



Please read these instructions for use carefully and keep them for later use, make them accessible to other users, and observe the information they contain.

Dear customer, Thank you for choosing a product from our range. Our name is synonymous with high-quality, thoroughly tested products for applications in the areas of heat, weight, blood pressure, body temperature, pulse, gesture therapy, massage, beauty, baby and air.

1. Included in delivery Check that the exterior of the cardboard delivery packaging is intact and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

2. Signs and symbols

Table with symbols and their meanings: WARNING, IMPORTANT, Note, Observe the instructions for use, %SpO2, PR bpm, Storage and humidity, Disposal of packaging, UDI, REF.

3. Intended use

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. To take a measurement, the pulse oximeter uses two rays of light with differing wavelengths, which strike the finger inserted into the housing.

Purpose

The pulse oximeter is used for the non-invasive measurement of arterial oxygen saturation (SpO2) and heart rate (pulse rate) at home and in hospital. This use is not suitable for long-term measurement.

Target group

The pulse oximeter is suitable for people who have a need for its diagnostic function. It is designed for those users with a fingertip width of approx. 10-20 mm and a thickness of approx. 5-15 mm who have no contraindications.

Indication

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). The pulse oximeter is also suitable for people without pre-existing conditions who want to measure their oxygen saturation or who show symptoms of low oxygen saturation.

Clinical benefits

Users can quickly and easily determine their oxygen saturation value through the device and detect a decreased oxygen saturation value. People with a low oxygen saturation value frequently 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. An acutely low oxygen saturation (with or without accompanying symptoms) must be clarified immediately by a doctor. This can be a life-threatening situation.

4. Warnings and safety notes

Read these instructions for use carefully! Failure to observe the following information may result in personal injury or material damage. Contraindication: 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, whilst taking a blood pressure measurement on the same arm using a cuff, on fingers with nail varnish or which are dirty or have a plaster or other dressing on them, large fingers that do not fit into the device easily (fingertip width approx. > 20 mm, thickness approx. > 15 mm), fingers that are too small, e.g. with small children for example (width approx. < 10 mm, thickness approx. < 5 mm), fingers with anatomical changes, oedemas, scars, or burns, on patients who cannot keep still at the site of application (e.g. trembling).

General warnings

Do not use any additional parts that are not recommended by the manufacturer or offered as accessories. Under no circumstances should the device be used for purposes other than those for which it was designed. Do not use the pulse oximeter for long-term measurement and it is therefore not suitable for evaluating medical results. The pulse oximeter displays an instantaneous measurement but cannot be used for continuous monitoring. 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 into 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 can be used by children over the age of 8 and by people with reduced physical, sensory or mental skills or a lack of experience or knowledge, provided that they are supervised or have been instructed on how to use the device safely and are aware of the consequent risks of use. Children should not play with the device. The display for the pulse value 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 variations at the measurement site and do not enable reliable diagnostics on the pulse. Do NOT use the pulse oximeter in close proximity to flammable or explosive gas mixtures.

General precautions

Non-observance of the following instructions can lead to incorrect or failed measurements. Do not use 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 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 fail completely. 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 be no 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 haemoglobin level may be affected by carbon monoxide poisoning and methaemoglobin poisoning, which can occur for example from the administration of local anaesthetics or from an existing methaemoglobin reductase deficiency. Protect the pulse oximeter from dust, shocks, and moisture as well as extreme temperatures and explosive materials.

Measures for handling batteries

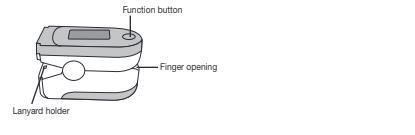
If your skin or eyes come into contact with battery fluid, rinse the affected areas with water and seek medical assistance. Choking hazard! Small children can swallow and choke on batteries. Therefore, batteries should be stored out of the reach of small children. Risk of explosion! Do not throw batteries into a fire. If a battery has leaked, do not touch the battery, and clean the battery compartment with a dry cloth. Do not disassemble, open or crush the batteries. Observe the plus (+) and minus (-) polarity signs. Protect the batteries from excessive heat. Do not charge or short-circuit batteries. If the device is not to be used for a relatively long period, take the batteries out of the battery compartment. Use identical or equivalent battery types only. Always replace all batteries at the same time. Do not use rechargeable batteries!

Notes on electromagnetic compatibility

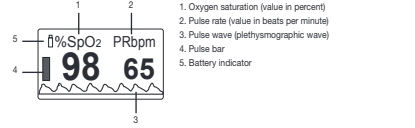
The device is suitable for use in all environments listed in these instructions for use, including domestic environments. The use of the device may be limited in the presence of electromagnetic disturbances. This could result in issues such as error messages or the failure of the device. Avoid using 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. Failure to comply with the above can impair the performance of the device.

5. Device description

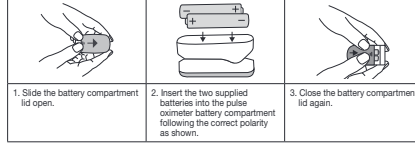


Display description

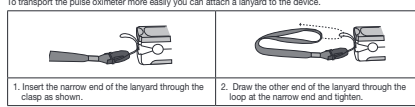


6. Initial use

6.1 Inserting the batteries



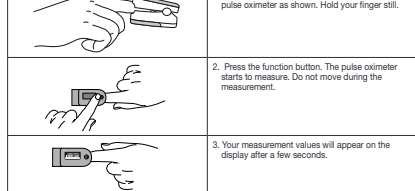
6.2 Attach lanyard



6.3 System requirements for "beurer HealthManager Pro" and "beurer HealthManager" apps

IOS 12.0 and above, Android™ 6.0 and above, Bluetooth® 4.0 and above

7. Usage



Function button

The function button on the pulse oximeter has four functions in total: Switch-on function: When the pulse oximeter is switched off, you can press the function button briefly to switch it on. Activate and deactivate Bluetooth: Briefly press the function button to switch on the pulse oximeter. After switching on the pulse oximeter, press and hold the function button for 5 seconds, in order to access the Bluetooth® setting. "ON" or "OFF" will appear in the display. Briefly press the function button in order to activate (ON) or deactivate (OFF) Bluetooth®. Return to the measurement: Press and hold the function button for 5 seconds. To switch off the pulse oximeter, wait for 10 seconds. The pulse oximeter switches itself off automatically. Transferring measurements to the app and synchronising time and date: See 7.1 "Transfer of the measured values via Bluetooth® low energy technology". Brightness function: To select your desired display brightness, hold down the function button for slightly longer during operation.

Note

The display orients automatically (vertical format, horizontal format). This means that you can easily read the values on the display at any time no matter how you hold the pulse oximeter.

7.1 Transfer of the measured values via Bluetooth® low energy technology

Note: Bluetooth® must be activated (ON) if you wish to transfer data. The "beurer HealthManager Pro"/"beurer HealthManager" app must be activated for transfer. Each time data is transferred, the time and date are synchronised with your smartphone. In order to save all of your measurements with the correct date, we recommend connecting your PO 60 to your smartphone before taking the first measurement. In order to transfer the measurements to your smartphone via Bluetooth®, proceed as follows: Activate Bluetooth® in the settings of your smartphone, open the "beurer HealthManager Pro"/"beurer HealthManager" app, and follow the instructions. In the settings menu of the app, select and connect the PO 60. A randomly generated six-digit PIN code is displayed on the pulse oximeter. At the same time, an input field appears on the smartphone. Here you must enter this six-digit PIN code. There are two ways in which you can synchronise data with your smartphone. In both instances, Bluetooth® must be activated on your smartphone and on the pulse oximeter (ON). In addition, the "beurer HealthManager Pro"/"beurer HealthManager" app must be opened on the smartphone.

Version 1: When the pulse oximeter is switched off, press and hold the function button for 5 seconds. "SYNC" will flash on the display. The device will now attempt to connect to the app for approx. 10 seconds. "SYNC" stops flashing as soon as a connection is established. All measurement data in the memory is automatically transferred to the app. The pulse oximeter will then switch off automatically. Version 2: After measurements are taken, the data will automatically be sent to the app. "SYNC" will flash on the display. The device will now attempt to connect to the app for approx. 10 seconds. "SYNC" stops flashing as soon as a connection is established. All measurement data in the memory is automatically transferred to the app. The pulse oximeter will then switch off automatically. If Bluetooth® is deactivated (OFF), the message OFF will appear after you have taken the measurement.

Note

Bluetooth® is activated automatically. The "beurer HealthManager Pro"/"beurer HealthManager" app must be activated for transfer. Each time data is transferred, the time and date are synchronised with the smartphone.

7.2 Evaluate measurement results

Table with 2 columns: SpO2 measurement (oxygen saturation) in % and Classification/measures to be taken. Values: 99-94 (Normal range), 93-90 (Decreased range: Visit to the doctor recommended), <90 (Critical range: Seek medical attention urgently).

Source: Windisch W et al. European consensus-based (S3) Guideline: Non-Invasive and Invasive Home Mechanical Ventilation for Treatment of Chronic Respiratory Failure, Update 2017; pneumologie 2017; 71: 727-795

Decline in oxygen saturation depending on altitude

Note: The following table informs you of the effects of various attitudes 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.

Table with 3 columns: Altitude, Expected SpO2 value (oxygen saturation) in %, Consequences for humans. Values: 1500-2500 m (>90, No altitude sickness (normally)), 2500-3000 m (~90, Altitude sickness, acclimatisation recommended).

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

8. Cleaning and maintenance

ATTENTION:

Do not use high-pressure sterilisation on the pulse oximeter! 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 with a soft, damp cloth after each use. After each use, clean the rubberised inner surface of the pulse oximeter with a soft cloth moistened with medical alcohol (e.g. Sargatan Hygiene Spray, Bacillol AF, Glassept FF new, or Heipur Plus N). The effectiveness of the cleaning can be improved if you follow the manufacturer's instructions of the respective medical alcohol. 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 leakage.

9. What if there are problems?

Table with 3 columns: Problem, Possible cause, Solution. Problems include: Batteries in the pulse oximeter are empty, The pulse oximeter is not displaying measurement values, Insufficient circulation in the measurement finger, The pulse oximeter is displaying measurement interruptions or high measurement value jumps, Finger, hand or body is moving, Cardiac arrhythmia, "beurer HealthManager Pro"/"beurer HealthManager" app is not activated or Bluetooth® is switched off in the smartphone settings, No data transfer possible for measured values, Bluetooth® not activated on the device (OFF).

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10. Disposal

The empty, completely flat batteries must be disposed of through specially designated collection boxes, recycling points or electronics retailers. You are legally required to dispose of the batteries. The codes below are printed on batteries containing harmful substances: Pb = Battery contains lead, Cd = Battery contains cadmium, Hg = Battery contains mercury. For environmental reasons, do not dispose of the device in the household waste at the end of its useful 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 - WEEE (Waste Electrical and Electronic Equipment). If you have any questions, please contact the local authorities responsible for waste disposal.

11. Technical specifications

Table with 2 columns: Type and Measurement method, Measurement range, Accuracy, Dimensions, Weight, Sensor to measure SpO2, Permissible operating conditions, Permissible storage and transport conditions, Power supply, Battery life, Classification, Data transfer.

The serial number is located on the top in the battery compartment. Technical information is subject to change without notification to allow for updates.

This device complies with European standards EN60601-1 and EN60601-1-2 (in compliance with CISPR 11, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-8) and is subject to special precautionary measures 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. The device complies with Regulation (EU) 2017/745 of the European Parliament and of the Council for medical devices as well as the respective national regulations and the standard DIN EN ISO 80601-2-61 (Medical electrical equipment - Particular requirements for basic safety and essential performance of pulse oximeter equipment). We hereby confirm that this product complies with the European RED Directive 2014/53/EU. The CE Declaration of Conformity for this product can be found at: www.beurer.com/web/web-landingpages/de/condemnationform-02np.

12. 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 excerpt 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 the 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, cables, seals, electrodes, light sources, attachments and rebuilder 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 copied, 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 provisions).

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

Notification of incidents

For users/patients in the European Union and identical regulation systems (EU Medical Device Regulation (MDR) 2017/745), the following applies: If during or through use of the product a major incident occurs, 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.

Subject to errors and changes