

Clinical benefits

Users can quickly and easily determine their oxygen saturation value through the device and detect a decreased oxygen saturation value.

Contraindication

⚠ WARNING

- Do NOT use the pulse oximeter
- if you are allergic to rubber products.
 - if the device or the finger you are using is damp.
 - on babies < 1 year.
 - on large fingers that do not fit into the device easily (fingertip: width approx. > 20 mm, thickness approx. > 15 mm).
 - on fingers that are too small, as with small children for example (fingertip: width approx. < 10 mm, thickness approx. < 5 mm).
 - on fingers with anatomical changes, oedemas, scars or burns.
 - on patients who are not steady at the site of application (e.g. trembling).

Undesirable side effects

- Finger injuries such as chemical or thermal burns, skin tanning, pressure erosion, sensory loss, gangrene
- Causes of these complications may include: pressure ischaemia, prolonged use, probe overheating, probe misuse, short circuit
- Possible measurement deviations if the finger is damaged. In this case, the SpO₂ value is recorded as too low.
- Low accuracy of SpO₂ measurement in critically ill patients: inherent potential error of 3–4% in measurements performed on these patients.

WARNINGS AND SAFETY NOTES

Read these instructions for use carefully! Failure to observe the following information may result in personal injury or material damage.

⚠ WARNING

- Check to ensure that the package contains all the parts that should be included in the delivery.
- Check the pulse oximeter regularly before use to ensure that there is no visible damage to the device and the batteries are still sufficiently charged. If you have any doubts, do not use the device and contact Beurer Customer Services or an authorised retailer.
- Do not use any additional parts that are not recommended by the manufacturer or offered as equipment.
- Under no circumstances should you open or repair the device yourself, as faultless functionality could no longer be guaranteed thereafter. Failure to comply with this instruction will void the warranty. For repairs, please contact Beurer Customer Services or an authorised retailer.

General warnings

- Using the pulse oximeter for long periods may cause pain for people with circulatory disorders. Therefore do not use the pulse oximeter for longer than 2 hours on one finger.
- The pulse oximeter displays an instantaneous measurement but cannot be used for continuous monitoring. The device is calibrated to indicate functional oxygen saturation.
- The pulse oximeter does not have an alarm function and is therefore not suitable for evaluating medical results.
- Do not self-diagnose or self-medicate on the basis of the measurements without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- If oxygen saturation is known to be chronically diminished, it requires monitoring using the pulse oximeter under medical supervision. An acutely low oxygen saturation (with or without accompanying symptoms) must be clarified immediately by a doctor. This can be a life-threatening situation.
- Do not look directly inside the housing during the measurement. The red light and the invisible infra-red light in the pulse oximeter are harmful to your eyes.
- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Supervise children around the device to ensure they do not play with it.
- Keep packaging material away from children (risk of suffocation).
- Do not modify the device.
- The displays for the pulse wave and pulse bar do not allow the strength of the pulse or circulation to be evaluated at the measurement site. Rather, they are exclusively used to display the current visual signal variation at the measurement site and do not enable reliable diagnostics for the pulse.
- Measurement deviations may occur if the skin is strongly pigmented.
- Do NOT use the pulse oximeter
 - during an MRI or CT scan.
 - whilst transporting a patient other than within a medical establishment.
 - whilst taking a blood pressure measurement on the same arm using a cuff.
 - on fingers that have nail varnish on, are dirty or have a plaster or other dressing on them.
 - near flammable or explosive gas mixtures.
 - in hospitals in AP and APG-class rooms.

General precautions

NOTICE

- Non-observation of the following instructions can lead to incorrect or failed measurements.
- There must not be any nail varnish, artificial nails, or other cosmetics on the finger to be measured.
 - Ensure that the fingernail on the finger to be measured is short enough that the fingertip covers the sensor elements in the housing.
 - Keep your hand, finger, and body still during the measurement.
 - For people with cardiac arrhythmia, the measurement values of SpO₂ and the heart rate may be incorrect or the measurement may not be possible at all.
 - If an electronic surgical device or defibrillator is used, the functioning of the pulse oximeter may be impaired.
 - In the case of carbon monoxide poisoning, the pulse oximeter displays a measurement value that is too high.
 - To avoid falsifying the measurement, there should not be any strong light sources (e.g. fluorescent lamps or direct sunlight) in the immediate vicinity of the pulse oximeter.
 - People with low blood pressure, who suffer from jaundice or take medication for vascular contraction, may experience incorrect or falsified measurements.
 - Incorrect measurements are likely for patients who have been administered medical dye in the past or for those who have abnormal haemoglobin levels. This applies in particular for cases of carbon monoxide poisoning and methaemoglobin poisoning, which can occur for example from the administration of local anaesthetics or from an existing methaemoglobin reductase deficiency.
 - The measurement may be falsified in patients with an arterial catheter, hypotension, severe vascular constriction, anaemia or hypothermia.
 - Use the device under the respective permissible operating and storage conditions.
 - Protect the pulse oximeter from dust, shocks, and moisture as well as extreme temperatures and explosive materials.
 - Keep away from children, pets and pests.
 - Do not use the device in the vicinity of strong electromagnetic fields and keep it away from radio systems or mobile telephones.
 - Ensure the device is at room temperature before taking a measurement. If the device has been stored close to the maximum or minimum storage and transport temperatures and is then moved into an environment with a temperature of 20°C, it is recommended that you wait approx. 4 hours before using the device.
 - The data averaging and signal processing results in a delay in updating the SpO₂ values. If the data update period is less than 30 seconds, the time to obtain the dynamic average values will be extended due to signal degradation, low perfusion or other faults.
 - Functional testers can be used to check if the device is functioning normally, e.g. Fluke INDEX-2LFE simulator, Fluke Index ProSim 8 simulator. Please refer to the manual for detailed operating steps.
 - Functional testers cannot be used to assess the accuracy of a pulse oximeter.

Notes on handling batteries

⚠ WARNING

- **Risk of explosion! Risk of fire!** Failure to comply with the following points can result in personal injury or cause overheating, leakage, venting, breakage, explosion, or fire on the battery.
- This device contains non-rechargeable batteries which must not be charged.
- Do not throw batteries into a fire.
- Never charge, forcibly discharge, heat, disassemble, open, crush, deform, encapsulate, or modify batteries.
- Never short-circuit batteries or battery compartment contacts.
- Protect the batteries from direct sunlight, rain, heat, and water.
- Exposure of batteries to an environment with extremely high temperatures or an extremely low air pressure may result in explosion or leakage of flammable liquids and gases.
- Dispose of defective and discharged batteries immediately and properly (see chapter on disposal).
- Do not use modified or damaged batteries.
- Always select the correct battery type.
- Always insert the batteries correctly, taking into account the polarity (+ / -).
- Never mix batteries of different manufacturers, capacities (new and used), size, or type within a device.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- If fluid from a battery comes into contact with your skin or eyes, wash the affected areas with water and seek medical assistance.
- **Choking hazard!** Keep batteries out of the reach of children. Seek medical attention immediately if swallowed. Swallowing them may cause burns, severe internal injuries, and death.
- Never allow children to replace batteries without adult supervision.

⚠ CAUTION

- Store batteries in a well-ventilated, dry, and cool place in a non-conductive container in which the batteries cannot be short-circuited to each other or by other metal objects.
- Keep batteries clean and dry.
- Keep batteries away from water.
- If the device is not going to be used for a long period of time, remove the batteries from the battery compartment.

NOTICE

- Do not use rechargeable batteries.

USAGE

Function button

The function button on the pulse oximeter has the following functions:

- Switch-on function: to switch on the pulse oximeter, press and hold the function button.

- Brightness function: to adjust the display brightness, press and hold the function button during operation.

- The display orients automatically (vertical format, horizontal format). This ensures that the values are easy to read on the display at all times, regardless of how you hold the pulse oximeter.

EVALUATING MEASUREMENT RESULTS

⚠ CAUTION	
The following table for evaluating your measurements does NOT apply to people with certain pre-existing conditions (e.g. asthma, cardiac insufficiency, respiratory diseases) or whilst staying at altitudes above 1500 metres. If you have a pre-existing condition, always consult your doctor to evaluate your measurements.	
SpO ₂ (oxygen saturation) measurement in %	Classification/measures to be taken
99–94	Normal range
93–90	Decreased range: visit to the doctor recommended
< 90	Critical range: seek medical attention urgently

Source: following "Windisch W et al. European consensus-based (S2k) Guideline: Non-Invasive and Invasive Home Mechanical Ventilation for Treatment of Chronic Respiratory Failure, Update 2017; Pneumologie 2017; 71: 722795"

Decline in oxygen saturation depending on altitude		
The following table informs you of the effects of various altitudes on oxygen saturation value and its impact on the human body. The following table does NOT apply to people with certain pre-existing conditions (e.g. asthma, cardiac insufficiency, respiratory diseases, etc.). People with pre-existing conditions may already show signs of illness (e.g. hypoxia) at lower altitudes.		
Altitude	Expected SpO ₂ value (oxygen saturation) in %	Impact on human body
1500–2500 m	> 90	No altitude sickness (normally)
2500–3500 m	~ 90	Altitude sickness, acclimatisation recommended
3500–5800 m	< 90	Very frequent altitude sickness, acclimatisation absolutely essential
5800–7500 m	< 80	Severe hypoxia, only limited length of stay possible
7500–8850 m	< 70	Immediate, acute danger to life

Source: Hackett PH, Roach RC: High-Altitude Medicine. In: Auerbach PS (ed): Wilderness Medicine, 3rd edition; Mosby, St.Louis, MO 1995; 1-37.

MAINTENANCE/CLEANING

⚠ CAUTION

Do not use high pressure or ethylene oxide sterilisation on the pulse oximeter! The device is not suitable for sterilisation. Under no circumstances should you hold the pulse oximeter under water, as this can cause liquid to enter and damage the pulse oximeter.

- Clean the housing and the interior rubber surface of the pulse oximeter with a soft cloth dampened with medical alcohol after each use.
- If a low battery status appears on the display of the pulse oximeter, change the batteries.
- If you are not going to use the pulse oximeter for more than one month, remove both batteries from the device in order to prevent possible leaking.

STORAGE

NOTICE

Store the pulse oximeter in a dry place. If the humidity is too high it may shorten the service life of the pulse oximeter or damage it.

DISPOSAL

For environmental reasons, do not dispose of the device in household waste at the end of its service life. Dispose of the device at a suitable local collection or recycling point in your country. Dispose of the device in accordance with EC Directive Waste Electrical and Electronic Equipment (WEEE). If you have any questions, please contact the local authorities responsible for waste disposal.

Batteries must not be disposed of in the household waste. They may contain poisonous heavy metals and are subject to special refuse treatment. The codes below are printed on batteries containing harmful substances:

Pb = battery contains lead
Cd = battery contains cadmium
Hg = battery contains mercury

WHAT IF THERE ARE PROBLEMS?

Problem	Possible cause	Solution
Measurement values are not correctly displayed	The measured SpO ₂ is too low (< 70%).	Do the measurement again. If the problem occurs repeatedly and the device is functioning properly, seek medical advice as a matter of urgency.
	There is a strong light source (e.g. fluorescent lamp or direct sunlight) in the vicinity.	Remove pulse oximeter from the vicinity of these light sources.
The pulse oximeter does not display any readings or cannot be switched on.	The batteries in the pulse oximeter are empty.	Replace the batteries.
	Batteries are not inserted correctly.	Reinsert the batteries.
	The pulse oximeter is faulty.	Contact the retailer or Customer Services.
The pulse oximeter is displaying measurement interruptions or high measurement value jumps.	Insufficient circulation in the measurement finger.	Pay attention to the warnings and safety notes!
	Measurement finger is too large or too small.	Fingertip must have the following measurements: Width between 10 and 20 mm Thickness between 5 and 15 mm.
	Finger, hand or body is moving.	Keep your finger, hand and body still during the measurement.
	Cardiac arrhythmia.	Seek medical attention.

TECHNICAL DATA

Type	PO 35
Measurement method	Non-invasive measurement of arterial oxygen saturation of haemoglobin and pulse rate in finger
Measurement range	SpO ₂ 0-100 %, Pulse 30 - 250 beats/minute
Accuracy	SpO ₂ 70 - 100 %, ± 2%, Pulse 30 – 250 bpm, ≤99 bpm ± 2 bpm, ≥100bpm ± 2%
Dimensions	L 59,3 mm x W 34 mm x H 34 mm
Weight	Approx. 54,5 g (including batteries)
Sensor to measure SpO ₂	Red light (wavelength 660 nm), optical output power < 6,65 mW; infrared (wavelength 905 nm), optical output power < 6,75 mW; Silicon receiver diode This information can be particularly useful for clinicians
Permissible operating conditions	+10 °C bis +40 °C, ≤ 75 % relative humidity, 700 - 1060 hPa ambient pressure
Permissible storage conditions	-40°C to +60°C, ≤95% relative humidity
Power supply	2 x 1.5 V  AAA batteries
Battery life	2 AAA batteries last for approx. 2.5 years of operation at 3 measurements per day (60 seconds each)
Expected service life of the device	Information on the service life of the product can be found on the homepage
Classification	IP22, application part, type BF
Display	TFT

The serial number is located on the device or in the battery compartment.

Technical specifications are subject to change without notification to allow for updates.

- This device conforms to the European standard EN 60601-1-2 (Group 1, Class B, in accordance with CISPR 11, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8) and is subject to particular precautions with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this device. For more details, please contact our Customer Services at the address indicated.

Notification of incidents

For users/patients in the European Union and identical regulation systems, the following applies: If a major incident occurs during or through use of the product, notify the manufacturer and/or their representative of this as well as the respective national authority of the member state in which the user/patient is located.

Notes on electromagnetic compatibility

NOTICE

- The device is suitable for use in all environments listed in these instructions for use, including domestic environments.
- The use of the device may be limited in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the display/device.
- Avoid using this device directly next to other devices or stacked on top of other devices, as this could lead to faulty operation. However, if it is necessary to use the device in such a manner, this device as well as the other devices must be monitored to ensure they are working properly.
- The use of accessories other than those specified or provided by the manufacturer of this device can lead to an increase in electromagnetic emissions or a decrease in the device's electromagnetic immunity; this can result in faulty operation.
- Keep portable RF communication devices (including peripheral equipment, such as antenna cables or external antennas) at least 30 cm away from all device parts, including all cables included in delivery.
- Failure to comply with the above can impair the performance of the device.

WARRANTY/SERVICE

Further information on the warranty and warranty conditions can be found in the warranty leaflet supplied.

Subject to errors and changes