

medivon.



USER MANUAL

A06

CE marking



The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive. The product complies with the requirement of standard EN 60601-1-2:2007 "Electromagnetic Compatibility - Medical Electrical Equipment".

Contact Information

Manufacturer: Beijing Fongrui-Century Science & Technology Co., Ltd. 3rd Floor, West zone No.1 Building No.7 Yard Fengxian Middle Road, Haidian District 100094 Beijing, PEOPLE'S REPUBLIC OF CHINA.

EC REPRESENTATIVE

Name: Shanghai International Holding Corp. GmbH (Europe) Address: Eiffelstrasse 80, 20537 Hamburg, Germany

Safety

Instructions for the Safe Operation and Use of the Pulse Oximeter. Do not attempt to service the pulse oximeter. Only qualified service personnel should attempt any needed internal servicing. Do not use the oximeter in situations where alarms are required. Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status and correct alignment at least every 2 hours. SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary. The following reasons will cause interference: High-frequency electrosurgical. 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. Fingernail polish or false fingernails may cause inaccurate SpO2 readings.

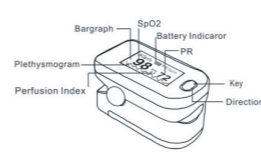
Warnings

WARNING: EXPLOSION HAZARD - Do not use the oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur. WARNING: Do not throw batteries in fire as this may cause them to explode. WARNING: Do not use the pulse oximeter in an MRI or CT environment. CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity. CAUTION: Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location. WARNING: Do not attempt to recharge normal dry-cell batteries, they may leak. And may cause a fire or even explode. CAUTION: Never use sharp or pointed objects to operate the front-panel switches. CAUTION: The battery must be taken out from the battery compartment if the device will not be used for a long time. CAUTION: The device shall only be used if the battery cover is closed. CAUTION: The battery must be proper disposed according to local regulation after their use.

Introduction

The Pulse Oximeter, based on all digital technology, is intended for noninvasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2). Advanced DSP algorithm can minimize the influence of motion artifact and improve measurement accuracy of low perfusion. The Oximeter can be used to measure human Hemoglobin Saturation and heart rate through finger. The product is suitable for family, hospital (including clinical use in internist/surgery, pediatrics, etc), Oxygen Bar, social medical organizations, physical care in sports and etc. This product is suitable for the hospital (including surgery, anesthesiology, paediatrics, and clinical use), oxygen bar, sports health (using them before or after sports, do not advise using them during the movement), and community health care, etc. Contraindication: It is not for intensive care and person whose finger is injured.

Installation, Setup, and Operation



Note: When battery power is at lowest level, the battery capacity indicates symbol of \* in TFT, remind users of replacement of battery. Install battery: Inserting two AAA batteries into battery cassette in correct polarities and cover it

WARNING: Do not attempt to recharge normal alkaline batteries, they may leak and may cause a fire or even explode.



Put one of fingers into rubber hole of the oximeter (it is best to put the finger thoroughly) with nail surface upward (as FIG.2), then releasing the clamp. Press the key, oximeter will go into the working state. The oximeter will automatic standby or go asleep after 8 seconds without finger in.



Long-press the direction button (>0.5s), the oximeter will enter into parameter setting. There are two submenu for choice: 1) When the \* \* \* signal is show on the "Alm setup", long-press the button, and enter into the alarm setting menu (FIG.4). Press the button to set on/off the alarm and beep. When the \* \* \* signal is show on the "Restore", long-press the button and the settings will back to the factory settings. 2) When the \* \* \* signal is show on the "Sounds setup", long-press the button, and enter into the sounds setting menu (FIG.5), you can press the button in turn to select the item, and press the button to change the data you need. Select \* \* \* or \* - \* to increase or decrease the number of settings.

Settings menu table with columns: Item, Value, and Action.

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Maintenance

Switch off the power and take out the batteries before cleaning. Cleaning exterior surface (screen included) of the unit with a dry and soft cloth. Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid alcohol permeates into the device

Disinfecting the machine after using by the patient if multiple patient use the machine in the hospital. Use 75% density of medical alcohol to clean the surface that contacting with the patient.

CAUTION: Don't use strong solvent, For example, acetone. CAUTION: Never use an abrasive such as steel wool or metal polish. CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids. CAUTION: Avoid pouring liquids on the device while cleaning. CAUTION: Don't remain any cleaning solution on the surface of the device.

Troubleshooting

Problem: Oxyhemoglobin or heart rate can not be shown normally

- 1. Finger is not plugged correctly. 2. Patient's perfusion is too low to be measured.

Solution:

- 1. Retry by plugging the finger. 2. Try some more times, if you can make sure about no problem existing in the product, please go to a hospital timely for exact diagnosis.

Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect or decontaminate the device appropriately before disposing of it in accordance with your country's law for equipment containing electrical and electronic parts.

Specification

Physical Characteristics Machine Dimensions: 57mm (L) \* 31mm (W) \* 30.5mm (D) Machine Weight -approx: 54 g (including 2 \* AAA battery) Classification Anti-electric Shock Type : Internally powered equipment Anti-electric Shock Degree : Type BF equipment EMC : Type B class I Mode of operation: Continuous Operation Enclosure Degree of ingress protection: IP22

Power specification table with columns: Item, Value.

Environmental Operating Temperature: 5°C to 40°C Storage Temperature: -20°C to 55°C Relative Humidity: 15% to 85% non-condensing

Electronic parameters

Table with columns: Parametr, Value. Lists Hemoglobin saturation Display, Pulse rate Display, Perfusion Index Display, Resolution, Measure Accuracy.

Accessories

- 1,One lanyard; 2,One user manual

Troubleshooting

WARNINGS Necessary maintenance must be performed by qualified service personal ONLY Users are NOT permitted to maintain the equipment by themselves. There are NO replaceable components in the equipment.

The equipment can't be turned on. The battery is drained away or almost drained away. Please replace battery

The battery installation is incorrect. Install the battery over again.

The malfunction of the equipment. Please contact the local service center.

The display is off suddenly. The equipment is set to shut down automatically in 8 seconds when there is no correct physiological Signals. That is normal

The battery is almost drained away. Please replace battery.

The SpO2 and Pulse Rate are not displayed stably. The thoroughfare from photo detector to light emitting diode was sheltered by some object. Check and clean the inside of the probe especially the two windows of sensors.

The finger is shaking or the patient is moving. The patient try to keep still.

The finger is not placed inside deep enough. Place the finger properly and try again.

The finger's size is too big or too small. Select the correct size finger to measure.

Excessive ambient light. Avoid the excessive ambient light irradiation.

Pulse rate value of the cyclical fluctuations. The measurement is normal, and the patient is arrhythmia.

The SpO2 and Pulse can't be displayed normally. The finger is not properly positioned. Place the finger properly and try again.

The patient's SpO2 is too low to be detected. Try again, go to a hospital for a diagnosis if you are sure the equipment works all right.

Pulse sound can't be turned off The key is bad, Check the key and press again.

The press time is not right Make sure the press time is 2-3 seconds.

TERMS OF WARRANTY

The product warranty is valid for a period of 24 months. The warranty covers the period from the date of receipt of the device from Medivon Sp. z o.o, and covers defects resulting from reasons inherent in the device received. The repair of the device will be made as soon as possible, not exceeding 21 business days from the date of accepting the device for repair by the Authorized Service Center. The Customer has the right to apply for the replacement of the equipment with a non-defective one, if the Authorized Service Center determines that the removal of the defect is impossible or requires excessive costs. If only a part of the product is defective and can be detached from a properly functioning part of the product, the Customer's rights under this warranty are limited only to the defective part of the product.

In order to benefit from the warranty conditions, you should send a complaint application together with the warranty card to the e-mail address serv@grmedia.pl or contact the service by phone at the helpline 41306 70 71. The exact terms of the guarantee are available at: www.profit-plus.eu



The symbol on the left means that in the European Union, after using the product, it should be disposed of in a separate, dedicated point. These products should not be disposed of with unsorted municipal waste.

Date of preparation and the last one update: October 30, 2020

Importer Medivon sp. z o.o, ul. Solec 18 lok. B-21, 00-410 Warszawa, Polska Assembled in China

- Type BF equipment; Consult the instruction manual / brochure; Manufacturing information incl name and address; The product must be sent to separate collection and recycling collection points; Serial number

Warning Information you should know to protect patients and healthcare professionals against possible injuries

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NAZWA / ADRES SPRZEDAWCY

NR DOWODU ZAKUPU

DATA SPRZEDAŻY

NAZWA URZĄDZENIA

NR SERYJNY / MODEL

Oświadczam, że zapoznałem się i akceptuję warunki zawarte w Karcie Gwarancyjnej. I represent that I have read and accepted the terms and conditions specified in the Warranty Certificate.