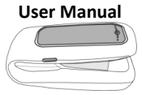
Fingertip Pulse Oximeter
User Manual



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Statement

Thanks for your purchasing Fingertip oximeter of Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd. (hereinafter called Konsung). Before using this oximeter, please read this manual carefully for understanding the operation and maintenance of the oximeter.

Konsung holds the rights to modify, update, and ultimately explain this manual.

Konsung owns the copyrights of this manual. Without prior written consent of Konsung, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

Materials protected by the copyright law, including but not limited to confidential information such as technical information and patent information are contained in this manual, the user shall not disclose such information to any irrelevant third party.

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which Konsung cannot be held liable.

Fingertip Pulse Oximeter is Class 1 LEDs product. It must be serviced by specified trained personnel.

Responsibility of the Manufacturer

Konsung only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

- Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Konsung, and
- The electrical installation of the relevant room complies with national standards, and
- The instrument is used in accordance with the instructions for use.

Upon request, Konsung may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which Konsung may define as user serviceable.

Chapter 1 Safety

1.1 Safety Information

The user should pay attention to and abide by the basic safety information which was referred to in this chapter.

WARNING

- A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

- A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

- A **NOTE** provides useful information regarding a function or a procedure.

WARNING

1. **This device is not intended for treatment.**
2. **Carefully read this manual about all safety information, operation and specifications before using this oximeter.**
3. **Do not open the shell of the instrument. Otherwise you may damage the instrument. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**
4. **Do not use this device with the defibrillator or other high-frequency equipment.**
5. **Explosion hazard: Do not use this device in an explosive atmosphere.**
6. **Check and change the applied site according to the different circumstances of the user while using this device for long-time continuous monitoring. It is recommended to check the finger after 2 hours. Change other finger to be measured if the finger seems to be unusual. If the oximeter is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.**
7. **The measuring data displayed on the device are for reference only and cannot be directly used for diagnostic interpretation.**
8. **This device is not intended to use of infant and neonate.**
9. **In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.**
10. **The presence of high ambient light may cause inaccurate SpO_2 measurements.**
11. **Charge this device only by connecting it to a designated device compliant with IEC60601-1 requirements of electrical safety and ensure the designated device's voltage and current meet the requirements of this Manual.**
12. **Do not connect it to any external device or operate it for measurement when this device is being charged.**
13. **Do not use this device in situations where alarms required. The oximeter does not support alarms.**
14. **Users who are allergic to rubber cannot use this product.**
15. **Disposal of this device and its accessories and packaging (plastic bags, foam and cartons, etc.) are subject to local laws and regulations.**

CAUTION

1. **To ensure patient safety, use only parts and accessories specified in this manual.**
2. **Keep the operating environment clean, no vibration, no corrosion or combustible material and avoid too high or too low temperature and humidity.**
3. **Do not use this device near by the source of electromagnetic interference, such as mobile phones or radio transmitter.**
4. **Do not spill liquid on the device. Do not immerse the device in liquid.**
5. **Always install or carry the device properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
6. **Do not use this device if the device cannot achieve satisfactory results.**

NOTE

1. **Too cold or too thin finger may affect the measurements; thicker finger (recommended thumb or middle finger) should insert into the cover fully.**
2. **Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line.**
3. **Check the device before using. Do not use it if there is significant damage.**
4. **Do not use the functional tester to access the SpO_2 accuracy.**
5. **This device is calibrated to display functional oxygen saturation.**
6. **The pictures and interfaces in this manual are for reference only.**
7. **This Manual is prepared based on the most complete configuration. Some configurations and functions may be not available in your device.**
8. **Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.**

1.2 Symbols

Symbols	Definition of symbols
	Follow instructions for use
	Caution
	No alarm
	Type BF Applied Part
	Battery indication
SpO_2	Oxygen saturation of arterial hemoglobin
PR	Pulse Rate
	The symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.
CE 1639	The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.
EC REP	Authorized representative in the European community
SN	Serial Number
P/N	Part Number
LOT	Batch number
	Manufacturer
	Date of manufacture
IP22	2 degree Protection Against Ingress of Liquids and dust.

Chapter 2 General

2.1 Introduction

Sonosat F fingertip pulse oximeter using spectrophotometry, by detecting the blood red and infrared absorption of light to obtain the oxygen saturation (SpO_2) and pulse rate (PR).
Oxygen saturation is a term referring to the fraction of oxygen-saturated hemoglobin (HbO_2) relative to total hemoglobin(Hb) in the blood, that is, the oxygen saturation in the blood, which is an important physiological parameter of the respiratory and circulatory system. Many respiratory diseases can cause oxygen saturation decrease. The body's automatic regulatory dysfunction caused by anesthesia, major surgery trauma, and injury caused by some medical examination etc., are likely to lead to the oxygen saturation decrease, resulting in patients with dizziness, weakness, vomiting and other symptoms; severe cases will be life-threatening. SpO2 has important significance in the field of clinical medical. And timely understanding of the patient's blood oxygen saturation situation will help physician find problems.
This device is not suitable for continuous monitoring of patients.

2.2 Intended Use and Contraindication

Intended use: The fingertip pulse oximeter is intended to measure the pulse oxygen saturation of arterial hemoglobin and pulse rate of adults and pediatrics in home care and medical outpatient environment.

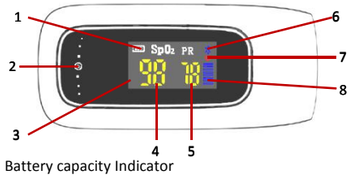
Contraindication: none

2.3 Applications

- This device is suitable for the following people: People with vascular disease, such as: coronary heart disease, hypertension, hyperlipidemia, cerebral thrombosis;
- People with respiratory diseases, such as: asthma, trachitis, chronic bronchitis, chronic cor pulmonale, chronic obstructive pulmonary disease;
- Old people above 60 years old
- People who works more than 12 hours a day;
- People works on extreme exercise or under the alpine hypoxic environment;
- Long-term alcohol people.

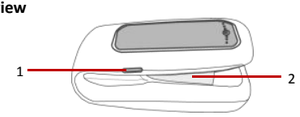
2.4 Appearance

2.4.1 Front view



1. Battery capacity Indicator
   - Full capacity, the middle part indicates the capacity.
   - Capacity is seriously empty, charge it immediately.
2. Power On/Off switch
   - Turn on the oximeter: Press the ON/OFF button to turn on the device.
   - Turn off the oximeter: Press this button for 2 seconds to turn the device off.
   - Press this button to highlight the display when the display is in low brightness.
3. Display screen
4. SpO_2 value
5. PR value: Pulse rate per minute.
6. Bluetooth icon
   - on: means connected to Bluetooth device
   - off: means disconnected to Bluetooth device
7. Heart symbol
8. Pulse rate bar graph

2.4.2 Side view



1. Micro USB connector: charging battery with specified charging cable connected to adaptor.
2. Rubber finger cover

Chapter 3 Unpacking and Storage

3.1 Open-case inspection

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or us. Take out all bulk packaging from the carton. If the packing case is intact, open the package and remove the equipment and accessories carefully.
Check whether there is any damage to the surface of the oximeter such as notches, dents, abrasions and so on. Check whether the components are missing according to packing list.

3.2 Storage

The oximeter is manufactured with precision parts. Do not place the oximeter in the following places:

- Easy to splash;
- With Direct sunlight, high temperature, humidity, dust, and corrosive gas;
- Tilt, generate vibration and impact;
- Store chemicals or corrosive gases.

Chapter 4 Measurement operation

1. Insert finger to oximeter's cover fully to obtain good measurements.

2. Press the ON/OFF button to turn the oximeter on.
3. SpO_2 and pulse rate value displays on screen.

NOTE:

1. **The oximeter cannot be measured while charging.**
2. **Finger can not apply nail polish and other cosmetics.**
3. **Do not shake the finger, hand or body during the measuring.**
4. **Tape or other light obstructions around the applied site may affect the accuracy of SpO_2 and pulse rate.**
5. **The oximeter will shut down if no any actions within 10 seconds after it turning on.**

The following factors may influence the accuracy of measurement:

- Ambient light
- Physical movement (passive and imposed motion)
- Diagnostic testing
- Low perfusion
- Electromagnetic interference, such as MRI environment
- Electrosurgical units
- Dysfunctional haemoglobin, such as carboxyhemoglobin (COHb)and methemoglobin (MetHb)
- Presence of certain dyes, such as methylene and indigo carmine
- Inappropriate positioning of the SpO_2 sensor, or use of incorrect SpO_2 sensor.
- Drop of arterial blood flow to immeasurable level caused by shock, anemia, low temperature or vasoconstrictor.

Chapter 5 Charging Battery

The oximeter uses a built-in non-removable rechargeable lithium battery. Symbol will flash when battery capacity is low. Charge the battery according to the following steps.

1. Take out the cable and connect it to oximeter's Micro USB connector.

2. Plug the other end of cable to USB adaptor. Battery symbol appear and flashes on the screen while charging.

The performance of the rechargeable lithium battery may deteriorate over time. If the operating time of the battery is noticeably shorter than that stated in the specifications, contact your service personnel.
Follow the appropriate local regulations and do not dispose of oximeter (includes battery).

Chapter 6 Accessories

Use only accessories specified in this manual. Using other accessories may cause damage to the pulse oximeter. Or the performance of oximeter cannot meet the specifications claimed in this specification.

The accessory material that contacts the user or other personnel has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.

- 1 USB Charging cable
- 1 User Manual
- 1 Quality Certificate

Chapter 7 Cleaning and Maintenance

7.1 Cleaning

To clean or disinfect the device should use materials and methods listed in this section. Otherwise, we shall assume no responsibility for the effectiveness.

The cleaning agents below can only be used for general cleaning. If you use them to control infections, we shall assume no responsibility for the effectiveness. Please consult the hospital infection prevention departments or epidemic experts for controlling infection.

To avoid damage to the oximeter, follow these rules：

- Dilute the agents according to your local distributor's suggestions. The recommended times of disinfection is three hundred.
- Never submerge the device in water or any cleaning agent, or pour or spray water or any cleaning agent on the device.
- Never permit fluids to run into the casing, switches, connectors, or any ventilation openings in the device.
- Do not allow liquid to enter the sensor connector
- Never use abrasive, erosive cleaners (such as steel wool, silver polishes), or cleaners containing acetone.

WARNING

1. **Disconnect power-supply before cleaning the pulse oximeter.**
2. **Be sure to shut down the oximeter and disconnect all power cables from the outlets before cleaning the oximeter.**
3. **Do not disinfect the oximeter with methods such as high temperature, high pressure, gas fumigation or liquid immerse. Follow the manufacturer's instructions of cleaning and disinfection for pulse oximeter.**
4. **Oximeter's regular calibration and maintenance should be taken by qualified professionals.**

Cleaning agents

- 70 vol% isopropyl
- 75 vol% ethyl alcohol

Do as follow steps when cleaning the device

1. Power off the oximeter.
2. Wipe the oximeter case with a soft cloth dampened with a cleaning agent. Recommended disinfection material, Alcohol based (Ethanol 75%, Isopropanol 70%) and aldehyde based.
3. Wipe off excessive cleaning agent with a dry cloth after cleaning.
4. Dry the oximeter in a cool ventilated environment.

Note:

1. **Don't attempt to disassemble the device or repair it unless you are trained personnel.**
2. **If you spill liquid on the equipment or accessories, Wipe the oximeter immediately and dry the oximeter. If the oximeter cannot work normal please contact us or your service personnel.**

7.2 Disinfection

Disinfection may cause damage to the oximeter. We recommend that you disinfect the oximeter only when necessary. Clean the oximeter before disinfection.

Recommended cleaning agent is Ethanol (75%).

The recommended times of disinfection is not more than 300.

Note: Never use EtO or formaldehyde for disinfection.

7.3 Maintenance

The overall check of the device should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

- If the environment condition and power supply meet requirement.
- If the device and accessories have damage.
- Specified accessories.
- Battery performance
- If all monitoring functions are in good conditions.

If any damage or abnormality is found, please don't use the device and contact local Customer Service Center.

Chapter 8 Specification

Safety specifications (classified according to IEC60601-1)	
Electric shock protection	Class II with internal power supply device
Degree of protection against electrical shock	Type BF applied part
Degree of protection against ingress of liquid	IPX1, non AP/APG type
Operating mode	Continuous

Physical Specifications	
LxWxH mm x mm x mm	SONOSAT-F01 series: 72 x 32 x 27 SONOSAT-F02 series: 68 x 32 x 27
Weight	SONOSAT-F01 series: less than 50g SONOSAT-F02 series: less than 50g

Hardware specifications	
Display screen	LCD
Buzzle	1, pulse tone
Charging connector	1, Micro USB connector

Environmental Specifications	**Working**	**Transport and Storage**
Temperature(℃)	5 ~ 40	-20 ~ 60
Relative humidity (non condensing)	30% ~ 80%	10% ~ 95%
Atmospheric Pressure(kPa)	70 ~ 106	70 ~ 106
Recommended maximum charge and discharge ambient temperature	Charge: 35℃； Discharge: 45℃	

Lithium battery (working power)	
Quantity	1
Voltage rating	3.7V
Battery capacity	300mAh
Run time	20 hours(Fully-charged new battery, Ambient temperature: 25℃)
Charging Voltage & Current	5V ~ 160mA
Charge time	2.5 hours (charge to 90% of capacity)
Shutdown delay	Max. 5 minutes after the low battery prompt first occurs.

Note: The information about wavelength range and maximum photic output consumption can be especially useful to clinicians, for example, clinicians performing photodynamic therapy.

Chapter 9 Troubleshooting

Problems	**Possible Reason**	**Solutions**
Device can't be powered on.	Critical low battery.	Please charge.
	Device might be damaged.	Please contact local customer service centre.
SpO_2 or PR value can't be shown normally.	The sensor is applied incorrectly.	Re-apply the sensor.
	There is very bright light.	Don't use the bright light device in the environment with high ambient light.
	Patient is in low perfusion or patient's oxyhemoglobin is too low to be measured.	Go to a hospital for diagnosis.
SpO_2 or PR value is unstable.	Finger might not be inserted deep enough.	Re-apply the senor.
	Finger is trembling or patient is moving.	Please keep quiet.

Chapter 10 Warranty and Service Policy

10.1 Warranty

Konsung warrants that **Konsung's** products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period. The warranty is void in cases of:

- damage caused by mishandling during shipping.
- subsequent damage caused by improper use or maintenance.
- damage caused by alteration or repair by anyone not authorized by Konsung.
- damage caused by accidents.
- replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, **Konsung** will, at its discretion, repair or replace the defective part(s) free of charge. **Konsung** will not provide a substitute product for use when the defective product is being repaired.

10.2 Contact Information

If any questions in equipment operation, please contact the manufacturer or local agency.

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Chapter 11 EMC

11.1 Electromagnetic Emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF(Radio frequency) emissions CISPR 11	Group 1	The oximeter uses 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(Radio frequency) CISPR 11	Class B	The oximeter is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Complies	

11.2 Electromagnetic Immunity-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the oximeter should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	2 kV for power supply lines 1 kV for input /output signal(>3m)	2kV for power supply lines 1 kV for input /output signal(>3m)	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	1 kV for line to line 2 kV for line to ground	1 kV for line to line 2 kV for line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC/EN 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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Oximeter requires continued operation during power mains interruptions, it is recommended that the Oximeter be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

11.3 Electromagnetic Immunity-for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of oximeter should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC/EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \frac{3.5}{V_1}\sqrt{P}$
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

			$d = \frac{3.5}{E_1}\sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{E_1}\sqrt{P}$ 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 Oximeter is used exceeds the applicable RF compliance level above, the Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Oximeter.

b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

11.4 Recommended Separation Distances

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

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter(m)**		
	150 kHz to 80 MHz $d = \frac{3.5}{V_1}\sqrt{P}$	**80 MHz to 800 MHz** $d = \frac{3.5}{E_1}\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \frac{7}{E_1}\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.36	0.37	0.74
1	1.16	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended 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) according 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.