

**Pulse oximeter** 

Beurer GmbH • Söflinger Str. 218 • 89077 Ulm • Germany www.beurer.com • www.beurer-healthguide.com



### **ENGLISH**

#### 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 accessible to other users and observe the information they contain

#### 1. Included in delivery

1x PO 45 pulse oximeter, 2x 1,5 V AAA batteries, 1x lanyard, 1x belt bag, 1x these instructions for use

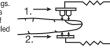
The Fingertip Pulse Oximeter PO 45 is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin  $(SpO_2)$  and Pulse Rate of adult, adolescent and child patients in hospitals, hospital-type facilities and homecare.

#### 3. Getting to know your instrument

The Beurer PO 45 pulse oximeter provides a non-invasive measurement of the arterial oxygen saturation (SpO<sub>2</sub>), 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

respiratorly furticulty.

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 (ed and infrared) to determine the percentage (%) of hemoglobin in the blood that is saturated with oxygen. The percentage is called blood oxygen saturation, or SpO<sub>2</sub>. A pulse oximeter also measures and displays the pulse rate at the same time it measures the SpO<sub>2</sub> level.



displays the pulse rate at the same unleft measures the SpO<sub>2</sub> 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 beatin, incleased mean task, weakness, liet obsciences and outbreas oil swalling. In Oxygen saturation is within the companying 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 (SpO<sub>2</sub>), pulse rate (PRbpm) and perfusion index (PI)
- 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

$\triangle$	WARNING Warning instruction indicating a risk of injury or damage to health	•••	Manufacturer
$\triangle$	IMPORTANT Safety note regarding potential for damage to the device/accessories	☀	Application part, type BF
i	<b>Note</b> Note on important information	Pb Cd Hg	Do not dispose of batteries containing hazardous substances with household waste.
<b>③</b>	Observe the instructions for use	<b>C</b> € <sub>0483</sub>	This product satisfies the requirements of the applicable European and national directives.
%SpO <sub>2</sub>	Arterial oxygen saturation of haemoglobin (in percent)	SN	Serial number
PR bpm	Pulse rate (beats per minute)	√×	
PI%	Perfusions index	ŠpO₂	Alarm suppression
Storage	Permissible storage temperature and humidity	IP22	Device protected against foreign objects ≥12.5 mm and against falling drops of water
Operating	Permissible operating temperature and humidity	X	Disposal in accordance with the Waste Electrical and Electronic Equipment EC Directive – WEEE
₩.	Low power indication	21) <b>P</b> AP	Dispose of packaging in an environ- mentally 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

## ⚠ 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.
- on fingers with anatomical changes, oedemas, scars or burns
- on intigers with area too small, as with small children for example (width approx. < 10 mm, thickness < 5 mm).</li>
   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 n and to safeguard e 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 person production.

at the measurement site. Rather, they are exclusively used to display the current visual signal variation at

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

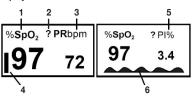
the measurement site and do not enable reliable diagnostics for the pulse.

- 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 finger look eneasured is element in the housing.
   If the person moves while the measurement is being taken. Keep your hand, finger and body steady during the
- For people with cardiac arrhythmia, the oxygen saturation level (SpO<sub>3</sub>) readings and the heart rate (PRbpm) may
- For people with cardiac armynmia, the oxygen saturation level (spb2) readings and the near rate (Priophn) me 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 dve in the past or for those who have abnormal haemoglobin levels. This applies in particular for cases of carbon monoxide policy in grant methaemoglobin 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 con-
- Protect the pulse oximeter from dust, shocks, moisture, extreme temperatures and explosive materials

#### 6. Unit description Device

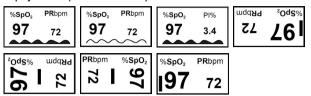
Finger oper

#### Display



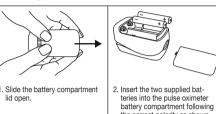
- 1 Oxygen saturation (value in percent) 2. Inaccurate measurement
- 3. Pulse rate (value in beats per minute) 4. Pulse bar
- 5. Perfusion index (value in percent) 6. Pulse wave

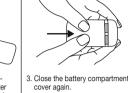
#### Display formats (7 different formats)



#### 7. Initial use

#### 7.1 Inserting the batteries



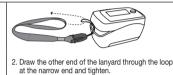


7.2 Attaching the lanyard

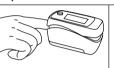
To transport the pulse oximeter more easily (e.g. whilst on the move) you can attach a lanyard to the device.

the correct polarity as shown





8. Operation







. Insert one finger into the finger opening of the pulse oximeter as shown and hold it steady.

Press the function button The pulse oximeter begins its measurement. Do not move during the measurement.

appear on the screen after a few seconds.

(i) 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.
- 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 <sub>2</sub> (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: 722795

## **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

## (i)<sub>Note</sub>

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 <sub>2</sub> 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 oximete

- · Clean the housing and the interior rubber surface with a soft cloth dampened with medical alcohol after each
- use.

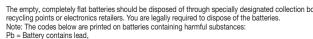
  If a low battery status appears on the display of the pulse oximeter, change the batteries.
- If you are not going to use the pulse oximeter for more than one month, remove both batteries from the device
  to avoid possible leaking.

# 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.

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



Cd = Battery contains cadmium. Hg = Battery contains mercury

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 <sub>2</sub> 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	Insufficient circulation in the measurement finger	Observe the warnings and safety notes in section 5
interruptions or high meas- urement value jumps	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	Batteries are flat	Replace the batteries
switch on.	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	PO 45	
Measurement method	Non-invasive measurement of arterial oxygen saturation of haemoglobin, pulse rate and perfusion index in finger.	
Measurement range	${\rm SpO_2}$ (oxygen saturation): 70–100 %, pulse: 30–250 beats/minute PI: 0.3–20 %	
Accuracy	$\rm SpO_2$ (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 <sub>2</sub>	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, ≤15-93 % relative humidity, 70-106 kPa ambient pressure	
Permissible storage conditions	-25 °C to +70 °C, ≤93 % 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 measurements per day (each of 60 seconds).	
Classification	IP22, application part, type BF	
Equipment response time	Response time of changing value is 8 seconds.	

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

• This device conforms with the European standards EN66601-1 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 - or infer edrains, please of material that counties enviros at the adulties 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

## Notes on electromagnetic compatibility

## ✓! WARNING

- The device is suitable for use in all environments listed in these instructions for use, including domestic envi-• The use of the device may be limited in the presence of electromagnetic disturbances. This could result in
- The use of it not evertice may be limited in the presence or 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
- 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 rise warranty conductors between start not affect the select statutory warranty congations will 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 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 accord ance with these warranty conditions.

If the buyer wishes to make a warranty claim, they should approach their local retailer in the first The buyer will then receive further information about the processing of the warranty claim, e.g. where they can

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:

Pb Cd He

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