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USER NOTICE

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 modification of the 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, assembly, 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, 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.
- 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 compatibility 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 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 electrostatic 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.

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 humans' 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.

- 1.1 Features**
A Hand-held design and exterior design are more robust and durable, easy to use when working outside, anti-stoidid 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 is a non-invasive device intended for the spot-check or continuously monitor of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult, pediatric and neonate patients through finger in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). The device is not intended for single use and out-of-hospital transport use.
- 1.3 Environment Requirements**
Storage Environment
a) Temperature: -40°C ~ +60°C
b) Relative humidity: ≤95%
c) Atmospheric pressure: 500 hPa~1060 hPa
Operating Environment
a) Temperature: +5°C~40°C
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 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.

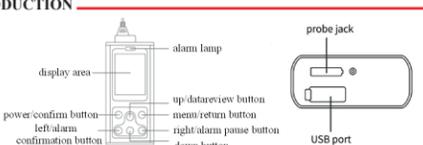
- The expected service life of the attached parts or accessories of the equipment is two year.
- The shelf life shall prevail if the accessory or part has a shelf life that is shorter than its intended service life.
- To further detect the alarm of individual measurement parameter, measure and check 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°C 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 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.
- Do not fix the SpO2 sensor with adhesive or else it may result in venous pulsation and inaccurate measure of SpO2 and pulse rate.
- 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 assembly 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.
- After the mains is interrupted, the device will automatically switch to backup power for working, it will automatically switch to mains after it is restored.

- 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, Raynaud's syndrome, 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 value.
- E. Contraindication:
a. The person who is allergic to silicone, PVC, TPU TPE or ABS.
b. The damaged skin tissue.
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 indication**
The Pulse Oximeter can be used in measuring the pulse oxygen saturation and pulse rate through finger.
- 1.6 Federal communications commission compliance statement**
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. Any Changes or modifications not expressly approved by the party responsible for compliance could void the users' authority to operate the equipment.
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/mobile exposure condition without restriction.
FCC ID:2ABOGCMS60D1

- 2 PRINCIPLE**
According to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO2) in red light & near-infrared light zones, the device adopts Lambert-Beer Law to establish an empirical formula for data processing. On the basis of the principle of Photoelectric Oxyhemoglobin Inspection Technology and Photopectrography technology, it uses two beams of light with 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.

- 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. External SpO2 probe can be connected

- 4 PRODUCT INTRODUCTION**
4.1 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.

- 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 Pulse sound: set the pulse sound, "on": turn on the pulse sound, "off": turn off the pulse sound.
E Pulse Volume: set the pulse volume, adjustable range: 1 ~ 3.
power/confirm button: the device is in power-off state, short press the button to 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:
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 in Chinese.

- up/down 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.
right button: move the choice bar down.
left/right 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.

- 4.2 Interface introduction**


- 4.3 SpO2 probe assembly**
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 and power adapter (optional) .
B. Accessories: one SpO2 probe, one USB cable, one power adapter (optional), one CD disk (including PC software, optional), one User Manual.
Please check the device and accessories according to the list to avoid that the device can not work normally.
C. Software description
Release version: V2

- 5 OPERATING**
5.1 Measurement
A Put the finger into the probe as Figure 5.


- 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.)

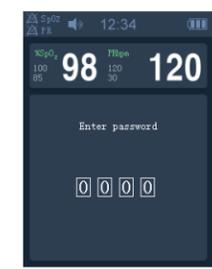
- 5.3 Menu operation**
Under the measurement interface, press the menu/return button to enter the main menu interface as shown in Figure 6, system, display, clock, alarm, record and password, etc. can be set, methods are as follows:



- 5.3.3 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 Pulse sound: set the pulse sound, "on": turn on the pulse sound, "off": turn off the pulse sound.
E Pulse Volume: set the pulse volume, adjustable range: 1 ~ 3.
power/confirm button: the device is in power-off state, short press the button to 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:
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 in Chinese.

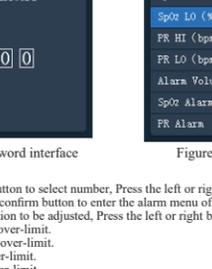
- 5.3.3 Clock setting**
In the main menu interface, move the choice bar to «Clock» item, then press the power/confirm button to enter the clock setting menu of Figure 11:

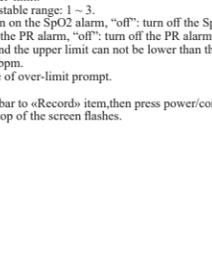

- 5.3.4 Alarm setting**
In the main menu interface, move the choice bar to «Alarm» item, then press power/confirm button to enter the password interface of Figure 12.



- 5.3.4 Alarm setting**
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 SpO2 HI (%): upper limit alarm for SpO2 over-limit.
B SpO2 LO (%): lower limit alarm for SpO2 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 SpO2 Alarm: set the SpO2 alarm, "on": turn on the SpO2 alarm, "off": turn off the SpO2 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. SpO2 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.

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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.
B Under "Manual" mode, select to turn on or off memory by "Record".
C 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.
D 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
 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.
5.5 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 and the nail pad, 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.

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.	Please operate the device according to the manual. 2.Please contact the after-sales.

8 KEY OF SYMBOLS

Symbols	Meaning	Symbols	Meaning
	Refer to instruction manual/booklet for information related to safety	PRbpm	Pulse rate (bpm)
	Type BF applied part	%SpO2	Pulse oxygen saturation (%)

	Manufacturer		Fully charged
	Serial number		Use-by date
	Symbol Indicating Separate Collection for EEE		USB
	IP22 It means this pulse oximeter is protection against ingress of solid foreign objects of 12.5mm and greater, protection against ingress of water dripping when device tilted up to 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		The finger is not inserted
	Power/Confirm button		Probe failure
	Recyclable		Perfusion index
	Material code		Batch No.
	The probe is disconnected.		1. The finger clip falls off (no finger inserted) 2. Probe error 3. Signal inadequacy indicator
	left/alarm confirmation button		Recording
	Authorized representative in the European Community		right/alarm pause button
	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.		DataReview
	Medical device		unique device identification
	Stacking limit by number		For indoor use only
	Class II equipment		Caution

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

9 SPECIFICATION

SpO2 [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%: SpO2: ±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 SpO2 deviation ≤ 1%

Pulse intensity	Continuous bar graph display, the higher display indicates the stronger pulse.
Upper and lower limit of alarm limits	
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 under auto mode, total duration does not exceed 72 hours. Up to 24-hour data under manual mode.
Safety class	ClassII, 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.
Operation time	After the new device is fully charged, continuous SpO2 and pulse rate measurement is performed without the prompt tone and pulse rate tone under normal conditions, and the working time is about 72 hours.(During normal data storage)
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 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.)
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. SpO2 and PR values are different due to low signal conditions, compare them with the known SpO2 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
Pulse Sound	on	
Mode(display mode)	Limit	
Wave	on	
Brightness	4	
Language	EN	
Alarm Volume	3	
SpO2 alarm high limit	100	%
SpO2 alarm low limit	85	%
Pulse rate alarm high limit	120	bpm
Pulse rate alarm low limit	30	bpm
alarm volume	3	
Password	7762	
SpO2 alarm	on	
PR alarm	on	
Mode(record mode)	Manual	

ATTACHED LIST

State	Alarm condition delay	Alarm signal generation delay
Low voltage alarm	1s	20ms
SpO2 alarm	330ms	20ms
Pulse rate alarm	330ms	20ms
Probe error alarm	16ms	20ms

EMC
 This equipment 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 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.

Product configuration

Serial number	Name	Cable length
1	SpO2 probe	1m
2	USB cable	1m

Table 1

Guidance and Declaration - Electromagnetic Emissions		
Emissions 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	IEC 60601 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines
Surge IEC 61000-4-5:	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s)
Voltage dips and Voltage interruptions IEC 61000-4-11	0% UT; 0.5 cycle At0°; 45°; 90°; 135°; 180°; 225°; 270° and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles ;Single phase at 0°; 0% UT ; 250/300 cycle	0% UT; 0.5 cycle At0°; 45°; 90°; 135°; 180°; 225°; 270° and 315° 0% UT; 1 cycle and 70% UT ; 25/30 cycles ;Single phase at 0°; 0% UT ; 250/300 cycle
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V 0.15MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15MHz to 80 MHz 80%AM at 1kHz	3 V 0.15MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15MHz to 80 MHz 80%AM at 1kHz
Radiated RF IEC61000-4-3	10V/m 80 MHz-2.7GHz 80%AM at 1kHz	10V/m 80 MHz-2.7GHz 80%AM at 1kHz

NOTE UT is the a.c.mains voltage prior to application of the test level

Table

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC60601-1-2	Compliance level
					Test level (V/m)	(V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wirelesscommunications 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	704 - 787	LTE Band 13,17	Pulse modulation b) 217 Hz	9	9
	745					
	780					
	810	800 - 960	GSM 800-900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	28	28
	870					
	930					
	1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28	28
	1845					
	1970					
	2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9	9	
5500						
5785						

GIMA WARRANTY TERMS
 The Gima 12-month standard B2B warranty applies.