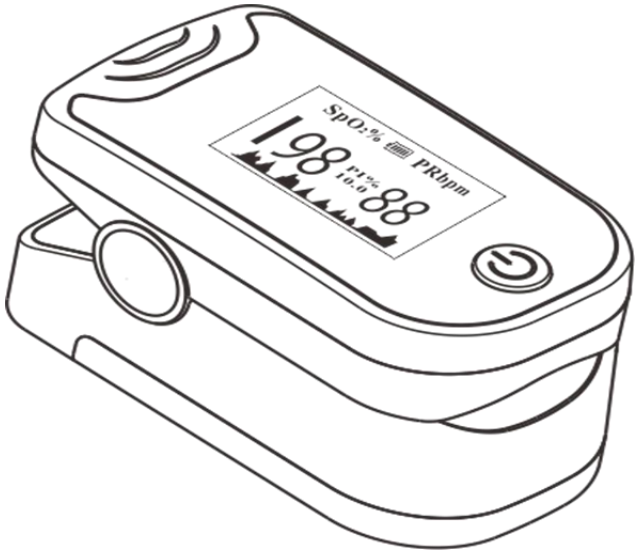
Instruction for Use



Product name: Fingertip Pulse Oximeter

Model BSX251, BSX233, BSX231, BSX253, BSX238B, BSX255B
Version: A/0
Ref. No.: 8187M25501
Released Date:2021.05.20
Software version: V1.0

Notes:
*Please thoroughly read the Instruction for Use before using the unit.
*Please save this Instruction for Use for further reference

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1. Instruction

Dear users, Thanks you for purchasing the Fingertip Pulse Oximeter (abbreviation: the Oximeter or the Equipment, the device).
This manual contains the instructions necessary to operate the product safety and in accordance with its function and intended use. Observance of this instruction for use is a prerequisite for proper product performance and correct operation and patient and operator safety.

2. Safety

2.1 ⚠Cautions

The Oximeter is designed to measure the percentage of arterial oxygen saturation of functional hemoglobin. Factors that may degrade oximeter performance or affect the accuracy of the measurement include the following:

1) Do not apply the oximeter on the same arm as a blood pressure cuff, arterial catheter or infusion line(s)(IVs).
2) Excessive light, such as sunlight or direct home lighting.
3) Moisture in the Equipment.
4) Finger is outside recommended size range.
5) Poor pulse quality.
6) Venous pulsations.
7) Anemia or low hemoglobin concentrations.
8) Cardio green and other intravascular dyes.
9) Carboxyhemoglobin.
10) Methemoglobin.
11) Dysfunctional hemoglobin.
12) Artificial nails or fingernail polish.

Please reading the following cations before using the Equipment:

1) Keep this oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and high humidity.
2) When the oximeter becomes wet, stop using it.
3) Do not operate the front panel buttons of the oximeter with sharp materials.

4) Do not sterilize the product with high temperature and pressure humidity. Please refer Maintenance, Cleaning, Disinfection.
5) The Oximeter consists of high-quality precision parts. Do not drop the product. Protect it from severe impact and shock.
6) Be careful with the lanyard of the oximeter. During use of the oximeter, please do not damage this lanyard to protect the oximeter. Do not use if the user has an allergic reaction to this lanyard.
7) Please remove the battery to prevent battery leakage from damaging the device when the oximeter is not used for a long time.
8) Don't shake the finger and try to keep the patient still during the measurement.
9) The user should fully insert the finger into the probe, otherwise it will cause incorrect measurement.
10) Uncomfortable or pain may appear if use the oximeter ceaselessly. Especially for microcirculation barrier patients, it recommended that the oximeter should not be used on the same finger more than 2 hours.
11) Please read the measure value when the waveform on screen is equably and steady-going, the measure value is optimal value, and the waveform at the moment is the standard one.
12) A functional tester is used to measure how accurately the Oximeter is reproducing the specified calibration curve and the PR accuracy. The model of functional tester is Index 2 FLUKE simulator and the version is V3.00.
13) Do not use the Oximeter in situations where alarms are required. The device has no alarms of the SpO2 and pulse.
14) Do not use the device in an MRI or CT environment. It may cause errors of measurement data.
15) Waveform display for the devices are non-normalized.
16) The value of SpO2 and PR were through average processing.

2.2 ⚠Warning

1) It is forbidden to use the measurement site for local lesions such as inflammation, trauma and postoperative.
2) Explosion hazard: Do not use the oximeter in a flammable and explosive gas environment, such as anesthetics, nitrous oxide.
3) Do not spray, pour, or spill any liquid on the oximeter and its accessories, connectors, and switches.
4) Do not use the oximeter while the patient is being scanned by MRI and CT.
5) The Equipment is NOT intended for neonate and infant, and the patient's finger thickness should between 8 to 25.4 mm.
6) It is recommended that the Equipment should be inspected before use, when there is obvious damage, stop using the Equipment.

7) Discomfort or pain may appear if using the Equipment ceaselessly，especially for microcirculation barrier patients, it recommended that the Equipment should not be used on the same finger more than 10 minutes.
8) For some patients, need a more careful examination of the measurement site, the oximeter shall not be placed in edema or fragile organization.
9) Be careful with the lanyard of the oximeter. During use of the oximeter, please do not damage this lanyard of the oximeter. Do not use if the user has an allergic reaction to this lanyard.
10) Do not use the oximeter if you have any allergic reaction to silicone and ABS plastic.
11) Do not stare at the light source. The infrared light emitted by the oximeter may hurt eyes.
12) As the ambient temperature rises, if the sensor is not properly perfused for a long time, the skin of the patient will be severely burned. To prevent this, need a more careful check the patient's application site. If the initial skin temperature does not exceed 35℃, all the sensors will not cause the skin temperature to exceed 41 ° C during operation.
13) After the oximeter is removed from the finger, the external light may make the device still display data and waveforms. That does not mean that the device is faulty and the value cannot be used as a basis for clinical diagnosis.
14) Portable electronic products and mobile communication equipment will affect the use of the oximeter.
15) The patient should not use enamel or other makeup;
16) The patient's nails should not be too long.
17) The oximeter is not suitable for treatment.
18) Please follow local ordinances and recycling instructions regarding disposal or recycling of the oximeter and batteries.
19) Please keep the oximeter dry. Humid environments can quickly shorten the product's life and even directly damage it.
20) The Equipment is just a clinical diagnosis of auxiliary equipment. The physiological data displayed on the Equipment are for reference only and cannot be directly used for diagnostic interpretation.
21) It is not recommended to use the Equipment in high frequency environment such as electrosurgical equipment.
22) Do not have the Equipment immerged in liquid.
23) Prevent children from swallowing the Equipment or its accessories.
24) Children must be accompanied by adult guardian using products.
25) Please follow local ordinances and recycling instructions regarding disposal or recycling of the Equipment and batteries.
26) As the patient is an intended operator, the oximeter should not be serviced and maintained while the ME equipment is in use.
27) This device has no alarm light and alarm sound, only prompt sound and prompt. (See Prompt function "Alm" in clause 7.2.3.2 and 7.2.3.3 for details)
28) The device is not suitable for patients with diseased finger.

29) Patients with severe jaundice will have a large amount of bilirubin, and the product of bilirubin metabolism is CO, so a large amount of carbon-oxygen-hemoglobin can be formed, resulting in the high pseudo-error phenomenon when the oximeter reads SpO2.
30) The SpO2 value will be biased in the presence of carboxyhemoglobin, methemoglobin, or dye dilution chemicals.
31) Patients who smoke too much may have the phenomenon of transient high CO content, which leads to the increase of CO hemoglobin content.
32) It is not intended to be used under motion or low perfusion scenarios.

3. Contraindications

No known contraindications.

4. The Principle

The principle of the Oximeter is based on the red and infrared light absorption of oxygenated and deoxygenated hemoglobin. Oxygenated hemoglobin absorbs more infrared light and allows more red light to pass through. Deoxygenated (or reduced) hemoglobin absorbs more red light and allows more infrared light to pass through. Red light is in the 660nm wavelength light band and its power is less than 60mW. Infrared light is in the 905nm wavelength light band and its power is less than 60mW.
The oximeter sensors have red and infrared low voltage light emitting diodes (LEDs) which serve as light source. The emitted light is transmitted through the tissue, then detected by the photodetector and sent to the microprocessor of the oximeter. All constituents of human body, venous and arterial blood, and tissue absorb light. The pulsating of arterial blood results in changes in the absorption to added hemoglobin(Hb) and oxygenated hemoglobin (HbO2)in the path of the light. Since HbO2 and Hb absorb light to varying degrees, this varying absorption is translated into plethysmographic waveforms at both red and infrared wavelengths. The relationship of red and infrared plethysmographic signal amplitude can be directly related to arterial oxygen saturation.

5. Intended Use

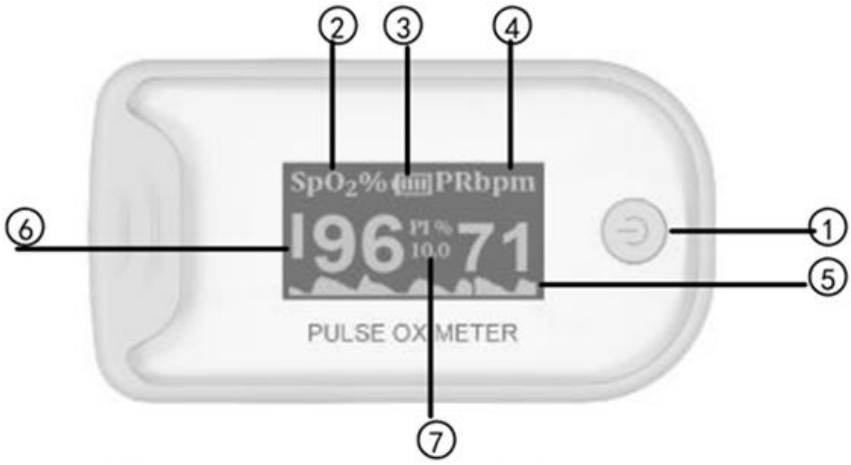
The Fingertip Pulse Oximeter is a non-invasive device intended for measure oxygen saturation (SpO_2) and pulse rate of adults or children.
This oximeter is intended for use in home, hospital, clinical institution, healthcare community.
The oximeter is NOT design for newborn and infant.
The product is suitable for adults (Weight should be between 25kg to 110kg).

6. Product Description

The oximeter consists of main unit (include silicone protective cover, and accessories.
Accessories include: lanyard, battery, instruction for use.

7. Operation Guide

7.1 User Interface



1. Power Button
2. SpO2 icon and value
3. Power indication
4. Pulse rate icon and value
5. Pulse bar graph
6. Finger Plethysmogram
7. PI% , the blood perfusion index (%)

Figure 1 User interface

7.2 Setting and Operation Method

7.2.1 Install batteries

1) Pull the battery cover out of the bottom of the oximeter.
2) Correctly install two "AAA" 1.5V batteries, and pay attention to the direction of the positive and negative electrodes of the battery.
3) Close the battery cover.

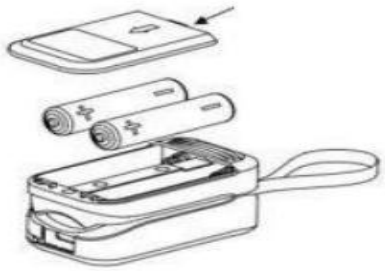


Figure 2 Install battery

Cautions:

1) Do not use the oximeter in an environment full of flammable and explosive gases.
2) In order to ensure the performance accuracy of the product and prevent device failure, please do not use it in very wet places.
3) Do not install used batteries on the oximeter and do not input external power supply.

7.2.2 Power indication

If the power voltage is low, the power indicator will appear as an empty box. Please replace your batteries with two new AAA batteries.

7.2.3 Function settings

7.2.3.1 Enter and Exit the setting interface

Press the power button to turn on the oximeter, then long press the power button and enter the setting interface. Then short press the power button, switch the icon " ∗ " to "Exit", and long press the power button to return to the test interface. (figure2)

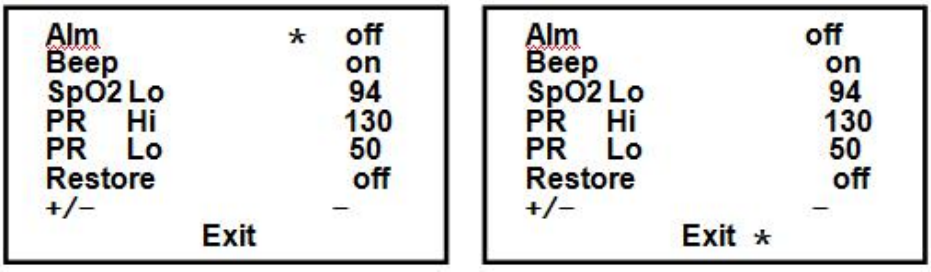


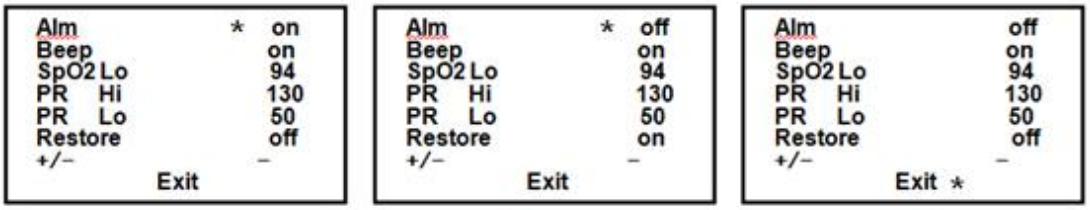
Figure 3 Setting interface

7.2.3.2 Turn on the prompt function "Alm"

Under the setting interface, short press the power button, move the icon "＊" to "Alm", and long press the power button to switch to "on", turn on the prompt function "Alm". Then when the SpO2 value is lower than the preset lower limit and / or the pulse rate value is higher than the preset upper limit or lower than the preset lower limit, the value of SpO2 and / or pulse rate displayed on the screen will continue to beat, and the buzzer will continue to sound with a "beep" sound.(figure 4)

7.2.3.3 Turn off the prompt function "Alm"

Under the setting interface, short press the power button, move the icon "＊" to "Alm", and long press the power button to switch to "off", turn off the prompt function "Alm". Then when the SpO2 value is lower than the preset lower limit and / or the pulse rate value is higher than the preset upper limit or lower than the preset lower limit, the value of SpO2 and / or pulse rate displayed on the screen will not beat, and the buzzer will not continue to sound.(figure 4)



Turn on the prompt function "Alm"

Turn off the prompt function "Alm"

Exit the seting interface

Figure 4 Turn on/off the prompt function “Alm”

7.2.3.4 Turn on and off the sound function "Beep"

Under the setting interface, short press the power button, move the icon "＊" to "Beep", and long press the power button to switch to "on", turn on the sound function "Beep"; Or long press the power button to switch to "off", turn off the sound function "Beep" . (figure 5)

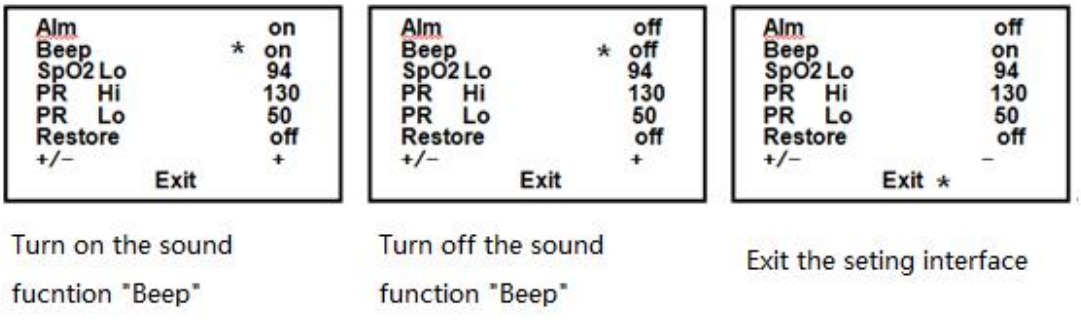


Figure 5 Turn on and off the sound function "Beep"

7.2.3.5 Restore setting

Under the setting interface, short press the power button, move the icon "∗" to "Restore ", and long press the power button to switch to "on", that means the device is already in the factory default state. (figure 6)

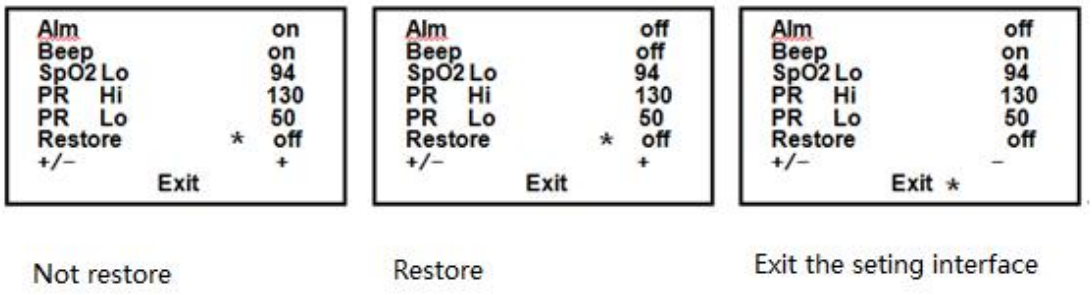


Figure 6 Restore setting

7.2.3.6 Preset “SpO2 Lo”

Under the setting interface, short press the power button, move the icon "∗" to "+/-", and long press the power button to switch to "+", then short press the power button, move the icon "∗" to " SpO2 Lo", increase SpO2 value; Or long press the power button to switch to "-", then short press the power button, move the icon "∗" to " SpO2 Lo", reduce SpO2 value.(figure 7)

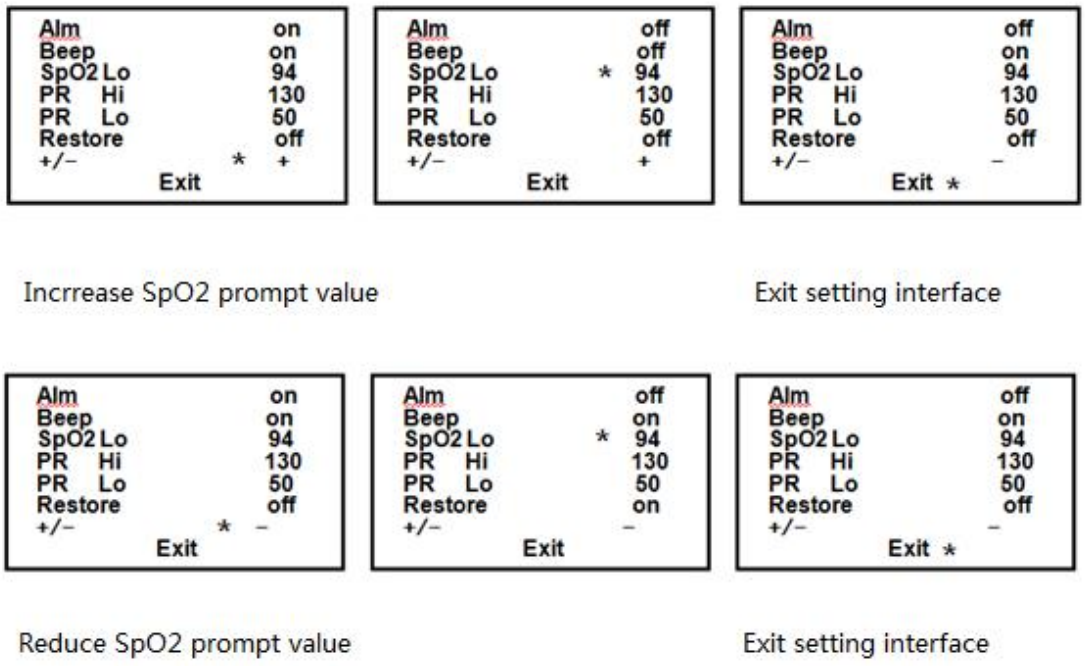


Figure 7 Preset “SpO2 Lo”

Notes: The SpO2 prompt value can be set to 100% highest and 70% lowest. The value in the range of 70% ~ 100% can be arbitrarily set as required.

7.2.3.7 Preset pulse rate (PR Hi) prompt value upper limit

Under the setting interface, short press the power button, move the icon "∗" to "+/-", and long press the power button to switch to "+", then short press the power button, move the icon "∗" to " PR Hi ", increase pulse rate (PR Hi) prompt value ;Or long press the power button to switch to "-", then short press the power button, move the icon "∗" to " PR Hi ", reduce pulse rate (PR Hi) prompt value value.(figure 8)

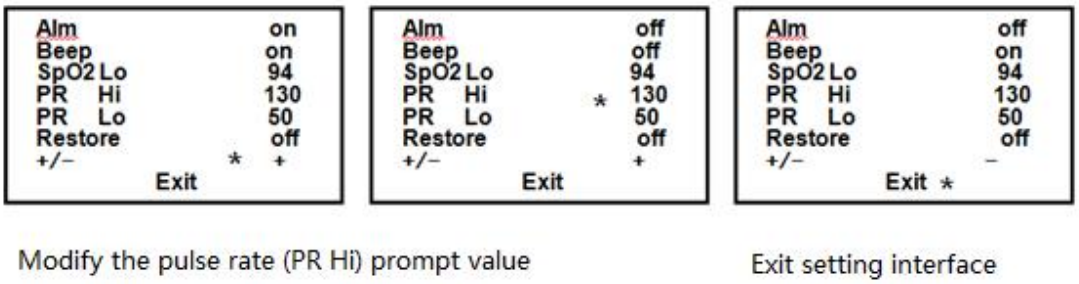


Figure 8 Preset pulse rate (PR Hi) prompt value upper limit

Notes: The maximum value of the pulse rate (PR Hi) prompt upper limit can be set to 200 bpm, the lowest can be set to 50 bpm, and the value in the range of 50 bpm to 200 bpm can be arbitrarily set as required.

7.2.3.8 Preset pulse rate (PR Lo) prompt value lower limit

Under the setting interface, short press the power button, move the icon "✳" to "+/-", and long press the power button to switch to "+", then short press the power button, move the icon "✳" to " PR Lo ", increase pulse rate (PR Lo) prompt value ;Or long press the power button to switch to "-", then short press the power button, move the icon "✳" to " PR Lo ", reduce pulse rate (PR Lo) prompt value value.(figure 9)

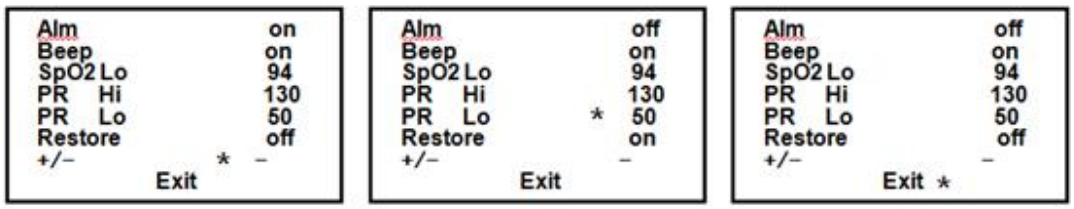


Figure 9 Preset pulse rate (PR Lo) prompt value upper limit

Notes: The maximum value of the pulse rate (PR Lo) prompt upper limit can be set to 200 bpm, the lowest can be set to 45 bpm, and the value in the range of 50 bpm to 200 bpm can be arbitrarily set as required.

After any one setting is completed, short press the power button, move the icon "✳" to "Exit", and long press the power button to return to the test interface.

7.3 Method for measuring pulse oximetry

1) Please check and confirm the appearance of the oximeter is in good condition before measurement, and check whether the battery is properly installed.
2) Turn on the oximeter.
3) Open the oximeter clip and place your finger (middle or index finger is recommended) on the silicone mat (confirm the correct position of the finger, the luminous window is aimed at the abdomen of the finger, and your finger completely covers the luminous window, then make the oximeter clamp your finger (as shown in the figure below).
4) Press the power button to turn on the oximeter, the display will light up, start measuring, and read the test results from the display area of the display.
   Caution: Do not test the machine under strong light environment (it will cause measurement error or the light is too strong, directly display "Finger out")

Figure 10 Method for measuring pulse oximetry

7.4 The Application for model with Bluetooth reads the measured value of the pulse oxygen saturation

Applicable model: BSX238B, BSX255B

At above clause 7.3 boot of measuring pulse oxygen saturation at the same time, open mobile phone Bluetooth, open the APP, click on the Bluetooth icon for Bluetooth connection, if no response muse refresh. read into the Bluetooth name and then click the connection, the connection is successful after return to measuring interface, blood oxygen meter to measure results if there are any normal, measuring interface and then display the corresponding results.

7.5 Cautions for Operation

1) Before use check and confirm that the people or finger size were applicable;
2) Before use check and confirm that the environment should be noncombustible material, as well as to avoid high or low temperature and humidity, but also need to pay attention to the following:
   a) To avoid glare and direct sunlight exposure;
   b) To avoid radiation infrared or ultraviolet radiation;
   c) Avoid contact with the organic solvent, mist, dust, corrosive gases;
3) The oximeter should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection;
4) The oximeter may not work normally on microcirculation barrier patients, warm or rub the finger, or re-position the oximeter could improve the measurement;
5) The ray between photo detector and light emitting diode should across patient's arteriole;
6) The patient should not use enamel or other makeup;
7) Avoid to insert a wet finger into the probe;
8) Don't shake the finger and try to keep the patient still during the measurement;
9) The user should fully insert the finger into the probe, otherwise it will cause incorrect measurement.

7.6 Warning for Operation

 Warning

1) Excessive light will affect the measurement results, such as direct fluorescent lamps, sunlight and etc.
2) Since the measurement of non-invasive blood oxygen saturation is based on the pulsation of small arteries, the blood of the patient should ensure a stable flow. When a subject is weakly perfused due to vibration, low temperature environment, major bleeding or the use of vasoconstrictor drugs, the waveform displayed by the device will be reduced, so it will sensitively interfere with the measurement of the oximeter.
3) Highly diluted colored medicines such as blue, indigo, green and acidic indigo methylene, or carboxyhemoglobin, or methionine, or heme thiocyanate and some jaundice problems can lead to incorrect results when measuring pulse oxygen saturation with this device. Related drugs such as dopamine, procaine, prilocaine, lidocaine, and bupivacaine are prone to cause serious errors in pulse oximetry.
4) The patient's physiological condition, treatment procedures, or external agents may interfere with the detection and measurement results of the oximeter, including heme dysfunction, arterial staining, melanin, and externally used tints, such as nail polish, Dye or skin cream.

8. Maintenance, Cleaning and Disinfection

8.1 Maintenance

The oximeter’s design life expectancy is about 5years, keep your oximeter and accessories free of dust and dirt, and follow these rules:

1) please clean the oximeter before use according to chapter 7.2; remove the batteries inside the battery cassette if the oximeter will not be operated for a long time;
2) Replace the batteries in time when the battery voltage indicate appears;
3) It is recommended that the oximeter should be keep in a dry environment with no corrosive gases and good ventilation anytime. The moisture and high –light environment will affect the lifetime and even might damage the oximeter;
4) Packaged oximeters can be transported by ordinary conveyance. The Equipment not be transported mixed with toxic, harmful, corrosive material;
5) It is best to preserve the oximeter in a place where the temperature is between-20℃to 55℃and the relative humidity is less than 93%.

 WARNING：Do not modify the oximeter without authorization.

8.2 Cleaning

Your oximeter should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the oximeter should be cleaned more frequently. Before cleaning the oximeter, consult your oximeter regulations for cleaning the oximeter. Recommended cleaning agents are:

1) Mild soap(diluted).
2) Ethanol (75%)
3) To clean your oximeter, follow the rules:
4) Shut down the oximeter.
5) Clean the display screen using a soft, clean cotton dampened with a glass cleaner;
6) Clean the exterior surface of the oximeter and probe using a soft, clean cotton dampened with a glass cleaner;
7) Wipe all off the cleaning solution with a dry cotton after cleaning if necessary;
8) Dry your oximeter in a ventilated, cool place.

To avoid damage to the oximeter, follow these rules:

Never immerse the oximeter into water or other liquids. Wipe the surface of the device with a soft cotton dipped in disinfectant if the product needs cleaning. Do not spray any liquid directly on this device.

Do not pour liquid onto the oximeter or accessories;

Never use the abrasive material (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

8.3 Disinfection

Clean the oximeter before disinfecting it. The recommended disinfectant is ethanol 75%. Disinfection steps are the same as cleaning.

⚠CAUTION

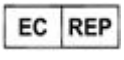
1) Never use to or formaldehyde for Disinfection.
2) Do not conduct high temperature, high pressure, gas fumigation, liquid, heated boiling bubble, heated boiling, boiling disinfection on the oximeter and its accessories.
3) As mentioned above, infection should be prevented during cleaning. Consult your physician when cleaning equipment for an infected person.

9. Trouble-Shooting

Trouble	Possible reason	solutions
The oximeter	Power button is not pressed properly.	Press the power button over again.

cannot be turned on.	The battery is drained away or almost drained away.	Please replace the battery.
	The battery installation is incorrect.	Install the battery over again.
	The oximeter works abnormally.	Please contact the product distributor.
The display is off suddenly	The oximeter shut down automatically in 8s when there are no physiological signals.	Normal
	The battery is almost drained away.	Please replace the battery.
Finger Out	The Finger is not inserted deep enough.	Fully insert the finger into the probe.
	Finger temperature is too low and blood vessel flow is too slow	After warming your fingers, measure again.
	Excessive ambient light.	Avoid excessive ambient light irradiation.

10. Symbols and Definition

Symbol	**Definition**
SpO2%	The pulse Oxygen Saturation (%)
PR bpm	The pulse rate (beat per minute)
PI%	The blood perfusion index (%)
	Manufacturer for Medical devices Health care - Medical equipment, to identify the manufacturer of a product.
	Indicates the Authorized Representative in the European community.
	Date of manufacture: to indicate the date on which a product was manufactured.
	Use by date, to indicate that the device should not be used after the date accompanying the symbol.

	Catalogue number: to identify the manufacturer's catalogue number.
	Batch code: to identity the manufacturer's batch or lot code.
	Serial number: identify the manufacturer's serial number.
	TYPE BF APPLIED PART
	Waste electrical and electronic product recycling icon.
	Operating instructions
AP	Rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to protect against HAZARDS of ignition of flammable anaesthetic mixtures.
APG	Rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to protect against HAZARDS of ignition of flammable anaesthetic mixtures.
	Distribution packages shall not be exposed to sunlight.
	Contents of the distribution packages are fragile therefore it shall be handled with care.
	Distribution packages shall be kept away from rain and be kept in dry conditions.
	Distribution packages shall be stored, transported, and handled within temperature limits indicated.
	This is the correct upright position of the distribution packages for transport and/or storage.
	Maximum number of identical transport packages/items which may be stacked on the bottom package, where "n" is the limiting number.
	WARNING. General warning sign, indicates a potentially hazardous situation Which, if not avoided, could result in death or serious injury.

	CAUTION. Indicates a potentially hazardous situation Which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the Equipment or other property.
	Refer to instruction manual/booklet, to signify that Instruction for use / booklet must be read.
IP22	The IP code (or International Protection Rating, sometimes also interpreted as Ingress Protection Rating), First Digit:(2) Against ingress of solid foreign objects, >=12.5mm (Fingers or similar objects). Second Digit :(2) Against ingress of water with harmful effects dripping water when tilted up to degree 15.

11. Disposal Treatment Statement

The product manufacturing date can be seen on the nameplate of the Monitor, and the product life is 5 years.

 **WARNING:** Do not throw away batteries with uncontrolled daily waste.

 **CAUTION:** Dispose of the device, components and optional accessories according

With applicable national or regional regulations. Unlawful disposal may cause environmental pollution.

The marking in this manual that the batteries in this product should be disposed with household trash at the end of its working life. If the batteries are not disposed of properly, the substances included can cause harm to human health and the environment. Please follow environmental laws and guidelines for proper waste disposal.

12. Limited Warranty (Warranty Card)

The Oximeter, not including batteries, is warranted to be free from defects in materials and workmanship appearing within 5 years from the date of purchase when used in accordance with the instructions provided with the monitor. the Cuff is warranted to be free from defects in materials and workmanship appearing within one year from the date of purchase when the monitor is used in accordance with the instructions provided with the monitor. The above warranties extend only to the original retail purchaser.

We will, at our option, repair or replace without charge any unit or cuff covered by the above warranties. Repair or replacement is our only responsibility and your only remedy under the above warranties.

To obtain warranty service contact Customer Service by calling +86-755-28719103 for the address of the repair location and the return shipping and handling fee.

Enclose the Proof of Purchase. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.

THE FOREGOING IS THE SOLE WARRANTY PROVIDED BY BSX IN CONNECTION WITH THIS PRODUCT, AND BSX HEREBY DISCLAIMS ANY OTHER WARRANTIES EXPRESS OR IMPLIED INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, IMPLIED WARRANTIES AND OTHER TERMS THAT MAY BE IMPOSED BY LAW, IF ANY, ARE LIMITED IN DURATION TO THE PERIOD OF THE ABOVE EXPRESS WARRANTY.

BSX SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER SPECIAL, INCIDENTAL, CONSEQUENTAIL OR INDIRECT COSTS EXPENSES OR DAMAGES.

This warranty provides you with specific legal rights, and you may have other rights that vary by jurisdiction. Because of special local requirements, some of the above limitations and exclusions may not apply to you.

13. Technical Specifications

Items	Parameter
Measuring Range	SpO2: 35%~100% Pulse Rate: 30~250 bpm
Display Resolution	SpO2: 1% Pulse Rate: 1bpm
Accuracy	SpO2: 70% ~79%: ±3%; 80%~100%: ±2%; 35~69%: unspecified Pulse Rate: ±3 bpm
Classification	Class IIa, Internal powered, Type BF applied part
Waterproof grade	IP22
Display	Color Display
Acoustic	buzzer
Memory	20 readings recall in the Memory Mode
Dimensions	Model BSX251, BSX233, BSX231, BSX253, BSX238B, BSX255B: L*W*T= 63.7*35*36.5mm
Operating environment range	10℃~ 40℃, 70~106Kpa, 30%~75%RH
Storage/ Transport environment range	-20℃~55℃, 70 ~ 106Kpa, ≤93%RH

Automatic Switch-off	Approx. 8 seconds after last measurement has been taken.
Battery	2*AAA 1.5V Batteries
Lifetime	3 years
Shelf Life	Unit: 3 years, package and battery: 6 months

If there is any performance improvement, the above specifications are subject to change without notice.

14. Electromagnetic Compatibility Warning and Statement

Notes:

The Equipment (it is mean the Fingertip Pulse Oximeter, the same below) complies with the relevant electromagnetic compatibility requirements of IEC 60601-1-2：2015, EN 60601-1-2: 2015, IEC 60601-1-11: 2015 clause 12, EN 60601-1-11: 2015 clause 12, IEC 80601-2-30: 2009+A1 clause 202, EN 80601-2-30: 2010 + A1 clause 202;

Users shall conduct installation and use according to the electromagnetic compatibility information provided by random files;

Portable and mobile RF communication equipment may affect the performance of the device, such as mobile phone and microwave oven which with strong electromagnetic interference shall be avoided when the Equipment is in use.

Warning:

The Equipment must not be close to or stacked with other equipment when in use, and if it is necessary to close to or stacked with other equipment when in use, it shall be observed and verified that whether it can run normally under its configuration;

Except for the cable sold by the Equipment manufacturer as the spare parts of internal components, the use of unspecified accessories and cables may lead to emission increase or anti-interference reduction of the Equipment.

– Potential allergic reactions to accessible materials used in the ME equipment.

Guidance and manufacturer's declaration - Electromagnetic Emissions		
The Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Equipment 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 Equipment is suitable for used in all establishments and those directly connected to the public low-voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance & Manufacturer's Declaration — Electromagnetic Immunity			
The Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Compliance Compliance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 *%.*
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1 kV for Input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11.	<5 % U_T (>95% dip in U_T.) for 0.5 cycle <5 % U_T (>95% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles <5% U_T (>95 % dip in U_T) for 5/6 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Equipment requires continued operation during power mains interruptions, it is recommended that the Equipment be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the A.C. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
The Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Equipment should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V rms, 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the Equipment including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
	6 V rms in ISM, bands	Not applicable	d=[3,5/V1] × P1/2
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7GHz	d=1.2×P1/2 80 MHz to 800 MHz
	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC60601-1-2:2014)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC60601-1-2:2014)	d=2.3×P1/2 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site

			survey [a] should be less than the compliance level in each frequency range [b]. Interference may occur In the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80MHz and 800MHz. the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Equipment is used exceeds the applicable RF compliance level above, the Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Equipment.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Equipment.

The Equipment is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Equipment are recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d=1.2\times P^{1/2}$	80MHz to 800MHz $d=1.2\times P^{1/2}$	800MHz to 2,5GHz $d=2.3\times P^{1/2}$
0.01	Not applicable	0.12	0.23
0.1	Not applicable	0.38	0.73
1	Not applicable	1.2	2.3
10	Not applicable	3.8	7.3
100	Not applicable	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to

the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) accordable to the transmitter manufacturer.
NOTE 1 At 80MHz and 800MHz. the separation distance for the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15. For Customer Service

 Manufacturer: Shenzhen BSX Technology Electronics Co., Ltd.

Address: Rm101&2/F~4/F, Building No.13, Ailian Industrial park, Wulian Community, Longgang District, Shenzhen 518116 Guangdong P.R. China
Web site: http://www.szbsx.com.cn

Telephone: 086-755-28719103

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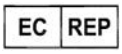 Authorized European Representative:

Company Name: MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Münster, Germany