BERRY
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Operation Manual

BM1000 Pulse Oximeter

BERRYMED LIMITED

Version: 1.0

Product Description

BM1000 Fingertip Pulse Oximeter is an important and common device to check oxygen saturation (SpO2) and pulse rate. It's a small, compact, simple, reliable and durable physiological monitoring device. Include the mainboard, OLED display and dry batteries. It is suitable for monitoring adults and children. It can be used in the hospital's operation room, ICU, clinic section office, out-patient department, sickroom and emergency treatment. It can also be used in the recovery and health care organizations, the community medical treatments, the oxygen bars, the family nursing, the physical care in sports (you can use it before or after the sport, but it is not recommended to use it during the sport).

Measurement Principle

An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LED s through process in electronic circuits and microprocessor.

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin (called spectrophotometer principle). It measures how much light, sent from light sources on the other side.

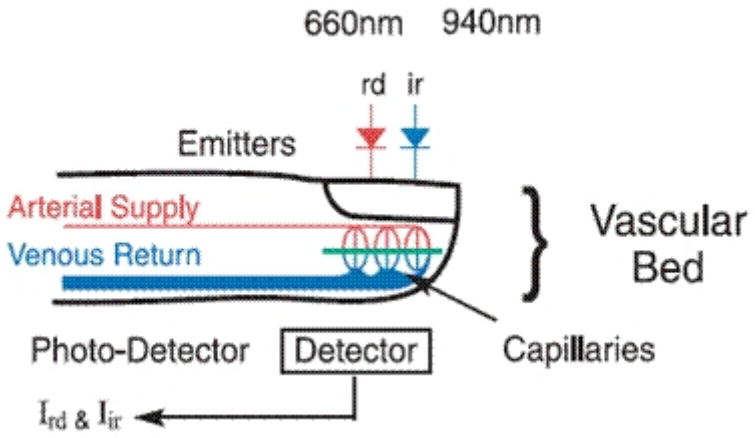

Diagram of Operation Principle

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.**
- **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.**
- **A functional tester can't be used to assess the accuracy.**
- **The patient is an intended operator and can perform the maintenance the equipment.**

Product Feature

1. Simple and convenient usage of product, simple one-touch operation.
2. Small volume, light weight, convenient to carry.
3. Lower consumption, original two AAA batteries can continuously work for 24 hours.
4. Low voltage reminder shows in screen when there's low battery, may influence the normal working.
5. The machine will automatically power off when there's no signal generated.
6. Daily maintenance and calibration is unnecessary.
7. Communication can be realized between the product and mobile phone with its wireless Bluetooth.

Display Introduction

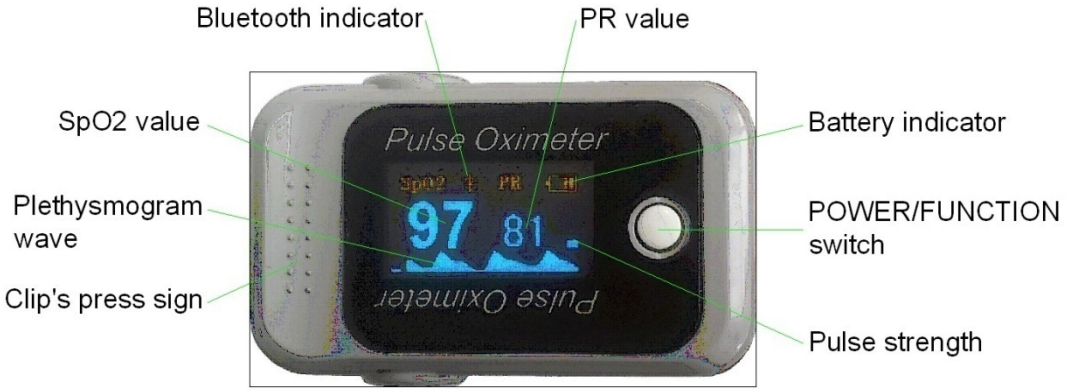

Figure 1

Battery Installation

1. Hold the product in one hand with the front panel facing the palm. Put the other hand's big finger on the battery cabinet lid's press sign, press downwards and push the lid open at the same time. The battery cabinet is opened as shown in **Figure 2**.
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.

- **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.**

Figure 2

Figure 3

Hang lace Installation

1. Thread thinner end of the hang lace through the hanging hole.
2. Thread thicker end of the lace through the threaded end before pulling it tightly.

Directions for use

1. Press Clip's press sign 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 4**, and then clip the finger.
2. Press the "POWER/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**.
   Display screen data refresh time for one second.

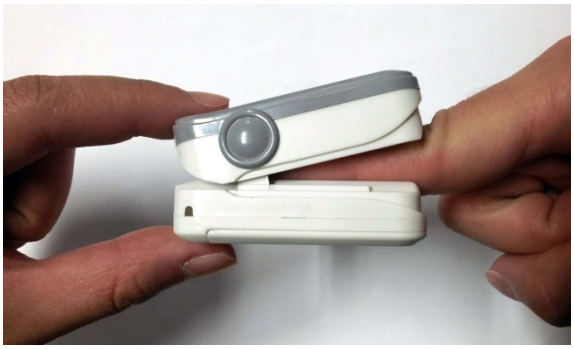

Figure 4

Figure 5

NOTE:

- **Don't put the product on extremities with arterial catheter or venous syringe.**
- **Cover the sensor with opaque material under the condition of strong light. Failure to do so will result in inaccurate measurement.**
- **Try to keep the patient still (specially the arm) and avoid the measured site suffering excessive motion.**
- **Don't use the product to measure patients whose pulse rate is lower than 30bpm, which may cause incorrect results.**
- **Make sure no contamination or scar exists in the size where the product is placed. 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.**
- **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.**
- **Don't perform SpO2 monitoring and NIBP measurements on the same arm simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO2 value.**
- **Testee's fingernail can't be too long. Otherwise the finger can't be inserted into the sensor to a suitable depth and the SpO2 measurements may be inaccurate.**
- **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.

- **The highest temperature of sensor contacts with patient's skin don't be allowed more than 41℃.**
- **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, change the display direction by pressing the "POWER/FUNCTION" button again. (as shown in **Figure 6**)

b. When the product is powered on, long press the "POWER/FUNCTION" button, Bluetooth function will be started. The Bluetooth indicator light on the top of display will flicker. (as shown in **Figure 7**)

c. The product will automatically be powered off when no finger is in the device for longer than 10 seconds. And switch to another display mode. (as shown in **Figure 8**)

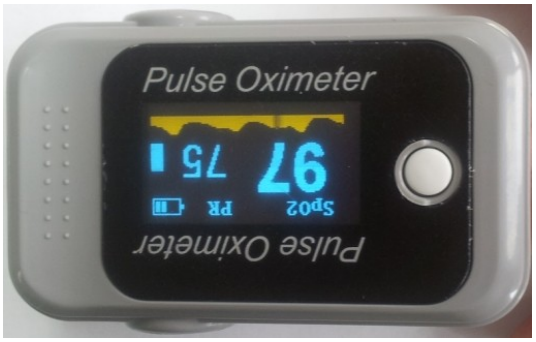

Figure 6

Figure 7

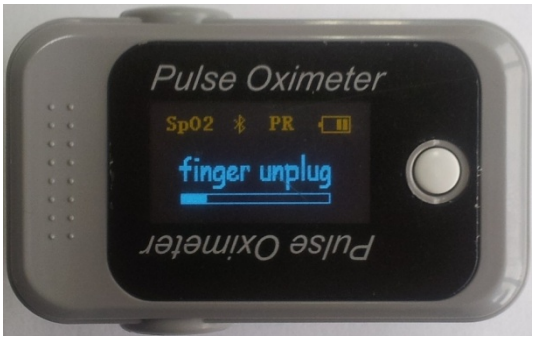

Figure 8

Bluetooth Communication Function

a. Open the mobile phone, and double-click SpO2 software icon " 

". And enter the following interface. (as shown in **Figure 9**)

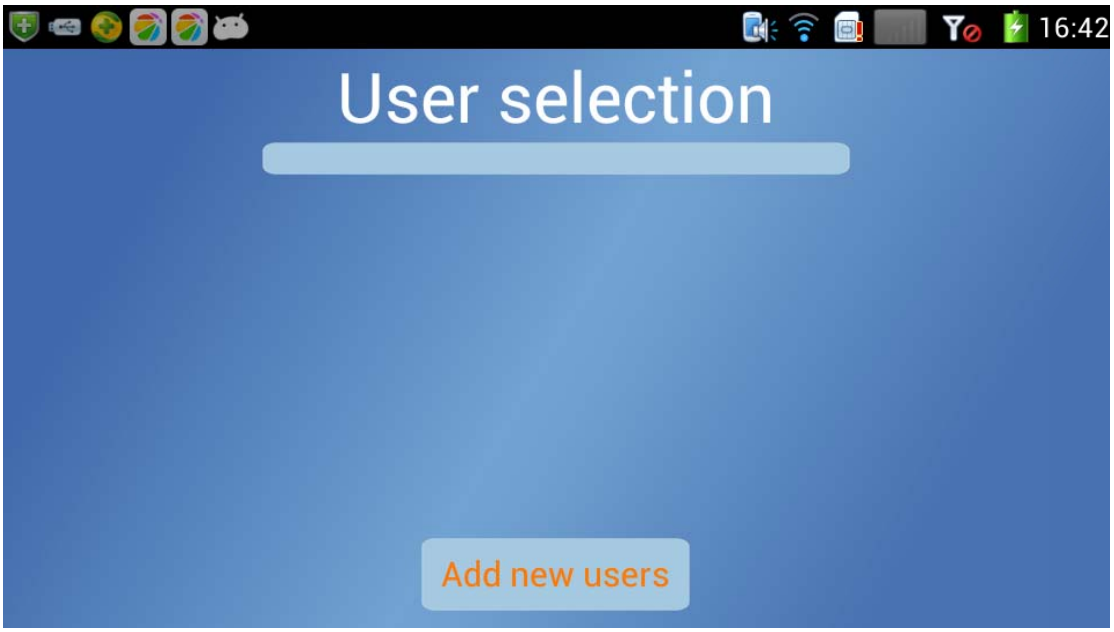

Figure 9

b. Click the "Add new users" and enter the following interface. (as shown in **Figure 10**)

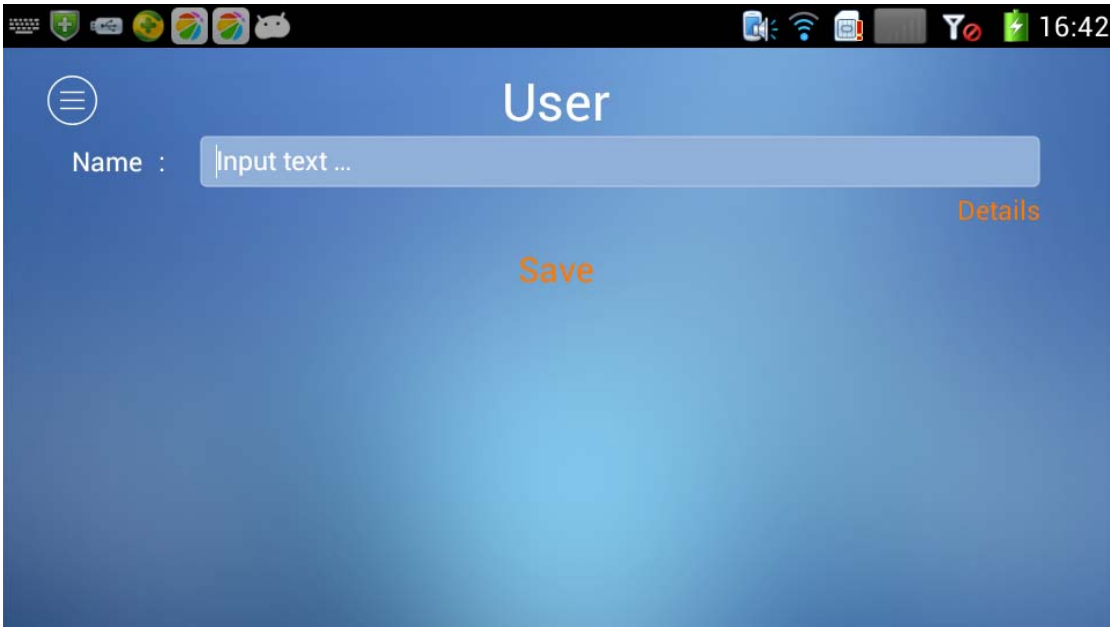

Figure 10

c. Input the user name, click the "Details" and jump the following information table. (as shown in **Figure 11**)

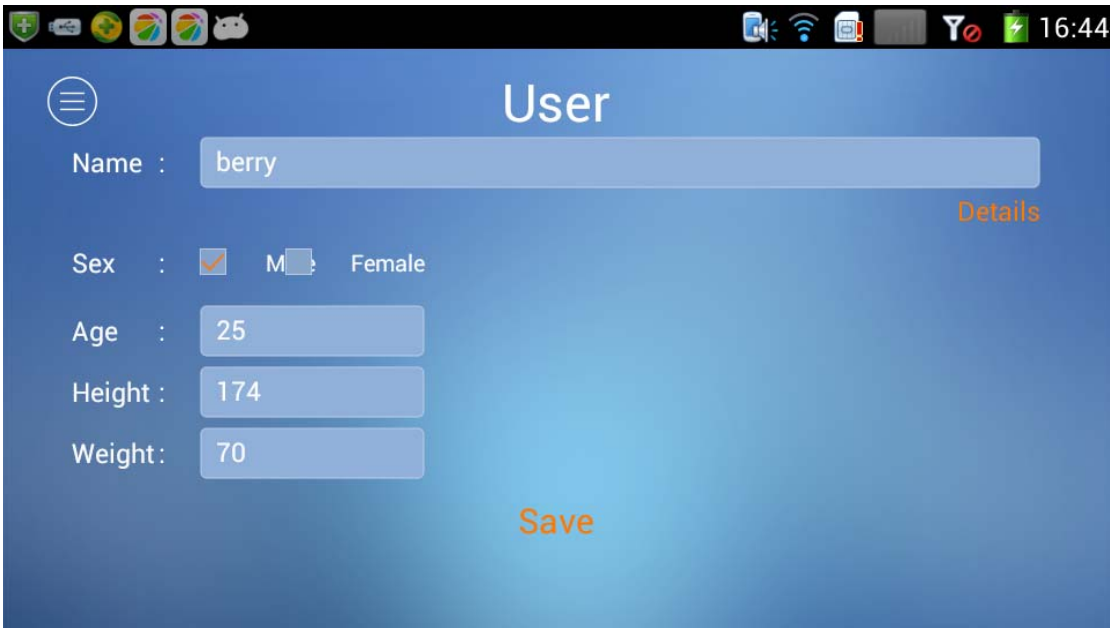

Figure 11

d. Input personal information, then click "Save" and enter the following interface. (as shown in **Figure 12**)

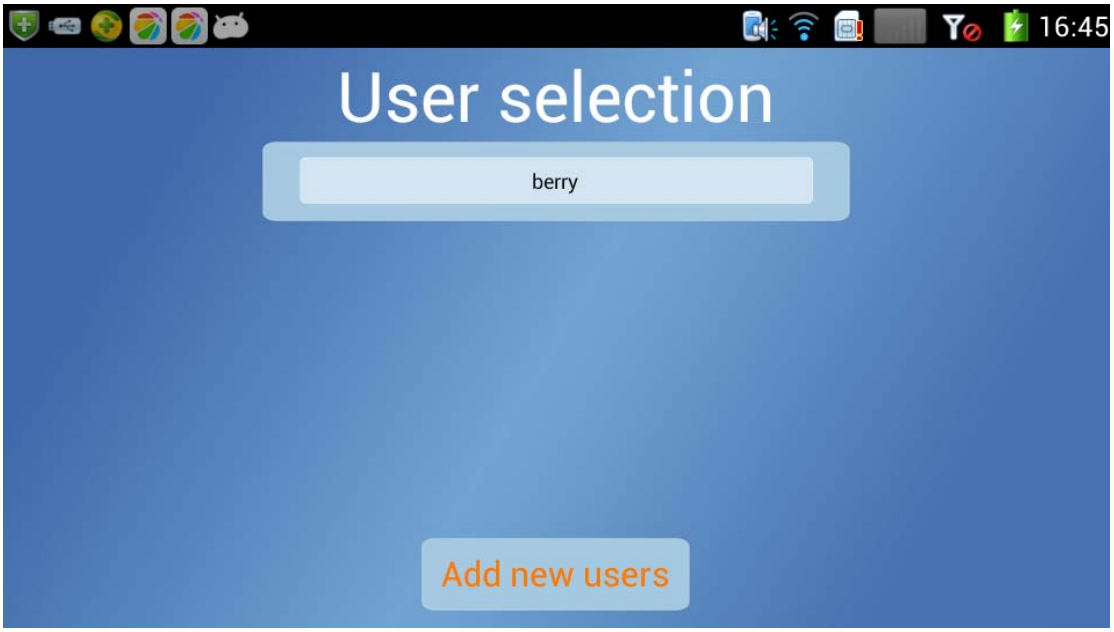

Figure 12

e. Click "berry" and enter the following interface. (as shown in **Figure 13**)

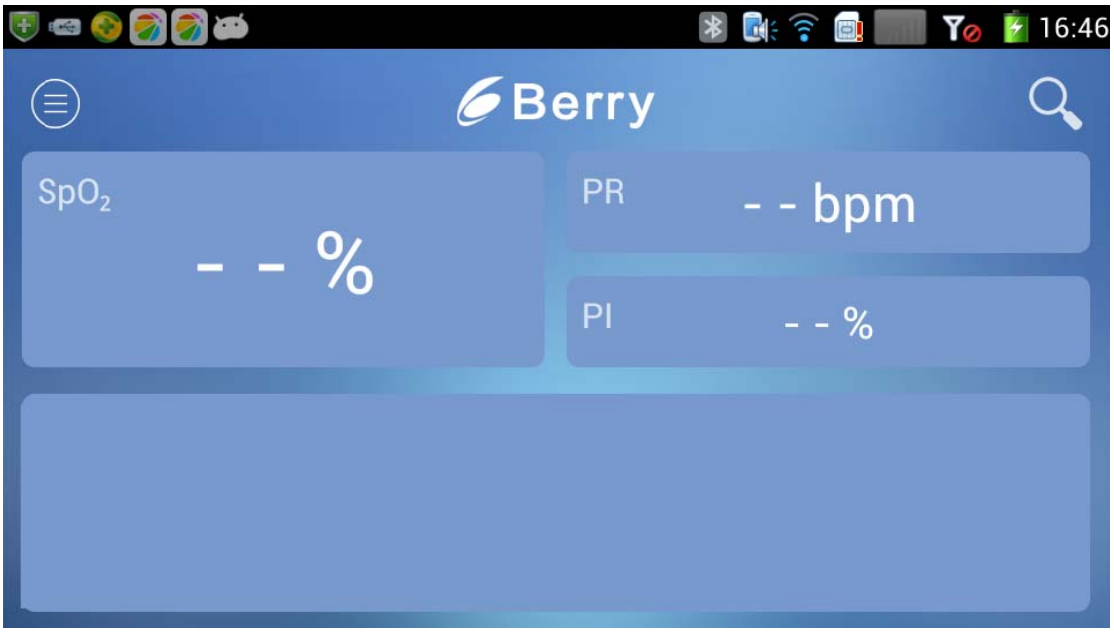

Figure 13

f. Click“ ”, search equipment and jump the following interface. (as shown in **Figure 14**)

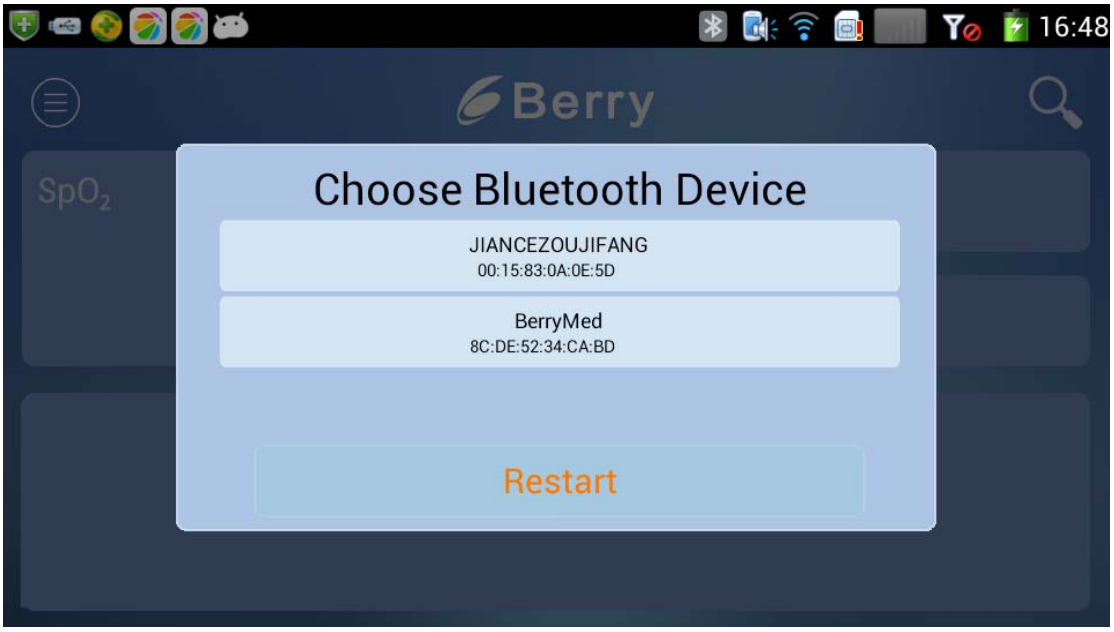

Figure 14

g. Wait to search out the equipment, c lick“BerryMed” and enter the follo wing in terface. (as shown in **Figure 15**)

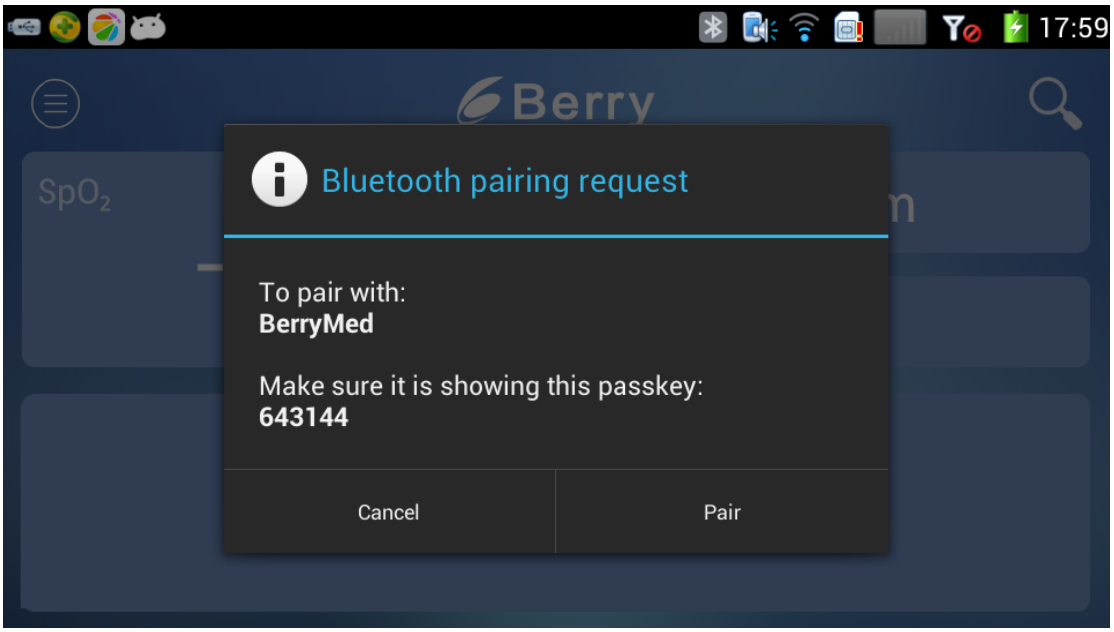

Figure 15

h. Click“Pair”, to pair with“BerryMed” and enter the following test interface. (as shown in **Figure 16**)

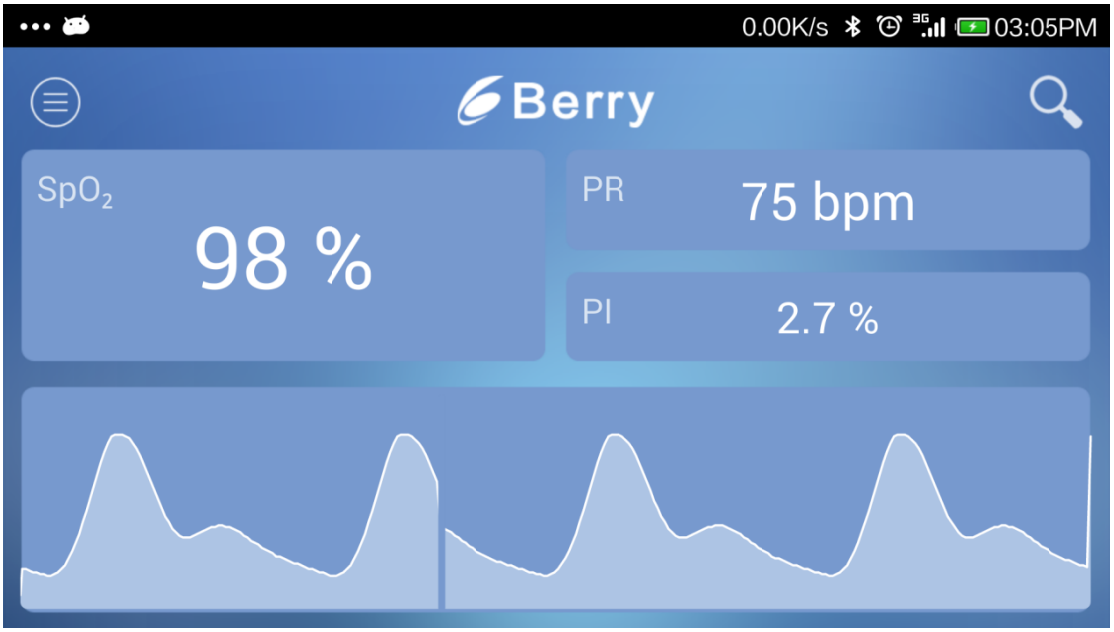

Figure 16

i. If you want to exit the software, click escape key of your mobile phone and jump the following window. And then click“OK”, exit the software. (as shown in **Figure 17**)

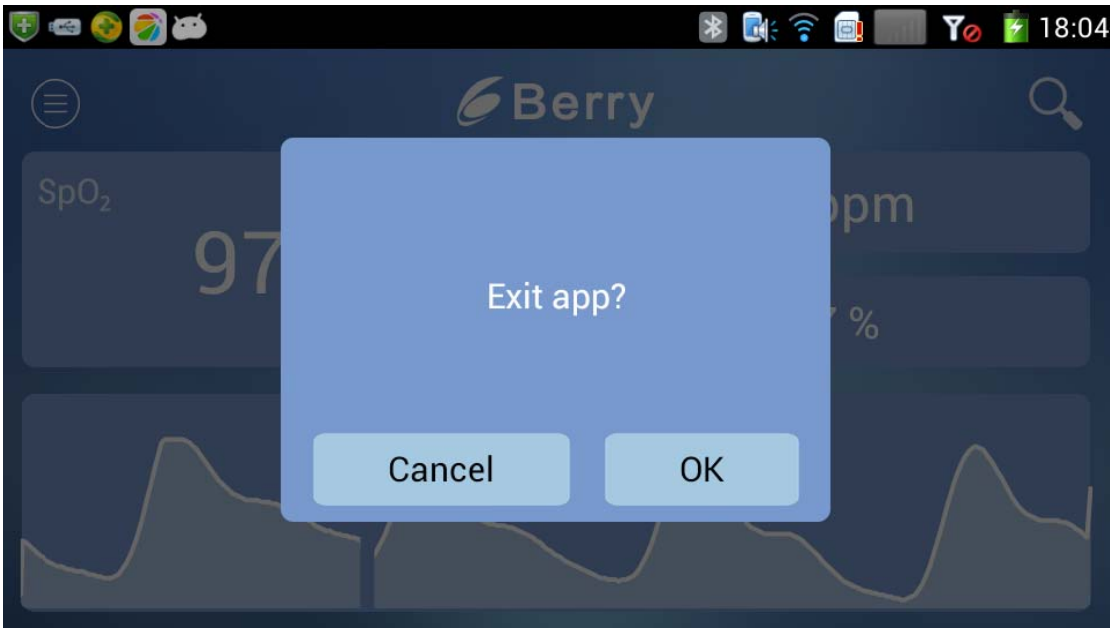

Figure 17

Cleaning and Disinfection

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: ethanol70%, isopropanol70%, 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 sensor to air dry.

Packing List

The standard configuration	
Fingertip pulse oximeter	1pc
Hang lace	1pc
The operation manual	1pc

Technical Specifications

1. **Display mode:** OLED
2. **SpO2:**

Measurement range: 35~100%

Accuracy: ±2%（80%~100%）； ±3%（70%~79%）

3. **Pulse Rate:**

   Measurement range: 25~250bpm

   Accuracy: ±2bpm

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:**

   Temperature:

   Operation: +5~+40℃

   Transportation and storage: -10~+50℃

   Humidity:

   Operation: 15%~80%（noncondensing）

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

   Atmospheric pressure:

   Operation: 860hPa~1060hPa

   Transportation and storage: 700hPa~1060hPa

Troubleshooting

Trouble	Possible reason	solution
The SpO2 and PR can't be displayed normally and the value disappeared.	1. The finger is not properly positioned. 2. The patient's SpO2 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 SpO2 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 batteries are not inserted properly. 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	1. Normal. 2. Replace the batteries.

	detected longer than 10 seconds. 2. Power quantity of the batteries is exhausted.	

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.
	European Union for approval.
	Serial Number.
	Batch Code.
	Type Number.
	The European Union authorized.
IP21	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 the company.

FCC warning statements:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Caution: Any changes or modif cations to this device not explicitly approved by manufacturer could void your authority to operate this equipment.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IC warning statements:

-English Warning Statement:

“This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device."

The digital apparatus complies with Canadian CAN ICES-3 (B)/NMB-3(B).

-French Warning Statement:

“Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement."

Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment and meets RSS-102 of the IC radio frequency (RF) Exposure rules. This equipment has very low levels of RF energy that are deemed to comply without testing of specifc absorption ratio (SAR).Cet équipement est conforme aux limites d’exposition aux rayonnements énoncées pour un environnement non contrôlé et respecte les règles d’exposition aux fréquences radioélectriques (RF) CNR-102 de l’IC. Cet équipement émet une énergie RF très faible qui est considérée conforme sans évaluation du débit d’absorption spécifque (DAS).