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EN

Fingertip Oximeter

OXY210

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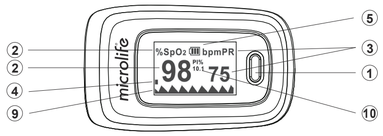
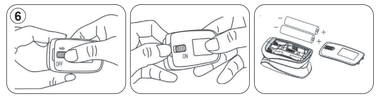
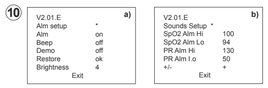
OXY 210 microlife®

IB OXY 210 EN 4721, Revision Date: 2021-11-25







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CE 0482

Pulse Oximeter EN

① ON/OFF button
② Oxygen saturation (value as percentage)
③ Pulse rate (value in beats per minute)
④ Pulse bar
⑤ Low battery indicator
⑥ Inserting the batteries
⑦ Attaching the lanyard
⑧ Operation principle
⑨ Display modes (6 different)
⑩ Settings menu
-a Interface 1
-b Interface 2

Dear Customer,
This Microlife fingertip pulse oximeter is a portable non-invasive device intended for spot-checking of the oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate of adults and pediatric patients. It is suitable for private use (at home, or on the go) as well as for use in the medical sector (hospitals, hospital-type facilities). It has been clinically proven to be of high precision during repeatability.
If you have any questions, problems or want to order spare parts please contact your local Microlife-Customer Service. Your dealer or pharmacy will be able to give you the address of the Microlife dealer in your country. Alternatively, visit the internet at www.microlife-asiapacific.com where you will find a wealth of invaluable information on our products.
Retain instructions in a safe place for future reference.
Stay healthy – Microlife AG!

1. Explanation of Symbols

Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.
Read the instructions carefully before using this device.
Type BF applied part
Manufacturer
Low battery indicator
SN Serial number
IP22 Protected against dripping water
EC REP Authorized representative in the European Community
% SpO_2 Oxygen saturation (value as percentage)
♥ /Min Pulse rate (value in beats per minute)
No alarm
Operating conditions: 5 - 40 °C / 41 - 104 °F
Storage conditions: -10 - +50 °C / 14 - 122 °F
CE 0482 CE Marking of Conformity

2. Important Safety Instructions

- Follow instructions for use. This document provides important product operation and safety information regarding this device. Please read this document thoroughly before using the device and keep for future reference.
- This device may only be used for the purposes described in these instructions. The manufacturer cannot be held liable for damage caused by incorrect application.
- **Never immerse this device in water or other liquids. For cleaning please follow the instructions in the «Cleaning and Disinfecting» section.**
- Do not use this device if you think it is damaged or notice anything unusual.
- Never open this device.
- This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the «Technical Specifications» section.
- Protect it from:
  - water and moisture
  - extreme temperatures
  - impact and dropping
  - contamination and dust
  - direct sunlight
  - heat and cold
- The function of this device may be compromised when used close to strong electromagnetic fields such as mobile phones or radio installations and we recommend a distance of at least 1 m (according to 60601-1-2 table 5). In cases where you suspect this to be unavoidable, please verify if the device is working properly before use.
- Do not use the device in an MRI or CT environment.
- This device is not intended for continuous monitoring.
- Do not sterilize this device using autoclaving or ethylene oxide sterilizing. This device is not intended for sterilization.
- If the device is not going to be used for a prolonged period the batteries should be removed.

Ensure that children do not use this device unsupervised; some parts are small enough to be swallowed. Be aware of the risk of strangulation in case this device is supplied with cables or tubes.
Use of this device is not intended as a substitute for a consultation with your doctor.

3. General Description

Oxygen saturation indicates the percentage of hemoglobin in arterial blood that is loaded with oxygen. This is a very important parameter for the respiratory circulation system. Many respiratory diseases can result in lower oxygen saturation within human blood.
Following factors can reduce oxygen saturation: Automatic regulation of organ dysfunction caused by anesthesia, intensive postoperative trauma, injuries caused by some medical examinations. These situations may result in light-headedness, asthenia and vomiting. Therefore, it is very important to know the oxygen saturation of a patient so that doctors can detect problems in a timely manner.

4. Measurement Principles

Principle of this fingertip pulse oximeter: A mathematical formula is established making use of Lambert Beer Law according to spectrum absorption characteristics of deoxygenated hemoglobin (Hb) and oxyhemoglobin (HbO_2) in red and near-infrared zones.
Operation principle of this device: Photoelectric oxyhemoglobin inspection technology is adopted in accordance with capacity pulse scanning and recording technology, so that two beams of different wavelength of lights (660 nm red and 905 nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the display through process in electronic circuits and microprocessor.

5. Directions for Use

1. Insert the batteries as described in the «Inserting the batteries ⑥» section.
2. Insert one finger (nail side up; index or middle finger is recommended) into the finger opening of the device. Be sure to fully insert the finger so that the sensors are completely covered by the finger.
3. Release the device allowing it to clamp down on the finger.
4. Press the ON/OFF button ① to turn the device on.
5. **Do not shake your finger during the test.** It is recommended that you do not move your body whilst taking a reading.
6. Your measurement values will appear on the screen after a few seconds.
7. Remove your finger from the device.
8. The device will automatically switch off after approx. 8 seconds after the finger is removed from the device.

The height of the bar graph ② is an indication of the pulse and signal strength. The bar should be greater than 30 % for a proper reading.
The device must be able to measure the pulse properly to obtain an accurate SpO_2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO_2 measurement.
The maximum application time at a single site should be less than 30 minutes, in order to ensure correct sensor alignment and skin integrity.

Inaccurate measurements may occur if:
- The patient suffers from significant levels of dysfunctional hemoglobin (such as carboxyhemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue have been injected into the patient.
- Used in the presence of high ambient light (e.g. direct sunlight). Shield the sensor area with a surgical towel if necessary.
- There is excessive patient movement.
- The patient experiences venous pulsations.
- 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 are applied.

6. Inserting the batteries ⑥

After you have unpacked your device, first insert the batteries. The battery compartment is on the bottom of the device. Remove the battery cover by sliding it in the direction shown. Insert the batteries (2 x 1.5 V, size AAA), thereby observing the indicated polarity.
Replace the batteries when the low power indicator ⑤ appears on the display.
Always replace both batteries at the same time.

7. ON/OFF button ① / Function button

Press and release the ON/OFF button ① to turn on, hold the button for about one second. The device shows the settings menu ⑩. Press or hold the ON/OFF button to perform corresponding operations. Hold it to set an item, or press it to switch an option or switch the display mode. Press means no more than 0.5 seconds, while hold means more than 0.5 seconds.

Alert Sound Setting
Hold ON/OFF button ① while the device is switched on.Settings menu (interface 1) is displayed ⑩-a. Move «*» to the corresponding option, and hold the function button to set **Alm** to **on** and set **Beep** to **off**. When **Alm** is set to **on** and the measured values of the blood oxygen saturation and pulse rate go beyond the upper limit or lower limit, the device gives off an alert sound. When **Beep** is set to **on**, a tick will be heard along with pulse beats during pulse rate measurement. While the «*» symbol stays on the **Restore** option, hold the functional button to restore default settings.

Brightness Setting
Press ON/OFF button ① to select the **Brightness** option and then hold the ON/OFF button to set the brightness to a value ranging from 1 to 5. The greater the value, the greater the brightness of the screen.

Alert Range Setting
On settings menu (interface 2) ⑩-b, press the ON/OFF button ① to switch between options. On this interface, you can set the upper limit and lower limit of **SpO2 Alm** and **PR Alm**. While the «*» symbol stays on the +/- option, hold the functional button to set the option to + or -.
In + mode, select the corresponding option and hold the ON/OFF button to increase the upper or lower limit; in - mode, hold the ON/OFF button to decrease the upper or lower limit. Move «*» to the **Exit** option, and hold the ON/OFF button to return to the monitoring interface.

8. Display Mode

When the device is switched on, shortly press the ON/OFF button ① to switch to another display mode to select your desired display mode ⑨. There are 6 different display modes. The default setting is mode 1.

9. Using the Lanyard ⑦

1. Thread the thinner end of the lanyard through the hanging hole at the rear end of the device.
2. Thread the thicker end of the lanyard through the threaded end before pulling it tightly.

10. Malfunctions and Actions to take

Description	Symptom/Possible causes	Solutions
SpO_2 or pulse rate do not display normally.	1. Finger is not inserted correctly. 2. Patient SpO_2 value is too low to be measured. 3. There is excessive illumination.	1. Retry inserting the finger. 2. & 3. Measure more times. If you determine the product is working correctly, consult your doctor.
SpO_2 or pulse rate is shown unstable.	1. Finger might not be inserted deep enough. 2. Excessive patient movement.	1. Retry inserting the finger. 2. Sit calmly and retry.
The device cannot be powered on.	1. No batteries or low battery power. 2. Batteries are not installed correctly. 3. The device may be damaged.	1. Replace the batteries. 2. Remove and reinstall the batteries. 3. Contact your local Microlife-Customer Service.
The display suddenly switches off.	1. The device is automatically powered off, when no signal was detected after 8 seconds. 2. The battery power is too low to operate.	1. Normal. 2. Replace the batteries.

11. Cleaning and Disinfecting

Use an alcohol swab or cotton tissue moistened with alcohol (70% Isopropyl) to clean the silicone that touches the finger inside of the device. Also clean the finger being tested using alcohol before and after each test. Allow the device to dry thoroughly before use.
Never use abrasive cleaning agents, thinners or benzene for cleaning and never immerse the device in water or other cleaning liquids.

12. Guarantee

This device is covered by a **2 year guarantee** from the date of purchase. During this guarantee period, at our discretion, Microlife will replace the defective product free of charge.
Opening or altering the device invalidates the guarantee. The following items are excluded from the guarantee:
- Transport costs and risks of transport.
- Damage caused by incorrect application or non-compliance with the instructions for use.
- Damage caused by leaking batteries.
- Damage caused by accident or misuse.
- Packaging/storage material and instructions for use.
- Regular checks and maintenance (calibration).
- Accessories and wearing parts: Battery.

Should guarantee service be required, please contact the dealer from where the product was purchased, or your local Microlife service. You may contact your local Microlife service through our website:
www.microlife-asiapacific.com/support
Compensation is limited to the value of the product. The guarantee will be granted if the complete product is returned with the original invoice. Repair or replacement within guarantee does not prolong or renew the guarantee period. The legal claims and rights of consumers are not limited by this guarantee.

13. Technical Specifications

Type:	Fingertip Pulse Oximeter OXY 210
Display:	OLED display
Display range:	Oxygen saturation: 35 - 100 % Pulse rate: 25 - 250 bpm
Resolution:	Oxygen saturation: 1 % Pulse rate: 1 bpm
Measurement range:	SpO2: 70 - 100% Pulse: 25 - 250 bpm
Measurement precision:	Oxygen saturation: ±2 % (70 - 100 %) % No requirement: (≤ 69 %) Pulse rate: ± 2 bpm
Alert error:	Oxygen saturation: ± 1 % of the preset value Pulse rate: the greater of ± 10% of the preset value and ± 5 bpm PI (Perfusion Index) Weak PI Min. 0.2 %
Operating conditions:	5 - 40 °C / 41 - 104 °F 15 - 80 % relative maximum humidity
Storage conditions:	-10 - +50 °C / 14 - 122 °F 10-93 % relative maximum humidity
Automatic switch-off:	Automatically shut down in 8 seconds, when no or low signal is detected.
Battery:	2 x 1.5 V alkaline batteries; size AAA
Battery lifetime:	approx. 30 hours (using new batteries)
Weight:	42.5 g (including batteries)
Dimensions:	62 x 37 x 32 mm
IP Class:	IP22
Reference to standards:	EN ISO10993-1/-5/-10; IEC 60601-1; EN 60601-1-2; ISO 80601-2-61; EN 62304; EN 60601-1-6
Expected service life:	5 years (when used 15 times/day; 20 minutes for each measurement)

Technical alterations reserved.