- 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 SpO_2 device, 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.
- The maximum temperature of sensors which the user will touch might reach 43°C when operating in the 40°C environment.
- The safety for user use in high-temperature environment 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 during its life cycle.

Cleaning

1. Please clean the surface of the device before using. Wipe the device with medical alcohol (70% isopropyl alcohol)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.

Troubleshooting

Symptoms	Check points	Corrections
SpO_2 or pulse rate cannot displayed	Applied finger improperly	Place the finger properly and try again
	SpO_2 is too low to detect	Try again; go to consult with your physician if you are sure the device works well
SpO_2 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

SpO_2	
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)
Dimensions	63.5(L) × 34(W) × 35(H) mm
Weight	About 37g (without the batteries)
Standards	IEC60601-1-2, Class B, IEC60601-1, Type BF, ISO80601-2-61, IEC60601-1-11
	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 SpO_2 and pulse rate:
- Data averaging: 4 seconds for SpO_2; 8 seconds for pulse rate.
- Data update delay: Less than 2 seconds.

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 Index2 SpO_2 simulator to verify operation of the pulse oximeter equipment.

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=[3.5/E1]√P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.67	11.67	23.33

Declaration – electromagnetic emissions and immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING and are specified for use only in a shielded location

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 150 kHz to 80 MHz	3V	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 80 MHz to 2.5 GHz	3V/m	

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	±6 kV contact ±8 kV air	±6 kV contact ±8 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	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	<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 s	<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 s	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	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.

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.

Emission test	Compliance	Electromagnetic environment-guidance
CE emissions CISPR11	Group 1	The Finger-tip pulse 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 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	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

⚠ Note:
1. The product is with a service life of 5 years in the course of regular use.
2. 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.
3. The text is subject to change without further notice.

rossmax

Model: **SB200**

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.
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ISO CE 13485 2460
RL_IB_SB200(com)_EN_2Yr_IP_ver2132
IN0582000000000313

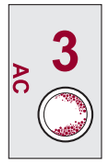
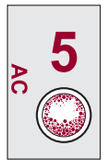
Introduction

Rossmax Fingertip Pulse Oximeter SB200 is used to measure arterial oxygen saturation (% SpO_2) 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 and clinics.

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

ACT (Artery Check Technology)

ACT processes the SpO_2 signal and determines the elasticity of blood vessel based on the derived wave form. It further classifies the vascular status into 6 levels and presents the result in an intuitive graphical interface.

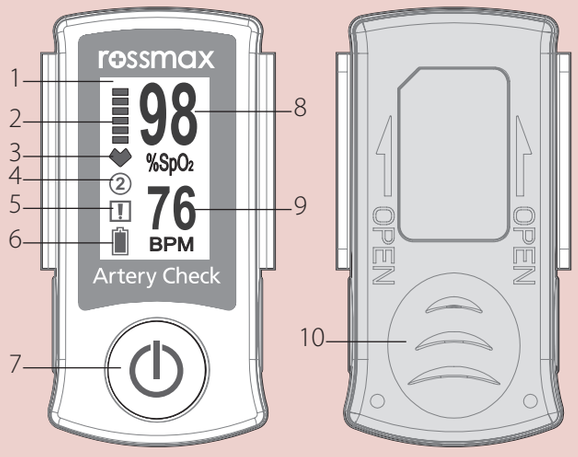
	Artery and blood circulation in excellent condition.
	Artery and blood circulation in good to average condition.
	Artery and blood circulation in average condition.
	Artery and blood circulation in below average condition.
	Artery and blood circulation in poor condition.
	Artery and blood circulation in critical condition.

⚠ Note: the classification of artery and blood circulation condition is for reference only, Please consult with your physician for further advice.

Error code for your reference

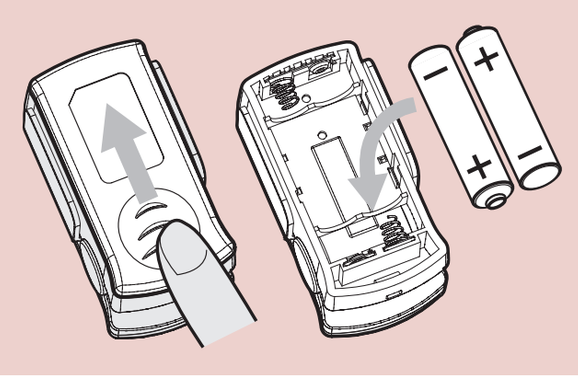
SENSOR ERROR: 	Sensor cannot be detected, return the device to your local distributor or service centre.
MEASURE ERROR: 	Signals cannot be detected, turn the device off and measure again.
AC ERROR: 	Weak signal for artery check, turn the device off and measure again.

Name/ Functions of each part



1. OLED display
2. Pulse strength
3. Pulse search icon
4. Artery check icon
5. Alarm icon
6. Battery indicator
7. Power On/Off Button
8. SpO_2 icon
9. Pulse icon
10. Battery cover

Installing Batteries



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

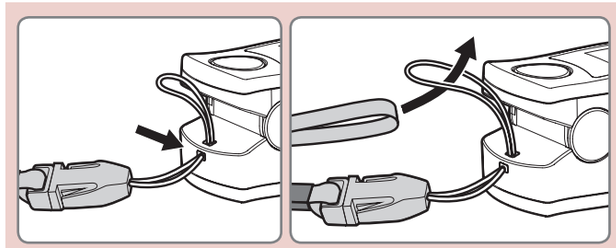
You need to replace the batteries when:

1. Low battery icon appears 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. The device will automatically shut down in low battery.

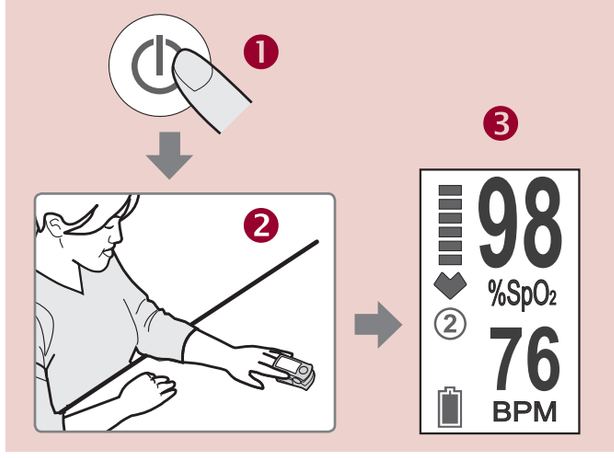
Attaching the lanyard

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.

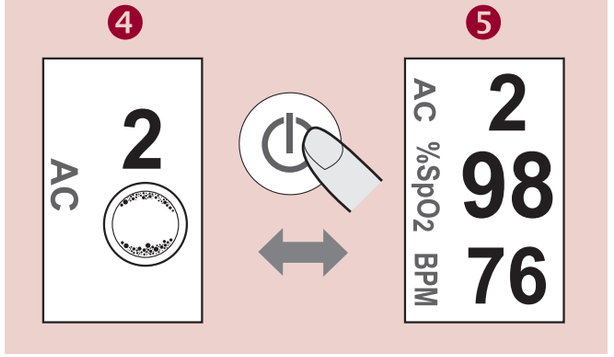


How to use

1. Open the clip; press the Power On/Off button as ❶.
2. Information of software version appears. Insert one finger(left hand middle finger is recommended), nail side up, into the finger opening of the pulse oximeter as ❷.
   Note: If no finger insert, the device will auto shut off after 30 seconds.
3. The display shows, pulse oximeter begins its measurement.
   Note: Make sure the finger is lying flat. Do not shake and keep body steady during measurement.



4. Your SpO_2 and pulse rate values will appear on the screen after few seconds and artery check result will appear on screen after 30 - 60 seconds as ❸.
   Note: If artery check result cannot be detected, "⊗" will appear on the screen.
5. Remove the finger, the screen will show artery check level as ❹.
6. Press button shortly to switch the display to the 3 parameters (artery check, SpO_2 and pulse rate) as ❺.



⚠ Note:

1. The SpO_2 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.
5. The device has a visual and audio signal when the measurement of SpO_2 is lower than 90%.

Cautionary Notes

- This device is to be operated by trained personnel only.
- The device has 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.