

Dear customer,

Thank you for choosing one of our products. Our name stands for high-quality, thoroughly tested products for applications in the areas of heat, weight, blood pressure, body temperature, pulse, gentle therapy, massage, beauty, baby and air. Please read these instructions for use carefully and keep them for later use, be sure to make them accessible to other users and observe the information they contain.

With kind regards,
Your Beurer team

1. Included in delivery

1x PO45 pulse oximeter, 2x 1.5 V AAA batteries, 1x lanyard, 1x belt bag, 1x these instructions for use

2. Intended use

The Fingertip Pulse Oximeter PO 45 is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homecare.

3. Getting to know your instrument

The Beurer PO45 pulse oximeter provides a non-invasive measurement of the arterial oxygen saturation (SpO2), the heart rate (pulse rate) (PRbpm) and the perfusion index (PI). Oxygen saturation indicates the percentage of haemoglobin in arterial blood that is loaded with oxygen. Therefore it is an important parameter for assessing the respiratory function.

Oxygen binds to hemoglobin in red blood cells when moving through the lungs. It is transported throughout the body as arterial blood. A pulse oximeter uses two frequencies of light (red and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO2. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO2 level.

1. Red and Infrared-ray Emission Tube 2. Red and Infrared-ray Receipt Tube

A low oxygen saturation value generally indicates underlying illnesses (respiratory diseases, asthma, heart failure etc.).

People with a low oxygen saturation value are more likely to experience the following symptoms: shortness of breath, increased heart rate, weakness, nervousness and outbreaks of sweating. If oxygen saturation is known to be chronically diminished, it requires monitoring using the pulse oximeter under medical supervision. If you have acutely diminished oxygen saturation, with or without the accompanying symptoms, you must consult a doctor immediately as it could lead to a life-threatening situation. The pulse oximeter is particularly suitable for patients at risk such as people with heart disease or asthma, but also for athletes and healthy people who exercise at high altitude (e.g. mountaineers, skiers or amateur pilots).

Features of the pulse oximeter

- Easy to use and to take with you (ideal for on the go)
- Compact, lightweight design
- Two-colour OLED display, readings for oxygen saturation (SpO2), pulse rate (PRbpm) and perfusion index (PI) are shown
- Adjustable display brightness (1 to 10)
- 7 display formats/low battery indicator/automatic switch-off after 8 seconds if no signal is received

4. Signs and symbols

The following symbols are used in these instructions for use, on the packaging and on the type plate for the device:

| | | | |
|-------------------------|--|--|---|
| | WARNING Warning instruction indicating a risk of injury or damage to health | | Manufacturer |
| | IMPORTANT Safety note regarding potential for damage to the device/accessories | | Application part, type BF |
| | Note Note on important information | | Do not dispose of batteries containing hazardous substances with household waste. |
| | Observe the instructions for use | | This product satisfies the requirements of the applicable European and national directives. |
| %SpO₂ | Arterial oxygen saturation of haemoglobin (in percent) | | Serial number |
| PR bpm | Pulse rate (beats per minute) | | Alarm suppression |
| PI% | Index perfusions | | |
| | Permissible storage temperature and humidity | | Device protected against foreign objects ≥12.5 mm and against falling drops of water |
| | Permissible operating temperature and humidity | | Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE |
| | Low power indication | | Dispose of packaging in an environmentally friendly manner |

5. Warnings and safety notes

Non-observance of the following information may result in personal injury or material damage. Store these instructions for use and make them accessible to other users. Make sure you include these instructions for use when handing over the device to third parties.

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. In case of doubt, 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 will result in voiding of the warranty. For repairs, please contact Beurer customer services or an authorised retailer.

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 small children or babies.
- during an MRI or CT scan.
- while 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.
- on large fingers that do not fit into the device easily (fingertip: width approx. > 20 mm, thickness approx. >15 mm).
- on fingers with anatomical changes, oedemas, scars or burns.
- on fingers that are too small, as with small children for example (width approx. < 10 mm, thickness < 5 mm).
- on patients who are not steady at the site of application (e.g. trembling).
- near flammable or explosive gas mixtures.

- Using the device for long periods may cause pain for people with circulatory disorders. Therefore do not use the pulse oximeter for longer than 30 minutes on one finger. This is essential to ensure correct sensor orientation and to safeguard the integrity of the skin.
- The pulse oximeter displays an instantaneous measurement but cannot be used for continuous monitoring.
- 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.

- 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.
- 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 PO 45. Otherwise, degradation of the performance of this equipment could result.
- The pulse oximeter equipment is calibrated to display functional oxygen saturation.
- 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. Children should be supervised around the device to ensure they do not play with it.
- The displays for the pulse wave and pulse bar allows 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.

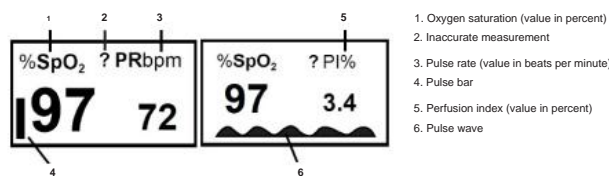
Non-observance of the following instructions can lead to incorrect or failed measurements:

- There must not be any nail varnish, artificial nails or other cosmetics on the finger to be measured.
- Ensure that the finger nail on the finger to be measured is short enough that the fingertip covers the sensor element in the housing.
- If the person moves while the measurement is being taken. Keep your hand, finger and body steady during the measurement.
- For people with cardiac arrhythmia, the oxygen saturation level (SpO₂) readings and the heart rate (PRbpm) 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 cases of carbon monoxide poisoning, the pulse oximeter displays a measurement value that is too high.
- To avoid falsifying the measuring result, 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 inherited methaemoglobin reductase deficiency.
- The measurement may be falsified in patients with an arterial catheter, hypotension, severe vascular constriction, anaemia or hypothermia.
- Protect the pulse oximeter from dust, shocks, moisture, extreme temperatures and explosive materials.

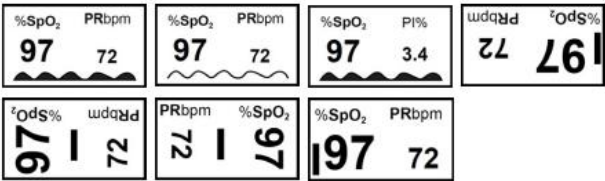
6. Unit description Device



Display

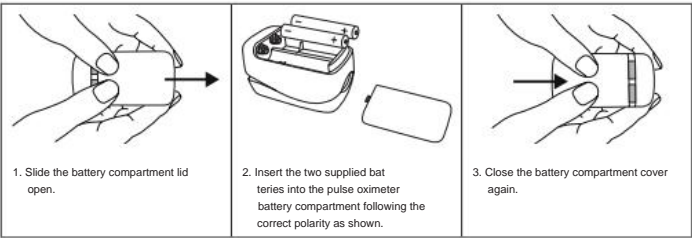


Display formats (7 different formats)



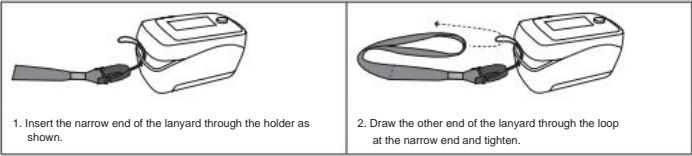
7. Initial use

7.1 Inserting the batteries

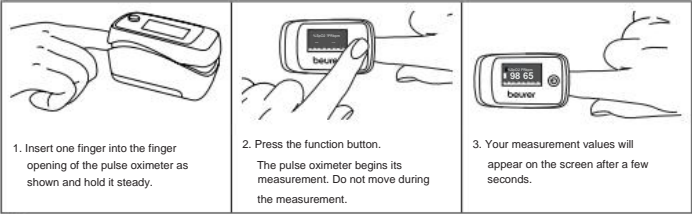


7.2 Attaching the lanyard

To transport the pulse oximeter more easily (e.g. whilst on the move) you can attach a lanyard to the device.



8. Operation



Note

- If the ? symbol appears on the display this indicates that the measurement signal is unstable, and the readings shown are invalid.
- When you remove your finger from the pulse oximeter, the device will automatically switch off after approx. 8 seconds.
- To select your desired display format, hold down the function button briefly during operation.
- To select your desired display brightness, hold down the function button for slightly longer during operation.

9. Evaluating measurement results

| WARNING The following table for evaluating your measurements does NOT apply to people with certain pre-existing conditions (e.g. asthma, heart failure, 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: Adapted to "Windisch W et al. Guidelines for Non-Invasive and Invasive Home Mechanical Ventilation for Treatment of Chronic Respiratory Failure Update 2017. Pneumologie 2017; 71: 722-795"

Evaluating perfusion index

The perfusion index (PI) may lie between 0.3% and 20%, and varies depending on the patient, measurement location and state of health. A very low PI value can impair the measurement.

| Decline in oxygen saturation depending on altitude | | |
|---|--|---|
| Note 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, heart failure, respiratory diseases etc.). People with pre-existing conditions can 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.

10. Maintenance/cleaning

IMPORTANT:

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 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 to avoid possible leaking.

11. Storage

IMPORTANT:

Store the pulse oximeter in a dry place (relative humidity <93%). If the humidity is too high it may shorten the service life of the pulse oximeter or damage it. Store the pulse oximeter in a place where the ambient temperature is between -25°C and 70°C.

12. Disposal

Please dispose of the device in accordance with EC Directive – WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

The empty, completely flat batteries should be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries.

Note: The codes below are printed on batteries containing harmful substances: Pb = Battery contains lead, Cd = Battery contains cadmium, Hg = Battery contains mercury.

13. What if there are problems?

| Problem | Possible cause | Solution |
|--|--|--|
| "Finger out" appears on the display | The finger on which the measure ment is being taken has not been inserted properly in the pulse oximeter | Insert the finger in the pulse oximeter again |
| Measurement values are not correctly displayed | The measured SpO ₂ is too low (<70%) | Do the measurement again. If the prob lem 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 is displaying measurement interruptions or high measurement value jumps | Insufficient circulation in the measurement finger | Observe the warnings and safety notes in section 5 |
| | 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 |
| Pulse oximeter will not switch on. | Batteries are flat | Replace the batteries |
| | The batteries have not been inserted correctly | Reinsert the batteries |
| | The pulse oximeter is faulty. | Contact the retailer or Customer Services |
| Indicator light goes out suddenly | The pulse oximeter switches off automatically after 8 seconds if it is not receiving a signal | Switch the pulse oximeter on again using the ON/OFF button. |
| | Batteries are flat | Replace the batteries |
| "Error 3" appears on the display | The red light receiving LED is faulty | Contact the retailer or Customer Services |
| "Error 4" appears on the display | The infrared light receiving LED is faulty | Contact the retailer or Customer Services |
| "Error 6" appears on the display | The display is faulty. | Contact the retailer or Customer Services |
| "Error 7" appears on the display | The receiving LEDs are faulty | Contact the retailer or Customer Services |

14. Technical data

| | |
|------------------------------------|---|
| Type | AFTER 45 |
| Measurement method | Non-invasive measurement of arterial oxygen saturation of haemoglobin, pulse rate and perfusion index in finger. |
| Measurement range | SpO ₂ (oxygen saturation): 70–100%, pulse: 30–250 beats/minute PI: 0.3–20% |
| Accuracy | SpO ₂ (oxygen saturation): 70–100%, ±2%, pulse: 30–250 bpm, ±2 beats/minute PI: 0.3% – 1%; ±0.2 digits; >1.1% ±20% |
| Dimensions | L 59 mm x W 33 mm x H 33 mm |
| Weight | Approx. 57 g (including batteries) |
| Sensor to measure SpO ₂ | Red light (wave length 660 nm ±3nm, 3.2 mW); infra-red (wave length 905 nm ±10 nm, 2.4 mW); silicon receiver diode |
| Permissible operating conditions | +5°C to +40°C, 45–93% relative humidity, 70–106 kPa ambient pressure |
| Permissible storage conditions | -25°C to +70°C, 45% relative humidity, 70–106 kPa ambient pressure |
| Power supply | 2 x 1.5V — AAA batteries |
| Battery life | 2 AAA alkaline batteries last for approx. 2 years of operation at 1 measurement per day (each of 60 seconds). |
| Classification | IP22, application part, type BF |
| Equipment response time | Response time of changing value is 8 seconds. |

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

Technical information is subject to change without notification to allow for updates.

- This device conforms with the European standards EN60601-1 and EN60601-1-2 (In accordance with CISPR, IEC 61000-4-2, IEC 61000-4-3 and 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.
- This device complies with EU Directive 93/42/EEC concerning medical devices, the Medizinproduktegesetz (German Medical Devices Act) and the DIN EN ISO 80601-2-61 standard (Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use).

Notes on electromagnetic compatibility

WARNING

- 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. If, however, it is necessary to use the device in the manner stated, 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.
- Failure to comply with the above can impair the performance of the device.

15. Warranty/service

Beurer GmbH, Söflinger Straße 218, 89077 Ulm, Germany (hereinafter referred to as "Beurer") provides a warranty for this product, subject to the requirements below and to the extent described as follows.

The warranty conditions below shall not affect the seller's statutory warranty obligations which ensue from the sales agreement with the buyer. The warranty shall apply without prejudice to any mandatory statutory provisions on liability.

Beurer guarantees the perfect functionality and completeness of this product.

The worldwide warranty period is 5 years, commencing from the purchase of the new, unused product from the seller.

The warranty only applies to products purchased by the buyer as a consumer and used exclusively for personal purposes in the context of domestic use. German law shall apply.

During the warranty period, should this product prove to be incomplete or defective in functionality in accordance with the following provisions, Beurer shall carry out a repair or a replacement delivery free of charge, in accordance with these warranty conditions.

If the buyer wishes to make a warranty claim, they should approach their local retailer in the first instance: see the attached "International Service" list of service addresses.

The buyer will then receive further information about the processing of the warranty claim, e.g. where they can send the product and what documentation is required.

A warranty claim shall only be considered if the buyer can provide Beurer, or an authorised Beurer partner, with - a copy of the invoice/ purchase receipt, and - the original product.

The following are explicitly excluded from this warranty: - deterioration due to normal use or consumption of the product; - accessories supplied with this product which are worn out or used up through proper use (e.g. batteries, rechargeable batteries, cuffs, seals, electrodes, light sources, attachments and nebuliser accessories); - products that are used, cleaned, stored or maintained improperly and/or contrary to the provisions of the instructions for use, as well as products that have been opened, repaired or modified by the buyer or by a service centre not authorised by Beurer; - damage that arises during transport between manufacturer and customer, or between service centre and customer;

- products purchased as seconds or as used goods;
- consequential damage arising from a fault in this product (however, in this case, claims may exist arising from product liability or other compulsory statutory liability provisions).

Repairs or an exchange in full do not extend the warranty period under any circumstances.

Subject to errors and changes