

12. 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®

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SIGNATURE FINGERTIP Pulse Oximeter (Black) - 201



Scan to View
Product Demo

www.drtrustusa.com/201

Thank you for purchasing the Dr Trust USA Signature Fingertip Pulse Oximeter (Black) - 201. Please read this manual carefully to operate it with care and safety.

Please visit www.drtrustusa.com

**USER
INSTRUCTIONS**

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1. INTRODUCTION

The Dr Trust USA Signature Fingertip Pulse Oximeter (Black) - 201, 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 family, hospital (including clinical use in internist/surgery, anesthesia, pediatrics, intensive care etc.) oxygen bar, social medical organizations, physical care in sports etc. It takes note of below mentioned measurements;

***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:** 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).

***PI (Perfusion Index):** It is the ratio of the pulsatile blood flow to the non-pulsatile static blood flow in a patient's peripheral tissue, such as fingertip, toe, or ear lobe. Perfusion index is an indication of the pulse strength at the sensor site.

2. PRODUCT FEATURES

- Lightweight for carrying & easy-to-use.
- Manually adjust the direction of interface.
- Color OLED display, simultaneous display for testing value and plethysmogram*.
- Low Perfusion: 0.2%. (Advanced DSP algorithm can improve measurement accuracy, under the condition of low perfusion.)
- Visual & Sound reminder functions for 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.

3. SAFETY INSTRUCTIONS

Below are key instructions for the Safe operation and use of the Dr Trust USA Signature Fingertip Pulse Oximeter (Black) - 201.

1. Do not attempt to service the Dr Trust USA Signature Fingertip Pulse Oximeter (Black) - 201. Only qualified service personnel should attempt any needed internal servicing.

2. 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.

3. 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 Dr Trust USA Signature Fingertip Pulse Oximeter (Black) - 201.

- High-frequency electrosurgical 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 readings.

WARNINGS

- Do not use the Dr Trust USA Signature Fingertip Pulse Oximeter (Black) – 201 in the presence of flammable anesthetics or other same category materials as explosion may occur.
- Do not throw batteries in fire as this may cause them to explode.
- Do not attempt to recharge normal dry-cell batteries, they may leak. And may cause a fire or even explosion.
- Do not use the Dr Trust USA Signature Fingertip Pulse Oximeter (Black) – 201 in an MRI or CT environment.
- Do not modify this equipment without authorization of the manufacturer.
- Do not modify this equipment without authorization of the manufacturer.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.
- Keep the operating environment free of dust, vibrations, corrosive or flammable materials and extremes of temperature and humidity.

- 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.
- Never use sharp or pointed objects to operate the front-panel switches.
- The batteries must be taken out from the battery compartment if the device will not be used for a long time.
- The device shall only be used if the battery cover is closed.
- The batteries must be properly disposed according to local regulation after their use.
- The device should keep away from the children and pests to avoid swallowing.

CAUTIONS

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

It 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 (SPO₂) 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.

4. PRODUCT SETUP

4.1 Description of the Front Panel



Part Definition and Description

Item	Name	Description
1	Power Button	Turn on the machine
2	OLED Panel	Display the SPO2/PR data & Plethysmogram
3	Battery Compartment	To Put Batteries

4.2. Display

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



Figure 4.2 OLED Display

Parameter Setting

Press the direction button for one second, the oximeter will enter into parameter setting. There are two submenus for choice.

When the * signal shown on the Alarm Setup, press the direction button for 1 second and enter into the Sound Setting menu. Press the direction button for 1 second to turn on/off the alarm and beep.

When the * signal on the Sound setup, press the direction button for 1 second and enter into the Alarm Setting menu, you can press the direction button in turn to select the item. And press the direction button for 1 second to change the data you need.

On the sound setup menu when the * signal shown on front of the "+/-", sign "+" on the right side can be changed to "-" by pressing the direction button for 1 second.

When "+" shows on the right side, press the direction button for 1 second can increase the SPO2 and PR's highest and lowest alarm value.

When "-" shows on the right side, press the direction button for 1 second can reduce the SPO2 and PR's highest and lowest alarm value.

On the alarm Setup menu, when the "*" signal shown on "Restore", press the direction button for 1 second, the right side can be changed to "OK", which cause the device to restore factory setting data.

Demo Mode

On the Alarm setting menu, you can set the device in demo mode, which shows how the device can change six different display modes by short pressing Direction button. Turn off the demo mode by long pressing of Direction button.

Note: In demo mode, device can not perform the detecting function.



Change Brightness

On the Alarm Setup menu, when the * signal shown on "Brightness", the brightness takes a float from 1 to 5 by long pressing of Direction button.

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

On the Reminder Limit setup menu page, when the * symbol show behind the "+/-". Press direction button for 1 second to change the "+" to "-" or change the "-" to "+".

When "+" shows on the right side, press the direction 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.)

Remind Setup	*
Sound Reminder	on
BEEP	off
Demo	on
Restore	OK
Brightness	4
Exit	

Figure (a)

Limit Setup	*
SpO2 Hi	100
SpO2 Lo	94
PR Hi	130
PR Lo	50
+/-	+
Exit	

Figure (b)

When "-" shows on the right side, press the direction 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:

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

5. OPERATIONS

5.1. Install battery

Install 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.

5.2. Turning the Pulse Oximeter On/OFF

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 pulse oximeter ON. The oximeter will be automatically powered off when no finger in the device for longer than 16 seconds.

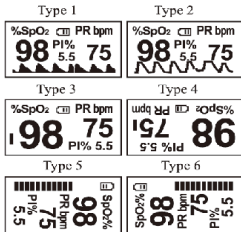


5.3. Reading the Correspondent Data from Display Screen.


Read pulse rate, PI, SPO2 data & Plethysmography on easy to read display.

5.4. Display Description of OLED

The display interface of "OLED" can rotate four directions with six different display modes after pressing the direction button for less than 0.5 second. It is shown as below:



Note:

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

6. CLEANING & DISINFECTION

A. Cleaning

- Switch off the power and take out the batteries before cleaning.

- Keep the exterior surface of the device clean and free of dust and dirt.
- Cleaning exterior surface (OLED display screen included) of the unit with a dry and soft cloth.
- Use 75% density of medical alcohol to clean the surface and use dry fabric with little alcohol to avoid alcohol permeates into the device.

B. Disinfection

- Disinfect the machine after every use especially when multiple patients use the machine in the hospital.
- Use 75% density of medical alcohol to clean the surface that contacting with the patient.

CAUTIONS

- Don't use strong solvent. For example, acetone.
- Never use an abrasive such as steel wool or metal polish.
- Do not allow any liquid into the product, and do not immerse any parts of the device into any liquid.
- Avoid pouring any liquid on the device while cleaning.
- Don't let remaining any cleaning solution on the surface of the device.

7. TROUBLESHOOTING & MAINTENANCE

7.1. Troubleshooting

Problems	Possible Reason	Resolutions
Oxyhemoglobin or heart rate cannot be shown normally	<ol style="list-style-type: none"> Finger is not plugged correctly. Patient's perfusion is too low to be measured. 	<ol style="list-style-type: none"> Retry by plugging the finger. Try some more times, if you can make sure about no problem existing in the product, please go to a hospital timely for exact diagnosis.
Oxyhemoglobin or heart rate is shown unstably	<ol style="list-style-type: none"> Finger might not be plugged deep enough Finger is trembling, or patient's body is in movement status 	<ol style="list-style-type: none"> Retry by plugging the finger Try not to move, Let the patient keep calm.

Oxyhemoglobin or heart rate is abnormal and cause sound reminder	<ol style="list-style-type: none"> Finger is not plugged correctly. Patient's SPO2 & PR is abnormal. 	<ol style="list-style-type: none"> Retry by plugging the finger Go to the hospital for further examination.
The Oximeter cannot be powered on	<ol style="list-style-type: none"> Power of batteries might be inadequate or not be there at all Batteries might be installed incorrectly The Oximeter might be damaged 	<ol style="list-style-type: none"> Please replace batteries Please reinstall the batteries Please contact with local customer service center
The screen are suddenly off	<ol style="list-style-type: none"> The product is automatically powered off when no signal is detected longer than 16 seconds Power quantity of the batteries is exhausted. 	<ol style="list-style-type: none"> Normal Replace the batteries

7.2. Maintenance

- Replace the batteries timely when battery indication is **low**. Clean surface of the Fingertip Pulse Oximeter before it is used in diagnosis for patients.
- Remove the batteries from 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 overtops, or lower temperature and humidity existed in operation conditions.

8. TECHNICAL SPECIFICATIONS

DR TRUST

General Data

Dimensions - 62 mm (l) x 34 mm (W) x 31 mm (d)

Net Weight - 50g (including 2xAAA battery)

Internal Power - 2 x AAA 1.5v alkaline battery

Power Consumption - Smaller than 30 mA (Normal)

Operating temperature - 5°C to 40 °C

Storage Temperature - (-10°C to 50 °C)

Relative Humidity -15% to 93% non-condensing

Air Pressure - 70Kpa-106Kpa

Environmental Factors

Operating Temperature	5°C to 40°C
Storage Temperature	-25°C to 55°C
Relative Humidity	15% to 93% non-condensing
Air Pressure	70Kpa-106Kpa

Electronics Parameters

Hemoglobin Saturation Display	35-100%	
Pulse Rate Display	30-250 BPM	
Resolution	Hemoglobin Saturation	1%
	Pulse rate	1 BPM
Measure Accuracy:	Hemoglobin Saturation	± 2% (90%-100%) ± 3% (70%-90%), Unspecified (<70%)
	Pulse rate	± 1 BPM
PI	Display	0-20%
	Resolution	0.1%
	Measure Accuracy	0-1%: 0.1% 1-20%: 1%

Probe LED Specification

	Wavelength	Radiant Power
RED	660 ± 2 nm	1.8 mW
Infra-RED	905 ± 2 nm	2.0 mW

9. CUSTOMER SUPPORT

DR TRUST

CONTACT ADDRESS

USA

Nureca INC. USA

276 5th Avenue, Suite 704-397, New York (NY) - 10001, USA

EUROPE

Nureca Gmbh

Colonus Carré, Subbelrather Str. 15a,
Cologne, 50823 Germany

INDIA

Corporate Office (Mumbai)

Nureca Private Limited

#103/104, Orbit Plaza, New Prabhadevi Marg,
Prabhadevi, Mumbai, Maharashtra-400025

Call On

USA : +1 212-234-45-63

India : +91-7527013265 / +91-9356658436

Website: www.drtrustusa.com

Email: customercare@nureca.com

Connect with us on social networks

Facebook: @drtrust

Instagram: @drtrustisin

Youtube: NurecaUSA

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