Wrist Pulse Oximeter

MD300W628

INSTRUCTION MANUAL

Copyright

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CONTENT

1 Introduction

1.1 Brief Introduction

Thank you for purchasing MD300W628 Wrist Pulse Oximeter. The main functions of the device include hemoglobin oxygen saturation (SpO_2), pulse rate (PR), and perfusion index (PI) measurements, visual and audible indication, data storage and transmission through Bluetooth®. Please read this manual carefully before using the device.

Note: The illustrations applied in the manual may differ slightly from the actual device.

1.2 Safety Information

Contraindications

None

Conception of Warning, Caution an 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.
- The wrist 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.
- The wrist 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.
- Do not use the device for treatment; we are not responsible for contretemps happened during measuring.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- Operation of the device may be affected by the use of an electrosurgical unit (ESU).
- Carefully route patient cables and connections to reduce the possibility of patient entanglement or strangulation.
- Check the oximeter sensor application site every half an hour to determine the positioning of the sensor and skin sensitivity of the patient.
- Do not use the wrist pulse oximeter in situations where alarms are required. The device has no alarms.
- Do not use the device under conditions of shocks and vibrations. Do not use it, either, with the patient connected to such medical electrical equipment as a cardiac pacemaker and other electrical stimulators.
- Do not, under any circumstance, perform any testing or maintenance on the wrist pulse oximeter while it

is being used to oximeter a patient.

- Products contain small parts; Keep the equipment away from children and pets.
- This equipment may cause allergy.
- This equipment is not intended for use during patient transport outside the healthcare facility.
- Do not use the wrist pulse oximeter in an MRI or CT environment.
- Explosion Hazard: Do not use the wrist pulse oximeter in an explosive atmosphere or in the presence of flammable anesthetics or gases.
- Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the equipment.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Cautions:

- Do not immerse the wrist pulse oximeter or sensors in any liquid.
- Do not place or pour liquids on the surface of the wrist pulse oximeter.
- Before cleaning or disinfecting the probe, unplug it from the oximeter to prevent probe or oximeter from

being damaged, and to protect user under safety situation.

- The wrist pulse oximeter is a precision electronic instrument. It must be repaired by trained personnel only.
- Ensure that the wrist strap fits comfortably on the patient's arm. Do not over-tighten the wrist strap.
- This equipment complies with IEC 60601-1-2:2014 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.
- Please use accessories specified for this device and do not change them casually.
- The malfunction of probe or worn-out data cables may cause inaccurate measurement results, so the user should check them frequently and make sure that they are in good working state.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the unit and unit components.
- The device is only for prescription use, federal law restricts this device to sale by or on the order of a physician.

Notes:

- The performance of this device may be affected by the portable and mobile RF communications equipment.

- Application of this device in the background of electromagnetic areas may influence the measuring accuracy such as in the environment of electro-surgery.
- SpO_2 measurements may be adversely affected in the presence of high ambient light. Shield the probe area (with a surgical towel, for example) if necessary.
- Significant levels of dysfunctional hemoglobin may affect the accuracy of the measurement.
- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may adversely affect the accuracy of the SpO_2 reading.
- 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.
- Remove fingernail polish or artificial fingernails before applying SpO_2 probes. Fingernail polish or artificial fingernails may lead to inaccurate SpO_2 readings.
- Optical cross talk can occur when two or more probes are located in adjoining area. 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 probe's red light or detector may cause a probe failure. Make sure the probe is clean.
- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.
- Our company will only provide the schematic, components list, legend and correction details for the

qualified technical personnel authorized by our company.

- As to the other concerns for attention, please carefully look through the specific chapter in this instruction.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: this device may not cause harmful interference and this device must accept any interference received, including interference that may cause undesired operation.
- Pulse oximeter monitor has been validated and tested for compliance with this international standard

1.3 Intended Use

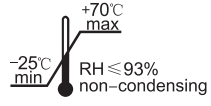
The MD300W628 Wrist Pulse Oximeter is a portable, non-invasive device intended for measuring the functional arterial oxygen saturation (SpO_2) and pulse rate of adult and pediatric patients in hospital and home care environment.

1.4 Electromagnetism Interference

This wrist pulse 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.

1.5 Explanation of Symbols

Symbol	Meaning	Symbol	Meaning
%SpO_2	Hemoglobin Oxygen Saturation	**PR**	Pulse Rate
	Type BF applied part	**IP33**	Protected against dripping water
	Attention, consult the accompanying documents.	**PR bpm**	Serial number
	Manufacture's information		Date of Manufacture
	No SpO_2 Alarm		Storage temperature and relative humidity
	Power button	?	Indicate the signal is not stable
	Low battery indication		Follow instruction for use
CE 0123	European union approval	EC REP	Authorized representative in the European community

1.6 Product Features

- ✧ Compact in design, easy to wear;
- ✧ Touch screen, simple operation;
- ✧ Data storage, bluetooth transmission;
- ✧ Abnormal data, vibration reminder.

2 General Description

The wrist pulse oximeter adopts OLED touch screen, which can display the SpO_2, PR and PI value. It can also provide information of date and time, remind you of the connection of Bluetooth®, probe or finger as well as record your walk steps.

2.1 Appearance

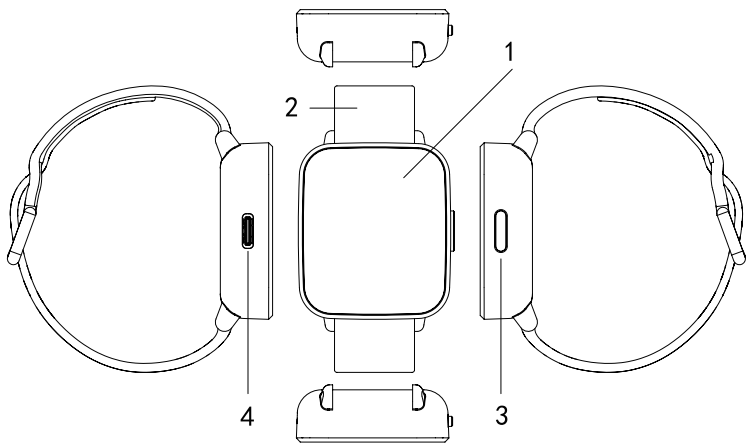


Fig.2-1

Description of Fig.2-1:

1: OLED touch screen: display SpO_2, PR and PI values, date & time, battery power, Bluetooth® connection.

2: Wrist

3: Power button: Press and hold the button for 3±1s to power the device on or off. Short press the button to

turn on or off the screen when the device is powered on.

4: The probe socket/charging interface: to connect SpO_2 probe for measurement and connect USB cable for battery charging.

2.2 Power Supply

The MD300W628 wrist pulse oximeter is powered by lithium-ion rechargeable battery. The battery will typically work for 10 hours in sleeping mode with the screen off.

Battery charging steps:

First, connect the device and the power adapter with the attached USB cable. The standard USB plug should be connected to the power adapter and the other end of the USB cable should be connected to the probe socket of the device.

Second, connect the power adapter into the power outlet.

In the charging process the screen will show "Charging". When the battery is full screen will show "Complete". The typical charging time is less than 2 hours.

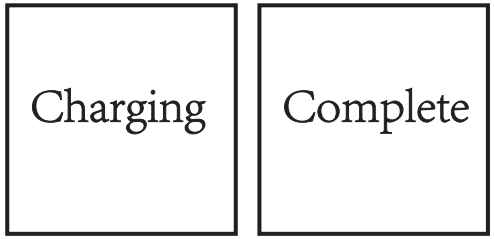


Fig.2-2

Notes:

- Keep the device and power adapter away from source of fire and/or heat;
- Do not touch the power adapter with your wet hands;
- The battery is not a detachable part, do not attempt to disassemble it;
- Charge the battery using specified chargers;
- Do not use the battery and power adapter in un-specified application.

3 Take a Measurement

3.1 Power On

Press and hold "Power button" for 3±1s to start up the device.

The display screen will be highlighted when powered on (see Fig.3-1).

Then the screen will show a time and a date (see Fig.3-2).

Swipping the screen left and right to switch the interfaces.

Fig.3-1

Fig.3-2

3.2 Probe Installation

1. Plug the SpO_2 probe into the probe socket of the Wrist Pulse Oximeter, ensure that the sensor is plugged correctly and firmly (see Fig.3-3).

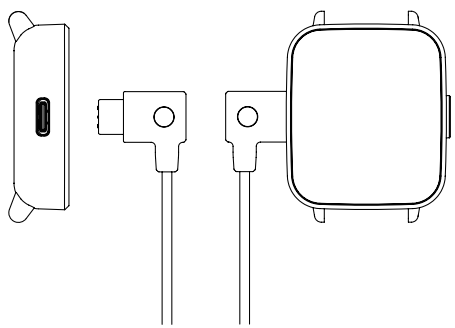


Fig.3-3

NOTE: Be sure to insert the sensor correctly, otherwise there will be no signal detected.

2. Place the patient's finger inside the sensor as shown in Fig.3-4.

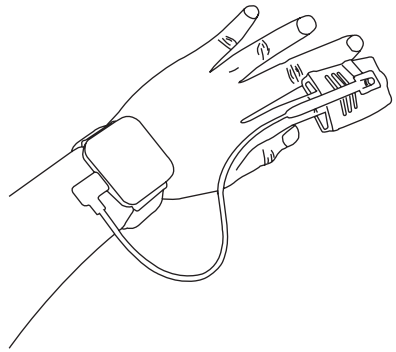


Fig.3-4

3.3 Take a Measurement

i Swipe the creen left to enter the measurement interface, as the Fig.3-5, the values will be horizontal lines "-" before the results show.

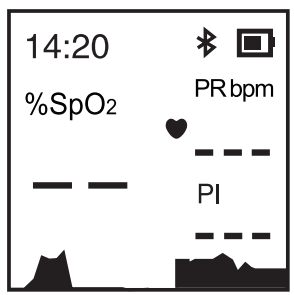


Fig.3-5

ii Then the measurement result will display as in Fig.3-6. Read the measured SpO_2 value, PR and PI values

from the screen. Swipe the creen left, you can check your walk steps, see Fig.3-7

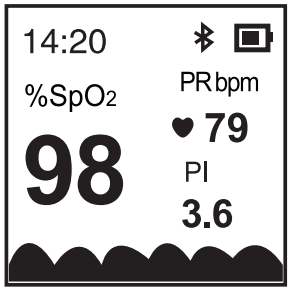


Fig.3-6

Fig.3-7

Description of measurement screen:

98 : %SpO_2 value

79 : PR value

3.6 : PI value

: Pulse waveform

: Battery power indication.

A low battery indication may be displayed, when the remaining power capability is insufficient.

The device will automatically shut down when the battery voltage is lower than 3.5V + 0.1V.

: The Bluetooth® indicator: The indicator keeps lighted for Bluetooth® working mode, but flashes if no device connection.

? : If the screen displays “?”, it means the signal is unstable, please keep your hands still and retry.

Note:

If the probe is inserted into the pulse oximeter but no finger is placed, “Finger Out” will appear on the screen (Fig.3-8). If there is no probe inserted after power on, “Probe Off” will appear on the screen (Fig.3-9).

Fig.3-8

Fig.3-9

iii Switch measuring modes:

The device will default to real-time measurement each time you power it on. Swipe down from the top on any screen and tap on the screen as shown in Fig.3-10, the device will switch to "sleeping mode" and the Bluetooth® will break. The measurements will also be recorded.

Fig.3-10

Factors that may affect the measurement

During operation, the accuracy of oximetry readings can be affected by the following factors:

(1) Instrument performance depends on the pulsatile character of the artery. The measurement would not be considered reliable and accurate if the following conditions take place during measurement.

- Shock or cardiac arrest
- Temperature beyond the limit
- After the administration of a cardiovascular drug
- Anemia
- Evidence of ventilation-perfusion mismatch

(2) Instrument performance depends on the wavelength absorption for oxyhemoglobin and deoxyhemoglobin. If there are substances absorbing the same wavelength, this would induce false or low SpO_2 values. The following may affect these values:

- carboxyhemoglobin
- methemoglobin
- methylene blue
- Indigo carmine

(3) Extremely high illumination could affect the SpO_2 measurement. Use a semi-translucent or opaque cover to shield the sensor.

(4) Other factors

a) High-frequency electrosurgical interference from external units, including defibrillators.

b) Placement of a sensor on an extremity that currently has been placed a blood pressure cuff, arterial

catheter, or intravascular line;

c) The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;

d) An arterial occlusion proximal to the sensor.

⚠ **Warnings!**

- Do not use an SpO_2 sensor with exposed optical components.
- Excessive patient movement may cause inaccurate measurements.
- Tissue damage can be caused by incorrect operation or misusing sensor; for example, by wrapping the sensor too tight. Inspect the sensor site to ensure the skin's integrity and the adhesion position of the sensor is correct. More frequent inspection should be taken if necessary.
- Loss of pulse signal can occur in any of the following situations:

  a) The sensor is too tight;

  b) There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight;

  c) Do not use the device on the same arm when taking a blood pressure reading.

3.4 Data storage and transfmission

Under Real-time/Sleeping mode: The device will automatically store 72-hour measurement data and the interval of every two records is 1 second.

Connect the device and the APP via Bluetooth® to upload the measurements to the APP.

When the storage is full, delete the records (**refer to section 4.2**) or upload them to the APP so to record new measurements.

4 Settings

Firstly, power the device on and swipe the screen right to enter the setting menu, shown as in Fig.4-1.

Fig.4-1

4.1 Indication Setting

Tap "**Indication Setting**" from the menu (see Fig.4-1) to enter its sub setting interface, shown as follow:

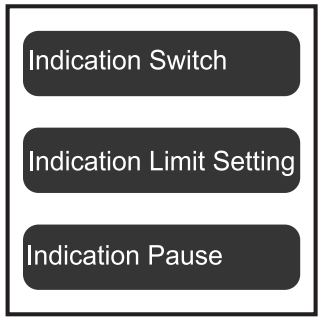


Fig.4-2

4.1.1 Tap "**Indication Switch**" and on the next screen tap the ON or OFF button the enable or disable the indication of SpO_2 or PR, as shown in Fig.4-3.

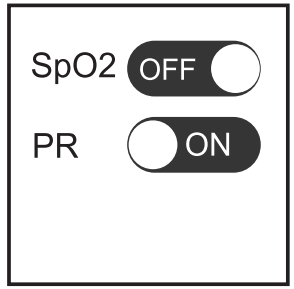


Fig.4-3

Indication on: When there is special case happens, the device will prompt the user by vibration.

Indication off: The vibration indication will be closed. Please be careful with this setting.

4.1.2 Tap "**Indication Limit Setting**" you can set the indication limits of SpO_2 (Fig.4-4) and PR (Fig.4-5).

On the first SpO_2 Indication Limit setting interface and the next PR Indication Limit setting interface tap "▶" or "◀" to change the limit figures. Swipe the screen back and forth the change the two setting interface.

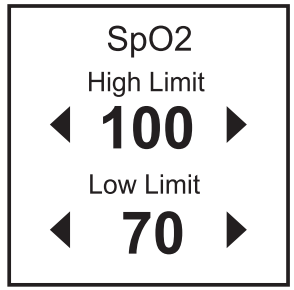


Fig.4-4

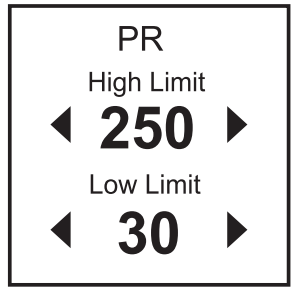


Fig.4-5

Note:

- The set range of SpO2 is 70%－100%.
- The set range of PR is 30bpm－250bpm.
- The high limit you set should be greater than that of the low limit of the same parameter.
- When the measurement results are out of the indication limits you set, the device will prompt the user by vibration.

4.1.3 Tap "**Indication Pause**". The screen will display as in Fig.4-6, tap the figure to set the pause time between "60s", "120s" and "180s".

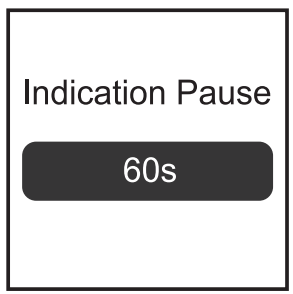


Fig.4-6

Note: To exit the setting and return to last step, you can swipe the screen right.

4.2 Data Management

Tap "**Data Management**" from the main setting menu (see Fig.4-1) to delete or check record data. On the submenu, shown as in Fig.4-7:

- Tap "Delete Data" and then select "√" to detele all data. Select "X" to cancel the move and return.
- Tap "Data review" to check record data under sleeping mode.

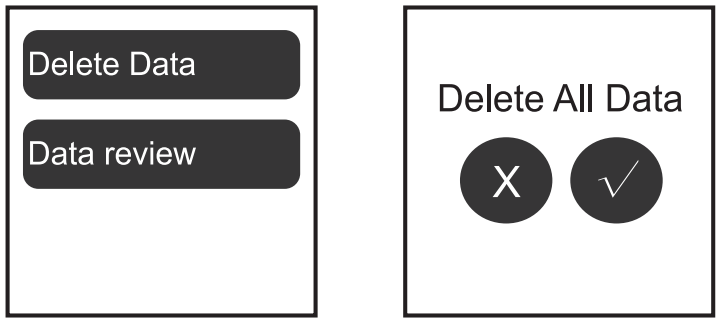


Fig.4-7

4.3 System Setting

Tap "**System Setting**" from he main setting menu (see Fig.4-1) to set the device date and time.

Tap "Date and Time" on submenu, see Fig.4-8 to set the date first and then swipe the creen left to set the time: tap and hold the figure on the screen, see Fig.4-9, slightly swipe up or down to change the figure.

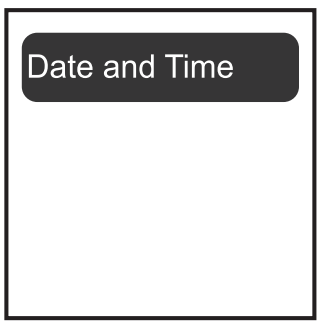


Fig.4-8

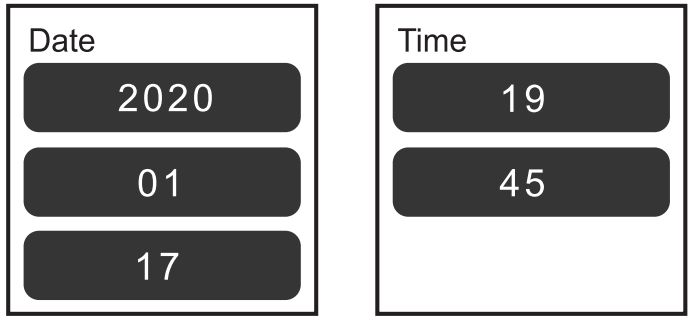


Fig.4-9

4.4 Other settings

Swipe down from the top on any screen, see Fig.3-10.

Tap to enable Bluetooth® function or not.

Tap to enable indication function or not.

Tap to enter sleeping mode.

36% indicates the remaining power.

5 Troubleshooting

Problems	Possible reasons	Solutions
SpO2 or PR can not be shown normally	1. Finger is not inserted correctly 2. Patient's SpO2 value is too low to be measured 3. Probe malfunction	1. Retry by inserting the finger 2. There is excessive illumination 3. Change the probe 4. Try some more times. If you can make sure no problem exist in the product, please go to a hospital timely for exact diagnosis.
SpO2 or PR is shown unstably	1. Finger might not be inserted deep enough. 2. Excessive patient movement	1. Retry by inserting the finger 2. Be calmness
The oximeter cannot be powered on	1. No battery or low power of battery 2. Batteries might be installed incorrectly 3. The oximeter might be damaged	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact with local customer service centre
Bluetooth® connection failure	1. The Bluetooth® function disabled 2. The oximeter might be damaged	1. Enable the Bluetooth® 2. Please contact with local customer service centre

6 Maintenance and Repairs

6.1 Maintenance

Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.

We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

- Always dilute according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse part of the equipment into liquid.
- Do not pour liquid onto the equipment or accessories.
- Do not allow liquid to enter the case.
- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

NOTE: To clean or disinfect reusable accessories, refer to the instructions delivered with the accessories.

6.2 Safety Checks

Before every use, or after your pulse oximeter has been used for 6 to 12 months, or whenever your pulse

oximeter is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability. Follow these guidelines when inspecting the equipment:

Make sure that the environment and power supply meet the requirements.

Inspect the equipment and its accessories for mechanical damage.

Make sure that only specified accessories are applied.

Inspect if the cautionary system functions correctly.

Make sure that the battery meet the performance requirements.

Make sure that the pulse oximeter is in good working condition.

In case of any damage or abnormity, do not use the pulse oximeter. Contact your hospital's biomedical engineers or your service personnel immediately.

Cleaning

Your equipment should be cleaned regularly. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- Mild soap (diluted)
- Ammonia (diluted)
- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)

- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

1. Shut down the pulse oximeter.
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.

Disinfecting

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.

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

CAUTION: Never use EtO or formaldehyde for disinfection.

6.3 Calibration and Verification

The performance should be checked every one year and after maintenance and repair.

Required Test Equipment: SpO_2 signal Simulator

Note: The simulator cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter.

6.3.1 Control Key Verification

Press Menu key, display the analysis results.

6.3.2 SpO_2 & Pulse Rate Measurement Value Verification

a). Connect SpO_2 Probe to the SpO_2 connector on the oximeter.

b). Insert the operator's finger into the finger sensor, the SpO_2 measured value of healthy person should be from 95% to 99%, and the pulse rate is same as heart rate.

c). If SpO_2 Simulator is available, verify the accuracy of Oxygen Saturation Value with probes as follows:

Oxygen Saturation	Accuracy
96%	±3%
86%	±3%
70%	±3%

6.4 Warranty and Repair

6.4.1 Maintenance Method

(1) Repair service: Including telephone support, field inspecting, fittings replacement.

- Telephone support: we can give guidance to customer's engineer to inspecting the instrument when you dial our service line. Professional repair engineer online provides technical support.

- Field inspecting: we will send engineers to repair the instrument if necessary. Certified engineers of our company or local repair team trained by our company provide this service.
- Fittings replacement: if necessary, we will replace the damaged fittings according to contract. The damaged fittings should be returned to us expect for special reason.

(2) Spare machine for repair: it is used to replace the damaged machine for customer using, customer should send the damaged machine to us to repair.

(3) Repair for sponsoring and contributing machine: customer should send the machine to us to repair.

(4) Updating software is free.

6.4.2 Exempt and limitation:

a) Our company isn't responsible for such damage caused by force nature. 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 cost and insurance charge of disassembling, refurbishing, repackaging and conveying of the oximeter or the part of it.
- Damage or loss sustained due to inspected or repaired by other institute that is not certified.
- The damage and failure caused by user or its representative who doesn't use the unit according to the operator's manual

c) The damage or lose sustained due to connection to peripheral equipment (such as printer, computer etc.),

that are not provided by our company are not covered by the warranty.

d）Responsibility limitation

In the duration of warranty, if user changes the parts manufactured by other manufacturers without our company permission, our company is entitled to cancel contract.

6.4.3 User Guarantees

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 must be maintained under manual specifications.

6.4.4 No-guarantee principle

- The unit does not remain in original condition.
- The shell of the unit is breached or cracked.
- Evidence of water damage.
- Accessories adulterated or appearance of physical abuse.
- Evidence of crushing damage to the probe.
- Original Packaging during transportation is not used.
- Non authorized service is performed on oximeter.
- Damage to a product as a result of not conforming to manual specifications.
- The work environment is not eligible.
- There is smear or marks that are not belong to the instrument and cannot be removed from the outside

surface of the instrument.

- The circuit is short and damaged due to liquor or other stuff flow in the instrument or its fittings.
- All probe and its accessories are not free replacement.
- If any code label of parts is damaged or missing, this warranty shall become null and void. For example of code label.
- 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.
- Maintenance seal of oximeter are not opened.

6.4.5 User's Special Request for Guarantee Time

As we stipulate the warranty period according to the relevant electronic regulation of country, which we stipulate is one year, accessory is three months. When customer requires to extend the warranty period, you should consider whether it is reasonable. Because electronic product is quickly replaced, as to the warranty period over three years, purchased accessories may be out of stock. In this case, we will adopt to entirely upgrade or replace the old, you should pay the minimum acceptable cost of renewed unit.

6.4.6 Repackage

- Take all the accessories and put them into plastic cover
- Try to use original package. 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°C～55°C, Relative Humidity ≤93%, no condensation.

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

Package: We pack the product with the hard bag and put the foam between the inner box and the cartoon to alleviate the shake.

Note: If it is necessary to store the oximeter for an extended period of time, the unit should be packed in its original shipping container. Storing the monitor for a long period of time may degrade the battery capacity. Battery should be removed from the monitor before storing.

Standard accessories

- One instruction manual;
- One Silicone sensor (Model: M-50G);
- One reusable wrist strap;
- One USB cable.

Optional accessories

- One Binding sensor (Model: M-50J);
- One Fingertip sensor (Model: M-50B).

Note: It requires no routine calibration, safety maintenance or in-service during the oximeter's life.

7 FCC Declaration

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) This device must accept any interference received, including interference that may cause undesired operation.

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, PR, PI, PR waveform

SpO_2

Display range: 7%~100%

Measurement range: 70%~100%

Resolution: 1%

Accuracy: 70%~100%: ±2%; <69%: unspecified.

Probe LED Specifications

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

Pulse Rate

Display range: 30~250bpm

Measurement range: 30~250bpm

Resolution: 1bpm

Accuracy: 30~99bpm, ±2bpm; 100~250bpm, ±2%

PI

Display range: 0.1~20.0%

Measurement range: 0.3~20.0%

Resolution: 0.1%

Accuracy: 0.3~1.0% (±0.2digits); 1.1~20.0% (±20%)

Power Supply

Lithium-ion rechargeable battery

DC 3.7V

Power Adapter

Input Voltage: AC 100~240V

Input Frequency: 50~60Hz

Output Voltage: DC 5V

Output Current: 1,000mA (MAX)

Bluetooth®

Working Distance: 10m

Bluetooth® 5.0

Operation Environment

Operating Temperature: 5℃~40℃

Ambient Humidity: 15%~93%, no condensation

Atmosphere Pressure: 70kPa~106kPa

Storage and Transportation Environment

Storage Temperature: -25℃~70℃

Ambient Humidity: ≤93% no condensation

Atmosphere Pressure: 70kPa~106kPa

Outline

Dimension: 44X38X13±2 mm（Length X Width X Height）

Weight: 25±5g (without battery)

Classification

According to the type of protection against electric shock: INTERNALLY POWERED EQUIPMENT;

According to the degree of protection against electric shock: TYPE BF APPLIED PART, (applied part: the rubber hole of the device);

According to the degree of protection against ingress of dust and water: IP33

According to the mode of operation: CONTINUOUS OPERATION

Note: the unit might not meet its performance specifications if stored or used outside the manufacturer's specified temperature and humidity ranges.

Appendix B Declaration

Table 1

Guidance and Manufacturer's declaration – electromagnetic emissions-For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic emission		
The MD300W628 Wrist Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of MD300W628 Wrist Pulse Oximeter should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic Environment – guidance
RF emissions CISPR 11	Group 1	The MD300W628 Wrist 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.
RF emissions CISPR 11	Class B	The Wrist Pulse Oximeter (MD300W628) is suitable for use in all establishment, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Table 2

Guidance and Manufacturer's declaration – electromagnetic immunity-For all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's declaration - electromagnetic immunity			
The MD300W628 Wrist Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300W628 Wrist 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	+/- 2,4,6,8kV contact +/-2, 4, 8, 15kV air	+/- 2,4,6,8kV contact +/-2, 4, 8, 15kV 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 (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Table 3

Guidance and Manufacturer's declaration – electromagnetic immunity-For all EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and Manufacturer's declaration - electromagnetic immunity			
The MD300W628 Wrist Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the MD300W628 Wrist Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Complian-ce Level	Electromagnetic Environment – guidance

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Wrist Pulse Oximeter (MD300W628), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=0.35√P 80 MHz to 800 MHz d=0.7√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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with following symbol:
NOTES 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTES 2 These guidelines may not apply in all situations, Electromagnetic propagation is affected by absorption and reflection structures, objects and people.			
a Field strengths from fixed transmitters, such as base station 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 Wrist Pulse Oximeter (MD300W628) should be observed to verify normal operation. If abnormal performance is observed, additional measurements may be necessary, such as reorienting of the relocating the Wrist Pulse Oximeter (MD300W628). b Over the frequency range 150 kHz to 80 MHz, fields strengths should be less than 3 V/m			

Table 4

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

Recommended separation distances between portable and mobile RF communications equipment and Wrist Pulse Oximeter (MD300W628)		
The Wrist Pulse Oximeter (MD300W628) is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wrist Pulse Oximeter (MD300W628) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Wrist Pulse Oximeter (MD300W628) 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)	
	80 MHz to 800 MHz $d=0.35\sqrt{P}$	800 MHz to 2.5 GHz $d=0.7\sqrt{P}$
0.01	0.035	0.070
0.1	0.111	0.222
1	0.35	0.70
10	1.107	2.214
100	3.5	7.0
For transmitters rated at a maximum output power not listed above, the recommended separation distanced 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. NOTES 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTES 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		