in home healthcare, hospital (including internal medicine, surgery, anesthetic, intensive care and etc.), oxygen bar, community medical centre, sports healthcare and etc.

Intended Use

The fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO₂) and pulse rate of adult in hospitals, hospital-type facilities, and home environments.

It applies to persons of all colors except infants and neonates. No special training in the use of the product, but requires the user to read the instructions before use. Readers are adults, and would be able to read and understand the operation manual; there are no reading and understanding barriers.

Measurement Principle

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger), to a receiver on the other side. Two beams of different wavelength of lights (660nm red and 895nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

⚠ SpO₂ is a measurement of the functional oxygen saturation.

⚠ The value of SpO₂ and PR were through average processing.

⚠ The light (the red light and the infrared light which is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance personnel cannot stare at the light.

⚠ The device don't have Technical specifications manual, the product specified see the instructions.

Operation Instruction

Before use, carefully read the user manual.

The LED digitron display oximeter can not change direction and no waveform display.

- ① Press the "power switch" key on front panel to turn the pulse oximeter power on.
- ② Place your one finger (forefinger or middle finger) into the cavity of the pulse oximeter. It is also available to measure if using your other fingers, such as thumb, ring finger or little finger.
- ③ Read the data display on the screen (about 3~4s). The bargraph height indicates the pulse strength.
- ④ The device will turn itself off automatically after 8 s idling.

⚠ The finger measured has no pathological change.

⚠ Do not use the fingertip pulse oximeter in situations where alarms are required. The device has no alarms of the SpO₂ and pulse.

⚠ Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical unit.

⚠ This fingertip pulse oximeter is neither suitable for continuous monitoring the same site of the same patient nor suitable for measuring neonate and infant. Check the finger touching site for every two hours. The finger measured should move or shift part if the finger skin changes. Some patients, such as the one with perfusion disorder or sensitive skin, may need frequent measurement. Long time continuous monitoring could increase the unexpected change in skin, such as sensitive, red, blister or pressure necrosis, etc.

⚠ The results may be wrong if you did not insert the finger thoroughly in the oximeter

⚠ Please use the medical alcohol to clean the finger and the oximeter rubber touched by finger. (The oximeter rubber is medical silicon, which has no toxin, no harmful to human skin and has passed biocompatibility test.)

⚠ Do not use the device in an MRI or CT environment. It may cause errors of measurement data.

⚠ Do not use the device in the presence of flammable anesthetic mixed with air, oxygen or nitrous oxide.

⚠ Portable and mobile RF communications equipment can affect medical electrical equipment.

⚠ These materials that contact with the patient's skin contain medical silicone and ABS plastic enclosure are all pass the ISO 10993-5 tests for invitro cytotoxicity and ISO 10993-10 Tests for irritation and delayed-type hypersensitivity.

⚠ Temperature may rise in the process of product use, but the temperature may not exceed 41 degrees and no harm will be caused to the user.

⚠ It is suggested that the device be used indoors or in the environment where there are no strong light and too much dust.

⚠ It is best to store the product in -20°C~+55°C and ≅93% humidity.

⚠ Do not dismount, take apart or maintain the product by self. Please contact the service provider if there is any problem of the product.

⚠ If the accuracy of the measurement by the device is uncertain, check the patient's vital signs by alternative means first. Then check the oximeter. Inaccurate measurement may be caused by the following factors.

- ① Ambient light radiation
- ② Patient movement
- ③ Diagnosis test
- ④ Low perfusion
- ⑤ Electromagnetic, such as using the cell phone nearby
- ⑥ Electrical equipment
- ⑦ The fingernail polish
- ⑧ Artery blood is too low to measure, which is caused by shock, anemia, low-temperature or vasoconstrictor.
- ⑨ Heavy smoking patient may appear instantaneous high CO, causing the increase of the hemoglobin CO.
- ⑩ Patients with severe jaundice will have high bilirubin, which metabolizes CO that shapes significant lever carboxyhemoglobin. Thus causes high SpO₂.

⚠ When the waveform display is not the law (AS-301, AS-302, AS-303, AS-304) or pulse bar graph does not bounce (AS-301-L, AS-302-L, AS-304-L), the displayed SpO₂ or pulse rate value is potentially incorrect. Because the waveform is under-normalized, so the signal waveform when the irregular or display line, the value of SpO₂ and PR displayed may be incorrect.

Product Accessories

- One lanyard
- One instruction manual

Battery Installation

- ① Open up the battery compartment cover
- ② Install two AAA batteries into the battery compartment correctly to match the positive and negative. Slide the battery door cover horizontally along the arrow

NOTE:

The device will automatically start and the luminous tube lights when the batteries installed correctly. Please remove the batteries if the pulse oximeter will not be used for long periods of time.

Cautions:

⚠ The battery power is showed in the middle of the screen. Please replace the Batteries when battery sign shows blank space.

⚠ Caution: Batteries polarities must be installed correctly, otherwise damage might be caused to the device.

⚠ Please remove the batteries from the battery compartment if the pulse oximeter will not be used for a long periods of time.

⚠ Follow local governing ordinance and recycling instructions regarding disposal of batteries, other electron devices and outer packing.

⚠ Keep the oximeter away from young children, Small items such as the battery door, battery and lanyard are choking hazards.

Using the Lanyard

Thread the thinner end of the lanyard through the loop which is used for lanyard. Thread the thicker end of the lanyard through the thinner end of it, and then pull it tightly.

⚠ Keep the pulse oximeter away from young children. Small items such as the battery door, battery, and lanyard are choking hazards.

⚠ Do not hang the lanyard from the device's electrical wire.

Maintenance

Cleaning:
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 device requires no routine calibration or maintenance other than replacement of batteries.

Disinfecting: Damage may be caused by disinfecting. It is recommended that the device should be disinfected when doctors think it is necessary. The device should be cleaned before disinfecting. Maintenance: Please power up three hours per three months to prevent the damage of the water vapor, if the device does not work for a long time or is stored in a moisture environment. Additional consideration for the maintenance, please follow the hospital maintenance plan.

⚠ Clean surface of the fingertips pulse oximeter before it is used to diagnosis for patient.

Do not use the caustic or abrasive detergent. It is recommended to keep the device in dry environment. Extreme moisture may affect product lifetime and cause damage.

Do not pour and spray liquids onto the fingertips pulse oximeter, accessories, connectors, switch, or do not allow any liquid to enter openings of the oximeter to prevent the damage of the oximeter.

The use life of the device is five years when it is used for 15 measurements every day and 10 minutes per one measurement. Please stop to use the product and follow local governing ordinance and recycling instructions regarding disposal waste.

⚠ The oximeter requires no routine calibration or maintenance during its life time. Please contact the service representative if one of the following cases occurs.

⚠ The oximeter is calibrated by simulation fingertip pulse oximeter before it leaves the factory, which can display the hemoglobin saturation.

- The device cannot show normally or do not display at all.
- The device cannot be powered on (New batteries have been changed.)
- The sensor of the oximeter was damaged seriously and causes the oximeter stop working properly.

⚠ If the sensor is damaged (not light), indicating that the sensor has been damaged. Please do not continue to use the oximeter. And contact your local dealer for processing.

NOTE:

A functional tester cannot be used to assess the accuracy of a pulse oximeter. Clinical testing is used to establish the SpO₂ accuracy. The measured arterial hemoglobin saturation value (SpO₂) of the sensors is compared arterial hemoglobin oxygen (SaO₂) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO₂ range of 70% - 99%. Accuracy data is calculated using the root-mean-squared (Arms value) of all subject, per ISO 80601-2-61 : 2011, Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

A functional tester is used to measure how accurately Fingertip Pulse Oximeter is reproducing the specified calibration curve and the PR accuracy. The model of functional tester is Index2 FLUKE simulator and the version is v3.00.

Technology

Display Type

LED digitron display

SpO₂

Measurement range: 36% ~ 99%

Resolution: 1%

Precision: ±2% (70% ~ 99%). Less than 70% no definition

Pulse Rate

Measurement range: 30bpm ~ 250bpm

Resolution: 1bpm

Precision: 1% or 1bpm choose the bigger one between the two

Low perfusion error

SpO₂ and pulse rate can be shown correctly when pulse-filling ratio is 0.2%.

Resistance to Ambient light interference ability

The deviation between the SpO₂ value measured in the condition of indoor day lighting or interior lights lighting, and that of darkroom is less than ±1%.

Power supply

d.c. 3.0V (2 × AAA alkaline batteries)

Working current

20mA ~ 130mA

Battery life

Not less than 12 hours

Safety type

Interior battery, Type BF

Direction sensor

Four directions 4 (optional)

Light sensor

Red light (wavelength 660nm ~ 666nm 7mW)

Infrared light (wavelength 890nm ~ 904nm 5.5mW)

Date update cycle

Not more than 12s

Degrees of protection

IP21

NOTE: The information about wavelength range can be especially useful to clinicians.

Dimensions

Length: 58.5mm Width: 32mm

Height: 32mm Weight: 30g

技术要求：
尺寸：285*206MM，不带出血

Environment Requirements

Operation temperature: 5-40°C
Ambient humidity: ≤80%
Atmosphere pressure: 86-106 kPa

Storage, transportation condition

Operation temperature: (-20~55) °C
Ambient humidity: ≤93% (no condensation)
Atmosphere pressure: (50~106) kPa

Troubleshooting

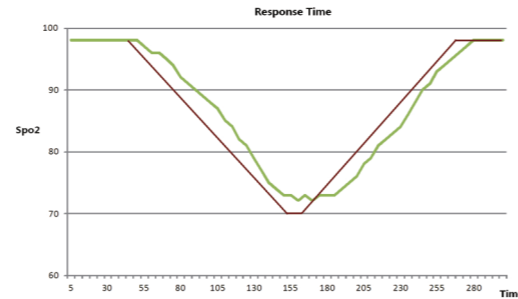
Problems	Possible Cause	Corrective Action
SpO2 or pulse rate is incorrect	Insert the finger incorrect position	Measure again after reinserting you finger
SpO2 or Pulse rate is erratic	①Finger might not be in the correct position ②Finger trembling or patient motion	①Reinsert the finger ②Patient must remain still
The oximeter does not turn on	①Batteries weak or batteries not installed ②Batteries incorrectly installed ③Damaged oximeter	①Replace the batteries ②Ensure the batteries are installed correctly ③Contact service representative
The screen suddenly shuts down	①The oximeter is powered off automatically when no signal of the finger is detected for long time ②Inadequate power of the batteries	①Normal ②Replace the new batteries
The oximeter blackout	The oximeter probe failure	The device failure, contact customer service
AS-301, AS-302 or AS-303, AS-304 displays waveform with no SpO2 and pulse rate	The signal of SpO2 is not integrity or not correct	Replace a finger and measure again The device failure, contact customer service
AS-301-L, AS-302-L, AS-304-L displays bargraph with no SpO2 and pulse rate	The signal of SpO2 is not integrity or not correct	①Replace a finger and measure again ②The device failure, contact customer service

Symbol Definitions

Symbol	Definitions	Symbol	Definitions
	Type BF Equipment		No SpO2 Alarm
	Attention! Consult accompanying documents		Use by date
	Oxygen saturation		CE MARK
	Pulse rate(BPM)		Manufacture's information
	Drip proof		Follow operating instructions
	Serial No.		Authorized representative in the European Community
	Symbol for disposed waste electrical and electronic equipment (Follow local governing ordinance and recycling instructions regarding disposal of batteries)		

Equipment Response Time

As shown in the following figure.
Response time of normal average is 10.4s



Electromagnetic compatibility

Note: Fingertip pulse oximeter AS-302-L, comply with the requirement of Electromagnetic Compatibility in YY 0505-2012. And IEC 60601-1-2:2007

The user needs to install and use according to electromagnetism compatibility information which is attached with it. Portable and mobile RF communication devices may influence fingertip pulse oximeter AS-302-L performance. So fingertip pulse oximeter AS-302-L should be kept away from the strong electromagnetic interference, such as adjacent to cellular phone, microwave oven etc. during using. Guidance and manufacturer's declaration stated in the appendix.

Warning: AS-302-L should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, AS-302-L should be observed to verify normal operation in the configuration in which it will be used.

Appendix:

Guidance and Manufacture's declaration – Electromagnetic emission		
The AS-302-L Fingertip Pulse Oximeter is intended for use in the Electromagnetic environment specified below. The customer or the user of AS-302-L should assure they are used in such an environment.		
Emission test	Compliance	Electromagnetic Environment-Guidance
FR emissions CISPR 11	Group 1	The AS-302-L Fingertip Pulse Oximeter use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
FR emissions CISPR 11	Class B	The AS-302-L fingertip pulse oximeter are 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 IEC 61000-3-2	Not Applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	
Guidance and Manufacture's declaration – electromagnetic immunity		
The AS-302-L Fingertip Pulse Oximeter is intended for use in the Electromagnetic environment specified below. The customer or the user of AS-302-L should assure they are used in such an environment.		

Immunity test	IEC60601 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 tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient /burst IEC 61000-4-4	±2kV Power supply lines ±1kV Input/output line	Not Applicable	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Line(s) to line(s) ±2 kV Line(s) to ground	Not Applicable	Main 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 % UT, for 0.5 cycle (>95% dip in UT) 40 % UT, for 5 cycles (60% dip in UT) 70 % UT, for 25 cycles (30% dip in UT) <5 % UT, for 5s (>95% dip in UT)	Not Applicable	Main power quality should be that of a typical commercial or hospital environment. If the user of the AS-302-L requires continued operation during power mains interruptions, it is recommended that the AS-302-L and be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field (50/60Hz) IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Note : UTis the a.c. mains voltage prior to application of the test level.			
Guidance and Manufacture's declaration – electromagnetic immunity			
The AS-302-L Fingertip Pulse Oximeter is intended for use in the Electromagnetic environment specified below. The customer or the user of AS-302-L should assure they are used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the AS-302-L including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance $d = 1.2\sqrt{P}$ $d = 2.3\sqrt{P}$ 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 D is the recommended separation distance in meters (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 the following symbol.
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Note 1 : Between 80MHz and 800MHz, 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 human bodies.

^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 AS-302-L is used exceeds the applicable RF compliance level above, the AS-302-L should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AS-302-L.
^b The frequency range between 150KHz ~ 80MHz, fields strengths should be less than 3 V/m.

Recommended distance between portable and mobile RF equipment and fingertip pulse oximeter AS-302-L

The AS-302-L are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AS-302-L can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AS-302-L as recommended below, according to the maximum output power of the communications equipment.

Maximum rated output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz ~ 80 MHz	80 MHz ~ 800 MHz	800 MHz ~ 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	Not Applicable	0.12	0.23
0.1	Not Applicable	0.38	0.73
1	Not Applicable	1.2	2.3
10	Not Applicable	3.8	7.3
100	Not Applicable	12	23

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 : Between 80 MHz and 800 MHz, the higher frequency range applies.
Note 2 : These guidelines may not apply in all situations. Electromagnetic transmission is affected by absorption and reflection of structures, objects and human bodies.

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Ver: A3 ISSUE Date: 2020.11.19

