

21. 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.





Pulse Oximeter

204



USER INSTRUCTIONS

Dear customers, thank you very much for choosing the Dr Trust Pulse Oximeter - 204. Before using the pulse oximeter, please read the user manual carefully and follow the instructions stated herein. Failure to follow these instructions can cause measuring abnormality, equipment damage and personal injury.

Safety Information



Warnings alert the user to potential serious outcomes, such as injury or adverse events to the patient or user. Cautions alert the user to exercise care necessary for the safe and effective use of the pulse oximeter. Notes contain important information that may be overlooked or missed.

Warnings!

- Do not strike or needle the battery.
- Do not use the pulse oximeter in an MRI or CT environment.
- Keep away from source of fire and/or heat.
- Do not disassemble the oximeter or its accessories.
- Do not use the pulse oximeter in the presence of flammable anesthetics.
- Do not use the pulse oximeter in an explosive atmosphere.
- Chemicals from a broken OLED panel are toxic when ingested.
- Be careful when the oximeter has a broken display screen.
- Change measurement site and check skin integrity, circulatory status, and correct alignment at least in every 4 hours.
- Check the pulse oximeter application site frequently to determine the positioning of the measurement and circulation and skin sensitivity of the patient.
- Prolonged use or the patient's condition may require changing the measurement site periodically.
- Inaccurate measurements may be caused by autoclaving, ethylene oxide sterilizing, or immersing the sensors in liquid.

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1. GENERAL INTRODUCTION

Dr Trust Pulse Oximeter-204 allows you determine your blood oxygen saturation levels, pulse strength, and pulse rate correctly and quickly. It comes with precision sensors that allow the device to provide accurate pulse rate and oxygen saturation readings every time. The device has developed for the purpose of measuring the Pulse Oxygen Saturation (SpO₂) level in your arteries. SpO₂ is an estimate of arterial oxygen saturation, or SaO₂, which refers to the amount of oxygenated haemoglobin in the blood. More specifically, it is the percentage of oxygenated haemoglobin (haemoglobin containing oxygen) compared to the total amount of haemoglobin in the blood (oxygenated and non-oxygenated haemoglobin). It comes with Perfusion Index (PI), a critically acclaimed feature that conveniently informs you about the pulse strength of the sensor site. The PI value can be used to assess the viability of limbs after vascular, aesthetic (plastic), limb re-implantation, and orthopedic surgery, and where there is soft tissue swelling or aortic dissection.

2. PRODUCT OVERVIEW

The **Dr Trust Pulse Oximeter - 204** is a reliable, durable and portable pulse oximeter. It is powered by 2X1.5V (AAA size) alkaline batteries. The monitor contains an easy-to-read display with a backlight for making easy to read the measurements in the low-light conditions. You can use it in situations where alarms are required as it has alarm feature. It is only necessary for patient to put one of his fingers into a fingertip photoelectric sensor for diagnosis.

Main features

1. Displays SpO₂ level with pulse rate in a pulse bar graph, and waveform.
2. Operation of the product is simple and convenient.
3. The product is small in volume and convenient in carrying.
4. Power consumption of the product is low, and the two originally equipped AAA batteries can be operated continuously for hours.
5. Automatic power off feature saves power.
6. Display direction can be changed automatically for convenient view.
7. Digital OLED display screen comes with adjustable brightness.
8. A neck/wrist cord included with casing for secure handling.
9. Accurate readings in different views.
10. 30+ hours of continuous monitoring of pulse rate.

3. INTENDED USE AND SCOPE



The Dr Trust Pulse Oximeter - 204 is intended for monitoring Peripheral Oxygen Saturation (SpO_2) and Pulse Rate (PR) for adult, pediatric or neonatal patients continuously. It measures human Hemoglobin Saturation and pulse rate through finger and indicate the pulse intensity by the bar-display. It is designed for spot-checking and continuous monitoring of functional oxygen saturation and pulse rate. This device can be used in both hospital and non-hospital environments including departments of internal medicine in hospitals, outpatient departments, emergency rooms and ordinary departments in clinics, nursing hospitals and community medical institutions etc. It is used on finger of adult and pediatric patients.

4. ENVIRONMENT REQUIREMENTS

Storage Environment

- a) Temperature: $-40\text{ }^{\circ}\text{C} \sim +60\text{ }^{\circ}\text{C}$
- b) Relative humidity: $\leq 95\%$
- c) Atmospheric pressure: $500\text{ hPa} \sim 1060\text{ hPa}$

Operating Environment

- a) Temperature: $10\text{ }^{\circ}\text{C} \sim 40\text{ }^{\circ}\text{C}$
- b) Relative humidity: $\leq 75\%$
- c) Atmospheric pressure: $700\text{ hPa} \sim 1060\text{ hPa}$

5. PRINCIPLE OF MEASUREMENT

The pulse oximeter works by the principal of Photoelectric Oxyhemoglobin Inspection Technology. The 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. 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.

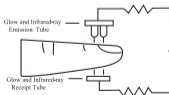


Figure 1
Operating principle

Cautions



1. The finger should be placed properly (see the attached illustration of this manual, Figure 5), or else it may cause inaccurate measurement.
2. The SpO₂ sensor and photoelectric receiving tube should be arranged in a way with the subject's arteriole in a position there between.
3. The SpO₂ sensor should not be used at a location or limb tied with arterial canal or blood pressure cuff or receiving intravenous injection.
4. Make sure the optical path is free from any optical obstacles like rubberized fabric.
5. Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual ruby light, infrared heater, direct sunlight etc.
6. Strenuous action of the subject or extreme electro surgical interference may also affect the accuracy.
7. Testee cannot use enamel or other makeup.

6. DISPLAY EXPLANATION

View of the Front Panel

Low-battery indication SpO₂

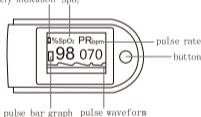


Figure 2 Front view

Color OLED screen displays:

Key information that appears on the display of the

Pulse Oximeter includes;

- SpO₂
- Pulse Rate (PR)
- Waveform and pulse bar
- 4 display modes.

7. BATTERY INSTALLATION

Step 1. Gently pull down the battery cover of your oximeter.

Step 2. Insert the battery into the opening on the back of it making sure the two AAA size batteries are placed properly in the right direction. (Refer Figure 3 to place the battery)

Step 3. Replace the back cover and press along the edges of it until it clicks into place.



Figure 3 Batteries installation

⚠ Cautions

Please take care when you insert the batteries. Improper insertion may damage the device.

8. MOUNTING THE LANYARD

Step 1. Put the end of the lanyard through the hole.

Step 2. Put another end of the lanyard through the first one and then tighten it.



Figure 4 Mounting the lanyard

9. OPERATING GUIDE

Insert the two batteries properly to the direction, and then replace the cover.

- Let the patient's finger put into the rubber cushions of the clip (make sure the finger is in the right position), and then clip the finger.
- Press the button once on front panel.
- Do not shake the finger and keep the patient at ease during the process.
- Human body is not recommended in movement status.
- You will get the result directly on OLED display.
- The button has two functions. When the device is in standby mode, pressing the button can exit it.
- When the device is in operation status, pressing the button long can change brightness of the screen.
- The device could change display direction according to the handing direction.



Put finger in this position

Figure 5

Caution



- Fingernails and the luminescent tube should be on the same side.
- The monitor also contains on-screen controls for changing monitor settings, such as alarm limits, volume, and the backlight. A lock function, when activated, protects against unintended changes to settings. The alarm system generates audible sound and visual signals that vary according to the priority of the alarm.

10. CLINICAL RESTRICTIONS

1. As the measurement is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO₂ waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.
2. For those with a substantial amount of staining dilution drug (such as methylene blue, indigo green and acid indigo blue), or carbon monoxide hemoglobin (COHb), or methionine (Me+Hb) or thiosalicylic hemoglobin, and some with icterus problem, the SpO₂ determination by this monitor may be inaccurate.
3. The drugs like dopamine, procaine, prilocaine, lidocaine and butacaine may also be a major factor blamed for serious error of SpO₂ measurement.
4. As the SpO₂ value serves as a reference value for judgement of anemic anoxia and toxic anoxia, some patients with serious anemia may also report good SpO₂ measurement.

11. ENSURING SAFE OPERATIONS

- Check the main unit and all accessories periodically to make sure that there is no visible damage that may affect patient's safety and monitoring performance about cables and transducers.
- It is recommended that the device should be inspected once a week at least. If there is obvious damage, stop using the monitor.
- Necessary maintenance must be performed by qualified service engineers ONLY. Users are not permitted to maintain it by themselves.
- The oximeter cannot be used together with devices not specified in the user's manual. Only the accessory that appointed or recommended by manufacture can be used with this device.
- This product is calibrated before leaving the factory. Keep the oximeter away from dust, vibration, corrosive substances, explosive materials, high temperature and moisture.
- If the oximeter gets wet, please stop operating it.
- When it is carried from cold environment to warm or humid environment, please do not use it immediately.
- DO NOT operate keys on front panel with sharp objects.

- High temperature or high-pressure steam disinfection of the pulse oximeter is not permitted. Please refer User Manual for instructions of cleaning and disinfection.
- Do not have the pulse oximeter immersed in liquid. When it needs cleaning, please wipe its surface with medical alcohol by soft material.
- Do not spray any liquid on the device directly.
- When cleaning the device with water, the temperature should be lower than 60°C.
- The fingers which are too thin or too cold may probably affect the normal measure of the patients' SpO₂ and pulse rate. Please clip the thick finger such as thumb and middle finger deeply enough into the probe.
- Do not use the device on infant or neonatal patients.
- The product is suitable for children above four years old and adults weigh between 15 kg to 110 kg.
- The device may not work for all patients. If you are unable to achieve stable readings, discontinue using it.
- The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.
- The waveform is normalized. Please read the measured value when the waveform on screen is equally and steady going, here this measured value is optimal value. And the waveform at the moment is the standard one.
- If some abnormal conditions appear on the screen during test process, pull out the finger and reinsert to restore normal use.
- The device has normal useful life for three years since the first electrified use.
- The lanyard attached to the product is made from Non- allergy material. If user is sensitive to the lanyard, stop using it.
- In addition, pay attention to the use of the lanyard. Do not wear it around the neck avoiding causes that may harm the patient.
- The instrument does not have low-voltage alarm function, it only shows the low-voltage. Please change the battery when the low battery sign flashes.
- Batteries must be removed if the device is going to be stored for more than one month, or else batteries may leak.
- The instrument does not have alarm function. Do not use the device in situations where alarm is required.
- A flexible circuit connects the two parts of the device. Do not twist or pull on the connection.

12. INSTRUCTIONS FOR USERS

- The uncomfortable or painful feeling may appear if using the device ceaselessly, especially for the microcirculation barrier patients.
- It is recommended that the sensor should not be applied to the same finger for over 2 hours.
- For the individual patient, there should be a more prudent inspecting in the placing process. The device cannot be clipped on the edema and tender tissue.
- The light (the infrared is invisible) emitted from the device is harmful to the eyes, so the user and the maintenance man, cannot stare at the light.
- Testee cannot use enamel or other makeup.
- Testee's fingernail cannot be too long.
- Please peruse the relative content about the clinical restrictions and caution.
- This device is not intended for treatment.

13. TECHNICAL SPECIFICATIONS

Display Format	OLED Display
SpO ₂ Measuring Range	0% ~ 300%
Pulse Rate Measuring Range	30 bpm ~ 250 bpm
Pulse Wave Display	Colorization display and the waveform display.
Power Requirements	2x1.5 V AAA alkaline battery (or using the rechargeable battery instead), adaptable range: 3.4 V - 3.8 V.
Power Consumption	Smaller than 20 mA
Resolution	1% for SpO ₂ and 1 bpm for Pulse Rate.
Measurement Accuracy	±2% in stage of 70%-100% SpO ₂ , and meaningless when stage being smaller than 70%. ±1 bpm during the pulse rate range of 30-99 bpm and ±1% during the pulse rate range of 100 ~ 250 bpm.
Measurement Performance in Weak Filling Condition	SpO ₂ and pulse rate can be shown correctly when pulse-filling ratio is 0.4%. SpO ₂ error is ±4%, pulse rate error is ±2 bpm during the pulse rate range of 30 ~ 99 bpm and ±1% during the pulse rate range of 100 ~ 250 bpm.
Resistance to surrounding light	The deviation between the value measured in the condition of man-made light or indoor natural light and that of darkness is less than ±2%.
It is equipped with a function switch	The product will enter standby mode when no signal is in the product within 5 seconds.
Optical Sensor	Red light (wavelength is 660 nm, 0.85 mW) Infrared (wavelength is 880 nm, 0.75 mW)

14. REPAIRING AND MAINTENANCE

- Please change the batteries when the low voltage displayed on the screen.
- Please clean the surface of the device before using. Wipe the device with medical alcohol first, and then let it dry in air or clean it by dry clean fabric.
- Using the medical alcohol to disinfect the product after use, prevent from cross infection for next time use.
- Please take out the batteries if the oximeter is not in use for a long time.
- The best storage environment of the device is - 40 °C to 60 °C ambient temperature and not higher than 95% relative humidity.
- Users are advised to calibrate the device termly (or according to the calibrating program of hospital).

Caution

- High-pressure sterilization cannot be used on the device.
- Do not immerse the device in liquid.
- It is recommended that the device should be kept in a dry environment. Humidity may reduce the useful life of the device, or even damage it.

15. ACCESSORIES












- One Lanyard
- Two batteries
- One User Manual
- Carry Pouch









16. TROUBLESHOOTING

Trouble	Possible Reason	Solution
The SpO ₂ and Pulse Rate can not be displayed normally	<ol style="list-style-type: none"> 1. The finger is not properly positioned. 2. The patient's SpO₂ is too low to be detected. 	<ol style="list-style-type: none"> 1. Place the finger properly and try again. 2. Try again; Go to a hospital for a diagnosis if you are sure the device works all right.
The SpO ₂ and Pulse Rate are not displayed stably	<ol style="list-style-type: none"> 1. The finger is not placed inside deep enough. 2. The finger is shaking or the patient is moving. 	<ol style="list-style-type: none"> 1. Place the finger properly and try again. 2. Let the patient keep calm
The device can not be turned on	<ol style="list-style-type: none"> 1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The malfunction of the device. 	<ol style="list-style-type: none"> 1. Change batteries. 2. Reinstall batteries. 3. Please contact the local service center.
The display is off suddenly	<ol style="list-style-type: none"> 1. The product will enter standby mode when no signal is in the product within 5 seconds 2. The batteries are almost drained. 	<ol style="list-style-type: none"> 1. Normal. 2. Change batteries.

17. KEY OF SYMBOLS



Symbol	Description
	Type BF
	Refer to instruction manual/booklet
%SpO ₂	The pulse oxygen saturation(%)
PRbpm	Pulse rate (bpm)
	The battery voltage indication is deficient (change the battery in time avoiding the inexact measure)
	1.No finger inserted 2. An indicator of signal inadequacy
	Battery positive electrode
	Battery cathode
	1.Exit standby mode. 2.Change brightness of the screen.
SN	Serial number
	Alarm indication
	Pulse sound indication
	WEEE (2002/96/EC)
IP22	International Protection
	Manufacturer

	Manufacture Date
	Storage and Transport Temperature limitation
	Storage and Transport Humidity limitation
	Storage and Transport Atmospheric pressure limitation
	This side up
	Fragile, handle with care
	Keep dry
	Recyclable

18. FUNCTION SPECIFICATION

Display Information	Display Mode
The Pulse Oxygen Saturation (SpO ₂)	OLED
Pulse Rate (PR)	OLED
Pulse Intensity (bar-graph)	OLED bar-graph display
Pulse wave	OLED

SpO₂ Parameter Specification	
Measuring range	0%~100%, (the resolution is 1%).
Accuracy	70%~100%:±2%, Below 70% unspecified.
Optical Sensor	Red light (wavelength is 660 nm) Infrared (wavelength is 880 nm)
Pulse Parameter Specification	
Measuring range	30 bpm ~ 250 bpm (the resolution is 1 bpm)
Accuracy	±2 bpm or±2% select larger
Pulse Intensity	
Range	Continuous bar-graph display, the higher display indicate the stronger pulse.
Battery Requirement	
1.5V (AAA size) alkaline batteries × 2 or rechargeable battery	
Battery Useful Life	
Two batteries can work continually for 20 hours	
Dimensions and Weight	
Dimensions	57(L) × 31(W) × 32(H) mm
Weight	About 50 g (with the batteries)

19. APPENDIX

Guidance and manufacture's declaration-electromagnetic emission for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration –electromagnetic emission
The Dr Trust Pulse Oximeter-204 is tested for use in the electromagnetic environment specified below. The customer or the user of the Dr Trust Pulse Oximeter-204 should assure that it is used in such an environment


Emission test	compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The <i>Dr Trust Pulse Oximeter-204</i> uses RF energy only for their 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	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emission IEC 61000-3-3	Not applicable	

**Guidance and manufacture's declaration-electromagnetic immunity
for all EQUIPMENT and SYSTEMS**

Guidance and manufacture's declaration-electromagnetic immunity			
The <i>Dr Trust Pulse Oximeter-204</i> is tended for use in the electromagnetic environment specified below. The customer or the user of the <i>Dr Trust Pulse Oximeter-204</i> should assure that it is used in such an environment			
Immunity test	IEC60601 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 floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50Hz) 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

**Guidance and manufacture's declaration-electromagnetic immunity
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Guidance and manufacture's declaration-electromagnetic immunity
The <i>Dr Trust Pulse Oximeter-204</i> is tended for use in the electromagnetic environment specified below. The customer or the user of the <i>Dr Trust Pulse Oximeter-204</i> should assure that it is used in such an environment

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Radiated RF IEC 61000 -4-3	3V/m 80MHz to 2.5GHz	3V/m	<p>Portable and mobile RF communication equipment should be used no closer to any part of the <i>Dr Trust Pulse Oximeter-204</i> including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>recommended separation distance</p> $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad \text{80MHz to 800MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad \text{800MHz to 2.5GHz}$
			<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

- 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-204* is used exceeds the applicable RF compliance level above, the *Dr Trust Pulse Oximeter-204* 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-204*.
- 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 or SYSTEM that not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *Dr Trust Pulse Oximeter-204*.

The *Dr Trust Pulse Oximeter-204* is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *Dr Trust Pulse Oximeter-204* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Dr Trust Pulse Oximeter-204* as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150KHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz
	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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.

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

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

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