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# microlife



Bluetooth® Pulse Oximeter







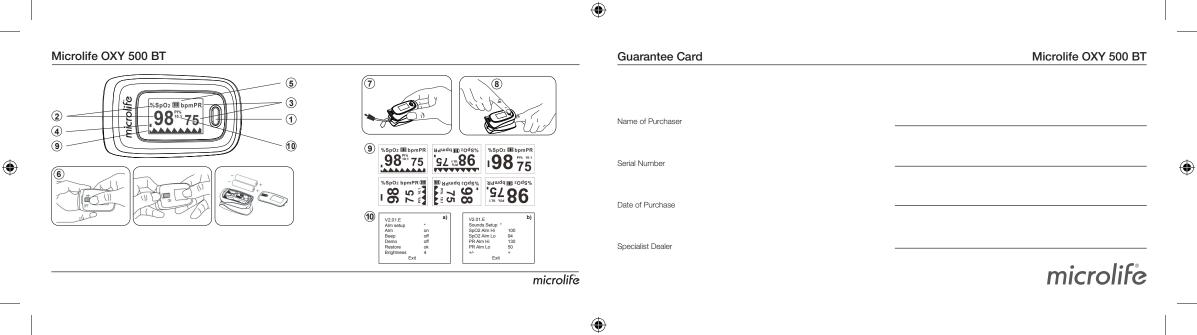












# Bluetooth® Pulse Oximeter



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

#### Dear Customer.

Stay healthy - Microlife AG!

This Microlife fingertip pulse oximeter is a portable noninvasive device intended for spot-checking of the oxygen saturation of arterial hemoglobin (SpO2) 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.com where you will find a wealth of invaluable information on our products. Retain instructions in a safe place for future reference.

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# 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





Serial number



Protected against dripping water



Authorized representative in the European Community

% SpO<sub>2</sub>

Oxygen saturation (value as percentage)



Pulse rate (value in beats per minute)





5 - 40 °C / 41 - 104 °F

Operating conditions:

Storage conditions: -10 - +50 °C / 14 - 122 °F

CE 0482 CE Marking of Conformity

# . 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.

  Output

  Description:

  Output

  Description

  Descriptio
  - 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

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- 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.

# 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.

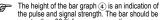
# Measurement Principles

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<sub>2</sub>) 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.

#### Directions for Use

- Insert the batteries as described in the «Inserting the batteries (6)» section. 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.
- Release the device allowing it to clamp down on the
- 4. Press the ON/OFF button (1) to turn the device on.
- Do not shake your finger during the test. It is recommended that you do not move your body whilst taking a reading.
- Your measurement values will appear on the screen after a few seconds.
  - Remove your finger from the device.
  - The device will automatically switch off after approx. 10±2 seconds after the finger is removed from the device.



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 SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO<sub>2</sub> measurement.



The maximum application time at a single site should be less than 30 minutes, in order to ensure correct sensor alignment and skin integ-

#### 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 methvlene 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.

# 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.

# ⴷ 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 ③. There are 6 different display modes. The default setting is mode 1.

# 9. Using the Lanyard (7)

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

# 10. Bluetooth® Function

This device can be used in conjunction with a smartphone running the «Microlife Connected Health+» App. The measurement results will be automatically transferred via Bluetooth®.

Downloading the «Microlife Connected Health+» App Download «Microlife Connected Health+» App for free from Google Play<sup>TM</sup> (Android) or App Store (iOS) and install it on your smartphone.

# How the Bluetooth® Function works

The Bluetooth® function on your device will automatically turn on and will be ready to connect with the «Microlife Connected Health+» App after the device is switched on. Your device will automatically upload the data once it is connected to the smartphone.

#### 11. Malfunctions and Actions to take

Descrip- tion	Symptom/Possible causes	Solutions
SpO <sub>2</sub> or pulse rate do not display normally.	Finger is not inserted correctly.     Patient SpO <sub>2</sub> value is too low to be measured.     There is excessive illumination.	Retry inserting the finger.     & 3. Measure more times. If you deter- mine the product is working correctly, consult your doctor.
SpO <sub>2</sub> or pulse rate is shown unstable.	Finger might not be inserted deep enough.     Excessive patient movement.	Retry inserting the finger.     Sit calmly and retry.

Descrip- tion	Symptom/Possible causes	Solutions
The device cannot be powered on.	No batteries or low battery power.     Batteries are not installed correctly.     The device may be damaged.	Replace the batteries.     Remove and rein- stall the batteries.     Contact your local Microlife-Customer Service.
The display suddenly switches off.	The device is automatically powered off, when no signal was detected after 10±2 seconds.     The battery power is too low to operate.	Normal.     Replace the batteries.

# 12. 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.

#### 13. Guarantee

This device is covered by a **2 year guarantee** from the date of purchase. During this guarantee period, at our discretion, Microlife will repair or 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.

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- Damage caused by incorrect application or noncompliance 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.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 remy the guarantee

period. The legal claims and rights of consumers are not

limited by this guarantee.

# 14. Technical Specifications

Type: Fingertip Pulse Oximeter OXY 500 BT

Display: OLED display

Display range: Oxygen saturation: 35 - 100 % Pulse rate: 25 - 250 bpm

Resolution: Oxygen saturation: 1 % Pulse rate: 1 bpm

Measurement Oxygen saturation: precision: ±2 % (70 - 100 %) No requirement: (≤ 69 %)

Alert range:

Oxygen saturation: Upper limit: 50 - 100 % Lower limit: 50 - 100 %

Pulse rate: Upper limit: 25 - 250 bpm Lower limit: 25 - 250 bpm

Alert error: Oxygen saturation: ± 1 % of the

Pulse rate: ± 2 bpm

preset value

Pulse rate: the greater of ± 10% of the

preset value and ± 5 bpm PI (Perfusion Index) Weak PI Min 0.2 %

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Operating condi- 5 - 40 °C / 41 - 104 °F

tions: 15 - 80 % relative maximum humidity

Storage conditions: -10 - +50 °C / 14 - 122 °F 10-93 % relative maximum humidity

Automatic switch- Automatically shut down in

off: 10±2 seconds, when no or low signal

is detected.

Communication: Bluetooth® Low Energy 4.0

Compatibility: iOS: iOS 10.0 or newer Android: Android OS 5 or newer 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 EN ISO10993-1/-5/-10;

standards: IEC 60601-1; EN 60601-1-2; ISO 80601-2-61; EN 62304;

EN 60601-1-6

Expected service 5 years (when used 15 times/day; 20

life: minutes for each measurement)

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