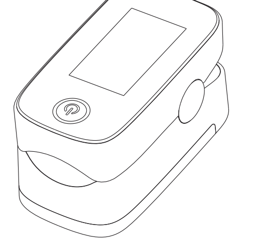
Scaleson

Pulse oximeter S250

User manual



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CE 0123

Thank you for choosing this product from Scaleson UG (haftungsbeschränkt). It is equipped with all the features of the latest technology and has been optimised for easy operation.

Please read the instructions for use carefully before use.

If you have any questions or if problems occur with your device that are not covered in the instruction manual, please contact your Scaleson UG (haftungsbeschränkt) service partner or our customer service department:

Phone: +49 3377 / 9979 395
E-Mail: service@scaleson.net

This manual describes the commissioning and operation of the Scaleson Pulse Oximeter S250.

Scope of delivery:
Pulse oximeter
2 x AAA alkaline batteries
Lanyard
User manual

Intended use:
The pulse oximeter is suitable for private use (at home) as well as for use in the medical sector (hospitals, medical establishments).Only use the pulse oximeter on humans to measure the arterial oxygen saturation (SpO_2) of haemoglobin and the heart rate (pulse rate).

1 Warnings and safety notes

Read these instructions for use carefully. 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.

Please report all serious incidents that have occurred in connection with the product directly to the manufacturer and the competent authority in your country.

⚠ **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 the 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 the customer services or an authorised retailer.
- Using the device for long periods may cause pain for people with circulatory disorders. Therefore do not use the pulse oximeter for longer than approx. 2 hours on one finger.
- The pulse oximeter displays a current 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.
- 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.
- Neither of 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.

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 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
- on fingers with anatomical changes, oedemas, scars or burns.
- on fingers that are too small, as with small children for example .
- on patients who are not steady at the site of application (e.g. trembling).
- near flammable or explosive gas mixtures.

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.
- Keep your hand, finger and body steady during the measurement.
- For people with cardiac arrhythmia, the measurement values of SpO_2 and the heart rate may be incorrect or the measurement may not be possible at all.
- 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 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.

2 Device description

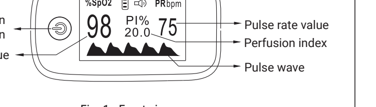

Fig. 1: Front view

3 Technical data

Model:	YM301
Classification:	IP22, application part type BF
Display type:	OLED display
Display colour:	blue
Displayed values:	Sp02%, Pulse Rate, PI%, Bar Graph Battery Indicator, Pulse Wave
Measurement method:	Non-invasive measurement of arterial oxygen saturation of haemoglobin and pulse rate in finger
Measurement range:	SpO_2 30 – 99 % Pulse 25 – 250 beats /minute
Accuracy:	SpO_2 70 – 100 %: ± 2 %, SpO_2 0 – 69 %: unspecified Pulse 30 – 250 bpm, ± 3 beats / minute
Dimensions:	57 x 30 x 31 mm (LxBxH)
Weight:	28 g (batteries not included)
Power supply:	Two 1,5 V AAA (LR03) batteries
Permissible operating conditions:	+10 °C to +40 °C, 10 to 95% relative humidity (non-condensing), 700 – 1060 hPa ambient pressure
Permissible storage conditions:	-20 °C to +60 °C, 0 to 95% relative humidity (non-condensing), 500 – 1074 hPa ambient pressure

Note:

1)The claim for oxygen saturation accuracy should be supported by clinical studies covering the entire claimed range, The fraction of inspired oxygen (Fi02) delivered to test subjects is varied to achieve a series of targeted steady-state saturation periods over the specified Sp02 accuracy range (e.g. 70 % to 100 %), then the Sp02 accuracy is calculated by comparing Sp02 readings of the pulse oximeter to the values of Sa02 determined with a Co-Oximeter.
2) The clinical trial included 11 subjects of different skin colour, including 6 males and 5 females, with an age range of 18 to 46 years.

4 Commissioning

4.1 Inserting the batteries

- Insert the two AAA batteries into the battery compartment with the correct polarity. (see fig. 2)
- Close the battery compartment lid again.

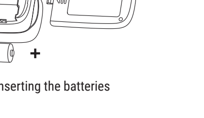

Fig. 2: Inserting the batteries

4.2 Attaching the lanyard

- Push the narrow end of the lanyard through the holder.
- Tighten the other end of the lanyard through the loop of the narrow end. (see Fig. 3)

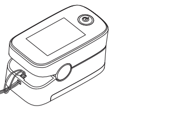

Fig. 3: Attaching the lanyard

5 Operation

- Insert one finger into the finger opening of the pulse oximeter as shown (see fig. 4) and hold it steady.
- Press the power button. The pulse oximeter begins its measurement. Do not move during the measurement.
- Your measurement values will appear on the screen after a few seconds.

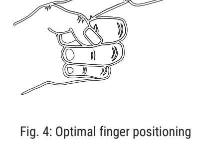

Fig. 4: Optimal finger positioning

Note
When you remove your finger from the pulse oximeter, the device will automatically switch off after approx. eight 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.
- Setting the parameters: To set the individual parameters, such as the display brightness, press and hold the function key during operation.

Setting the parameters
After switching on the oximeter, press and hold the function key for about 2 seconds. The oximeter calls up the interface for setting the parameters.

Settings	
Alm setup	*
Alm	on
Beep	off
Demo	off
Restore	ok
Brightness	1
Exit	

Settings	
Sounds setup	*
SpO2 Alm Hi	100
SpO2 Alm Low	94
Pr Alm Hi	120
Pr Alm Low	50
+/-	+
Exit	

Fig. 5: Interface 1 and 2 settings menu

Press the function key briefly to cycle through the individual parameters. The star shows which parameter you are currently at. By pressing and holding the function key, you can select the parameter and then make the desired changes. To exit the setting menu, select the item "Exit" and keep the function key pressed for a long time.

Display	Parameter	Setting options
Alm	Alarm	Activate (on) or deactivate (off) the alarm. When the alarm is activated and the measured Sp02 or PR values exceed the upper or lower limit, these values flash in the display.
Beep	Whistle sound	Activate (on) or deactivate (off) the whistle sound. When the whistle sound is activated, a beep synchronised with the pulse sounds during the measurement.
Demo	Demo view	By activating the demo view, a sample view of the measured values appears permanently on the display.
Restore	Factory setting	By pressing the function key for a long time, you can reset all settings to factory default.
Brightness	Display brightness	Press the button and select the brightness level in the range from 0 to 5. The larger the value, the brighter the screen.
SpO2 Alm hi	Upper limit of the SpO2 alarm	Press the button and select the upper limit of the SpO2 alarm: 95, 96, 97, 98, 99 or 100.
SpO2 Alm low	Lower limit of the SpO2 alarm	Press the button and select the lower limit of the SpO2 alarm: 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93 or 94.
Pr Alm hi	Upper limit of the pulse alarm	Press the button and select the upper limit of the pulse alarm: 90 - 200 beats/minute
Pr Alm low	Lower limit of the pulse alarm	Press the button and select the lower limit of the pulse alarm: 40 - 70 beats/minute
+/-	Increase or decrease the limit values	Select "+" to increase the limit values listed above. Select "-" to decrease the limit values.

6 Maintenance and cleaning

⚠ **IMPORTANT:**
Do not use high-pressure sterilisation on the pulse oximeter!

The recommended disinfectant is 70% ethanol.
Never use ETO or formaldehyde for disinfection.

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.

7 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. (Cf. chapter 3)

8 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.

9 Malfunctions - causes and elimination

Malfunction	Possible causes	Description / solution
The device cannot be switched on.	The batteries are discharged or almost discharged.	Replace batteries.
	The polarities of the batteries are reversed.	Make sure that the batteries are inserted correctly.
	The device is damaged.	Please contact the dealer.
The SpO_2 and PR values are not displayed normally	The measuring finger is too big or too small.	Select a suitable finger.
	Excessive ambient light.	Avoid excessive exposure to ambient light.
	User's blood perfusion is very low.	Warm the finger and try again.
The display is suddenly off	The unit switches off automatically after 8 sec. if it does not receive any signals.	Normal state. No error.
	The batteries are discharged or almost discharged.	Replace batteries.
The SpO_2 and PR values are not displayed stably	The finger is not inserted deep enough.	Reinsert the finger and try again.
	Finger, hand or body is in motion.	Keep fingers, hand and body still during measurement.
	Not used in the working environment recommended in this manual.	Please use in a normal working environment.
	The device is damaged.	Please contact the dealer.

6 Note on electromagnetic compatibility

The device complies with the requirement of EN 60601-1-2 "Electromagnetic Compatibility - Medical Electrical Equipment".

1	Guidelines and manufacturer's declaration - electromagnetic emissions		
2	The Pulse Oximeter Model YM301 is intended for use in the ELECTRICAL ENVIRONMENT specified below. The customer or the user of the pulse oximeter should ensure that it is used in such an environment.		
3	**Emissions test**	**Compliance**	**Electromagnetic environment - guidance**
4	RF emissions CISPR 11	Group 1	The Pulse Oximeter Model YM301 uses RF energy only for its internal FUNCTION. Therefore, RF emissions are very low and are unlikely to interfere with neighbouring electronic devices.
5	RF emissions CISPR 11	Class B	The Model YM301 Pulse Oximeter is intended for use in all establishments, including residential establishments and those directly connected to a PUBLIC SUPPLY NETWORK that also supplies buildings used for residential purposes.
6	Harmonic emissions IEC 61000-3-2	N/A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

Guidelines and manufacturer's declaration - electromagnetic immunity

The Pulse Oximeter Model YM301 is intended for use in the ELECTRICAL ENVIRONMENT specified below. The customer or the user of the pulse oximeter should ensure that it is used in such an environment.

Immunity test	IEC 60601-Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 2, ± 4, ± 8, ± 15 kV air discharge	± 8 kV contact discharge ± 2, ± 4, ± 8, ± 15 kV air discharge	Floors should be made of wood or concrete or be covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	N/A	N/A
Surge IEC 61000-4-5	± 0,5 kV, ± 1 kV differential mode line-line	N/A	N/A
Voltage dips, short interruptions and voltage variations in power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60 Hz	30 A/m, 50/60 Hz	Magnetic fields at the mains frequency should correspond to the typical values found in the business and hospital environment.
NOTE: UT is the AC mains voltage before applying the test level.			

Guidelines and manufacturer's declaration - electromagnetic immunity

The Pulse Oximeter Model YM301 is intended for use in the ELECTRICAL ENVIRONMENT specified below. The customer or the user of the pulse oximeter should ensure that it is used in such an environment.

Immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms 150 kHz to 80 MHz outside ISM bands	N/A	Portable and mobile RF communications equipment should be used at no less distance from the pulse oximeter, including the leads, than the recommended separation distance, calculated according to the equation appropriate for the transmission frequency.
Radiated RF IEC 61000-4-3	10 V/m 80 kHz to 2,7 GHz	10 V/m	**Recommended separation distance:** $d\left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d\left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2,7 GHz where P is the rated power of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d is the recommended safety distance in metres (m). Field strengths form fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance b level in each frequency range.
			Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies
NOTE 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections of buildings, objects and people.

a) The ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553MHz to 13.567 MHz; 26.957 MHZ to 27.283 MHz and 40.66 MHz to 40.7 MHz.
The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b) The compliance values in the ISM frequency bands between 150 kHz and 80 kHz and in the frequency range from 80 MHz to 2.7 GHz are intended to reduce the likelihood that mobile/portable communication devices can cause interference if accidentally brought into patient areas. For this reason, an additional factor of 10/3 has been added to the formulae used to calculate the recommended separation distance for transmitters in these frequency ranges. distance for transmitters in these frequency ranges.

c) The field strength of stationary transmitters, such as base stations of radio telephones and mobile land radios, amateur radio stations, AM and FM radio and television transmitters cannot be predicted theoretically with any accuracy. To determine the electromagnetic environment with regard to stationary transmitters, a study of the site should be considered.

If the measured field strength at the site where the equipment is used exceeds the above compliance level, the equipment should be observed to verify that it is functioning as intended. If unusual performance characteristics are observed, additional measures may be necessary, such as changing or relocating the equipment.

d) Over the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

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