

beurer

PO 35

CE0123

EC REP

Distributed by: Beurer GmbH, Söflinger Str. 218, 89077 Ulm, Germany

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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 them accessible to other users and observe the information they contain.

With kind regards,

Your Beurer team

1. Included in delivery

1x PO 35 pulse oximeter, 2x 1.5 V LR03 AAA batteries, 1x Lanyard, 1x Belt bag, 1x these instructions for use

2. Intended use

Only use the Beurer PO 35 pulse oximeter on humans to measure the arterial oxygen saturation (SpO₂) of haemoglobin and the heart rate (pulse rate). The pulse oximeter is suitable for private use (at home) as well as for use in the medical sector (hospitals, medical establishments).

3. Getting to know your device

The Beurer PO 35 pulse oximeter provides a non-invasive measurement of the arterial oxygen saturation (SpO₂) and the heart rate (pulse rate). 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.

Principle of the Oximeter is as follows: An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (O₂) in glow & near-infrared zones. Operation principle of the instrument is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.

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).

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		Permissible storage temperature and humidity
	Note Note on important information		Permissible operating temperature and humidity
	Permissible ambient pressure		Application part, type BF
	Observe the instructions for use		Serial number
	Arterial oxygen saturation of haemoglobin (in percent)		Pulse rate (beats per minute)
	Pulse rate (beats per minute)		The CE labelling certifies that the product complies with the essential requirements of Directive 93/42/EEC on medical products.
	Disposal in accordance with EC Directive WEEE (Waste Electrical and Electronic Equipment)		Alarm suppression
	Do not dispose of batteries containing hazardous substances with household waste.		Device protected against foreign objects ≥12.5 mm and against falling drops of water
	Dispose of packaging in an environmentally friendly manner		European Authorized Representative
	Positive battery contact		Negative battery contact
	Stand-by		Manufacture Date

example from the administration of local anaesthetics or from an existing methaemoglobin reductase deficiency.

- Protect the pulse oximeter from dust, shocks, moisture, extreme temperatures and explosive materials.

Notes on handling batteries

- If your skin or eyes come into contact with battery fluid, flush out the affected areas with water and seek medical assistance.
- Choking hazard!** Small children may swallow and choke on batteries. Store the batteries out of the reach of small children.
- Observe the plus (+) and minus (-) polarity signs.
- If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth.
- Protect the batteries from excessive heat.
- Risk of explosion!** Never throw batteries into a fire.
- Do not charge or short-circuit batteries.
- If the device is not to be used for a 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.
- Do not disassemble, split or crush the batteries.

6. Unit description

Display description

1. Oxygen saturation (value in percent)

2. Pulse rate (value in beats per minute)

3. Pulse wave (plethysmographic wave)

4. Pulse bar

5. Battery level indicator

7. Initial use

7.1 Inserting the batteries

1. Slide the battery compartment lid open.

2. Place the two batteries supplied in the pulse oximeter as shown. Ensure that the correct battery polarity is observed.

3. Close the battery compartment lid again.

7.2 Attaching the lanyard

To transport the pulse oximeter more easily you can attach a lanyard to the device.

1. Insert the narrow end of the lanyard through the holder as shown.

2. Draw the other end of the lanyard through the loop at the narrow end and tighten.

8. Operation

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

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

3. Your measurement values will appear on the screen after a few seconds.

Note

When you remove your finger from the pulse oximeter, the device will automatically switch off after approx. five seconds.

Function button

The function button on the pulse oximeter has two functions in total:

- Switch-on function:** When the pulse oximeter is switched off you can hold down the function button briefly to switch it on.
- 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 ensures that the values are easy to read on the display at all times, regardless of how you hold the pulse oximeter.

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 measurement (oxygen saturation) 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"

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.

IMPORTANT:

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 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 ≤ 95 %). 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 -40 °C and 60 °C.

12. Disposal

For environmental reasons, do not dispose of the device in the household waste at the end of its useful life. Dispose of the unit at a suitable local collection or recycling point. 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 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.

13. What if there are problems?

Problem	Possible cause	Solution
The pulse oximeter is not displaying measurement values.	The batteries in the pulse oximeter are empty.	Replace the batteries.
	Batteries not inserted correctly.	Reinsert the batteries. If after reinserting the batteries correctly there are still no measurement values displayed, contact customer services.
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 chapter 5.
	Measurement finger is too large or too small.	Fingertip must have the following measurements: Width between 10 and 22 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.

14. Technical Data

Model	PO 35
Type	CMS50D
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, ± 2 beats/minute
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 (wave length 660 nm); infra-red (wave length 880 nm); silicon receiver diode
Permissible operating conditions	+10 °C to +40 °C, < 75 % relative humidity, 700–1060 hPa ambient pressure
Permissible storage conditions	-40 °C to +60 °C, ≤ 95 % relative humidity, 500–1060 hPa ambient pressure
Power supply	2x 1.5V – AAA batteries
Battery life	2 AAA batteries last for approx. 2 years of operation at 3 measurements per day (each of 60 seconds).
Classification	IP22, application part type BF
Display	TFT

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 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.
- This device complies with the 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

- 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

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APPENDIX

Guidance and manufacture’s declaration-electromagnetic emissionfor all EQUIPMENT and SYSTEMS

Guidance and manufacture’s declaration –electromagnetic emission		
The PO 35 Pulse Oximeter is tended for use in the electromagnetic environment specified below. The customer of the user of the PO 35 Pulse Oximeter should assure that it is used in such an environment.		
Emission test	compliance	Electromagnetic environ-ment-guidance
RF emissions CISPR 11	Group 1	The PO 35 Pulse Oxime-ter uses RF energy only for their internal function. Therefore, its RF emissions are very low and are not likely to cause any interfe-rence in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PO 35 Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connec-ted to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Not applicable	

Guidance and manufacture’s declaration-electromagnetic immunity for all EQUIPMENT and SYSTEMS

Guidance and manufacture’s declaration-electromagnetic immunity			
The PO 35 Pulse Oximeter is intended for use in the electromagnetic environment speci-fied below. The user of PO 35 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floors should be wood, concrete or ceramic tile. If floor is covered with syn-thetic material, the relative humidity should be at least 30%.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency mag-netic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Guidance and manufacture’s declaration-electromagnetic immunity for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture’s declaration-electromagnetic immunity			
The PO 35 Pulse Oximeter is intended for use in the electromagnetic environment speci-fied below. The customer or the user of PO 35 Pulse Oximeter should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment -guidance
Radiated RF ICE 61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Portable and mobile RF communication equipment should be used no closer to any part of the PO 35 Pulse Oximeter, including cables, than the recommen-ded separation distance calculated from the equation applicable to the frequency of the transmitter. recommended separation distance $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{2}{E_1} \right] \sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determi-ned by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:Ⓔ
NOTE 1 At 80MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cord-less) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which The PO 35 Pulse Oximeter is used exceeds the applicable RF compliance level above, the PO 35 Pulse Oximeter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PO 35.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM for EQUIPMENT or SYSTEM that not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the PO 35 Pulse Oximeter			
The PO 35 Pulse Oximeter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PO 35 Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PO 35 Pulse Oximeter as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150KHz to 80MHz	80MHz to 800MHz $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	800MHz to 2.5GHz $d = \left[\frac{2}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distanced in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmit-ter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			