- For safe use by all individuals, measure for 10 minutes, then turn off the device for 20 minutes before measuring again.
- The oximeter is factory-calibrated before sale and does not require recalibration during its service life.
-. The product has a service life of 5 years under normal use.
-. Any serious incident (e.g., death) related 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 located.

Cleaning

1. Please clean the surface of the device before use. Wipe the device with medical alcohol (70% w/w ethanol), then allow it to air dry or clean it with a dry cloth. If cleaning the device with water, the water temperature should not exceed 60°C.
2. Disinfect the product with medical alcohol after use to prevent cross-contamination during the next use.
3. The optimal storage conditions for the device are an ambient temperature of -25°C to 70°C and a relative humidity not exceeding 90%.
Note: 1. Do not sterilize, autoclave, or immerse the device in any liquid. Do not pour or spray liquids onto the device.
2. Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropanol.

Maintenance

It is recommended that the user return this device to the manufacturer to 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: The manufacturer uses a simulator (model Index 2) to verify the operation of the pulse oximeter equipment..

Troubleshooting

Issue	Check points	Solution
SpO₂ or pulse rate cannot be displayed.	Finger is improperly positioned.	Place the finger correctly and try again.
	SpO₂ is too low to be detected.	Try again. If you are confident that the device is working correctly, please consult your physician.

	Finger is improperly positioned.	Place the finger correctly and try again.
SpO₂ or pulse rate is not displayed in a stable manner.	The finger is shaking or the body is moving.	Keep the body steady.
No display appears when the button is pressed.	Batteries are depleted.	Replace the batteries with new ones.
	Batteries are not inserted correctly.	Re-insert the batteries.
The display may suddenly turn off.	The device will automatically power off when no signal is detected.	Normal operation
	The battery is low	Replace the batteries with new ones.

⚠ Note: If the unit malfunctions, return it to your dealer. Do not attempt to disassemble or repair it yourself.

Specification

SpO2

Measuring range	35%–99% (resolution: 1%)
Accuracy	70%–99%: ±2%; 35%–69%: unspecified
Optical Sensor	The red LED has a wavelength of 660 nm, and the infrared LED has wavelengths of 905 nm and 880 nm, with a maximum optical output power of 4 mW/sr.

Pulse

Measuring range	30–250 bpm (resolution: 1 bpm)
Accuracy	±3 bpm
Power source	2 × AAA (Alkaline)
Battery life	The device can operate continuously for 16 hours using two alkaline batteries.
Operating Condition	• Temperature: 5–40°C (41–104°F) • Relative Humidity: 15–95% (non-condensing) • Atmospheric Pressure: 700–1060 hPa • Altitude: -1,280 to 12,000 ft (-390 to 3,658 m)
Storage / Transportation Condition	• Temperature: -25 to +70°C (-13 to 158°F) • Relative Humidity: 15–90% (non-condensing) • Atmospheric Pressure: 700–1060 hPa • Altitude: -1,280 to 12,000 ft (-390 to 3,658 m) • Recovery Time: 3 hours (time required to return to operational condition after exposure to -25°C or 70°C)
Dimensions	63.5(L) × 34W) × 35(H) mm
Weight	approx. 37 g (without batteries)
Standards	IEC60601-1-2, Class B, IEC60601-1, Type BF, ISO80601-2-61, IEC/EN60601-1-11
🚶	Applied Part Type: BF
IP Classification	Protection against solid objects >12.5 mm and vertically falling water drops

Note: Effect on displayed and transmitted SpO₂ and pulse rate:
- Data averaging: 4 s for SpO₂; 8 s for pulse rate.
- Data update delay: less than 2 s.

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	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	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 health-care 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	27 V/m 385 MHz	
	28 V/m 450 MHz	28 V/m 450 MHz	
	9 V/m 710 MHz 745 MHz 780 MHz	9 V/m 710 MHz 745 MHz 780 MHz	
	28 V/m 810 MHz 870 MHz 930 MHz	28 V/m 810 MHz 870 MHz 930 MHz	
	28 V/m 1720 MHz 1845 MHz 1970 MHz	28 V/m 1720 MHz 1845 MHz 1970 MHz	
	28 V/m 2450 MHz	28 V/m 2450 MHz	
	9 V/m 5240 MHz 5500 MHz 5785 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 volt- age variations on power supply input lines IEC 61000-4-11	0 % U₁; 0, 5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U₁; 1 cycle And 70 % U₁; 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.
Proximity Magnetic Field IEC 61000-4-39	30 kHz (8 A/m) 134.2 kHz (65 A/m) 13.56 MHz (7.5 A/m)	30 kHz (8 A/m) 134.2 kHz (65 A/m) 13.56 MHz (7.5 A/m)	Proximity magnetic fields quality should be that of professional healthcare facility or home health-care environment.

⚠ Note: The manufacturer uses a simulator (model Index 2) to verify the operation of the pulse oximeter equipment.

rossmax

Model: **SB100**

🇪🇳 **Fingertip Pulse Oximeter**

www.rossmax.com

⚠ **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.

Introduction

Rossmax Fingertip Pulse Oximeter SB100 is used to measure arterial oxygen saturation (%SpO$_2$) of hemoglobin and pulse rate, which are important indicators of respiratory function. It is a non-invasive device intended for spot-checking adults and children over 3 years old in home or hospital settings.

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 %SpO$_2$
6
2
3
4 BPM
5 AUTO POWER OFF
7
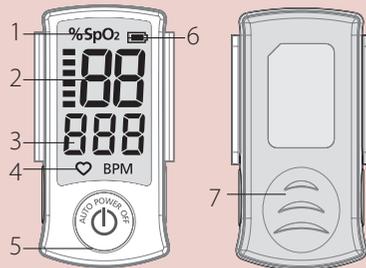
1. SpO2 icon
2. Pulse strength indication
3. Beats per minute
4. Pulse rate icon
5. Power On Button
6. Battery icon
7. Battery compartment

Installing Batteries

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

You need to replace the batteries when:
1. The battery icon is blinking on the display.
2. The function button is pressed and nothing appears on the display.

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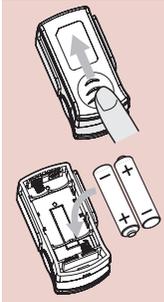
Attaching the lanyard

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.
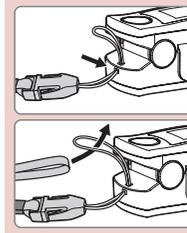
How to use

1. Open the clip; press the Power On button as ❶.
2. The software version information will appear on the display. Insert one finger, with the nail facing upward, into the finger opening of the pulse oximeter.
Note: If no finger is inserted, the device will automatically 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.

❶ AUTO POWER OFF
❷ %SpO$_2$ / BPM
❸
❹ %SpO$_2$ 96 72 BPM
❺ %SpO$_2$ / BPM
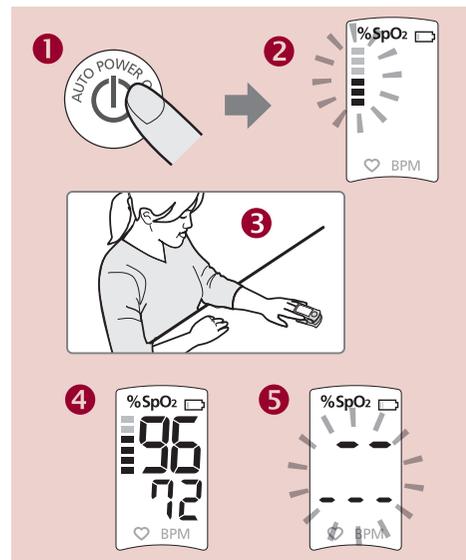
Note:
1. The SpO$_2$ sensor and the photoelectric receiving tube should be positioned so that the subject's arteriole lies between them.
2. Ensure that the oobsptical path is free from any obstructions, such as rubberized fabrics.
3. Excessive ambient light may affect the measurement results. This includes fluorescent lighting, dual-ruby lights, infrared heaters, direct sunlight, etc.
4. Strenuous movement by the subject or strong electrosurgical interference may also affect measurement accuracy.

Error code for your reference

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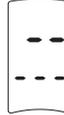
MEASURE ERROR:	
- - / - - -	Signals cannot be detected, turn the device off and measure again.

Cautionary Notes

- This device is to be operated by trained personnel only.
- This device does not have an audible alert and is intended solely for spot-checking, not for evaluating medical results.
- 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 prolonged periods may cause discomfort in people with circulatory disorders. Reposition the device at least once every 4 hours to allow the patient's skin to breathe and to regularly check the patient's condition.
- Do not use the device near flammable or explosive gas mixtures.
- Do not use the device during an MRI or CT scan. The device must be kept at least 30 cm (12 inches) away from any part of the device, including cables specified by the manufacturer.
- The device may not function properly when circulation is reduced. Warm or rub the finger, or reposition the device.
- This device is a precision electronic instrument and must be repaired by qualified technical personnel. Field repairs are not possible. Do not 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 assess 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.
- Warning: Other cables and accessories may adversely affect EMC performance.
- Warning: Do not stack the device or place it too close to other equipment.
- Warning: Use of unauthorized accessories may result in noncompliance.
- The maximum temperature of sensors which the user will touch might reach 42°C when operating in the 40°C environment.