

● 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.

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● ABOUT US ●

Step1

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

Step2

Open the clamp and insert a finger into the oximeter.

Step3

Gently release the clamp and press the power/direction button to ON the oximeter.

Step4

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

Step5

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

Step6

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

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PLEASE NOTE:
THIS MEDICAL INSTRUMENT MUST BE USED ACCORDING TO INSTRUCTIONS TO ENSURE ACCURATE READINGS.

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● SAFETY ●

Instructions for the Safe Operation and Use of the Dr Trust Junior Pulse Oximeter -212

1.1 Instructions

- 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 Junior Pulse Oximeter -212.
 - 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.

1.2 Warnings

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

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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 Junior Pulse Oximeter - 212 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: EXPLOSION HAZARD

Do not use the Dr Trust Junior Pulse Oximeter - 212 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.

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.

WARNING:

Don't 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.

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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 Junior Pulse Oximeter - 212, 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.

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.

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CAUTION:

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

CAUTION:

The batteries must be properly 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 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 the equipment.

CAUTION:

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

CAUTION:

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.

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*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 finger tip, toe, or earlobe. Perfusion index is an indication of the pulse strength at the sensor site.

1.3 Definitions and Symbols

Symbol	Description	Symbol	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		The information you should know to protect the equipment from possible damage
	Follow user manual		The important information you should know
	Anti Dust & Anti-Water Class		The information you should know to protect patients and medical staff from possible injury

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● INTRODUCTION ●

2.1 General

This chapter provides a general description of the Dr Trust Junior Pulse Oximeter -212 including:

- Brief device description
- Product features

2.2 Intended Use

The Dr Trust Junior Pulse Oximeter - 212 is a non-invasive device intended for spot checking 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 Junior Pulse Oximeter -212 can be used to measure human SpO₂ and heart rate through finger. The product is suitable for family hospital (including clinical use in internet/surgery, Anesthesia, pediatrics etc.) Oxygen Bar, social medical organizations, physical care in sports etc.

2.3 Brief Device Description

The Dr Trust Junior Pulse Oximeter - 212, 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 Junior Pulse Oximeter -212 can be used to measure human SpO₂ and heart rate through finger. The product is suitable for family hospital (including clinical use in internet/surgery, Anesthesia, pediatrics 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 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 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.

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● Installation, Setup and Operation ●

3.1 Description of the Front Panel (as figure 3.1.1)

This chapter provides a general description of the Dr Trust Junior Pulse Oximeter -212 including:




Figure 3.1.1 Parts of front & back panel

Table 3.1.1 Part Definition and Description

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

3.2 Display

After switching on, the OLED of the Dr Trust Junior Pulse Oximeter -212 looks like as follows:

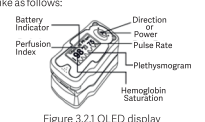


Figure 3.2.1 OLED display

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3.3 Suitable for OLED display parameter setting

When the device is under measuring interface, press the direction 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.

3.3.1 Remind Setup

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

- Visual Reminder**
Press the direction button for 1 second, move the "*" symbol to the back of Visual Reminder, long press the direction 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.)
- Restore**
When the "*" symbol show behind "Restore", long press the direction button to change to "OK", which causes the device restore factory data setting.
- Demo**
Press the direction button for 1 second, move the "*" symbol to the back of Demo, long press the direction button to turn it on/off.
- Brightness**
When the "*" symbol show on "Brightness", long press the direction 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 direction button until enter into the Remind Limit setup menu (figure 3.3.2). User can press the direction button to select the items. And press the direction button for 1 second to change the data you need.

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Remind Setup

Visual Reminder	on	Limit Setup	SpO ₂ HI	100
Beep	on	SpO ₂ LO	94	
Restore	off	PR HI	130	
Brightness	4	PR LO	50	

Exit

Figure 3.3.1

Limit Setup

SpO ₂ HI	100
SpO ₂ LO	94
PR HI	130
PR LO	50

Exit

Figure 3.3.2

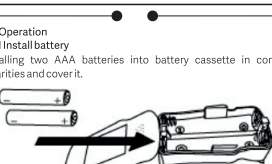
Note:
1. The visual reminder has 1 second delay after the incorrect result being detected.
2. The customer can preset the limit value to the 98 or 99 to check whether it is normal for visual reminder setting.
3. If no visual reminder that includes the capability to detect an SpO₂ or pulse rate physiological sound reminder condition is provided, a statement to that effect.
4. The range of the peak wavelengths and maximum optical output power of the light emitted by the pulse oximeter probe and a statement to the effect that information about wavelength range can be especially useful to clinicians.

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3.4 Operation

3.4.1 Install battery

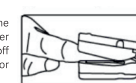
Installing two AAA batteries into battery cassette in correct polarities and cover it.



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

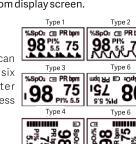
3.4.2 Turn the Pulse Oximeter ON

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.



3.4.3 Read correspondent data from display screen.

Display Description of OLED.



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

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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 plethysmogram can be regarded as correct if the wave is fluctuated regularly.

● 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 (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. For example, 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.

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● 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°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.

5.2 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 SpO ₂ &PR is abnormal.	1. Retry by plugging the finger. 2. Go to the hospital for further

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The Oximeter cannot be powered on

- Power of batteries might be inadequate or not be there at all
- Batteries might be installed incorrectly

The screen is suddenly off

- The product is automatically powered off when no signal is detected longer than 16 seconds
- Power quantity of the batteries is exhausted.

1. Please replace batteries

2. Please reinstall the batteries

3. Please contact with local customer service center

1. Normal

2. Replace the batteries

● SPECIFICATION ●

Name	Dr Trust Junior Pulse Oximeter-212
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
SpO ₂ Display	35-100%
Pulse rate Display	30-250 BPM
Resolution	SpO ₂ : 1% Pulse rate: 1BPM
Measure Accuracy	SpO ₂ : ±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

● 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 Junior Pulse Oximeter - 212 is intended for use in the electromagnetic environment specified below. The customer or the user of Dr Trust Junior Pulse Oximeter - 212 should assure that it is used in such an environment.

Emissions test	Compliance level	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Dr Trust Junior Pulse Oximeter -212 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.

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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	52.5mm×31mm×30mm
Weight	43±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 Junior Pulse Oximeter - 212 is intended for use in the electromagnetic environment specified below. The customer or the user of Dr Trust Junior Pulse Oximeter - 212 should assure that it is used in such an environment.

Emissions test	Compliance level	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Dr Trust Junior Pulse Oximeter -212 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.

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RF emissions CISPR 11	Class B	The Dr Trust Junior Pulse Oximeter -212 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 – for all EQUIPMENT AND SYSTEMS

The Dr Trust Junior Pulse Oximeter -212 is intended for use in the electromagnetic environment specified below. The user of the Dr Trust Junior Pulse Oximeter -212 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 %.

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Electrostatic transient /burst IEC 61000-4-4 <th>± 2 kV for power supply lines ± 1 kV for input/output lines<th>N/A</th><th>Main power quality should be that of a typical commercial or hospital environment.</th></th>	± 2 kV for power supply lines ± 1 kV for input/output lines <th>N/A</th> <th>Main power quality should be that of a typical commercial or hospital environment.</th>	N/A	Main 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	Main power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage fluctuations on power supply lines IEC 61000-4-11	0 % UT; 0.5 cycle @ 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle at 0 % UT; 25/30 cycle	N/A	Main power quality should be that of a typical commercial or hospital environment. If the user of the Dr Trust Junior Pulse Oximeter - 212 requires continued operation during power mains interruptions, it is recommended that the Dr Trust Junior Pulse Oximeter -212 be powered from an uninterrupted power supply or a battery.
Power frequency magnetic field IEC 61000-4-8	30 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.

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

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 Junior Pulse Oximeter -212 is intended for use in the electromagnetic environment specified below. The user of the Dr Trust Junior Pulse Oximeter -212 should assure that it is used in such an environment.

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	1 Vrms 150 kHz to 80 MHz 10 Vrms in ISM bands between 80 MHz to 5 GHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Dr Trust Junior Pulse Oximeter -212, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance P<0.5, 31+ P<0.5, 31+ P<0.5, 31+ 80 MHz to 800 MHz P<0.71+ P<0.71+ 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 strength 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:

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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 Junior Pulse Oximeter - 212 is used exceeds the applicable RF compliance level above, the Dr Trust Junior Pulse Oximeter -212 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 Junior Pulse Oximeter - 212.

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 Junior Pulse Oximeter -212

The Dr Trust Junior Pulse Oximeter -212 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Dr Trust Junior Pulse Oximeter -212 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Dr Trust Junior Pulse Oximeter -212 as recommended below, according to the maximum output power of the communications equipment.


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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	$d = \frac{1.5}{f_1} \sqrt{P}$	$d = \frac{3.5}{f_1} \sqrt{P}$	$d = \frac{7}{f_1} \sqrt{P}$
0.1	/	0.12	0.23
1	/	0.38	0.73
10	/	1.2	2.3
100	/	3.8	7.3
1000	/	12	23

For transmitters rated at a maximum output power not listed above the recommended separation distance in d 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 Junior Pulse Oximeter - 212 and batteries. This Junior 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 Junior Pulse Oximeter -212. 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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● CUSTOMER SUPPORT ●

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Youtube: NurecaUSA

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Scan to View Product Demo Video www.drtrustusa.com/212

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● SAFETY ●

Instructions for the Safe Operation and Use of the Dr Trust Junior Pulse Oximeter -212

1.1 Instructions

- 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 Junior Pulse Oximeter -212.
 - 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.

1.2 Warnings

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

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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 Junior Pulse Oximeter - 212 in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

WARNING: EXPLOSION HAZARD

Do not use the Dr Trust Junior Pulse Oximeter - 212 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.

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.

WARNING:

Don't 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.

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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 Junior Pulse Oximeter - 212, 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.

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.

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CAUTION:

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

CAUTION:

The batteries must be properly 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 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 the equipment.

CAUTION:

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

CAUTION:

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.

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*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 finger tip, toe, or earlobe. Perfusion index is an indication of the pulse strength at the sensor site.

1.3 Definitions and Symbols

Symbol	Description
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