

Model SO911 Fingertip Pulse Oximeter Instruction Manual



Welcome to use the Fingertip Pulse Oximeter SO911.

To ensure the accuracy of measurement and safety of use, please read the manual carefully before use.

INDEX

GENERAL INFORMATION	3
PRODUCT INFORMATION	3.1
EXPLANATION OF SYMBOLS	3.2
SAFETY INFORMATION	4/5
SAFETY STANDARDS	4.2
SAFETY CONVENTIONS	4.3
SAFETY REQUIREMENTS	4.4
CAUTION	5.1
EMC STATEMENT	5.2
SCOPE OF APPLICATION	6
PRODUCT SCOPE	6.1
GENERAL DESCRIPTION	6.2
MEASUREMENT PRINCIPLE	6.3
FEATURES	6.4
OPERATION	7/8
PRODUCT OPERATION	7.1
DISPLAY DESCRIPTION	7.2
BUTTON OPERATION	8.1
ALARM	9
TYPES OF ALARM	9.1
LOW POWER ALARM	9.2
AUDIBLE ALARM	9.3
SPO2 AND PR ALARM	9.4
SPECIFICATIONS	10/11
SPO2 SPECIFICATIONS	10.1
POWER SPECIFICATIONS	11.1
PHYSICAL SPECIFICATIONS	11.2
ENVIRONMENTAL SPECIFICATIONS	11.3
TROUBLESHOOTING	12
REPAIR, MAINTENANCE & TROUBLESHOOTING	12.1
CERTIFICATE OF COMPLIANCE	13
WARRANTY & AFTER SALES SUPPORT	13.1
CERTIFICATE OF COMPLIANCE	13.2
WARRANTY CARD	13.3

3.1 Product Information

Product Name: Pulse Oximeter
 Product Model: SO911
 Display Mode: LCD Display
 Specifications: Finger Clip Type

3.2 Explanation of Symbols

The following symbols appear on the Pulse Oximeter and its packaging.









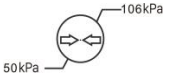


Symbol	Description	Symbol	Description
	BF Applied Part F-Type		Caution, Consult Accompanying
	Keep Upright		Date of Manufacture
	Keep Dry		Fragile, Handle with Care
	Humidity Limitations		Temperature Limitations
	Atmospheric Pressure Limitations		Serial Number
IPX1	Protective Grade		Compliance to WEEE Standard

Table 1: Pulse Oximeter and Packaging Symbols

4.1 Safety Standards

The manual uses the following Conventions for Notes, Cautions and Warnings.

Parameter	Specifications
Degree of Protection	Type BF Defibrillator-Proof: as per IEC 60601-1 Degree of Noxious Liquid-Proof as IPXI Anti-Shock Degree as BF Applied Part According to the Degree of Safety of Application in the Presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide, the Equipment is not suitable for use in the presence of a Flammable anesthetic mixture with air or with Oxygen or Nitrous Oxide.
Sterilization and Disinfection	As recommended by Manufacturer
Mode of Operation	Continuous

4.2 Safety Conventions

The manual uses the following conventions for Notes, Cautions and Warnings.

Note-A Note calls attention to an important point in the text.

Caution-A Caution calls attention to a condition or possible situation that could damage or destroy the product or the users work.

Warning-A Warning calls attention to a condition or possible situation that could cause injury to the user and/ or users.

4.3 Safety Requirements / Warning

- This device is intended for sport and recreational use.
- The Pulse Oximeter is not for diagnostic or therapeutic use.
- Never use the Pulse Oximeter during MRIs or CT scans.
- Never use the Pulse Oximeter in an environment of anesthetic gases.
- FUNCTIONAL TESTER cannot be used to assess ACCURACY.
- The skin temperature is initially at 35°C for each PULSE OXIMETER, the APPLIED PART temperature cannot exceed 41°C.
- The material that the Pulse Oximeter contacted to body is Non-toxic silica gel which meets the ISO10993 requirements, so can be safely used. But to some natural rubber latex sensitive user, there may be some allergic reactions.
- Only use accessories recommended by the manufacturer. Using other kinds of accessories might cause damage or personal injury. Modification of the Pulse Oximeter could be unsafe as applicable.
- The degrade sensor may degrade the performance.

5.1 Caution

This product is intended for use only as described in the instructions.

- I. To avoid personal injury, only use accessories and parts produced or recommended by our distributors, otherwise damage to the Pulse Oximeter may occur.
- II. The Pulse Oximeter must conform to the international standard IEC6001-1-2 and other applicable EMC standards. Interference takes place when electromagnetic energy is extremely high. Ensure that any nearby instruments are also in compliance with EMC standards. Never turn on or use portable communication devices like Mobile Phones or Portable Dual Channel Radios near a Pulse Oximeter.
- III. When power is lost for less than or equal to 30s, the ALARM SETTINGS prior to the power loss shall be restored automatically.
- IV. Ensure that qualified service representatives annually calibrate and maintain the Pulse Oximeter.
- V. Periodically check the Pulse Oximeter for damage. Dispose it according to your local hospital waste disposal regulations.
- VI. Clean and sterilize the Pulse Oximeter and accessories according to local requirements. Turn off the Pulse Oximeter before cleaning or sterilization.
- VII. Keep all Pulse Oximeter packing materials away from Children, Pet or Pests, or dispose of them in accordance with your local environmental regulations.
- VIII. Inhalation or swallowing of small parts which might be detached from Pulse Oximeter may cause choking.
- IX. Always properly dispose of the Pulse Oximeter and all accessories at the end of their service life. Dispose of batteries according to your local regulations. Never incinerate batteries or expose them to high temperatures.
- X. Ensure that no water condenses into or on the Pulse Oximeter. Condensation can occur from changes in temperature or exposure to humidity.

Warning: This device is not a complete substitute for medical treatment. It is not waterproof and shall not be used in liquids.

5.2 EMC Statement

1. Pulse Oximeter meets the requirement of electromagnetic compatibility in IEC60601-1-2.
2. The user needs to install and use according to the electromagnetic compatibility information which is attached with it.
3. Portable and Mobile RF communication devices may influence Pulse Oximeter performance, so Pulse Oximeter should be kept away from them during the usage.
4. Guidance and Manufacturer's declaration stated in the appendix.

6.1 Product Operation Scope

This Pulse Oximeter is a kind of innovated detection device with non-invasive and continuous features for artery SpO₂ and PR detection. It is portable and easy to measure the SpO₂ and PR value quickly and precisely. This can be through the finger Pulse Oximeter to meas Oxygen Saturation and Heart Rate.

This product is suitable for family, clinic, oxygen bar, sports health (use before and after exercise, it is not recommended to use during exercise), community health and other areas. Suitable age group is 15 to 60 years.

6.2 General Description

Hemoglobin Saturation is percentage of Oxyhemoglobin (HbO₂) capacity compounded with oxygen, by all combinative Hemoglobin (Hb) Oxygen (HbO₂) capacity in blood. In other words, it is consistence of Oxyhemoglobin in blood. It is a very important ecological parameter for Respiratory Circulation System. Many respiratory diseases can result in hemoglobin saturation might be reduced: such as Automatic Organic Regulation Malfunction caused by Anesthesia, Intensive Postoperative Trauma, Hurts resulted by some medical examination etc. In the situation, illness, such as light head, asthenia, vomitory etc., might happen to users and even endanger the user's life. Therefore, it is very important to know Hemoglobin Saturation of users timely in clinical medical aspects so that doctors can find problems in time. It is only necessary for users to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured value of Hemoglobin Saturation.

6.3 Measurement Principle

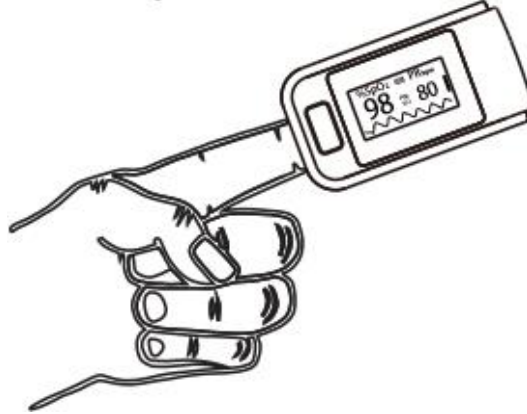
Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Beer-Lambert law according to Spectrum Absorption Characteristics of reductive Hemoglobin (R Hb) and Oxyhemoglobin (O₂Hb) in glow and near-infrared zones. Operation principle of the instrument is photoelectric Oxyhemoglobin Inspection Technology adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (600nm glow and 940nm near-infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor, then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LED through process in electronic circuits and microprocessor.

6.4 Features

1. LCD Display, Figure and Oxygen Volume Chart Display on Interface
2. Adjust the Display Interface Direction Manually, according to the user's observation data needs.
3. Audible Alarm Function.
4. Low Power Consumption (24 hours of continuous usage).
5. Low Perfusion $\leq 0.6\%$.
6. Low Voltage Indicator.
7. Automatic Power Off If No Signal in 8s.
8. Small and Light Weight Design, Convenient to Carry.

7.1 Product Operation

1. Install 2 x AAA (Triple-A) Batteries into the battery compartment in correct polarity as indicated and close the lid.
2. Press the Clamp, place one finger into the rubbery part with nail surface upward and release the clamp.



3. Press the Switch Button to Turn On the front panel.
4. Do not shake / tremble your finger when the Oximeter is measuring, also stay still and calm, do not move your body.
5. Read correspondent date from display screen.

Note: Please use the medical alcohol to clean the rubber touching the finger inside of Oximeter, and clean the test finger using medical alcohol before and after each test (the rubber inside of the Oximeter is medical grade rubber which has no toxin and not harmful to the human skin). Remove batteries when there is no use of it for a longer period.

Warning: The maximum application time for a PULSE OXIMETER PROBE is 4 hours continuously. The misapplication of a PULSE OXIMETER PROBE with excessive pressure for prolonged periods can induce pressure injury.

7.2 Display Description

Setting interface	<pre> Alm off Pulse Beep off SpO2 Lo 94 PR Hi 130 PR Lo 50 Restore on +/- + Exit + </pre>	
Pulse Oximeter interface	Without detection signal interface diagram	A detection signal interface diagram
Interface 1	<pre> %SpO2 PR bpm ----- P% ----- </pre>	<pre> %SpO2 PR bpm 98 P% 80 10.2 </pre>
Interface 2	<pre> %SpO2 PR bpm ----- P% ----- </pre>	<pre> %SpO2 PR bpm 80 P% 98 10.2 </pre>
Interface 3	<pre> P% PR bpm %SpO2 ----- </pre>	<pre> P% PR bpm %SpO2 10.2 80 98 </pre>
Interface 4	<pre> %SpO2 PR bpm P% ----- </pre>	<pre> %SpO2 PR bpm P% 98 80 10.2 </pre>

8.1 Button Operation

1. Install 2 x AAA (Triple-A) Batteries according to the instructions, the device will turn on automatically and display Interface #1; then place your finger for measuring, if there is no finger for detection and it is without the operation, it will power off automatically in 8s.
2. When there is a battery, but the Pulse Oximeter is powered off, press the button to turn on again.
3. During the measurement (there is a measurement signal and figure), press and hold the button during the measurement, it can turn to settings menu interface. Switch to different options by short press, modify the option by long press.

Option	Value	Description
Alm	On/Off, Default Off	Alarm Total Switch Include Pulse Beep
Pulse Beep	On/Off, Default Off	On: Buzzer On Off: Buzzer Off
SPO2 Lo	Range: 70~99, Default 94 Step Value 1%	Alm=On: The measurement of SPO2 value will flicker under the settings. Alm=Off: No effect
PR Hi	Range: 50~205, Default 130 Step Value 5 BMP	Alm=On: The measurement of PR Hi value will flicker above the settings. Alm=Off: No effect
PR Lo	Range: 45~200, Default 50 Step Value 5 BMP	Alm=On: The measurement of PR Lo value will flicker above the settings. Alm=Off: No effect
Restore	On/Off, Default On	On: Restore the default Off: Other options changed
+/-	"+" / "-", Default "+"	"+": The selected options of SPO2 Lo/PR Hi/PR value will increase. "-": The selected options of SPO2 Lo/PR Hi/PR Lo value will decrease.
Exit	None	Exit the settings.

Table 1: Button Operation

9.1 Alarm

The Pulse Oximeter uses the following alarm indicators: Audible Alarm and Visual Alarms.

Note: To correctly identify visual alarms, always observe the Pulse Oximeter within 1 meter of its position.

9.2 Low Power Alarm

When battery power is at lowest level, the battery capacity indicates empty in the LCD to remind users of replacement of the battery cells.

Note: When power is left for less than or equal to 30s, the ALARM SETTINGS prior to the power loss shall be restored automatically.

9.3 Audible Alarm

The audible alarm is a buzzer alarm; the auditory sound pressure range is 45dB~70dB.

9.4 SpO2 and PR Alarm

- Default alarming value of PR: High Limit = 130bpm, Lower Limit = 50bpm.
- Default alarming value of SpO2: 94%.
- When it is under operation conditions, if the measurement of the PR and SpO2 value exceed the set alarm limit and the alarm switch is on, it has a sound alarm and long buzzer alarm.
- When it is under operation conditions, if the PR sound switch is on, the measurement of PR will go with a PR sound.

To test the alarm according to the following:

- a) Connect the Pulse Oximeter to simulator.
- b) The simulator settings: SpO2 90%, PR 200bpm.
- c) The Pulse Oximeter alarm setting: SpO2 95%, PR High Limit 130bpm.
- d) Verify the Pulse Oximeter Alarm.

10.1 SpO2 Specifications

The update rate for the SpO2 value and pulse rate is typically 1 second of data on an average, and other signal processing on the displayed and transmitted data values of SpO2 and pulse rate is not more than 20 seconds. Depending on the magnitude of difference between the alarm limit and the displayed value, the alarm signal generation delay maybe from 1~20 seconds. The maximum alarm condition delay is 4 seconds, the Alum alarm signal delay is 20 seconds, the average alarm condition is 2 seconds, the average alarm signal is 10 seconds.

Because Pulse Oximeter measurements are statistically distributed, only approximately two-thirds of Pulse Oximeter equipment measurements can be expected to fall within Arms value measured by Co-Oximeter.

The signal adequacy is indicated by waveform, and it is NORMALIZED.

Note: The Pulse Oximeter EQUIPMENT is calibrated to display FUNCTIONAL OXYGEN SATURATION. It is not necessary to have a SpO2 calibration when the Pulse Oximeter is in use.

The following table describes the SpO2 specifications

Parameter	Specification
SpO2 Measurement Range	70%~100%
SpO2 Accuracy	$\pm 2\% \sim \pm 3\%$ in the range of 70%~100% Other scope is not defined
SpO2 Alarm Range	Consistent with the display range, the set step length is 1%
Pulse Rate Range	30bpm~250bpm
Pulse Rate Accuracy	$\pm 2\text{bpm}$ or $\pm 2\%$ to the maximum
Pulse Rate Alarm Range	Consistent with the display range, the set step length is 5bpm
Data Update Cycle	0.25s~2s
SpO2 PR Average	8s
Pulse Beep	Support
Peak Wavelength Range	500nm~100nm
Maximum Optical Output Power	150mW
Pulse Rate Display	Numeric
Display Specifications	LCD
Power Dissipation	In Normal Measurement, less than 25mA

Table 1: SpO2 Specifications

11.1 Power Specifications

The following table describes the power specifications

Parameter	Specification
Battery	DC3V, 2 x AAA (Triple-A)
	The Pulse Oximeter powers off if the battery power is almost depleted.

Table 1: Power Specifications

11.2 Physical Specifications

The following table describes the physical specifications

Parameter	Specification
Size	57.8 x 31.3 x 35.9 mm

Table 2: Physical Specifications

11.3 Environmental Specifications

The following table describes the environmental specifications

Parameter	Specification
Temperature	Operating: 5° C~50° C Storage: -10° C~+40° C for the device
Relative Humidity	Operating: 15%~80% (non-condensing) Storage: Less than 95% (non-condensing)
Biometric	Operating: 86kPa~106kPa Storage: 50kPa~106kPa

Table 3: Environmental Specifications

12.1 Repair, Maintenance & Troubleshooting

1. Regular inspection is required to make sure that no obvious damage exist to affect the safety and performance of the device.
2. Make sure that no flammable substance, overtop or lower temperature and humidity exist in the operation conditions.
3. When lower power capacity light is in red color, please replace the battery right away.
4. Please clean the surface before applying for detection.
5. Please take out the battery when device is not being used for a longer period of time.
6. If there is a dust or dirt on the surface, medical alcohol with 75% density can be used to clean the surface, please use dry fabric with little alcohol to wipe it with.
7. The transportation and storage conditions are: Temperature: 10 °C~40 °C, Humidity: Less than 95%.

Please use the following instructions for Troubleshooting

Trouble	Possible Reason	Solution
Instability of SpO2 and Pulse Rate Display	Finger is not placed inside enough. Finger is shaking or user is moving.	Place the finger properly and try again. Let the user to keep calm.
Device cannot Power On	Batteries are drained or low power. Batteries are not inserted properly. Device is malfunctioning.	Change the Batteries. Reinstall Batteries. Please contact the local service center.
Indicator Light has Turned Off Suddenly	Device powers off automatically if there's no signal for 8s. The Batteries are drained or low power.	Normal. Change the Batteries.
SpO2 and Pulse Rate Alarm	Value has exceeded the high alarm limit or it is below the low alarm limit.	Check the user's physical status, and alarm limit setup.

Table 1: Troubleshooting

13.1 Warranty & After Sales Support

1. This product is used for five years from the date of purchase; you can enjoy one-year free warranty.
2. The packaging is not covered by the warranty.
3. For the following damage caused by the user, please forgive us for not providing free warranty service;
 - a) Failure caused by unauthorized disassembly and modification.
 - b) Failure caused by accidental drop during use or handling;
 - c) Failure caused by not following the correct instructions in the manual;
 - d) Failure caused by lack of reasonable maintenance;
 - e) When requesting to provide free warranty service, you must hold the warranty card filled with the date of purchase and the seal of the purchase dealer (including the name and address of the dealer).
 - f) Repair services outside the warranty scope will be charged according to the corresponding regulations;
 - g) When requesting free warranty service, please take this product to the dealers of our company for repair.

13.1 Certificate of Compliance

CERTIFICATE OF COMPLIANCE			
PRODUCT NAME	FINGERTIP PULSE OXIMETER	MODEL	SO911
DATE OF INSPECTION		INSPECTOR	

This product has passed the inspection and is allowed to leave the factory.

13.2 Warranty Card

WARRANTY CARD			
BATCH NUMBER		PRODUCT CODE	
SELLER		DATE OF PURCHASE	
CUSTOMER'S NAME		CUSTOMER'S PHONE	
CUSTOMER'S ADDRESS		CUSTOMER'S EMAIL	
FAULT DESCRIPTION			