BERRY®

Operation Manual Pulse Oximeter BM1000C



Shanghai Berry Electronic Tech Co., Ltd.

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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 a small, compact, simple, reliable and durable physiological monitoring device. Include the mainboard, display and dry batteries.

Intended Use

The pulse oximeter is a reusable device and it is intended for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment to check the user for hypoxemia. This medical device can be reused. Not for continuously monitoring.

Applicable people and scope

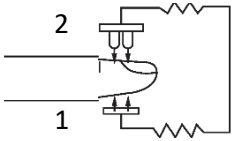
It is suitable for monitoring adults. It is used in clinic section office, out-patient department, sickroom. It can also be used in the recovery and health care organizations, the community medical treatments.

Contraindications

The product only applies to adults. Please don't use the product for children, infant and neonate. It is not suitable for injured skin. Products shall not be used for anesthesia, ICU, and Emergency care.

Measurement Principle

The operating principle is based on light transmission through the hemoglobin. The light transmission of a substance is determined by the Beer-Lambert law, which determines the concentration of a solute (oxyhemoglobin) in a solvent (hemoglobin) can be determined by light absorption. The blood stain depends on the blood oxygen levels, and the blood with high oxygen concentration presents red color due to high concentration of oxyhemoglobin. When the concentration is reduced, the blood takes on a more bluish, due to a greater presence of deoxyhemoglobin (combination of hemoglobin molecules with carbon dioxide). That is, blood is based on spectrophotometry, measuring the amount of light transmitted through the capillaries of the patient, synchronized with the heart pulse.



1. Infrared Light emitting 2. Infrared Light receiver

Safety information

• Adequate user training is necessary before device operation.
• The pulse oximeter is intended to used only as adjunct in patient assessment and without treatment purposes. It must be used in conjunction with clinical signs and symptoms.
• When using the pulse oximeter together with the electrical surgery equipment, the user should pay attention to and guarantee safety of the patient being measured.
• EXPLOSION HAZARD: Do not use the pulse oximeter in the presence of flammable anesthetics, explosive substances, vapors or liquids.
• Make sure not to use the pulse oximeter during MRI (magnetic resonance imaging) scanning or CT (Computed Tomography) environment because induced current could potentially cause burns.
• The pulse oximeter is without alarm function. Continuous monitoring for a long time is not suitable.
• No modification of this product is allowed. Maintenance should be operated by professional maintenance personnel who are approved by manufacturers.
Please shut off the power before cleaning the pulse oximeter.
• Never permit high-pressure and high-temperature disinfec-tion of the device. Never use cleaning agents/disinfectants other than the recommended.
• The product is commonly seal product. Keep its surface dry and clean, and prevent any liquid from infiltrating it.
• The pulse oximeter is precision and fragile. Avoid pressure, knock, strong vibration or other mechanical damage. Hold it carefully and lightly. If it is out of use, it should be appropri-ately placed.
• For disposal of pulse oximeter and accessories, follow local regulations or your hospital's policy regarding disposal of such pulse oximeter and accessories. Do not dispose random-ly.
• Use AAA alkaline batteries. Do not use carbon or poor quality batteries. Remove the batteries if the product is not to be used for a long time.
• A functional tester can't be used to assess the accuracy.
• If patient is an intended operator, you must read the operation manual carefully and understand deeply or consult with the doctor and manufacturer before using. If you have any discomfort when use, please stop using immediately and go to the hospital.
• Avoid electrostatic, before using the pulse oximeter, confirmed all the operators and patients are free from direct or indirect electrostatic.
• During operation, try to make the pulse oximeter far away from radio receiver.
• Please use the pulse oximeter which has specified EMC test system configuration, otherwise the anti-electromagnetic interference performance will be weakened or disappeared.
• The normal use of the pulse oximeter can be affected by portable and mobile radio frequency communication equipment.
• The pulse oximeter should not be stacked closely with other equipment, if you have to do it, you should observe and verify that it can run normally with the configuration which it uses.
• It should ensure that there is no dirt or wound on the tested part.
• Federal law restricts this device to sale by or on the order of a physician.
• If the product is intended to allow direct diagnosis or monitoring of vital physiological processes, then it is likely to result in the immediate danger to the patient.
• Please keep this oximeter and its accessories in a safe place to prevent pet bites from breaking or pests from entering. Keep oximeters and small parts such as batteries out of the reach of children to avoid accidents.
• Mental retarded persons must be under the guardianship of normal adults when using the device to avoid strangulation due to Lanyard.
• Connect accessory carefully to avoid the patient being twined or strangulated.

Product features

- Simple and convenient usage of product, simple one-touch operation.
- Small Compact, lightweight, convenient to carry.
- Lower consumption, original two AAA batteries can continuous-ly work for 15 hours.
- Low voltage reminder shows in screen when there's low battery.
- The machine will automatically switch off after 10 seconds when there's no signal generated.
- Communication can be realized between the product and mobile phone with its wireless Bluetooth.

Display introduction

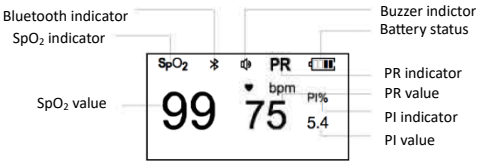


Figure 1

Measuring Steps

1. Install batteries into the slots according to the "+" and "-" symbols as shown in ***Figure 2.***
2. Let the tester's finger put into the rubber cushions of the clip, make sure the finger is in the right position as shown in ***Figure 3***, and then loosen the clip.
3. Press the power and function switch button on the front panel to tum on the product. Using first finger, middle finger or ring finger when doing test. The readings will be displayed on the screen a moment later as shown in ***Figure 4.***

• The positive and negative electrodes of batteries should be installed correctly. Otherwise, the device will be damaged.
• When install or remove batteries, please follow the correct operation sequence to operate. Otherwise, the battery compartment will be damaged.
• If the pulse oximeter isn't used for long time, please remove the batteries of it.
• Make sure to place the product on the finger in a correct direction. The LED part of the sensor should be at the backside of the patient hand and photodetector part at the inside. Make sure to insert the finger to suitable depth into the sensor so that the fingernail is just opposite to the light emitted from the sensor.
• Don't shake the device during use.
• Data update period is less than 30 seconds.

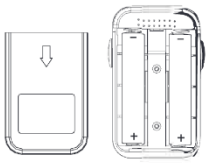


Figure 2

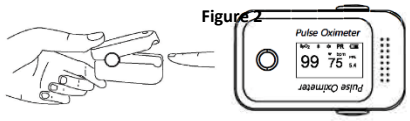


Figure 3 **Figure 4**

NOTE:

• Before measuring, the pulse oximeter should be checked whether it is normal, ifit is damaged, please don't use.
• Don't put the pulse oximeter on extremities with arterial catheter or venous syringe.
• Don't perform SpO_2 monitoring 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 patients whose pulse rate is lower than 30bpm, which may cause incorrect results.
• The measurement part should be chosen well perfusion and be able to fully cover the test window of the sensor. Please clean the measurement part before place the pulse oximeter, and ensure drying.
• Cover the sensor with opaque material under the condition of strong light. Otherwise, the light can cause inaccurate measurements.
• Make sure that there is no contamination and scar on the tested finger. Otherwise, the results may be incorrect, because the signal received by the sensor is affected.
• When used on different patients, the product is prone to crossed contamination, which should be prevented and controlled by the user. Disinfection is recommended before using the product on other patients.
• Incorrect placement of the sensor may affect the accuracy of the measurement, and it is at the same horizontal position with heart, measurement effect is the best.
• The highest temperature of sensor contacts with patient's skin don't be allowed more than 41 °C.
• The maximum application time at a single site does not exceed 2 hours.

Factors affecting measurement accuracy:

• The measurements also depend on absorption of special wavelength ray by oxidized hemoglobin and deoxyhemoglo-bin. Concentration of nonfunctional hemoglobin may affect the accuracy of the measurement.
• Shock, anemia, hypothermia and the application of vasocon-striction drug may decrease arteria blood flow to an unmeasurable level.
• Pigment, or deep color (for example: nail polish, artificial nails, dye or pigmented cream) may cause inaccurate measurements.
• When glycohemoglobin Ale levels are higher than 7%, such as in patients with type 2 diabetes, an overestimation of arterial oxygen saturation may occur. These situations may require an arterial blood gas to determine oxygen saturation accurately. It is also necessary to consider the clinical diagnosis when evaluating a patient with hypoxemic symptoms, as in the case of carbon monoxide toxicity.

Directions for use

1. After the product is turned on, pressing the power button can rotate the display direction. (as shown **in Figure 5, 6**)
2.Press the power button again, the display direction will return to its previous state. At the same time, the buzzer indicator will disappear and the buzzer will turn off temporarily. (as shown in ***Figure 7***)
3. After the product is turned on, long pressing the power button can permanently turn on/off the buzzer prompt function.
4. When the received signal is inadequacy, " -- --- " will be displayed on the screen. (as shown on ***Figure 8***)
5. When Bluetooth is not connected, the Bluetooth indicator will flicker, otherwise, the Bluetooth indicator will remain on.
6. The product will automatically shut down in IO seconds when the product does not detect finger insertion.

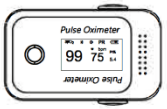


Figure 5

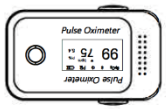


Figure 6

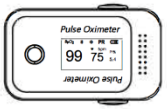


Figure 7

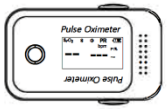


Figure 8

Signal inadequacy considerations

SpO^2 accuracy may be affected by signal inadequacy in various physiological and environmental conditions. This pulse oximeter indicates signal inadequacy through one or more of the following indicators:

1. PI (Perfusion Index)

The perfusion index can reflect the strength of the oxygen saturation signal.

2. Indicator

When the received signal is inadequacy, " -- --- " will be displayed on the screen.

In fact, many factors contribute to degradation of signal adequacy with potential loss of accuracy. The factors can include, but are not limited to: signal strength, noise frequency and amplitude, source of noise.

Bluetooth Communication Function

BMI 1000C pulse oximeter is with the Bluetooth communication function. It can send data to intelligent terminal and computer (Related software has been installed.) with communication function.

NOTE: The usage of Bluetooth communication software which is installed in the computer or intelligent terminal is written into the "APP operation guide".

Lanyard Installation

1. Thread thinner end of the lanyard through the hanging hole. The position of the hanging hole as shown in Figure 9. (Notice: the hanging hole is on both sides).
2. Thread thicker end of the lace through the threaded end before pulling it tightly.

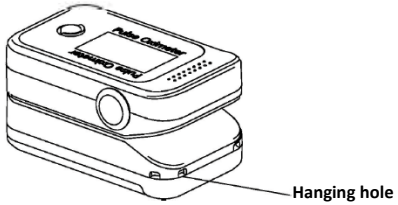


Figure 9

Cleaning and Disinfection

• Never immerse or soak the poise oximeter.

• We recommend cleaning and disinfecting the product when necessary or when used in different patients to avoid damage to the product.

• Never use cleaning agents/disinfectants other than the recommended.

• Never permit high-pressure and high-temperature disinfec-tion of the device .

• Please shut off the power and take out the batteries before clean and disinfect.

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. Allow the product to air dry.

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. Allow the product to air dry.

Packing List

The standard configuration	
Pulse Oximeter	1 pc
Lanyard	1 pc
The operation manual	1 pc

Expected service life: 3 years

Technical Specifications

1. Display mode: LCD

2. SpO_2:

Measurement range: 0-100%

Accuracy: ±2% (70%-100%)

3. Pulse Rate:

Measurement range: 25-250bpm

Accuracy: ±2bpm

• Pulse Rate accuracy has passed proving and comparison with Sp02 simulator.

4. Perfusion Index:

Measurement Range: 0.5%-20%

5. Electrical specifications:

Working voltage: DC2.2 V-DC3.4V

Battery Type: Two 1.5V AAA alkaline batteries (included)

Power consumption: less than 50mA

6. Product specifications:

Size: 58 (H) x 34 (W) x 30(D) mm

Weight: 50g (include two AAA batteries)

7. Environment requirements:

NOTE:

• When the environment temperature is 20°C, the time required for Pulse Oximeter to warm from the minimum storage temperature between uses until it is ready for intended use is 30 to 60 minutes.

• When the environment temperature is 20°C, the time required for Pulse Oximeter to cool from the maximum storage temperature between uses until it is ready for intended use is 30 to 60 minutes.

Temperature:

Operation: +5-+40°C

Transport and storage: -10-+50°C

Humidity:

Operation: 15o/.-80% (noncondensing)

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

Atmospheric pressure:

Operation: 860hPa-1060hPa

Transport and storage: 700hPa-1060hPa

8. LED:

Wavelength: 660nm/940nm

Output power: less than 15m W

9. Bluetooth:

Frequency range: 2402.00-2480.00MHz

Transmission distance: 10 m

Transmission rate: 4k Bytes/s

Modulation system: GFSK

Bluetooth protocol version: V5.0 and above

Arms Specifications

1. SpO_2 Arms:

SpO_2 range	Arms Specification
70-80%	1.65
80-90%	1.22
90-100%	1.11

2. Clinical Data Graphical Plot:

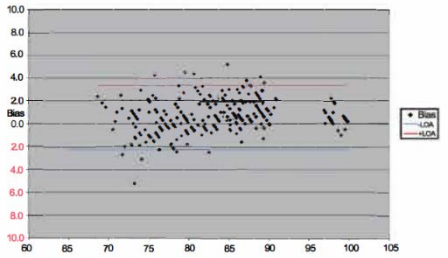
The clinical trial was performed according to ISO 80601-2-61. The purpose of the clinical trial was to evaluate the Sp02 accuracy of the BM! 000 series Fingertip Pulse oximeter during stationary(non-mo-tion) conditions over a wide of arterial blood oxygen saturation levels as compared to arterial blood CO-Oximetry.

After IRB approval. 12 healthy adult volunteer subjects (ages 20-41 yr, 42-95kg, 155-18lcm, with light to dark pigmentation) were included in the study conducted Nov. 9-10, 2013 to evaluate the SpO, accuracy performance of proposed devices.

BM1000C Pulse Oximeter

Hernoximeter Range	60-80	80-100	60-100	70-100	60-70	70-80	80-90	90-100
Mean	0.27	0.74	0.58	0.57	0.90	0.25	1.00	0.12
Count	102	185	287	284	3	99	131	54
Missing Data	0	2	2	2	0	0	0	2
Standard Deviation	1.84	1.25	1.42	1.42	1.23	1.85	1.22	1.11
Standard Error	0.16	0.09	0.08	0.08	0.71	0.17	0.11	0.15
95% Confidence Interval	0.32	0.18	0.16	0.17	1.39	0.33	0.21	0.30
Upper LOA	3.55	3.22	3.38	3.38	N/A	3.55	3.42	2.29
Lower LOA	-3.01	-1.73	-2.23	-2.24	N/A	-3.05	-1.42	-2.05
Maximum	4.50	5.20	5.20	5.20	1.80	4.50	5.20	2.40
Minimum	-5.20	-3.10	-5.20	-5.20	-0.50	-5.20	-1.60	-3.10
Root Mean Square	1.66	1.45	1.53	1.53	1.35	1.67	1.57	1.11

BM 1000C Pulse Oximeter



NOTE:

• A functional tester can't be used to assess the accuracy.

• The method of confirming the blood oxygen measurement accuracy is to compare the oximetry measurement value with the value of blood gas analyzer.

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. 3. Bluetooth signal is interrupted.	1. Please the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
		3. Check the Bluetooth connection and reconnect.
The SpO_2 and PR display instable.	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected. 3. Bluetooth signal is interrupted.	1. Place the finger properly and try again. 2. Make sure that the patient is calm and is not moving.
The device can't be powered on.	1. The batteries are drained or almost drained. 2. The installation of the 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
	Refer to instruction manual/booklet.
	Type BF applied part
UDI	UDI code
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
CE 0123	European Union for approval.
	Manufacturer
	Date of manufacture
SN	Serial Number
LOT	Batch Code
REF	Catalogue number
EU REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
IP22	The product is protected against harmful effects of dripping water per !EC 60529
	Recyclable

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