

Operation Manual CMS-50F-BLE Pulse Oximeter



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Instructions

This manual provides the instructions necessary to operate Pulse Oximeter in accordance with its function and intended use. Observation of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety. Content of this manual is subject to change without prior notice. Issued date: 2019/01/07 Version: 1.0

Statement

The manufacturer is responsible for safety, reliability and performance of this product only in the condition that:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by manufacturer authorized personnel; and
- The electrical installation of the relevant room complies with the applicable national and local requirements; and
- This product is operated under strict observance of this manual.

Guarantee

Free service scope

- The manufacturer provides free service to any product which conforms to the warranty regulations.

Chargeable service scope

- The manufacturer's obligation or liability under his warranty does not include the service of any factitious damage, or misuse, or irresistible natural disaster, or delay resulting from the improper use or application of the product, or repairs by people other than the manufacturer authorized personnel.

Return Policy

In the event that it becomes necessary to return a unit to the manufacturer, please obtain a return authorization first. Please contact the manufacturer and provides the model number, serial number, and a brief description of the reason for return. Return shipments will not be accepted if the serial number is not clearly visible.

The customer is responsible for freight charges when this product is shipped to the manufacturer for service (including any relevant customs fees or other freight related charges).

Safety Information

WARNING:

It indicates a potential hazard situation or unsafe practice that if not avoided, could result in death or serious injury.

CAUTION:

It indicates a potential hazard or unsafe practice that if not avoided, could result in minor personal injury or product/property damage.

NOTE:

It provides application tips or other useful information to ensure that you get the most you're your product.

WARNING

- The person who uses the pulse oximeter must receive adequate training before use.

- The pulse oximeter is intended only as adjunct in patient assessment. It must be used in conjunction with clinical signs and symptoms. It is not intended as a device used for treatment purposes.
- When using the pulse oximeter together with the electrical surgery equipment, the user should pay attention to and guarantee safety of the patient being measured.
- EXPLOSION HAZARD:** Do not use the pulse oximeter in the presence of flammable anesthetics, explosive substances, vapors or liquids.
- Make sure not to use the pulse oximeter during MRI (magnetic resonance imaging) scanning or CT (Computed Tomography) environment because induced current could potentially cause burns.
- The pulse oximeter is without alarm function. Continuous monitoring for a long time is not suitable.
- No modification of the pulse oximeter is allowed. Maintenance should be operated by professional maintenance personnel who are approved by manufacturers.
- The pulse oximeter is commonly seal product. Keep its surface dry and clean, and prevent any liquid from infiltrating it.
- The pulse oximeter is precision and fragile. Avoid pressure, knock, strong vibration or other mechanical damage. Hold it carefully and lightly. If it is not in use, it should be appropriately placed.
- For disposal of pulse oximeter and accessories, follow local regulations or your hospital's policy regarding disposal of such pulse oximeter and accessories. Do not dispose randomly.
- Don't dismantle and replace the battery without authorization. When the battery is low or it has not been used for a long time, please charge the battery in time but protecting against overcharging.
- Please use the SpO₂ sensor matching with the product or use the SpO₂ sensor which the manufacturer has approved of it. The operator is responsible for checking the compatibility of the pulse oximeter, sensor and cable before use. And incompatible components can result in degrading performance. If there are signs of damage, please stop using.
- If the accessories are intended for single-use, please scrap according to relevant regulations after use. It is forbidden to re-use.
- A functional tester can't be used to assess the accuracy.
- Avoid static electricity, before using the pulse oximeter, confirmed direct or indirect static electricity of all the operators and patients who contact with the instrument.
- When in use, try to make the pulse oximeter keep away from radio receiver.
- If the pulse oximeter uses unspecified and without EMC test system configuration, it can enhance electromagnetic radiation or reduce anti-electromagnetic interference performance. Please use the specified configuration.
- Portable and mobile radio frequency communication equipment can affect the normal use of the pulse oximeter.
- The pulse oximeter should not be close to or stacked with other equipments, if you must be close to or stacked them in use, you should observed and verify that it can run normally with the configuration which it uses.

CAUTION

- Federal law restricts this device to sale by or on the order of a physician.

NOTE

- Important! Before use, carefully read this manual, all safety information and specifications.

Product Description

The CMS-50F-BLE Pulse Oximeter is wearable device with detachable SpO₂ sensor (BST09001S), and it has following features:

- Simple and convenient usage of product, simple one-touch operation.
- Small volume, light weight, convenient to carry.
- Lower consumption, original one 3.7V lithium battery can continuously work for 20 hour
- Low voltage reminder shows in screen when there's low battery, may influence the normal working.
- It will automatically power off when there's no signal generated.
- Daily maintenance and calibration are unnecessary.
- Rechargeable.

Applicable people and scope

The pulse oximeter is suitable for monitoring adults and pediatric. It is used in the hospital's operation room, ICU, clinic section office, out-patient department, sickroom, emergency treatment. It can also be used in the recovery and health care organizations, the community medical treatments.

Intended Use

The pulse oximeter is reuse device and intended use for spot and

continuously checking of the pulse oxygen saturation and pulse rate for adult in clinic/home/sport environment. This medical device can be reused.

Contraindications

The pulse oximeter only applies to adults and pediatric, please don't use the product for children under the age of two, infant and neonatal.

Structure and Composition

The pulse oximeter is composed of a pulse oximeter and a SpO₂ sensor.

Measurement Principle

An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of hemoglobin (Hb) and Oxyhemoglobin (HbO₂) in glow and near-infrared zones. Operation principle of the instrument is Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 940nm near infrared light) can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on two groups of LEDs through process in electronic circuits and microprocessor.

Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different spectra absorption of hemoglobin and oxyhemoglobin (called spectrophotometer principle). It measures how much light, sent from light sources on the other side.

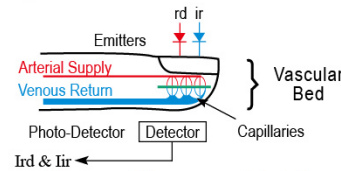


Diagram of Measurement Principle

Cleaning and Disinfection

CAUTION

- Never immerse or soak the pulse oximeter.
- Exercise caution during cleaning/disinfection to avoid wetting the pins.
- We recommend that the pulse oximeter be disinfected only necessary to avoid long term damage to the pulse oximeter.
- Never use cleaning agents/disinfectants other than the recommended.
- Please shut off the power before clean the pulse oximeter. Never permit high-pressure and high-temperature disinfection of the pulse oximeter.
- Please clean and disinfect the SpO₂ sensor (shell and silicone cushion) every time before and after you use the device as the following instruction.

Cleaning

- Clean the pulse oximeter/SpO₂ sensor with cotton or soft cloth moistened with water.
- After cleaning, wipe off the water with a soft cloth.
- Allow the pulse oximeter/SpO₂ sensor to air dry.

Disinfection

The recommended disinfectants: ethanol solution (70% Concentration); isopropanol solution (70% Concentration); or glutaraldehyde solution (2% Concentration).

- Clean the pulse oximeter/SpO₂ sensor as instructed above.
- Disinfect the pulse oximeter/SpO₂ sensor with cotton or soft cloth moistened with one of the recommended disinfectants.
- After disinfection, be sure to wipe off the disinfectant left on the pulse oximeter/SpO₂ sensor with a soft cloth moistened with water.
- Allow the pulse oximeter/SpO₂ sensor to air dry.

Technical Specifications

1. Product specifications:

Display mode: OLED
Size: 68 (H) × 58 (W) × 20(D) mm
Weight: 50g (Do not contain sensor and Wrist strap)

2. Electrical specifications:

Working voltage: D.C. 3.4V~D.C.4.3V
Battery type: one 3.7V lithium battery.
Battery life: Charging cycle count is not less than 500 times.
Power consumption: smaller than 50mA

3. SpO₂:

Measurement range: 0~100%
Resolution: 1%
Accuracy: ±3% (70%~100%)

NOTE

- The method of confirming the blood oxygen measurement accuracy is to compare the oximetry measurement value with the value of blood gas analyzer.

4. Pulse Rate:

Measurement range: 25~250bpm
Resolution: 1%
Accuracy: ±2bpm

5. Low perfusion:

Range: 0.5%~20%
SpO₂ accuracy: ±3% (70%~100%)
PR accuracy: 25~250bpm ±2bpm

6. Environment requirements:

Temperature:

Operation: +5~+40°C
Transportation and storage: -10~+50°C

Humidity:

Operation: 15%~80% (noncondensing)
Transportation and storage: 10%~90% (noncondensing)

Atmospheric pressure:

Operation: 860hPa~1060hPa
Transportation and storage: 700hPa~1060hPa

Packing List

The standard configuration	
Pulse oximeter	1pc
SpO ₂ sensor	1pc
Wrist strap	1pc
Charging cable	1pc
The operation manual	2pc

Expected service life:

Pulse oximeter: 3 years
SpO₂ sensor: 2 years (expect the disposable SpO₂ sensor)

Display Introduction

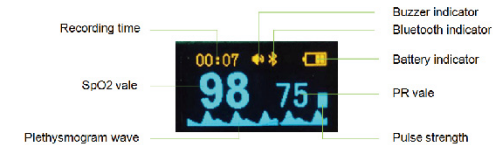


Figure 1

Directions for use

- Insert the plug of the sensor into the slot of the pulse oximeter. (as shown in Figure 2.)
- Power on the pulse oximeter, monitoring interface appears on OLED display.(as shown in Figure 3.)
- Installing the sensor on the appropriate part of the patient's body. (The correct placement as shown in Figure 4.)
- Wait 10-15 seconds, data can be read from the screen.(The correct placement as shown in Figure 4.)
- Display screen data refresh time for one second.
- When the received signal is inadequacy, " " will be displayed on the screen.(as shown in Figure 3.)



Figure 2



Figure 3

