CMS60D1

USER MANUAL
Pulse Oximeter

CE 0123

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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 SpO_2 probe accompanied is only suitable for using with the device. The device can only use the SpO_2 probe described in the Manual, so the operator has the responsibility to check the compatibility between the device and the SpO_2 probe before using, incompatible accessories may cause device performance degradation, device damage or patient injury.
- Do not reprocess the accompanying SpO_2 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 SpO_2 probe is disconnected or line fault occurs. Check the connection of the SpO_2 probe and whether there is damage for the probe, if necessary, please replace the probe to avoid risksThe probe fault will not result in a safety hazard.
- Functional testers can not be used to assess the accuracy of the SpO_2 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 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.
- 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 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, 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 SpO_2 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 SpO_2 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 SpO_2 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 SpO_2 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 SpO_2 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 SpO_2 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 sulfhaemoglobin (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

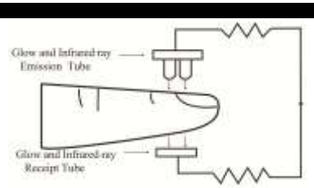

Figure 1. Operating principle

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 (HbO_2) 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 SpO_2 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 SpO_2 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 SpO_2 probe can be connected

4 Installation

4.1 Appearance

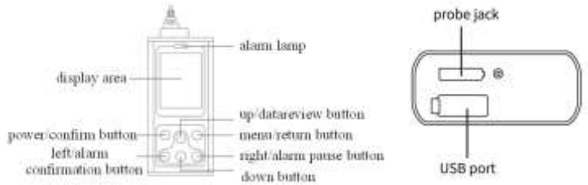

Figure 2. Front and top appearance

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 SpO_2 probe installation

Inserting the SpO_2 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, SpO_2 probe, USB cable, power adapter (optional) and Bluetooth adapter (optional).
B. Accessories: one SpO_2 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

Press the Up or Down button to select the option to be adjusted, Press the left or right button to change the value.The device adopts 24-hour clock.
A set year: set the year
B set month: set the month
C set day: the day
D set hour: set the hour
E set minute: set the minute

5.3.4 Alarm setting

In the main menu interface, move the choice bar to "Alarm" item, then press power/confirm button to enter the password interface of Figure 12.

Figure 12.password interface

Figure 13. Alarm menu

Inputting password (Press the Up or Down button to select number, Press the left or right button to adjust input position, The factory default password is 7762.), then press power/confirm button to enter the alarm menu of Figure 13.
Press the Up or Down button to select the option to be adjusted, Press the left or right button to change the value.
A SpO_2 HI (%): upper limit alarm for SpO_2 over-limit.
B SpO_2 LO (%): lower limit alarm for SpO_2 over-limit.
C PR HI (bpm): upper limit alarm for PR over-limit.
D PR LO (bpm): lower limit alarm for PR over-limit.
E Alarm Volume: set the alarm volume, adjustable range: 1 ~ 3.
F SpO_2 Alarm: set the SpO_2 alarm, "on": turn on the SpO_2 alarm, "off": turn off the SpO_2 alarm.
G PR Alarm: set the PR alarm, "on": turn on the PR alarm, "off": turn off the PR alarm.
Lower limit can not exceed the upper limit, and the upper limit can not be lower than the lower limit when adjusting the values. SpO_2 range: 0 % ~ 100 %, PR range: 0 bpm ~ 254 bpm.
Please refer to Chapter 10 for the initial value of over-limit prompt.

5.3.5 Record setting

In the main menu interface, move the choice bar to "Record" item,then press power/confirm button to enter Figure 14. It indicates that the device is storing, when the red dot "●" at the top of the screen flashes.

Figure 14. Record Menu

Figure 15. Record 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: record mode selection, including: "Auto" and "Manual" mode, manual mode show as Figure 14, auto mode show as Figure 15.
Under "Manual" mode, select to turn on or off memory by "Record".
Auto record: start recording after stable data appear, pull out the finger to finish recording a group of data (99 group of data at most), the total duration does not exceed 72 hours.
Manual record: after manual storage is started, the storage state needs to be terminated manually to complete a group of store, store up to 24-hour data.
When the storage space is full, it displays "Memory is full" on the screen.
Note: Under manual mode, when "Record" is "ON", the device will prompt to clear the data stored last time.
It will display "Recording..." when there is no operation under record state for 15s, then it will enter energy saving mode after several seconds, pressing the "menu/return button", the device would return to the measure interface; pressing power/confirm button, it will display "Recording"; pressing any button(power/confirm and menu/return button excluded), it will be no response.
B Seg: data segment.
C DataReview: view record data (see figure 3).
D Delete All: delete all records.

5.3.6 Password setting

In the main menu interface, move the choice bar to "Password" item, then press power/confirm button to enter the password interface of Figure 16.

Figure 16. password interface

Figure 17.new password interface

Press the Up or Down button to select number, Press the left or right button to adjust input position(The factory default password is 7762), then pressing the power/confirm button, you can set a new password of Figure 17.
NOTE: The new password needs to be enter twice, the first time is to set, the second time is to confirm.

5.4 Data upload

5.4.1 Wired transmission

Connect the device to computer by the USB cable, upload the data after connecting with the PC software properly, refer to "Software operating instruction" for details.

5.4.2 Bluetooth transmission (selection function)

Turn on the device Bluetooth and the PC software to upload data, refer to "Software operating instruction" for details.

5.5 Charging

Power adapter can be selected to charge for the device.
When the device is closed and the battery is charging up, short press power/confirm button and the device will display dynamic charge icon, it means that the device is charging up. When the device is open and the battery is charging up, the battery status icon on the right top will display state of charge. It means that the device is charging up. When the battery status is full, the charging has been finished.

5.6 Reset

Long press the power/confirm button for several seconds, and press the menu/return button at the same time to reset.

6 Maintain, Transport and Storage

6.1 Cleaning and disinfection

Please turn off the device and disconnect it from the power, do not immerse it into liquid.
Use 75% alcohol to wipe the device enclosure, 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.

6.2 Maintenance

A. Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patients safety and monitoring performance. It is recommended that the device should be inspected weekly at least. When there is obvious damage, stop using it.
B. Please clean and disinfect the device before/after using it according to the User Manual (6.1).
C. Please charge the battery in time when low battery appears.
D. 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
E. The device need not to be calibrated during maintenance.

6.3 Transport and Storage

A. 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.
B. The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: -40℃ ~ + 60℃; Relative humidity: ≤95%.

7 Troubleshooting

Trouble	Possible Reason	Solution
The values can not be displayed normally or stably.	1.The finger is not properly inserted. 2.The finger is shaking or the patient is moving 3.The device is not used in environment required by the manual. 4.The device works abnormally.	1.Please insert the finger properly and measure again. 2.Let the patient keep calm. 3.Please use the device in normal environment. 4.Please contact the after-sales.
The device can not be turned on	1.Low battery or the battery is drained away. 2.The device works abnormally.	1.Please charge the battery. 2.Please contact the after-sales.
The display disappears suddenly	1.The device enters into the energy saving mode. 2.Low battery. 3.The device works abnormally.	1.Normal. 2.Please charge the battery. 3.Please contact the after-sales.
The device can not be used for full time after charge.	1.The battery is not charged fully. 2.The device works abnormally.	1.Please charge the battery. 2.Please contact the after-sales.
The battery can not be full charged even after 10 hours charging time.	The device works abnormally.	Please contact the local after-sales.
The data can not be stored.	1.The device is not operated according to the manual. 2.The device works abnormally.	1.Please operate the device according to the manual. 2.Please contact the after-sales.

8 Key of Symbols

Symbols	Meaning	Symbols	Meaning
	Caution, consult accompanying documents	PRbpm	Pulse rate (bpm)
	Type BF applied part	%SpO_2	Pulse oxygen saturation (%)
	Manufacturer		Fully charged
SN	Serial number		Use-by date
	Recycling garbage WEEE (2012/19/EU)		USB
IP22	It means this pulse oximeter is protected against harmful effects of dripping water when tilted at 15°		Humidity limitation
	Temperature limitation		This way up
	Atmospheric pressure limitation		Keep away from rain
	Fragile, handle with care		Close the pulse sound
	Low battery		Alarm on
	Alarm pause		Open the pulse sound
	Alarm off		Manufacture Date
	Menu/Return button	Finger Out	The finger is not inserted
	Power/Confirm button	Sensor Fault	Probe failure
	Recyclable	PI%	Perfusion index
P/N	Material code	LOT	Batch No.
	Bluetooth icon (Bluetooth device)		1. The finger clip falls off (no finger inserted) 2. Probe error 3. Signal inadequacy indicator
Sensor Off	The probe is disconnected.	•	Recording
	left/alarm confirmation button		right/alarm pause button
EC REP	European Representative		DataReview
CE 0123	This item is compliant with Directive 93/42/EEC of 14 june 1993 concerning medical devices; Including, at 21 march 2010, the amendments by Council Directive 2007/47/EC.		

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

9 Specification

SpO_2 [see note 1]	
Display range	0% ~ 100%
Measured range	0% ~ 100%
Accuracy [see note 2]	70% ~ 100%: ±2%; 0% ~ 69%: unspecified.
Resolution	1%
PR	
Display 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 ±2% during the pulse rate range of 100 bpm ~ 250 bpm.
Resolution	1 bpm
PI (selection function)	
Display range	0% ~ 20%
Measured range	0% ~ 20%
Accuracy	1% ~ 20% : ±1% 0% ~ 0.9%: ±0.2%
Resolution	0.1%
Accuracy under low perfusion [see note 4]	Low perfusion 0.4%: SpO_2: ±4%; 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 SpO_2 deviation ≤ 1%
Pulse intensity	Continuous bar graph display, the higher display indicates the stronger pulse.
Upper and lower limit of alarm limits	
SpO_2	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 under auto mode, total duration does not exceed 72 hours. Up to 24-hour data under manual mode.
Safety class	Class Ⅱ, type BF applied part
International Protection	IP22
Alternating current supply	DC 3.6 V ~ 4.2 V
Working current	≤0.84VA
Power supply	A rechargeable lithium battery (3.7 V) (The red wire on the battery denotes anode, the black wire on the battery denotes cathode.)
Battery life	Charge and discharge: no less than 500 times.
Adapter specification	Output voltage: DC 5V Output current: 1000 mA
Dimension and Weight	
Dimension	159(L) ×72(W) ×31(H) mm
Weight	About 250 g (with a lithium battery)

Note 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.(It is applicable for the probes equipped.)
There are 12 healthy volunteers (male: 6. female: 6; age: 18~50; skin color: black: 2, light: 8, white: 2) data in the clinical report.
Note 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.
Note 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.
Note 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.
Note 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.

10 Factory Default

	default	unit
Bluetooth (selection function)	off	
Pulse Sound	on	
Mode(display mode)	Limit	
Wave	on	
Brightness	4	
Language	EN	
Alarm Volume	3	
SpO_2 alarm high limit	100	%
SpO_2 alarm low limit	85	%
Pulse rate alarm high limit	120	bpm
Pulse rate alarm low limit	30	bpm
alarm volume	3	
Password	7762	
SpO_2 alarm	on	
PR alarm	on	
Mode(record mode)	Manual	

Attached List

State	Alarm condition delay	Alarm signal generation delay
Low voltage alarm	1s	20ms
SpO_2 alarm	330ms	20ms
Pulse rate alarm	330ms	20ms
Probe error alarm	16ms	20ms

EMC

Table 1:

Guidance and manufacturer's declaration –electromagnetic emission	
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The purchaser or the patient of the device should assure that it is used in such environment.	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Applicable

Table 2:

Guidance and manufacturer's declaration-electromagnetic immunity
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The purchaser or the patient of the Pulse Oximeter should assure that it is used in such environment.

Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ± 15kV air	±8kV contact ±15kV air
Electrical fast transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/output line	±2kV for power supply lines Not Applicable
Surge IEC 61000-4-5	±1kV lines to lines ±2kV lines to earth	±1kV lines to lines Not Applicable
Voltage dips, short interruptions and voltage vatiations on power supply input lines IEC 61000-4-11	<5%UT(>95%dip in UT) for 0.5 cycle 40% UT(60%dip in UT) for 5 cycle 70%UT(30%dip in UT) for 25 cycle <5%UT(>95%dip in UT) for 5 sec	<5%UT(>95%dip in UT) for 0.5 cycle 40% UT(60%dip in UT) for 5 cycle 70%UT(30%dip in UT) for 25 cycle <5%UT(>95%dip in UT) for 5 sec
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	30 A/m	30A/m

Table 3:

Guidance and manufacturer's declaration – electromagnetic immunity		
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer the patient of the Pulse Oximeter should assure that it is used in such environment.		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz- 2.7 GHz	10 V/m80 MHz- 2.7 GHz
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulse Oximeter is used exceeds the applicable RF compliance level above, the Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulse Oximeter.		

Table 4:

Guidance and manufacturer's declaration - electromagnetic Immunity						
The [Code SI] is intended for use in the electromagnetic environment specified below. The customer or the patient of the Pulse Oximeter should assure that it is used in such an environment						
	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST 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	1,8	0,3	27
	450	380 –390	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28
	710 745 780	704 –787	LTE Band 13,17	Pulse modulation b) 217 Hz	0,2	0,3	9
	810 870 930	800 –960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	1720 1845 1970	1700 –1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	2450	2400 –2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240 5500 5785	5100 –5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.							
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.							

Warning

1) 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.
2) 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.
3) 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."
4) 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 device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
5) Active medical devices are subject to special EMC precautions and they must be installed and used in accordance with these guidelines.

Note:

- **When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.**

Bluetooth (selection function) Specification
Working frequency: 2402 MHz ~ 2480 MHz
Modulation mode: GFSK
Transmitting power: -6 dBm, +4 dBm

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