

ABOUT US

Driven by the passion for innovation, we at Dr Trust endeavour to provide our customers with the latest medical inventions with an objective to promote good health and wellness all around the world. All the medical devices and health monitors provided by Dr Trust are supported by accurate, latest and ground breaking technologies, innovated at our headquarters in NY, USA. All our products adhere to the most stringent CE and FDA guidelines and are strongly recommended by doctors and health practitioners. Our products are designed in the utmost exemplary ways to ensure that their accuracy and convenience are unrivalled. The ease of their use and operation makes them even more suitable for users of all age groups.

Dr Trust strives to enhance the quality of lifestyle by providing with the most trusted and innovative health care and wellness products. Being a renowned global leader in health care products, Dr Trust ensures that our technically efficient team works dynamically and tirelessly to provide the best of the medical devices to our clients. The products that we have to offer are suitably designed for use at homes, laboratories and hospitals.

Our ground breaking solutions allow you to monitor your health in the easiest ways possible. In today's era when all of our lives are too hassled to handle, it becomes a bit difficult to pay attention to our health. But it has now become easier with the coming of the monitoring devices which can be conveniently used at homes and even on the go.

We bring to you a variety of best self medical devices, trusted and used by Doctors, medical professionals and home users all over the world.

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Dr Trust Pulse Oximeter- 213

Quick start Guide

Step 1
Install 2 AAA batteries into battery cassette in correct polarities and cover it.

Step 3
Gently release the clamp and press the power button to ON the oximeter.

Step 5
Keep the probe ON for as long as needed to monitor your pulse and oxygen saturation.

Step 2
Open the clamp and insert a finger into the oximeter.

Step 4
Read the displayed SpO2%, PI and PR measuring values after a few seconds.

Step 6
Once the test is over, the clip or probe will be removed.

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SAFETY

Instructions for the Safe Operation and Use of the Dr Trust Pulse Oximeter- 213

- Do not attempt to service the Pulse Oximeter. Only qualified service personnel should attempt any needed internal servicing.
- Prolonged use or the patient's condition may require changing the sensor site periodically. Change sensor site and check skin integrity, circulatory status, and correct alignment at least every 2 hours.
- SpO2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, or direct sunlight, for example) if necessary.
- 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 may cause inaccurate SpO2 readings.
- The device should be kept at least 10 minutes from non-working temperature to normal temperature.
- The device is non-sterile and not intended to be sterilized.

Warnings

WARNING: Although the ME equipment conforms to the intent of the standard EN 60601-1-2 in relation to electromagnetic compatibility, electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive device.

WARNING: The portable and mobile RF communication equipment can affect this instrument's normal operation.

WARNING: EXPLOSION HAZARD — Do not use the Dr Trust Pulse Oximeter- 213 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: Do not throw batteries in fire as this may cause them to explode.

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WARNING: EXPLOSION HAZARD

Do not use the Pulse Oximeter in an MRI or CT environment.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.

WARNING: Do not use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

WARNING: 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.

WARNING: 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.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Dr Trust Pulse Oximeter- 213, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: High-pressure sterilization cannot be used on the device.

CAUTION: Keep the operating environment free of dust, vibrations, corrosive, or flammable materials, and extremes of temperature and humidity.

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CAUTION:

Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

CAUTION: Never use sharp or pointed objects to operate the front-panel switches.

CAUTION: The batteries must be taken out from the battery compartment if the device will not be used for a long time.

CAUTION: The device shall only be used if the battery cover is closed.

CAUTION: The batteries must be proper disposed according to local regulation after their use.

CAUTION: The device should keep away from the children, pets and pests to avoid swallowing.

CAUTION: The device cannot be used to measure the child below 3 years as the test result is not guaranteed to accurate.

CAUTION: The Pulse Oximeter is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.

CAUTION: The patient is an intended operator and can perform the maintenance of the equipment.

CAUTION: A function tester cannot be used to assess the accuracy of a Pulse Oximeter monitor or sensor.

CAUTION: Pulse simulator shall be used to assess pulse rate Accuracy. The measured pulse rate is compared to the preset pulse rate value in simulator. Accuracy data is calculated using the root-mean-square (Arms value) for all subjects.

Clinical testing is used to establish the SpO2 accuracy. The measured arterial SpO2 value (SpO2) of the sensor is compared to arterial hemoglobin oxygen (SaO2) 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 SpO2 range of 70-100%. Accuracy data is calculated using the root-mean-square (Arms value) for all subjects. Only about two-thirds of PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by a CO-oximeter

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1.3. Definitions and Symbols

Symbols	Description	Symbols	Description
	Type BF Equipment		Batch code*
	Information of manufacture including name and address		Date of manufacture*
	Temperature limitation		Serial No*
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling		Information of EU authorized representative
	Follow user manual		Caution: The information you should know to protect the equipment from possible damage
	Anti-dust & Anti-water class		Note: The important information you should know

Warning: The information you should know to protect patients and medical staff from possible injury

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INTRODUCTION

2.1 Brief Device Description

The Oximeter can be used to measure human Hemoglobin Saturation and pulse rate through finger. The product is suitable for family, hospital (including clinical use in internist/surgery, pediatrics, etc), Oxygen Bar, social medical organizations, physical care in sports etc.

2.2 Intended Use

The product is intended for noninvasive monitoring of the adult or child's SpO2 and PR.

2.3. Contraindication

It is not for intensive care or person whose finger is injured.

2.4 Product Features

- Lightweight for carrying and Easy-To-Use.
- Manually adjust the direction of insertion.
- OLED display, simultaneous display for testing value and plethysmogram.
- Real-time spot-checks.
- Low Battery voltage indicator.
- Automatically standby or sleep.
- Sleep monitoring function.
- Data storing and data analysis function.

3.1 Installation

3.1.1 Install battery

Install two AAA batteries into battery compartment in correct polarities and put cover back on.

WARNING: Do not attempt to recharge normal alkaline batteries, they may leak and may cause fire or explosion.

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INSTALLATION, SETUP, AND OPERATION

3.2 Display Description

Note: When battery power is at the lowest level, the battery capacity displays symbol of low battery in OLED, to remind users of replacement of battery.

3.3 Install Hanging Cable

Let the thin end of the rope go through the cable hole, next let the big point of cable go through the hole, then tighten the cable.

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3.4 Data analysis

There are two ways to operate the button according to the pressing time, long-press is longer than 0.5 second and short-press is shorter than 0.5 second. Short-press is used to select a item by moving a light bar to the line of this item, long-press is used to change the item's value, status or open a new page.

Long press on the power button, the oximeter will display Data Analysis page as shown in Figure 3.41. When the bar is on the second row, long-press make the screen display the next page (as Figure 3.4.2 and Figure 3.4.3).

3.4.1 How to start a new analysis?

Just before going to bed, select the item of "Store", change its status to "on", select "OK" when the display is shown as Figure 3.4.1. Then put the Finger into rubber hole of the oximeter to start a new continuous measurement. Take off the oximeter 2 hours later or after getting up, the oximeter will shut down automatically after the device is taken off. When storing mode is working, the oximeter will display "Rec" and battery volume alternately in the same position of screen. The maximum of recording time is 8 hours.

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3.4.2 How to see the Analysis Results?

Turn on the oximeter again, long press to enter "Data analysis" page as shown in Figure 3.4.1. Now the status of "Store" is off, and "Summary Graph" and "Statistics" is OK.

Select "Summary Graph", long press to open the graph page as shown in Figure 3.4.5. Each full-page display 15 minutes' data. Long press on the power button, the oximeter will display Data Analysis page as shown in Figure 3.4.1. When the bar is on the second row, long-press make the screen display the next page (as Figure 3.4.2 and Figure 3.4.3).

Select "Statistics" and long press to open the Statistics page as shown in Figure 3.4.6.

Pulse oximeter indicates the severity of hypoxia during sleep, if this number is greater than 5, please go to the hospital for further examination.

Pulse Oximeter (Oxygen desaturation Index of 4%) means Events of Desaturation which is not less than 4% per hour during the total recording time.

*Time means the total recording time of fast storage.

Max SpO2/PR is the maximum SpO2/PR value of the entire storage.

Min SpO2/PR is the minimum SpO2/PR value of the entire storage.

Note: If starting a new storage and the time is longer than ten minutes, the previous storage information will be replaced.

Note: "Summary Graph" and "Statistics" cannot be opened when the storage is empty.

Note: The analysis results of Dr Trust Pulse Oximeter 213 may be inaccurate when total sleep time is less than 2 hours.

WARNING: This pulse oximeter is not permitted for either medical diagnosis or relevant advertising.

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3.5 Settings of the oximeter

3.5.1 Settings in Figure 3.4.2

Select "Alarm"/"Beep"/"Demo", long press the button to turn on/off the item.

Select "Reset", long press the button will reset all settings.

Select "Brightness", long press the button to change the brightness of screen.

3.5.2 Settings in Figure 3.4.3

Select the SpO2 or PR alarm limits, long-press will change the limits.

Select "+/-", long-press will set the direction of changing the limits. "+", "is increasing the number," "-" is decreasing the number.

3.5.3 Settings in Figure 3.4.4

Select "Store", long press to enter "Data analysis" page as shown in Figure 3.4.1. Now the status of "Store" is off, and "Summary Graph" and "Statistics" is OK.

Select "Summary Graph", long press to open the graph page as shown in Figure 3.4.5. Each full-page display 15 minutes' data. Long press on the power button, the oximeter will display Data Analysis page as shown in Figure 3.4.1. When the bar is on the second row, long-press make the screen display the next page (as Figure 3.4.2 and Figure 3.4.3).

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MAINTENANCE AND TROUBLESHOOTING

5.1 Maintenance

Replace the batteries timely when battery indication is low. Clean surface of the Fingertip Pulse Oximeter before it is used in diagnosis patients.

Remove the batteries inside the battery cassette if the Oximeter will not be operated for a long time.

It is better to preserve the product in a place where ambient temperature is -25°C to 55°C (-13°F to 131°F) and humidity is 15%-93%. Regular inspection to make sure that no obvious damage existed to affect the safety and performance of device.

No flammable substance, overlap or lower temperature and humidity existed in operation conditions.

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5.2 Troubleshooting

Table 5.2.1 Troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemoglobin or heart rate cannot be shown normally	1. Finger is not plugged correctly. 2. Patient's perfusion is too low to be measured.	1. Retry by plugging the finger. 2. Try some more times, if you can make sure about no problem existing in the
Oxyhemoglobin or heart rate is shown unstably	1. Finger might not be plugged deep enough. 2. Finger is trembling, or patient's body is in movement status	1. Retry by plugging the finger. 2. Try not to move. Let the patient keep calm.
Oxyhemoglobin or heart rate is abnormal, and cause sound remind	1. Finger is not plugged correctly. 2. Patient's SPO2&PR is abnormal.	1. Retry by plugging the finger. 2. Go to the hospital for further
The Oximeter cannot be powered on	1. Power of batteries might be inadequate or not be there at all. 2. Batteries might be installed incorrectly	1. Please replace batteries 2. Please reinstall the batteries 3. Please contact with local customer service center
The screen is suddenly off	1. The product is automatically powered off when no signal is detected longer than 15 seconds 2. Power quantity of the batteries is exhausted.	1. Normal 2. Replace the batteries

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SPECIFICATION

Name	Dr Trust Pulse Oximeter - 213
Anti-electric Shock Type	Internally powered equipment
Anti-electric Shock Equipment Degree	Type BF
EMC type	Type B Class I
Enclosure Degree of ingress protection	IP22
Internal Power:	2xAAA 1.5v alkaline battery
Power Consumption:	Below 45mA
Screen	0.9"LED
SpO2 Display	35-100%
Pulse rate Display	30-250 BPM
Resolution	SpO2: 1% Pulse rate: 1BPM
Measure Accuracy	SpO2 +3% (70%-100%) Unspecified (<70%)
Data averaging and another signal processing	BS
Data Update Period	1S
Operating Environment	Temperature: 5°C to 40°C (41°F to 104°F) Humidity: 15% to 80% non-condensing Air Pressure: 70Kpa-106Kpa
Storage & Transport environment	Temperature: -25-55°C (-13°F to 131°F) Humidity: 15% to 93% non-condensing
Dimensions	62mm*34mm*31mm
Weight	50±2g including 2 x AAA battery
Accessories	AAA battery-----2 pcs Hang String-----1 pc User Manual-----1 pc

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MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration – electromagnetic emission –for all EQUIPMENT and SYSTEMS

Guidance and Manufacturer's Declaration – Electromagnetic Emission

The Dr Trust Pulse Oximeter-213 is intended for use in the electromagnetic environment specified below. The customer or the user of Dr Trust Pulse Oximeter-213 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Dr Trust Pulse Oximeter-213 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 Dr Trust Pulse Oximeter-213 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

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Guidance and manufacturer's declaration – electromagnetic immunity –for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity

The Dr Trust Pulse Oximeter-213 is intended for use in the electromagnetic environment specified below. The user of the Dr Trust Pulse Oximeter-213 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with carpets, the relative humidity should be at least 30 %.
Electrostatic burst IEC 61000-4-4	± 2 kV for power transients ± 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dr Trust Pulse Oximeter-213 requires continued operation during power mains interruptions, it is recommended that the Dr Trust Pulse Oximeter-213 be powered from an uninterruptible power supply or a battery.

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Power frequency magnetic field IEC 61000-4-8

Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE 1: UT is the a. c. mains voltage prior to application of the test level.

Guidance and manufacturer's declarations – electromagnetic immunity –for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity

The Dr Trust Pulse Oximeter-213 is intended for use in the electromagnetic environment specified below. The user of the Dr Trust Pulse Oximeter-213 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 3 Vrms	N/A	Portable and mobile RF communications equipment should be that of a typical commercial or hospital environment. If the user of the Dr Trust Pulse Oximeter-213 requires continued operation during power mains interruptions, it is recommended that the Dr Trust Pulse Oximeter-213 be powered from an uninterruptible power supply or a battery.
Radiated RF IEC 61000-4-3	80 MHz to 27 GHz 10 V/m	10 V/m	Portable and mobile RF communications equipment should be that of a typical commercial or hospital environment. If the user of the Dr Trust Pulse Oximeter-213 requires continued operation during power mains interruptions, it is recommended that the Dr Trust Pulse Oximeter-213 be powered from an uninterruptible power supply or a battery.

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Immunity test IEC 60601 test level Compliance level Electromagnetic Environment - Guidance

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations 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 Dr Trust Pulse Oximeter-213 is used exceeds the applicable RF compliance level above, the Dr Trust Pulse Oximeter-213 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Dr Trust Pulse Oximeter-213.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

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

Recommended separation distances between portable and mobile RF communications equipment and the Dr Trust Pulse Oximeter-213

The Dr Trust Pulse Oximeter-213 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Dr Trust Pulse Oximeter-213 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dr Trust Pulse Oximeter-213 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter	Separation distance according to frequency of transmitter
W	150 kHz to 80 MHz 150 kHz to 80 MHz 800 MHz to 2.7 GHz
0.01	/ 0.12 0.23
0.1	/ 0.38 0.73
1	/ 1.2 2.3
10	/ 3.8 7.3
100	/ 12 2.3

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DISPOSAL

Observe the applicable regulations when disposing of the Dr Trust Pulse Oximeter-213 and batteries.

This pulse oximeter must not be disposed of together with domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether or not they contain toxic substances, at a municipal or commercial collection point so that they can be disposed of in an environmentally acceptable manner.

Please remove the batteries before disposing of the Dr Trust Pulse Oximeter-213. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop.

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