SANTAMEDICAL

Operation Manual

Pulse Oximeter

SM-519BR-BL

Gurin Products, LLC
Warranty/Support Email - support@gurinproducts.com

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Product Description

Pulse Oximeter is an important and common device to check oxygen saturation (SpO_2) and pulse rate. It's compact, portable, easy to use, reliable and durable monitoring device.

Intended Use

This device is not intended to diagnose or treat any medical condition or disease. It is intended for non-medical use in healthy people to monitor their pulse and blood oxygen levels during sports and/or aviation only.

Contraindications

The pulse oximeter only applies to adults. And it is not suitable for injured skin tissue.

Measurement Principle

Arterial oxygen saturation is measured via a method which is called oximetry. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin (called spectrophotometer principle).
An experience formula of data process is established by taking use of Lambert Beer Law, and according to Spectrum Absorption Characteristics of hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow and near-infrared zones. The operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology. Two beams of different wavelength of lights (666nm visible red light and 905nm near infrared light) can be focused on human nail tip via emitters by adopting the Capacity Pulse Scanning and Recording Technology. Then measured signal will be obtained via a photosensitive element. The amount of light absorbed is related to the amount of oxygen in the blood during these pulses. The ratio of the two absorbed spectrums can be calculated via the microprocessor and the results are compared with the saturation value in the memory, so the blood oxygen saturation value is obtained.

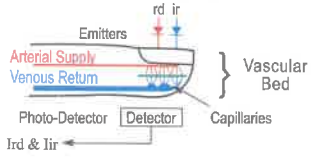

Diagram of Measurement Principle

Safety Information

- **Anyone who uses the pulse oximeter must receive adequate training before use.**
- **This device is not intended to diagnose or treat any medical condition or disease. It is intended for non-medical use in healthy people to monitor their pulse and blood oxygen levels during sports and/or aviation only. When using the pulse oximeter in conjunction with the electrical surgery equipment, the user should ensure safety of the user.**
- **EXPLOSION HAZARD: Do not use the pulse oximeter in the presence of flammable anesthetics, explosive substances, vapors or liquids.**
- **It is forbidden to use the pulse oximeter in MRI (magnetic resonance imaging) scanning or CT (Computed Tomography) because the induced current could cause potential burning.**
- **The pulse oximeter does not include an alarm function. Therefore, continuous monitoring for long periods of time is not suitable.**
- **Modification of the pulse oximeter is not allowed. Any product maintenance should be done by manufacturer-approved, professional maintenance personnel.**
- **Please switch off the power before cleaning the pulse oximeter. Disinfecting the pulse oximeter via high-pressure and high-temperature methods is prohibited. Any cleaning agents/disinfectants other than recommended ones listed in the operation manual are not allowed for use.**
- **The pulse oximeter is not waterproof. Keep its surface dry and clean and prevent any liquid from infiltrating the product.**
- **The pulse oximeter is fragile and requires precision to function properly. Avoid any pressure, jostling, strong vibrations, or other potential mechanical damage. Hold it carefully and lightly. If it is not in use, the pulse oximeter should be appropriately stored.**
- **Do not dispose the pulse oximeter randomly. Disposal procedure should follow local laws and regulations.**
- **Use AAA alkaline batteries. Do not use carbon or poor quality batteries. Remove the batteries if the pulse oximeter will not going to be used for a long time.**
- **A functional tester can't be used to assess the accuracy.**
- **User must read the operation manual carefully or consult with manufacturer before usage. If there's any discomfort while using the pulse oximeter, stop using it immediately.**
- **To avoid any static electricity damage to the pulse oximeter, direct or indirect static electricity should be discharged before usage.**
- **Try to keep the pulse oximeter away from any radio receivers when it's in use.**
- **The pulse oximeter should not be in close proximity (or stacked) with other devices. If that's not possible, it should be observed and verified that the oximeter can run normally with the close proximity /stacked configuration.**
- **There should be no dirt or wound on the tested surface (i.e finger).**

Product Feature

1. Simple and convenient operation with one button.
2. Compact, lightweight, and convenient to carry.
3. Long battery life of 15 hours.
4. Battery indicator on screen.
5. Will automatically turn off after 10 seconds when there's no signal.

Display Introduction

Figure 1

Battery Installation

1. Hold the product in one hand with the front panel facing the palm. Put the other hand's big finger on lid's press sign of the battery compartment, press downwards and push the lid and open it at the same time. The battery compartment is opened as shown in **Figure 2**
2. Install batteries into the slots according to the "+" and "-" symbols as shown in **Figure 3.**
   Cover the lid onto the battery compartment and push it upwards to make it close.

- **The positive and negative ends of batteries must be installed correctly, otherwise the device may be damaged.**
- **When installing or removing batteries, please follow the correct operation procedure, otherwise the battery compartment may be damaged.**

Figure 2

Figure 3

Lanyard Installation

1. Thread the thinner end of the lanyard through the lanyard hole. The position of the lanyard hole is shown in **Figure 4**. (Notice: the lanyard hole is on both sides.)
2. Thread the thicker end of the lanyard through the thinner end of the lanyard. Then, pull the thicker end of the lanyard until it's tight.

Figure 4

Directions for use

1. After properly installing two AAA batteries, press lid's press sign as shown in the **Figure 1** and open the clip. Let the testee's finger put into the rubber cushions of the clip, make sure the finger is in the right position as shown in **Figure 5**, and then loosen the clip.
2. Just wait for a moment, the SpO_2 value and PR value will be displayed on the OLED screen after plethysmogra wave and measured values are stable, as shown in **Figure 6.**

- **Be sure to place the user's finger inside the product in the correct orientation. The LED part of the sensor should be at the backside of the user hand. Be sure to insert the finger deep enough into the sensor so that the fingernail is opposite to the light emitted from the sensor.**
  Don't move the finger and remain motionless during the measurement.
- **Data update period is less than 30 seconds.**

Figure 5

Figure 6

NOTE:

- **Check the pulse oximeter for damage before use. If it's damaged, don't use it.**
- **Don't put the pulse oximeter on extremities with arterial catheter or venous syringe.**
- **Don't perform SpO_2 and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO_2 value.**
- **Don't use the pulse oximeter to measure users whose pulse rates are lower than 30 bpm (this may cause incorrect results).**
- **The well perfusion of measuring instrument should fully cover the test window of the sensor. Clean and dry the measurement part before storing the pulse oximeter.**
- **Cover the sensor with opaque material under strong light. Otherwise, the light can cause inaccurate measurements.**
- **Make sure that there is no contamination or scarring on the tested finger. Otherwise, the results may be incorrect.**
- **The product is prone to cross-contamination when used on different users. Disinfection is recommended before using the product on other users.**
- **Incorrect placement of the sensor may affect the accuracy of the measurements. The same horizontal position with heart should be chosen to achieve the best measurements.**
- **The highest temperature of usage shouldn't exceed 106 °F (41°C).**
- **Change sensor location and check skin integrity and circulatory status at least every 2 hours.**

Factors affecting measurement accuracy:

- **The measurements depend on absorption of special wavelength ray by oxidized hemoglobin and deoxyhemoglobin. The concentration of non-functional hemoglobin may affect the accuracy of the measurement.**
- **Shock, anemia, hypothermia, and vasoconstrictive drugs may decrease arterial blood flow to an unmeasurable level.**
- **Pigments or deep colors (i.e nail polish, artificial nails, dyes, or pigmented cream) may cause inaccurate measurements.**

Cleaning and Disinfection

- **Do not immerse the oximeters and any relevant accessories in water or disinfectant.**
- **We recommend that the product be disinfected only when necessary to avoid long-term damage to the product.**
- **Don't use cleaning agents/disinfectants other than the recommended models.**
- **Don't disinfect the device via high-pressure and high-temperature.**
- **Switch off the power and take out the batteries before cleaning and disinfecting.**

Cleaning

1. Clean the product with cotton or soft cloth moistened with water.
2. After cleaning, wipe off the water with a soft cloth.
3. Leave the device to dry naturally.

Disinfection

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde (2%) solution disinfectants.

1. Clean the product as instructed above.
2. Disinfect the product with cotton or soft cloth moistened with one of the recommended disinfectants.
3. After disinfection, be sure to wipe off the disinfectant left on the product with a soft cloth moistened with water.
4. Leave the device to dry naturally.

Packing List

The standard configuration	
Pulse Oximeter	1pc
Lanyard	1pc
The operation manual	1pc
Carrying pouch	1pc
AAA size battery	2pc

Expected service life: 3 years

Technical Specifications

1. Display mode: OLED

2. SpO_2:

Measurement range: 0~100%

Accuracy: ±3% （70%~100%）

3. Pulse Rate:

Measurement range: 25~250bpm

Accuracy: ±2bpm

- **Pulse Rate accuracy has passed the verification and comparison with SpO_2 simulator.**

4. Low perfusion:

Range: 0.5%~20%

SpO2 accuracy: ±3% (70%~100%)

PR accuracy: 25~250bpm ±2bpm

5. Electrical specifications:

Working voltage: D.C.2.2 V~D.C.3.4V

Battery Type: Two 1.5V AAA alkaline batteries

Power consumption: smaller than 50mA

6. Product specifications:

Size: 58 (H) × 34 (W) × 30(D) mm

Weight: 50g (include two AAA batteries)

7. Environment requirements:

Temperature:

Operation: +5~+40℃

Transport and storage: -10~+50℃

Humidity:

Operation: 15%~80%(noncondensing)

Transport and storage: 10%~90%(noncondensing)

Atmospheric pressure:

Operation: 860hPa~1060hPa

Transport and storage: 700hPa~1060hPa

NOTE:

- **A functional tester can't be used to assess this product's accuracy.**
- **The purpose of confirming the blood oxygen measurement's accuracy is to compare the oximetry measurement value with the value of blood gas analyzer.**

8. LED:

Wavelength: 666nm/905nm

Output power: <0.1mW

Troubleshooting

Trouble	Possible reason	solution
The SpO_2 and PR can't be displayed normally and the value disappeared.	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Please try again. 2. Replace the batteries.
The SpO_2 and PR display instable.	1. The finger is not placed inside enough. 2. The finger is shaking or the testee is moving.	1. Place the finger properly and try again. 2. Let the testee keep calm.
The device can't be powered on.	1. The batteries are drained or almost drained. 2. The installation of batteries is not correct. 3. The device's malfunction.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the supplier.
The screen is suddenly off.	1. The product is automatically powered off when no signal is detected longer than 10 seconds. 2. Power of the batteries is exhausted.	1. Normal. 2. Replace the batteries.

Symbol Meaning

Symbol	Meaning
	"CAUTIOUS"! Please refer to the operation manual.
	Type BF Equipment.
	The product does not contain alarm function.
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
	Information of manufacture, including name and address.
	Date of manufacture.
SN	Serial Number.
LOT	Batch Code.
REF	Type Number.
IP22	Degrees of protection provided by enclosure.

Appendix A EMC Declaration

Guidance and manufacturer's declaration - electromagnetic emissions - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration - electromagnetic emission		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The 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 CISPR11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity			
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
ELECTROSTATIC DISCHARGE [a] 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 floor are covered with synthetic material, the relative humidity should be at least 30%.
RATED power frequency magnetic fields [b] [c] IEC 61000-4-8	30A/m [d] 50 Hz or 60 Hz	30A/m [d]	Mains power quality should be that of a typical commercial environment.

[a] Discharges shall be applied with no connection to an artificial hand and no connection to USER simulation. USER simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.
[b] Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.
[c] During the test, the ME EQUIPMENT or ME SYSTEMS may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).
[d] This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEMS and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEMS will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS that are not LIFE - SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulse Oximeter should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted disturbances included by RF fields [a] IEC 61000-4-6	3 V [b] 0.15 MHz - 80 MHz 6 V b) in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V [b] 6 V [b]
Radiated RF EM fields [c] IEC 61000-4-3	10 V/m [b] 80 MHz – 2.7 GHz [d] 80% AM at 1 kHz [e]	10 V/m [b]

[a] The following apply:
- All USER-COUPLED cables shall be tested, either individually or bundled
- USER-COUPLED cables shall be tested, using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.
- No intentional decoupling device shall be used between the injection point and the USER COUPLING POINT in any case.
- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
- Tubes that are intentionally filled with conductive liquids and intended to be connected to a USER shall be considered to be PATIENT-COUPLED cables.
- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
- The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MZHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

[b] Before modulation is applied

[c] The interface between the USER physiological simulation, if used, and the ME EQUIPMENT or ME EQUIPMENT shall be located within 0, 1 m of the vertical plane of the uniform field area in one orientation of the ME EQUIPMENT of ME SYSTEM.

[d] ME EQUIPMENT and ME SYSTEM that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS. This test assesses the BASIC SAFETY and ESSENTIAL PERFORMANCE of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

[e] Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380—390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430—470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704—787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
810 870 930	800—960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
1720 1845 1970	1700—1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
2450	2400—2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240 5500 5785	5100—5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.
[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Distributed by

Gurin Products, LLC.

2522 Chambers Rd, #100

Tustin, CA-92780, USA

WEB: www.gurinproducts.com

Support – support@gurinproducts.com