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1 Introduction

1.1 Brief Introduction

Thank you for purchasing the HCSMD400 pulse oximeter. The main functions of the device include SpO_2 PR and PI (Pulse Amplitude Index) measurements, visual and audible alarm, data storage, review and transmission, etc. Please read this manual carefully before using the device.

Notes:

1. The illustrations applied in the manual may differ slightly from the actual device.
2. The specifications are subject to change without prior notice.
3. The device is designed of handheld structure and please be sure not to turn upside down when using it.

1.2 Intended Use

The HCSMD400 pulse oximeter is intended for continuous monitoring, spot-checking of oxygen saturation (SpO_2) and pulse rate (PR) of single adult, adolescent, child and infant patients in hospitals and clinics.

1.3 Measurement Principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin(RHb) and Oxyhemoglobin (HbO_2) in red and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.

Diagram of Operation Principle

1. Red and Infrared-ray Emission Tube
2. Red and Infrared-ray Receipt Tube

1.4 Safety Information

Conception of Warning, Caution and Note

The Warning, Caution and Note at this document are special information in favor of user's operation.

- Warning - Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.
- Caution - Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.
- Note - Provides application tips or other useful information to ensure that you get the most from your product.

⚠ **Warnings!**

● Before use, carefully read the manual. This device is intended for use by persons trained in professional health care. Our company will assume no warranty for using this equipment improperly.

● The pulse oximeter is to be operated by qualified personnel only.

● Operation of the pulse oximeter may be affected by the use of an electrosurgical unit (ESU).

● Sensor malfunction may cause inaccurate data possibly resulting in patient injury or death, so pay close attention to the sensor and inspect it often.

● Do not use the pulse oximeter in an MRI or CT environment.

● Although the pulse oximeter has alarms, it is not suggested for long time continuous monitoring.

● Do not use the pulse oximeter in an explosive atmosphere.

● The pulse oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

● Check the pulse oximeter sensor application site half an hour to determine the positioning of the sensor and circulation and skin sensitivity of the patient.

● When link this equipment to other peripherals, make sure you are sophisticated operator to handle this device. Any peripherals should be in the light of protocol of IEC 60601-1. Any input/output device should be following the protocol of IEC 60601-1.

● Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.

● Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.

● This equipment complies with IEC 60601-1-2:2007 for electromagnetic compatibility for medical electrical equipment and/or systems. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device.

● Portable and mobile RF communications equipment can affect medical electrical equipment.

● You should operate the equipment according to the EMC information provided in the accompanying documents.

● This equipment should not be used adjacent to or stacked with other equipment.

● This equipment is not intended for use during patient transport outside the healthcare facility

● When connecting this device to other peripherals, make sure that you are qualified to operate this device. Any peripheral must be certified according to the protocol of IEC 60601-1. Any input/output device should follow the protocol of IEC 60601-1.

Rx only: "Caution: Federal law restricts this device to sale by or on the order of a physician."

Cautions:

● The handheld pulse oximeter must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.

● Worn-out data cables may also cause inaccurate data, so if the data is used as a reference

to treat a patient, pay special attention to data cable and check it more frequently.
- Do not tangle the SpO_2 cable with the wires of ES (Electrosurgery) equipment.
- Single use accessories should never be reused.
- Only use SpO_2 sensors specified by the manufacturer. Other SpO_2 sensors may cause improper performance.
- Unplug the sensor from the monitor before cleaning or disinfecting to prevent sensor or monitor from being damaged, and to prevent user under safety situation.
- Alarm must be set up according to different situation of individual patient. Make sure that audio sound can be activated when alarm occurs.
- To avoid an electrical hazard, never immerse the unit in any fluid or attempt to clean it with liquid cleaning agents. Always take out the batteries before cleaning.
- If oximeter becomes accidentally wet during use, stop operation of the oximeter until all affected components have been cleaned and permitted to dry completely. Contact your local representative if additional information is required.
- Remove the batteries from this unit or unplug the SpO_2 probe when you are not going to use it for a long period of time (approximately one month).

Notes:

- Optical cross talk can occur when two or more sensors are located in adjoining areas. It can be eliminated by covering each site with opaque material. Optical cross talk may adversely affect the accuracy of the SpO_2 readings.
- Obstructions or dirt on the sensor's red light or detector may cause a sensor failure. Make sure there are no obstructions and the sensor is clean.
- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause a failure to determine accurate pulse rate and SpO_2 readings.
- Hazards arising from software errors have been minimized. Hazard analysis conforms to meet ISO14971: 2000 and EN60601-1-4: 1996. Significant levels of dysfunctional hemoglobin, such as carboxyhemoglogin or methhemoglobin, will spawn an affection of the accuracy of the SpO_2 measurement.
- The pulse oximeter can monitor only one patient synchronously.
- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.
- As to the other concerns for attention, please carefully look through the specific chapter in this instruction.
- All the waveforms have been uniformed.
- The material of the device has no nature latex.

Inaccurate measurements may be caused by:

- Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin);
- Intravascular dyes such as indocyanine green or methylene blue;
- High ambient light. Shield the sensor area if necessary;
- Excessive patient movement;
- High-frequency electrosurgical interference and defibrillators;

- Venous pulsations;
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- The patient is in cardiac arrest or is in shock;
- Fingernail polish or false fingernails;
- Weak pulse quality (low perfusion);
- Low hemoglobin;

1.5 Electromagnetism Interference

This oximeter is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the electronic medical device - IEC 60601-1-2. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (e.g. cellular phones, mobile two-way radios, electrical appliances), it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

This apparatus complies with the IEC 60601-1-2 international standard. The requirements of this international standard are: CISPR11, GROP1, and CLASS B.

1.6 Explanation of Symbols

Symbol	Explanation	Symbol	Explanation
	Attention		Type BF applied part
IPX1	Protected against dripping water		Storage temperature and relative humidity
	Prevent from rain	SN	Serial number
SpO_2	Hemoglobin Oxygen Saturation	PR	Pulse Rate
	The adapter is connected		Audible alarm inhibition
	USB cable is connected		Battery power indication
	Manufacturer's information		Power on/off

	Class II equipment		Date of Manufacture
	Follow instructions for use	bpm	Pulse rate
	The waste electrical and electronic equipment		Battery cover unlock / lock
	Adpater polarity symbol		Do not discard the device and other components

1.7 Product Features

- High resolution 2.8" TFT screen display SpO_2, PR, and PI (Pulse Amplitude Index) waveform and pulse bar.
- Adjustable audible and visual alarms.
- 127 ID setup; 72-hour data storage and review.
- Medview software for data analysis.
- 3 AA alkaline batteries or power adapter.
- Muti-language (Menu): English, French, German, Spanish, Italian, Japanese, Russian and Chinese

1.8 Contraindication

None

2 General Description

The HCSMD400 pulse oximeter adopts 2.8 inch TFT screen, which can display the SpO_2, pulse rate, Pulse Amplitude Index and other indication parameters, such as time, ID number, pulse amplitude bar and battery power status, alarm limits and the connections of probes, etc.

2.1 Appearance

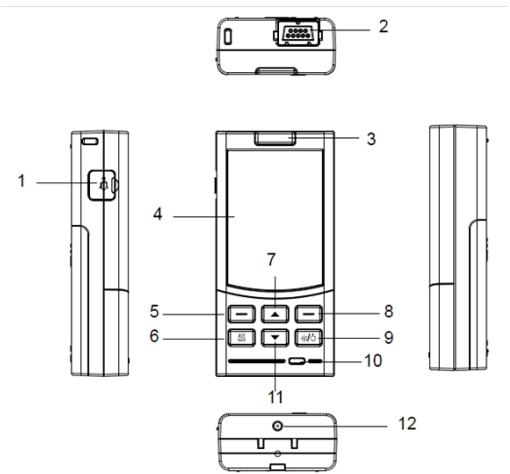


Fig.2-1

Description of these figures:

(1) USB socket: used to connect the USB cable for data transmission.

(2) SpO_2 socket: For connecting the SpO_2 probe with the pulse oximeter.

(3) Alarm lamp: When SpO_2 or/and PR alarm occurs, It flashes.

(4) Display screen

(5) Menu/OK button: For entering main menu, or confirming the selection/setting.

(6) Alarm silence button: Press this button to silence the audible alarm.

(7) Navigation button(Up): Press this button to increase the value by one increment. Or press it and hold it down to continuously increase the value. Or select the item you want.

(8) Back/Shift button: On the measuring screen, press it to change the display mode; On the sub-menu screen, it serves as Back button.

(9) Power switch: Press and hold it for 3 seconds to power the device on, and for about 4 seconds to turn the device off.
(10) Charge indicating lamp: If the battery is full charged, the green light will appear. If the battery is less than 20% charged, a red light will flash. Charging is needed.
(11) Navigation button(Down): Press this button to decrease the value by one decrement. Or press it and hold it down to continually decrease the value. Or select the item you want.
(12) Adapter socket: For connecting the power adapter.

2.2 Power Supply

2.2.1 Powered by alkaline batteries

Batteries Installation

1) Open the battery cover: Slide the fixing screw slightly in the rear panel to the position which is marked with "" and then push the cover as indicated by arrowhead, as shown in

2) Install three batteries lightly as indicated by the polarity signs in battery compartment.

3) Close battery cover

Close the battery cover and slide the screw to the position which is marked with . And the battery cover is locked.

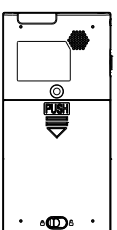


Fig.2-2

Warning!
Make sure the polarities of the batteries are correct.

Battery life and replacement

There are five shapes of the indicator: the centre with 4 bars (full), 3 bars, 2 bars, 1 bar, empty and the frame in red. That the frame of indicator become red means few of battery capacity remains. You should replace the batteries with new ones timely. Or else, the unit shuts down.

Cautions!

- Be sure to install batteries with correct polarities.
- Only the approved batteries are recommended to be used.
- Do not use batteries not specified for this unit.
- Do not dispose of batteries in fire.

- If battery fluid gets on your skin or clothing, rinse with plenty of clean water immediately.
- Remove the batteries from this unit when you are not going to use it for a long period of time (approximately one month).
- Do not use batteries of different types together.
- Do not use new and used batteries together.
- Dispose of batteries in accordance with the local ordinances and regulations.

2.2.2 AC Power Supply

The device can be supplied by AC power through connecting the device to AC adapter.

Note: Use the AC power supply, make sure put the device in the safety and proper place and convenient to power off.

Warnings!

- Be sure to use the adapter that specified for this device.
- Plug and unplug the adapter cautiously to avoid injuries caused to your body.
- If the device suddenly power off, please take out your finger at once, and then connect power or install the batteries.
- The device can measure normally during the process of charging, but we won't recommend doing so.

3 Take a Measurement

3.1 Probe Connection

Insert the SpO_2 probe to the socket, as shown in Fig.3-1. If the SpO_2 probe is disconnected from the unit, “Probe Off” will appear in the status column.

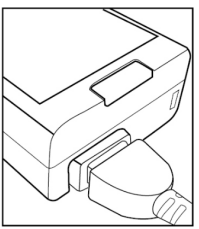


Fig.3-1

Notes:

- Please check the SpO_2 probe compatibility before use, the probe should meet the ISO80601-2-61.
- Select the suitable probe in terms of type and dimension. Attach the sensor to the appropriate site of the user’s finger, refer to Fig.3-2.

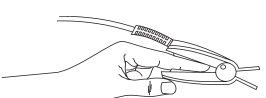


Fig.3-2 placement of the sensor

If the finger is not in the probe, “Finger off” will be shown.

3.2 Basic Operation

Press and hold the power switch for 3 seconds to power the device on. After several seconds, the measuring screen will be displayed as follows.

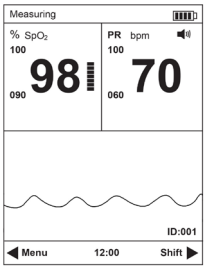


Fig.3-3 Wave display

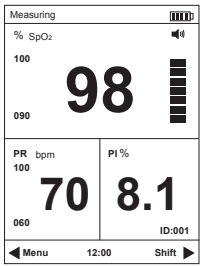


Fig.3-4 Digital display

Description of measurement screens:

1. **Measuring:** The pulse oximeter is in the status of measuring.
   - It shows “Finger off” when there is no finger inserted or no signal is detected.
   - It shows “Probe off” when the probe is not connected to the pulse oximeter.
2. **%SpO_2:** SpO_2 display area
   - It shows the oxygen saturation level of functional hemoglobin during normal measurement.
   - The color of the SpO_2 value will become red when the SpO_2 is beyond the alarm limits.
   - It shows two dashes throughout probe off and finger out conditions.
3. **100:** SpO_2 high alarm limit; 90: SpO_2 low alarm limit.
4. : Pulse bar
5. **100:** PR high alarm limit; 060: PR low alarm limit.
6. **PRbpm:** PR area of display
   - It shows the pulse rate in beats per minute during normal measurement.
   - The color of the PR value will become red when the PR is beyond the alarm limits.
   - It shows three dashes throughout probe off and finger out conditions.
7. **ID:** 001, the ID number of the current patient is 001.
8. **12:00:** The current time.
9. **PI%:** Pulse Amplitude Index indicator display area.

Note: When no signal is detected or no operation, one minute later the pulse oximeter will automatically turn off the screen display and enter into standby status.

3.3 Factors that may affect the measurement

Warnings!

- **The measurement would not be performed if the following instances come across in operation:**

1) Shock
2) Low temperature of hand
3) Have taken vascular activity medicine
4) Anemia

5) carboxyhemoglobin
6) methemoglobin
7) methylene blue
8) Indigo carmine

- **Do not use the SpO_2 probe with exposed optical components.**
- **Tissue damage can be caused by incorrect application or use of probe, for example by wrapping the probe too tightly. Inspect the probe site to ensure skin integrity and correct positioning and adhesion of the probe. More frequently inspection should be taken depending on different patients if necessary.**
- **Inaccurate measurements may be caused by:**

1) Incorrect application or use of probe
2) Significant levels of dysfunctional hemoglobin (such as carboxyhemoglobin or methemoglobin)
3) Intravascular dyes such as indocyanine green or methylene blue
4) Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight
5) High-frequency electro surgical interference and defibrillators
6) Venous pulsations
7) Placement of a probe on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.
8) The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
9) There is arterial occlusion proximal to the probe
10) The patient is in cardiac arrest or is in shock

- **Loss of pulse signal can occur in any of the following situations:**

1) The probe is too tight
2) There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight
3) A blood pressure cuff is inflated on the same extremity as the one to which an SpO_2 probe is attached

Note: SpO_2 probe should be kept from the light source, e.g. radial lamp or infrared lamp.

3.4 Alarm

ALARM PRIORITY:

There are two-level priorities for selection.
High priority: indicates the patient is in the very dangerous situation.
Low priority: indicates the technical alarm caused by the device itself.
Alarms of the oximeter include technical and physiological alarms. All the two priorities are divided by built-in module and cannot be changed by user.

Assignment of priority:

	High	Low
Paramter	SpO_2	/
Value	Red	/
Alarm lamp	Flashing	/
Lamp Frequency	1.5Hz	/
Audiblesound	Di- Di – Di ----- Di - Di	Di
Alarm cycle	3 s	20 s
Alarm info	SpO_2 too high/low, Battery power low	Probe off/Finger out

Notes:

1. The alarm will appear if the measurement value out of range.
2. The alarm sound will go on until alarm disappears or is turned off.
3. After silencing the alarm, the corresponding indicator will indicate this.
4. The power low alarm: the corresponding indication lamp will be flashing with a red frame.

AUDIBLE ALARM INHIBITION:

Short press the button to silence the audible alarm for 60s/120s, the audible alarm indicator will be displayed as together with the countdown, short press it again, you can cancel alarm inhibition;

⚠ Warnings!

- When an alarm occurs, check patients' conditions immediately.
- Check the parameter which is alarming.
- Check patient's condition.
- Search for the source of the alarm.
- Make the alarm mute if necessary.
- Check the alarm when no warning.

After measurement

After measurement, please take off your finger and press and hold the power button to turn off the device.

Remove the batteries from this unit or unplug the SpO_2 probe when you are not going to use it for a long period of time (approximately one month).

Alarm delay

The alarm condition delay and alarm signal generation delay: less than 1s.

4 Settings

Always set the date and time before using the unit for the first time. Set different ID numbers for different users.

Check the date and time are correct before using the unit, and reset them if necessary. The date and time are important indicators when a measurement is taken.

4.1 Date & Time Settings

Set the correct time according to the following steps:

1) Press the power switch for 3 seconds to power on the oximeter and then press the menu button to enter the main menu, refer to the Fig.4-1.

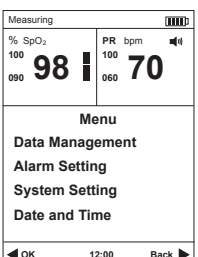


Fig.4-1

2) Press the Navigation button to select “Date and Time” item, and then press the OK button to enter the time setup screen, refer to Fig.4-2.

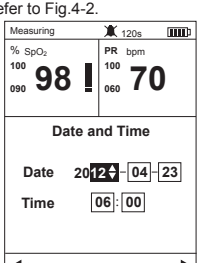


Fig.4-2

Press the Navigation button to select it and then press the OK button to confirm it. At last, press the Navigation button adjust the value, and then press the OK button to confirm the

value.
The date is displayed as the order of Year-Month-Day and Time of Hour-Minute

4.2 User ID Setting

Every time, when you insert your finger, the ID icon will flash about 5 seconds. If you press the OK button in 5 seconds, the ID number will not change, or else the ID number will ncrease after 5 seconds.

4.3 Alarm Setting

Note: Every time enter into the Alarm Setting in the main menu, you should input the password.
From the main menu, select and enter the “Alarm setting” screen, refer to Fig.4-3.

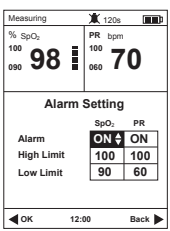


Fig.4-3

You can select the Alarm on or off.
High limit SpO_2 range is71~100
Low Limit SpO_2 range is 70~99
High Limit PR range is 31~250
Low Limit PR range is 30~249

4.4 Data Management

From the main menu screen, select and enter the “Data Manage” screen, refer to Fig.4-4.

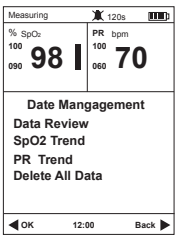


Fig.4-4

Press the Navigation button to select the sub-item to set, and then press the OK button to confirm or Back button to return to the previous screen.

4.4.1 Data Review

Pick and enter the “Data review” interface as shown in Fig.4-5. By pressing the Navigation button to review the records page by page.

The pulse oximeter can record the alarming parameter marked with red color. Press the Back button, the pulse Oximeter returns to the previous interface.

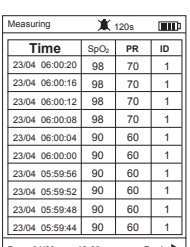


Fig.4-5

4.4.2 SpO_2 Trend

Pick and enter the "SpO_2 Trend" interface as shown in Fig.4-6. By pressing the Navigation button to review the records page by page. Press the Back button, the pulse Oximeter returns to the previous interface.

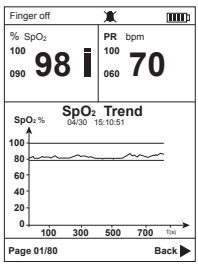


Fig.4-6

On the above of the trend, the date and time of the first item are displayed, with month/day; hour: minute: second.

4.4.3 PR Trend

Pick and enter the "PR Trend" interface as shown in Fig.4-7. By pressing the Navigation button to review the records page by page. Press the Back button, the pulse Oximeter returns to the previous interface.

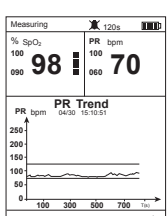


Fig.4-7

4.4.4 Delete all data

Pick and enter the "Delete all data" interface as shown in Fig.4-8. You can select "Yes" or "No" by pressing the Navigation button, and by pressing the OK button to confirm your selection.

Note: Please take caution to the deletion of data; you will never get the data back once deleted.

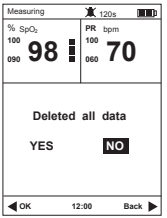


Fig.4-8

4.5 System Setting

Pick and enter the [System Setting] interface from the main menu. And then press the Navigation buttons to select different item to set.

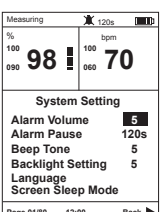


Fig. 4-9

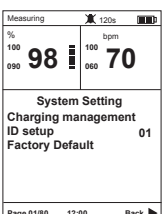


Fig. 4-10

Alarm Volume: you can adjust the value of alarm volume, there are 7 levels, and the default level is 3.

Alarm Pause: there are two modes,60s and 120s, and the default mode is 120s. The device audibly alarm upon new alarm conditions.

Beep Tone: the level is from 0 to 7, and the default level is 3.

Backlight Setting: the level of brightness is from 1 to 7, and the default level is 3.

Language: English, French, German, Spanish, Italian, Japanese, Russian and Chinese.

Screen Sleep Mode: 1minute, 10 minutes, 30 minutes, screen always on, and the default is 1minutes

Charging management: Charging Activated, Charging stop.

ID setup: ① press OK button, ② press Navigation button to change the number, ③ press OK button to confirm.

Factory Default: recover to factory reset.

5 Data Transmission

Use USB cable to transmit the measurements to PC for further review and analyze.

Before data transmission, make sure to turn the device on and connect it with a computer by the attached USB cable. The operations refer to the User Manual of the data transmission Software.

6 Maintain and Repair

⚠ **Warnings!**

The advanced circuit inside the oximeter does not require periodic calibration and maintenance, except replacing the batteries.

Don't open the cover of oximeter or repair electronic circuits. Its open will cause the damage of the device and the annulment of the guarantee.

6.1 Maintenance

Replace the batteries in a timely manner when low voltage indication appears.
Clean surface of the oximeter before it is used in diagnosis for patients.
Remove the batteries if the oximeter is not operated for a long time.
It is best to store the product in -20℃~+70℃ and ≤93% humidity.
Keep in a dry place. Extreme moisture may affect oximeter lifetime and may cause damage.
Dispose of batteries properly; follow any applicable local battery disposal laws.

6.2 Cleaning and Disinfecting

Cleaning

Please use medical alcohol to clean the silicone touching the finger inside of SpO_2 probe with a soft cloth dampened with 70% isopropyl alcohol. Also clean the being tested finger using alcohol before and after each test.

To clean your equipment, follow these rules:

1. Shut down the pulse oximeter and take the batteries out of the battery wharf.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated, cool place.

Do not pour or spray liquids onto the oximeter, and do not allow any liquid to enter any openings in the device. Allow the oximeter to dry thoroughly before reuse.

Disinfecting

The applied parts touching the patients' body are required to be disinfected once after each use. The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

Disinfection may cause damage to the equipment and is therefore not recommended for this pulse oximeter unless otherwise indicated in your hospital's servicing schedule. Clean the pulse oximeter before disinfecting it.

CAUTION: Never use EtO or formaldehyde for disinfection.

6.3 Calibrating

A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. Clinical testing is used to establish the SpO_2 accuracy. The measured arterial hemoglobin saturation value (SpO_2) of the sensors is compared to arterial hemoglobin oxygen (SaO_2) value, determined from blood samples with a laboratory CO-oximeter. The accuracy of the sensors in comparison to the CO-oximeter samples measured over the SpO_2 range of 70%~99%. Accuracy data is calculated using the root-mean-squared (Arms value) for all subjects, per ISO 9919:2005, Medical Electrical Equipment–Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

6.4 Trouble Shooting

a) The oximeter can't be powered on
Please check the batteries. If you use the external power supply, please check if the power supply is connected with oximeter properly.
b) "Probe off" alarm
Please check if the probe is connected with the oximeter correctly. If the sensor is with extension cable please check if the extension cable is connected with the sensor correctly.
c) "No finger" alarm
Please check whether the sensor is correctly connected with patient's finger.

6.5 Warranty and Repair

6.5.1 Maintenance Method

a) Maintenance responding time: 9:00am~17:30pm, Monday to Friday
b) Service support: our company offers the support by hot line, e-mail or spares parts.
Spare parts: our company changes parts if it is necessary free of charge in the warranty period.
Because parts are the sources of maintenance, user should send them back to our company if not specified.
c) Update the system software free of charge.

6.5.2 Exempt and Limitation

a) Our company isn't responsible for such damage caused by force majeure. For example: fire, thunder flash, flood, cyclone, hail, earthquake, house collapse, commotion, plane failing and traffic accident, deliberate damage, lack of fuel or water, labor and capital bother, strike and stop-working etc.

b) Non-service items
● The corresponding charge and insurance charge of disassembling, refurbishing, repackaging and moving the oximeter or the part of it.
● The damage caused by the third company not commended by our company to adjust, install replace the parts of the oximeters.
● The damage and failure caused by the users incorrect operations not complying with the operator's manual.

c) Our company will not provide the free maintenance in the warranty if the oximeter is

installed or connected with the external devices which are not permitted by Our company, e.g. printer, computer, cable and lead to oximeter failure. Our company will charge for the maintenance.

d) Responsibility limitation

During the period of warranty, if user changes the parts manufactured by the third party without our company permission, our company is entitled to stop contract.

6.5.3 Non-guarantee principle

- There is no-dispelled smut and not-original mark in the crust.
- There is physical damage on oximeter and its accessory.
- There are liquid leftover and eyewinker on oximeter and lead to short circuit and plugboard failure.
- All the probe and accessories belong to consumption and beyond free change range.
- Such damage of probe caused by mechanical force doesn't belong to free change range.
- During measurement of SpO_2, principle leads to measure value difficult or inaccurate measurement.
- Maintenance seal of oximeter are not opened.
- Not-original package lead to oximeter during transportation
- Not-professional person operation lead to oximeter failure. Not our company professionals or authorized personnel disassemble oximeter and lead to oximeter failure.
- Not carefully read manual and so wrong operation lead to oximeter damage and failure.

6.5.4 User's Special Request for Guarantee Time

Our guarantee constitution for oximeter complies with electronic product after-sale service standard regulated by national laws. We regulate the guarantee time of hoistboard is one year and all the accessories are three months. If users request the guarantee time beyond our regulated guarantee time, we should take it into consideration. Because electronic product has such character of quick changing, for such user asking more than three years guarantee time, our company will not buy oximeter parts during maintenance. Our company will upgrade oximeter or change new maintenance methods, for this, we charge the lowest price for new oximeter with user permission.

6.5.5 Repackage

Take out all the accessories and put them into plastic cover. Try to use original package and packing material. The user will be responsible for such damage caused by bad package during transportation.

Please offer guarantee list and copy of invoice to standby with the period of guarantee.

Please describe failure phenomenon in detail and altogether offer the oximeter.

APPENDIX A Specifications

Notes:

- Specifications may be changed without prior notice.
- The circuit diagrams, the list of components, the illustration of diagrams, and the detailed rules of calibration, are provided exclusively to professional personnel authorized by our company.
- The equipment has been calibrated , users do not to calibrate. In order to ensure the accuracy of the probe, please change the probe once a year. Make sure that the type of probe need to be specified.

Specifications:

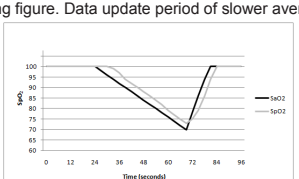
Display:

Data: SpO_2%, PR, PI, pulse bar

Others: connection status of probe and other alarm information.

Equipment data update period

As shown in the following figure. Data update period of slower average is 8s.



Alarm:

Alarm: SpO_2 and pulse rate value, probe off, battery exhausted

Alarm mode: audible alarm, visual alarm and information

Alarm limits range: SpO_2 70%~100%, PR 30bpm-250bpm

Default limits: SpO_2 High 100%, low 90%; PR High 100 bpm, low 60 bpm

SpO_2

Measurement range: 0%~100%

Resolution: 1%

Accuracy: 70%~100%: ±2%；<70% unspecified

Pulse Rate

Measurement range: 30bpm~250bpm

Resolution: 1 bpm

Accuracy: ±2 bpm or 2%(The larger)

Pulse Amplitude Index

Measurement range: 0.1%~20%

Probe

Emitter: OL660905HM2-2(H2)-C
Receiver: OP30TMF-3

Probe LED Specifications:

	Wavelength	Radiant Power
RED	660±3nm	3.2mW
IR	905±10nm	2.4mW

Environment Requirements

Operation temperature: 0℃~40℃
Operation humidity: ≤80%,no condensation
Storage / transport temperature: -20℃~+70℃
Storage / transport humidity: ≤93%, no condensation
Power supply: Three AA alkaline batteries, rechargeable batteries or adapter
Working time: alkaline batteries: more than 10 hours; NI-MH battery: 6 hours
Atmosphere pressure: 86kPa~106kPa

AC adapter(optional)

Input Voltage: AC 100~240V
Input Frequency: 50~60Hz
Output Voltage: DC 5V±5%
Output Current: 2A MAX

Fuse

Type: 1206L050

I(hold)0.5A, I(trip)1A, V(max)15V

Store and Replay

Store and replay 72 hours SpO_2% and Pulse rate value, the time interval is 4 seconds.

Outline of Product

Dimension: 125mmX60mmX30mm
Weight: 195g (excluding the batteries)

Equipment Classification

Classification according to IEC-60601-1	
According to the type of protection against Electrical shock	Internal electrical power source equipment and Class II equipment
According to the degree of protection against Electrical shock	Type BF equipment
According to the degree of protection against harmful ingress of water.	IPX1
According to the methods of sterilization or disinfection.	Non-sterile: Use of Liquid surface disinfectants only.
According to the mode of operation.	Continuous operation
Equipment not suitable for use in the presence of a flammable anesthetic mixture air or with oxygen or nitrous oxide.	

Note: the applied part of the device: the SpO_2 probe.
Box contents:

1. Three AA alkaline batteries.
2. One instruction manual
3. One adult finger probe: M-50E012CS09
4. One pediatric finger probe: M-50B008CS09 (optional)
5. One single use probe: M-50J033CS045 (optional)
6. Software CD
7. USB Cable
8. Adapter(optional)

APPENDIX B Clinical study summary

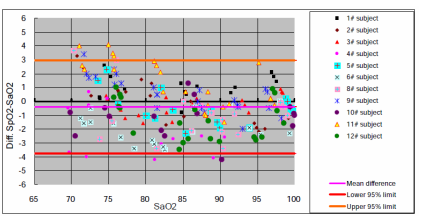
The following details are provided to disclose actual performance observed in the clinical validation study of healthy adult volunteers. The ARMS value analysis statement and Bland-Altman plot of data for HCSMD400 and its supporting probes are shown as following:

B.1 Clinical study details of HCSMD400 Pulse Oximeter and its supporting M-50E012CS09

Oximeter probe:

Table 6-1 ARMS Value Analysis Statement

Item	90--100	80--<90	70--<80
#pts	78	74	66
Bias	-0.73	-0.59	0.45
ARMS	1.46	1.80	1.99



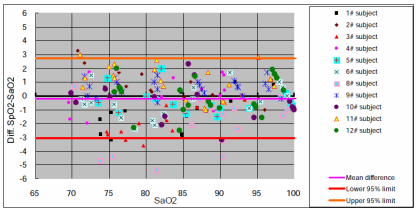
Bland-Altman Plot Graphic

B.2 Clinical study details of HCSMD400 Pulse Oximeter and its supporting M-50B008CS09

Oximeter probe

Table 6-2 ARMS Value Analysis Statement

Item	90--100	80--<90	70--<80
#pts	78	74	66
Bias	-0.10	-0.31	-0.03
ARMS	1.19	1.40	1.82

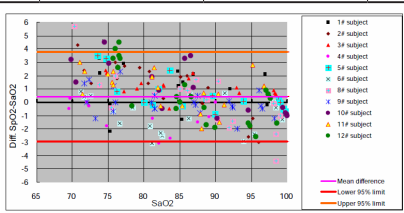


Bland-Altman Plot Graphic

B.3 Clinical study details of HCSMD400 Pulse Oximeter and its supporting M-50J033CS045 Oximeter probe

Table 6-3 ARMS Value Analysis Statement

Item	90--100	80--<90	70--<80
#pts	78	74	66
Bias	-0.51	-0.41	1.56
ARMS	1.34	1.49	2.36



Bland-Altman Plot Graphic

APPENDIX C Statement of Manufacturer

Guidance and manufacturer's declaration - Electromagnetic emission---- for all EQUIPMENT AND SYSTEM

1	Guidance and manufacturer's declaration- electromagnetic emission		
2	The model HCSMD400 Pulse Oximeter is intended for use in the electromagnetic specified below. The customer or the user of the model HCSMD400 Pulse Oximeter should assure that it is such an environment.		
3	Emissions test	Compliance	Electromagnetic environment-guidance
4	RF emissions CISPR11	Group 1	The model HCSMD400 Pulse Oximeter 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.
5	RF emissions CISPR11	Group B	The HCSMD400 are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage powere supply network that supplies building used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	Class A	
7	Voltage fluctuations/ IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - Electromagnetic Immunity- For all Equipment and Systems

Guidance and manufacturer's declaration- electromagnetic immunity			
The model HCSMD400 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the model HCSMD400 Pulse Oximeter 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	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Electrostatic transient/burst IEC 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95%dip in UT) for 0.5 cycles 40% UT (60%dip in UT) for 5 cycles 70% UT (30%dip in UT) For2 5 cycles <5% UT (>95%dip in UT) for 5 sec	<5% UT (>95%dip in UT) for 0.5 cycles 40% UT (60%dip in UT) for 5 cycles 70% UT (30%dip in UT) For2 5 cycles <5% UT (>95%dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model HCSMD400 Pulse Oximeter requires continued operation during power main interruptions, it is recommended that the model HCSMD400 Pulse Oximeter be powered from an uninterruptible power supply or a battery.
Power frequency(50/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration- electromagnetic immunity-
For EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The model HCSMD400 Pulse Oximeter is intended for use in the electromagnetic specified below. The customer of the user of the HCSMD400 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the model HCSMD400 Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacture and d is the recommended separation distance in meters (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:
NOTE1 At 80MHz and 800MHz, the higher frequency range applies. NOTE2 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 situation 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 model HCSMD400 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, the additional measures may be necessary, such as reorienting or relocating the model HCSMD400 Pulse Oximeter.
b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

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

Recommended separation distances between portable and mobile RF communications equipment and the HCSMD400 Pulse Oximeter

The model HCSMD400 Pulse Oximeter is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the model HCSMD400 Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the model HCSMD400 Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter(W)	Separation distance according to frequency of transmitter (m)		
	150KHz to 80 MHz $d=1.2\sqrt{P}$	80MHz to 800 MHz $d=1.2\sqrt{P}$	800MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance in meters (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.
NOTE1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE2 These guidelines may not apply in all situations. Electromagnetic interference is affected by absorption and reflection from structures, objects and people.