

Pulse Oximeter

FOX-200 (JPD-500E(LED))

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MNPG302-00

Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter. This Manual is written and compiled in accordance with the council directive MDD 93/42/EEC for medical devices and harmonized standards. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

Please read the User Manual carefully before using this product.

WARNING:

- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patient. It is recommended that the sensor should not be applied to the same finger for over 2 hours.
- The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.
- Enamel or Acrylic fingernail polish or other fingernail applications may distort and/or produce inaccurate readings.
- Please refer to the correlative literature about the clinical restrictions and caution.

1 Safety

1.1 Instructions for Safe Operations

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cable and transducers. It is recommended that the device should be inspected once a week at least. When there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in User Manual. Only the accessory that appointed or recommendatory by manufacture can be used with this device.
- This product is calibrated before leaving factory.

1.2 Warning

- Explosive hazard---DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic agents.
- DO NOT use the oximeter while the user is measured by MRI and CT.
- The person who is allergic to rubber cannot use this device.
- The disposal of scrap instrument and its accessories and packing (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.
- Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.

1.3 Attentions

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- High temperature or high-pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter for instructions of cleaning and disinfection.
- Do not have the oximeter immersed in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- Do not use the device on infant or neonatal patients.
- The product is suitable for children above four years old and adults (Weight should be between 15kg to 110kg).

- The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- The instrument does not have low-voltage alarm function, it only shows the low-voltage, please change the battery when the battery energy is used out.
- Batteries must be removed if the device is going to be stored for more than once month, or else batteries may leak.

1.4 Indication for use

The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO₂) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). This device is not intended for continuous monitoring.

2 Overview

The pulse oxygen saturation is the percentage of HbO₂ in the total Hb in the blood, so-called the O₂ concentration in the blood. It is an important bio-parameter for the respiration. For the purpose of measuring the SpO₂ more easily and accurately, our company developed the Pulse Oximeter. At the same time, the device can measure the pulse rate simultaneously. The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis, and a display screen will directly show measured valued of Hemoglobin Saturation.

2.1 Classification:

Class II a (MDD 93/42/EEC IX Rule 10)


Class II (U.S.FDA)

2.2 Feature

- Operation of the product is simple and convenient.
- The product is small in volume, light in weight (total weight is about 50g including batteries) and convenient in carrying.
- Power consumption of the product is low.
- The product will automatically be powered off when no signal is in the product within 16 seconds.

2.3 Major Applications and Scope of Application

The Pulse Oximeter can be used to measure human Hemoglobin Saturation and pulse rate through finger, and indicate the pulse intensity by the bar-display. The product is suitable for use in family, hospital (Ordinary sickroom) and social medical organizations and also the measure of saturation oxygen and pulse rate.

 The product is not suitable for use in continuous supervision for patients.

2.4 Environment Requirements

Operation Temperature: 5°C-40°C

Storage Temperature: -10°C-50°C

Ambient Humidity: 15%-80% RH, no condensation in operation
10%-93% RH, no condensation in storage

Atmospheric Pressure: 70 kPa to 106 kPa, in operation
50kPa - 106 kPa, in storage

3 Principle and Caution

3.1 Principle of Measurement

Principle of the Oximeter is as follow: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO₂) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human fingertip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be show on screen through treatment in electronic circuits and microprocessor.

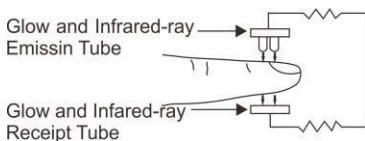


Figure 1 Operating principle

3.2 Caution

1. The finger should be placed properly (see the attached illustration of this manual, Figure 5), or else it may cause inaccurate measurement.
2. The SpO₂ sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
3. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight etc.
4. Strenuous action of the subject or extreme electrosurgical interference may also affect the accuracy.

4 Accessories

1. One hanging rope;
2. Storage bag;
2. Two AAA batteries;
3. One user's manual.

5 Installation

5.1 View of the Front panel

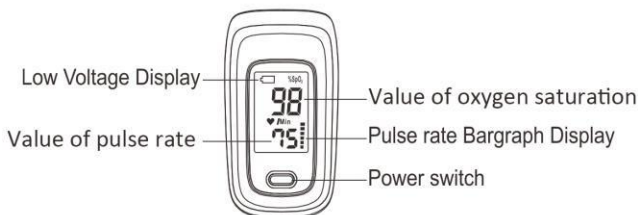


Figure 2. Front View

5.2 Battery

Step 1. Refer to Figure 3. and insert the two AAA size batteries properly in the right direction.

Step 2. Replace the cover.

⚠ Please take care when you insert the batteries for the improper insertion may damage the device.

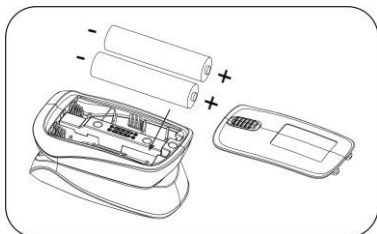


Figure 3. Batteries Installation

Step 2. Put another end of the rope through the first one and then tighten it.

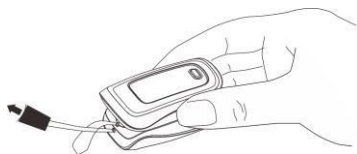


Figure 4. Mounting the hanging rope

6 Operating Guide

6.1 Insert the two batteries properly to the direction, and then replace the cover.

6.2 Open the clip as shown in Figure 5.



Figure 5. Put finger in position

6.3 Let the patient's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.

6.4 Press the switch button once on front panel.

6.5 Do not shake the finger and keep the patient at ease during the process. Meanwhile, human body is not recommended in movement status.

6.6 Get the information directly from screen display.

6.7 In boot-strap state, press button, and the device is reset.

⚠ Warning: Fingernails and the luminescent tube should be the same side.

7 Repairing and Maintenance & cleaning and disinfection

- Please change the batteries when the low-voltage display on the screen.
- Please clean the surface of the device before using. Wipe the device with medical alcohol first, and then let it dry in air or clean it by dry clean fabric.
- Using the medical alcohol to disinfect the product after use, prevent from cross infection for next time use.
- Please take out the batteries if the oximeter is not use for a long time.

Warning: High-pressure sterilization cannot be used on the device.

Warning: Do not immerse the device in liquid.






Warning: It is recommended that the device should be kept in a dry environment. Humidity may reduce the useful life of the device, or even damage it.

8 Troubleshooting

Trouble	Possible Reason	Solution
The SpO ₂ and Pulse Rate cannot be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO ₂ is too low to be detected.	1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO ₂ and Pulse Rate are not displayed stably	1. The finger is not placed inside deep enough. 2. The finger is shaking, or the patient is moving.	1. Place the finger properly and try again. 2. Let the patient keep calm
The device cannot be turned on	1. Low battery or no battery. 2. The batteries are not inserted properly. 3. The malfunction of the device.	1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.

The display is off suddenly	1.The device will power off automatically when there is no signal within 16 seconds. 2.The batteries are almost drained.	1.Normal. 2.Change batteries.
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9 Key of Symbols

Symbol	Description
	Type BF applied part
	Caution: Please see this manual.
%SpO ₂	Symbol of oxygen saturation.
bpmPR	Symbol of pulse rate.
	No SpO ₂ alarms.
	Consult the instructions for use.
IP22	The degree of protection against harmful ingress of water and particulate matter.
	When end users abandon this product, they must send the product to the collection place for recycling.

10 Technical Specification

Display Information	Display Mode
Display Format	LED display
The Pulse Oxygen Saturation (SpO ₂)	Digital
Pulse Rate (PR)	Digital
Pulse Intensity (bar-graph)	Digital bar-graph display
SpO ₂ Parameter Specification	
Measuring range	35%-100% (the resolution is 1%).
Accuracy	70%-100%; ±2%, Below 70% unspecified.
Pulse Parameter Specification	
Measuring range	25bpm-250bpm (the resolution is 1 bpm)
Accuracy	±2bpm
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicates the stronger pulse.
Alert conditions	
SpO ₂	Less than 94%
PR	Less than 50bpm or more than 130bpm
Battery Requirement	
2 X 1.5V (AAA size) alkaline battery	
Power Consumption	
Smaller than 35 mA.	
Battery Useful Life	
Two batteries can work continually for 24 hours	
Power off	
The Oximeter can be powered off in case no finger is the Oximeter within 16 seconds.	

Optical Sensor	
Red light (wavelength is 660nm) Infrared (wavelength is 905nm)	
Dimensions and Weight	
Dimensions	62 (L)X37 (W)X32(H) mm
Weight	About 50g (with the batteries)
Manufacturing date: see the label	

11 Appendix: Electromagnetism Compatibility

Guidance and manufacture's declaration – electromagnetic emissions-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The <i>FOX-200(JPD-500E)</i> is intended for use in the electromagnetic environment specified below. The customer of the user of the <i>FOX-200(JPD-500E)</i> should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>FOX-200(JPD-500E)</i> 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 emission CISPR 11	Class B	The <i>FOX-200(JPD-500E)</i> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Warranty

Your product is warranted to be free of defects in materials and workmanship for one year from the original purchase date.

The device was built to exacting standards and carefully inspected prior to shipment. In the event of a defect covered by this warranty, we will at option, repair or replace the device.

This warranty does not cover device failure due to owner misuse or negligence, or normal wear and tear. If you have questions about your device, or this warranty, please contact I.A.C.E.R. Srl.

After-sale service unit: I.A.C.E.R. Srl

Address: Via S. Pertini 24/A, 30030 Martellago (VE), Italy

Tel: +39 041 5401356

Fax: +39 041 5402684

mail: iacer@iacer.it

Website:

www.itechmedicaldivision.com

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Überblick

Die Sauerstoffsättigung ist der Prozentsatz von Oxyhämoglobin (HbO₂), der mit Sauerstoff gegen alle kombinierbaren Hämoglobinen (Hb) kombiniert wird. Es ist ein wichtiger physiologischer Parameter, der in die Atmung und den Kreislauf einbezogen ist. Mit diesem Instrument kann die Pulsfrequenz über die Arterie gemessen werden.

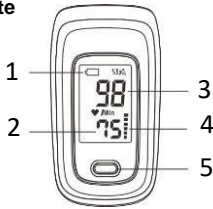
Produktmerkmale

- Leicht, tragbar und einfach zu bedienen
- Lesbarer LED-Bildschirm
- Batterie-Unterspannungsanzeige
- Das Gerät wird 16 Sekunden später automatisch heruntergefahren, wenn

kein Signal erkannt wird.

· Das Gerät ist mit zwei 1.5 V AAA-Trockenbatterien ausgestattet, die Energie für einen Betrieb von mehr als 24 Stunden liefern können.

Ansicht der Frontplatte



- 1: Niederspannungsanzeige
- 2: Pulsfrequenz
- 3: Sauerstoffsättigung
- 4: Pulsfrequenz-Balkendiagramm
- 5: Stromschalter

Bedienführung

Öffnen Sie den Clip wie in Abbildung gezeigt



1. Lassen Sie den Finger des Patienten in die Gummikissen des Clips stecken (stellen Sie sicher, dass sich der Finger in der richtigen Position befindet) und klemmen Sie dann den Finger.
2. Drücken Sie die Schaltertaste einmal auf der Vorderseite.
3. Schütteln Sie nicht den Finger und beruhigen Sie den Patienten während des Vorgangs. In der Zwischenzeit wird der menschliche Körper im Bewegungsstatus nicht empfohlen.
4. Holen Sie sich die Informationen direkt von der Bildschirmanzeige.
5. Drücken Sie im Boot-Strap-Zustand die Taste, und das Gerät wird zurückgesetzt.

⚠ Fingernägel und Lumineszenzrohr sollten auf derselben Seite liegen.

Fehlersymptome, Ursachen und Lösungen

Symptom	Mögliche Ursache	Solution
Das Oximeter zeigt keine Daten zur Sauerstoffsättigung und Pulsfrequenz an.	<ol style="list-style-type: none"> 1. Der Finger befindet sich nicht in der richtigen Position. 2. Der Patient konzentriert sich nicht gut auf die Untersuchung 	<ol style="list-style-type: none"> 1. Bringen Sie den Finger in die richtige Position. 2. Versuchen Sie es mehrere Male. Wenn Sie sicher sind, dass das Produkt gut funktioniert, empfehlen Sie dem Patienten, rechtzeitig medizinische Hilfe in Anspruch zu nehmen.
Der angezeigte Wert der Sauerstoffsättigung oder Pulsfrequenz schwankt.	<ol style="list-style-type: none"> 1. Der Finger ist nicht in Position eingeführt. 2. Der Finger vibriert oder der Körper des Patienten bewegt sich. 	<ol style="list-style-type: none"> 1. Setzen Sie den Finger erneut ein. 2. Stellen Sie sicher, dass sich der Körper des Patienten nicht bewegt, und bitten Sie den Patienten, ruhig zu bleiben.

Das Oximeter kann nicht eingeschaltet werden.	1. Die Batterien haben keinen Strom oder sind überhaupt nicht installiert. 2. Die Batterien sind falsch eingesetzt. 3. Das Oximeter ist beschädigt.	1. Ersetzen Sie die Batterien. 2. Legen Sie die Batterien korrekt gemäß der Polaritätsanz ein. 3. Wenden Sie sich an das Kundendienstpersonal oder den Hersteller.
Der Bildschirm ist plötzlich ausgeschaltet.	Erkennt das Oximeter innerhalb von 16 Sekunden kein Signal, wird es automatisch ausgeschaltet	1. Das ist normal. 2. Ersetzen Sie die Batterien.

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Vue d'ensemble

La saturation en oxygène est le pourcentage d'oxyhémoglobine (HbO₂) associé à l'oxygène contre toutes les hémoglobines combinables (Hb). C'est un paramètre physiologique important impliqué dans la respiration et la circulation. Cet instrument peut être utilisé pour mesurer le pouls via l'artère.

Caractéristiques du Produit

- Poids léger, utilisation portable et opération simple.
- Écran LED visible.
- Indication de basse tension de la batterie.
- L'appareil s'éteindra automatiquement 16 secondes plus tard si aucun signal n'est détecté.
- L'appareil est équipé de deux piles sèches 1,5 V AAA, qui peuvent lui fournir de l'énergie pour fonctionner plus de 24 heures.

Vue du panneau avant



1. Affichage basse tension
2. Fréquence du pouls
3. Saturation d'oxygène
4. Fréquence du pouls Bargraphe
5. Interrupteur d'alimentation

Guide d'utilisation

Ouvrez le clip comme indiqué dans la figure



1. Laissez le doigt du patient placé dans les coussins en caoutchouc du clip (assurez-vous que le doigt est dans la bonne position), puis clipsez le doigt.
2. Appuyez une fois sur le bouton de l'interrupteur sur le panneau avant.
3. Ne bougez pas votre doigt et gardez le patient au repos pendant le processus. En attendant, assurez-vous que le corps du patient reste stationnaire.
4. Obtenez les informations directement à partir de l'affichage à l'écran.
5. En état de démarrage, appuyez sur le bouton et l'appareil est réinitialisé.

 **Les ongles et le tube luminescent doivent être du même côté.**

Dépannage

Difficulté	Raison possible	Solution
La SpO2 et la fréquence du pouls ne peuvent pas	1. Le doigt n'est pas correctement positionné. 2. La SpO2 du patient est trop faible pour être détectée.	1. Placez le doigt correctement et réessayez. 2. Réessayez ; Allez à l'hôpital pour un diagnostic si vous êtes sûr que l'appareil fonctionne bien.
La SpO2 et la fréquence du pouls ne sont pas affichées de manière stable	1. Le doigt n'est pas placé assez profondément à l'intérieur. 4. Le doigt tremble ou le patient bouge.	1. Placez le doigt correctement et réessayez. 2. Laissez le patient garder son calme
L'appareil ne peut pas être allumé	1. Batterie faible ou pas de batterie. 2. Les piles ne sont pas insérées correctement. 3. Le dysfonctionnement de l'appareil.	1. Changez les piles. 2. Réinstallez les piles. 3. Veuillez contacter le centre de service local.
L'écran s'éteint soudainement	1. L'appareil s'éteint automatiquement en l'absence de signal dans les 16 secondes. 2. Les batteries sont presque épuisées.	1. Normal. 2. Changez les piles.

IT

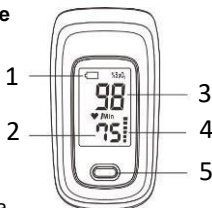
Panoramica

La saturazione pulsata dell'ossigeno è la percentuale di HbO2 nel totale di Hb nel sangue, la cosiddetta concentrazione di O2 nel sangue. E' un importante parametro biologico per la respirazione e la circolazione. Il dispositivo può misurare simultaneamente la saturazione d'ossigeno e la frequenza cardiaca.

Caratteristiche del prodotto

- Uso leggero, portatile e funzionamento semplice
- Schermo LED leggibile
- Indicatore di bassa tensione della batteria
- Il dispositivo si spegne automaticamente quando non viene rilevato alcun segnale per 16 secondi.
- Il dispositivo è dotato di due batterie AAA da 1,5 V, che possono fornire energia per funzionare per più di 24 ore.

Vista del pannello frontale



1. Indicatore batteria scarica
2. Battito cardiaco
3. Saturazione dell'ossigeno
4. Grafico battito a barre
5. Pulsante accensione

Guida operativa

Aprire la clip come mostrato in Figura



1. Far sì che il dito del paziente si inserisca tra i cuscinetti di gomma del fermaglio (assicurarsi che il dito sia nella posizione corretta), quindi agganciare il dito.
2. Premere una volta il bottone di accensione sul pannello frontale.
3. Non muovere il dito e tenere il paziente a riposo durante il processo. Nel frattempo assicurarsi che il corpo del paziente rimanga fermo.
4. Rilevare le informazioni direttamente dallo schermo.
5. In fase di caricamento, premere il bottone per resettare il dispositivo.

 **Le unghie e il tubo luminescente devono essere dallo stesso lato.**

Risoluzione problemi

Problema	Possibile causa	Soluzione
LaSpO ₂ e il battito cardiaco non vengono visualizzati correttamente	<ol style="list-style-type: none">1. Il dito non è posizionato correttamente.2. LaSpO₂ del paziente è troppo bassa per essere rilevata.	<ol style="list-style-type: none">1. Posizionare il dito correttamente e riprovare.2. Riprovare. Si consiglia di andare in ospedale se si è sicuri che il dispositivo funzioni correttamente
LaSpO ₂ e il battito cardiaco non vengono visualizzati stabilmente	<ol style="list-style-type: none">1. Il dito non è posizionato abbastanza in fondo.2. Il dito o il paziente si sta muovendo.	<ol style="list-style-type: none">1. Posizionare il dito correttamente e riprovare.2. Tranquillizzare il paziente.
Il dispositivo non si accende	<ol style="list-style-type: none">1. Batteria bassa o non presente.2. Le batterie non sono inserite correttamente.3. Malfunzionamento del dispositivo.	<ol style="list-style-type: none">1. Cambiare batterie.2. Reinserrire le batterie.3. Si prega di contattare il servizio di assistenza locale.
Lo schermo si è spento improvvisamente	<ol style="list-style-type: none">1. Il dispositivo si spegne automaticamente quando non rileva segnale per 16 secondi.2. Le batterie sono quasi scariche.	<ol style="list-style-type: none">1. Normale.2. Si prega di cambiare batterie.

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Visión General

La saturación de oxígeno es el porcentaje de oxihemoglobina (HbO₂) que se combina con oxígeno contra toda la hemoglobina combinable (Hb). Es un importante parámetro fisiológico involucrado en la respiración y la circulación. Este instrumento se puede utilizar para medir la frecuencia del pulso a través de la arteria.

Características del producto

- Peso ligero, uso portátil y operación simple
- Pantalla LED legible
- Indicación de bajo voltaje de la batería.

- El dispositivo se apagará automáticamente 16 segundos después que no se detecte ninguna señal.
- El dispositivo está equipado con dos baterías AAA de 1.5 V, que pueden suministrar energía para que funcione más de 24 horas.

Vista del panel frontal



Guía de operación

Abra el clip como se muestra en la Figura



1. Introduzca el dedo del paciente entre los cojines de goma del clip (asegúrese de que el dedo esté en la posición correcta).
2. Presione el botón de encendido una vez, situado en el panel frontal.
3. No agite el dedo y mantenga al paciente tranquilo durante el proceso. Mientras se realiza la medición se recomienda que el cuerpo humano no esté en estado de movimiento.
4. Obtenga la información directamente de la pantalla.
5. En estado de arranque, presione el botón de encendido y el dispositivo se reiniciará.



Las uñas y el tubo luminiscente deben estar del mismo lado.

Solución de problemas

Problema	Posible razón	Solución
La SpO ₂ y la frecuencia del pulso no se muestra normalmente	<ol style="list-style-type: none"> 1. El dedo no está colocado correctamente. 2. El valor de la SpO₂ en el paciente es demasiado bajo para ser detectado. 	<ol style="list-style-type: none"> 1. Coloque el dedo correctamente y vuelva a intentarlo. 2. Inténtelo de nuevo. Vaya al hospital para un diagnóstico, si está seguro de que el dispositivo funciona correctamente.
La SpO ₂ y la frecuencia del pulso no se muestran de forma estable	<ol style="list-style-type: none"> 1. El dedo no se ha colocado dentro del pulsioxímetro con suficiente profundidad. 2. El dedo está sacudiéndose o el paciente se está moviendo. 	<ol style="list-style-type: none"> 1. Coloque el dedo correctamente y vuelva a intentarlo. 2. Deje que el paciente mantenga la calma
El dispositivo no se puede encender	<ol style="list-style-type: none"> 1. Batería baja o sin batería. 2. Las pilas no están insertadas correctamente. 3.- Mal funcionamiento del dispositivo. 	<ol style="list-style-type: none"> 1. Cambie las pilas 2. Reinstale las pilas 3. Póngase en contacto con el servicio de mantenimiento
La pantalla se apaga de repente	<ol style="list-style-type: none"> 1. El dispositivo se apaga automáticamente cuando no hay señal en 16 segundos. 2. Las pilas están casi agotadas. 	<ol style="list-style-type: none"> 1. Situación normal 2. Cambie las pilas



Wellkang Ltd
Suite B, 29 Harley Street, London W1G 9QR,UK



Shenzhen Jumper Medical Equipment Co., Ltd
Address: D Building, No. 71, Xintian Road, Fuyong Street,
Baoan, Shenzhen, Guangdong, China
E-mail: info@jumper-medical.com
Tel: +86-755-26692192, 26696279
Web: www.jumper-medical.com

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Website: www.itechmedicaldivision.com