

Dr Trust® Pulse Oximeter - 211

USER
INSTRUCTIONS



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www.drtrustusa.com/211

Thank you very much for purchasing the Dr Trust Pulse Oximeter-211! Please read this manual thoroughly before start using the pulse oximeter. Also, keep it in hand for future reference.

1. INTRODUCTION

Dr Trust Pulse Oximeter- 211 is designed to measure continuously the level of oxygen saturation of hemoglobin in the arterial blood. It consists of the monitor containing the batteries and display, and the probe that senses the pulse. Its display shows the oxygen saturation and the pulse rate. It can be connected to the patient via the probe and during use, the monitor gives you regular updates about its calculations. It can detect hypoxia much sooner than the anesthesia provider and essential for safe anesthesia.

1.1 Intended Use

The Pulse Oximeter is a portable, convenient, non-invasive device, used for monitoring arterial hemoglobin oxygen saturation (SPO2) and pulse rate (PR) for adult, pediatric or neonatal patients. The personal application are adult patients (weight: >30kgs) and pediatric patients (weight:20-30kgs). We recommend index finger, middle finger and ring finger are suitable position for monitor. It is intended for spot-checking or attended-care monitoring in Outpatient Departments, Nursing Hospitals, Medical Facilities, and community medical institutions. It also used in the Home Health Care.

Note

The pulse oximeter is NOT designed for newborn and infant. For adults and children, it recommended that the finger thickness should between 8-25.4mm.

2. SAFETY

Warnings

- Do not use oximeter in a magnetic resonance (MR or CT) environment.
- Keep the oximeter away from young children.
- Small parts such as the battery door, battery and lanyard may trigger choking hazards.

Cautions

- Do not use oximeter in the present of flammable anesthetics.
- The oximeter needs to be used according to information provided in the user manual.
- The equipment is NOT intended for neonate and infant.
- Do not use a damaged oximeter which may affect measurement performance.
- Do not place the oximeter on the same hand/arm when using a blood pressure cuff or monitor.
- Do not use the oximeter for more than 5 minutes without relocating the device to another finger.
- Do not place the oximeter on edema or fragile tissues.
- Do not use the oximeter as the only basis for making medical decision, it is intended only to be used as additional information that you can give to your licensed health care professional.
- Do not use the oximeter in high frequency environment such as electrosurgical equipment.
- Do not place the oximeter in liquid.
- Follow local disposal and recycling laws for the oximeter and its components, including the battery.
- Do not stare the light (the infrared is invisible) which emitted from the oximeter is harmful to the eyes.
- For clinical limitations and contraindications, please carefully review the medical literature
- The equipment is just a clinical diagnosis of auxiliary equipment. The physiological data displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.
- Not suitable for the users with arrhythmia / heart failure / Low perfusion (PI <0.3) / finger trembling.
- Not suitable for the users with large finger size or exceeding pulse oximeter's finger measurement cavity size.
- Please do not use the thumb and tail finger to measure.
- Discomfort or pain may appear if using the equipment ceaselessly, especially for microcirculation barrier patients, it recommended that the equipment should not be used on the same finger more than 5 minutes.
- The oximeter is designed to measure the percentage of arterial oxygen saturation of functional hemoglobin.

Any of the following conditions may reduce the performance of the oximeter.

- Moisture in the oximeter
- The individual weight less than 20kgs
- Weak pulse quality (low perfusion)
- Venous pulsations
- Low hemoglobin
- Cardio green and other intravascular dyes
- Carboxyhemoglobin
- Methemoglobin
- Dysfunctional hemoglobin
- Artificial nails or fingernail polish
- The Finger is too cold
- Patients with abnormal circulation of finger endings caused by COPD.

3. THE BASICS

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter for respiration. A number of diseases relating to respiratory system may cause the decrease of SpO2 in the blood, furthermore, some other causes such as the malfunction of human body's self-adjustment, damages during surgery, and the injuries caused by some medical checkup would also lead to the difficulty of oxygen supply in human body. And the corresponding symptoms would appear as a consequence, such as vertigo, impotence, vomit etc. Serious symptoms might bring danger to human's life. Therefore, prompt information of patients SpO2 is of great help for the doctor to discover the potential danger and is of great importance in the clinical of medical field.

3.1 Principle

An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption characteristic of Reductive hemoglobin (Hb) and oxyhemoglobin (HbO2) in glow & near-infrared zones.

Operation Principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

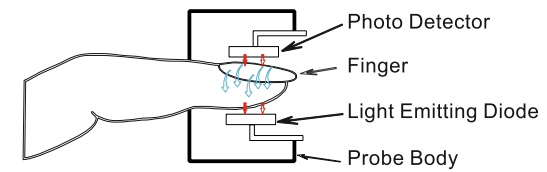


Figure 1. Oximeter schematic diagram

NOTE

- The probe is the hole in the middle of the equipment to which the finger inserts.
- The probe is the Applied part of the equipment.

4. FEATURES

The pulse oximeter is small in volume, light in weight and easy to carry.

- One button and easy to operate.
- There are three modes: power off, sleep and measure.
- Automatically turning into sleep mode within 8 seconds after there is no signal.

NOTE

- Press the operating button to activate oximeter (measure mode) from sleep mode.
- Power off after removing the batteries.

4.1 Front View

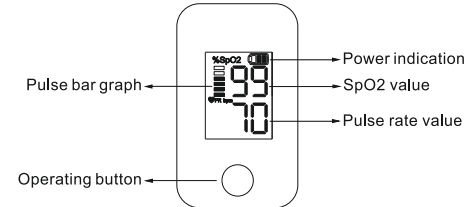


Figure 2. Front view of pulse oximeter

Display	OLED
SPO2 Parameter Measurement	Yes
Pulse Rate Parameter measurement	Yes
Bar Graph Display	Yes
Battery Display	Yes
Automatically Enters Sleep Mode	Yes

5. BATTERY INSTALLATION

- Put the two AAA batteries into battery compartment in correct polarities.
- Push the battery cover horizontally along the arrow shown as figure 3.

WARNINGS:

- Battery polarities should be correctly installed, otherwise damage may be caused to the equipment.
- Please remove the batteries if the oximeter will be stored for more than 30 days.
- Please remove the batteries if you want to turn off the oximeter. Otherwise it is always in power state.
- Battery may leak or explode if used or disposed of improperly.

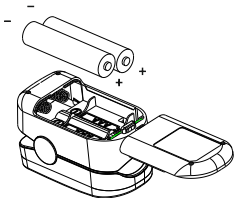


Figure: Battery Installation

6. OPERATING GUIDE

6.1 Application Method

- Remove the battery cover and insert the two AAA batteries following polarity markings indicated inside of the battery compartment, then reposition the cover.
- Hold the oximeter with the display facing toward you, slide your finger into the opening probe of the device, as shown below (Figure 4), until the fingertip touches the built-in stop guide. For best results, make sure the finger is centered with in the finger guide.
- Press the button to activate the oximeter from sleep mode, and then measurement interface will appear in 3 seconds.
- The measurement result will be read directly from the screen.
- The oximeter will turn into sleep mode automatically within 8 seconds after the finger left the probe.

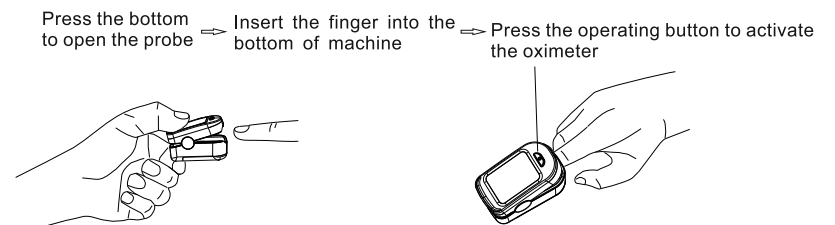


Figure 4. Operation Guide

6.2 Attention for Operation

- Ring finger, middle finger and index finger are recommended as suitable monitor position.
- Excessive or rapid movement may affect measurement accuracy.
- Improper sensor placement may affect the measurement accuracy.
- The oximeter can be reused after cleaning and disinfection.
- The measurement comes to the best when the oximeter and the heart are at the same level.
- The bar graph can be used as pulse intensity indicator. The displayed parameters might be unreliable with un-periodic change.
- The displayed parameters will show invalid indicator as '---' if signal quality is very low.
- The displayed parameters will show invalid indicator as '---' if oximeter fault occur.
- The maximum continuous test time does not exceed 5 minutes.

7. SPECIFICATIONS

7.1 Classification

Type of protection against electric shock	II (Internally powered equipment)
Degree of protection against electric shock	Type BF-Applied part (non-defibrillation proof)
Operating mode	Spot checking
Degree of protection against hazards of explosion	Ordinary equipment: Note protected
Equipment type	Fingertip oximeter

7.2 Measurement Specifications

Spo2 declared accuracy	
Range	70%~99%2 digits 0%~69%: unspecified
Resolution	1%
Update Period	1s
Averaging Time	8s

7.3. PR declared accuracy

Range	25~250:3 digits
Resolution	1bpm Update
Period	1s
Averaging Time	8s

7.4 Power Requirements

Specification of batteries	Two 1.5V(AAA)
Operating voltage	DC 2.5-3V

7.5. Environmental Specifications

Temperature	
Operating	+41 to +104F/5 to +40°C
Storage/Transportation:	-4 to +140F/-20 to

Atmosphere Pressure	
Operating	70~106kpa
Storage/Transportation	50~107.4kpa

7.6. Physical Specifications

Size:- 37x31x63mm

Weight:- About 60g (including the batteries)

7.8. LED Wavelengths

Probe LED Specifications

	Wavelength	Radiant Power
RED	660±6nm	1.8mW
IR	905±10nm	2.0mW

8. TECHNICAL DESCRIPTION

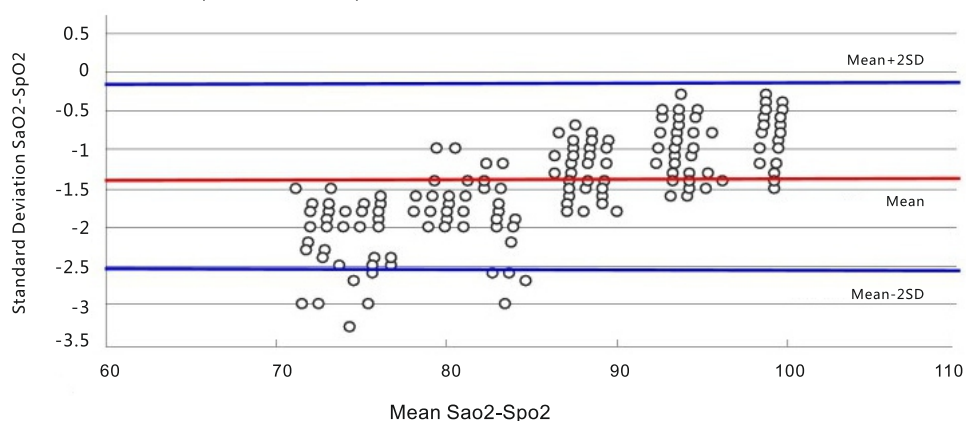
The below table shows statistic conclusion of an invasive controlled desaturation study which guided by "ISO 80601-2-61, Annex EE, Guideline for evaluating and documenting SpO2 Accuracy in human subjects". The statistic result displayed the accuracy distribution between the range of 70%~100%, which may helpful to user.

SaO2-Radiometer ABL800 FLEX-CO-Oximeter

Analysis	Bias			
	70-80 (%)	80-90 (%)	90-100 (%)	70-100 (%)
SPO2 Pulse Oximeter				
Mean Bias (Bs)	1.94	1.45	0.89	1.4
Precision (Sres)	2	1.55	0.98	1.53
Accuracy (Arms)	1.98	1.53	0.96	1.52

The below is the Bland-Altman graphical plot of samples from invasive controlled desaturation study.

Bland-Altman Graph for SaO2-SpO2



9. MAINTENANCE, CLEANING, DISINFECTION

9.1 Maintenance

The equipment's design life expectancy is about 2 years, keep your equipment and accessories free of dust and dirt, and follow these rules:

- Please clean the equipment before use according to chapter 6.2; Remove the batteries inside the battery cassette if the equipment will not be operated for a long time.
- Replace the batteries in time when the battery voltage indicate lamps were empty.
- It is recommended that the equipment should be kept in a dry environment with no corrosive gases and good ventilation anytime. The moisture and high-light environments will affect its lifetime and even might damage the equipment.
- It is best to preserve the product in a place where the temperature is between -20 to 60°C and the relative humidity is less than 95%.
- The packed equipment can be transported by ordinary conveyance. The equipment cannot be transported mixed with toxic, harmful, corrosive materials.

WARNING:

No modification of this equipment is allowed.

9.2 Disposal

Dispose of the pulse oximeter in accordance with local environment and waste disposal laws and regulations.

10. CLEANING/DISINFECTION

CAUTIONS

- Never immerse or soak the oximeter.
- We recommend that the oximeter be cleaned and disinfected after use every time or determined by your hospital's policy, to avoid long term damage to the oximeter.
- Never use cleaning agents/disinfectants other than the recommended.
- The sensor component is not cleaned and disinfected during testing.

10.1 Cleaning

The recommended cleaning agents include: water

- Shut down the pulse oximeter and remove the battery.
- Clean the oximeter with cotton or soft cloth moistened with water.
- After cleaning, wipe off the water with a soft cloth.
- Allow the oximeter to air dry.

10.2 Disinfection

The recommended disinfectants include: ethanol 70%, isopropanol 70%.

- Shut down the pulse oximeter and remove the battery.
- Clean the oximeter as instructed above.
- Disinfect the oximeter with cotton or soft cloth moistened with one of the recommended disinfectants.
- After disinfection, be sure to wipe off the disinfectant left on the oximeter with a soft cloth moistened with water.
- Allow the oximeter to air dry.

11. ACCESSORIES

- One lanyard
- Two AAA batteries
- One user manual
- One certificate card

Note:

For configuration of accessories please refer to the product package list.

12. TROUBLESHOOTING

WARNINGS:

- Necessary maintenance must be performed by qualified service personal ONLY.
- Users are NOT permitted to maintain the equipment by themselves.
- There are NO replaceable components in the equipment.

Trouble	Possible Reason	Solution
The Oximeter can't turn to measure mode	<ul style="list-style-type: none"> • The batteries are completely exhausted • An incorrect battery installation • The oximeter breakdown 	<ul style="list-style-type: none"> • Please replace batteries • Verify and correct the batteries installation • Please contact local service
The display is off suddenly	<p>The device will turn into sleep mode automatically if there is no signal in 8 seconds</p> <p>The batteries are completely exhausted</p>	<p>Press the button again to reactivate the oximeter</p> <p>Replace batteries</p>
The Spo2 and Pulse Rate display unstable	<p>The luminescent or photoelectric window is sheltered by some object</p> <p>Excessive movement</p> <p>The finger is not placed inside deep enough</p> <p>Finger size is not within the recommended range</p> <p>Excessive ambient light</p> <p>Pulse rate value of the cyclical fluctuations</p>	<p>Check the luminescent and photoelectric window</p> <p>Stop moving finger, hand and body</p> <p>Place the finger properly and try again.</p> <p>Change another finger</p> <p>Avoid the excessive light</p> <p>The measurement is normal, and the patient is arrhythmia.</p>
The Spo2 and PR are not displayed normally	<p>The finger is not properly positioned</p> <p>The patient's SpO2 is too low to be detected</p>	<p>Place the finger properly and try again.</p> <p>Try again, GO to a hospital for a diagnosis if you are sure the device works all right</p>

13. CUSTOMER SUPPORT

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