Instructions to User

Dear users, thank you very much for purchasing the Pulse Oximeter.

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.

The Manual describes, in accordance with the Pulse Oximeter's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. As well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly.Failure to follow the User Manual may cause measuring abnormality, equipment damage and human injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, human injury and equipment 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.

This product is medical device, which can be used repeatedly.

WARNING:

- **Uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients. It is recommended that the sensor should not be applied to the same finger for over 2 hours.**
- **For the special patients, there should be a more prudent inspecting in the placing process. The device can not be clipped on the edema and tender tissue.**
- **The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man should not stare at the light.**
- **Testee can not use enamel or other makeup.**
- **Testee's fingernail can not be too long.**
- **Please refer to the correlative literature about the clinical restrictions and caution.**
- **This device is not intended for treatment.**

Contents

1. Safety

1.1. Instructions for safe operations

✧ Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and transducers. It is recommended that the device should be inspected at least once a week. Please stop using the oximeter if there is obvious damage to the device.

✧ Necessary maintenance must be performed by qualified service engineers ONLY. The users are not permitted to service the device by themselves.

✧ The oximeter cannot be used together with devices not specified in User's Manual.Only the accessory that is appointed or recommendatory by manufacture can be used with this device.

✧ This product is calibrated before leaving factory.

✧ Do not maintain the device while the equipment is in use.

1.2. Warning

✧ Explosive hazard—DO NOT use the oximeter in environment with inflammable gas such as some ignitable anesthetic.

✧ DO NOT use the oximeter while the patient is being scanned by MRI or CT.

✧ DO NOT strand the lanyard in order to avoid device drop and damage.The lanyard is made of non-sensitive material.Please do not use lanyard if the user is allergic to lanyard.Do not enwind neck with lanyard in order to avoid accident.

✧ The disposal of scrap instrument and its accessories and packings(including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

✧ The person who is allergic to rubber can not use this device.

✧ Please check the packing before use to make sure the device and accessories are totally in accordance with the packing list, or else the device may have the possibility of working abnormally.

✧ The product is suitable for children above four years old and adults (Weight should be between 15kg to 110kg).

✧ Please choose the accessories which are appointed or recommended by the manufacturer for avoiding device damage.

✧ Please choose the battery chargers which should be ensured compliance with the requirements of IEC 60601-1, or else it may damage the device.

✧ Please don't use the device in the course of charging.

✧ The device can only be matched with the compatible probe(optional).

✧ Please don't measure this device with functional tester for the device's related information.

- Please don’t change the battery yourself.
- The patient is an intended operator.
- The probe of the device is the applied part.
- Please don’t use multiple wireless devices connected to the product at the same time.

1.3. Hazards

- Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop using it immediately.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately
- DO NOT operate keys on front panel with sharp materials.
- High temperature or high pressure steam disinfection of the oximeter is not permitted. Refer to User Manual in the relative chapter (7.1)for instructions of cleaning and disinfection.
- Do not have the oximeter immerged in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material. Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60℃.
- The fingers which are too thin or too cold may affect the measure accuracy , please clip the thicker finger such as thumb or middle finger deeply enough into the probe.
- The pulse oximeter can be used to adult or infant. Whether the device is used to adult or infant,it depends on the probe selected (optional).
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- Please read the measured value when the waveform on screen is equably and steady-going, This measured value is optimal value. And the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal life for three years since the first electrified use.
- This device has the function of alarming, users can check on this function according to chapter 6.1 as a reference.
- The device has the function of limits alarming, when the measured data is beyond the highest or lowest limit, the device would start alarming automatically on the premise of the alarming function is on.
- The device has the function of alarming, this function can either be paused, or closed (default setting) for good.This function could be turned on through menu operation if you need.please check

the chapter 6.1 as a reference.

🔔 The device may not work for all patients. If you are unable to achieve stable reading, discontinue use.

🔔 Do not contort or drag the connection of the device.

1.4. Indication for Use

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
A. This device may not cause harmful interference;
B. 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 user's authority to operate the equipment.

Some electronic devices are susceptible to electromagnetic interference sent by this equipment if inadequately shielded. Please use this equipment at least 20cm or as far as you can from TV set, radio and other automated office equipment so as to avoid interference.

This device is a radio transmitter and receiver. It is designed and manufactured not to exceed limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission (FCC) of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age or health.

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:
A. Reorient or relocate the receiving antenna.
B. Increase the separation between the equipment and receiver.
C. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
D. Consult the dealer or an experienced radio/ TV technician for help.

⚠A minimum separation distance of at least 0.2m between this equipment and all persons shall be guaranteed to satisfy the RF exposure compliance.

2. Overview

The pulse 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 bio-parameter for the respiration. A number of diseases relating 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. The Pulse Oximeter features in small volume, low power consumption, convenient operation and being portable.It is only necessary for patients to put one of his fingers into a probe for diagnosis, and a display screen will directly show the measured value of pulse oxygen saturation with the high veracity and repetition.

2.1. Classification

Class II b(MDD93/42/EEC IX Rule 10)

2.2. Features

A. Operation of the product is simple and convenient.
B. The product is small in volume, light in weight and convenient in carrying.
C. Low power consumption.

2.3. Major applications and scope of application

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.

⚠The problem of overrating would emerge when the patient is suffering from toxicosis which caused by carbon monoxide, the device is not recommended to be used under this circumstance.

2.4. Environment requirements

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

Operating Environment
a) Temperature:10℃~40℃
b) Relative Humidity :≤75%
c) Atmospheric pressure:700hPa~1060hPa

3. 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.

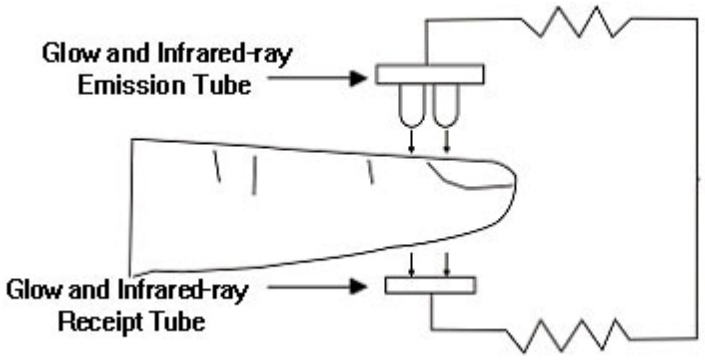

Figure 1

4. Technical specifications

4.1. Main performance

A. SpO_2 value display
B. Pulse rate value display, bar graph display
C. Pulse waveform display
D. Low-voltage indication: low-voltage indicator appears before working abnormally which is due to low-voltage
E. Automatically power off function: when the device is under the state of measuring interface (without external probe), it will automatically power off within 5 seconds if the finger falls out of probe.
F. The display mode can be changed
G. Screen brightness can be changed
H. With pulse rate sound indication
I. With alarm function
J. With SpO_2 and pulse rate value record function, the record data can be uploaded to computer.
K. It can be connected with an external oximeter probe(optional)
L. Data can be observed on computers synchronously by PC software
M. With two kinds of data transmission mode:data line and bluetooth.

4.2. Main Parameters

A. Measurement of SpO_2

Measurement Range:0%~100％

Accuracy:70~100%,±2%;0~69%,unspecified

B. Measurement of pulse rate

Measurement Range:30bpm~250bpm

Accuracy: ±2 bpm or ±2% (select the larger)

C. Resolution

SpO_2 : 1%, Pulse rate: 1bpm.

D. Measurement Performance in Weak Filling Condition:

SpO_2 and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO_2 error is ±4%, pulse rate error is ±2 bpm or ±2% (select the larger).

E. Resistance to surrounding light:

The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkroom is less than ±1%.

F. Power supply requirement: : DC 3.6 V ~ 4.2V.

G. Optical Sensor

Red light (wavelength is 660nm,6.65mW)

Infrared (wavelength is 880nm, 6.75mW)

H. Adjustable alarm range:

SpO_2 : 0%~100%

Pulse Rate: 0bpm~254bpm

I. Bluetooth specifications

Bluetooth protocol：Bluetooth Specification v2.0+EDR、V2.0、V1.2

USB protocol：USB V1.1、V2.0

Operating frequency：2.4GHz ISM band

Modulation：GFSK(Gaussian Frequency Shift Keying)

Transmitting power：≤4dBm, Class 2

Sensitivity：≤-84dBm at 0.1% BER

Transfer rate：Asynchronous: 2.1Mbps(Max) / 160 kbps Synchronous: 1Mbps/1Mbps

Safety features：Authentication and encryption

Support Services：Bluetooth SPP

J. FCC ID:2AB0GCMS50EW

5. Installation

5.1. View of the front panel

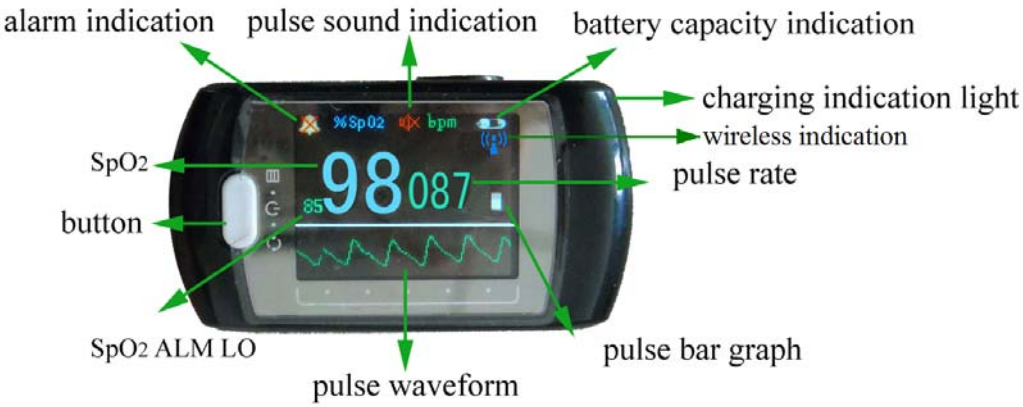

Figure 2. Front View

5.2. Installing the hanging rope

A. Put the thinner side of the rope through the hole.

B. Put the wider side of the rope through the thinner side which has been put through the hole, then tighten it.

5.3. Accessories

A. a hanging rope
B. a user manual
C. a power adapter
D. a data line
E. a disk (PC software)
F. a oximeter probe(optional)

6. Operating Guide

6.1. Application method

6.1.1 Measurement

A Squeeze the clamp, put a finger into the rubber hole, then release it.
B Press the button on the front panel until the device turns on.
C Do not shake the finger and keep the patient in a stable state during the process.
D The data can be read directly from the screen in the measuring interface.

6.1.2 Lay finger

The right method of laying finger is as Figure 3 or Figure 4.

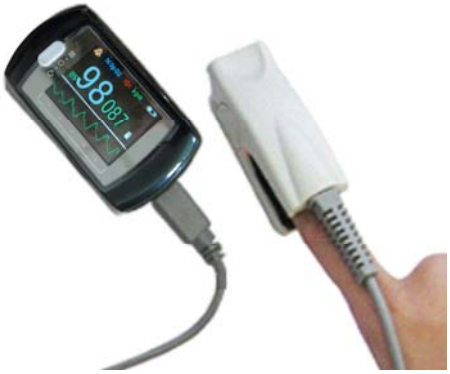

Figure 3

(Actual probe may be different from the probe as Figure 3, please accept the actual probe with the device)

Figure 4

⚠ Fingernails and the luminescent tube should be in the same side.

⚠ If the alarm function is on,the device will provide medium-priority alarm signal when probe or finger is out.Intermittent alarm will occur and the user interface presents "FINGER OUT".
Medium priority indicating that prompt operator response is required.

6.1.3 Change display mode:

In the measuring interface, you can change the display mode by short pressing the button .

6.1.4 Pause alarm:

A Alarm includes the alarm of measure data's going beyond the limits, the alarm of low-power, and the alarm of finger out.

B In the measuring interface, if the alarm function is on, during the period of alarming, alarm can be suspended by short pressing the button, but the function will be renewed in about 60 seconds.

C If you want to turn off the alarm for good, you should enter the menu for operation.

6.1.5 Menu operations:

In the measuring interface,the display direction can be changed by pressing the button with a short push (click). There are four modes of data display that can be viewed.

Press the button with a prolonged push (1 second) to enter the Settings Menu Interface (see Figure 5).Please Note: When the display direction is lengthways, you can not enter the main menu interface.Click the power button to switch to landscape orientation.

The user can setup the following content in the Settings Menu:Backlight Brightness, Alarm setting,ID setting, data storage (Record), turning on/off Wireless.The specific operation methods are as follows:

Please note in the Settings Menu:

CLICK = short push of button and PRESS = prolonged push of power button (1sec)

Figure 5 Main Menu Interface

A Backlight adjustment

In the main menu interface, click the button to select “Brightness”, press the power button and hold to adjust the backlight brightness.

B Alarm setting

In the main menu interface, click the power button to select “Alarm”, press the power button (1sec) to enter the alarm setting interface as shown in Figure 6:

a) Adjusting the high and low limits of alarms

Click button to change the position of menu selection bar,and press button to set menu item.Move the selection bar to “Dir” ,and press button to choose value adjusting direction : up or down.By pressing button operation,the user could adjust the value of SpO_2 high limit (SpO_2 ALM HI), SpO_2 low limit (SpO_2 ALM LO), Pulse rate high limit (PR ALM HI), Pulse rate low limit (PR ALM LO).The alarm low limit can't be beyond the alarm high limit.The SpO_2 alarm range is 0%~100%,the pulse rate alarm range is 0bpm~254bpm.

⚠If the alarm function is on,the device will provide medium-priority alarm signal when the measure value is beyond the limit. Intermittent alarm will occur and the measure value shows in yellow.

Medium priority indicating that prompt operator response is required.

b) The alarm state setting

Click the button to select “Alarm”, then press the button to choose alarm on/off. Choose “ on” to turn on the alarms and “ off” to turn off the alarms.

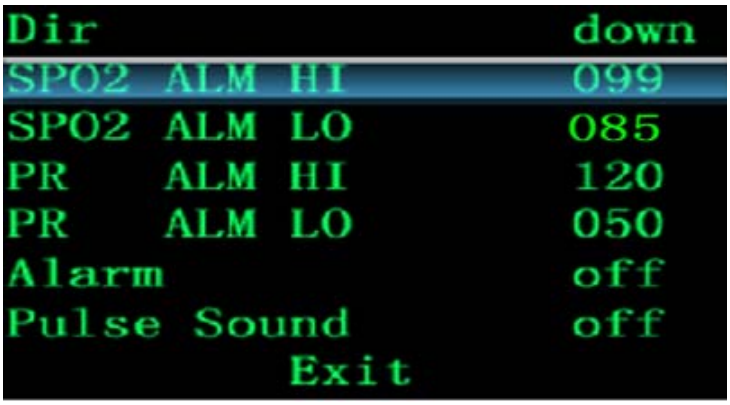

Figure 6 Alarm Setting Menu

c) Pulse sound indication setting

Click the button to select “Pulse Sound”, then press button to choose to have the Pulse Sound (heart beat) “on” or “off”.

d) Exit the Alarm settings

Click button to select “EXIT”, then press button to exit the Alarm Settings Menu.

C ID setting

The user could set device ID by software "SpO_2 Assistant".The user could set character string which could only be made of number or letter and not be beyond 7 bits

Figure 7 SpO_2 Assistant program

⚠If the users choose to turn on the synchronizing display function on computer, it would probably take several seconds for the data to appear on the computer screen.

D Data storage setting

This device can record 24 hours data including pulse rate and SpO_2 value accurately and upload the data to the computer for display and analysis.

a) In the main menu interface,click button to move the selection bar to "Record" item,then press button to enter the record beginning time setting dialog box as Figure 8.

b) Click button to move the underline to the number that you want to set,then press button to set time. After setting time,move the underline to "Y",then press button to exit the “time setting menu”, and recording will begin.If move the underline to "N",then press button to cancel record,and the data stored in memory will not be deleted.

c) If the data storage function is turned on, when return to the measuring interface, a red "REC"sign and a flashing red dot would appear on screen, which means the device is in a state of record.

d) In the state of record,whatever interface the device is in (measuring interface, menu interface),

the sign "Recording" would appear on the screen in 30 seconds, then the screen will be automatically shut down. If click the button at this moment, the sign "Recording" would appear on the screen, and then the screen will be automatically shut down again; if press the button,the device would return to the former interface.

e) If turning on the data storage function, the former saved data will be automatically deleted.

f) When recording, the pulse sound indication would be turned off for saving power, after the screen is shut down automatically.

g) When the storage space is full, it displays “Memory is full” on the screen, and then shut down in a few seconds. But it will still display “Memory is full” by the next time you turn on the device on the purpose of warning the user, if press the button again, it will enter the measuring interface.

Figure 8

E Set Wireless state

Move the menu selection bar to"Wireless" item,then press button to turn on/off Wireless.If there is no data transmission,the Wireless will be closed 5 minutes later..

⚠ When the data is being transmitted between device and computer,the user can't change the state of "Wireless".

F Exit the main menu

Click button to select “EXIT”, then Press button to exit the Main Menu.

6.1.6 PC software operation

By PC software,the user could upload Real-time measure data and storage data.Here the user should connect the device to the computer by the USB data line or bluetooth adapter.It is recommended to use the ORICO 4.0 bluetooth adapter. Please refer to "SpO_2 Assistant user manual" for detailed operation explanation.

⚠ The user can't use the USB data line or bluetooth adapter at the same time.Please don't pull out the USB data line or bluetooth adapter when the data is being transmitted between device and computer.

6.1.7 Charge

There are two kinds of charge method:

A Connect the device to computer with data line, then the device should be in charge state.

B Connect the device to power supply with power adapter, then the device should be in charge state.

C When the device is in the state of battery charging, the indication light is on, when the battery capacity is full, the indication light would be off accordingly.

⚠If the alarm function is on,the device will provide high-priority alarm signal when the battery is

in low power status .Intermittent alarm will occur and the battery icon turns red in the state of flashing.
High priority indicating that immediate operator response is required.

6.2. Attention for operation

A.Please check the device before using, and confirm that it can work normally.
B.The finger should be in a proper position (see the attached illustration of Figure 3 and Figure 4 for reference), or else it may result in inaccurate measure.
C. The ray between luminescent tube and photoelectric receiving tube must get across subject's arteriole.
D. The oximeter should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
E. Ensure nothing, such as a plaster, can impede the light passage., or else it may result in inaccurate measure of SpO_2 , and pulse rate .
F. Excessive ambient light may affect measurement accuracy. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight and etc.
G.Intense activity of the subject or extreme electrosurgical interference may also affect the accuracy.
H.Testee can not use enamel or other makeup.
I. Please clean and disinfect the device after operating according to the User Manual (7.1).

6.3. Clinical restrictions

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. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO_2 determination by this device may be inaccurate.
C. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor resulted in serious error of SpO_2 measure.
D. The SpO_2 value serves as a reference value for judgment of anemic anoxia and toxic anoxia, for some patients with serious anemia may also report good SpO_2 measurement.

7. Maintain,transportation and storage

7.1. Cleaning and disinfecting

Using medical alcohol to wipe the device for disinfecting, nature dry or clean it with clean soft cloth.

7.2. Maintain

A. Please clean and disinfect the device before using according to the User Manual(7.1).
B. Please recharge the battery when the screen shows .
C. Recharge the battery soon after the over-discharge. The device should be recharged every six

months when it is no regular used. It can extend the battery life following this guidance.
D.Users are advised to calibrate the device termly (or according to the calibrating program of hospital). It also can be performed at the state-appointed agent or just contact us for calibration.

7.3. Transportation and storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. The device 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°C~60°C; Relative Humidity: ≤95%

8. Troubleshooting

Trouble	Possible Reason	Solution
The SpO_2 and Pulse Rate can not be displayed normally	1. The finger is not properly positioned. 2. The patient's SpO_2 is too low to be detected.	1. Lay the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO_2 and Pulse Rate are not displayed stably	1. The finger is not laid inside deep enough. 2. The finger is shaking or the patient is moving.	1. Lay the finger properly and try again. 2. Let the patient keep calm
The device can not be turned on	1. The batteries are drained or almost drained. 2. The device's malfunction	1.Please recharge the battery 2. Please contact the local service center.
The display is off suddenly	1. This device is set to be automatically power off within 5 seconds when it cannot detect any signal (without external probe) 2. The battery is drained away or almost drained away .	1.Normal 2.Please recharge the battery
The battery can not be full charged even after 10 hours charging time.	The battery is broken	Please contact the local service center.

9. Key of Symbols

Signal	Description
	Refer to instruction manual/booklet

%SpO_2	The pulse oxygen saturation(%)
bpm	Pulse rate (bpm)
	Full-voltage
	Low-voltage
	Close the alarm sound indication
	Pause the alarm sound indication
	Open the alarm sound indication
	Close the pulse sound indication
	Open the Wireless indication
	Open the pulse sound indication
	menu button/power button/function button
	USB
	Type BF
SN	Serial number
	1. The finger clip falls off (no finger inserted)] 2. Probe error 3. Signal inadequacy indicator
IP22	International Protection
	WEEE (2002/96/EC)
	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
	Atmosperic pressure limitation
	Temperature limitation

	Humidity limitation

10. Function Specification

Information	Display Mode
The Pulse Oxygen Saturation(%SpO_2)	2-digit digital OLED display
Pulse Rate(bpm)	3-digit digital OLED display
Pulse Intensity (bar-graph)	bar-graph OLED display
SpO_2 Parameter Specification	
Measuring range	0%~100% (the resolution is 1%).
Accuracy	70%~100%:±2% ,Below 70% unspecified.
Average value	Calculate the Average value in every 4 measure value. The deviation between average value and true value does not exceed 1%.
Pulse Parameter Specification	
Measuring range	30bpm~250bpm, (the resolution is 1bpm)
Accuracy	±2bpm or ±2% (select the larger)
Average pulse rate	Moving calculate the Average pulse rate every 4 cardio-beat's cycle. The deviation between average value and true value does not exceed 1%
Safety Type	Interior Battery,BFType
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
Voltage 3.7 rechargeable lithium battery × 1 (The red wire on the battery denotes anode,the black wire on the battery denotes cathode.)	
Battery working life	
Charge and discharge no less than 500 times.	

Power Adapter	
Input Voltage	100 to 240 VAC, 50/60 Hz
Output voltage	5 V DC
Output current	1000mA
Output power	5 W
Oximeter Probe	
Wavelength:660nm 880nm	
Dimensions and Weight	
Dimensions	57(L) × 32(W) × 32 (H) mm
Weight	About 50g (with the lithium battery*1)

Appendix 1

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

Appendix 2

Guidance and manufacturer's declaration – electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The *CMS50EW* is intended for use in the electromagnetic environment specified below. The customer of the user of the *CMS50EW* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *CMS50EW* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emission CISPR 11	Class B	The *CMS50EW* is suitable for use in all establishments, including domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity			
The *CMS50EW* is intended for use in the electromagnetic environment specified below. The customer or the user of *CMS50EW* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE			

Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The *CMS50EW* is intended for use in the electromagnetic environment specified below. The customer or the user of *CMS50EW* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the *CMS50EW*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz

			Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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 *CMS50EW* is used exceeds the applicable RF compliance level above, the *CMS50EW* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *CMS50EW*.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the CMS50EW

The *CMS50EW* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *CMS50EW* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *CMS50EW* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.