

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.

Dr Trust Pulse Oximeter – 217

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

1.1 Instructions for the Safe Operation and Use of the Fingertip Pulse Oximeter

- Do not attempt to service the Dr Trust Pulse Oximeter – 217.
- 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. The following reason will cause interference to the testing accuracy of the Fingertip Pulse Oximeter.
- High-frequency electro-surgical equipment.
- 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.

WARNING: EXPLOSION HAZARD

Do not use the Fingertip Pulse Oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other material may occur.

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

WARNING: Do not attempt to recharge normal dry-cell batteries, they may leak. And may cause a fire or even explode.

WARNING: Do not use the Dr Trust Fingertip Pulse Oximeter- 217 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.

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

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.

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		The information you should know to protect the equipment from possible damage
	Anti-dust & Anti-water class		The important information you should know
	The information you should know to protect patients and medical staff from possible injury		

INTRODUCTION

2.1 General

This chapter provides a general description of the Dr Trust Pulse Oximeter – 217 including:

- Brief device description
- Product features

2.2 Indication for Use/Intended Use

The Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of Arterial Hemoglobin (SpO2) and Pulse Rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environments.

2.3. Brief Device Description

The Dr Trust Fingertip Pulse Oximeter - 217, based on all digital technology, is intended for noninvasive spot-check measurement of functional Oxygen Saturation of Arterial Hemoglobin (SpO2), Advanced DSP algorithm* can minimize the influence of motion artifact and improve measurement accuracy of low perfusion*.

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

2.4 Product Features

- Lightweight for carrying and easy-to-use.
- Manually adjust the direction of interface.
- Color OLED display, simultaneous display for testing value and plethysmogram.
- Low Perfusion: 0.3%. (Advanced DSP algorithm can improve measurement accuracy, under the condition of low perfusion).
- Visual & sound reminder function. Real-time spot-checks.
- Low Battery voltage indicator.
- Automatically switch off.
- Standard two AAA 1.5V Alkaline Battery support more than 20 hours continuous work.

CAUTION:

- The device cannot be used to measure the child below 3 years as the test result is not guarantee to accurate.
- The Dr Trust Fingertip Pulse Oximeter 217 is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- A function tester cannot be used to assess the accuracy of a Fingertip Pulse Oximeter monitor or sensor.
- Clinical testing is used to establish the SpO2 accuracy. The measured arterial hemoglobin saturation 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 FINGERTIP PULSE OXIMETER EQUIPMENT measurements can be expected to fall within ±Arms of the value measured by CO-oximeter.
- 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.

*DSP algorithm: Digital Signal Processor algorithm.

*Low Perfusion: In physiology, perfusion is the process of a body delivering blood to a capillary bed in its biological tissue. Under the condition of low perfusion, the measurement of non-invasive saturation of pulse-blood oxygen is low-accurate.

*Plethysmograph: It is an instrument for measuring changes in volume within an organ or whole body (usually resulting from fluctuations in the amount of blood or air it contains).

INSTALLATION, SETUP, AND OPERATION

3.1 Description of the Front Panel (as figure 3.1.1)

Item	Name	Description
1	Power button	Turn on the machine
2	OLED Panel	Display the SpO2/PR data & Plethysmogram
3	Battery Compartment	

3.2 Display

After switching on, the OLED display of the Dr Trust Pulse Oximeter-217 is as follows:

3.3 Parameter setting

When the device is under measuring interface, press the Parameter setting button for 1 second in order to enter into menu page (figure 3.3.1 and figure 3.3.2). There are two submenus for choice:

Remind Setup	Limit Setup
Sound Remind	SpO2 HI
Beep on	SpO2 LO
Beep off	PR HI
Restore OK	PR LO
Brightness Exit	Exit

3.3.1 Remind Setup

Press the Parameter setting button for 1 second and enter into the Remind Setup. User can adjust the setting through moving the "*" symbol to the back of the Sound Reminder, Beep, Restore or Brightness.

Sound Reminder

Press the Parameter setting button for 1 second, move the "*" symbol to the back of Sound Reminder, long press the Parameter setting button to turn it on/off.

(Note: If the measured value exceeds the maximum or minimum value of SpO2 or PR, there will give off sound when sound reminder is turned on.)

Beep

Press the Parameter setting button for 1 second, move the "*" symbol to the back of Beep, long press the Parameter setting button to turn it on/off.

(Note: When Beep is turned on, the sound emitted during the test indicates the pulse rate sound)

Restore

When the "*" symbol shows behind "Restore", long press the Parameter setting button can be changed to "OK", which causes the device to restore factory data setting.

Demo

Press the Parameter setting button for 1 second, move the "*" symbol to the back of Demo, long press the Parameter setting button to turn it on/off.

Brightness

When the "*" symbol show on "Brightness", long press the Parameter setting button to change the Brightness value from 1 to 5.

3.3.2 Limit Value Setting

When the * symbol show on the Remind Setup, long press the Parameter setting button until enter into the Reminder Limit setup menu (figure 3.3.2). User can press the Parameter setting button to select the items. And press the Parameter setting button for 1 second to change the data you need.

On the Reminder Limit setup menu page (figure 3.3.2), when the * symbol show behind the "+/-". Press Parameter setting button for 1 second to change the "+" to "-" or change the "-" to "+". When "-" shows on the right side, press the Parameter setting button for 1 second, move the "*" after the SpO2 Hi or PR Hi setting, can increase the value to a higher value (until it reaches to the highest.)

When "+" shows on the right side, press the Parameter setting button for 1 second, move the "*" after the SpO2 Lo or PR Lo value setting, can reduce the value to a lower value (until it reaches to the lowest).

Note:

- The sound reminder have 1 second delay after the incorrect result being detected.
- The customer can preset the limit value to the 98 or 99 to check whether it is normal for sound reminder setting.

3.4 Operation

3.4.1 Install battery

Installing two AAA batteries into battery cassette in correct polarities and cover it.

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

3.4.2 Turn the Fingertip Pulse Oximeter on

Put one of fingers into rubber hole of the Oximeter (it is best to put the finger thoroughly) with nail surface upward, then releasing the clamp.

Press power button for 2 seconds to turn the Fingertip Pulse Oximeter on. The oximeter will be automatically powered off when no finger in the device for longer than 16 seconds.

3.4.3 Read correspondent data from display screen.

Note:

- When battery power is at lowest level, the battery capacity indicates symbol of in OLED, remind users of replacement of battery.
- The plethysmogram can be regarded as correct if the wave is fluctuated regularly.

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-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, overtop or lower temperature and humidity existed in operation conditions.

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 16 seconds. 2. Power quantity of the batteries is exhausted.	1. Normal 2. Replace the batteries

SPECIFICATION

Name	Dr Trust Pulse Oximeter - 217
Anti-electric Shock Type	Internally powered equipment
Anti-electric Shock equipment Degree	Type BF
EMC Type	Type B Class 1
Enclosure Degree of ingress protection	IP22
Internal Power:	2xAAA 1.5V alkaline battery
Power Consumption	Below 45mA
Screen	OLED
SpO2 Display	35-100%
Pulse rate Display	30-250 BPM
PI Display	0.20% SpO2: 1% Pulse rate: 1BPM
Resolution	
Measure Accuracy	SpO2 +3% (70%-100%) PI: 0.1% (±70%)
Operating Environment	Temperature: 5°C to 40°C (41°F to 104°F) Humidity: 15% to 93% 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

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 -217 is intended for use in the electromagnetic environment specified below. The customer or the user of Dr Trust Pulse Oximeter -217 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 -217 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 -217 is suitable for use in all establishments, 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	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

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

Guidance and manufacturer's declaration – electromagnetic immunity

The Dr Trust Pulse Oximeter -217 is intended for use in the electromagnetic environment specified below. The user of the Dr Trust Pulse Oximeter -217 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 synthetic material, the relative humidity should be at least 30 %.
Electrostatic burst IEC 61000-4-4	± 2 kV for power lines ± 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.
Voltage dips, short-circuits, variations and voltage variations on power supply input lines IEC 61000-4-11	0% UT: 0.5 cycle 80% UT: 30% 100% UT: 25% 0% UT: 1 cycle 70% UT: 25/30 cycle at 0% UT: 250/300 cycle	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Dr Trust Pulse Oximeter -217 requires continued operation during power mains interruptions, it is recommended that the Dr Trust Pulse Oximeter -217 be powered from an uninterruptible power supply or a battery.

Power frequency magnetic fields

Power frequency (50/60 Hz) field IEC 61000-4-6	30 A/m	30 A/m
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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 -217 is intended for use in the electromagnetic environment specified below. The user of the Dr Trust Pulse Oximeter -217 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	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Dr Trust Pulse Oximeter -217, including cables, than the recommended separation distance calculated from the frequency applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	10 V/m	10 V/m	Recommended separation distance $d = \frac{3.5}{E_1} \sqrt{P}$ $d = \frac{3.5}{E_1} \sqrt{P}$ $d = \frac{3.5}{E_1} \sqrt{P}$

80 MHz to 800 MHz to 2.5 GHz

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 -217 is used exceeds the applicable RF compliance level above, the Dr Trust Pulse Oximeter -217 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 -217.		
b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.		

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 -217

The Dr Trust Pulse Oximeter -217 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 -217 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dr Trust Pulse Oximeter -217 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
150 kHz to 80 MHz	150 kHz to 80 MHz
800 MHz to 2.7 GHz	800 MHz to 2.7 GHz
0.01 W	/ 0.12 0.23
0.1 W	/ 0.38 0.73
1 W	/ 1.2 2.3
10 W	/ 3.8 7.3
100 W	/ 12 2.3

DISPOSAL

Observe the applicable regulations when disposing of the Dr Trust Pulse Oximeter -217 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 -217. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop.

CUSTOMER SUPPORT

CONTACT ADDRESS
USA
Nureca INCLUSA
276 5th Avenue, Suite 704-397,
New York (NY)-10001, USA
INDIA
Corporate Office (Mumbai)
Nureca Limited
128 Gala Number Udoy Bhavan,
1st Floor Sonawala Lane, Goregaon East
Mumbai City Maharashtra 400063
Contact us
India: +91-757013265 / +91-9356658436
Website: www.drtrust.in
Corp Website: www.nureca.com
Email: customercare@nureca.com
Connect with us on social networks
Facebook: [drtrustusa](https://www.facebook.com/drtrustusa)
Instagram: [drtrustusa](https://www.instagram.com/drtrustusa)
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