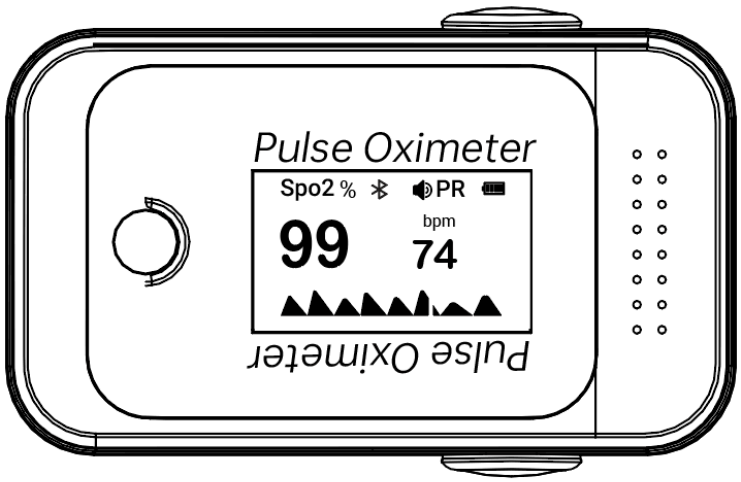
BERRY

Operation Manual

Pulse Oximeter

BM1000B/BM1000D



Shanghai Berry Electronic Tech Co., Ltd.

Release date: 07/28/2020 Version: 3.2

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 mnitoring device. Include the mainboard, OLED display and dry batteries.

Intended Use

The pulse oximeter is reuse device and intended use for spot checking of the pulse oxygen saturation and pulse rate for adult in clinic environment. This medical device can be reused. Not for continuously monitoring.

Applicable people and scope

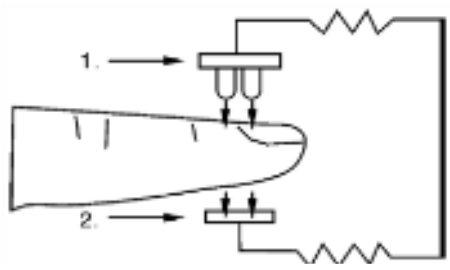
It is suitable for monitoring adults. It is used in clinic section office, out-patient department, sickroom. It can also be used in the recovery and health care organizations, the community medical treatments.

Contraindications

The product only applies to adults. Please don't use the product for children, infant and neonatal. The damaged skin tissue can't be measured.

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

- **The person who uses the pulse oximeter must receive adequate training before use.**
- **The pulse oximeter is intended only as adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. It is not intended as a device used for treatment purposes.**
- **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 clean the pulse oximeter. Never permit high-pressure and high-temperature disinfection 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 not in use, it should be appropriately 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 randomly.**
- **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 in use, please stop using immediately and go to the hospital.**
- **Avoid static electricity, before using the pulse oximeter, confirmed direct or indirect static electricity of all the operators and patients who contact with the instrument.**
- **When in use, try to make the pulse oximeter keep away from radio receiver.**
- **If the pulse oximeter uses unspecified and without EMC test system configuration, it can enhance electromagnetic radiation or reduce anti-electromagnetic interference performance. Please use the specified configuration.**
- **Portable and mobile radio frequency communication equipment can affect the normal use of the pulse oximeter.**
- **The pulse oximeter should not be close to or stacked with other equipments, if you must be close to or stacked them in use, you should observed 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 used under the guardianship of normal adults to**

avoid strangulation due to Lanyard.

- **Connect accessory carefully to avoid the patient being twined or strangulated.**

Product Feature

- Simple and convenient usage of product, simple one-touch operation.
- Small volume, light weight, convenient to carry.
- Lower consumption, original two AAA batteries can continuously work for 15 hours.
- Low voltage reminder shows in screen when there's low battery.
- The machine will automatically power off after 10 seconds when there's no signal generated.
- Communication can be realized between the product and mobile phone with its wireless Bluetooth. (Except "**BM1000D**")

Display Introduction

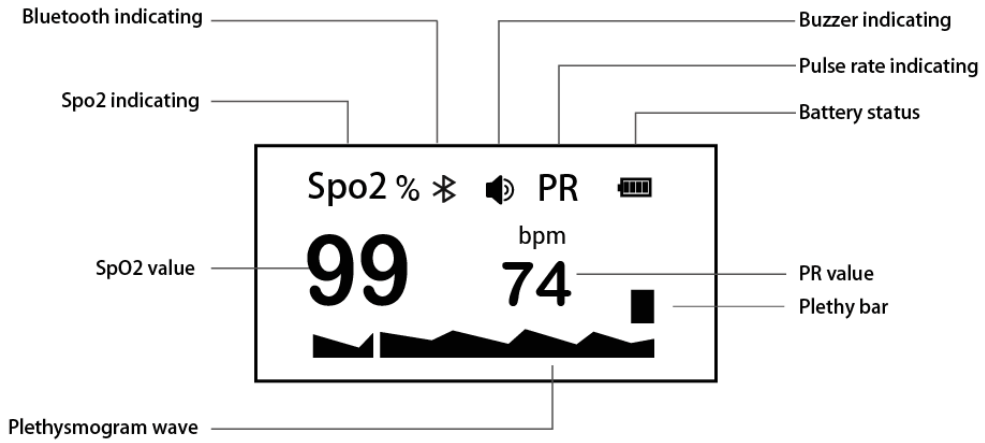


Figure 1

Measuring Steps

1. Hold the product in one hand with the front panel facing the palm. Put the other hand's big finger on the battery cabinet lid's press sign as shown in **Figure 2**, press downwards and push the lid open at the same time. The battery cabinet is opened.
2. Install batteries into the slots per the "+" and "-" symbols as shown in **Figure 3**.
   Cover the lid onto the cabinet and push it upwards to make it close well.
3. Press Clip's press sign in the figure 1and 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 4**, and then clip the finger.
4. Press the power and function switch button on the front panel to turn on the product. Using

first finger, middle finger or ring finger when doing test. Don't shank the finger and keep the testee at case during the process. The readings will be displayed on the OLED screen a moment later as shown in **Figure 5**.

- **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 finger and keep the testee calm during the process.**
- **Data update period is less than 30 seconds.**

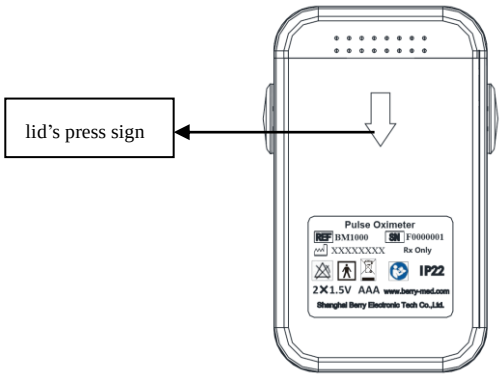


Figure 2

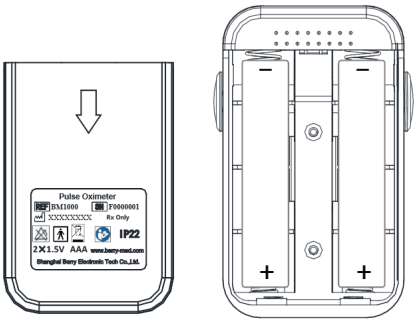


Figure 3

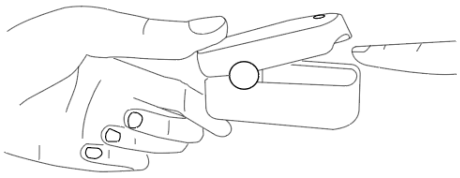


Figure 4

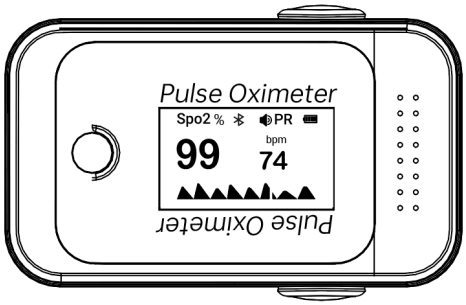


Figure 5

NOTE:

- **Before measuring, the pulse oximeter should be checked whether it is normal, if it 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. Failure to do so will result in inaccurate measurement.**
- **Make sure that there is no contamination and scar on the tested part. Otherwise, the measured result 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℃.**
- **Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least even 2 hours.**

Factors affecting measurement accuracy:

- **The measurements also depend on absorption of special wavelength ray by oxidized hemoglobin and deoxyhemoglobin. Concentration of nonfunctional hemoglobin may affect the accuracy of the measurement.**
- **Shock, anemia, hypothermia and the application of vasoconstriction 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.**

Function Description

a. When the data has been displayed on the screen, short press the "POWER/FUNCTION" button one time, the display direction will be rotated. (as shown in **Figure 6,7**)

b. Then short press the "POWER/FUNCTION" button once again, the display direction will be restored to the previous state. And buzzer indicating will disappear at the same time, the buzzer will be turned off. (as shown in **Figure8**)

c. When Bluetooth function is not connected successfully, Bluetooth indicating will flicker. When Bluetooth function is connected successfully, Bluetooth indicating will continue to be alight.

d. When the received signal is inadequacy, " - - - - - " will be displayed on the screen. (as shown in **Figure 9**)

e. The product will automatically be powered off when no signal after 10 seconds.

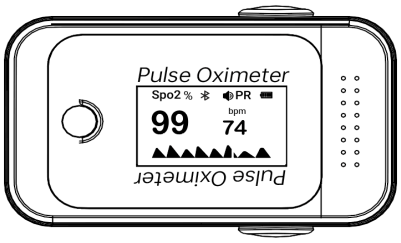


Figure 6

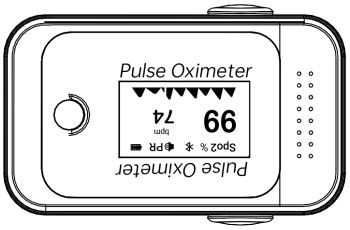


Figure 7

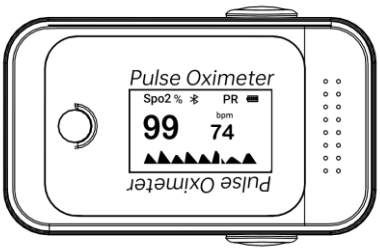


Figure 8

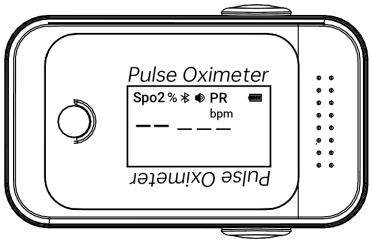


Figure 9

Bluetooth Communication Function (optional)

BM1000B 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".

Hang lace Installation

1. Thread thinner end of the hang lace through the hanging hole. The position of the hanging hole as shown in **Figure 10**. (Notice: the hanging hole is on both sides.)
2. Thread thicker end of the lace through the threaded end before pulling it tightly.

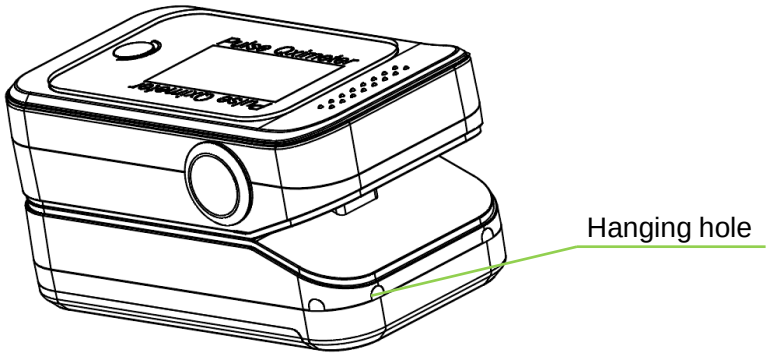


Figure 10

Cleaning and Disinfection

- **Never immerse or soak the pulse 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 disinfection 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	1pc
Hang lace	1pc
The operation manual	1pc

Expected service life: 3 years

Technical Specifications

1. **Display mode:** OLED
2. **SpO_2:**
   Measurement range: 35~100%
   Accuracy: ±2%（80%~100%）; ±3%（70%~79%）
3. **Pulse Rate:**
   Measurement range: 25~250bpm
   Accuracy: ±2bpm

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

4. **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

5. **Product specifications:**

   Size: 58 (H) × 34 (W) × 30(D) mm

   Weight: 50g (include two AAA batteries)

6. **Environment requirements:**

   NOTE：

   ● When the environment temperature is 20℃, 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℃, 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℃

   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 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 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 quantity 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.
CE 0123	European Union for approval.
	Information of manufacture, including name and address.
	Date of manufacture.
SN	Serial Number.
LOT	Batch Code.
REF	Type Number.
EC REP	The European Union authorized.
IP22	The product is protected against harmful effects of dripping water per IEC 60529.

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If you need additional information, please contact with us.

Appendix A EMC Declaration

Table 1 – EMISSION limits per environment

Phenomenon	HOME HEALTHCARE ENVIRONMENT
Conducted and radiated RF EMISSIONS	Group 1 Class B
Harmonic distortion	See IEC 61000-3-2
Voltage fluctuations and flicker	See IEC 61000-3-3

Table 2 – * ENCLOSURE PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table4
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3– * PATIENT coupling PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
		HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

Table 4– Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	**Band** a) (MHz)	**Modulation**	**Distance** (m)	**TEST LEVEL IMMUNITY** (V/m)
385	380 –390	Pulse modulation 18 Hz	0,3	27
450	430 – 470	FM ± 5 kHz deviation 1 kHz sine	0,3	28
710	704 – 787	Pulse modulation 217 Hz	0,3	9
745				
780				
810	800 – 960	Pulse modulation 18 Hz	0,3	28
870				
930				
1 720	1 700 – 1 990	Pulse modulation 217 Hz	0,3	28
1 845				
1 970				
2 450	2 400 – 2 570	Pulse modulation 217 Hz	0,3	28
5 240	5 100 – 5 800	Pulse modulation 217 Hz	0,3	9
5 500				
5 785				