70.00 mm

58.0 mm

正面

Pulse Oximeter
SK-006

Overview

Oxygen saturation is the percentage of Oxyhemoglobin (HbO2) that is combined with oxygen against all combinable Hemoglobin (Hb) and an important physiological parameter involved in respiration and circulation. Oxygen saturation is an important indicator of the oxygen level in the human body. The normal oxygen saturation of arterial blood in human body is 98% and in general should not be lower than 94%. If the oxygen saturation level is lower than 94%, it is considered to be insufficient supply of oxygen in the body.

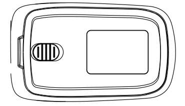
Pulse rate is the number of pulse beats per minute. Normally, the pulse rate is consistent with the heart rate. In general, the pulse rate of every person is 60 to 90 beats per minute.

Working principle and Scope of use

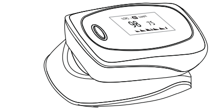
Shikon Fingertip Pulse Oximeter employs non-invasive, nexgen digital technology to measure the actual content (oxygen saturation) of oxyhemoglobin (HbO2) in arterial blood using the optical transmittance method. It measures the blood oxygen saturation and pulse rate of human body via finger artery.

The suggested use is applicable to a wide areas including domestic, medical, hospitals, oxygen bars, sports & health facilities to name a few. This device should not be used during sports activities or for continuous care of patients.

Appearance of the structure

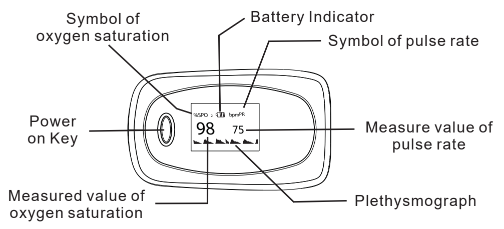


Battery Cover



Power on Key / function Key

Screen Display



The above figure shows the information display on the OLED screen of the Oximeter in normal detection state.

Operation Guide

- Insert two AAA Alkaline batteries in the battery compartment to operate the unit.
- Insert the finger into the measuring grip of the Oximeter by pressing open the clip. Ensure that the fingernail surface is acing upwards and release the clip.
- The finger should be inserted completely to get an accurate measurement.
- Press the power button to turn on the Oximeter.
- Keep the finger steady during measurement and ensure that the body does not move.
- Once the readings become stable, read the measured values of oxygen saturation (SpO2) and the pulse rate (PR) displayed on the screen.

⚠ NOTE: The Oximeter will automatically turn off within 10 secs after removing the finger.

Precautions

- Do not attempt to service / repair the Oximeter unless you are a professionally qualified service personnel.
- Please change the contact position between the oximeter probe and the fingertip periodically for anaccurate measurement. The contact position of the fingertip, once used lasts for two hours. Hence adjust the fingertip position, check the integrity of skin, the blood circulation condition of the fingertip before measuring in the Oximeter.
- This product should not be used for the measurement of newborn babies.
- Seek for medical assistance in case the measured value goes beyond the permissible limit with normal function of the Oximeter.
- Do not expose your eyes to the light-emitting component of the Oximeter as it is harmful when in direct contact to the eyes.
- To learn more about clinical limitations and contraindications, please consult the relevant medical literatures.
- The following factors may disturb or affect the accuracy during measurement:

» When the product is used in an environment involving high frequency devices, such as high-frequency electric knives and CT apparatuses.

» When the Oximeter probe is placed on the same body part or limb which is being used with blood pressure cuffarterial duct or intravenous injection.

» If the user is suffering from hypotension, severe vascular atrophy, severe anemia or low oxygen.

» If the user suffers sudden cardiac arrest or is in a state of shock.

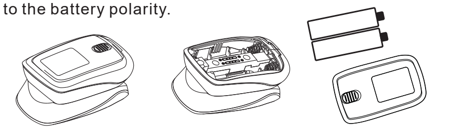
» A nail polished finger or a fake fingernail as it would display wrong readings of pulse oxygen saturation.

Warning:

- Do not use the Oximeter in an environment with any flammable gases, flammable anesthetic or any other flammable substances.
- Always use under adult supervision. Keep small children away from the Oximeter and the lanyard attached to it as may cause entanglement or choking hazard.
- Do not use the Oximeter in an MRI or CT scan environment.
- Do not operate the Oximeter if it is wet. Avoid moving the Oximeter from a cold to a hot and humid environment.
- Install the batteries properly before use. Remove the batteries when not in use for a long period.
- Always close the battery compartment while using the device.
- Do not modify the device or use it for any other purpose.
- No functional tester should be used to evaluate the accuracy of pulse oximetry probe or pulse oximetry monitor.

Replacing the batteries

⚠ Battery replacement is necessary once the battery symbol (▭) starts flickering on the display screen. This indicates low battery capacity which can affect the performance of the Oximeter.The batteries should be replaced correctly according to the battery polarity.



Cleaning Tips

- Turn off the device and remove the batteries before cleaning.
- Always ensure that the surface of the Oximeter should be neat, dust and dirt free.
- Clean the outer surface of the device (including the OLED display) using 75% medical alcohol and a piece of dry soft cloth.

背面

Disinfection Tips

- Before use, wipe the silicone finger pads using a piece of dry soft cloth dipped in 75% medical alcohol.
- Clean the finger to be measured using medical alcohol to disinfect before and after use.

⚠ Avoid pouring liquid on the device during the cleaning process as this may cause damage to the device.

⚠ Do not immerse any part of the device into any liquid.

⚠ Do not disinfect the device by use of high temperature or high-pressure or gas disinfecting process.

Maintenance

- Remove the batteries from the battery compartment and store properly if and when Oximeter is not in use for a long period.
- Avoid using the Oximeter in an environment with inflammable gases or 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 Specification

1. Dimensions: 62 mm × 37 mm × 32 mm
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 details: see the printed label on the box.
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 2.0V ~ 3.0V

6. Default values and Alert parameter

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

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

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℃ - 50℃ (14℉ - 144℉)
Relative humidity : 10% - 93% (no condensation)
Atmospheric pressure : 50 kPa - 106 kPa

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

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 ensure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 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 atleast 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV Input / output line	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Surge IEC 61000-4-5	± 1kV Differential mode voltage ± 2kV Common mode voltage	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
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 secs	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)
Power frequency (50Hz / 60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/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.			

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 is recommended below, according to the maximum output power of the communications equipment.			
Maximum output power of transmitter (W)	Separation distance according to freqency 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, their commended separation distance (d) in metres (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.			
NOTE 1: At 80 MHz and 800 MHz the separation distance for 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.			
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 $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output opwer 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, mamteur 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 aplicable 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 realocating the Blood Pressure Monitor. b) Over the frequency range 150 KHz to 80 KHz, field strengths should be less than [Vi] V/m.

This device is assembled in India using parts / components confirming to their respective technical specifications with knowhow from the respective manufacturer of these parts / components.The specifications / parameters may vary or maybe improved / amended for better efficacy and performance.

For any queries / assistance, please write to us with your concern by email to **feedback@myspaceage.com**.

Symbol Conversions

Symbol	Description
🯅	Type BF applied part
⚠	Caution: Please see this manual
%SpO2	Symbol of oxygen saturation
bpmPR	Symbol of pulse rate
⊠ SpO2	No SpO_2 alarms
ⓘ	Consult the instructions for use
IP22	The degree of protection against harmful ingress of water and particulate matter
🗑	When the product is abandoned, it must be disposed properly for recycling

Made in India by:
SPACEAGE MULTIPRODUCTS PRIVATE LIMITED
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