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# CONTEC CMS50SP Pulse Oximeter

**Specifications:**

- **Brand:** Contec Medical Systems Co., Ltd.
- **Model:** CMS50S+
- **Type:** Pulse Oximeter
- **Storage Temperature:** -40°C to +60°C
- **Storage Humidity:** Up to 95%
- **Operating Temperature:** +5°C to +40°C
- **Operating Humidity:** Up to 90%
- **Operating Pressure:** 700hPa to 1060hPa

## Product Usage Instructions

### Overview

Insert the finger when measuring, the device will directly display the SpO2 value measured, it has a higher accuracy and repeatability.

**Features:**

- A. Easy to use.
- B. Small in volume, light in weight, convenient to carry.
- C. Low power consumption.

**Indication for Use:**

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

**Storage Environment:**

- a) Temperature: -40°C to +60°C
- b) Relative humidity: Up to 95%
- c) Atmospheric pressure: 500hPa to 1060hPa

**Operating Environment:**

- a) Temperature: +5°C to +40°C
- b) Relative Humidity: Up to 90%
- c) Atmospheric pressure: 700hPa to 1060hPa

## User Notice

Dear users, thank you very much for purchasing the Pulse Oximeter (hereinafter referred to as device).
It is a medical device, which can be used repeatedly.
The Manual describes, in accordance with the device's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and device. Refer to the respective chapters for details.

Please read the User Manual carefully before using this device. The User Manual which describes the operating procedures should be followed strictly. Failure to follow the User Manual may cause measuring abnormality, device damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and device damage due to users' negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Owing to the forthcoming renovation, the specific products you received may not be totally in accordance with the description of this User Manual. We would sincerely regret for that.
Our company has the final interpretation to this manual. The content of this manual is subject to change without prior notice.

**Warnings**
Remind that it may cause serious consequences to tester, user or environment.

- Explosive hazard—DO NOT use the device in environment with inflammable gas such as anesthetic.
- DO NOT use the device while examining by MRI or CT, as the induced current may cause burn.
- Do not take the information displayed on the device as the sole basis for clinical diagnosis. The device is only used as an auxiliary means in diagnosis. And it must be used in conjunction with doctor’s advice, clinical manifestations and symptoms.
- The maintenance to the device or replacement of the batterycan only be performed by qualified service personnel specified by manufacturer, dangers (such as over-temperature, fire or explosion) may occur when replacing the battery by the personnel not fully trained. Users are not permitted to maintain or refit the device or replacement of the battery by themselves.Unauthorized modification of the device would result unacceptable risk.
- Uncomfortable or painful feeling may appear if using the device ceaselessly,especially for the microcirculation disturbance users. It is not recommended that the sensor is used on the same finger for more than 2 hours.
- For some special users who need a more careful inspection on the test site, please don’t place the device on the edema or tender tissue.
- Please do not stare at the red and infrared light emitter (the infrared light is invisible) after turning on the device, including the maintenance staff, as it may be harmful to the eyes.
- Each part of the device is firmly fixed,if accidental falling leads to the small parts such as a button to fall off,avoid swallowing of these parts,it may cause suffocation.
- The device contains silicone, PVC, TPU, TPE and ABS materials, whose biocompatibility has been tested in accordance with the requirements in ISO 10993-1,

and it has passed the recommended biocompatibility test. The person who is allergic to silicone, PVC, TPU, TPE or ABS can not use this device.

- Do not wrap the SpO2 probe or USB cable around neck to avoid an accident.
- The disposal of scrap device, its accessories and packaging should follow the local laws and regulations, to avoid polluting to the local environment. And the packaging materials must be placed in the region where the children are out of reaching.
- The device can not be used with the equipment not specified in the Manual. Only the accessories appointed or recommended by the manufacturer can be used, otherwise it may cause injury to the tester and operator or damage to the device.
- The SpO2 probe accompanied is only suitable for using with the device. The device can only use the SpO2 probe described in the Manual, so the operator has the responsibility to check the compatibility between the device and the SpO2 probe before using, incompatible accessories may cause device performance degradation, device damage or user injury.
- Do not reprocess the accompanying SpO2 probe.
- Check the device before use to make sure that there is no visible damage that may affect user's safety and device performance. When there is obvious damage, please replace the damaged parts before use.
- When the message —Sensor Off‖ or —Sensor Fault‖ appears, it indicates that the SpO2 probe is disconnected or line fault occurs. Check the connection of the SpO2 probe and whether there is damage for the probe, if necessary, please replace the probe to avoid risks. The probe fault will not result in a safety hazard.
- Functional testers can not be used to assess the accuracy of the SpO2 probe and Pulse Oximeter.
- Some functional testers or patient simulators can be used to verify whether the device works normally, for example, INDEX-2LFE Simulator (software version: 3.00), please refer to the Manual for the detailed operation steps.
- Some functional testers or patient simulators can measure the accuracy of the device copied calibration curve, but they can not be used to evaluate the device accuracy.
- When using the device, please keep it away from the equipment which can generate strong electric field or strong magnetic field. Using the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.
- When storing the device, keep it away from children, pets and insects to avoid

affecting its performance.
- Do not place the device in places exposed to direct sunlight, high temperature, humidity, dust, cotton wool or easy to splash water, to avoid affecting its performance.
- The measured accuracy will be affected by the interference of electrosurgical equipment.
- When several products are used on the same patient simultaneously, danger may occur which is arisen from the overlap of leakage current.
- CO poisoning will appear excessive estimation, so it is not recommended to use the device.
- This device is not intended for treatment.
- The intended operator of the device may be a patient.
- Avoid maintaining the device during using.
- Users should read the product manual carefully before use and operate according to the requirements.

## Overview

Insert the finger when measuring, the device will directly display the SpO2 value measured, it has a higher accuracy and repeatability.

### Features

- **A.** Easy to use.
- **B.** Small in volume, light in weight, convenient to carry.
- **C.** Low power consumption.

### Indication for Use

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

### Environment requirements

**Storage Environment**

- Temperature: -40℃~+60℃
- Relative humidity: ≤95%
- Atmospheric pressure: 500hPa~1060hPa

**Operating Environment**

- Temperature:+5 ℃~+40℃
- Relative Humidity: ≤90%
- Atmospheric pressure: 700hPa~1060hPa

**Precautions**

**Attention**

Point out conditions or practices that may cause damage to the device or other properties.

- Before using the device, make sure that it locates in normal working state and operating environment.
- In order to get a more accurate measurement, it should be used in a quiet and comfortable environment.
- When the device is carried from cold or hot environment to warm or humid environment, please do not use it immediately, wait four hours at least is recommended.
- If the device is splashed or coagulated by water, please stop operating.
- High temperature, high pressure, gas sterilizing or immersion disinfection for the device is not permitted. Refer to User Manual in the relative chapter (6.1) for cleaning and disinfection.Please turn off the device before cleaning and disinfection.
- The device is suitable for adult.
- The device may not be suitable for all users, if you can’t get a satisfactory result, please stop using it.
- Data averaging and signal processing have a delay in the upgrade of SpO2 data values. When the data update period is less than 30 seconds, the time for obtaining dynamic average values will increase, which is arisen from signal degradation, low

perfusion or other interference, it depends on the PR value.

- The device has 3-year service life, date of manufacture: see the label.
- The expected service life of the attached parts or accessories of the equipment is two year.
- If the shelf life is less than the expected service life, the shelf life of the attached parts or accessories of the equipment is two year.
- The device does not provide over-limit alarm function for SpO2 and PR, so it is inapplicable for using in the place where need such function.
- The maximum temperature at the SpO2 probe -tissue interface should be less than 41℃ which is measured by the temperature tester.
- During measuring, when abnormal conditions appear on the screen, please pull out your finger and reinsert it to measure again.
- Do not contort or drag the wire of the device.
- The plethysmographic waveform is not normalized, as a signal inadequacy indicator,when it is not smooth and stable, the accuracy of the measured value may degrade.

  When it tends to be smooth and stable, the measured value read is the optimal and the waveform at this time is also the most standard.
- The device can not be used during charging.
- If necessary, please visit our official website to get the information about SpO2 probe that can be used with this device.
- If the device or component is intended for single-use, then the repeated use of these parts will pose risks on the parameters and technical parameters of the equipment known to the manufacturer.
- If necessary, our company can provide some information (such as circuit diagrams,component lists, illustrations, etc.), so that the qualified technical personnel of the user can repair the device components designated by our company.
- The measured results will be influenced by the external colouring agent (such as nail polish, colouring agent or color skin care products, etc.), so don’t use them on the test site.
- As to the fingers which are too cold or too thin or whose fingernail is too long, it may affect the measured results, so please insert the thicker finger such as thumb or middle finger deeply enough into the probe when measuring.
- The finger should be placed correctly (see Attached figure 3), as improper installation

or improper contact position for sensor will influence the measurement.

- The light between the photoelectric receiving tube and the light-emitting tube of the device must pass through the subject's arteriole. Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate results.
- Excessive ambient light may affect the measured results, such as surgical light (especially xenon light sources), bilirubin lamp, fluorescent lamp, infrared heater and direct sunlight, etc. In order to prevent interference from ambient light, make sure to place the sensor properly and cover the sensor with opaque material.
- Frequent movement (active or passive) of the subject or severe activity can affect the measured accuracy.
- The SpO2 probe should not be placed on a limb with the blood pressure cuff, arterial ductus or intraluminal tube.
- The measured value may be inaccurate during defibrillation and in a short period after defibrillation, as it has not defibrillation function.
- The device has been calibrated before leaving factory.
- The device is calibrated to display functional oxygen saturation.
- The equipment connected with the Oximeter interface should comply with the requirements of IEC 60601-
- Please select medical power adapter to charge it, when connecting the special adapter with the socket, make sure there is no shelter near the socket and it is easy to plug and unplug, otherwise the power will not be cut off in time when necessary, causes damage.

**Clinical restriction**

- As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO2 waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
- The measurement will be influenced by intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.
- The measured value may be normal seemingly for the tester who has anemia or dysfunctional hemoglobin(such as carboxyhaemoglobin (COHb), methaemoglobin

(MetHb) and sulfhaemoglobin (SuHb)), but the tester may appear hypoxia, it is recommended to perform further assessment according the clinical situations and symptoms.

- Pulse oxygen only has a reference meaning for anemia and toxic hypoxia, as some severe anemia users still show better pulse oxygen measured valued.
- Contraindication:
  - The person who is allergic to silicone, PVC, TPU TPE or ABS.
  - The damaged skin tissue.
  - During cardiopulmonary resuscitation.
  - When the patient is hypovolemic.
  - For assessing the adequacy of ventilatory support.
  - For detecting worsening lung function in patients on a high concentration of oxygen.

**Clinical indications**

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger.

## Principle

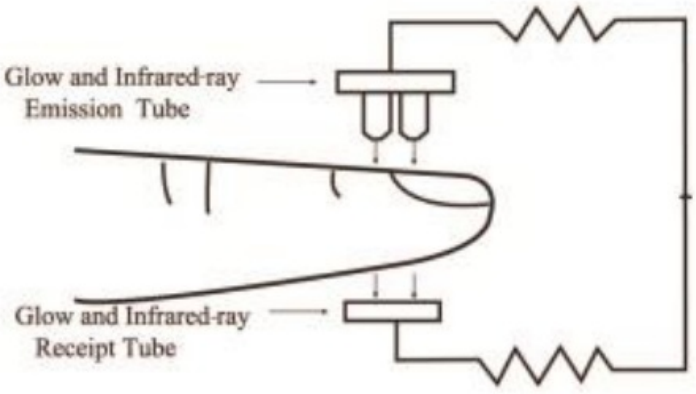


Figure 1 Operating principle

An experience formula of data processing is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in red light & near-infrared light zones. On the basis of the principle of Photoelectric Oxyhemoglobin Inspection Technology and Photoplethysmography technology, it uses two light beams of different wavelengths to irradiate the human fingertip to obtain the measurement information from the

photosensitive element, after processed by the electronic circuits and microprocessor, displays the measured results on the screen.

## Functions

- SpO2 value display
- PR value and bar graph display
- PI value display
- Pulse waveform display
- Low-voltage indication: the low-voltage indication symbol appears when the voltage is too low to work.
- Automatic standby function.
- Memory function.
- The data can be uploaded to terminal equipment by wireless mode.
- Charging function.
- With clock function

## Installation

### Appearance

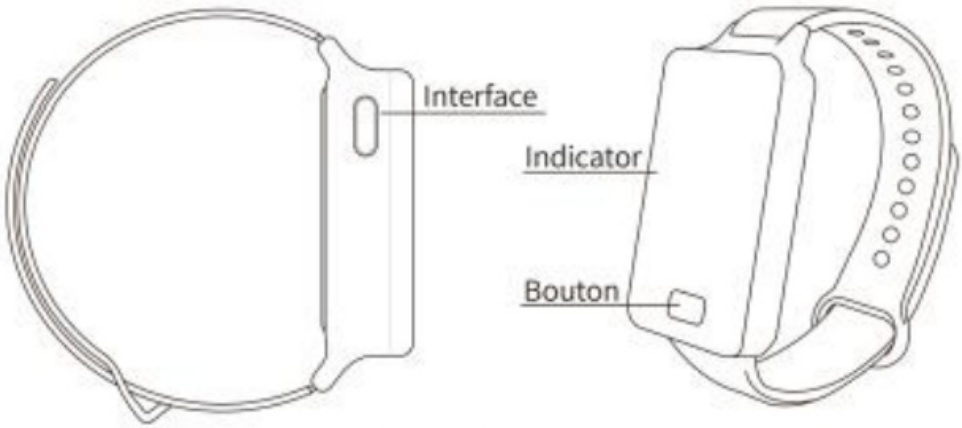


Figure 2 Appearance

- USB interface: connect with USB cable or SpO2 probe
- Button: exit/enter the standby mode.

### Installation of SpO2 probe

Insert the SpO2 probe interface into the USB port of the device.

### Connection of USB cable

Insert the type-c end into the interface of the device, the other end to the power adapter.

Structure and accessories and software description

- Structure: main unit, SpO2 probe, USB cable and Bluetooth adapter (optional).
- Accessories: one SpO2 probe, one USB cable Bluetooth adapter (optional).
  Please check the device and accessories according to the list to avoid that the device can not work normally.
- **Software description**
  - Software name: CMS50S+ embedded software
  - Software specification: no
  - Release version: V2.0
  - Naming rule for version: V <Major enhancive software upgrade>.<Minor enhancive software upgrade>.<Improvement software upgrade>
  - Involved algorithm: name: plethysmography; type: mature arithmetic
  - Purpose: be used to measure SpO2, pulse rate, etc.
  - Clinical function: calculate SpO2 and pulse rate values by collecting and processing the testee’ s pulse signal.

## Operation

### Measurement

- Insert a finger into the probe, as shown in Figure 4.

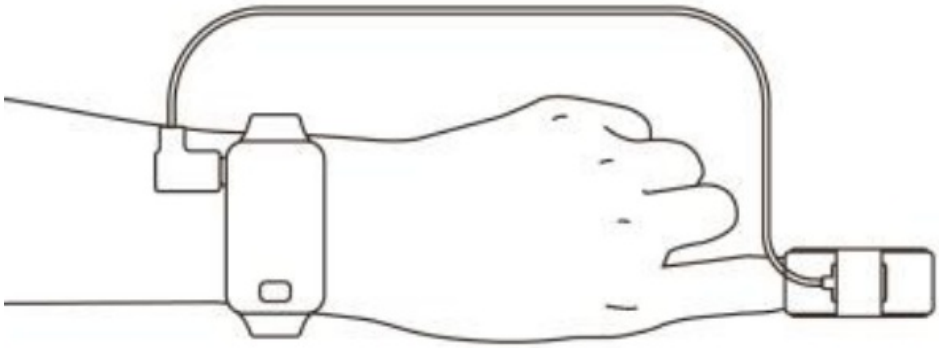

Figure 4 Sketch map for finger placement

(the appearance of the actual probe may be different with the one shown as Figure 4,please refer to the actual one.)

**Note:** when inserting the finger, the light emitting from the sensor must be directly irradiated to the side of the fingernail.

**Note:** during measuring, do not shake the finger and keep quiet, not move.

- Long press the Button to enter the measurement interface.
- The measured result can be directly read from the interface after a period of time.

**Exit/Enter standby mode**

- Under the standby state, long press the Button to exit from this mode.
- Under non-memory state, the device will automatically enter the standby mode after 30 s.

**Change of display direction and mode**

Double click the screen to change the display direction and mode.

**Bluetooth setting**

- Under the measurement interface, long press the Button to enter the Bluetooth setting interface.
- Short press the Button to switch the Bluetooth mode between Constant ON mode and Smart mode, as shown in Figure 5 and Figure 6.
- Long press the Button to exit from this setting interface.

Figure 5 Constant ON mode

Figure 6 Smart mode

**Constant ON mode:**

The Bluetooth is always ON.

**Smart mode:**

Under the memory state, the Bluetooth is OFF; under the non-memory state, it is ON.

### Clock setting

The clock can be synchronized by connecting the device to the PC software.

### Data storage

- After inserting the finger, the device will automatically measure and store data,and a small white dot will flash on the measurement interface. When the finger is pulled out, it will stop measuring.
- After entering the memory mode for 30 s, the device will automatically enter the energy-saving mode, and short press the Button to exit from this mode.
- When the storage space is full, it will display a full storage icon, then it will enter the standby mode after 5 s. When exiting from this mode next time, there is the full storage icon on the interface, prompting the user that the storage space is full, and after 5 s, it will enter the measurement interface, but it will not store the data.
- Up to 99 sets of data can be stored, and the total data duration should not exceed 72 hours.

### Data upload

- The Bluetooth is in ON state.
- The PC software can realize such functions as time synchronization, data upload,and data deletion.

### Charging

A power adapter can be used to charge for the device.
When charged under OFF state, it will display a white dynamic battery icon after short pressing the Button, indicating that it is charging; and it will display a full battery icon when it is fully charged. When charged under ON state, it displays a dynamic battery icon, indicating that it is charging, and it indicates that it is fully charged when it displays a full battery icon.

## Maintain, Transport and Storage

### Cleaning and disinfection

The device must be turned off before cleaning, and it should not be immersed into liquid.

Please turn off the device before cleaning , do not immerse it into liquid.
Use 75% alcohol to wipe the device enclosure and the probe ,and use liquid soap or isopropanol to wipe the watchband for disinfection,nature dry or clean it with clean and soft cloth. Do not spray any liquid on the device directly, and avoid liquid penetrating into the device.

**Maintenance**

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect user's safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.
- Please clean and disinfect the device before/after using it according to the User Manual (6.1).
- Please charge the battery in time when low battery appears.
- Recharge the battery soon after over-discharge. The device should be recharged every three months when it is not used for some time. It can extend the battery life following this guidance.
- The device need not to be calibrated during maintenance.

**Transport and Storage**

- The packed device can be transported by ordinary conveyance or according to transport contract. During transportation, avoid strong shock, vibration and splashing with rain or snow, and it can not be transported mixed with toxic, harmful, corrosive material.
- The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40°C~+60°C; Relative humidity: ≤95%.

## Troubleshooting

| Trouble | Possible Reason | Solution |
| --- | --- | --- |

| | | |
|---|---|---|
| The finger can n ot be recognized. corr ectly. | 1) The finger is not properly inserte d.<br>2) The finger is shaking or the user is moving.<br>3) The device is not used in environ ment required by the manual.<br>4) The device works abnormally. | 1) Please insert the finger properly and measure again .<br>2) Let the user keep calm.<br>3) Please use the device in normal environment.<br>4) Please contact the<br>after-sales. |
| The device can n ot be turned on. | Low battery or the battery is draine d away.<br>The device works abnormally. | Please charge the battery.<br>Please contact the after-sal es. |
| The device can n ot be used for ful l time after<br>charge. | The battery is not charged fully.<br>The device works abnormally. | Please charge the battery.<br>Please contact the after-sal es. |
| The battery can not be fully charg ed even after 10-hour<br>charging time. | The device works abnormally. | Please contact the after-sal es. |

| | | |
|---|---|---|
| The data can not be stored. | The device is not operated according to the manual.<br>The device works abnormally. | Please operate the device according to the manual.<br>Please contact the after-sales. |

## Key of Symbols

| Symbols | Meaning | Symbols | Meaning |
|---|---|---|---|
|  | Refer to instruction manual/booklet |  | Type BF applied part |
|  | Alarm inhibit |  | Bluetooth icon |
| IP22 | International Protection |  | Recyclable |
|  | Battery anode |  | Battery cathode |
| PRbpm | Pulse rate (bpm) | %$SpO_2$ | Pulse oxygen saturation (%) |
| PI% | Perfusion index |  | The finger is not inserted. |
|  | The probe is disconnected. |  | Probe failure |
|  | Manufacturer |  | Use-by date |
|  | Temperature limitation. |  | Humidity limitation. |
|  | Atmospheric pressure limitation. |  | This way up. |
|  | Fragile, handle with care. |  | Keep away from rain. |
| SN | Serial number |  | Exit/enter standby mode |
|  | Date of manufacture |  | WEEE (2012/19/EU) |

| | | | |
|---|---|---|---|
| P/N | Material code | LOT | Batch No. |
| MD | Medical device | | USB |
| | Low battery | | Fully charged |
| | Power button | • | Recording |

**Note Your** device may not contain all the following symbols.

## Specification

| | |
|---|---|
| SpO2 [see note 1] | |
| Displayed range | 0%~100% |
| Measured range | 0%~100% |
| Accuracy [see note 2] | 70% ~ 100%: ±2%;<br>0% ~ 69%: unspecified. |
| Resolution | 1% |
| **PR** | |
| Displayed range | 30 bpm ~ 250 bpm |
| Measured range | 30 bpm ~ 250 bpm |
| Accuracy [see note 3] | ±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and<br>±2% during the pulse rate range of 100 bpm ~ 250 bpm. |
| Resolution | 1 bpm |

| | |
|---|---|
| **Low perfusion [see note 4]** | Low perfusion 0.4%:<br>SpO2: ±4%;<br>PR:±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm. |
| **Light interference** | Under normal and ambient light conditions, the SpO2 deviation ≤ 1% |
| **Pulse intensity** | Continuous bar graph display, the higher display indicates the stronger pulse. |
| Upper and lower limit of measured values | |
| SpO2 | 0% ~ 100% |
| PR | 0 bpm ~ 254 bpm |
| **Optical sensor[see note 5]** | |
| Red light | Wavelength: about 660 nm, optical output power: <6.65 mW |
| Infrared light | Wavelength: about 905 nm, optical output power: <6.75 mW |
| **Memory** | Up to 99 group of data,total duration does not exceed 72 hours. |
| **Safety classification** | Internally powered equipment, type BF applied part |

| | |
|---|---|
| **International Protection** | IP22 |
| **Working voltage** | DC 3.6 V – 4.2 V |
| **Working current** | ≤100 mA |

| | |
|---|---|
| **Power supply** | A rechargeable lithium battery (3.7V) (The red wire on the battery denotes anode, the black wire on the battery denotes cathode.) |
| **Battery working life** | Charge and discharge: no less than 500 times. |
| **Operation time** | After the new device is fully charged, continuous SpO2 and pulse rate measurement is performed under normal conditions, and the working time is about 8 hours.(During normal data storage) |
| **Adapter specification** | Output voltage: DC 5V<br>Output current: 1000 mA |
| **Dimension and Weight** | |
| **Dimension** | 46 mm(L) × 26 mm(W) × 15 mm(H) |
| **Weight** | About 23 g (including a lithium battery) |

**Note**

1. the claims of SpO2 accuracy shall be supported by clinical study measurements taken over the full range. By artificial inducing, get the stable oxygen level to the range of 70 % to 100 % SpO2, compare the SpO2 values collected by the secondary standard pulse oximeter equipment and the tested equipment at the same time, to form paired data, which are used for the accuracy analysis.It is applicable for the probes equipped.
2. because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a CO-OXIMETER.
3. Patient simulator has been used to verify the pulse rate accuracy, it is stated as the

root-mean-square difference between the PR measurement value and the value set by simulator.

4. percentage modulation of infrared signal as the indication of pulsating signal strength, patient simulator has been used to verify its accuracy under conditions of low perfusion. SpO2 and PR values are different due to low signal conditions, compare them with the known SpO2 and PR values of input signal.
5. optical sensors as the light-emitting components, will affect other medical devices applied the wavelength range. The information may be useful for the clinicians who carry out the optical treatment.For example, photodynamic therapy operated by clinician.

**EMC**

This equipmen is suitable for professional healthcare facility environments and home healthcare environments

**Warning**

- Don’t near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**NOTE**

- this equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- The basic performance:. SpO2 measured range: 70% ~ 100%, absolute error: ±2%; PR measured range: 30 bpm ~ 250 bpm, accuracy:±2 bpm during the pulse rate range of 30 bpm ~ 99 bpm and ±2% during the pulse rate range of 100 bpm ~ 250 bpm.
- When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.
- Other devices may affect this device even though they meet the requirements of CISPR.

**Bluetooth Specification**

- **Working frequency:** 2402 MHz ~ 2480 MHz
- **Modulation mode:** GFSK
- **Transmitting power:** 0 dBm, +4 dBm
- **Receiving sensitivity:** -93 dBm\

**Product configuration**

| Serial number | name | Cable length |
|---|---|---|
| 1 | SpO2 probe | 0.35m |
| 2 | USB cable | 1.0m |

**Table 1:**

| Guidance and Declaration – Electromagnetic Emissions | |
|---|---|
| Emission test | Compliance |
| Conducted and radiated RF EMISSIONS CISPR 11 | Group 1 |
| Conducted and radiated RF EMISSIONS CISPR 11 | Class B |
| Harmonic distortion IEC 61000-3-2 | Class A |

| | |
|---|---|
| Voltage fluctuations and flicker IEC 61000-3-3 | Complies |

**Table 2:**

| Guidance and Declaration – Electromagnetic Immunity | | |
|---|---|---|
| Immunity test | IEC60601 test level | Compliance level |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±8 kV contact<br>±15 kV air | ±8 kV contact<br>±15 kV air |
| Electrical fast transient/burst IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/<br>output lines | ±2 kV for power supply lines |
| Surge<br>IEC 61000-4-5: | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth |

| | | |
|---|---|---|
| Voltage dips and Voltage interruptions IEC 61000-4-11 | 0%UT;<br>0,5 .cycle .At0°,45°,90°,135°,<br>180°,225°,270°and315°.<br>0 % UT; 1 cycle and 70 % UT ; 25/30 cycles ;Single phase:at 0°.<br>0 % UT ; 250/300<br>cycle | 0%UT;<br>0,5 .cycle .At0°,45°,90°,135°,<br>180°,225°,270°and315°.<br>0 % UT; 1 cycle and 70 % UT ; 25/30<br>cycles ;Single phase:at 0°. 0 % UT ; 250/300<br>cycle |
| Power frequency(50/60Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m<br>50Hz/60Hz | 30 A/m<br>50Hz/60Hz |
| Conduced RF IEC61000-4-6 | 3 V<br>0,15MHz – 80 MHz<br>6 V in ISM and amateur radio bands between<br>0,15MHz to 80 MHz<br>80%AM at 1kHz | 3 V<br>0,15MHz – 80 MHz<br>6 V in ISM and amateur radio bands between<br>0,15MHz to 80 MHz<br>80%AM at 1kHz |
| Radiated RF IEC61000-4-3 | 10V/m<br>80 MHz-2,7GHz<br>80%AM at 1kHz | 10V/m<br>80 MHz-2,7GHz<br>80%AM at 1kHz |
| NOTE UT is the a.c.mains voltage prior to application of the test level | | |

**Table 3:**

| Guidance and manufacturer's declaration - electromagnetic Immunity | | | | | | |
|---|---|---|---|---|---|---|
| | Test Frequency (MHz) | Band (MHz) | Service | Modulation | IEC6060 1-1-2 Test level (V/m) | Compliance level (V/m) |
| Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment) | 385 | 380 –390 | TETRA 400 | Pulse modulation b) 18 Hz | 27 | 27 |
| | 450 | 430 –470 | GMRS 460, FRS 460 | FM c) ±5 kHz deviation 1 kHz sine | 28 | 28 |
| | 710<br>745<br>780 | 704 –787 | LTE Band 13,17 | Pulse modulation b) 217 Hz | 9 | 9 |
| | 810<br>870<br>930 | 800 –960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | Pulse modulation b) 18 Hz | 28 | 28 |
| | 1720<br>1845<br>1970 | 1700 –1990 | GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4,25; UMTS | Pulse modulation b) 217 Hz | 28 | 28 |
| | 2450 | 2400 –2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | Pulse modulation b) 217 Hz | 28 | 28 |
| | 5240<br>5500<br>5785 | 5100 –5800 | WLAN 802.11 a/n | Pulse modulation b) 217 Hz | 9 | 9 |

## FCC Caution

**§ 15.19 Labeling requirements.**

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.

**§ 15.21 Information to user.**

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**§ 15.105 Information to the user.**

**Note:** 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 radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. 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 to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into 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.

The device has been evaluated to meet general RF exposure requirement.

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## FAQ

**Q: Can the Pulse Oximeter be used for out-of-hospital transport?**
**A:** No, the device is not intended for out-of-hospital transport use.

**Q: What should be done if the device is exposed to an inappropriate environment?**

**A:** When using the device, please keep it away from equipment that can generate strong electric fields or strong magnetic fields to avoid interference with surrounding radio equipment or affecting its working.

**Q: How should users store the Pulse Oximeter?**

**A:** Store the device away from children, pets, insects, direct sunlight, high temperature, humidity, dust, cotton wool, or water splashes to avoid affecting its performance.

# Documents / Resources

| | |
|---|---|
|  | CONTEC CMS50SP Pulse Oximeter [pdf] User Manual<br>CMS50SP, CMS50SP Pulse Oximeter, Pulse Oximeter, Oximeter |

## References

- User Manual

Contec

CMS50SP, CMS50SP Pulse Oximeter, Contec, Oximeter, Pulse Oximeter

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