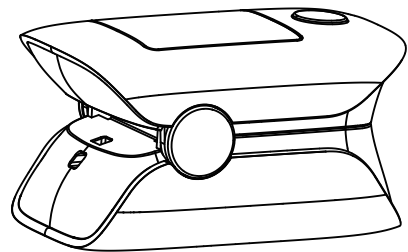


Size:400\*297mm

Owner's Manual Fingertip Pulse Oximeter XM-111



Document No.: JDXM-0104-058 Version:A

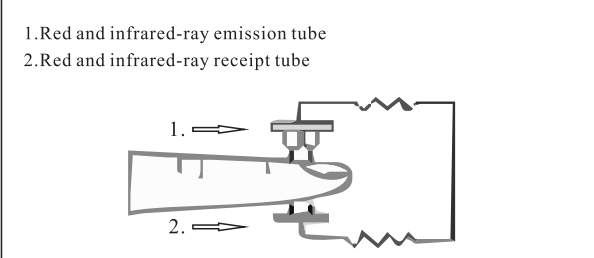
General Description

Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage of hemoglobin in the blood that is saturated with oxygen.

Measurement Principle

PRINCIPLE of the oximeter is as follows: The pulse oximeter works by applying a pulsating arterial vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light the other is 905nm, which is infrared-red light.

Diagram of Operation Principle



Safety Notice

- 1. Before use, carefully read the manual.
2. Do not use the pulse oximeter:
-if you are allergic to rubber products.
-if the device or finger is damp.
-during MRI or CT scan.
-while taking a blood pressure measurement on the arm.
-nail polish, dirty, coating fingers and false nails applied fingers.
-fingers with anatomical changes, edemas, scars or burns.
-Too big finger: the width of finger is over than 20mm and the thickness is over than 15mm.
-Too small finger: the width of finger is less than 10mm and the thickness is less than 5mm.
-Minors under 18 years old.
-The environmental light changes strongly.
-near flammable or explosive gas mixtures.
3. Extended use may cause pain for people with circulatory disorders. Do not use the pulse oximeter for longer than two hours on one finger.
4. Measurements are for your information only - they are no substitute for a medical examination.
5. Check the pulse oximeter regularly before use to ensure that there is no visible damage and the batteries are still sufficiently charged. In case of doubt, do not use the device and contact customer services or authorized retailer.
6. Do not use any additional parts that are not recommended by the manufacturer.
7. Any circumstances do not open or repair the device by yourself. Failure to comply will result in voiding of the warranty. For repairs, please contact customer services or authorized retailer.
8. Do not look directly inside the housing during the measurement. The red light and the invisible infrared light in the pulse oximeter are harmful to your eyes.
9. This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.
10. If the unit has been stored at temperatures below 0°C, leave it in a warm place for about two hours before using it.
11. If the unit has been stored at temperatures above 40°C, leave it in a cool place for about two hours before using it.
12. Neither of the displays for the pulse wave and pulse bar allows the strength of the pulse or circulation to be evaluated at the measurement site. Rather, they are exclusively used to display the current visual signal variation at the measurement site and do not enable diagnostics for the pulse.
13. Operation of the Fingertip Pulse Oximeter may be affected by the use of an electro-surgical unit (ESU).
14. Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
15. This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and systems. In healthcare center or other environment, their radio transmission equipment and electromagnetic interference may affect the performance of the oximeter.
16. This equipment is not intended for use during patient transport outside the healthcare facility.
17. When the signal is not stable, the reading may be inaccurate. Please do not reference.
18. Portable and mobile RF communications equipment can affect medical electrical equipment.
19. WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be separated to verify that they are operating normally.
20. WARNING: PORTABLE RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Fingertip Pulse Oximeter, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.

Important Testing Guidelines

- 1. Non-observance of the following instructions can lead to incorrect or failed measurements
-There must not be any nail polish, artificial nails or other cosmetics on the finger to be measured.
-Ensure that the finger nail on the finger to be measured is short enough that the fingertip covers the sensor element in the housing.
-Keep your hand, finger and body steady during the measurement.
-In cases of carbon monoxide poisoning, the pulse oximeter will display a measurement value that is too high.
-To avoid incorrect results, there should not be any strong light sources (e.g. fluorescent lamps or direct sunlight) in the immediate vicinity of the pulse oximeter.
-Protect the pulse oximeter from dust, shocks, moisture, explosive materials.
-Excessive patient movement.
2. The following situations may cause inaccurate measurements
-Significant levels of dysfunctional hemoglobin (such as carboxyl-hemoglobin or methemoglobin).
-Venous pulsations.
-Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
-The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
-The patient is in cardiac arrest or is in shock.
-Weak pulse quality (low perfusion).
-Low hemoglobin.

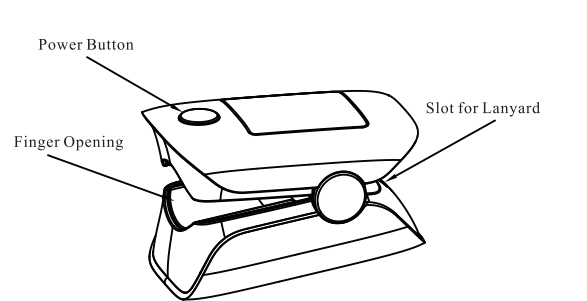
Intended purpose/Indications/Contraindications

- 1. Indications for use/Intended Use: The Fingertip Pulse Oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin and pulse rate of adult at home and hospital (including clinical use in restraints/surgery/anesthesia etc).
2. Medical indications: Oxygen saturation normal and hypoxemia.
3. Name of disease or condition: Well-being and the disease which may result in hypoxemia.
4. Patient population: Adults.
5. Intended user: Professionals and Lay person.
6. Contraindications: The device is not for continuously monitoring.

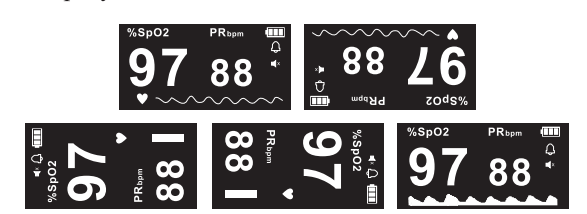
Unit Illustration

- Package contents
- 1 x XM111 pulse oximeter
- 1 x Owner's Manual
- 1 x Lanyard
Optional accessories
- 2 x 1.5V AAA batteries

Monitor Unit



Display

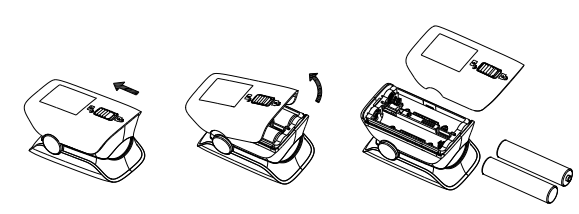


Features

- 1. Simple to operate and convenient to carry.
2. Small volume, light weight and low power consumption.
3. Displays SpO2, PR, Pulse bar, and waveform.
4. Level 1-5 adjustable brightness.
5. 5 display modes.
6. A low voltage warning will be indicated in visual window when battery voltage is so low that normal operation of the oximeter might be influenced.
7. When it shows "Finger out", the pulse oximeter will power off automatically in 10 seconds.
8. Beep.
9. When the buzzer and reminder function are turned on, the numbers on the screen will flash when the reminder occurs, and the buzzer will beep.
10. Perfusion index (value in percent).

Unit Operation

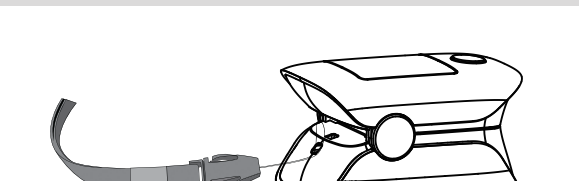
Battery Installation
Follow the arrow to unlock the battery cover. Install 2 new AAA alkaline batteries according to polarity, install the battery cover and lock it in the opposite direction of the arrow.



Note:

- 1) Be sure to follow the correct polarity when installing the batteries. Reversed batteries may cause damage to the device.
2) Use only the same type and type of batteries specified.
3) Do not mix different types of batteries together or old batteries with fresh ones. Always replace batteries as a simultaneous set.
4) Replace the batteries in a timely manner when low voltage lamp is lighted.
5) If the batteries in the device are depleted or the device will not be used for a long period of time, remove the batteries to damage or injury from possible battery leakage.
6) Do not try to recharge batteries not intended to be recharged; they can overheat and rupture.
7) Do not dispose of batteries in fire, batteries may explode or leak.
8) Keep batteries away from children and pets. Batteries may be harmful if swallowed. Should a child or pet swallow a battery, seek medical assistance immediately.
9) Please follow the law of the local government to deal with used batteries.

Attaching the Lanyard



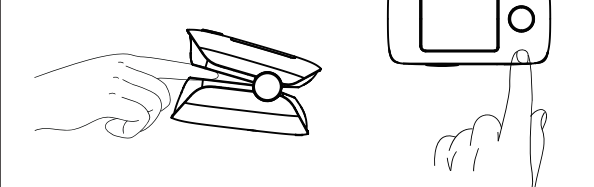
System Settings

With power off, Press the power button about 2 seconds to actuate system setting.
Setting available for Tips, Beep, Language, Default, SpO2 Tips Lo, PR Tips Hi, PR Tips Lo and EXIT. Long press to enter the specific value setting, short press to switch among the setting items.

Settings menu table with options for On/Off, SpO2 Tips Lo, PR Tips Hi, PR Tips Lo, and Exit.

To Use

- CAUTION: Please make sure your finger size is appropriate (fingertip width is about 10-20 mm, thickness is about 5-15 mm)
CAUTION: This device cannot be used in strong radiation environment. It can only be used after binding.
CAUTION: This device cannot be used with other medical devices or non-medical devices.
CAUTION: When placing your fingers, ensure your fingers can completely cover the LED transparent window in the finger clamp compartment.
1. As shown in the figure, squeeze the clip of the pulse oximeter, fully insert your finger into the finger clip compartment, and then loosen the clip
2. Press the power button one time on front panel to turn the pulse oximeter on.
3. Keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.
4. Read the data from the display screen.
5. To select your desired display brightness, press and hold the power button during operation until the brightness level changes.
6. To choose among the various display formats, press the power button briefly during operation.
7. If you remove the oximeter from your finger, it will shut off after about 10 seconds.



Cleaning and Maintenance

- 1. Please use medical alcohol to clean the silicone covering the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.
2. Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device allow the oximeter to dry thoroughly before reuse.
3. The Fingertip Pulse Oximeter requires no routine calibration or maintenance other than replacement of batteries.
4. The expected lifetime of the device is 3 years when it is used for 10 measurements every day and 10 minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:
- An error in the Possible Problems and solutions is displayed on screen.
- The oximeter cannot be powered on in any case and not the reasons of battery.
- There is a crack on the oximeter or damage on the display resulting readings cannot be identified; the spring is invalid; or the key is unresponsive or unavailable.
5. Cleaning procedures:
a) Put the oximeter on a clean table.
b) Use a clean lint-free soft cloth dipped in water to wring it out and clean the surface of the oximeter and the upper and lower finger pads.
c) If there are obvious stains, use commercially available neutral detergent to wipe and clean. After the stains are cleaned up, use a clean lint-free soft cloth dipped in water to wring it out and clean the surface of the blood oxygen meter and the upper and lower finger pads.
d) Fully dry the oximeter in a ventilated place.

Troubleshooting Guide table with columns for Problem, cause, and Solution.

Specifications table with columns for Model, Display, SpO2, Pulse Rate, Power supply, Weight, Dimensions, Operating Environment, Storage Environment, Ingress Protection Rating, and Classification.

Note: The functional tester cannot be used to assess the accuracy of the oximeter. The test methods used to establish the SpO2 accuracy is clinical testing. The oximeter used to measure the arterial haemoglobin oxygen saturation levels and these levels are to be compared to the levels determined from arterial blood sampling with a CO-oximeter.

- 1. EN ISO 80601-2-61, medical electrical equipment - part 2-61: particular requirements for the basic safety and essential performance of pulse oximeter equipment.
2. EN 60601-1: medical electrical equipment -- part 1: general requirements for basic safety and essential performance.
3. EN 60601-1-2, medical electrical equipment -- part 1-2: general requirements for basic safety and essential performance -- collateral standard: electromagnetic disturbances -- requirements and tests (General II (ES/EMC)).
4. EN 60601-1-11, medical electrical equipment -- part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
Correct disposal of this product.
(Waste electrical & electronic equipment)
This icon shown on the product indicates that it should not be disposed with other household waste at the end of its life. To prevent potential harm to the environment or to human health, please separate this product from other types of wastes and recycle it responsibly. When disposing this type of product, contact the retailer where product was purchased or contact your local government office for details regarding how this item can be disposed in an environmentally safe recycling center. Business users should contact their supplier and check the terms and conditions of the purchasing agreement. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.

Icon Explanation table with columns for Symbol, Definition, and corresponding icons for CE, UDI, Caution, IP22, Direct Current, Type BF applied part, Follow instruction for use, Authorized representative in the European community, and SpO2%.

Statement of Essential performance

- a) When the Oximeter is placed on the patient's finger or simulated finger, the SpO2 values and PR values can be displayed normally.
b) Measurement accuracies:
- Clinical accuracy of SpO2: in the range of 70%-100% (Arms: < 3)
- For each range specified, SpO2 ACCURACY OF THE PULSE OXIMETER EQUIPMENT shall be stated in terms of the root-mean-square (rms) difference between measured values (SpO2i) and reference values (SaO2).
Arms = sqrt((sum(SpO2i - SaO2)^2) / n)

Probe Accuracy of Oximeter

Items and Descriptions table listing Clinical SpO2 accuracy (70-80%), (80-90%), (90-100%), Sterile, Default settings, and Reuse.

- 1. Instructions for the frequency of inspection of the application site for skin integrity:
Before each finger is inserted into the oximeter probe, the integrity of the skin should be visually checked to ensure that the skin is free from injury and other conditions.
2. Instructions for the frequency of sensor relocation:
There is no need to replace the blood oxygen sensor within the service life of the product.
3. Use during exercise and weak perfusion:
(1) DO NOT move your finger, arm and body during the measurement.
Movement, including talking, coughing, or sneezing, during measurement, can affect the accuracy of the measurement results.
(2) The reading should NOT be considered reliable and accurate in the condition of low perfusion during measurement.

The sensor with specific monitor has been validated and tested for compliance with EN ISO 80601-2-61:2017 and FDA Guidance--Pulse Oximeters--Premarket Notification Submissions [510(k)]. In the clinical recruitment, the data is obtained from a controlled, induced hypoxia study in healthy adult volunteers. A total of 12 subjects including 5 females and 7 males were recruited from the healthy adult volunteers aged from 22 to 45 without smoker. In the clinical evaluation, 288 paired data of the 12 adults were validated.

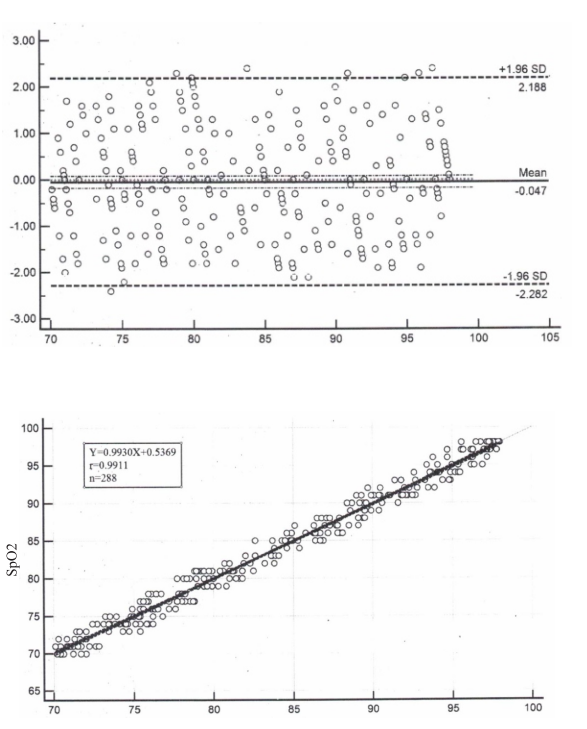


Fig. 2: Linear regression fit (X-axis is SaO2, Y-axis is SpO2 for the subject device)

Electromagnetic Compatibility Information

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which will be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Guidance and manufacturer's declaration - electromagnetic emission

Table 1: Emission test results for Conducted RF, Radiated RF, and Voltage Fluctuations/Flicker Emissions.

Guidance and manufacturer's declaration - electromagnetic immunity

Table 2: Immunity test results for Electrostatic Discharge, Electromagnetic transient/burst, Surge, and Voltage dips, dips, interruptions and voltage variations.

Guidance and manufacturer's declaration - electromagnetic immunity

Table 3: Immunity test results for Conducted RF, Radiated RF, and Voltage dips, dips, interruptions and voltage variations.

Guidance and manufacturer's declaration - electromagnetic immunity

NOTE 1: At 80 MHz and 800 MHz, 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.

Recommended separation distances between RF wireless communications equipment

Table 4: Recommended separation distances between RF wireless communications equipment based on Frequency, Maximum Power, Distance, IEC 60601 Test Level, and Compliance Level.

NOTE 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNINGS!

- This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transmitter or radio control products. If you have to do so, the device should be observed to verify normal operation.
The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

Warranty

The Fingertip Pulse Oximeter is guaranteed for 1-year from the date of purchase. If the Fingertip Pulse Oximeter does not function properly due to defective components or poor workmanship, we will repair or replace it freely. The warranty does not cover damages to your Fingertip Pulse Oximeter due to improper handling. Please contact local retailer for details.

Contact Information: JOYTECH Healthcare Co., Ltd. No.365, Wuzhou Road, 311100 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Importer: Cano Healthcare, W19 6XR, UK, www.canohealthcare.com