

SB100 Fingertip Pulse Oximeter

Instruction for Use•••

1. Safety information

⚠ WARNING: The SpO₂ device is to be operated by trained personnel only.

⚠ WARNING: Do not use the SpO₂ device in the presence of flammable anesthetics to prevent explosion hazard.

⚠ WARNING: Do not use the SpO₂ device in the Magnetic Resonance Imaging (MRI) ambience.

⚠ WARNING: The SpO₂ readings and pulse signals can be affected by the conditions of ambience and patient.

⚠ WARNING: Do not open up the SpO₂ device except for the battery cover. The SpO₂ device is without any user-serviceable part inside and only qualified service personnel can perform maintenance service.

⚠ WARNING: Do not expose the SpO₂ device to extreme moisture (such as rain) to ensure accurate performance and device safety.

⚠ WARNING: If the accuracy of measurement by the SpO₂ 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.

⚠ WARNING: The SpO₂ device is not intended for the use of neonatal.

⚠ WARNING: Do not use the SpO₂ device with other devices (such as, the cuff of blood pressure monitor) that may interfere with blood flow and cause inaccurate measurement.

⚠ Warning: The SpO₂ device will be affected by electromagnetic interference during operation.

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

2. Introduction

The Fingertip pulse oximeter is to spot-check oxygen saturation in blood (SpO₂) 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. The ratio of light absorbed is translated in an oxygen saturation measurement (SpO₂). Because a measurement of SpO₂ is dependent on light from the device, excessive ambient light can interfere with this measurement.

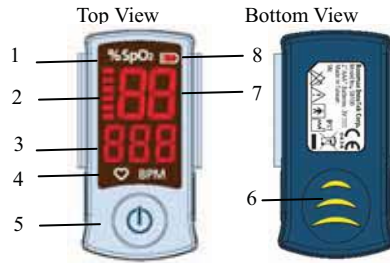
The wavelength of red LED is 660nm and Infrared LED is 905/880nm with maximum optical output power of 4mW.

There is no visual or audio alarm.••

3. Features

- Measure and display reliable SpO₂ value and heart rate.
- Single turn-on key for easy operation.
- Bright 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.••

4. Product introduction



1	% SpO ₂ signal	5	Power On/Off Button
2	Pulse strength	6	Battery compartment
3	Pulse rate	7	SpO ₂ icon
4	Beats per minute	8	Battery indicator

5. 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. All icons appear on the LED 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."

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 LED screen in 8 seconds average. If the measurement fails, the icon "- -" will appear on LED screen.

The device will turn itself off automatically after 8-second idling.

While the battery power is low, the LED icon will flash twice per second. Please replace the batteries as soon as possible or the device will be off automatically in 30 seconds.

6. Specifications

6.1 Performance

Scope of measurement: SpO₂: 35% - 99%

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

Precision: SpO₂: 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• - - 104•)

Storage temperature: -20• - - 70• •(-4• - - 158•)

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 9919: 2005

6.6 Markings••

	Type BF (Body Floating)
	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.
	Alarm function is off
	Complies with the European Medical Device Directive 93/42/EEC

••••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. 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.

8. 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 disconnection 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.••
August, 2008



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