3D Hi-Resolution Technology Pulse Oximeter

Instruction Manual

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CONTENTS

1 Introduction

1.1 Brief Introduction

Thank you for purchasing SLEEPSAT (MD300W314-PS) wrist pulse oximeter. The main functions of the device include hemoglobin oxygen saturation (SpO_2) and pulse rate (PR) measurements, visual and audible indication, data storage and transmission by USB cable or 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

- 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.

Warnings, Cautions, and Notes

Warnings and cautions noted in this manual are provided to prevent accidental misuse caused by erroneous handling of the equipment.

- 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 using the equipment, carefully read the instruction manual in its entirety.
- 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 which happen 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 4 hours to determine the positioning of the sensor and skin sensitivity of the patient.
- Do not use the wrist pulse oximeter in situations where alarms or monitoring are required. The device has no alarm and is not meant for continuous monitoring.
- 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 circumstances, perform any testing or maintenance on the wrist pulse oximeter while it is being used to monitor a patient.

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 the probe or oximeter from being damaged, and to protect the patient.
- 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 60601-1-2:2007 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

interference due to close proximity or strength of a source might disrupt the performance of this device.

- Please use only accessories specified for this device.
- The malfunction of a 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 a state of good working order.
- Follow local governing ordinances and recycling instructions regarding disposal or recycling of the unit and unit components.
- The device is only for use under the management and order of a heath care professional.

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 an 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 Maintenance and Repairs section in this manual.
- 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.

1.3 Intended Use

The SLEEPSAT (MD300W314-PS) wrist pulse oximeter is a portable, non-invasive device intended for spot checking and/or non-real time overnight monitoring of the functional arterial oxygen saturation (SpO_2) and pulse rate of adult and pediatric patients in hospital and home care environments. The SpO_2 and pulse rate data collected on this device is downloaded for future interpretation and analysis.

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	**IP22**	Protected against dripping water
	Attention	**SN**	Serial number
	Manufacture's information		Date of Manufacture
	Prevent from rain		Storage temperature and relative humidity.
	Power button		Function button
	Low battery indication	**bpm**	The unit of pulse rate
	No SpO_2 Alarm		Consult the accompanying documents.
	Waste electrical and electronic equipment		European union approval
EC REP	Authorized representative in the European community		

1.6 Product Features

- Portable, compact in design
- LCD display screen
- Powered by lithium-ion rechargeable battery
- USB for data transmission
- Visual and audio indication

2 General Description

The wrist pulse oximeter uses an LCD screen, which can display the SpO_2 and PR value, pulse bar and other indications. You can also review the date and time, indication set information, and the connection of probe, etc.

2.1 Appearance

Fig. 2-1

1. **The probe socket:** to connect the SpO_2 probe for measurement and connect the USB cable for data transmission or battery charging.
2. **The Bluetooth® indicator:** Bluetooth is not enabled on this device.
3. **Screen Display**
4. **Power button:** press and hold the button for 3 seconds to power the device on. Note: The device powers off automatically when the probe is removed from the finger and left off for 2 minutes.
5. **Function button:** This button is not enabled on this device
6. **The speaker.**

Contents of Package

- (1) SpO_2 SleepSat Oximeter
- (1) USB Cable
- (1) Adult Finger Probe
- (1) Re-Usable Wrist Strap
- (1) Quick Start Reference
- Packaging

2.2 Power Supply

The SLEEPSAT (MD300W314-PS) wrist pulse oximeter is powered by a lithium-ion rechargeable battery. The battery with capability of 530mAh will typically work for 10 hours in real time mode and 20 hours in non-real time mode.
A low battery-warning indication may be displayed, which means that the remaining power capability is insufficient and only can support the device working for 10 minutes or less. When the interface shown in Figure 2-2 appears on the screen, the device will shut down automatically in 5 seconds.

Fig. 2-2

When the above interface occurs, it indicates the battery needs to be charged.

The steps for charging the device battery are as follows:

1) Connect the device and the power adapter with a standard 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.

2) Connect the power adapter into a power outlet.

When the device is charging, the interface shown in Figure 2-3 is displayed. The typical charging time is 4 hours. When charging, the display will blink periodically and when fully charged, the display will stop blinking.

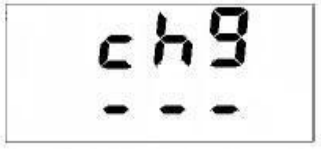


Fig. 2-3

Warning:

- Keep the device and power adapter away from sources of fire and/or heat;
- Do not touch the power adapter with wet hands or submerse in water;
- Charge the battery using only using standard USB chargers.

Caution

- The battery is not a detachable part, do not attempt to disassemble the device;
- Do not use the battery and power adapter in un-specified application;

3. Preparation For Measuring

3.1 Wrist Strap Placement

Follow the steps below to apply the wrist strap:

1) Begin by laying the device face down on a flat surface with the Power switch facing you. Start by threading the round end of the wrist strap, with Velcro side down, through the right-side bar on the device. Continue threading the wrist strap through the left side bar and pull the strap to left as shown in Figure 3-1.

2) Next, create a loop with the round end of the wrist strap and thread it through the metal loop as shown in Figure 3-2.

3) Next, place the device over the wrist and pull on the wrist strap to comfortably fit the wrist. Press the Velcro portion firmly against the wrist strap to secure.

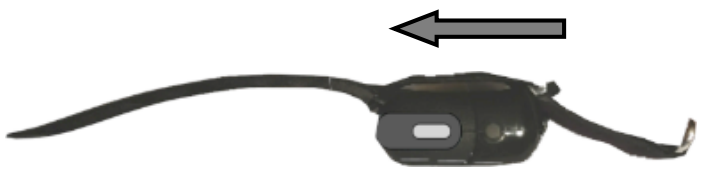


Fig. 3-1

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 oriented and plugged in correctly and firmly, refers to Fig.3-5.

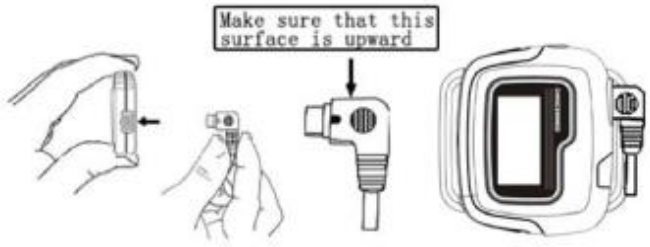


Fig. 3-5

NOTE: Be sure that the sensor is inserted correctly, otherwise there will be no signal detected.

2. Place the patient's finger inside the probe sensor as shown in Fig.3-6.

Fig. 3-6

NOTE: If the finger is not completely inserted into the probe sensor, there will be no signal detected.

4 Take a Measurement

4.1 Power On

Press and hold the Power button for 3 seconds to start up the device. The display screen will be highlighted for a self-test when powered on. The interface shown in Figure 4-1 will appear.

Fig. 4-1

The next screen will display the version of the software. If there is no probe inserted, after power on, “Prob OFF” appears on the screen as shown in Figure 4-2. If the probe is inserted into the pulse oximeter but no finger is placed, “Sen oFF” will appear on the screen as shown in Figure 4-3.

Fig. 4-2

Fig. 4-3

4.2 Take a Measurement

Insert one finger inside the sensor as shown in Figure 3-6. The signal searching picture is shown as in Figure 4-4.

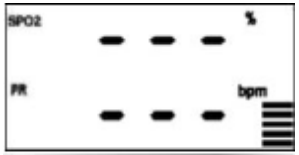


Fig. 4-4

The resulting measure is provided on the screen as shown in Figure 4-5.

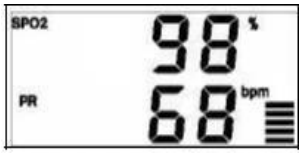


Fig. 4-5

The measured SpO_2 value and PR value in the example shown in Figure 4-5 are respectively 98% and 68bpm, and the pulse bar is displayed at the bottom right corner of the screen.

Note: 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 probe limits

- 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;

⚠ **Warning!**

- 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 the 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.

4.3 Power Off

Remove the probe and the unit will automatically power down in two (2) minutes. If the patient did not intend to power off the unit, the Power On procedure detailed in Section 4.1 should be followed and Patient Safety's Connection Center will offer to combine the multiple recordings into one report. The display will show "SEn oFF" for two (2) minutes as shown in Figure 4-3. The blue light will also display during this two (2) minute time period.

Fig. 4-3

Chapter 5 Settings

The following device settings are pre-defined by the manufacturer and cannot be modified. The following settings are provided for reference.

5.1 No Alarms

⚠ **Warning!** This device has NO alarm and is set to be OFF.

Indication Off

Indication off: the visual and audio indication signals are turned OFF.

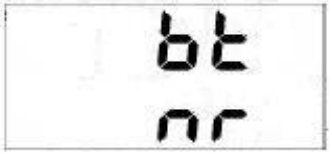
5.2 Date and Time Setting

The Date and Time Settings are managed from the Patient Safety Connection Center. The current Date and Time are set when the device is connected to the Connection Center.

The setting ranges are as follows:
Year: 10～40 (2010~2040)
Month: 01～12
Day: 01～31/30/29/28 (according to the specific month)
Hour: 00～23
Minute: 00～59
Second: 00～59

5.3 Bluetooth® Mode

The Bluetooth® working mode is set as non-real time.



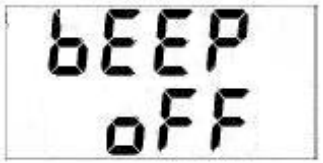
Non-real time mode

While in the non-real time working mode, the Bluetooth® will be turned off during measurement. When the finger is pulled from the probe to end the measurement, the Bluetooth® indicator will be lighted momentarily which means the Bluetooth® is turned on. The data transmission occurs via the USB cable plugged into the device and not Bluetooth.

In the process of data transmission, the screen will display the quantity of the remaining data item. The interface is shown below.

5.4 No Pulse Sounds

⚠ **Warning!** The pulse sound is set to be OFF.



Chapter 6 Troubleshooting

Problem	Cause	Solution
The device does not start.	The battery level is too low to power the device.	Charge the battery for 4 hours.
LCD displays ‘E1’	The blood oxygen blood module is damaged.	Contact the service center for help.
LCD displays ‘SEN OFF’	The battery level is too low to power the device. The sensor cable of the probe is unconnected.	Charge the battery for 4 hours. Connect the sensor cable to the device.
LCD displays ‘Prob OFF’	The finger is not placed fully inside the probe. The sensor of the probe may be damaged.	Insert the finger fully into the probe; Use a new probe.
LCD displays ‘E13’	The battery level is too low to power the device.	Charge the battery for 4 hours.

Chapter 7 Maintenance and Repairs

7.1 Maintenance

Use only the approved substances and methods listed in this chapter to clean or disinfect your equipment. The 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. Keep your equipment and accessories free of dust and dirt.

To avoid damage to the equipment, follow these rules:

- Always dilute substances according the manufacturer's instructions or use lowest possible concentration.
- Do not immerse any part of the equipment or accessories into liquids.
- Do not pour liquids 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.

7.2 Safety Checks and Cleaning

Before every use, a thorough inspection should be performed by qualified personnel to ensure the equipment is still functioning properly. Follow these guidelines when inspecting the equipment:

- Inspect the equipment and its accessories for mechanical damage.
- Make sure that only approved accessories are used with the device.
- Make sure to turn on the device and ensure the battery can be charged and review any error messages.

If there is any mechanical or electronic damage such that the device and accessories may be non-functional, do not attempt to use the pulse oximeter. Contact the service center to determine how to proceed.

Cleaning

Your equipment should be cleaned regularly. Recommended cleaning solutions 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. Turn off the pulse oximeter if it is on.
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 a recommended cleaning solution.
4. Wipe off all the cleaning solution with a dry cloth after cleaning.
5. Dry your equipment in a ventilated, cool place.

Disinfecting

Clean the equipment before disinfecting it. To disinfect the equipment, wipe the exterior of the equipment completely with one of the following disinfectants:

- Ethanol (70%)
- Isopropanol (70%)
- Glutaraldehyde-type 2% liquid disinfectants

CAUTION: Never use EtO or formaldehyde for disinfection.

7.3 Performance Verification

The performance of the equipment should be checked at least once per year and after maintenance and repair.

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.

7.4 Warranty and Returns

7.4.1 Warranty Period

Patient Safety, Inc. (PSI) warrants the equipment be free from defects in workmanship and materials, under normal use conditions, for a period of one hundred, twenty (120) days from the original invoice date. Shipping and handling fees for returns are to be paid for by the customer. PSI agrees, at its option during the warranty period, to repair the defect in material or workmanship or to furnish a repaired or refurbished product of equal value in exchange without charge to the customer. Such repair or replacement is subject to verification of the defect or malfunction and proof of purchase.

7.4.2 Product Returns

Customer may return unused equipment within thirty (30) days from the original invoice date. Equipment must be in the original packaging and unopened. Shipping and handling fees for unused returned product will be paid for by the customer. Any credits to the customer are subject to verification that the equipment is unopened and unused.

7.4.3 Warranty Limitations

This warranty does not include:

- Any condition resulting from other than ordinary use for which the equipment was not intended
- Any condition resulting from incorrect or inadequate maintenance or care
- Damage resulting from misuse, abuse, negligence, accidents or shipping damage

PSI makes no express warranty or condition whether written or oral and the company expressly disclaims all warranties and conditions not stated in this limited warranty. To the extent allowed by the local law of jurisdictions outside the United States, the Company disclaims all implied warranties or conditions, including any implied warranties of merchantability and fitness for a particular purpose. For all transactions occurring in the United States, any implied warranty of condition of merchantability, satisfactory quality, or fitness for a particular purpose is limited to the duration of the express warranty set forth above.

All warranty claims must be filed by the customer to the service center for return or replacement.

7.4.4 Claim Procedures

Claims for defective equipment or returns must be made to the service center within the time period specified.
Claims for missing equipment must be made to the service center within thirty (30) days from the original invoice date.
Any claim for defective equipment returns must be packed in original packaging

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

CHAPTER 8 Declaration

FCC-ID: WWIMMD300W314

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: --Reorient or relocate the receiving antenna.

--Increase the separation between the equipment and receiver.
--Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Appendix 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: LCD

Parameters: SpO_2%, PR, Pulse bar, Low Battery Indicator;

Others: connection status of probe and error codes.

SpO_2

Display range: 0%~100%

Measurement range: 70%~100%

Resolution: 0.1%

Accuracy: 70%-100%: ±3%; <70%: unspecified.

Averaging Time: 4 pulse beats

Probe LED Specifications

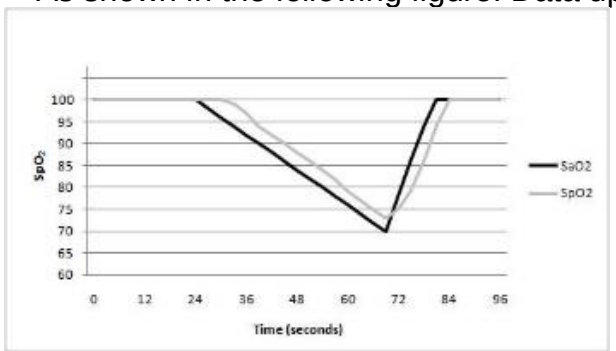
	Wavelength	Radiant Power
RED	660±3nm	1.8mW
IR	940±10nm	2.0mW

Pulse Rate

Display range: 0~254bpm
Measurement range: 30~235bpm
Resolution: 1bpm
Accuracy: ±2% or 2 bpm, whichever is greater

Equipment data update period

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



Fuse

Type: 466*
63V, 1000mA

Indication

Indication: SpO_2% and PR value, probe off, finger out, battery exhausted;
Indication mode: audible indication, visual indication and prompt information.
Default indication limits: SpO_2 high 100%, low 90%; PR high 100 bpm; low 60 bpm

Antenna Information

Antenna Type/Patten: Internal
Frequency Range: 2402 to 2480 MHz

Power Supply

Lithium-ion rechargeable battery
DC3.7~4.2V
530mAh

Power Adapter

Input Voltage: AC 100~240V
Input Frequency: 50~60Hz
Input Current: 120mA
Output Voltage: DC 5V
Output Current: 500mA MAX

Operation Environment

Operating Temperature: 5℃~40℃;
Relative Humidity: ≤ RH80%, no condensation.
Atmosphere Pressure: 86kPa～106kPa

Storage and Transportation Environment

Operating Temperature: -20℃~55℃;
Relative Humidity: ≤ RH93%, no condensation.
Atmosphere Pressure: 50kPa～106kPa

Data Storage

Store and replay 72-hour SpO_2% and Pulse rate value, the interval of every two records is 1 second.

Outline

Dimension: 67mmX66mmX28mm（Length X Width X Height）
Weight: 65g (without battery)

Equipment Classification

Type of Protection Against Electric shock: Internally Powered;
Mode of operation: Continuous;
Degree of Protection Against ingress of Liquids: IPX1;
Degree of Protection Against Electric Shock: Type BF;
Safety Requirements: EN60601-1-4;
The Applied part: SpO_2 Probe.

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

Declaration

Guidance and manufacturer's declaration - Electromagnetic emission----for Wrist Pulse Oximeter

1	Guidance and manufacturer's declaration- electromagnetic emission		
2	The MD300W314 Wrist Pulse Oximeter is intended for use in the electromagnetic specified below. The customer or the user of the MD300W314 Wrist Pulse Oximeter should assure that it is such an environment.		
3	Emissions test	Compliance	Electromagnetic environment-guidance
4	RF emissions CISPR11	Group 1	The MD300W314 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.
5	RF emissions CISPR 11	Class B	The MD300W314 Wrist Pulse Oximeter is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	Harmonic emissions IEC 61000-3-2	Not applicable	
7	Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - Electromagnetic Immunity- for Wrist Pulse Oximeter

Guidance and manufacturer's declaration- electromagnetic immunity			
The MD300W314 Wrist Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of The MD300W314 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	±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	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	Not applicable	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) For 25 cycles <5% UT(>95%dip in UT) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MD300W314 Wrist Pulse Oximeter requires continued operation during power main interruptions, it is recommended that the MD300W314 Wrist 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 MD300W314 Wrist Pulse Oximeter is intended for use in the electromagnetic specified below. The customer of the user of the MD300W314 Wrist Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance

<table>
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<tr><td>Radiated RF IEC 61000-4-3</td><td>3V/m 80MHz to 2.5 GHz</td><td>3V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the MD300W314 Wrist Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

$d=1.2\sqrt{P}$ 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. Interference may occur in the vicinity of equipment marked with the following symbol:

  </td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

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 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 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 Pulse Oximeter		
Rated maximum output of transmitter(W)	Separation distance according to frequency of transmitter (m)	
	80MHz to 800 MHz $d=1.2\sqrt{P}$	800MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	2.3
100	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.		

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