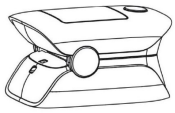
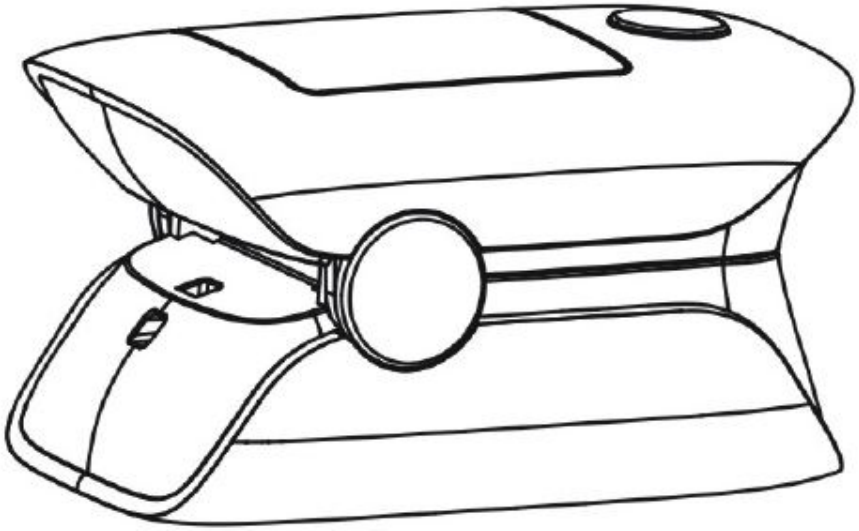


Joytech Healthcare XM-101 Fingertip Pulse Oximeter Owner's Manual

Contents

Joyetech®

Joytech Healthcare XM-101 Fingertip Pulse Oximeter



General Description

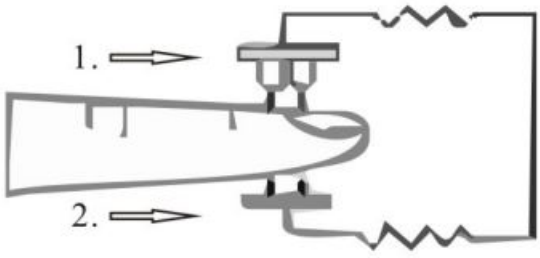
Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as ancrial blood. A pulse uses two frequencies of light(n:d and infrared) lo determine the percent.is(%)of hemoglobin in the blood that is saturated with oxygen The large park is called blood oxygen:n saturation, or Sp02. A pulse oximeter also measures and displays the pulse 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 sun:l' and photo detector . The om: wavelength of light source is 660nm,whit:h is red light the other is 905nm,which is infrared-red light Skin, bone,tissue and venous vessels normally and a constant amount of light over time.The rho to the detector in the finger sensor collects and converts the light into an 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 diaslOk is translated into an oxygen saturation measurement. This measurement is referred to as SpU2.

Diagram of Operation Principle

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



Safety Notice

- Before use,carefully read the manual
- Do not use the pulse oximeter:

    - if you arc allergic to rubber products.
    - if The device: o that: (ingter you .ire using is damp.
    - on small children or babies.
    - during an MR I or CT scan.
    - while taking a blood pressure measurement on the arm
    - on large fingers that do not fit into the device easily.
    - on fingers that have nail polish, are dirty, have other coatings on them, or have false nails applied.
    - on fingers with anatomical changes, condemns, scars or burns.
    - on fingers that arc too small. as with small children.
    - on people who are not steady at the site of application.
    - 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.
- The pulse oximeter displays an instantaneous measurement but can not be used for continuous monitoring.
- Measurements an: fur your information only – they an: no substitute for a medical examination.
- Check the pulse oximeter regularly before use tO ensure that there is no visible damage to the device and the batteries arc still sufficiently charged. In case of doubt, do nol ust Lhc device and contact customer services or an authorized retailer.
- Do not use any additional parts that are not recommended by the manufacturer.
- Under no circumstances should you open or repair 1hc device yourself. Failure to comply will result in voiding of the warranty. r or rcpai rs. please con tact customer services or an authorized n: tailer.
- Do not look directly inside the housing during the measurement. The red light and the invisible infra-red light in the pulse oximeter arc harmful to your eyes.
- . This dn·iec 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 responsihility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around Lhe device to cns,1re they do not play with it.
- If the unit has been stored at temperatures below OL”, leave it in a warm place for about two hours before using it.
- If the unit has been stored at temperatures below 40’C, leave it in a cool place for about two hours before using it.
- Ncithcr of thc displays for thc pulse ·wave and pulse bar allows the stn:ngth of thc pubte or circulation to he ev.il at thte measurement site. Rather. they are exclusively used to display the current visufll signal vflriation at the measurement site and do not enable diagnostics for Lhe pulse.
- Operation of the fingertip pulse oximeter may be affected by the use of an eleetrnsurgieal untt(ESIJ).
- Follow local ordinnnces and recycling instructions regnrding disposal or recycling or the device and device components, including batteries.
- This equipment complies with I EC 6060 \-1-2:2014 for electromagnetic compatibility for medical electrical equipment and/or systems.However. because of t he proliferntion or radio-frequency transmitting eq11ipment and other sources of electrical noise in healthcare and other cnvironmcnts,it is possible that high kveh of such inlerforcm:e due to close proximity or strength of a source might disrupt the performance of this device. Portable and mohile RF communications equipment can affect medical electrical equipment.
- This equipment is not intended for use during patient transport outside the healthcare facility.

- This equipment should not be used adjacent to or stacked witch other equipmcnL When the signal is not stable,the reading may inaccurnte. Please do not reference.Rx only:”Camion: Federal law (USA) restricts this device to sale by or on the order of a licensed prlilioncr.”
- Contraindication: It is nol fur eonlinuous monitoring.

Important Testing Guidelines

- Non-observance of the following instructions crin lerid to incorrect or failed mcarnrcmcnts
  - There must not be any nail polish, artificial nails or other cosmetics on the finger to be measured
  - Ensurte lhal Lhe finger nail 011 Lhe finger Lo be measured is shorl enough that the fingertip covern the sensor clement in the housing.
  - Ktet:p your hand. lingter and body steady during the mteasurcmenl.
  - In eases of carbon monoxide poisoning. the pulse oximetcr will display a measurement value that is too high.
  - To avoid incorrect results, there should not be any strong light sources(c .g. nuorcsceot lamps or direct sunlight) in the immediate vicinity of the pulse oximctcr.
  - Protect the pulse oximeter from dust, shocks, moisture, explosive materials.
  - Exctessivte patitenl IllO\·emenl.
- 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,scvcrc anemia, or hypothermia.
  - The patient is in cardiac arrest or is in shock.
  - Weak pulse: quality (low perfusion).
  - Low hemoglobin.

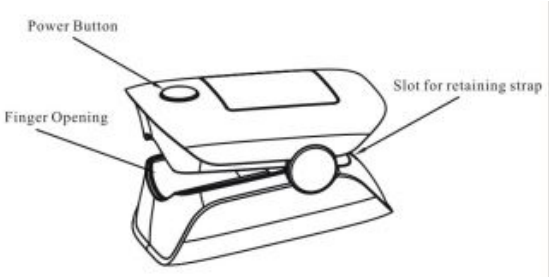
Intended Use
the Fingertip Pulse Oximctcr is a portable non-invasive, spot-check, oxygen saturation of arterial hemoglobin and pulse rate of adult at home, and hospital (including clinical use in internit/surgcry. Anesthesia etc). IL is nol for continuously monitoring.

Unit Illustration

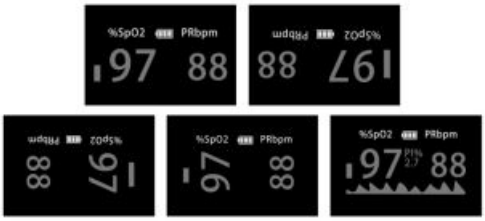
Contents

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

Monitor Unit



Display



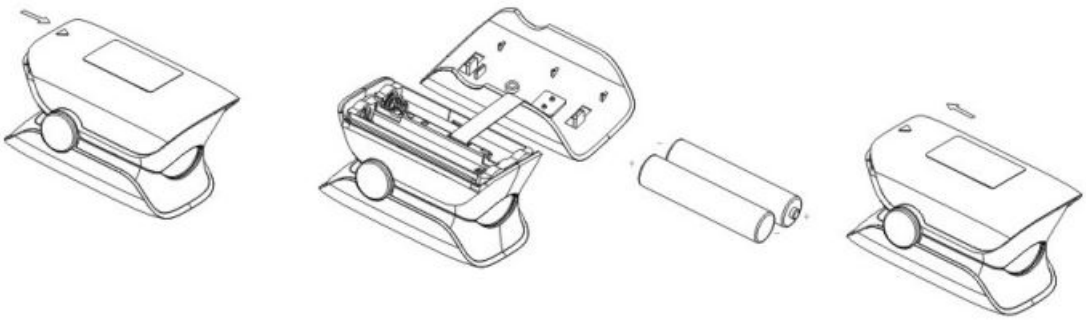
Features

- Simple to operate and convenient to carry
- Small volume,lightweight and low power consumption. 3.!Displays Sp02,PR, 1’1, Pulse bar, and \vavcform.
- Level l-10 adjustable brightness.
- 5 display mode.
- A low voltage warning will be indicated in visual window when battery voltage is so low that the normal operation of the oximeter might be influenced.
- When it shows ·•ringer out”,the pulse oximeter will power off automatically in 10 seconds.
- Beep
- Alarm.
- Bluetooth function.

Unit Operation

Battery Installation

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



Note:

- He sure to follow the correct polarity when installing the ballerinas. llcvcrsed bal! cries may cause damage to

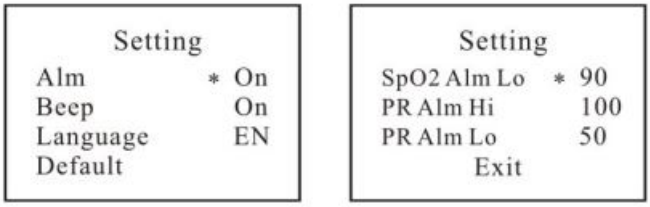
the device.

- Use only the si.:e and type of balleries specified.
- Do not mix different types of halt crimes together or old batteries with fresh ones. Always replace batteries as a simultaneous set.
- Replace the batteries in a timely manner when low voltage lamp is lighted.
- If 1fthe batteries in the device are depleted or the device will not he used for a long period of time, remove the batteries to damage or in_jury from possible battery leakage.
- 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. !)Keep batteries away from children and pets. Haltcries may be harm fol of swallowed. Should a child or pet swallow a hattery, seek medical I assistance immediately.
- Please follow the law of the local government to deal with used batteries.

Attaching the retaining strap

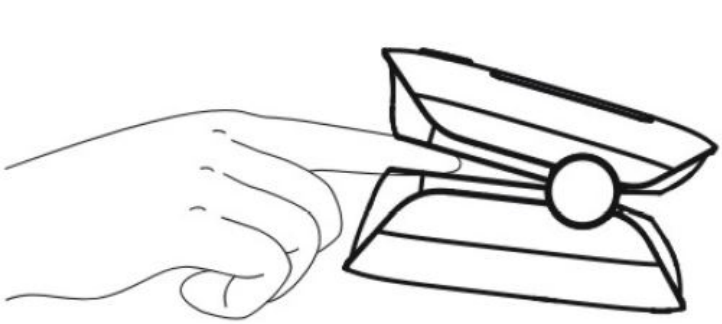
System Settings

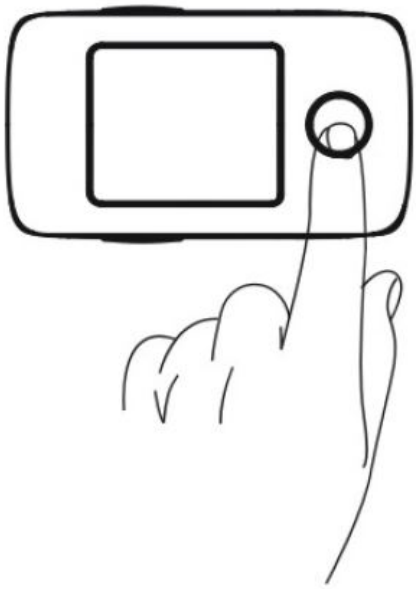
With power off, Press the power button for about 5 seconds to actuate the system setting. Selling a\·ailable for Alm, Beep, Language, Default, Sp02Alm Lo, PR Almlli, PR Alm Lo and EXIT. Long press to enter the specific value setting, short press to switch among the setting items.



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 S\v·itch button one time on front panel to turn the pulse oxunelt'r 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 unti II rltc brightness level changes.
6. To choose among the various display formats, press the power button briefly during operation.
7. Jf you remove the monitor from your finger, it will shut off after about IO seconds.





8. Using Bluetooth Download and install the “JOYTECll I healthcare:” app from your smartphone’s app store.
9. open lhe App on your phone. I requested you should tenable Bluetooth on your phone. You can enable Bluetooth under the Settings menu on your smart phone.
10. Create a new user login, or login with your existing user name and password.
11. 0pen your oximeter t1nd pairing with your phone.
12. When your oximeter is connected successfully to your smart phone, Tbe data transfer wil I begin automatically. .Nole: The monitor requires a smart device with Android S.0 or later, IUS9.0 or later.

Cleaning and Maintenance

1. Please use medical alcohol to clean the silicone touching the lingter inside of oximeler with a rnft cloth dampened with 70% isopropyl alcohol.Also ckan the being tested finger using alcohol herure and alter each lest.
2. Do not pour or spray liquids onto the oximeter,and do not allow any liquid to enter any openings in the device,\llow the oximeter to dry thoroughly before re11se.

   3. The fingertip pulse oximeter requires no routine calibration or maintenance other turn the replacement of batteries.

   4. The use life of the device is five years when it is used for l 5 measurements every day and l O minutes per one measurement. Stop using and contact local service center if one of the following cases occurs:
      1. An error in the Possible Problems and solutions is displayed on screen.
      2. The oximeter cannot he powered on in any case and not the reasons of battery.
      3. There is a crack on the oximeter or damage on the
3. Disinfecting The applied parts touching the patient’s body are rl, quired lo disinfect once after each use. The recommended disinfectants include: ethanol70%. isopropanol 70%. glutaraldehyde-type 2% liquid disinfectants. Disinfection may c.iusc damage lo the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your ho8pirnl’s 8ervicing scl1edule.Clean the pulse oximeter before disinfecting it. CAUTION use EtO or formaldehyde for disinfection

Troubleshooting Guide

Problem	cause	Solution
The monitor do not display	Batteries arc repleted	Replace the batteries
	Oatteries not inserted COITCCt]y	Reinsert the batteries. lf after reinserting the batteries correctly, There are still no measurement values displayed. contact customer service
Measurements arc errati c	iInstuhffie mcieanstmciermcuelnat ofinnger Fminogvcmr,hand or body is measurement	GOubsideervlienethse Important Kanedee6ydoyurstfiilnl acurr,.Manthe
	Cardiac, rhythmic	Seek medical attention
Finger i, nul internal aurrelly Retry by inserting the tingc1 Measurements can not be shown ourme itnimatieosn. :flavor,uTrcyansome too low to be measured er.l xleisatsein thetoparohdouscpt1,tal imdyeor exact diagnosis.		There is excessive Connally make sure no problem
The oximeter might not he Connection failure/ Data is range mid is too far from music the o ,:imc\cr withe not being try,1guin		If there arc no causes of data porperly placed within the transmission interference srrn1rl device's transmission found 11car the oximeter, l6fl. the sm,111 devices (5m) of thi;, smart device;mg
transmitted	The oximeter did not pair successfully to the	Try to pair the devices once again sman device
	The application on the try sen mg the data agam	Check the asplication smart device is not ready

Specifications

Model Display;	XM-101 OLED, Display	
	DisplayR.nnge	O%-99%
Sp02	Mearsument Range Accuracy	70%-100% 70%-100% ±2%: 0 %-69% no “definition
	Rasolation	
PulseRate	DisplayR.angc)measurement Ramge	0-241lhpm 30-240bpm

	Accuracy Resolution	30~100bpm+- .2bpm 101~240bpm±2% lbpm
Power >upply Power Consumption	2xl.5v AAA battries <60ma	
Weight	Approx.’i4g	
Dimensions	Approx.60.2111m •:,5mm*35.5mm	
	Temperature	ff>40T:
Operating environment	Humidity	l5%-93%RH
	Pressure Tcm(lcmlurc	700hpa-l0l60hpa -20C-70C
StorageEnvrronmmt	Humidity	l 5%- 93%RH
	Pressure	700hPa·1060hPa
Ingress Protection Rating Classification	1P22 internal power eqipment type BF	

Bluetooth communication probe LEDSpccificalinn, RED ‘”	Frcqumc} range	2.40Hzll40(.)-.24H5MHz}
	Mndulatinn Wavcl1:11ilh Approx660nm	gFSK Power Consurnplio11 Approx.3.2mW
	approx..905nm	Approx.2.4mW Lcsstlrnn 1.2&
TheDate UPDATE period		
Measurement , Performance inLowl’erfusionCondition: required the test equipment(FLUKE· INDEX)(2XL the p ulse wave is available without failure when the simulation puls wave amplitude is at 0.4%		

Note: The functional tester cannot he used to the accuracy of the oximeter. The test method used to establish the Sp02 accuracy is clinical testing. The oximeter used to measure the arterial hemoglobin oxygen saturation levels and these levels arc to be compared to the levels determined from arterial blood sampling with a CO-oximeter. Specifications are subject to change without notice.

1. SO 80601-2-GI, medical electrical equipment – pan 2 GI: particular:ir requirements for the basic safety and essential performance of pulse oximeter compact.
2. .AA.MI I ANSI ES6060 l-1:2005/(R)2012 and CI :2009/(R)2012 and, a2:2010/(r)2012 (consolidated text) medical electrical equipment — part I: general requirements for basic safety and essential performance.
3. AAMliANSl/IEC 60601-1-2. Medical Electrical Equipment — Part 1-2: General Requirements For Dasie. Safety /\nd Essential Performance — Collateral Standard: Electromagnetic 11isturhances — Requirements And Tests (General II (ES/D,·1C)).
4. lEC 60601-1-11, medical electrical – part l -11 . general requirements for basic safety and essential I performance – collateral: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. Correct!Disposal of this product (\Vaste Electrical & Electronic Equipment) This marking shown on the product indicates that it should nut be disposted:d wilh ulster household waslt’ al the cod of its !ire. To prevent potential harm to the environment or to human health, please separate this product from other types of waste and recycle it responsibly. When disposing of this type of product, contact the retailer where the product was purchased or contact your local go\’ernment office for details regarding how this item can be disposed of in an en\’ironmentally sn fc recycling center. Business users should contact their supplier and check the terms and conditions of thc purchasing agreement. This product should nol be mixed wilh 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.	SpO_2%	Oxygen saturation
PR_{bpm}	Pulse rate (BPM)		Low power indication
	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 response i ble for com planet corn lrl vild the er authority to operate the cqui prncnt. This rlcvice com pl ics with Part 15 of the rec Rules. Operation is subject to the following two conditions: this device may not cause harm fol interference, and 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 conditions without restriction. This equipment has hecn teted anrl found to comply with the limits for a Class 13 digital device. pursuant to Pan l 5 of the FCC Rules. These limits arc 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 c.an be determined by turning the equipment off and on, the user is encouraged to try and correct you: InstaForex,,e by one or more of lhe following me:1sun:s:

- 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 (O whid1 lh.: receive is ..: connected.
- Consult the d.:akr or <1n experiment radio/TV technician for help

Warranty

Th, Fingertip Pulse Oximeter is guaranteed fur 2-year from lhc date of purchase. If the Fingertip Pulse Oximeter does not function properly due to defective components or poor workmanship, WC will repair or replace,t freely. The warranty does not cover damages to your Fingertip Pulse Oximeter due to improper h.indling. Please contact local retailer ror details. Co11Lacl Information

JOY TECH Healthcare Co., Ltd.
No.365, Wuzhou Road, Ynhang Economic 11evelopment Zone, Hangzhou City, 311100 Zhejiang, China
Please contact us on:
Email: info@sejoy.com
Telephone: +86-571-8195 7767
Fax: +86-571-81957750

Documents / Resources

	Joytech Healthcare XM-101 Fingertip Pulse Oximeter [pdf] Owner's Manual 0009, 2AQVU0009, XM-101 Fingertip Pulse Oximeter, Fingertip Pulse Oximeter