INSTRUCTION MANUAL FOR CITIZEN PULSE OXIMETER CMS50DL1

CITIZEN

Thank you very much for purchasing the CITIZEN PULSE OXIMETER

- Please read all of the information in this instruction manual before operating the device.
- Be sure to have this instruction manual to hand during use.

Rev.2401

Date of issue: 2024/2/15

• Intended use:	The Pulse Oximeter is used to measure Oxygen Saturation (SpO_2) and pulse rate through finger, and indicate the pulse intensity by the bar-display.
• Intended operator:	The device is suitable for persons weighing more than 40 kg.

Safety Precautions

Be sure to read the following instructions before using the device.

Warning:
Indicates a potentially hazardous situation which it may result in death or serious injury.

- Consult your physician before using the device. Do not use measurement results for self-diagnosis and self-treatment. Always consult your physician.
- If the battery fluid gets in your eyes or on your skin, rinse it off with water immediately and then receive treatment from your physician.
- Do not use the device in the vicinity of flammable gases such as those used for anesthesia. It could ignite the gases and cause an explosion.
- 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 should only be used as an auxiliary means in diagnosis. And it must be used in conjunction with the doctor's advice, clinical manifestations, and symptoms.
- Do not remove the lanyard to avoid dropping the device and causing damage. The lanyard is made of insensitive material. Do not use it if any person is allergic to the lanyard. Do not wrap the lanyard around your neck to avoid accidents.
- Check the device before use to make sure that there is no visible damage that may affect the user's safety and device performance. When there is obvious damage, do not use it and please contact distributor.
- When using the device, keep it away from equipment that can generate strong electric or magnetic fields. Using the device in an inappropriate environment may cause interference to surrounding radio equipment or affect its working.
- Using several products on the same patient simultaneously may be dangerous due to the overlap of leakage current.
- CO poisoning is shown as an over-estimation, so it is not recommended to use the device for this purpose.

Caution:
Indicates a potentially hazardous situation which it may result in injury or property damage. The property damage refers to consequential damage to buildings, household, belongings, livestock, and pets.

- An uncomfortable or painful feeling may appear if the device is used for a long period, especially for users with a microcirculation disturbance. It is not recommended to use the sensor on the same finger for more than 2 hours.
- For some special users who need a more careful inspection on the test site, do not place the device on the edema or tender tissue.
- Do not stare at the red or infrared light emitter (the infrared light is invisible) after turning on the device, including maintenance staff, as it may be harmful to the eyes.
- 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. Persons who are allergic to silicone, PVC, TPU, TPE or ABS cannot use this device.
- The device cannot be used with equipment not specified in the Manual. Only accessories appointed or recommended by the manufacturer can be used. Failure to observe this instruction may cause injury to the tester and operator or damage to the device.
- Measured accuracy is affected by interference from electrosurgical equipment.
- Measurement can be affected by or unreliable readings may result from
  – fingers are too thin, having too long fingernails
  – lotions, nail polish and unclean fingertip
  – strong lights such as sun light or surgical light
- Measurement cannot be taken correctly If your fingertip is cold. Before making a measurement, warm your finger by massaging etc. to improve the blood flow.
- Do not attempt to disassemble, repair or modify the device.
- If the device is splashed or coagulated with water, stop operating and do not expose the device to water.
- Before using the device, make sure that it is in a normal working state and is located in a normal operating environment.
- In order to obtain more accurate measurements, the device should be used in a quiet and comfortable environment.
- Do not use the device immediately after it has been carried from a cold environment to a warm or humid environment.
- Do not operate the device using a sharp object.
- Do not twist or drag the device wire.
- There is no alarm function. Do not use the device if you need an alarm.
- Do not drop the device and give any shocks or vibrations.

Symbol Explanations

Refer to instruction manual before use.

Type BF applied part

Warning

Caution

Alarm inhibit

2012/19/EU WEEE
Please do not dispose of the product in the household waste at the end of its useful life.
Disposal can take place at appropriate collection points provided in your country.

To protect the environment, dispose of empty batteries at your retail store or at appropriate collection sites according to national or local regulations.

IP22 Protection level of solid particle and liquid ingress

Paper Recycling

Manufacturer
Name: Contec Medical Systems Co., Ltd.
Address: No.112 Qinhuang West Street, Qinhuangdao, Hebei Province, P.R. China

Date of manufacture

SN Serial number

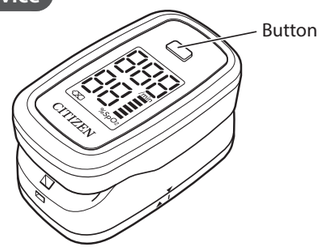
EC REP Authorized representative in the European cummunity
Name: Prolinx GmbH
Address: Brehmstr. 56,40239 Duesseldorf, Germany
Tel: 0049 211 3105 4698
E-mail: med@eulinx.eu

CE 0123 The CE mark and Notified Body Registration Numbers

Names of Parts

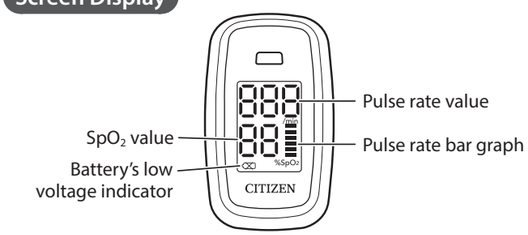
The device and its accessories

Device



Make sure that the package contains all the following items.
- Device
- Instruction manual and EMC technical data
- Test Batteries
- Lanyard

Screen Display

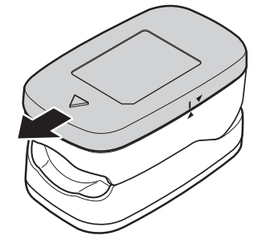


Overview

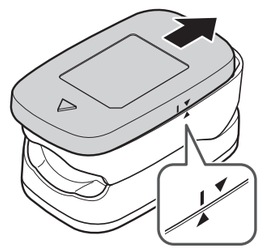
Oxygen Saturation (SpO_2) is the percentage of HbO_2 in the total Hb in the blood, so-called the O_2 concentration in the blood, it is an important physiological parameter for the respiratory and circulatory system.
A number of diseases related to respiratory system may cause the decrease of SpO_2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body, and the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients' SpO_2 is of great help for the doctor to discover the potential danger, and is of great importance in the clinical medical field. Insert the finger when measuring, the device will directly display the SpO_2 value measured.

INSERT THE BATTERIES

1. Slide open the battery cover on the bottom of the device.



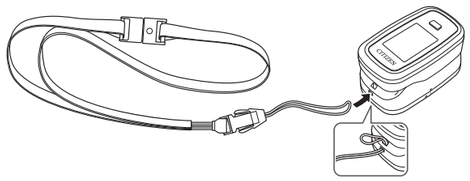
2. Be sure to inset the batteries into negative ⊖ side with the protruding springs first so as not to mix up the positive ⊕ and negative ⊖ terminals.
3. Align the "▲" mark on the main unit with the "▼" mark on the battery cover. Slide the battery cover so that the "▲" mark on the main unit aligns with the "**I**" mark on the battery cover.



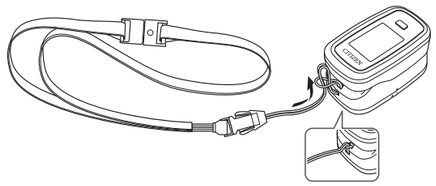
* The device does not have low-voltage prompt function, it only shows the low-voltage, please change the battery when the battery voltage is used up.
* Do not use any other type of battery except alkaline.
* Do not mix up the kind of batteries.

Attach the lanyard

1. Put the end of the loop in the hole.

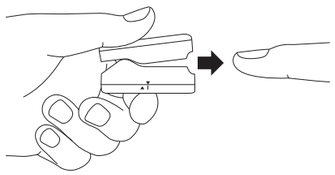


2. Put another end of the loop through the first one and then tighten it.

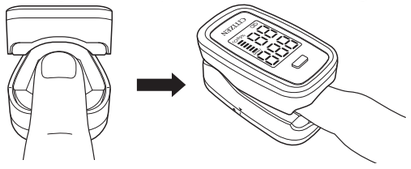


Measuring value

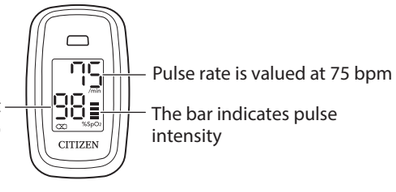
1. Open the clip as shown below.



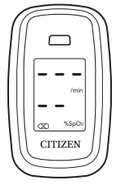
2. Place the patient's finger on the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
   * Please insert the thicker finger such as thumb or middle finger deeply enough into the probe when measuring.



3. Press the button on the front panel once.
4. Do not shake the finger and keep the patient at ease during the process. It is recommended that the patient stays still during the measurement.
5. Read the information directly from the screen display.
   * Fingernails and the luminescent tube should be on the same side.



   * After pull out your finger, the device enteres into energy saving mode.



Maintain, Transport and Storage

Cleaning and disinfection

The device must be turned off before cleaning, and should not be immersed in liquid.
Take out the internal batteries before cleaning, and do not immerse it in liquid.
Use 75% alcohol to wipe the device enclosure and use liquid soap or isopropanol to wipe the display for disinfection. Allow it to dry naturally or clean it with clean and soft cloth. Do not spray any liquid on the device directly and do not let liquid penetrate into the device.

Maintenance

A. Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and measurement performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.
B. Clean and disinfect the device before/after using it according to the User Manual.
C. Replace the batteries promptly when the low-battery indication appears.
D. Remove the batteries if the device will not be used for a long time.

Transport and Storage

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

Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate cannot be displayed normally	1) The finger is not properly inserted. 2) The finger is shaking or the patient is moving. 3) The device is not being used in the environment required by the manual. 4) The device is faulty.	1) Insert the finger properly and measure again. 2) Help the patient stay calm. 3) Use the device in the proper environment. 4) Contact the distributor.
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) Help the patient stay calm.
The device cannot be turned on	1) The battery is drained or almost drained. 2) The battery is installed incorrectly. 3) The device is faulty.	1) Change the batteries. 2) Insert the batteries again. 3) Contact the distributor.
The display turns off suddenly	1) The device has entered energy saving mode. 2) Low battery. 3) The device is faulty.	1) The device is working properly. 2) Change the batteries. 3) Contact the distributor.

Function Specification

SpO_2 (*1)	
Display range	0%SpO_2 ~ 99%SpO_2
Measured range	0%SpO_2 ~ 100%SpO_2
Accuracy (*2)	70%SpO_2 ~ 100%SpO_2: ±2%SpO_2; 0%SpO_2 ~ 69%SpO_2: unspecified.
Resolution	1%SpO_2
Pulse rate	
Display range	30 bpm ~ 250 bpm
Measured range	30 bpm ~ 250 bpm
Accuracy (*3)	±2 bpm or ±2%, whichever is greater.
Resolution	1 bpm
Accuracy under low perfusion (*4)	Low perfusion 0.4%: SpO_2: ±4%SpO_2; Pulse rate: ±2 bpm or ±2%, whichever is greater
Light interference	Under normal and ambient light conditions, the SpO_2 deviation ≤ 1%SpO_2
Red light (*5)	Wavelength: about 660 nm, optical output power: < 6.65 mW
Infrared light (*5)	Wavelength: about 905 nm, optical output power: < 6.75 mW
Safety class	Internally powered equipment, type BF applied part
Operating environment	Temperature: +10°C~+40°C Relative humidity: ≤75% Atmospheric pressure: 700hPa~1060hPa
Storage environment	Temperature: -40°C~+60°C Relative humidity: ≤95% Atmospheric pressure: 500hPa~1060hPa
International Protection	IP22
Working voltage	DC 2.6 V ~ 3.6 V
Working current	≤ 25 mA
Power supply	1.5V (AAA (LR03)size) alkaline batteries × 2
Battery life	Two batteries can work continually for 24 hours
Service life	3 years
Dimension	61 (L) × 36 (W) × 32 (H) mm
Weight	Approximately 55g (with the batteries)

* 1: The claims of SpO_2 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 % SpO_2, compare the SpO_2 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. There are 12 healthy volunteers (male: 6. female: 6; age: 18~45; skin color: black: 2, light: 8, white: 2) data in the clinical report.
* 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. SpO_2 and PR values are different due to low signal conditions, compare them with the known SpO_2 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.

This device corrsponds to the below standards:
IEC 60601-1/EN 600601-1 (Medical electrical equipment - Part 1), IEC 60601-1-2/ EN 60601-1-2 (Medical electrical equipment - Part 1-2), ISO 80601-2-61 (Medical electrical equipment - Part 2-61)

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