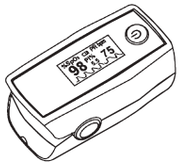
EN

PRONTEX
SOLUZIONI MEDICALI

Pulse Oximeter
User Manual



Model Pulse 02

Carefully read this manual before use and keep it with the device.

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

CE 0123

A330 | Model: Pulse 02

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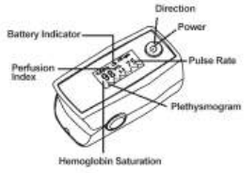
CE 0123

Tabella 1: Parts identification

Modello Pulse 02
Annotated diagram



Components

Lanyard | Manual | 2 x 1.5V Batteries (LR03 or AAA)

1 Safety

1.1 Instructions for the Safe Operation and Use of the PULSE O2 Pulse Oximeter

- Do not attempt to service the PULSE O2 Pulse Oximeter. Only qualified service personnel should attempt any needed service.
- Prolonged use or the patient's condition may require changing the sensor placement periodically. Change the sensor placement and check sensor is in contact with exposed skin, circulatory status, and correct placement at least every 2 hours.
- Oxygen saturation (SpO2) measurements may be adversely affected in the presence of high ambient light. The sensor area should be shielded with a towel, plaster, or bandage if necessary.
- The following factors may cause interference to the testing accuracy of the PULSE O2 Pulse Oximeter:
- High-frequency electrosurgical equipment.
- Placement of the sensor on an extremity with a blood pressure impacted by arterial catheter, or intravascular line.
- If the patient has severe hypotension, vasoconstriction, severe anemia, or hypothermia.
- If the patient is in cardiac arrest or in shock.
- Fingernail polish or false fingernails may cause inaccurate SpO2 readings.
- The device should be given at least 10 minutes to come to normal working temperature if stored in a hot or cold environment.
- The device is non-sterile and not intended to be sterilized.
- There are no alarms for SpO2 or pulse rate (for configuration, refer to "Installation, Setup, and Operation").
- When signal is inadequate, an unnormalized waveform will be provided.
- When the signal detected by the device is incomplete or weak, SpO2 and pulse rate readings shown in the display are "---" and "---" respectively. After powering up, "Finger out" appears on the display when the device does not detect a signal.
- PI only represents the instantaneous blood flow perfusion ability, which is also known as the perfusion index. Whether PI is normal is a relative concept, compared to the absolute value of the patient being tested in a healthy state.

1.2 Warning

The MEDICAL ELECTRONIC EQUIPMENT is suitable for home healthcare environments:

- Although the medical electronic 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 the equipment away from the sensitive device.
- Portable and mobile RF communication equipment can affect this instrument's normal operation.
- Explosion hazard - Do not use the Pulse Oximeter in a flammable atmosphere where concentrations of flammable anesthetics or other materials 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 explode.
- Do not use the Pulse Oximeter in an MRI or CT environment.
- Do not modify this equipment without the authorization of the manufacturer.
- Do not use near active high frequency surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- 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.
- 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to PULSE O2 Pulse Oximeter, including cables specified by the manufacturer. Otherwise, it may result in a degradation of the performance of this device.
- High-pressure sterilization cannot be used.
- Electromagnetic field are capable of interfering with the proper performance of the device. Therefore, make sure that all external devices operated in the vicinity of the device comply with the relevant EMC requirements. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
- The user and/or patient should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

1.2.1 Cautions

- 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 (Approximately 3 months).
- The device shall only be used with the battery cover closed.
- The batteries must be disposed of properly, according to local regulation after their use. Dispose of the batteries separately from the device.
- Keep the device away from children and pets to avoid swallowing.
- The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.
- 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.
- 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.
- 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 the Pulse Oximeter, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 2: Definitions and Symbols

Symbol	Description	Symbol	Description
	Type BF Equipment.	LOT	Batch code. [1]
MD	Indicates the item is a medical device.	UDI	Indicates a carry that contains unique device identifier information.
	Information of manufacturer, including name and address.		
	Information of importer, including name and address.		Date of manufacture. [2]
	Temperature limitation.		Information of distributor, including name and address.
	For its disposal, this product must be sent to separate collection facilities for recovery and recycling.	SN	Serial No. [3]
		EC REP	Information of EU authorized representative.
		SpO_2	No SpO2 Alarms.
	Follow the instructions for use.	IP22	Anti-dust & Anti-water class
Cautions:	The information you should know to protect the equipment from possible damage.	ME	Medical Electronics Equipment.
		Note:	The important information you should know.
Warning:	The information you should know to protect patients and medical staff from possible injury.		

Note: [1][2][3] *Batch code; Date of manufacture and Serial No. are printed on the label on the battery cover.*

2 Introduction

2.1 Intended use

The PULSE O2 Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is suitable for adult patients and children over the age of 3, for home use.

2.2 Brief Device Description

The PULSE O2 Pulse Oximeter, is based on digital technology. The device is intended for non-invasive spot-check measurement of functional oxygen saturation of arterial hemoglobin (SpO2). Advanced DSP algorithm [4] can minimize the influence of motion artifact and improve measurement accuracy of low perfusion[5]. The PULSE O2 Pulse Oximeter can be used to measure human SpO2 and pulse rate through the finger. The product is suitable for private home-use, social medical organizations, physical care in sports etc.

Note:
[4] DSP algorithm: Digital signal processor algorithm.
[5] 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 not accurate.

2.3 Product Features

- Lightweight for easy carrying and use.
- Manually adjust the direction of interface.
- Color OLED display, simultaneous display for testing value and plethysmography [6].
- Visual & Sound reminder function. Real-time spot-checks.
- Low Battery voltage indicator.
- Automatic switch-off.
- Includes two standard AAA 1.5V alkaline batteries

Note:[6] 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).

CAUTION: The device must not be used on children below 3 years of age.

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: A function tester cannot be used to assess the accuracy of the 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.
A pulse simulator shall be used to assess pulse rate accuracy. The measured pulse rate is compared to the preset pulse rate value in the simulator. Accuracy data is calculated using the root-mean-square (Arms value) for all subjects.

2.4 Expected Service Life

The expected service life of the PULSE O2 pulse oximeter is 24 months. Battery not included.

2.5 Contraindications

Do not use the device on the persons whose finger is injured.

3 Installation, Setup and Operation

3.1 OLED display parameter setting

When the device is in the measuring interface, press the direction button for 1 second in order to enter the menu page (figure 3.1.1 and figure 3.1.2). There are two sub-menus.

figura 3.1.1

3.1.1 Remind Setup

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

- **Sound reminder**
  Press the direction button for 1 second, move the "*" symbol to the "Sound Reminder", long press the direction button to turn on/off beeps. If the measured value exceeds the maximum or minimum value of SpO2 or PR, there will be a beep sound, if this function is turned on.
- **Beep**
  Press the direction button for 1 second, move the "*" symbol to the back of "Beep", long press the direction button to turn the beep sound on/off. When the beep is turned on, the sound emitted during the test indicates the pulse rate.
- **Restore**
  With the "*" symbol next to "Restore", long press the direction button. This will change to "OK", which restores the device to factory settings.
- **Demo**
  With the "*" symbol next to "Demo", long press the direction button to turn Demo mode on/off.
- **Brightness**
  With the "*" symbol next to "Brightness", long press the direction button to change the Brightness value on a scale from 1 to 5.

3.1.2 Limit Value Setting

With the "*" symbol next to "Reminder Setup", long press the direction button until the "Limit Setup" menu appears (figure 3.3.2). You can then press the direction button to select the items. Press the direction button for 1 second to change to the data you need.
On the "Limit Setup" menu page (figure 3.3.2), with the "*"symbol next to "+/-", press the direction button for 1 second to change the "+" to "-" or change the "-" to "+". When "+" shows on the right side, by pressing the direction button for 1 second and moving the "*" next to the Spo2 Hi or PR Hi setting, you can increase the value to a higher value (until it reaches the maximum).
When "-" shows on the right side, by press the direction button for 1 second and moving the "*" next to the Spo2 Lo or PR Lo value setting, you can reduce the value to a lower value (until it reaches the minimum).

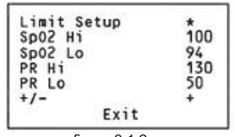
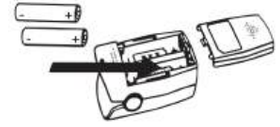


figura 3.1.2

3.2 Operations

3.2.1 Installing batteries

Place two AAA batteries into the battery compartment taking care to align the polarities, then close the cover.



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

3.2.2 Turning on and applying the Pulse Oximeter

Put one of your fingers into the rubber opening of the PULSE O2 Pulse Oximeter with nail facing upward, then release the clamp. Press the power button to turn the PULSE O2 Pulse Oximeter on. The oximeter will automatically turn off, if there is no finger in the device for more than 16±2 seconds.

3.2.3 Read data from display screen

Display OLED Screen Model PULSE 02 Description The screen display can scroll through four directions with six different display modes by pressing the power button.

Type 1 Type 2

Type 3 Type 4

Type 5 Type 6

Note:
1. When the battery power is at its lowest level, the battery symbol will be shown, reminding users to replace the batteries.

2. The plethymogram can been considered accurate if the wave symbol is fluctuating regularly.

4 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. Clean the exterior surface (display screen included) of the unit with a soft dry cloth. Use 75% medical alcohol to clean the surface by applying a small amount with a dry cloth to avoid the alcohol entering the device.

4.2 Disinfection

Disinfect the device after each use, if multiple patients use the device.
Use 75% medical alcohol to clean the surface that was in contact with the patient.

CAUTION: Do not use strong solvent, e.g., acetone.

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

CAUTION: Do not allow any liquid to enter the product and do not immerse any part of the device in liquid.

CAUTION: Avoid pouring liquid on the device while cleaning.

CAUTION: Do not leave cleaning solution on the surface of the device.

5 Troubleshooting and Maintenance

5.1 Maintenance

- Replace the batteries in a timely manner, if the battery indication is low.
- Clean the surface of the oximeter before it is used for diagnosis of patients
- Remove the batteries from the battery compartment if the oximeter will not be operated for a long time.
- It is best to store the product where the ambient temperature is between -25°C and 55°C and humidity is 15% to 93%.
- Regular inspection is recommended in order to make sure that no obvious damage is present that may affect the safety and performance of the device.
- Do not expose the device to flammable substances, high or low temperatures or humidity levels outside those in the operation conditions.

5.2 Troubleshooting

Problem	Possible Reason	Resolution
Oxyhemoglobin or heart rate cannot be shown.	1. Finger is not inserted correctly. 2. Patient's perfusion is too low to be measured.	1. Retry by inserting the finger thoroughly. 2. Try a few more times to make sure there is no problem with the product itself. Otherwise seek medical help for exact diagnosis.
Oxyhemoglobin or heart rate is unstable.	1. Finger might not be inserted correctly. 2. Finger is trembling, or patient's body is moving.	1. Retry by inserting the finger thoroughly. 2. Try to help the patient keep calm and still.
Oxyhemoglobin or heart rate is outside of the standard range.	1. Finger might not be inserted correctly. 2. Patient's SPO2 & PR is abnormal.	1. Retry by inserting the finger thoroughly. 2. Seek medical help for further examination.
The Oximeter cannot be turned on.	1. Batteries may need replacement. 2. Batteries might be installed incorrectly. 3. The oximeter might be damaged.	1. Please replace batteries. 2. Please reinstall the batteries. 3. Please contact your point of purchase.
The screen suddenly turns off.	1. The device automatically turns off, if there is no signal detected for more than 16 seconds. 2. Batteries may need replacement.	1. This is a normal process. 2. Replace the batteries correctly.

6 Specification

Device Name	PULSE O2
Dimensionas (L×W×H)	63*36*34 mm
Weight	Approx.50g - 60g (including 2 × AAA battery)
Anti-electric Shock Type	Internally powered equipment
Anti-electric Shock Equipment Degree	Type BF
EMC Type	Group I Class B
Enclosure Degree of ingress protection	IP22
Internal Power:	2×AAA 1,5V alkaline batteries
Power Consumption	Below 45mA
Screen	0.96' OLED
SpO2 Display	35-100%
Pulse rate Display	30-250 BPM
Resolution	SpO2: 1% Pulse rate: 1BPM
Measure Accuracy	SpO2: ±3% (70%-100%); Unspecified (<70%) PR: ±2BPM
Data averaging and other signal processing	8s
Data Update Period	1s
Operating Environment	Temperature: +5°C to +40°C Humidity:15% to 93% non-condensing Air Pressure: 70Kpa-106Kpa
Storage & Transport Environment	Temperature: -25° to +55° Humidity:15% to 93% non-condensing Air Pressure: 70Kpa-106Kpa
Service life	24 months

7 Clinical SpO2 Accuracy

The below table shows statistic distribution of an invasive controlled desaturation study, which guided by ISO80601-2-61, Annex EE, Guideline for evaluating and documenting SpO2 Accuracy in human subjects.
The statistic distribution displayed the accuracy distribution between the range of 70% ~ 100%, which may helpful to user.

Device	Item	100-70%	100 - 90%	90- 80%	80 - 70%
PULSE 02	Bs	1.0	0.80	1.26	0.86
	Sres	1.94	0.86	1.61	2.91
	Arms	2.18	1.17	2	2.99

The below is the Bland-Altman graphical plot of samples from invasive controlled desaturation study.

Figure 7.1-Bland & Altman

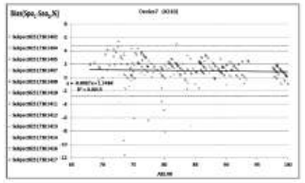
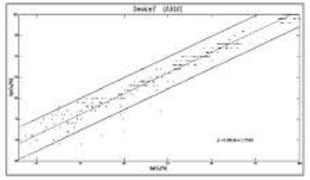


Figura 7.7.2-Linear regression for SpO_2 vs SaO_2



8 Disposal

Consider the applicable regulations when disposing of the PULSE O2 Pulse Oximeter and batteries. The pulse oximeter must not be disposed of in the domestic waste. All users are obliged to hand in all electrical or electronic devices, regardless of whether 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 pulse oximeter. **Dispose of the batteries separately from the device.**
Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop. Dispose of the batteries separately from the device.

9 Certificate of guarantee

Safety S.p.A. guarantees the PULSE 02 pulse oximeter against any manufacturing defects for a period of 2 years from the date of purchase, provided it is returned to the retailer where it was purchased, in its original packaging and accompanied by the purchase receipt.
During this period, the unit will be repaired or replaced free of charge if the fault is attributable to design or manufacturing errors. This warranty does not cover damages or malfunctions resulting from improper use or use contrary to the instructions in this manual. It does not apply to the commercial batteries supplied with the product at the time of purchase. The manufacturer/distributor shall not be held liable for accidental or indirect damages if unauthorized modifications, repairs, or technical interventions have been performed on the device, or if any product components have been incidentally damaged due to improper use and/or abuse. Any unauthorized intervention, even minor, immediately voids this warranty and, in any case, does not ensure compliance with the technical and safety requirements of the Medical Devices Regulation (EU) 2017/745 (MDR) (and subsequent regulations) and related standards.to repair it.

10 Manufacturer's EMC Declaration

1.All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE regarding electromagnetic disturbances for the expected service life.
2.Guidance and manufacturer's declaration - Electromagnetic Emissions and Immunity.

Table 8 - Guidance and manufacturer's declaration - electromagnetic emissions

Emissions test	Compliance
RF emissions - CISPR 11	Group 1
RF emissions - CISPR 11	Class B
Harmonic emissions - IEC 61000-3-2	Not application
Voltage fluctuations/ flicker emissions - IEC 61000-3-3	Not application

Tabella 2 – Guida e dichiarazione del produttore – Immunità Elettromagnetica

Test di Immunità	IEC 60601-1-2 - Test level	LCompliance level
Scariche elettrostatiche (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Transitori elettrici/burst IEC 61000-4-4	Power supply lines: ±2 kV input/output lines: ±1 kV	Not applicable
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV.; line(s) to earth: ±2 kV. 100 kHz repetition frequency	Not applicable
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle; At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle; And 70% 25/30 cycles Single phase: at 0; 0% 300 cycles	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms, 6Vrms (in ISM and amateur radio bands); 80% Am at 1kHz	Not applicable
Radiated RF - IEC61000-4-3	10 V/m; 80 MHz – 2,7 GHz; 80 % AM at 1 kHz	10 V/m; 80 MHz – 2,7 GHz; 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134,2 kHz: 65A/m 13,56 MHz: 7,5A/m	30 kHz: 8A/m 134,2 kHz: 65A/m 13,56 MHz: 7,5A/m
NOTE U_t is the a.c. mians voltage prior to application of the test level.		

Tabella 3 – Guidance and manufacturer's declaration - Electromagnetic Immunity

	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	Immunity test Level (V/m)
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380–390	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27
	450	430–470	GMRS 460, FRS 460	FM ±5kHz deviation, 1 kHz sinusoidale	2	0,3	28
	710	704–787	LTE Band 13, 17	Pulse Modulation 217 Hz	0,2	0,3	9
	745						
	780						
	810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0,3	28
	870						
	930						
	1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4, 25; UMTS	Pulse Modulation 217 Hz	2	0,3	28
	1845						
	1970						
	2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0,3	28
	5240	5100–5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0,2	0,3	9
	5500						
	5785						

Tabella 4 - Guidance and manufacturer's declaration - electromagnetic Immunity

TEST FREQUENCY	MODULATION	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation a 2,1 kHz	65 b
13,56 MHz	Pulse modulation a 50 kHz	7,5 b

a) The carrier shall be modulated using a 50% duty cycle square wave signal.
b) r.m.s., before modulation is applied.