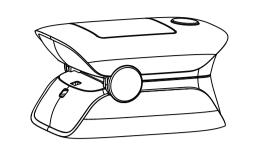
Owner's Manual

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. The percentage is called blood oxygen saturation, or SpO2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO2 level.

This device conforms to IEC60601-1, IEC60601-1-2, IEC60601-1-11, ISO 80601-2-61.

Measurement Principle

PRINCIPLE of the oximeter is as follows: The pulse oximeter works by applying a pulsating arteriolar 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 skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as

Diagram of Operation Principle

1.Red and infrared-ray emission tube 2.Red and infrared-ray receipt tube



Safety Notice

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
- -Too small finger: the width of finger is less than 10mm and the thickness is less
- -Minors under 18 years old.
- -The environmental light changes strongly. -near flammable or explosive gas mixtures.
- . 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
- . 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

- 6. Do not use any additional parts that are not recommended by the
- 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 3. 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 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
- on how to use the device. Children should be supervised around the device to ensure they do not play with it. 0. If the unit has been stored at temperatures below 0°C, leave it in a warm

lack of knowledge, unless they are supervised by a person who has

responsibility for their safety or they receive instructions from this person

- place for about two hours before using it. 1. If the unit has been stored at temperatures above 40°C, leave it in a cool
- place for about two hours before using it. 2. 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
- 13. Operation of the Fingertip Pulse Oximeter may be affected by the use of
- an electrosurgical unit (ESU). 4. Follow local ordinances and recycling instructions regarding disposal or
- recycling or 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. 6. This equipment is not intended for use during patient transport outside the healthcare facility
- 7. When the signal is not stable, the reading may inaccurate. Please do not
- 18. Portable and mobile RF communications equipment can affect medical
- 19. WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in imprope operation. If such use is necessary, this equipment and the other
- equipment should be observed to verify that they are operating normally. 20. WARNING:PORTABLE RF communications equipment (includeing 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

- Non-observance of the following instructions can lead to incorrect 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 carbonyl 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 hemoglobir Intended purpose/Indications/Contraindications

- 1.Indications for use/Intended Use:The Fingertip Pulse Oximeter is portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin and pulse rate of adult at home, and hospital (including clinical use in internist/surgery,anesthesia etc).
- 2.Medical indications:Oxygen saturation normal and hypoxemia.
- 3.Name of disease or condition: Well-being and the disease which may be esult in hypoxemia.
- 4.Patient population:Adults.
- 5.Intended user:Professionals and Lay personal. 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







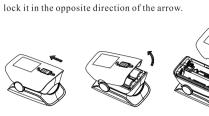
Features

- 1. Simple to operate and convenient to carry. .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.
- 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



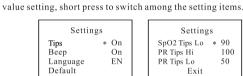
- 1)Be sure to follow the correct polarity when installing the batteries Reversed batteries may cause damage to the device.
- 2)Use only the size and type of batteries specified. 3)Do not mix different types of batteries together or old batteries with fresh ones. Always replace batteries as a simultaneous set.
- 4)Replace the batteries in a timely manner when low voltage lamp is 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.
- Do not dispose of batteries in fire, batteries may explode or leak. 8)Keep batteries away from children and pets. Batteries may be harmful of 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

Attaching the Lanyard



System Settings

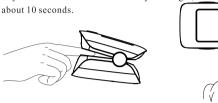
With power off, Press the power button about 2 seconds to actuate Setting available for Tips, Beep, Language, Default, SpO2 Tips Lo, PR Tips Hi, PR Tips Lo and EXIT. Long press to enter the specific



SpO2 Tips Lo * 90 PR Tips Hi

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-
- CAUTION: When placing your fingers, ensure your fingers can completely cover the LED transparent window in the finger clamp compartment. . As shown in the figure, squeeze the clip of the pulse oximeter, fully insert your finger into the finger clip compartment, and then loosen
- Press the power button one time on front panel to turn the pulse
- 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 operaion untill the brightness level changes. 5.To choose among the various display formats, press the power
- button briefly during operation. If you remove the oximeter from your finger, it will shut off after about 10 seconds.



Cleaning and Maintenance

- .Please use medical alcohol to clean the silicone touching the finger inside of oximeter with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and
- 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
- An error in the Possible Problems and solutions is displayed on
- The oximeter cannot be powered on in any case and not the reasons
- 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 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 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

Problem	cause	Solution			
	Batteries are depleted	Replace the batteries			
Monitor do not display	Batteries not inserted correctly	Reinsert the batteries. If after reinserting the batteries correctly There are still no measurement values displayed, contact customer service			
Measurements are erratic	Insufficient circulation in the measurement finger	Observe the Important Guidelines			
	Finger,hand or body is moving	Keep your finger, hand and body still during the measurement			
	Cardiac arrhythmia	Seek medical attention			
	Finger is not inserted correctly	Retry by inserting the finger			
Measurements can not be shown normally	Patient's SpO2 value is too low to be measured	There is excessive illumination; Or, Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.			

Specifications

Model	XM-111		
Display	0.96" display		
	Display Range	0%~100%	
	Measurement Range	70%~100%	
SpO2	Accuracy	70%~100% ±2% 0%~69% no definition	
	Resolution	1%	
	Display Range	0~240bpm	
	Measurement Range	30~240bpm	
Pulse Rate	Accuracy	30~100bpm,±2bpm; 101~240bpm,±2%	
	Resolution	1bpm	
Power supply	2x1.5vAAA batteries		
Weight	Approx.54g		
Dimensions	Approx.60.2mm*35mm*35.5mm		
	Temperature	5°C~40°C	
Operating Environment	Humidity	15%~93%RH	
	Pressure	700hPa~1060hPa	
	Temperature	-20°C~55°C	
Storage Environment	Humidity	15%~93%RH	
	Pressure	700hPa~1060hPa	
Ingress Protection Rating		IP22	
Classification	Internal Powered	Equipment Type BF	
The Data UPI	Less than 12s		

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

- 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
- 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

		0		0	I
Symbol	Definition	Symbol	Definition	Symbol	Definition
C € ₀₁₂₃	European union approval	•	Manufactu- rer's information	MD	Medical device
X	Conformity to WEEE Directive	M	Date of Manufactu- re	UDI	Unique device Identifier
\triangle	Caution	LOT	Batch Code	((₄))	Non-ionizing electromagen etic radiation
IP22	Protected against dripping water.	X	Temperature Limit	Î	Low power indication
===	Direct Current	%	Humidity limitation	×	Beep OFF
木	Type BF applied part	<u></u>	Atmospheric pressure limitation	•	Beep ON
③	Follow instruction for use	SN	Serial No.	Ø	Tips OFF
EC REP	Authorized representat- ive in the European community	Sp02	Alarm inhibit	Q	Tips ON
SpO ₂ %	Oxygen saturation	PR _{bpm}	Pulse rate (BPM)		

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 (SRi).

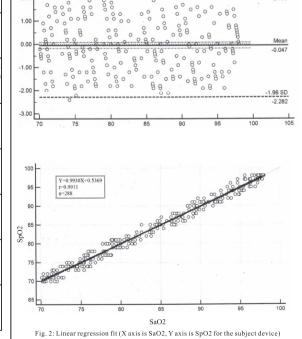
Items	Descriptionss	
Clinical SpO2 accuracy (70-80%)		
Clinical SpO2 accuracy (80-90%)	Arms: < 3	
Clinical SpO2 accuracy (90-100%)		
Sterile	Non-sterile	
D 6 1:		

- 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. . 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)s]. 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.



The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The ments are satisfied under the conditions described in the table below. The device is an lectrical medical product and is subject to special precautionary measures with regard to EMC erectrical inequal product and is supposed to special precautionary ineasures with regard to ENC which must 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

Probe Accuracy of Oximeter			Table 1			
•			Gui	dance and manufact	urer's declaration – electromagnetic emission	
tems Descriptionss			The device is intended for use in the electromagnetic environment specified below. The customer or the used assure that it is used in such an environment.			
accuracy (80-90%)	Arms: < 3	١	Emissions test	Compliance	Electromagnetic environment – gu	
accuracy (80-9070)		١	Conducted emission			
ccuracy (90-100%)			CISPR 11	Not applicable		
terile	Non-sterile		Radiated emission	Group 1	The device is suitable for use in all establishments, including domestic establishments and	
lt settings	None	١	CISPR 11	Class B	those directly connected to the public low-voltage power	
it settings	TVOILE	١	Harmonic emissions		supply network that supplies buildings used for domesti purposes.	
euse	Disinfect for repeated use		IEC 61000-3-2	Not applicable	hirhogan	
		- 1		,		

Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	
Table 2	1	

Guidance and manufacturer's declaration - electromagnetic immunit

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidit
IEC 61000-4-2	air	air	should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT	N/A	N/A

IEC 61000-4-8 OTE: UT is the Table 3 uipment should be used no closer to any part of the device, including cables, than the

Conducted RF IEC 61000-4-6 10 V/m IEC 61000-4-3 $d = \left[\frac{7}{E_1}\right] \sqrt{P} \quad 800 \text{MHz to } 2.7 \text{GHz}$ the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range b equipment marked with the following symbol

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies

eflection from structures, objects and people. t The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The ateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz.

The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz a patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the

in AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electr ation in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify nor

Table 4

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidan
385	1.8	0.3	27	27	RF wireless communicati equipment should be used
450	2	0.3	28	28	closer to any part of the de including cables, than th
710 745 780	0.2	0.3	9	9	recommended separation distance calculated from the equation applicable to the frequency of the transmitt Recommended separation distance
810 870 930	2	0.3	28	28	$E = \frac{6}{d} \sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter
1720 1845 1970	2	0.3	28	28	manufacturer and d is the recommended separation distance in meters (m). Fiel strengths from fixed RF transmitter, as determined l an electromagnetic site sur
2450	2	0.3	28	28	should be less than the compliance level in each
5240					frequency range. Interferent may occur in the vicinity of

• This device should not be used in the vicinity or on the top of other electronic equipment such cell phone, transceiver 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

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.

MDR2017/745,"0123"is the identification number

JOYTECH Healthcare Co., Ltd. No.365, Wuzhou Road,311100 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA EC REP Shanghai International Holding Corp.GmbH(Europe) Eiffestrasse 80,20537 Hamburg,Germany $C \in \mathbb{C}_{0123}$ The product is in compliance with requirements of

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Cano Healthcare

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of notify body

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Statement of Essential performance

) When the Oximeter is placed on the patient's finger or simulated finger, the SpO2 value

Electromagnetic Compatibility Information affect the device negatively and alter the electromagnetic compatibility. The device should not be