康尚 Konsung

SONOSAT-W Series
Wrist Pulse Oximeter
User Manual

Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd

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Statement

Thanks for your purchasing wrist pulse 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.

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.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your measuring system.

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 equipment is not intended for treatment. Ensure that the equipment is in normal working condition and operating environment before using.**
2. **Carefully read this manual about all safety information, operation and specifications before using this oximeter.**
3. **Do not open the shell of instrument; otherwise you may damage the instrument. Only the authorized trained maintenance engineers are allowed to repair or upgrade this equipment. Any modification unauthorized will lead to data inaccurate or even damage of device.**
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. **It is recommended to check the applied finger during the measurement. Change other finger to be measured if the finger seems to be unusual.**
7. **The oximeter is intended only as an adjunct in patient assessment. It must be used with other methods of assessing clinical signs and symptoms. It is not intended as a device used for treatment purposes.**
8. **In some circumstances, the device may interpret motion as good pulse quality. Minimize patient motion as much as possible.**
9. **High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of a SpO_2 sensor.**
10. **Charge this equipment only by connecting it to a designated device compliant with electrical safety requirements and ensure the designated device's voltage and current meet the requirements of this Manual.**
11. **Do not connect it to any external device or operate it for parameter measurement when this equipment is being charged.**
12. **Do not use this device in situations where alarms required. This oximeter does not support alarms.**

CAUTION

1. **To ensure user's safety, use only parts and accessories specified in this manual.**
2. **Follow local governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.**
3. **Do not use this device near by the source of electromagnetic interference, such as mobile phones or radio transmitter.**
4. **Please keep the device surface dry and clean. Keep the device away from corrosive chemicals, dust, high temperature and humidity environment.**
5. **The environment temperature should be guaranteed (working temperature: 5°C to 40°C, transport and storage temperature: -20°C to +60°C).**
6. **This device should be appropriately placed. Keep it from falling, strong vibration, or other mechanical damage.**

NOTE

1. **Make sure the nail covers the light window. The wire should be on the backside of the hand.**
2. **Avoid placing the sensor on extreme cold finger. Fingernail polish or false fingernails may cause inaccurate SpO_2 readings.**
3. **The SpO_2 waveform is disproportionate to pulse.**
4. **Do not use this equipment on any limb with arterial cannula, intravenous infusion set or inflated blood pressure cuff.**
5. **Do not use any function tester to measure the SpO_2 accuracy.**
6. **The device was calibrated. Display arterial oxygen saturation (SpO_2) and pulse rate (PR).**
7. **If the detected signal is incomplete, the equipment will not display the parameter value but display the waveform as a straight line.**
8. **The pictures and interfaces in this manual are for reference only**
9. **This Manual is prepared based on the most complete configuration. Some configurations and functions may be not available in your equipment.**

1.2 Symbols

Symbols	Definition of symbols
	Follow instructions for use
	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
	Manufacturer
	Date of manufacture
IP22	2 degree Protection Against Ingress of Liquids and dust.

Chapter 2 General

2.1 Introduction

This device is a small, lightweight, portable device intended for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO_2) and pulse rate (PR). The device measures the patient's SpO_2 and PR with a SpO_2 senor. The measurements display on the screen after certain further processing.

2.2 Intended Use and Contraindication

Intended use: The Wrist Pulse Oximeter intended to be used for home care and medical outpatient measure pulse oxygen saturation and pulse rate of adults and pediatrics.

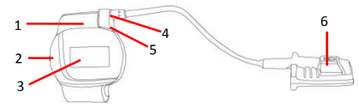
Contraindication: none

Structure and composition: This equipment mainly composed of the motherboard, SpO_2 transducer and built-in battery.

There are several type of Wrist Pulse Oximeter, refer to below chart for specifications.

Model	Battery	Bluetooth(Yes or No)
SONOSAT-W01T	Lithium	No
SONOSAT-W01W	Lithium	No
SONOSAT-W01P	Lithium	No
SONOSAT-W01LT	Lithium	Yes
SONOSAT-W01LW	Lithium	Yes
SONOSAT-W01LP	Lithium	Yes

2.3 Structure and composition



1. Wrist belt
2. Switch button
   Press this button to switch the display interface (measuring, time, step counter, battery indicator).
   Press and hold this button for 3 seconds, the screen display will change its display direction.
   Press and hold this button for 6 seconds to turn off the oximeter.
3. Display screen
4. SpO_2 probe connector
5. USB interface
   Connect SpO_2 probe
   Connect the USB charging cable
6. Probe finger sleeve

Screen display and description

Display	Description
SpO2%	Blood oxygen saturation
PR	Pulse rate
39%	Battery capacity
15:14 07/02 Mon	System time
100	Steps

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

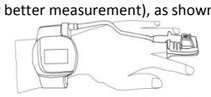
The oximeter is manufactured with precision parts. Do not place the oximeter in the following places:

- 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

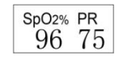
Follow the following steps to operate the oximeter.

1. Wear the oximeter on your wrist.
2. Connect the probe to the oximeter's USB interface, the probe sensor works, and emits red light.
3. Insert your finger into the probe's fingertip (fully insert your finger and make sure the probe sensor shines on the nail for better measurement), as shown below.



Note: The finger should be placed in the fingertip during working status of the probe sensor (lights red). If the probe sensor does not light red, you need to unplug the probe and re-connect it to the oximeter.

4. Press the function key to switch the oximeter to the measurement display, and the oximeter starts the measurement.
5. The oxygen saturation and pulse rate values are displayed on the screen.



WARNING

1. **Do not use the oximeter for measurement when the oximeter is in charge.**
2. **Do not shake fingers during measuring. Do not move your body and keep quite.**
3. **Inspect the sensor site every two or three hours and make sure that the good measurement site and sensor applied properly. Move the sensor to another site if the skin quality changes. Change the application site every four hours.**

The system time setting, the measurement reminder time setting, the walking steps function, and device settings such as screen lighting time, alarm setting and parameter alarm limit setting of the oximeter should be used with the mobile APP software. This manual does not describe these operations in detail.

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. Connect the adaptor connector into the Mini USB connector of oximeter.
2. Connect the adaptor into socket to charge the oximeter (the battery charging icon displays on the screen).

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

- 1 USB Charging Cable
- 1 SpO_2 Probe
- 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 Designations	
Type of protection against electric shock	Internally powered equipment
Degree of protection against electric shock	Type BF
Protection against ingress of liquids	IP22 (protected against ingress of water when the water is dripping vertically and the monitor is tilted up to 15°)
Mode of operation	Continuous
Power	150mW
Expected service life of device	5 years
Expected service life of SpO_2 sensor	3 years

Environment	**Working**	**Storage**
Temperature (°C)	5～40	-20～60
Humidity (non condensing)	30%～80%	10%～95%
Atmospheric pressure (kPa)	86～106	70～106

Lithium battery (working Power)	
Rated voltage	DC 3.5～4.2V
Battery capacity	300mAh
Battery run time	16h (fully-charged new battery, ambient temperature:25°C)
Charging voltage & current	5V, 160mA
Charge Time	2.5h
Battery service life	500 times of charge-discharge
Adaptor	
Input voltage	100-240V~, 50/60Hz
Output voltage	5V
Output current	1A
Output power	5W

Physical Specifications	
Size	68(L)×51(W)×11(H)(mm)
Maximum weight	<50g(including battery)

Hardware specifications	
Display screen	OLED, TFT-LCD
Motor	1, vibration prompt
Charging interface	1 USB interface

SpO2 probe specification	
SpO2 interface	8 pin USB interface
Length of probe	240±20mm
Transducer wavelength	Red light: 660nm; Infrared light: 940nm

Measurement specifications	
Refreshing time	1s
SpO_2	
Measuring range	0% to 100%
Measurement precision	70% to 100%, ±2% Less than 70%, unspecified
Measurement resolution	1%
Pulse rate	
Measuring range	18bpm to 250bpm
Measurement precision	25bpm to 250bpm, ±3bpm
Measurement resolution	1bpm
Update time	1s
Measurement	Red light: 660±3 nanometers
Wavelengths	

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.
Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.
Address: No. 8, Shengchang West Road, Danyang Development Zone, Jiangsu Province, China
Tel: +86-511-86375968
Fax: +86-511-86371668
E-mail: info@konsung.com

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 Radiated RF IEC/EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	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** $d = \frac{3.5}{V_1}\sqrt{P}$
3			
			$d = \frac{3.5}{E_1}\sqrt{P}$ 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.			