SB200 Fingertip Pulse Oximeter Instruction for Use

1. Safety information

⚠ WARNING: The SpO_2 device is to be operated by trained personnel only.

⚠ WARNING: Do not use the SpO_2 device in the presence of flammable anesthetics or gas to prevent explosion hazard.

⚠ WARNING: Do not use the **SpO_2** device in the Magnetic Resonance Imaging (MRI) ambience.

⚠ WARNING: The SpO_2 readings and pulse signals can be affected by the conditions of ambience and patient.

⚠ WARNING: Do not open up the SpO_2 device except for the battery cover. The SpO_2 device is without any user-serviceable part inside and only qualified service personnel can perform maintenance service.

⚠ WARNING: Do not expose the SpO_2 device to extreme moisture (such as rain) to ensure accurate performance and device safety.

⚠WARNING: If the accuracy of measurement by the SpO_2 device is uncertain, check the patient's vital signs by alternate means.

⚠ Warning: This device is intended only as an adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms.

⚠ WARNING: Reposition the device at least once every 4 hours to allow the patient's skin to breath and to check patient's condition regularly.

⚠ WARNING: The SpO_2 device is not intended for the use of neonatal.

⚠ WARNING: Do not use the SpO_2 device with other devices (such as, the cuff of blood pressure monitor) that may interfere with blood flow and cause inaccurate measurement.

⚠ Warning: The SpO_2 device will be affected by electromagnetic interference or strong ambient light source during operation.

⚠ WARNING: User should stay calm and position finger stably. The accuracy of measurement taken right after exercise or during hand shaking could be compromised.

⚠ WARNING: SpO_2 should not be applied to a body part other than the finger or to a wounded body part.

⚠ Warning: Please remove the batteries from the battery compartment if the device will not be used for a long period of time.

1. Introduction

The Fingertip pulse oximeter is to spot-check oxygen saturation in blood (SpO_2) and pulse rate. The pulse oximeter is used on adults and pediatric at hospital, clinics, and/or home.

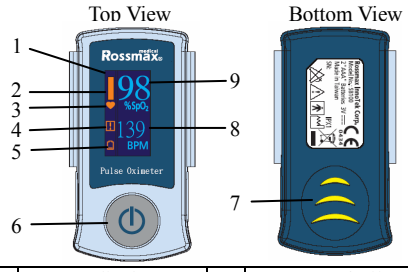
The device contains a dual light source (Red LED and Infrared red LED) and a photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations of blood flow. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO_2). Because a measurement of SpO_2 is dependent on light from the device, excessive ambient light can interfere with this measurement.

The wavelength of red LED is 660nm and Infrared LED is 905/880nm with maximum optical output power of 4mW.

2. Features

- Measure and display reliable SpO_2 value and heart rate and vascular age analysis.
- Single turn-on key for easy operation.
- Bright Organic LED display.
- Light, compact, and portable.
- Battery power is for a continuing use of 16 hours.
- Two "AAA" Alkaline batteries for power supply.
- Device will be off automatically after 8 seconds in idling.
- Visual alarm and audio alarm.

3. Product introduction



1	OLED display	6	Power On/Off Button
2	Pulse strength	7	Battery compartment
3	Pulse search icon	8	Pulse rate icon
4	Alarm icon or vascular age	9	SpO_2 icon
5	Battery indicator		

4. Operation

Open up battery compartment cover carefully and then install two "AAA" Alkaline batteries according to the (+/-) polarity.

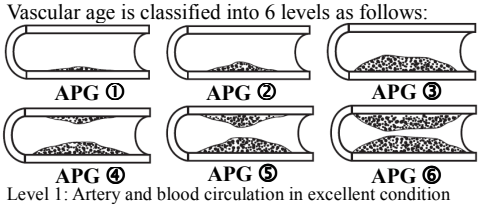
Press the "power switch" key for 1 second to activate the device. Information of version appears on the screen. The device is then in the "self-test" mode with the software version shown. The measurement starts at the completion of the "self-test."

Insert your finger into the device. For best results use the middle finger on your left hand.

The pulse bar with "-"icon on the screen up and down means the measurement result will be ready soon.

The readings of oxygen saturation, pulse rate, and pulse strength will appear on screen in 8 seconds average. The readings and icon of vascular age will appear on the screen in 30 seconds or maximum 2 minutes. Pressing "power switch" is to change the viewing direction. While SpO_2 exceeds the Min. threshold (90); the device will sound the alarm with two beeps and alarm icon flickering. If the measurement fails, the icon "- -"will appear on screen. Reading flashing while SpO_2 is low. While LED or sensor is malfunctioning, displaying "Er" signal.

Vascular age is classified into 6 levels as follows:



Level 1: Artery and blood circulation in excellent condition

Level 2: Artery and blood circulation in good condition

Level 3: Artery and blood circulation in above average Condition

Level 4: Artery and blood circulation in average condition

Level 5:Artery and blood circulation in below average condition

Level 6: Artery and blood circulation in poor condition

⚠ Warnings: The classification of artery and blood circulation condition is for reference only. Please consult your physician for further advice.

When the vessel elasticity cannot be measured, it will show ⊗

The device will turn itself off automatically after 8-second idling. While the battery power is low, the battery indicator icon will flash twice per second. Please replace the batteries as soon as possible or the device will be off automatically in 30 seconds.

5. Specifications

6.1 Performance

Scope of measurement: SpO_2: 35% - 99%

Pulse rate: 30-250 bpm (beats per minute)

Accuracy: SpO_2:70%-99%:±2%,35%-69%: unspecified

Pulse rate: 30-250 ± 3 bpm

6.2 Electrical specifications

Battery (2 "AAA" Alkaline batteries)

Battery capability: Can be used for 16 hours continuously depending on the type of battery used.

6.3 Environmental conditions

Operating temperature 5℃ - 40℃ (41˚F – 104˚F)

Storage temperature: -20℃ - 70℃ (-4˚F – 158˚F)

Relative humidity: 15% -95% (no condensing)

6.4 Physical characteristics

Weight: 37g (excluding battery) Size: 63.5 x 34 x 35 mm

6.5 Standards

IEC60601-1-2, Class B, IEC60601-1, Type BF, ISO 80601-2-61

6.6 Markings

	Type BF (Body Floating)
IPX 1	Drip proof
	ATTENTION Read instructions for use before use.
	Date of manufacture
	Used batteries should not be disposed of in the household rubbish. Batteries should be deposited at a collection point for used batteries. At the end of its life, the appliance should not be disposed of in household rubbish. Enquire about the options for environment-friendly and appropriate disposal. Take into account local regulations.
CE 0434	Complies with the European Medical Device Directive 93/42/EEC as amended by 2007/47/EC

7. Problem shooting and maintenance

7.1 Dysfunction and resolution

Low battery-Please replace the battery

Switch On failure-

- Check the power of battery
- Check the placement of battery
- Return to manufacturer for calibration

7.2 Cleaning

Surface cleanings is by using a soft cloth dampened with either a commercial, non-abrasive cleaner or a solution of 70% isopropyl alcohol in water, and lightly wiping the surfaces of the oximeter.

⚠Please switch off pulse oximeter before cleaning.

Clean the LED and photo-sensor with moist cloth or cotton ball and alcohol gently.

The aforementioned general cleaning process is not for infection prevention. Please contact the specialist for the process of contagious infection.

7.3 Disposal

Used batteries should not be disposed of in the household rubbish. Batteries should be deposited at a collection point for used batteries.

At the end of its life, the appliance should not be disposed of in household rubbish. Enquire about the options for environment-friendly and appropriate disposal. Take into account local regulations.

7.4 Electromagnetic interference

Caution: This device has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2 and MDD 93/42/EEC as amended by 2007/47/EC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare environments (for example, electrosurgical units, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may result in disruption of performance of this device.

This Fingertip pulse oximeter is not designed for use in environments in which the pulse can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly.

6. Warranty

The company warrants pulse oximeter at the time of its original purchase and for the subsequence time period of one year.

The warranty does not cover the followings:

- The device series number label is torn off or cannot be recognized.
- Damage to the device resulting from misconnection with other devices.
- Damage to the device resulting from accidents.
- Changes performed by users without the prior written authorization of the company.

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The text is subject to change without further notice.

CE 0434

Version 11; Jan. 20, 2016

EC REP IBP innovative business promotion GmbH
Botzstrasse 6, D-07743 Jena, Germany

Declaration of Conformity for EN 60601-1-2

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 $d=\left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
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	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV 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 sec	<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 sec	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.		
Emissions 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.
RE emissions CISPR11	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	