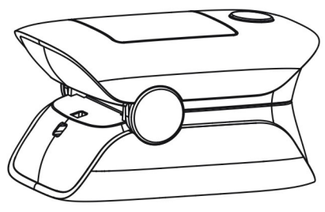
size:340*297mm

Owner's Manual

Fingertip Pulse 0ximeter

XM-101



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General Description

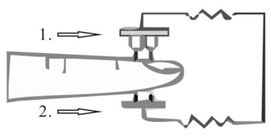
Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light(red and infrared) to determine the percentage(%)of hemoglobin in the blood that is saturated with oxygen. The percentage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

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 wacelength 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 SpO2.

Diagram of Operation Principle

1.Red and infrared-ray Emission Tube
2.Red and infrared-ray Receipt Tube



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 o the finger you are using is damp.
   - on small children or babies.
   -during an MRI or CT scan.
   - while taking a blood pressure measurement on the arm.
   - on large fingers that do not fit into the device easily.
   - on finger that have nail polish, are dirty, have other coatings on them, or have false nails applied.
   - on fingers with anatomical changes, edemas, scars or burns.
   - on fingers that are too small, as with small children.
   - on people who are not steady at the site of application.
   - 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. The pulse oximeter displays an instantaneous measurement but can not be used for continuous monitoring.
5. Measurements are for your information only - they are no substitute for a medical examination.
6. Check the pulse oximeter regularly before use to ensure that there is no visible damage to the device and the batteries are still sufficiently charged. In case of doubt, do not use the device and contact customer services or an authorized retailer.
7. Do not use any additional parts that are not recommended by the manufacturer.
8. Under no circumstances should you open or repair the device yourself. Failure to comply will result in voiding of the warranty. For repairs, please contact customer services or an authorized retailer.
9. Do not look directly inside the housing during the measurement. The red light and the invisible infra-red light in the pulse oximeter are harmful to your eyes.
10. This device is not intended for use by people(including children) with restricted physical, sensory or mental skills or a lack of experience and/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.
11. If the unit has been stored at temperatures below 0℃ , leave it in a warm place for about two hours before using it.
12. If the unit has been stored at temperatures below 40℃ , leave it in a cool place for about two hours before using it.
13. 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.
14. Operation of the fingertip pulse oximeter may be affected by the use of an electrosurgical untt(ESU).
15. Follow local ordinances and recycling instructions regarding disposal or recycling or the device and device components, including batteries.
16. This equipment complies with IEC 60601-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems.However, because of the proliferation or radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments,it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.
17. Portable and mobile RF communications equipment can affect medical electrical equipment.
18. This equipment is not intended for use during patient transport outside the healthcare facility.
19. This equipment should not be used adjacent to or stacked witch other equipment.
20. When the signal is not stable,the reading may inaccurate. Please do not reference.Rx only:“Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.”
21. Contraindication: It is not for continuous monitoring.

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 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 hemoglobin.

Intended Use

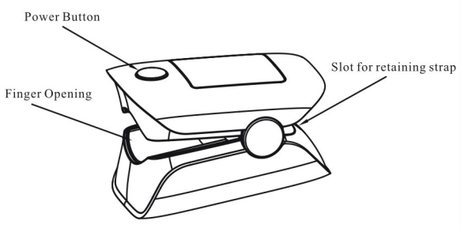
the Fingertip Pulse Oximeter is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin and pulse rate of adult at home, and hospital (including clinical use in internist/surgery, Anesthesia etc). It is not for continuously monitoring.

Unit Illustration

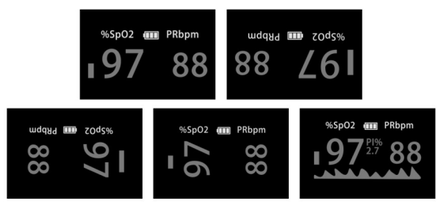
Contents

- 1 x XM101 pulse oximeter
- 1 x Owner’s Manual
- 1 x Retaining strap
- 1 x Storage Bag
- 2 x 1.5v AAA batteries

Monitor Unit



Display



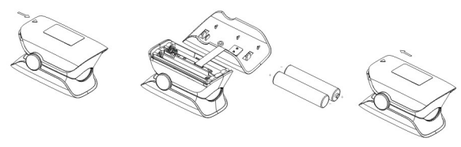
Features

1.Simple to operate and convenient to carry
2.Small volume,light weight and low power consumption.
3.Displays SpO2,PR, PI, Pulse bar, and waveform.
4.Level 1-10 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.Alarm.
10.Bluetooth function.

Unit Operation

Battery Installation

Slide battery cover off as indicate by arrow. Install 2 new AAA alkaline batteries according to polarity. Close battery Cover.



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 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 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 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 batteries.

Attaching the retaining strap

System Settings

With power off, Press the power button about 5 seconds to actuate system setting.

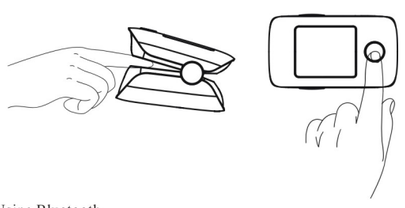
Setting available for Alm、Beep、Language、Default、SpO2 Alm Lo、PR Alm Hi、PR Alm Lo and EXIT . Long press to enter the specific value setting, short press to switch among the setting items.

Setting	
Alm	* On
Beep	On
Language	EN
Default	

Setting	
SpO2 Alm Lo	* 90
PR Alm Hi	100
PR Alm Lo	50
Exit	

To Use

1.Press the back ends of the monitor together to open and insert index finger into the opening and hold it steady.
2.Press the switch 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 operaion untill the brightness level changes.
6.To choose among the various display formats, press the power button briefly during operation.
7.If you remove the monitor from your finger, it will shut off after about 10 seconds.



8.Using Bluetooth
1)Download and install the “JOYTECH Healthcare” app from your smartphone’s app store.
2)Open the App on your phone. If requested, you should enable Bluetooth on your phone. You can enable Bluetooth under the Settings menu on your smart phone.
3)Create a new user login, or login with your existing user name and password.
4)Open your oximeter and pairing with your phone.
5)When your oximeter is connected successfully to your smart phone, The data transfer will begin automatically.
Note: The monitor requires a smart device with: Android 5.0 or later, IOS9.0 or later.

Cleaning and Maintenance

1.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 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 use life of the device is five years when it is used for 15 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.Disinfecting
The applied parts touching the patients’body are required to be disinfected once after each use.
The recommended disinfectants include: ethanol70%, isopropanol 70%. glutaraldehyde-type 2% liquid disinfectants.
Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital’s servicing schedule.Clean the pulse oximeter before disinfecting it.
CAUTION:Never use EtO or formaldehyde for disinfection.

Troubleshooting Guide

Problem	cause	Solution
Monitor do not display	Batteries are depleted	Replace the batteries
	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
Measurements can not be shown normally	Finger is not inserted correctly	Retry by inserting the finger
	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.
Connection failure/ Data is not being transmitted	The oximeter might not be porperly placed within the smart device’s tranmission range and is too far from the smart device	If there are no causes of data transmission interference found near the oximeter, move the oximeter withe16ft. (5m) of the smart device ang try again
	The oximeter did not pair successfully to the smart device	Try to pair the devices once again
	The application on the smart device is not ready	Check the application then try sending the data again

Specifications

Model	XM-101	
Display	OLED display	
SpO2	DisplayRange	0%~99%
	Measurement Range	70%~100%
	Accuracy	70%~100% ±2%; 0%~69% no definition
	Resolution	1%
Pulse Rate	DisplayRange	0~240bpm
	Measurement Range	30~240bpm

	Accuracy	30~100bpm, ±2bpm; 101~240bpm,±2%
	Resolution	1bpm
Power supply	2x1.5v AAAbatteries	
Power Consumption	<60mA	
Weight	Approx.54g	
Dimensions	Approx.60.2mm*35mm*35.5mm	
Operating Environment	Temperature	5℃~40℃
	Humidity	15%~93%RH
	Pressure	700hPa~1060hPa
Storage Environment	Temperature	-20℃~70℃
	Humidity	15%~93%RH
	Pressure	700hPa~1060hPa
Ingress Protection Rating	IP22	
Classification	Internal Powered Equipment Type BF	

Bluetooth communication	Frequency range	2.4GHz(2400~2483.5MHz)
	Modulation	GFSK
Probe LED Specifications	Wavelength	Power Consumption
RED	Approx.660nm	Approx.3.2mW
IR	Approx.905nm	Approx.2.4mW
The Date UPDATE period		Lessthan 12s

Measurement Performance in Low Perfusion Condition: required the test equipment (FLUKE-INDEX 2XL) the pulse wave is available without failure when the simulation pulse wave amplitude is at 0.4%.

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.

Specifications are subject to change without notice.
1.ISO 80601-2-61, medical electrical equipment - part 2-61: particular requirements for the basic safety and essential performance of pulse oximeter equipment.
2.AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012 (consolidated text) medical electrical equipment -- part 1: general requirements for basic safety and essential performance.
3.AAMI/ANSI/IEC 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.IEC 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 marking 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.

Symbol	Definition	Symbol	Definition
	Type BF applied part.		Attention
IP22	Protected against dripping water.	SpO2%	Oxygen saturation
PRbpm	Pulse rate (BPM)		Low power indication
SpO2	No SpO2 Alarm	SN	Serial No.
	Storage temperature and relative humidity		Follow instruction for use
	Date of Manufacture	EC REP	Authorized representative in the European community
CE 0123	European union approval		Manufacturer’s information
	Conformity to WEEE Directive	Bluetooth	The Bluetooth® Smart word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by JOYTECH Healthcare Co.,Ltd.

FCC Information

Caution: Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user authority to operate the equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.
*Note:
The device has been evaluated to meet general RF exposure requirement.The device can be used in portable exposure condition without restriction.
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 radiofrequency energy. 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 and correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna.
- Increase the distance between the equipment and the receiver.
- Connect the equipment to 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

Warranty

The Fingertip Pulse 0xineter is guaranteed for 2-year from the date of purchase. If the Fingertip Pulse 0xineter 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 0xineter due to improper handling. Please contact local retailer for details.

Contact Information
JOYTECH Healthcare Co., Ltd.
No.365, Wuzhou Road, Yuhang Economic Development Zone,
Hangzhou City, 311100 Zhejiang, China
Please contact us on:
Email: info@sejoy.com
Telephone: +86-571-81957767
Fax: +86-571-81957750