

8.1 Function button

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

- **Switch-on function:** When the pulse oximeter is switched off you can hold down the function button to switch it on.
- **Display function:** To select your desired display format (vertical format, horizontal format), press the function button during operation. There are four different display formats to choose from.
- **Settings menu function:** To enter the settings menu, you must first set the display format to a horizontal format. To call up the settings menu, press and hold down the function button during operation. You can set the following parameters in the settings menu: display brightness, alarm settings, activate/deactivate data transfer, data storage and upload data to a PC.



Note
To be able to set the following functions (sections 8.2 to 8.6), you must select a horizontal format as the display format (see 8.1 Function button / Display function). If the display format is set to a vertical format and you would like to use the following functions, an error message appears on the display ("Please change direction first!").

8.2 Display brightness

- To set the display brightness, switch on the pulse oximeter and press and hold down the function button. In the settings menu, the menu item "Brightness" is selected.
- There are four different brightness levels to choose from. To set the desired display brightness, press and hold down the function button until the desired level of brightness has been reached.
- To exit the settings menu, use the function button to select the "Exit" menu item and confirm by pressing and holding down the function button.

8.3 Alarm settings

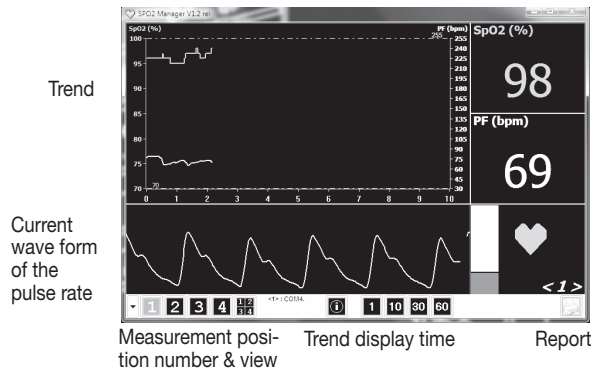
- Switch on the pulse oximeter and press and hold down the function button. The settings menu appears on the display.
- In the settings menu, use the function button to select the "Alarm" menu item and confirm by pressing and holding down the function button.
- Use the function button to select the desired parameter and set the desired value by pressing and holding down the function button.


You can set the following parameters in the alarm menu:

"Dir"	Here you can set whether the setting value runs up or down when setting the alarm limits in the alarm menu. It is necessary to change the setting direction if you would like to move the limits up or down.
"SPO2 ALM HI"	Here you can set an upper limit for oxygen saturation. If, during a measurement, the set limit is exceeded, the saturation value appears yellow and a signal sounds (if the alarm is activated).
"SPO2 ALM LO"	Here you can set a lower limit for oxygen saturation. If, during a measurement, the set limit is undercut, the saturation value appears yellow and a signal sounds (if the alarm is activated).
"PR ALM HI"	Here you can set an upper limit for the pulse rate. If, during a measurement, the set limit is exceeded, the pulse rate appears yellow and a signal sounds (if the alarm is activated).
"PR ALM LO"	Here you can set a lower limit for the pulse rate. If, during a measurement, the set limit is undercut, the pulse rate appears yellow and a signal sounds (if the alarm is activated).
"Alarm"	Here you can activate ("on") or deactivate ("off") the alarm. If you have activated the alarm and the set upper or lower limit is exceeded or undercut, a signal sounds.
"Pulse Sound"	Here you can activate ("on") or deactivate ("off") the pulse tone. If you have activated the pulse tone, a signal sounds at every beat during the measurement.


- To exit the alarm menu, use the function button to select the "Exit" menu item and confirm by pressing and holding down the function button.

8.4 Displaying measurement values in real time on a PC ("USB")





Note
You can create a printout at any time during measurement data recording by using the print function. The printout shows the trend of the current measurement up to that point.



Note
You can view the measurement data of up to four devices at once in the software program. In the software program, you can enlarge the view of the individual measurement data by selecting the corresponding measurement position number.

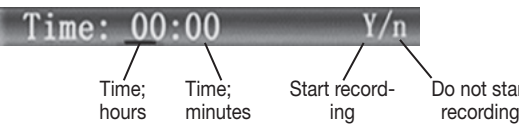
- Connect the pulse oximeter to your PC using the supplied USB data cable.
- Start the "SpO2-Viewer" program on your PC. If you have not yet installed the program, follow the instructions in section 7.2 (Installing the "SpO2-Viewer/Manager" software).
- Switch on the pulse oximeter and press and hold down the function button. The settings menu appears on the display.
- Select the "USB" menu item using the function button.
- Press and hold down the function button. The word "on" is displayed in the "USB" menu item. Insert one finger into the finger opening of the pulse oximeter. After a few seconds, the measurement data is displayed on your PC in real time.
- If you disconnect the data cable from the computer or close the program, an entry mask appears on the PC screen. Here you can enter personal details and store the current measurement data. As standard, the measurement data is stored under C:/Programs/SpO2/Data.
- If you no longer want to display the measurement data on your PC, press and hold down the function button. The word "off" is displayed in the "USB" menu item.
- To exit the settings menu, use the function button to select the "Exit" menu item and confirm by pressing and holding down the function button.

8.5 Recording measurement data


With the pulse oximeter PO 80, you can record your measurement data over a period of up to 24 hours. If required, the measurement data can be stored on your computer or printed out as a report.

To record the measurement data, follow these steps:

- Switch on the pulse oximeter and press and hold down the function button. The settings menu appears on the display.
- Select the "Record" menu item using the function button.
- Press and hold down the function button. The word "Time" will appear on the display. Here you can enter the current time of day so that, later on in the PC software program, you are able to read off the time you started your recording.



- To enter the current time of day, press and hold down the function button and confirm your entry by pressing the function button briefly.



Note
If you start a new recording, the previous recording is automatically **overwritten and cannot be recalled**. The maximum recording duration is 24 hours.


- To start the recording, use the function button to select the "Y" on the display and confirm by pressing and holding down the function button. The pulse oximeter starts recording. If you do not want to start recording, select "N" and confirm by pressing and holding down the function button.



Note
If you have started a recording and return to the display, a red recording symbol appears (REC ●). To save battery power, the device automatically switches to energy-saving mode 30 seconds after the recording starts. If the pulse tone is activated, it is automatically deactivated.

- If you press the function button briefly when in energy-saving mode, "Recording" appears on the display for 2 seconds.
- If you press and hold down the function button when in energy-saving mode, the normal display appears.
- "Memory is full" appears on the display when the pulse oximeter memory is full.

8.6 Uploading measurement data to a computer

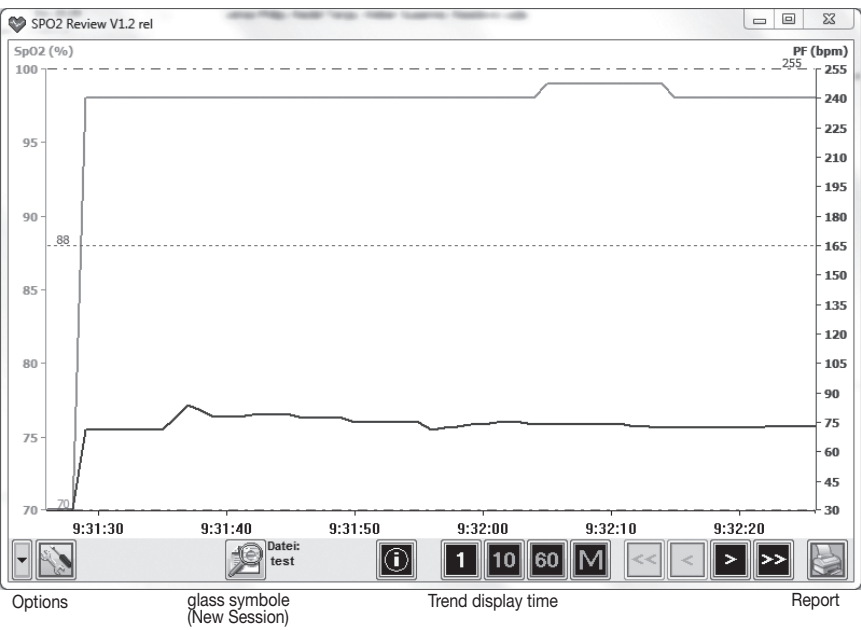


Note
You cannot transfer measurement data to the computer while a measurement data recording is underway.

You can upload the measurement data that you previously stored on the pulse oximeter to your computer.

To upload your stored measurement data to your computer, follow these steps:

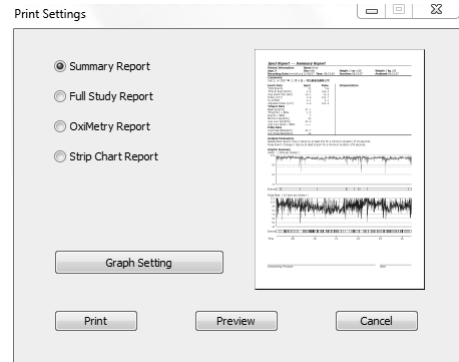
- Connect the pulse oximeter to your PC using the supplied USB data cable.
- Start the "SpO2-Manager" program on your PC.




- Click the magnifying glass symbol in lower section of the program. The "New Session" window opens.
- Please enter your user data. To confirm the user data, click "ok". The program now displays that the pulse oximeter is connected to the computer and that the program is ready to receive the measurement data ("Device connected : waiting for data ...").
- Switch on the pulse oximeter.
- Press and hold down the function button on the pulse oximeter. The settings menu appears.
- Select the "Upload" menu item by pressing the function button briefly.
- Briefly press the function button. The word "on" is displayed in the "Upload" menu item. Your measurement data are now transferred to the computer. It is not possible to cancel the transfer of the measurement data manually.
- When the transfer of the measurement data is complete, the "Exit" menu item is highlighted automatically. To exit the settings menu, press and hold down the function button.
- As soon as your measurement data has been transferred to the computer, your measurement data appears in the software program.

After the measurement data has been transferred successfully to the PC, you can also print out the data in the software program, if required. To do so, follow these steps:

- Click the print symbol in the bottom right-hand corner of the program. The "Report" window opens.





Note
When printing the measurement data, you can choose between four different display variants (Summary Report, Full Study Report, OxiMetry Report, Strip Chart Report). Together with the printout, the user is offered an automatic appraisal of the recorded measurement data. This printout serves exclusively to support the diagnostic findings of your attending doctor. The printout is not a substitute for a medical certificate and is not exhaustive!

8.7 Calling up stored measurement data

To call up previously stored measurement data in the software program, follow these steps:

- Start the "SpO2-Manager" program on your PC.
- Click the magnifying glass symbol in the lower section of the program. Select "Review" in the upper section of the window and click "Find File" in the lower section.
- Select the file you stored (as standard, the files are located under C:/Programs/SpO2/Data) and click "Open" followed by "Ok".
- Your stored measurement data is now displayed in the software program.

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
94-90	Decreased range: visit to the doctor recommended
< 90	Critical range: seek medical attention urgently

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 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.

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

Batteries must not be disposed of with household waste. As a consumer, you are required by law to recycle used batteries. You can recycle your old batteries and rechargeable batteries at public collection points in your community, or wherever batteries of the relevant type are sold.



Note

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 devices including the batteries in the household waste at the end of their service life. Dispose of the unit at a suitable local collection or recycling point. Observe the local regulations for material disposal.

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

13. What if there are problems?

Problem	Possible cause	Solution
The pulse oximeter is not displaying measurement values	The pulse oximeter has run out of battery.	Charge the battery via the USB connection.
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 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 no.	PO 80
Measurement method	Non-invasive measurement of arterial oxygen saturation of haemoglobin and pulse rate in finger
Measurement range	SpO ₂ 0 – 100%, Pulse 0 – 254 beats/minute
Accuracy	SpO ₂ 70 –100%, ±2%, Pulse 30-250 bpm, ±2 beats/minute
Dimensions	L 57 mm x W 32 mm x H 30 mm
Weight	Approx. 42 g
Sensor to measure SpO ₂	Red light (wave length 660 nm); infra-red (wave length 905 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	Integrated, rechargeable lithium battery, 500 mAh / 3.7 V
Classification	IP22, application part, type BF
System requirements for software	Supported operating systems: Windows XP, Windows Vista and Windows 7

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

- This device complies with European Standard EN60601-1-2 and is subject to particular precautions with regard to electromagnetic compatibility. Please note that portable and mobile HF communication systems may interfere with this unit. More details can be requested from the stated Customer Service address or found at the end of the instructions for use.
- This device complies with the EU Directive 93/42/EC concerning medical devices, the Medizinproduktegesetz (German Medical Devices Act) and the DIN EN ISO 9919 standard (Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use)


Guidance and manufacture's declaration-electromagnetic emission for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration –electromagnetic emission		
The PO80 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of the PO80 Pulse Oximeter should assure that it is used in such an environment.		
Emission test	compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The PO80 Pulse Oximeter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PO80 Pulse Oximeter is suitable for use in all establishments, including domestic establishments and those directly connected 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 emissions 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 PO80 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of PO80 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 ±6kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. The manufacturer may recommend the ESD precautionary procedures to user.
Power frequency (50 / 60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic 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 PO80 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the user of PO80 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the PO80 Pulse Oximeter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>recommended separation distance</p> $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800\text{MHz to } 2.5\text{GHz}$ <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined 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:</p> 
<p>NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) 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 PO80 Pulse Oximeter is used exceeds the applicable RF compliance level above, the PO80 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 PO80 Pulse Oximeter.</p>			
<p>^b Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3V/m.</p>			

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 PO80 Pulse Oximeter		
The PO80 Pulse Oximeter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PO80 Pulse Oximeter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PO80 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)	
	80MHz to 800MHz	800MHz to 2.5GHz
	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.117	0.233
0.1	0.369	0.738
1	1.167	2.333
10	3.689	7.379
100	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 <i>P</i> is the maximum output power rating of the transmitter 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.		