- A warning regarding stacking and location close to other equipment.
- A warning that use of other accessories results in non-compliance.
- The maximum temperature of sensors which the user will touch might reach 42°C when operating in the 40°C environment.
- The safety way for all people use is measuring for 10 minutes, and turn it off for 20 minutes before measure again.
- The oximeter is calibrated in the factory before sale, there is no need to calibrate it during its life cycle.
-. The product is with a service life of 5 years in the course of regular use.
-. If any serious incident (e.g. death) has occurred in relation to the device should be reported to the dealer, manufacturer, and the competent authority of the Member State in which the user and/or patient is established.

Cleaning

1. Please clean the surface of the device before using. Wipe the device with medical alcohol (70%(w/w) Ethanol) first, and then let it dry in air or clean it by dry clean fabric. When cleaning the device with water, the water temperature should be lower than 60°C
2. Using the medical alcohol to disinfect the product after use, prevent from cross infection for next time use.
3. The best storage environment of the device is - 25°C to 70°C ambient temperature and not higher than 90% relative humidity.

Note: 1. Do not sterilize, autoclave or immerse this device in liquid. Do not pour or spray any liquids onto the device.
2. Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.

Maintenance

Recommends user to return this device to the manufacturer perform the following checks every 24 months.
- Inspect the equipment for mechanical and functional damage or deterioration.
- Ensure all user interface keys and accessories function normally.

Note: Manufacturer use simulator of model Index 2 to verify operation of the pulse oximeter equipment.

Troubleshooting

Symptoms	Check points	Corrections
SpO2 or pulse rate cannot displayed	Applied finger improperly.	Place the finger properly and try again.
	SpO2 is too low to detect	Try again; go to consult with your physician if you are sure the device works well.
SpO2 or pulse rate are not displayed stably	Applied finger improperly.	Place the finger properly and try again.
	Finger is shaking or body is moving.	keep body steady
No display when button is pressed	Batteries run down	Replace with new batteries
	Batteries not inserted correctly.	Re-insert batteries
The display disappears suddenly	The device will auto power off when it gets no signal.	Normal
	Low battery	Replace with new batteries

⚠ Note: If the unit does not work, return it to your dealer. Under no circumstance should you disassemble and repair the unit by yourself.

Specification

SpO2	
Measuring range	35%~99%, (the resolution is 1%).
Accuracy	70%~99%: ±2%, Below 35~69%: unspecified.
Optical Sensor	The wavelength of red LED is 660 nm and Infrared LED is 905/880 nm with maximum optical output power of 4 mW/sr.
Pulse	
Measuring range	30 bpm~250 bpm (the resolution is 1 bpm)
Accuracy	±3 bpm
Power source	AAA × 2 (Alkaline)
Battery life	Continually for 16 hours with two alkaline batteries
Operating Condition	Temperature: 5°C~40°C (41°F ~ 104°F), Relative Humidity: 15-95% (non condensing), Atmospheric pressure: 700hPa ~ 1060hPa, Attitude: -1,280 to 12,000 feet (-390m to 3,658m)
Storage / Transportation Condition	Temperature: -25°C~+70°C(-13°F ~ 158°F), Relative humidity: 15-90%(non condensing), Atmospheric pressure: 700hPa ~ 1060hPa, Attitude: -1,280 to 12,000 feet (-390m to 3,658m), The time from 70°C or -25°C back to use : 3 hours
Dimensions	63.5(L) × 34W) × 35(H) mm
Weight	About 37g (without the batteries)
Standards	IEC60601-1-2, Class B, IEC60601-1, Type BF, ISO80601-2-61, IEC/EN60601-1-11
	Type BF applied parts
IP Classification	IP22: Protection against harmful ingress of water and particulate matter

Note:
- A description of the effect on displayed and transmitted SpO2 and pulse rate:
- Data averaging: 4 seconds for SpO2; 8 seconds for pulse rate.
- Data update delay: Less than 2 seconds.

EMC guidance and manufacturer's declaration

Recommended separation distances between portable and mobile RF communications equipment and the ME equipment

The Finger-tip pulse oximeter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Finger-tip pulse oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Finger-tip pulse 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=[3.5/V1]√P	80 MHz to 800 MHz , d=[3.5/E1]√P	800 MHz to 2,5 GHz , d=[7/E1]√P
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

Declaration – electromagnetic emissions

The Finger-tip pulse oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Finger-tip pulse oximeter should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
RF emissions CISPR 11	Class B	The Finger-tip pulse oximeter is suitable for use in all establishments, including domestic establishments 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	N/A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	N/A	

Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are use in the professional healthcare facility environment or in the home healthcare environment

The Finger-tip pulse oximeter declaration – electromagnetic immunity

The Finger-tip pulse oximeter system is intended for use in the electromagnetic environment specified below. The customer or the user of the Finger-tip pulse oximeter system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms ; 6 Vrms ; 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Radiated RF IEC 61000-4-3	3 V/m ; 10V/m ; 80 MHz – 2.7 GHz	80% 3 V/m ; 10V/m ; 80 MHz – 2.7 GHz ; 80%	
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710 MHz 745 MHz 780 MHz 28 V/m 810 MHz 870 MHz 930 MHz 28 V/m 1720 MHz 1845 MHz 1970 MHz 28 V/m 2450 MHz 9 V/m 5240 MHz 5500 MHz 5785 MHz	27 V/m 385 MHz 28 V/m 450 MHz 9 V/m 710 MHz 745 MHz 780 MHz 28 V/m 810 MHz 870 MHz 930 MHz 28 V/m 1720 MHz 1845 MHz 1970 MHz 28 V/m 2450 MHz 9 V/m 5240 MHz 5500 MHz 5785 MHz	

Declaration – electromagnetic immunity

The Finger-tip pulse oximeter system is intended for use in the electromagnetic environment specified below. The customer or the user of the Finger-tip pulse oximeter system should assure 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	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV ±1 kV differential mode ±2 kV common mode	N/A	Mains 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	0 % U_T; 0, 5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle And 70 % U_T; 25/30 cycle Single phase: at 0°	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

⚠ Note: The text is subject to change without further notice.

rossmax

Model: **SB100**

EN Fingertip Pulse Oximeter

www.rossmax.com

Warranty Card

This instrument is covered by a 2 year guarantee from the date of purchase, batteries and accessories are not included. The guarantee is valid only on presentation of the guarantee card completed by the dealer confirming date of purchase or the receipt. Opening or altering the instrument invalidates the guarantee. The guarantee does not cover damage, accidents or non-compliance with the instruction manual. Please contact your local seller/dealer or www.rossmax.com.

Customer Name: _____

Address: _____

Telephone: _____

E-mail address: _____

Product Information: _____

Date of purchase: _____

Store where purchased:

_____

WARNING: The symbol on this product means that it's an electronic product and following the European directive 2012/19/EU the electronic products have to be dispose on your local recycling centre for safe treatment.

Rossmax InnoTek Corp.
12F., No. 189, Kang Chien Rd.,
Taipei, 114, Taiwan.

EC REP CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº 18, CP 29006,
Málaga, Spain

ISO CE 13485 2460

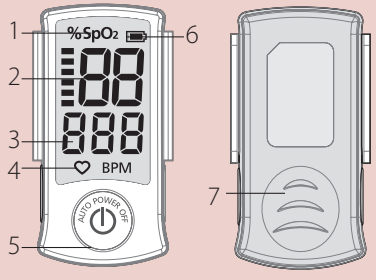
RL_IB_SB100_EN_2Yr_
TPCMC_ver2301
IN0SB100000000254

Introduction

Rossmax Fingertip Pulse Oximeter SB100 is used to measure arterial oxygen saturation (% SpO2) of hemoglobin and pulse rate, an important indicator of your respiratory function. It is non-invasive device intended for spot-check of adult and pediatric whose age is over 3 at home, hospital.

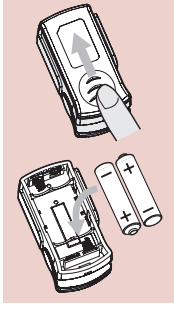
Attention: Consult the accompanying documents. Please read this manual carefully before use. Please be sure to keep this manual.

Name/ Functions of each part



1. SpO2 icon
2. Pulse strength indication
3. Beats per minute
4. Pulse rate icon
5. Power On Button
6. Battery icon
7. Battery compartment

Installing Batteries



1. Use thumb to slide battery cover out
2. Insert or replace 2 "AAA" sized batteries down with the correct electrical polarity.

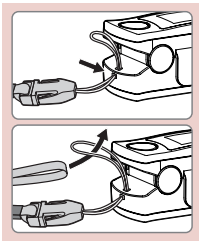
You need to replace the batteries when

1. Battery icon is blinking on display.
2. The function button is pressed and nothing appears on display.

Caution: Batteries may leak or explode if used or disposed of improperly. Remove batteries if the device will be stored for long time. Do not use different types or brands of batteries at the same time. Do not mix fully charged and partially charged batteries at the same time.

Attaching the lanyard

1. Insert the narrow end of the lanyard through the holder.
2. Draw the other end of the lanyard through the loop at the narrow end and tighten.



How to use

1. Open the clip; press the Power On button as ❶.
2. Information of software version appears; insert one finger, nail side up, into the finger opening of the pulse oximeter.

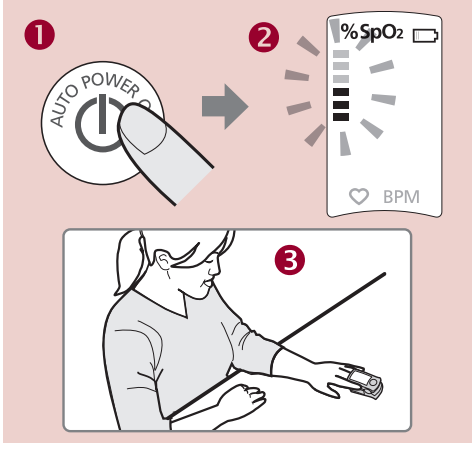
Note: if no finger insert, the device will auto shut off after 8 seconds.

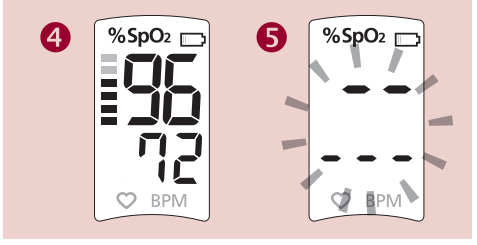
3. The pulse strength indication shows "▬", pulse oximeter begins its measurement as ❷.

Note: make sure the finger is lying flat, Do not shake and keep body steady during measurement as ❸.

4. Your SpO2 and pulse rate values will appear on the screen after few seconds as ❹.

Note: 1. Don't remove your finger until the measurement is completed.
2. If SpO2 and pulse rate cannot be detected, "-- --" will appear on the screen as ❺.
3. While pulse strength is low, the reading will flicker.

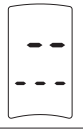




⚠ Note:

1. The SpO2 sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
2. Make sure the optical path is free from any optical obstacles like rubberized fabric.
3. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
4. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

Error code for your reference

SENSOR ERROR: 	Sensor cannot be detected, return the device to your local distributor or service centre.
MEASURE ERROR: 	Signals cannot be detected, turn the device off and measure again.

Cautionary Notes

- This device is to be operated by trained personnel only.
- This device has no audible and it intended only for spot-checking, but not medical result evaluation.
- This device is designed to determine the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade pulse oximeter performance or affect the accuracy of the measurement include the following:
  - Do not apply the pulse oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line(s)
  - Excessive light, such as sunlight or direct home lighting.
  - Not steady at the site of application (e.g. trembling)
  - Moisture in the device
  - Improperly applied device
  - Finger is too large or too small to fit into the device.
  - Poor pulse quality
  - Venous pulsations
  - Anemia or low hemoglobin concentrations.
  - Cardiogreen and other intravascular dyes
  - Carboxyhemoglobin
  - Methemoglobin
  - Dysfunctional hemoglobin
  - Artificial nails or fingernail polish
  - On fingers with anatomical changes, oedemas, scars or burns.
- Using the device for long periods may cause pain for people with circulatory disorders. Reposition the device at least once every 4 hours to allow the patient's skin to breath and to check patient's condition regularly.
- Do not use the device near flammable or explosive gas mixtures.
- Do not use the device during an MRI or CT scan, be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer
- The device may not work when circulation is reduced. Warm or rub the finger, or re-position the device.
- This device is a precision electronic instrument and must be repaired by qualified technical professionals. Field repair of the device is not possible. Do no attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- Do not overextend the device's spring.
- A functional tester cannot be used to access the accuracy of a pulse oximeter monitor.
- Do not self-diagnose or self-medicate on the basis of the measurements without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- Do not look directly inside the housing during the measurement. The red light and the invisible infra-red light in the pulse oximeter are harmful to your eyes.
- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.
- Neither of the displays for the pulse wave and pulse bar allows the strength of the pulse or circulation to be evaluated at the measurement site. Rather, they are exclusively used to display the current signal variation at the measurement site and do not enable reliable diagnostics for the pulse.
- A warning that other cables and accessories may negatively affect EMC performance.