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 headquarter 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 – 215 (Black, White, Blue)

Quick start Guide

Step 1 Install 2 AAA batteries into battery cassette in correct polarities and cover it.	Step 2 Open the clamp and insert a finger into the oximeter.
Step 3 Gently release the clamp and press the power button to ON the oximeter.	Step 4 Read the displayed SpO2% and pulse rate measuring values after a few seconds.
Step 5 Keep the probe ON for as long as needed to monitor your pulse and oxygen saturation.	Step 6 Once the test is over, the clip or probe will be removed.

Note:
The Medical instrument must be used according to instructions to ensure accurate readings.

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SAFETY

1.1 **Instructions for the Safe Operation and Use of the Dr Trust Pulse Oximeter–215**

- 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.
- The following reason will cause interference to the testing accuracy of the Dr Trust Pulse Oximeter–215.
- 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 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.

1.2 **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 or contact us.
The portable and mobile RF communication equipment can affect this instrument's

WARNING: EXPLOSION HAZARD — Do not use the Pulse Oximeter in a flammable atmosphere. Some concentrations of flammable anesthetics or other materials 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 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.

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	LOT	Batch code*
	Information of manufacture, including name and address		Date of manufacture*
	Temperature limitation	SN	Serial No*
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.	EC REP	Information of EU authorized representative
	Follow user manual	Caution:	The information you should know to protect the equipment from possible damage
IP22	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		
	If a Pulse Oximeter Monitor is not provided with a low SpO2 ALARM CONDITION, a statement to the effect "NoSpO2 Alarms" or Symbol IEC 60417-85319 (DB2002810) (see IEC 60601-1:88-2006 + AMD1:2012,Table C.1, Symbol 3).		

INTRODUCTION

2.1 **General**
This chapter provides a general description of the Dr Trust Pulse Oximeter–215 including:

- Brief device description
- Product features

2.2 **Indication for Use/ Intended Use**
The Dr Trust Pulse Oximeter – 215 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 Pulse Oximeter –215, 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 Dr Trust Pulse Oximeter–215 can be used to measure human SpO2 and heart rate through finger. The product is suitable for use in family, hospital (including clinical use in internist/surgery, Anesthesia, pediatrics and etc.) Oxygen Bar, social medical organizations, physical care in sports and etc.

2.4 **Product Features**

- Lightweight for carrying and easy-to-use.
- Manually adjust the direction of interface.
- Color LED display, simultaneous display for testing value and plethysmography.
- 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.

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.

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.

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.

***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)**

Figure 3.1.1 Parts of front & back panel

Item	Name	Description
1	Power button	Turn on the machine
2	LED Panel	Display the SPO2/PR data & Plethysmogram
3	Battery Compartment	

3.2 **Display**

After switching on, the LED display of the Dr Trust Pulse Oximeter-215 is as follows:

Figure 3.2.1 LED display

3.3 **Operation**

3.3.1 **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.

3.3.2 **Turn the Pulse Oximeter ON**

Put one of fingers into rubber hole of the Pulse Oximeter (it is best to put the finger thoroughly) with nail surface upward, then releasing the clamp.
Press power button to turn the Pulse Oximeter on. The oximeter will be automatically powered off when no finger in the device for longer than 16 seconds.

3.3.3 **Read correspondent data from display screen.**

3.3.4 **Press the "power" button for 3 seconds to turn on / off the beep sound**

Note: When battery power is at lowest level, the battery capacity indicates symbol ▭ of in LED, remind users of replacement of battery.

CLEANING AND DISINFECTION

4.1. **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 (LED 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.

4.2. **Disinfection**

Disinfect the machine after using by the patient if multiple patients use the machine in the hospital.
Use 75% density of medical alcohol to clean the surface that contacting with the patient.

CAUTION: Don't use strong solvent like acetone.

CAUTION: Never use an abrasive such as steel wool or metal polish.

CAUTION: Do not allow any liquid into the product, and do not immerse any parts of the device into any liquids.

CAUTION: Avoid pouring liquids on the device while cleaning.

CAUTION: Don't remain any cleaning solution on the surface of the device.

MAINTENANCE AND TROUBLESHOOTING

5.1 Maintenance

- Replace the batteries timely when battery indication is low. Clean surface of the Pulse Oximeter before it is used in diagnosis for 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-25-55 °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 overtops 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 of 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 is 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- 215
Anti-electric Shock Type	Internally powered equipment
Anti-electric Shock equipment Degree	Type BF
Enclosure Degree of ingress protection	IP22
Internal Power:	2xAAA 1.5v alkaline battery
Power Consumption	Below 45mA
Screen	0.96'LED
SpO2 Display	35-100%
Pulse rate Display	30-250 BPM
Resolution	SpO2: 1% Pulse rate: 1BPM
Measure Accuracy	SpO2 ±3% (70%-100%) PR: ±2BPM Unspecified (<70%)
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

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 -215 is intended for use in the electromagnetic environment specified below. The customer or the user of Dr Trust Pulse Oximeter -215 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 - 215 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 - 215 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 -215 is intended for use in the electromagnetic environment specified below. The user of the Dr Trust Pulse Oximeter -215 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 transient / burst IEC 6100 0-4-4	± 2 kV for power supply 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 interruptions and voltage variations on power supply input lines IEC 6100 0-4-11	0 % UT; 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0° 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 -215 requires continued operation during power mains interruptions, it is recommended that the Dr Trust Pulse Oximeter -215 be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000 -4-8	10 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE : 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 -215 is intended for use in the electromagnetic environment specified below. The user of the Dr Trust Pulse Oximeter -215 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 Radiated RF IEC 61000 -4-3	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM bands between 150 kHz to 80 MHz 80 MHz to 2.7 GHz	N/A 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Dr Trust Pulse Oximeter -215, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[\frac{3.5}{V_1}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ $d=[\frac{7}{E_1}]\sqrt{P}$ 80 MHz to 800 800 MHz to 2.5 GHz

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
			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 metres (m).b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:

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 -215 is used exceeds the applicable RF compliance level above, the Dr Trust Pulse Oximeter -215 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 -215.
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 -215

The Dr Trust Pulse Oximeter -215 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 -215 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dr Trust Pulse Oximeter -215 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter 150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_1}]\sqrt{P}$
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

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (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 80 MHz and 800 MHz, 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.

DISPOSAL

Observe the applicable regulations when disposing of the Dr Trust Pulse Oximeter -215 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 -215. 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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