BERRY
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Operation Manual

Fingertip Pulse Oximeter

Shanghai Berry Electronic Tech Co., Ltd

Instructions

This manual provides the instructions necessary to operate Fingertip Pulse Oximeter (hereinafter called as the product) in accordance with its function and intended use. Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

Content of this manual is subject to change without prior notice.

Issued date: 2013/11/25

Version: 1.0

Statement

The manufacturer is responsible for safety, reliability and performance of this product only in the condition that:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by manufacturer authorized personnel; and
- The electrical installation of the relevant room complies with the applicable national and local requirements; and
- This product is operated under strict observance of this manual.

Guarantee

Free service scope

- The manufacturer provides free service to any product which conforms to the warranty regulations.

Chargeable service scope

- The manufacturer's obligation or liability under his warranty does not include the service of any factitious damage, or misuse, or irresistible natural disaster, or delay resulting from the improper use or application of the product, or repairs by people other than the manufacturer authorized personnel.

Return Policy

In the event that it becomes necessary to return a unit to the manufacturer, please obtain a return authorization first. Please contact the manufacturer and provides the model number, serial number, and a brief description of the reason for return. Return shipments will not be accepted if the serial number is not clearly visible.

The customer is responsible for freight charges when this product is shipped to the manufacturer for service (including any relevant customs fees or other freight related charges).

I. Safety Information

 **WARING**

Indicate a potential hazard situation or unsafe practice that, if not avoided, could result in death or serious injury.

 **CAUTION**

Indicate a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

NOTE

Provide application tips or other useful information to ensure that you get the most from your product.

WARING

- **The person who uses the product must receive adequate training before use.**
- **The product 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 product 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 product in the presence of flammable anesthetics, explosive substances, vapors or liquids.**
- **Make sure not to use the product during MRI (magnetic resonance imaging) scanning because induced current could potentially cause burns.**
- **The product is without alarm function. Continuous monitoring for a long time is not suitable.**
- **No modification of this product is allowed.**
- **Use AAA alkaline batteries. Do not use poor quality batteries. Remove the batteries if the product is not to be used for a long time.**
- **For disposal of the Pulse Oximeter and batteries, follow local regulations or your hospital's policy regarding disposal of such accessories. Do not dispose randomly.**
- **The product is commonly sealed product. Keep its surface dry and clean, and prevent any liquid from infiltrating it.**
- **The device 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.**
- **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.**
- **The pulse oximeter equipment is calibrated to display functional oxygen saturation.**

NOTE

- **Important! Before use, carefully read this manual, all safety information and specifications.**

II. 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, except changing the batteries.
7. Communication can be realized between Bluetooth and computer or mobile phone.
8. The product will automatically be powered off when no signal generates in the device for longer than 8 seconds.

III. Applicable people and scope

It is suitable for monitoring adults and children. It is used in the hospital's operation room, ICU, clinic section office, out-patient department, sickroom, 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 the product before or after the sport, but it is not recommended to use it during the sport).

IV. Intended use

This product can be used to monitoring the physiological signal, included: arterial oxygen saturation (SpO2), pulse rate (PR) and pulse strength. The product measures these physiological signals of patients, and further processing, then the numerical results will be displayed in OLED screen or in the computer interface/mobile phone with its wireless Bluetooth.

NOTE

- **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.**

V. Contraindications

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

VI Structure and composition

This product is composed of one fingertip pulse oximeter.

VII. Measurement Principle

SpO2 plethysmogram measurement is employed to determine the oxygen saturation

of hemoglobin in the arterial blood. The SpO2/PLETH parameter can also provide a pulse rate signal, pulse strength and a plethysmogram wave.
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.
The sensor measurement wavelengths are nominally 660nm for the Red LED and 940nm for Infrared LED. Maximum optical power output for LED is 4 Mw.

VIII. Cleaning and Disinfection

 **CAUTION**

- **Never immerse or soak the product.**
- **Exercise caution during cleaning/disinfection to avoid wetting the pins.**
- **We recommend that the product be disinfected only when necessary as determined by your hospital's policy, to avoid long term damage to the product.**
- **Never use cleaning agents/disinfectants other than the recommended.**
- **Never permit high-pressure and high-temperature disinfection of the device.**

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 pulse oximeter to air dry.

IX. General

Display mode: OLED
Size: 58 (H) × 34 (W) × 30(D)mm
Weight: 50g (include two AAA batteries)

X. Electrical specifications

Working voltage: D.C.2.2 V~D.C.3.4V
Battery Type: Two common 1.5V AAA alkaline batteries.
Power consumption: smaller than 50mA

XI. Parameter Specification

SpO2

Range: 35~100%

Resolution: 1%

Accuracy: ±2%（80%-100%）； ±3%（70%-79%）

PR

Range: 25~250bpm

Resolution: 1bpm

Accuracy: ±2bpm

Low perfusion:

Range: 0.5%~20%

SpO2 accuracy: ±2% (70%~100%)

PR accuracy: 25~250bpm ±2bpm

XII. Environment

Temperature

Operation: 5-40℃

Transportation and storage: -20-70℃

Humidity

Operation: <80%

Transportation and storage: <93%

Altitude

Operation: -390~3012meter (-1254~9882feet)

Transportation and storage: -390~5574meter (-1254~18288feet)

Atmospheric pressure

Operation: 86Kpa~106Kpa

Transportation and storage: 50Kpa~106Kpa

Enclosure flame class: V-0

XIII. Packing list

The standard configuration	
Fingertip pulse oximeter	1pc
Rope	1pc
The Operator manual	1pc

Expected service life: three years

XIV. Operating Instructions

CAUTION

- **Check if the product is in normal condition before monitoring. Do not use the product once it is found damage.**
- **Don’t put the product on extremities with arterial catheter or venous syringe.**
- **The product can’t be clipped on the edema and tender tissue.**

- **If no pulse is found or reading is unreasonable, first check the testee's condition, and then check the product placement on the finger, finally asking the qualified engineer to check the product for proper functions.**
- **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.**
- **The product is not appropriate for the ceaseless monitoring of the patients. Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the patient of poor perfusion or immature dermographia by light collimation. It is recommended that the device should not be applied to the same finger for over 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.**
- **To acquire accurate results, please read data until the product is steadily placed.**

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.**
- **Interference of high frequency electricity and bright light may affect the accuracy of the measurement.**

Appearance and Display

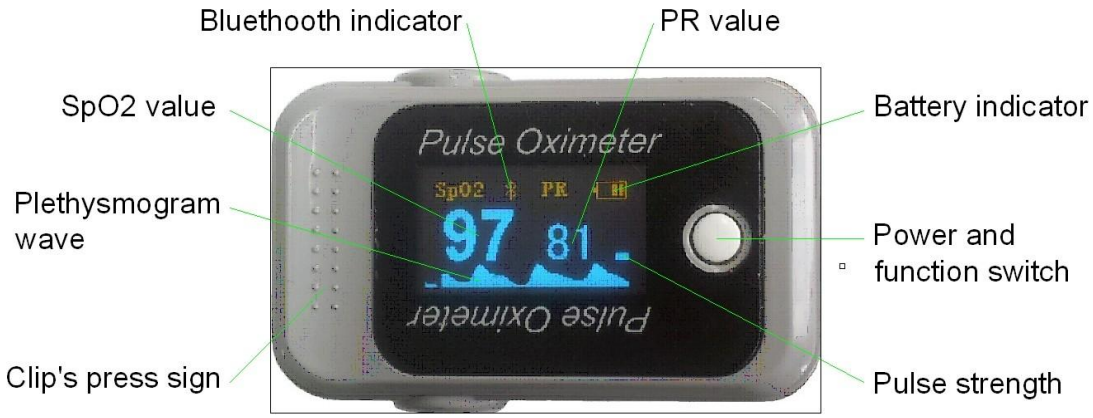


Figure 1

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, 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.
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 LED screen a moment later as shown in **Figure 5**.

WARRING

- **When your finger is plugged into the Oximeter, your nail surface must be upward.**
- **The results may be wrong if you did not plug the finger thoroughly in the Oximeter.**

Figure 2

Figure 3

Figure 4

Figure 5

Function instructions

a. When the data has been displayed on the screen, change the display direction by pressing the power and function button again. (as shown in **Figure 6**)

b. When the product is powered on, long press the power and 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 8 seconds. And switch to another display mode. (as shown in **Figure 8**)

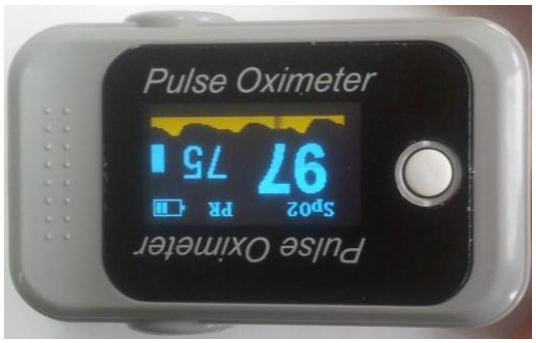


Figure 6

Figure 7

Figure 8

Communication with computer

a. Open the Bluetooth of the computer, search for the Bluetooth device, the pulse oximeter's user name is BerryMed, pairing code is 0000.

b. Check the Bluetooth serial no. when connected, such as com18.

c. Open pc software "SpO2-EN.exe"(as shown in **Figure 9**)

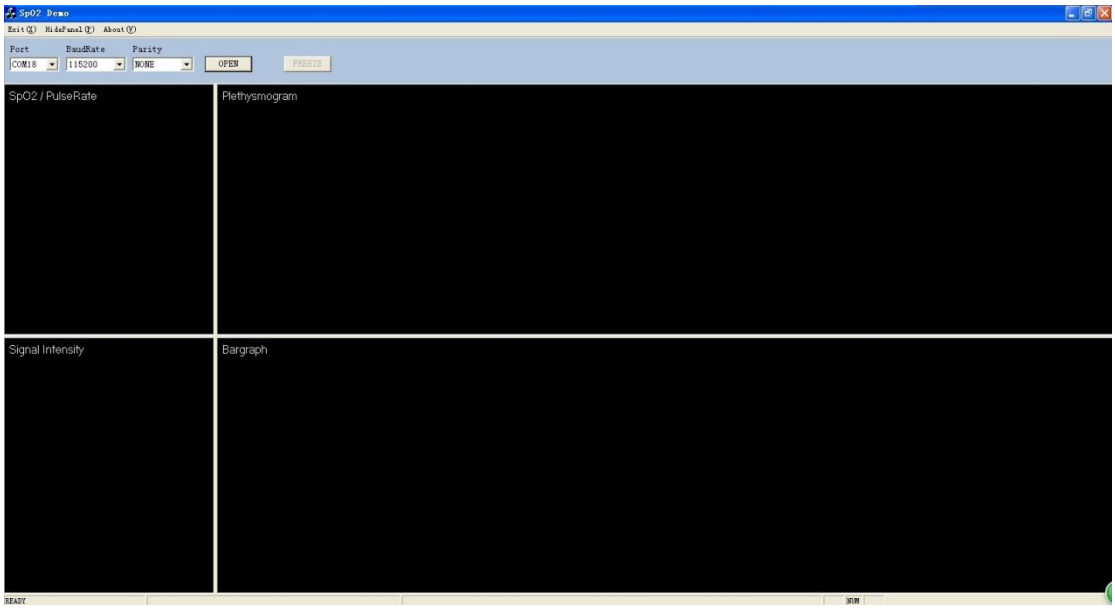


Figure 9

d. Choose Bluetooth serial no., such as com18. (as shown in **Figure 10**)

Figure 10

e. Click to open. (as shown in **Figure 11**)

Figure 11

f. Enter display interface. (as shown in **Figure 12**)

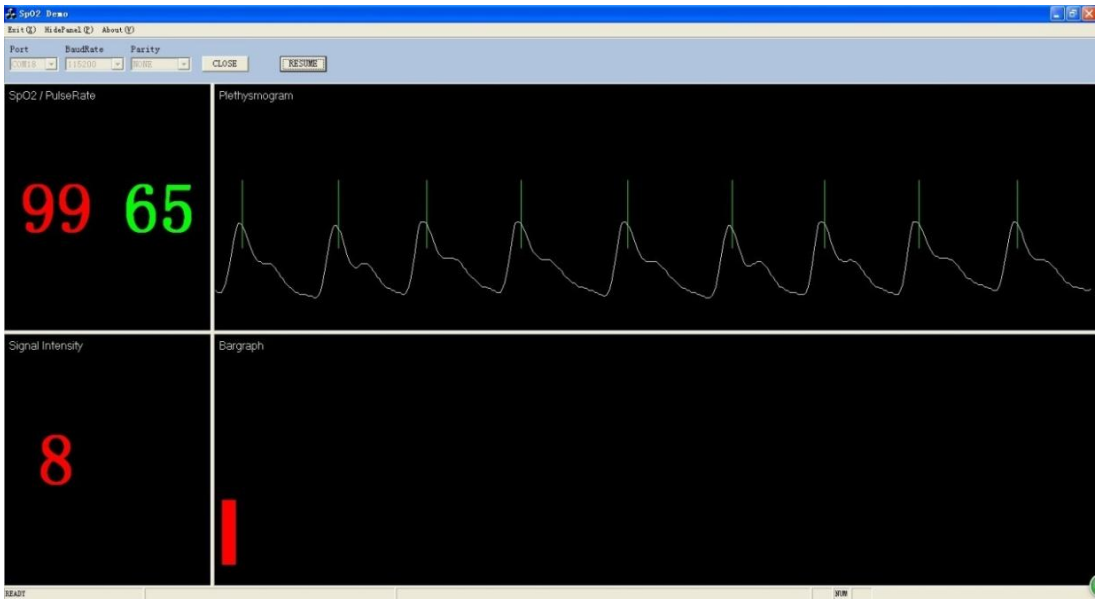


Figure 12

Communication with mobile phone

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

". And enter the following interface. (as shown in **Figure 13**)

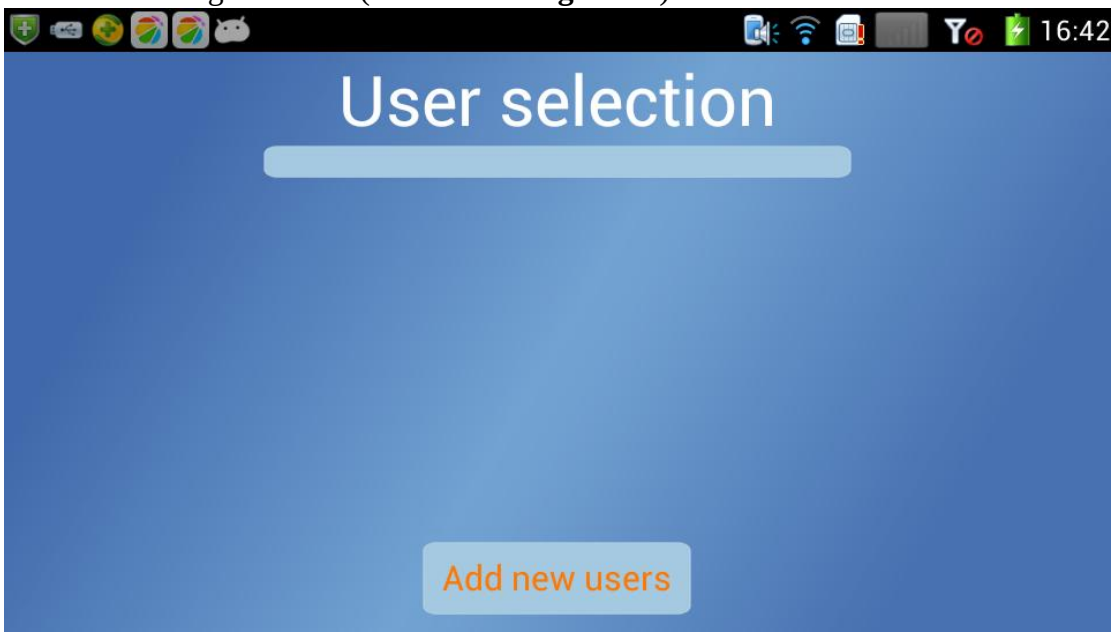


Figure 13

b. Click the "Add new users" and enter the following interface. (as shown in **Figure 14**)

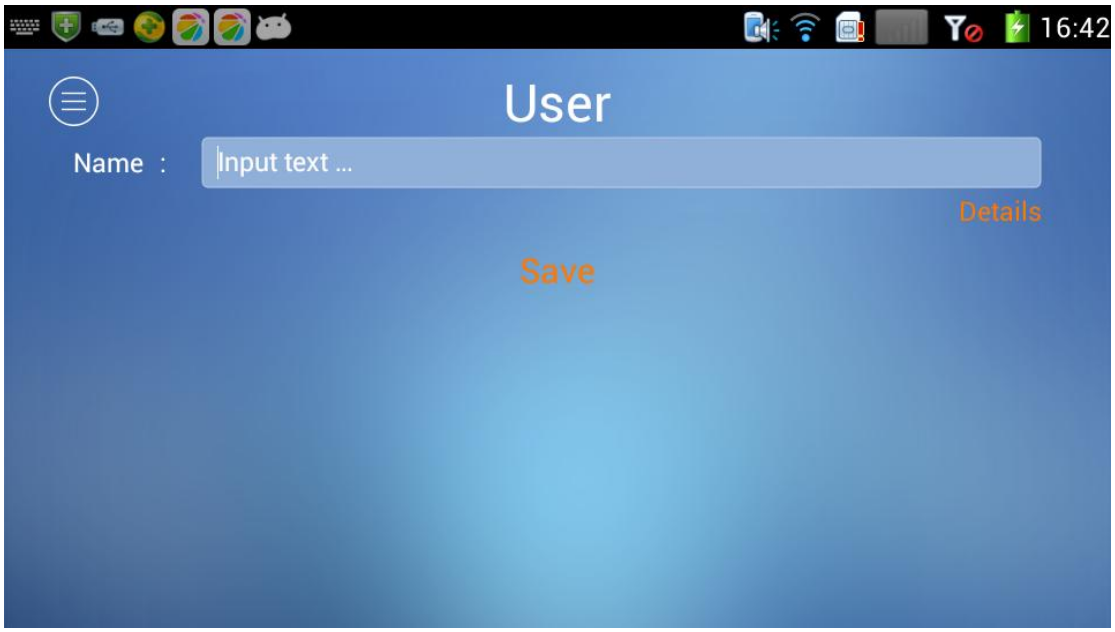


Figure 14

c. Input the user name, click the "Details" and jump the following information table. (as shown in **Figure 15**)

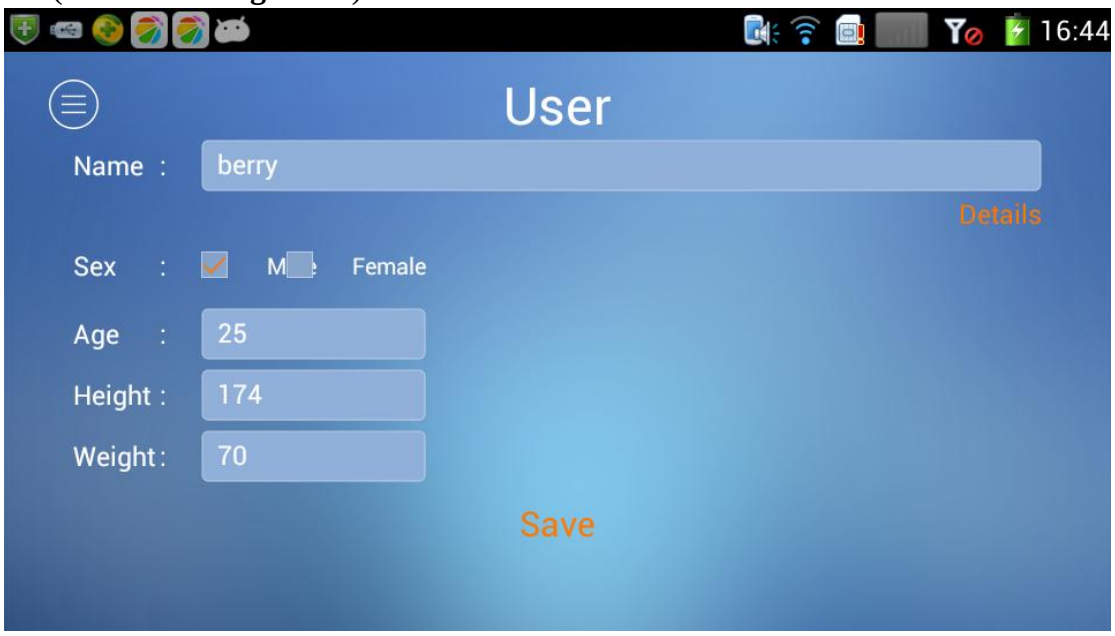


Figure 15

d. Input personal information, then click "Save" and enter the following interface. (as shown in **Figure 16**)

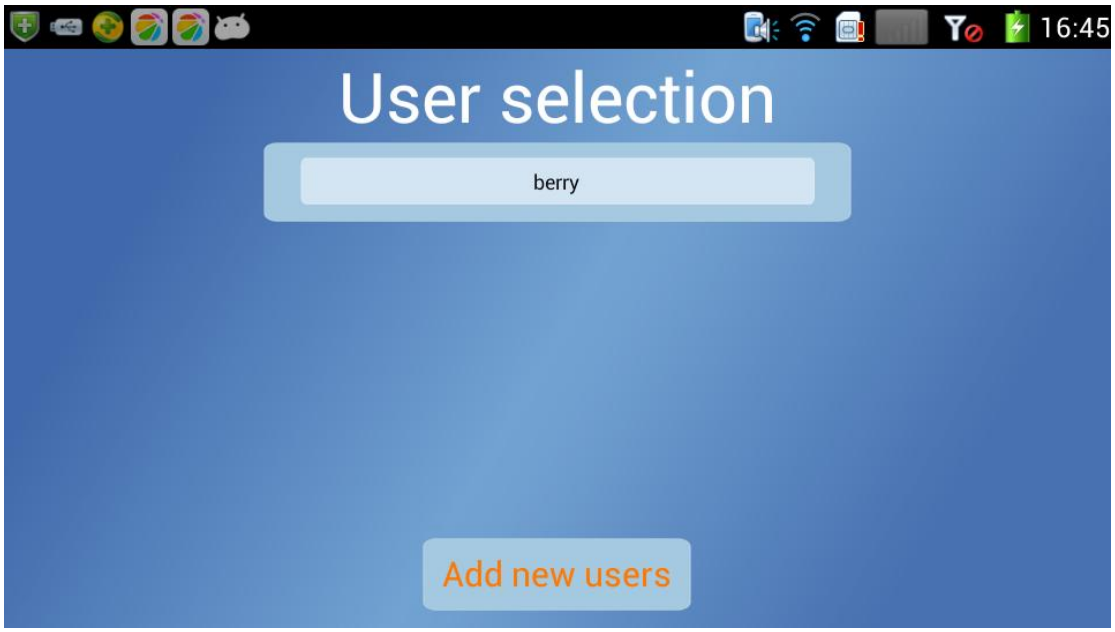


Figure 16

e. Click “berry” and enter the following interface. (as shown in **Figure 17**)

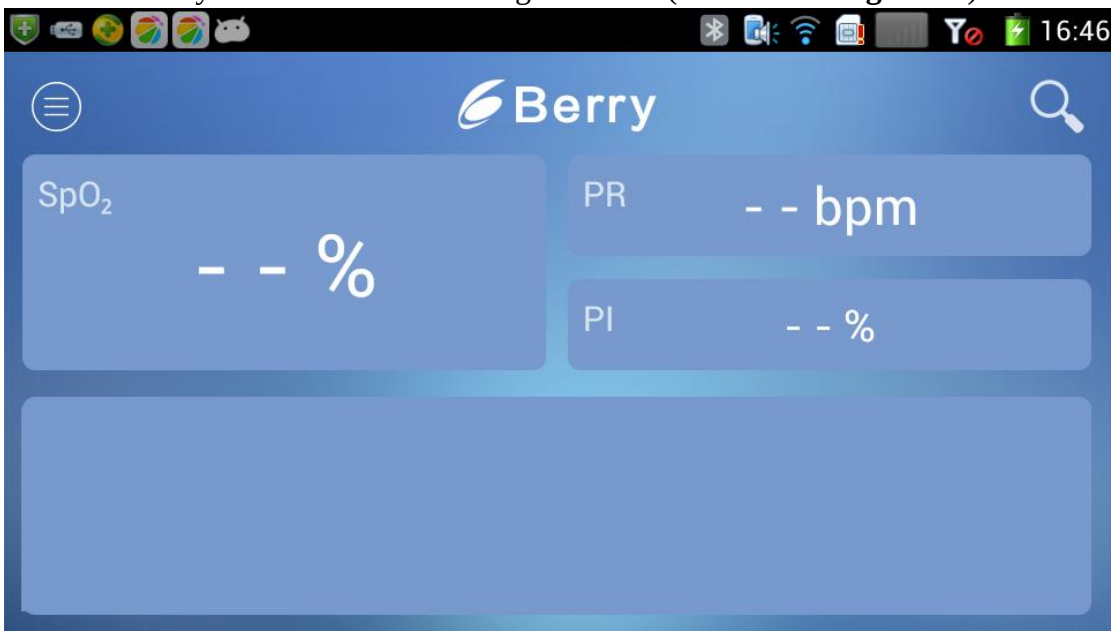


Figure 17

f. Click “  ” , search equipment and jump the following interface. (as shown in **Figure 18**)

Figure 18

g. Wait to search out the equipment, click "BerryMed" and enter the following interface. (as shown in **Figure 19**)

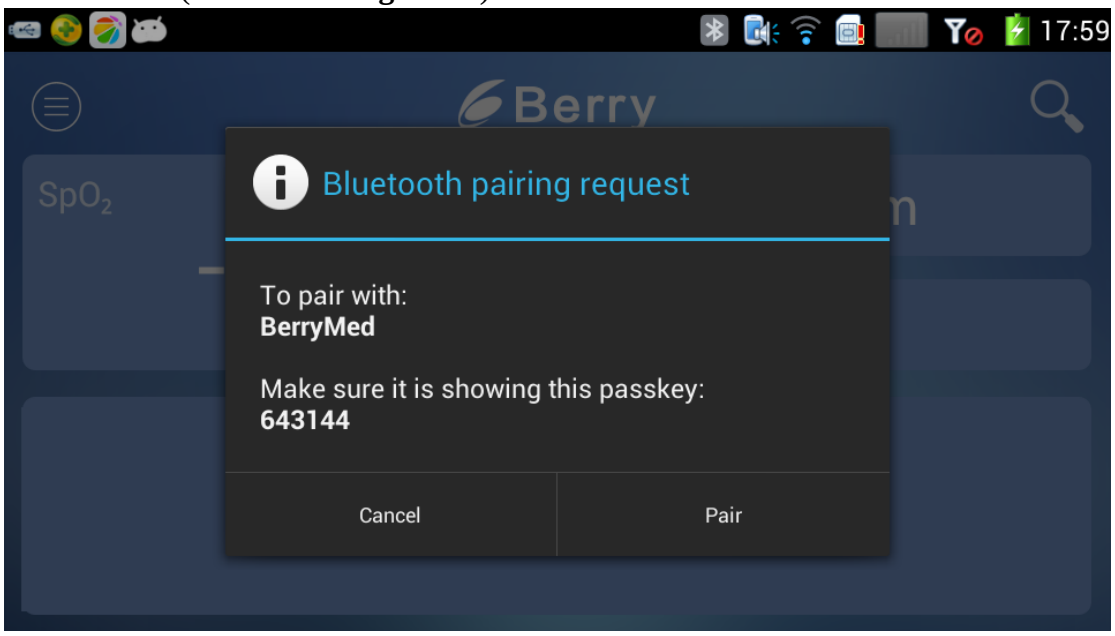


Figure 19

h. Click "Pair", to pair with "BerryMed" and enter the following test interface. (as shown in **Figure 20**)

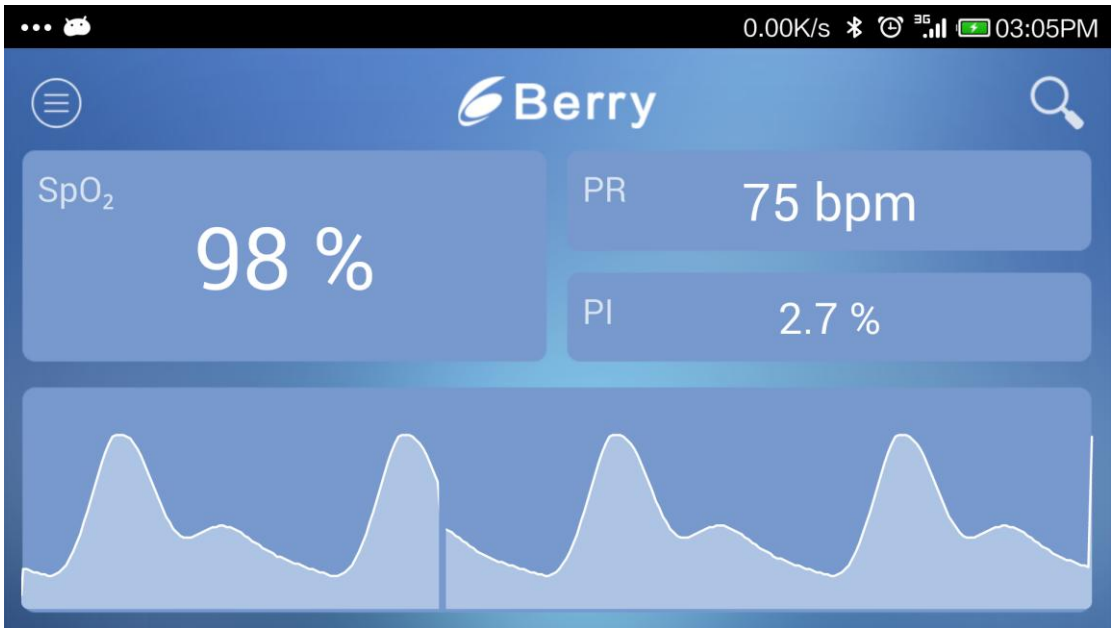


Figure 20

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 21**)

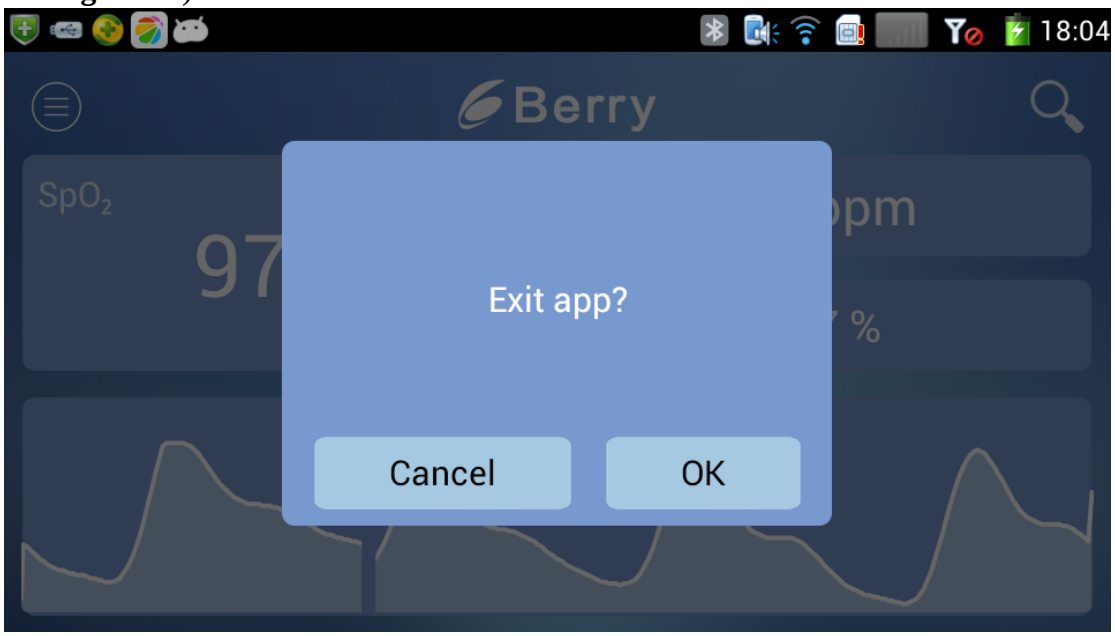


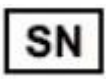
Figure 21

XV. Troubleshooting

Trouble	**Possible reason**	**solution**
The SpO2 and PR can't be displayed normally.	1. The finger is not properly positioned. 2. The patient's SpO2 is too low to be detected.	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.

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 turned 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 detected longer than 10 seconds. 2. Power quantity of the batteries is exhausted.	1. Normal 2. Replace the batteries.

XVI. Symbolic 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.

IC Warning

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.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.
This device complies with Canadian ICES-003 and RSS-210

“Le présent appareil est conforme aux CNR d'Industrie Canada applicable 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, meme 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.

FCC Warning

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.
NOTE 1: 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.

NOTE 2: Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

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If you need additional information, please contact with the company.