ChoiceMMed

PULSE OXIMETER INSTRUCTION MANUAL

MD300I

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Content

1 Introduction

1.1 Brief Introduction

Thank you for purchasing the handheld pulse oximeter for the functional oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate (PR) measurement. The pulse oximeter features PR tone modulation, data storage and data transmission capabilities. Please read the user manual carefully before using this instrument.

Note:

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

1.2 Intended Use

The MD300I pulse oximeter is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult and pediatric patient at home and hospital (including clinical use in internist/surgery, Anesthesia, intensive care and etc). It is not for continuous monitoring.

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 (HbO2) in glow 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 glow and 940nm 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 handheld pulse oximeter is to be operated by qualified personnel only.
- Operation of the handheld 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 handheld 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 handheld pulse oximeter in an explosive atmosphere.
- The handheld 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 every 4 hours 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 950 and IEC 601-1-1. Any input/output device should be following the protocol of IEC 601-1-1.
- 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 950 and IEC 601-1-1. Any input/output device should follow the protocol of IEC 601-1-1.
- 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 SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO2 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 SpO2 cable with the wires of ES (Electrosurgery) equipment.
- Single use accessories should never be reused.
- Only use SpO2 sensors specified by the manufacturer. Other SpO2 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.
- Portable and mobile RF communications equipment can affect medical electrical equipment.
- This equipment is not intended for use during patient transport outside the healthcare facility
- This equipment should not be used adjacent to or stacked with other equipment.
- Do not disassemble, repair or modify the equipment without authority.
- These materials that contact with the patient’s skin contain medical silicone and ABS plastic enclosure are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.

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 SpO2 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 SpO2 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 SpO2 measurement.
- The handheld 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.

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;

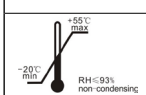
1.5 Electromagnetic Interference

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	Definition
	Caution
	Follow instructions for use
	Type BF applied part.
	Protected against dripping water.
SpO_2%	Oxygen Saturation.
	Low power indication.
	No SpO_2 Alarm.
SN	Serial No.
	Storage temperature and relative humidity.
	Waste electrical and electronic equipment
	Manufacturer's information.
	Date of Manufacture.
	European union approval.
EC REP	Authorized representative in the European community.

1.7 Product Features

- Simple to use and easy to operate.
- Portable and compact in design.

- OLED display screen with adjustable backlight.
- Up to 10 patients' IDs and 72-hour records can be saved.
- Data transfer to PC by USB cable.
- Powered by two AA alkaline.
- Suitable for adult and pediatric patients.

CHAPTER 2 General Descriptions

2.1 Appearance

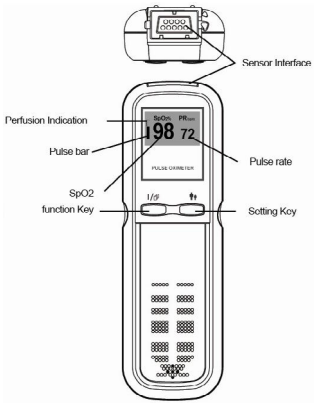


Fig.2-1 Appearance of the oximeter

Sensor Interface: This interface is designed for two purposes, one is to connect the SpO2 probe for measurement, and the other is to connect the pulse oximeter to PC with USB cable for data transmission.

Function key - at the left of the oximeter, acts as a power on switch when the oximeter is power off. While the oximeter is power on, it acts as a function key.

Setting key - at the right of the oximeter, while the oximeter is power on, it acts as a setting key.

While there is no measurement or operation the oximeter will power off automatically in 30 seconds.

2.2 Battery Installation

1. Slide the battery door cover along the arrow as shown in Fig.2-2.

2. Install two AA batteries into the battery compartment. Match the plus (+) and minus (-) signs in the compartment. If the polarities are not matched, damage may be caused to the oximeter.

3. Replace the battery cover.

Warning!

Install the batteries with the correct polarity. Incorrect placement may cause damage to the bracket.

Note:

Please remove the batteries if the pulse oximeter will not be used for long periods of time.

A low voltage warning will be indicated with flashing when the battery voltage is lower than 2.7V. Please replace the batteries as soon as possible, otherwise normal operation of the oximeter might be influenced.

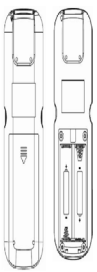


Fig.2-2

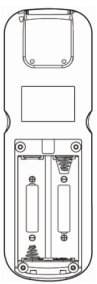


Fig.2-3

2.3 Sensor Connection

Select an appropriate sensor, and then connect the sensor to the top of the oximeter as shown in Fig.2-4. Ensure that the sensor is firmly plugged in.

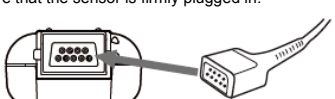


Fig.2-4

The interface is also used for transferring data to the software for management. To transfer data, please connect the data cable to the interface. For detailed information, refer to MedView software instruction manual.

Notes:

1. Please make the raised lump side of sensor cable upside when inserting the sensor.

2. Do not insert the sensor forcefully.

CHAPTER 3 Take a Measurement

Definition of key press

There are three ways to press the key:

1. Press: press the key quickly, the duration time should no more than 1 second.

2. Double press: Two-time continuous press, the time between the two press action should no more than 0.5 second.

3. Longtime press: press the key for a long time, the time should more than 1.5 seconds.

3.1 Before Measurement

Press the key in the left of the oximeter to power the device on.

Clip the sensor to the rational position of the patient finger, and ensure the patient's nail surface is facing upward as shown in Fig.3-1.

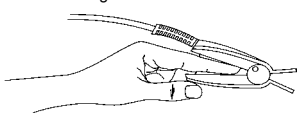


Fig.3-1 Placement of the finger

3.2 Display

The handheld pulse oximeter can display the SpO2 and pulse rate (PR) value, pulse bar as well as SpO2 waveform and perfusion indication.

There are 3 display modes for the handheld pulse oximeter. After turning on the device, each time the function key (left key) is pressed, the handheld pulse oximeter will switch to another display mode as shown in the following figures.

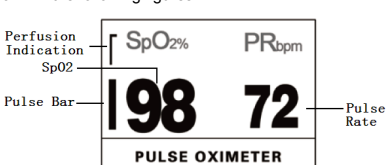


Fig.3-2 (1) Pulse column display mode

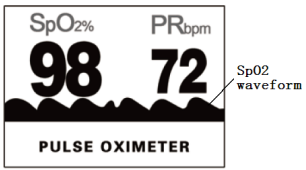


Fig.3-2 (2). Filled waveform mode

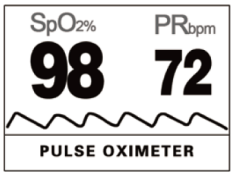


Fig.3-2 (3). Line waveform mode

The first figure is pulse column display mode. The second figure is filled waveform mode. The third figure is line waveform mode indicating SpO_2% trend.

PR tone modulation: Beeps in sync with the patient's pulse, even under most challenging patient motion conditions, except when in the (2) mode.

3.3 Warning

Warning: Technical warning and physiological warning.

Technical warning: finger out, probe off, power low and error code.

In the situation that the finger is not inserted correctly or the connection state of the probe is not good results in failure of measurement, "Finger out" or "Sensor off" may be displayed on the normal screen.

When battery power is lower than 2.6±0.1V, the sign will flicker in its display area. Replace the batteries as soon as possible.

In the failure state, the oximeter will display error codes, and will automatically power off if the error code display lasts for more than 30 seconds. For the details and definitions on error, please refer to chapter 5.3.

Physiological warning: SpO_2 and PR

If the measured SpO_2 and/or PR value is beyond the default limit, the corresponding value will flash with audible sound.

By default:

SpO_2: The upper limit: 100%, The lower limit: 90%

PR: The upper limit: 100bpm, The lower limit: 60bpm

Note: During the warning is issued, press the functional button, you can silence the alarm for 30 seconds. And press it again, the screen switches between pulse column display mode, filled waveform mode and line waveform mode.

ALARM PRIORITY:

There are three-level priorities for selection.

High priority: indicates the patient is in the very dangerous situation.

Medium priority: indicates the warnings should be paid attention to.

Low priority: indicates the technical alarm caused by the device itself.

Alarms of the oximeter include technical and physiological alarms. All the three priorities are divided by built-in module and cannot be changed by user.

Assignment of priority:

Alarm priority	Event	Display	Audiblesound
High	The SpO_2 is beyond the limits	The SpO_2 value is flashing	"Di- Di – Di ----- Di - Di", "Di-Di – Di ----- Di - Di" once circularly every 3 seconds
Medium	The pulse rate is beyond the limits	The pulse rate value is flashing	"Di - Di - Di", once circularly every 5 seconds
Low	The probe or finger is not inserted	Finger out Probe off	"Di", once circularly every 20 seconds

CHAPTER 4 Settings

4.1 Brief Introduction of Setting

You can enter or exit the setting only under “measure mode” and “information display mode” in order to set the brightness, patient ID, date and time.

Enter setting: Press the function key for more than one second, the oximeter will enter setting.

Save and exit setting: Press function key and setting key simultaneously, the modification under the setting mode will be saved, at the same time, the system will exit from setting mode and return to “non-setting mode”.

Cancel and exit from setting: Under the “setting mode”, press function board twice, the modification under setting mode will be canceled, at the same time, the system will exit from setting and return to “non-setting mode”.

If there is no operation under “setting mode” in 10 seconds, the modification under “setting mode” will be canceled automatically, at the same time, the system will exit from “setting mode” and return to “non-setting mode”.

4.2 Parameters Change

Enter the Setting Mode under the “Measure mode”, you can only set Brightness and Patient ID. Enter the Setting Mode under the “Information Display mode”, you can set Brightness, Patient ID, Date and Time. Current parameters and data will be displayed at the top right corner which is used to display the “PR”. The various parameters display title is as follows:

Br(brightness)-->ID(patientID)-->Y(year)-->M(month)-->D(date)-->H(hour)-->m(minute)-->S(second)--Br(brightness)-->...

Br: brightness, range: 1-7.

ID: patient ID, range: 1-10.

Y: year, range: 0-99, short for 2000-2099.

M: month, range: 1-12.

D: day, range: 1-31.

H: hour, range: 0-23.

m: minute, range: 0-59.

S: second, range: 0-59.

Change current value of the parameter

Press “setting key”, current parameter setting will be added by 1 unit.

Double press or longtime press “setting key”, current parameter setting will be added by 10 units.

4.3 Brightness Adjustment

Holding the function key (left key) for more than one second, the brightness level headed with “Br” will be shown on the top right of the screen. You can adjust the brightness by degrees by pressing the setting key (right key). There are 7 levels of brightness in all. The default is level 3.

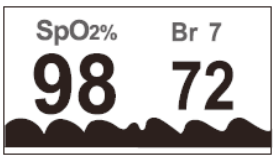


Fig.4-1

4.4 Data Replay and Transmission

The oximeter can record SpO_2 and PR value for more than 72 hours, and can analyze records one by one. You can transfer the history data to a PC by using “MEDVIEW” software and an attached data cable. As for detailed setup and operation, please refer to the “MEDVIEW” operator’s manual.

CHAPTER 5 Maintenance 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.

5.1 Maintenance

Replace the batteries in a timely manner when low voltage lamp is lighted.

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℃～ +55℃ 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.

5.2 Cleaning and Calibrating

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.

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.

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.

5.3 Troubleshooting

a) Error Definitions

Err 1: program memory damaged.

Err 2: data memory damaged.

Err 3: sensor Red Emission Diode damaged.

Err 4: sensor Infrared-ray Emission Diode damaged.

Err 5: sensor Infrared-ray Receipt Diode damaged.

Err 6: exterior crystal oscillator damaged.

Err 7: sensor emission diode or receipt diode damaged.

Err 9: real time clock damaged.

Err 10: EEPROM chip damaged.

b) Possible problems and corresponding solutions

Problems	Possible Reason	Solution
SpO_2 or PR cannot be displayed normally	1. Finger is not plugged correctly 2. Patient's Oxyhemoglobin value is too low to be measured	1. Retry by plugging the finger 2. Attempt several times to obtain a reading, If you are sure that no problem exists, obtain further clinical examination
SpO_2 or PR display is unstable	1. Finger might not be plugged deep enough 2. Finger is trembling or patient is moving continually	1. Retry by plugging the finger 2. Urge the patient to remain still
The Oximeter cannot be powered on	1. Battery power may be inadequate or not installed 2. Batteries might be installed incorrectly 3. The Oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3.Contact local customer Technical Service
"Error3" or "Error4" Displayed on screen	1. Receiving diode may be shielded or damaged together with broken connector. 2. Mechanical Misplace for receive-emission diode 3. Amp circuit malfunction.	1.Contact local customer Technical Service 2.Contact local customer Technical Service 3.Contact local customer Technical Service
"Error7" displayed on screen	1. Emission diode damaged. 2. Current control circuit malfunction.	1 Contact local customer Technical Service 2 Contact local customer Technical Service
"Probe off" displayed on screen	1. The sensor is not connected 2 The connection between the Probe and Oximeter is loose	1.Connect the sensor 2. Please check if the probe was connected with oximeter correctly

5.4 Warranty and Repair

5.4.1 Service Method

Service support: Our company will offer user telephone and e-mail support as well as in-house repair at our facility.

Parts replacement: Our company will replace parts, accessories, free of charge during the warranty period.

Our company will update the system software free of charge.

5.4.2 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) No-service offer

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 oximeter.

The damage and failure caused by user or its representative doesn't comply with the operator's manual.

c) The oximeter is installed or connected with such external device without our company permission as printer, computer, net line and lead to oximeter failure. Our company will charge for the maintenance.

d) Responsibility limitation

During the period of maintenance contract validity, if user changes the parts manufactured by other manufacturers without our company permission, our company is entitled to stop contract.

5.4.3 User Guarantee

a) Please read user manual carefully before operation.

b) Please operate and make daily maintenance as request of manual and guarantee.

c) Power supply and environment.

5.4.4 No-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, which may lead to short circuit and plug board 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 measuring value difficultly or inaccurate measurement.
- Not-original package leads to damaging oximeter during transportation
- 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.

5.4.5 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 hoist board 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 sell 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.

5.4.6 Repackage

- Take all the accessories and put them into plastic cover.
- Try to use original package and packing material. 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 oximeter.

Storage and Transportation

Storage: Storage Temperature -20℃ ~ +55℃ , Relative Humidity ≤93%, no condensation.

Transportation: Transport by airline, train or vessel after packing according to request.

Package

Pack the product with the hard bag, and put the foam between the inner box and the carton to alleviate the shake.

APPENDIX A Specifications

Notes:

Specifications may be changed without prior notice.

The circuit diagrams, the list of components, the illustrations of diagrams, and the detailed rules of calibration are provided exclusively to professional personnel authorized by our company.

Display

Type: OLED

Parameters: SpO_2, Pulse Rate, Plethysmogram, Pulse bar

Mode: 3 display modes.

Data update time: 15s

SpO_2

Display Range: 0% ~ 99%

Resolution: 1%

Accuracy: 70% ~ 99%: ±2% 0% ~ 69%: unspecified

Pulse Rate

Measuring Range: 30bpm ~ 235 bpm

Resolution: 1bpm

Accuracy: ±2bpm

Probe LED Specifications

	Wavelength	Radiant Power
RED	660±2nm	1.8mW
IR	940±10nm	2.0mW

Alarm

Alarm: Probe off, Finger out, Low power

Modes: visual information

Record

Patient ID: 10 patients

Data record: Up to 72 hours

Data Transmission

Transmission Method: Cable Transmission

Data Cable Interface: DB9 (Connect to Pulse Oximeter); USB (Connect to PC)

Environment Requirements

Operating Temperature: 5℃ ~ 40℃

Storage Temperature: -20℃ ~ +55℃

Operating Humidity: ≤80%RH, no condensation

Storage Humidity: ≤93%RH, no condensation

Classification per IEC60601-1

Classification according to IEC-60601-1	
According to the type of protection against Electrical shock:	Internal electrical power source 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-sterilizable: 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.	

Dimensions: 110 x 35 x 27mm (Length×Width×Height)

Weight: 110g (with alkaline batteries)

Power Supply

Type: 2 AA Alkaline batteries

Operation time: About 24 hours of typical operation

Voltage: +3.3 ± 0.17 V DC

Average Current: 30mA

Accessories

Standard accessories:

One user manual;

One finger sensor for adult (Model: M-50A);

Two AA-Size Alkaline batteries;

One MedView software CD;

One data cable;

Optional accessories:

Binding sensor for pediatric

(Pediatric 15-45 Kg).

Model: M-50B

Confirm that the items listed are packed with the pulse oximeter. If any item on this list is missed or damaged, contact your distributor. Contact the carrier immediately if the shipping carton is damaged.

APPENDIX B Declaration

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

1	Guidance and manufacturer's declaration- electromagnetic emission		
2	The model MD300I Pulse Oximeter is intended for use in the electromagnetic specified below. The customer or the user of the model MD300I 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 MD300I 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	
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 MD300I Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the model MD300I 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 MD300I Pulse Oximeter requires continued operation during power main interruptions, it is recommended that the model MD300I 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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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 MD300I Pulse Oximeter is intended for use in the electromagnetic specified below. The customer of the user of the MD300I Pulse Oximeter 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 model MD300I Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3V	$d=1.2\sqrt{P}$ 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:
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	

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 MD300I 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 MD300I 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 MD300I Pulse Oximeter

The model MD300I 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 MD300I Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the model MD300I 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	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
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.

Beijing Choice Electronic Technology Co.,Ltd.

Room 4104, No. A12 Yuquan Road, Haidian District, Beijing 100143, P.R.China.

EC REP Shanghai International Holding Corp.GmbH(Europe)

Eiffestraße 80, 20537
Hamburg GERMANY

CE 0123

MD300I