

CMS60D1

USER MANUAL Pulse Oximeter

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Instructions to User

Dear user, thank you very much for purchasing the Pulse Oximeter (hereinafter referred to as device).

This Manual is written and compiled in accordance with the council directive MDD93/42/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.

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 patient 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 patients' 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, patient 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 battery (non-detachable lithium battery) can 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. Patients are not permitted to maintain or refit the device by themselves.**
- Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation disturbance patients. It is not recommended that the sensor is used on the same finger for more than 2 hours.
- For some special patients 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.
- 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.
- 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 patient 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 patient'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 on the screen, 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 Oxim. eter.
- 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 place 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.
- Do not rely on the alarm system of the device solely, the alarm function must be verified regularly. The most reliable method of use is to closely monitor and correctly use it .
- 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.
- Patients should read the product manual carefully before use and operate according to the requirements.

1 Overview

The 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 physiological parameter for the respiratory and circulatory system. A number of diseases related to respiratory system may cause the decrease of SpO₂ 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' SpO₂ 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 SpO₂ value measured, it has a higher accuracy and repeatability.

1.1 Features

- A Hand-held design and exterior design are more robust and durable, easy to use when working outside,anti-stolid design and strengthen the probe fastness to make the work more safe.
- B Dustproof and waterproof design makes it competent for harsh working environment.
- C The patient can also view the measured value when operating the menu interface.
- D Comply with alarm regulations.

1.2 Intended purpose

The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger. The product is suitable for being used in family, hospital, oxygen bar, community healthcare, physical care in sports (It can be used before or after doing sports, and it is not recommended to use the device during the process of having sport) and etc.

1.3 Environment Requirements

Storage Environment

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

Operating Environment

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

1.4 Precautions

1.4.1 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.
- DO NOT operate the device with sharp things.
- 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 and disconnect it from the power before cleaning and disinfection.
- The device is suitable for children and adult.
- The device may not be suitable for all patients, 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 years.
- 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 years.
- To further detect the alarm of individual measurement parameter, measure and check oneself or with a simulator, adjust the alarm limit setting and check whether the correct alarm can be triggered.
- This device has the function of alarm, patients can check on this function according to chapter 5.3.4 as a reference.
- The device has the function of limits alarm, when the measured data is beyond the highest or lowest limit, the device would start alarm automatically on the premise of the alarm function is on.
- The device has the function of alarm, this function can either be paused, or closed for good. This function could be turned on through menu operation if you need. Please check the chapter 5.3.4 as a reference.
- 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.
- If some unknown error appears during measuring, reset it refer to User Manual in the relative chapter (5.6).
- Do not contort or drag the wire of the device.
- The alarm sound is less than the surrounding noise, which will affect the operator's recognition of the alarm.**
- Never surround the the SpO₂ probe around the neck, avoiding risks.**
- At the measuring point with a radius of 1 meter, when the alarm volume level is 3, the sound pressure is about 75db.**
- If the upper and lower limit of alarm limits is set to the extreme value, the alarm system may invalid.**
- 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.
- 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 patient 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 5), 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 60601-1.
- 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.

1.4.2 Clinical restriction

- A. 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.
- B. The measurement will be influenced by intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.
- C. The measured value may be normal seemingly for the tester who has anemia or dysfunctional hemoglobin(such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulphaemoglobin (SuHb)), but the tester may appear hypoxia, it is recommended to perform further assessment according the clinical situations and symptoms.
- D. Pulse oxygen only has a reference meaning for anemia and toxic hypoxia, as some severe anemia patients still show better pulse oxygen measured valued.
- E. Contraindication:
 - a. The person who is allergic to silicone, PVC, TPU TPE or ABS can not use this device.
 - b. The damaged skin tissue can't be measured.
 - c. During cardiopulmonary resuscitation.
 - d. When the patient is hypovolemic.
 - e. For assessing the adequacy of ventilatory support.
 - f. For detecting worsening lung function in patients on a high concentration of oxygen.

1.5 Clinical indications

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

2 Principle

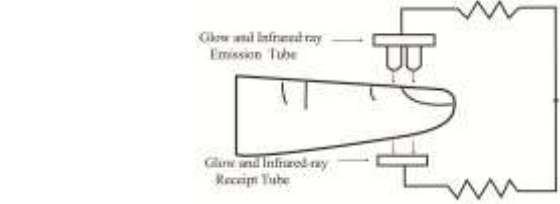


Figure 1. Operating principle

Principle of the Oximeter is as follows: 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 device 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 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 screen through treatment in electronic circuits and microprocessor.

3 Functions

- A. Color screen
- B. Display of SpO₂ value
- C. Display of pulse rate value and bar graph
- D. Display of pulse waveform
- E. Display of PI value(selection function)
- F. Chinese and English bilingual switch
- G. With function menu
- H. Clock function
- I. Review function
- J. Code lock protection alarm function
- K. Alarm function(Finger out or out of limit)
- L. Battery power indication, Ultra low power warning function
- M. Adjustable screen brightness
- N. Adjustable sound volume
- O. Restore factory Settings
- P. Storage function for SpO₂ and PR values,and data stored can be uploaded to PC
- Q. Real-time data can be uploaded to PC
- R. Bluetooth connection to PC(optional)
- S. External SpO₂ probe can be connected

4 Installation

4.1 Appearance

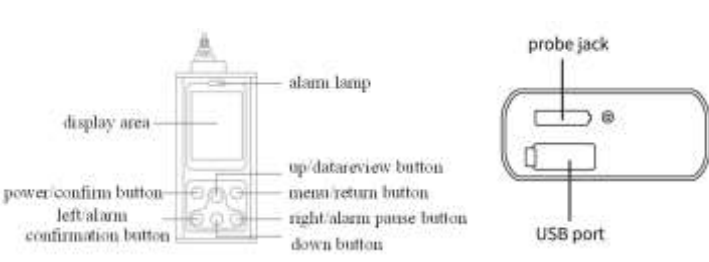


Figure 2. Front and top appearance

alarm lamp: When data's going beyond the limits, low-voltage, finger out, sensor off or sensor fault, the alarm light will be on. when the device is turned on, the red and yellow alarm lamp flash alternately once, which indicates that the alarm system is working.

display area: display measure information.

power/confirm button: the device is in power-off state, short press the button to turn on the device; in power-on state, long press the button to turn off the device, in main menu interface, short press the button to enter the corresponding sub menu.

menu/return button: in measure interface, press the button to enter the main menu interface; in main menu interface and sub menu interface, press the button to return to the previous interface.

up/dataReview button: in measure interface, press the button to enter the dataReview interface(see figure 3); in main menu interface and sub menu interface, move the choice bar up.

down button: move the choice bar down.

right/alarm pause button: move the choice bar right; when the alarm occurs, in the measurement interface, short press the button to pause the alarm.

left/alarm confirmation button: move the choice bar left; when the alarm occurs, in the measurement interface, short press the button to confirm the alarm.

USB port: It is used to connect a personal computer to export the trend data(or real-time data) or charge the lithium battery via a data line.

Probe jack: It is used to connect a SpO₂ sensor to measure the oxygen saturation and pulse rate.

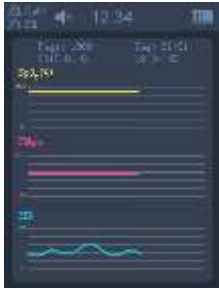


Figure 3. DataReview interface

4.2 Interface introduction



Figure 4. Measurement interface

4.3 SpO₂ probe installation

Inserting the SpO₂ probe of the pulse oximeter in the probe jack, use a screwdriver to screw the screws (The probe is limited to the one that is provided by our company; and can't be replaced with the similar one by other manufacturers).

4.4 Connection of USB cable

Open the USB plug of the device, insert the micro end of USB cable into the USB port interface, the other end into computer or power adapter.

4.5 Structure, accessories and software description

- A. Structure: main unit, SpO₂ probe, USB cable, power adapter (optional) and Bluetooth adapter (optional).
 - B. Accessories: one SpO₂ probe, one USB cable, one power adapter (optional), one CD disk (including PC software, optional), one User Manual, Bluetooth adapter (optional).
- Please check the device and accessories according to the list to avoid that the device can not work normally.
- C. Software description
 - Release version: 2.0

5 Operating

5.1 Measurement

A Put the finger into the probe as Figure 5.



Figure 5. Sketch map for finger placement

(The appearance of actual probe may be different with the one shown as Figure 5, please refer to the actual probe.)

B Press the power/confirm button to turn on the device, it displays the measurement interface.

C Wait a few seconds, the device directly shows measurement result on the screen.

Note: when inserting the finger, fingernails and the luminescent tube should be at the same side.

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

5.2 Alarm prompt

A Alarm including the alarm of measure data's going beyond the limits, the alarm of low-voltage, the alarm of finger out, the alarm of sensor off, the alarm of sensor fault.(The alarm level of measure data's going beyond the limits, low-voltage and sensor fault is high, in these three alarm states, the alarm light is red and flashes continuously; the alarm level of finger out and sensor off is medium, the alarm light is yellow and flashes continuously; high level alarm is prior to medium level alarm.)

Note: the alarm of measure data's going beyond the limits is physiological alarm, the alarm of low-voltage, the alarm of finger out, the alarm of sensor off, the alarm of sensor fault is technical alarm.

Note: The alarm of low-voltage has two stages: stage I, the data can be measured, alarm can be confirmed; stage II, the data cannot be measured, alarm can not be confirmed. (the first stage voltage is higher than the second stage voltage.)

B When alarm is on, short press the right button to make the alarm pause, pause time is 60 s, if you want to turn off the sound prompt permanently, please set it in menu.

Note: alarm pause can only pause the alarm of measure data's going beyond the limits.

C Physiological alarm occurs, short press the left button to confirm the alarm, and there will be no alarm this time. Technical alarm occurs, alarm confirmed there is still light alarm.(sensor fault and low-voltage alarm second stage can not confirm the alarm.)

5.3 Menu operation

Under the measurement interface, press the menu/return button to enter the main menu interface as shown in Figure 6, system,

display, clock, alarm, record and password, etc. can be set, methods are as followings:



Figure 6. Main menu

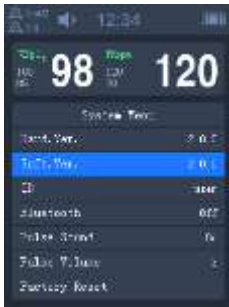


Figure 7. System setting menu

5.3.1 System setting

In the main menu interface, choose "System" item, then press power/confirm button to enter the System setting menu as figure 7:

Press the Up or Down button to select the option to be adjusted, Press the left or right button to change the value.

A Hard. Ver.: hardware version.

B Soft. Ver.: software version.

C ID: user name.

D Bluetooth(selection function): set the Bluetooth, "on": turn on the Bluetooth, "off": turn off the Bluetooth.

E Pulse sound: set the pulse sound, "on": turn on the pulse sound, "off": turn off the pulse sound.

F Pulse Volume: set the pulse volume, adjustable range: 1 ~ 3.

G Factory Reset: press the power/confirm button, pop-up "enter the password" interface, (Please refer to chapter 5.3.4), then press the power/confirm button, in the pop-up interface select "yes": restore factory settings; "no": return(do not restore factory settings).

5.3.2 Display setting

In the main menu interface, choose "Display" item, then press power/confirm button to enter the display setting menu as Figure 8:



Figure 8. Display setting menu

Press the Up or Down button to select the option to be adjusted, Press the left or right button to change the value.

A Mode: press left or right button to switch display mode (two kinds of display mode) as figure 9 and figure 10.

B Wave: set the pulse wave, "on": turn on the pulse wave, "off": turn off the pulse wave.

C Brightness: set the brightness, adjustable range: 1 ~ 4.

D Demo: set the Demo mode, "on": turn on the Demo mode, "off": turn off the Demo mode.

E Language: set the language, "EN": display in English, "中文": display Chinese.



Figure 9. Limit mode



Figure 10. PI mode

5.3.3 Clock setting

In the main menu interface, move the choice bar to "Clock" item, then press the power/confirm button to enter the clock setting menu of Figure 11:



Figure 11. Clock setting menu

Receiving sensitivity: -93 dBm

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. The device can be used in portable exposure condition without restriction