medisana®

GB **Instruction manual** ***Pulse Oximeter PM 100 connect***

Thank you very much for your confidence in us and congratulations on your purchase!
You have acquired a **medisana** quality product with your purchase. To ensure the best results and long-term satisfaction with your **medisana** Pulse Oximeter **PM 100 connect**, we recommend that you read the following operating and maintenance instructions carefully.

IMPORTANT INFORMATION! RETAIN FOR FUTURE USE!

Read the instruction manual carefully before using this device, especially the safety instructions, and keep the instruction manual for future use. Should you give this device to another person, it is vital that you also pass on these instructions for use.

Explanation of symbols

This instruction manual belongs to this device. It contains important information about starting up and operation. Read the instruction manual thoroughly. Non-observance of these instructions can result in serious injury or damage to the device.

WARNING
These warning notes must be observed to prevent any injury to the user.

CAUTION
These notes must be observed to prevent any damage to the device.

NOTE
These notes give you useful additional information on the installation or operation.

IPX1 **Protection Rating regarding dust and water**

Classification: Type BF applied part

No SpO_2 alarm

LOT **Lot number**

Storage conditions

Manufacturer

SN **Serial number**

Date of manufacture

ASSIGNED PURPOSE

The Pulse Oximeter PM 100 connect is a portable non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adult. It is not suitable for continuous monitoring.

SAFETY INFORMATION

- Pulse oximeters are sensitive to motion artefacts. Therefore keep hands still while taking a reading.
- Pulse Oximeters require sufficient blood flow to obtain proper readings. If your hands are cold or you have poor circulation, warm your hands by rubbing them together or use another method before attempting to obtain a reading. A tourniquet, blood pressure cuff or other blood flow hindrances may also result in inaccurate readings.
- **Fingernail polish or acrylic nails obstruct the light transmission and may also result in inaccurate readings.**
- Your finger and the pulse oximeter must be clean for proper reading.
- If a reading is difficult to obtain, switch to another finger or to the other hand.
- *Inaccurate measurement results may also caused by:*

- dysfunctional hemoglobin or low hemoglobin
- the use of intravascular dyes
- high ambient light
- excessive patient movement
- high-frequency electrosurgical interference and defibrillators
- venous pulsations
- placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intra-vascular line
- patients suffering from hypotension, severe vasoconstriction, severe anemia, or hypothermia
- cardiac arrest or shock
- false fingernails
- circulatory disorder

- The Pulse Oximeter will **not alert** you if your readings are out of normal range.
- Explosion hazard: Do not use the Pulse Oximeter in an explosive atmosphere.
- The device is not suitable for continuous blood oxygen monitoring.
- To ensure a correct sensor alignment and skin integrity, the maximum application time on a single measurement place should be less than half an hour.
- Operation of the Pulse Oximeter may be affected by the use of an electrosurgical unit (ESU).
- Do not use the Pulse Oximeter in an MRI or CT environment.
- 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 advised by a professional physician.
- The device is not autoclavable and is not intended for sterilization or for cleaning with liquids.
- This equipment is not intended for use during patient transport outside the healthcare facility.
- This equipment should not be used adjacent to or stacked with other equipment.
- The device must not be used with accessories, detachable parts and other materials not described in the instructions for use.
- Please do not attempt to repair the unit yourself in the event of malfunctions. Stop using the device and conact the service centre.
- The materials that contact with the patient's skin have been tested to be in tolerance. In case you should detect skin irritations etc., stop using the device and contact a doctor.
- The swallowing of small parts like packaging bag, battery, battery cover and so on may cause suffocation.
- In case of an unstable signal the measurement values may be faulty. Do not use these values as reference values.

SAFETY NOTES FOR BATTERIES

- Do not disassemble batteries!
- Never leave any low battery in the battery compartment since it may leak and cause damage to the unit!
- Increased risk of leakage! Avoid contact with skin, eyes and mucous membranes!
- If battery acid comes in contact with any of these parts, rinse the affected area with copious amounts of fresh water and seek medical attention immediately!
- If a battery has been swallowed, seek medical attention immediately!
- Insert the batteries correctly, observing the polarity!
- Keep batteries out of children's reach!
- Do not attempt to recharge batteries! **There is a danger of explosion!**
- Do not short circuit! **There is a danger of explosion!**
- Do not throw into a fire! **There is a danger of explosion!**
- Do not throw used batteries into the household refuse; put them in a hazardous waste container or take them to a battery collection point, at the shop where they were purchased!

Items supplied and packaging

Please check first of all that the device is complete and is not damaged in any way. If in doubt, do not use it and contact the service centre. The following parts are included:

- 1 **medisana Pulse Oximeter PM 100 connect**
- 2 Batteries (type AAA) 1,5V
- 1 Lanyard
- 1 Instruction manual

The packaging can be reused or recycled. Please dispose properly of any packaging material no longer required. If you notice any transport damage during unpacking, please contact your dealer without delay.

WARNING
Please ensure that the polythene packing is kept away from the reach of children! Risk of suffocation!

Device and controls

❶ OLED Screen
❷ Start-button
❸ Opening for finger
❹ Battery compartment lid (on rear side of the device)

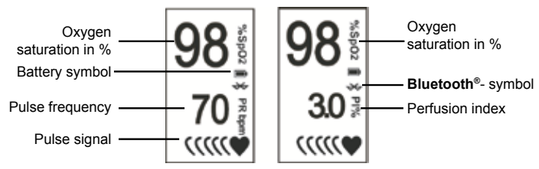
Insert / change battery

Insertion: You must insert the batteries provided before you can use your unit. The lid of the battery compartment ❹ is located on the backside of the unit. Open it, remove it and insert the 2 x AAA type 1.5 V batteries supplied. Ensure correct polarity when inserting (as marked inside the battery compartment). Close the battery compartment.

Removal: Replace the batteries when the battery exchange symbol appears in the display. If nothing is displayed the batteries are completely empty and need to be replaced immediately.

Use

1. Open the finger opening by pressing the left upper and lower parts of the device together.
2. Place your finger as far as possible into the opening ❸ on the right side of the device and release the upper and lower parts.
3. Press the Start-button ❷. The OLED-screen will switch on immediately.
4. Keep your finger and your whole body still for the reading. After a short time, the values for the pulse frequency and the blood oxygen saturation appear on the OLED screen:



5. By repeatedly pressing the Start-button ❷ shortly, you may switch between 7 different display modes (showing the already explained values in different view modes) and you can change the displayed parameters from SpO_2 and PR (Pulse frequency) to SpO_2 and PI (Perfusion index).
6. Remove your finger. The Pulse Oximeter will power off automatically after approx. 8 seconds.

Test mode and brightness level setting

Test mode: Press and hold the start-button ❷ until Settings appears on screen, then press and hold the start-button ❷ to Real-time or Spot-check and release the button.

Brightness level: Press the start-button ❷ and go to Brightness, press and hold the start-button ❷ to adjust the brightness level and release the button.

Exit: Press the start-button ❷ and go to Exit, then long press the start-button ❷ to return to the measurement value display.

What does the measured result mean?

The oxygen saturation (SpO_2) of the blood is a term referring to the concentration of oxygen attached to human hemoglobin. The normal value lies between 95 and 100 % SpO_2. A too low value may be an indication for existing diseases like e.g. cardiac defect, problems of the circulatory system, asthma or specific diseases of the lung. A too high value may be caused by a too fast and too deep breathing, what bears the danger of a too low blood carbon dioxide level. PI indicates the perfusion index, which is a measure for the pulse strength. The results lie in between 0.1% (very weak pulse amplitude) and 20% (very strong pulse amplitude).

The value measured with this device is not suitable in any way to make or confirm a diagnosis - contact your doctor under all circumstances to get a correct diagnosis.

Data transmission with Bluetooth® 4.0 to the app

1. Switch on the device. The **Bluetooth®** symbol flashes. After successful pairing, the symbol will constantly light up. In some cases it may keep flashing. The **Bluetooth®** connection will automatically be cancelled when the device is switched off.
2. Spot-Check: The current measurement will automatically be transferred to the app. After successful trans-mission, the measured value will flash for 8 seconds. Afterwards, the device will switch off automatically. If no Bluetooth® connection can be established for more than one minute, the device will be switched off automatically and the measured values will not be stored. **NOTE:** Transmission to the app will only work in spot-check mode.
3. If no measured value is available for transmission, the device will be switched off automatically.
4. The maximum transmission distance is 10 m.

Using the Lanyard

A Lanyard is included in the scope of delivery of the **medisana Pulse Oximeter PM 100 connect**. You may attach it to the device by threading the thinner end of the lanyard through the hanging hole on the left side of the device.

Troubleshooting

Error: SpO_2 and / or pulse frequency values are not displayed or are not displayed correctly.
Remedying: Place on of your fingers completely into the finger opening ❸ on the backside of the device. Use a new battery. Do not move or speak during the measurement and avoid bright surrounding light. If still no correct values can be measured, contact the service centre.

Error: The device cannot be switched on.
Remedying: Remove the old battery and insert a new one. Press the START-button ❷. If the device still cannot be switched on, contact the service centre.

If the screen displays " ⃠ ", it means the signal is unstable, please retry your finger and keep your hands still for the reading. Do not shake your finger during the test. It is recommended that you do not move your body while taking a reading.

Cleaning and maintenance

Remove the batteries before cleaning. Never use strong detergents or hard brushes. Clean the unit with a soft cloth, moistened with isopropyl alcohol. Do not let water enter the unit. After cleaning, only use the unit when it is completely dry.

Disposal

This product 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 device. Do not dispose of old batteries with your household waste, but at a batterycollection station at a recycling site or in a shop. Consult your municipal authority or your dealer for information about disposal.

Directives / Norms

This device is certified in accordance with EC Guidelines and carries the CE symbol (conformity symbol) "CE 0297". The specifications of EU Guideline "93/42/EEC of the Council Directive dated 14 June 1993 concerning medical devices" are met. **Electromagnetic compatibility:** The device complies with the EN 60601-1-2 standard for electromagnetic compatibility.

Electromagnetic compatibility - Guidance and manufacturer's declaration
Effective: 19-Jul-2014

Electromagnetic emissions
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR11	Group 1	The Pulse Oximeter 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 CISPR11	Class B	The Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions nach IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the device 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 ± 2,4,8,15 kV air	± 8 kV contact ± 2,4,8,15 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 %.
Power frequency (50/60 Hz) 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.

Electromagnetic immunity
The Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment – guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the thermometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** d=1.2 √P d=1.2 √P 80 MHz to 800 MHz d=2.3 √P 800 MHz to 2,7 GHz
			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). 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 propagation 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Technical specifications

Name and model :	**medisana** Pulse Oximeter **PM 100 connect**
Display system :	Digital display (OLED)
Power supply :	3 V ⎓ , 2 batteries (type LR03, AAA) 1,5V 600 mAh
Measuring range :	SpO_2: 70-100 %, Pulse: 30 - 250 beats / min.
Accuracy :	SpO_2: ± 2 %, Pulse: (30 - 99) = ± 2; (100 - 250) = ± 2 %
Display resolution :	SpO_2: 1 %, Pulse: 1 beat / min.
Response time :	ø 8 seconds
Life cycle :	approx. 5 years (if used for 15 measurements à 10 minutes per day)
Automatic switch-off :	After approx. 8 seconds in absence of any signal
Operating conditions :	+5°C - +40°C, 15% - 93% rel. humidity without condensation, pressure 70 kPa - 106 kPa
Storage conditions :	-25°C - +70°C, max. 93 % rel. humidity, pressure 70 kPa - 106 kPa
Dimensions :	approx. 58 x 34 x 35 mm
Weight :	approx. 53 g
Article number :	48506
EAN number :	40155 88 48506 0

In accordance with our policy of continual product improvement, we reserve the right to make technical and optical changes without notice.

Warranty and repair terms

Please contact your dealer or the service centre in case of a claim under the warranty. If you have to return the unit, please enclose a copy of your receipt and state what the defect is. The following warranty terms apply:

1. The warranty period for **medisana** products is three years from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Defects in material or workmanship will be removed free of charge within the warranty period.
3. Repairs under warranty do not extend the warranty period either for the unit or for the replacement parts.
4. The following is excluded under the warranty:
   a. All damage which has arisen due to improper treatment, e.g. non-observance of the user instructions.
   b. All damage which is due to repairs or tampering by the customer or unauthorised third parties.
   c. Damage which has arisen during transport from the manufacturer to the consumer or during transport to the service centre.
   d. Accessories which are subject to normal wear and tear.
5. Liability for direct or indirect consequential losses caused by the unit are excluded even if the damage to the unit is accepted as a warranty claim.

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CE 0297