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CE 0197

1 General

1.1 Information on Operating Instructions

These operating instructions describe the safe and appropriate handling of the unit. Adherence to specific safety notices and instructions as well as to the applicable on-site accident prevention regulations and general safety regulations is an imperative requirement.

Before beginning all work on the unit, read the operating instructions completely; in particular the chapter regarding safety and the respective safety notices. The reading must have been understood.

The manual is a component of the unit. It is to be kept accessible at all times in direct proximity of the unit. The operating instructions must always be passed on with the unit to third parties.

1.2 Symbol Designation

Important technical safety notices in these operating instructions are designated by symbols.

These specified notices on industrial safety must be strictly complied with and adhered to. Behave cautiously in these cases especially in order to avoid accidents, damages to unit and people.

WARNING! Injury or Mortal Danger!

This symbol marks notices that, if not observed, can lead to health impairments, injuries, lasting bodily injury or to death.

CAUTION! Electric Shock Hazard!

This symbol draws attention to dangerous situations from electric current. The danger of severe injury or death exists from not observing the safety notices. Required work may be performed only by a qualified electrician.

ATTENTION! Risk of Unit Damage!

This symbol designates notices that, if not observed, can lead to damages, malfunctions, and/or loss of the equipment.

NOTICE!

This symbol designates tips and information that are to be considered for efficient and trouble-free handling of the unit.

INFORMATION!

This symbol marks notices to clarify specific specialized terms.

1.3 Liability and Warranty

All data and notices in this operating manual were arranged in consideration of valid regulations, the current state of the art, as well as our many years of knowledge and experience.

This operating manual must be read carefully before beginning all work on and with the unit! The manufacturer does not accept liability for damages and malfunctions that result from not observing the operating instructions.

The German version of these operating instructions is applicable. Translations of the operating instructions also have been provided to the best of our knowledge. However, we cannot accept liability for translation errors.

The text and graphic representations do not correspond necessarily to the supply scope. The designs and diagrams do not correspond to the scale 1:1.

The current supply scope can vary from the presently described data and notices, as well as the graphic representations due to the use of additional order options with special unit or based on the newest technical changes. If you have question, please contact the manufacturer.

We reserve the right to make technical changes on the product within the context of improving and advancing performance characteristics.

We warrant our sat 805 to be free from manufacturing defects in materials and workmanship for two years starting from the date of delivery.

Product warranties remain valid provided the product was properly installed and used.

Defects, malfunctions, or failures of the warranted product caused by damage resulting from Acts of God (such as floods, fire, etc.), environmental and atmospheric disturbances other external forces such as power line disturbances, host computer malfunction, misconnections, and damage caused by misuse, abuse, and unauthorized alteration or repair, are not warranted.

A product will not be warranted in the following situations:

• The product has been found to be defective after the warranty period has expired.

• The product has been subjected to misuse, abuse, or unauthorized repair, whether by accident or other cause. Such conditions will be determined by HUM Gesellschaft für Homecare und Medizintechnik mbH at its sole and unfettered discretion.

• The product is damaged beyond repair due to natural disasters, such as by lightning, flood, earthquake, etc.

• The product in question is either software, or an expendable item, such as a fuse, battery, etc.

This warranty is limited to the repair and/or replacement, at HUM Gesellschaft für Homecare und Medizintechnik mbH sole discretion, of the defective product during its warranty period. HUM Gesellschaft für Homecare und Medizintechnik mbH will replace any product found to be defective within the first three months of purchase provided said product was properly installed and used.

For Masimo cables and sensors, the warranty terms of manufacturer Masimo Corp. apply.

1.4 Copyright Protection

The instruction manual is to be kept confidential. It is exclusively intended for active personnel that work on and with the unit.

All textual data, texts, drawings, illustrations, and other representations are predicted by copyright laws and are entitled additionally to commercial patent rights. Each abusive use is subject to prosecution.

Transfer to third parties, duplication in any shape or form (also in part), as well as the utilization and/or reporting of the contents are not permitted without written permission from the manufacturer. Offences are subject to compensation. Additional rights remain reserved.

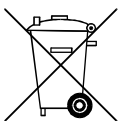
We reserve the right to exercise all rights relating to conditional patent rights.

This device is covered by one or more of the following U.S. Patents:

RE38,492, RE38,476, 7,221,971, 7,215,986, 7,215,984, 6,850,787, 6,826,419, 6,822,564, 6,816,741, 6,745,060, 6,699,194, 6,684,090, 6,654,624, 6,650,917, 6,643,53, 6,606,511, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,157,850, 6,067,462, 6,011,986, 6,002,952, 5,919,134, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036 and their international equivalent patents. Other US and international patents are pending.

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables, which would, alone, or in combination with this device, fall into the scope of one or more of the patents relating to this device.

1.5 Removal and Disposal



– Keep the packaging in order to ship the unit intact in case service is required. Nonetheless, if the packing material should nevertheless be disposed of, the disposal regulations valid in the respective country are to be followed.

- The disposal of infectious supplies (e.g. Masimo sensor with an infection from the user) has to be accomplished by a certified disposal company. You can request its address from city council.
- The unit contains batteries, which are not allowed to be discarded into the domestic refuse. Therefore, rather than throw the batteries into the domestic refuse, dispose of them instead at an appropriate collection site.
- If the unit's end of usage stage has been reached, it is to be disposed of according to the laws. Alternatively, the unit can be returned to the dealer, who then takes over the professional disposal.

2 Safety

This section gives an overview of all important safety aspects for optimal prediction of humans as well as for the safe and trouble-free operation of the unit.

Additionally, the individual chapters contain precise safety notices (designated by symbols) for the prevention of imminent danger. Furthermore, existing pictograms, signs, and inscriptions on the unit must be observed and are to be maintained in well readable condition.

2.1 Intended Use

The unit is intended to be used for the continuous monitoring of functional oxygen saturation and pulse frequency. It has an alarming function in case of deviations from the adjusted alarm limits.

The unit is suitable for monitoring newborns, pediatric and adult patients. Only the certified Masimo sensor may be used for the respective patient type.

Due to its structure and its configuration, the unit can be used domestically, in the clinical setting and in the sleep laboratory stationary and mobile, inside and outside of these areas.

The pulse oximeter is considered to be an early warning system. If a possible undersupply of a patient's oxygen is indicated, a more exact investigation is immediately necessary.

ATTENTION!

Each use of the unit beyond that recommended by law and or misuse is forbidden and is considered to be in violation of the law.

Claims of any kind against the manufacturer and/or its authorized personnel on account of damage from improper use of the unit are forbidden.

The user of the unit is solely responsible for all damages resulting from improper use.

Proper adherence to these operating conditions, as well as the data and the instructions are considered to be proper use.

The unit may not be opened or modified.

Parts other than those pertaining to the supply scope may be used only after release by the company, HUM Gesellschaft für Homecare und Medizintechnik mbH.

2.1.1 Possible Misapplications

WARNING! Fire Hazard!

The pulse oximeter may not be used during nuclear magnetic resonance imaging tests. The electrical current induced there can cause burns. This may affect the MRI image and the MRI device may affect the accuracy of the Pulse Oximetry parameters and measurements.

- This device is to be operated by qualified personnel only. This manual, all precautionary information and specifications should be read before use.
- The pulse oximeter may not be used to monitor breathing (apnea monitor.). This may take place only with special respiratory monitoring equipment.
- A pulse oximeter should be considered an early warning device. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- Explosion hazard. The pulse oximeter may not be used in a combustible atmosphere. This can develop when working with flammable anesthetics, laughing gas, or other combustible gases and liquids.
- If an alarm condition (other than the exceptions listed herein) occurs while the alarm tone volume is set to off, the only alarm indications will be visual displays and symbols related to the alarm condition.
- Do not use any extensions power cords or adapters of any type. The plug-in power supply must be intact and undamaged.
- The pulse oximeter may not be operated in a switchable power socket. Such a plug socket is unsuitable for a secured power supply.
- The pulse oximeter works with an optical measurement procedure and should not be operated near to strong and/or direct light sources.
- Only use one sensor per measuring point to avoid interferences.
- Pay attention to a secured and fixed location of the sensors!

- The presence of carboxyl (HbCO)-, methaemoglobin, (Hbmet) or diluted dyes or substances containing dyes in the blood stream can influence the measurements and can lead incorrectly to higher values.
- When using the pulse oximeter near equipment, which emits strong electromagnetic signals, (e.g. mobile telephones, monitors, etc.) the functionality can be reduced.
- SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.
- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO_2 measurements.

  When elevated levels of MetHb are suspected, laboratory analysis (co-oximetry) of a blood sample should be performed.
- Elevated levels of Carboxyhemoglobin (COHb) will lead to inaccurate SpO_2-measurements. When elevated levels of COHb are suspected, laboratory analysis (co-oximetry) of a blood sample should be performed.
- Elevated levels of Total Bilirubin may lead to inaccurate SpO_2 measurements.
- Severe anemia may cause erroneous SpO_2 readings.

2.2 User Responsibility

This user manual information must be kept within direct proximity of the unit and must be available to those using the equipment at any time.

The unit may only be used in technically sound and operational condition. Before each use the unit must be examined for any possible defects.

The directions in the user manual are to be followed completely and without any changes!

In order to use the unit, the directions in this user manual, the stated safety indicators, the local accident prevention regulations and general safety guidelines, as well as current environmental provisions are to be observed and implemented.

The user and his authorized personnel are responsible for the functioning of the unit without interference as well a defined designation of responsibility for installation, usage, maintenance and cleaning of the unit.

The equipment requires responsible and prudent usage. Unauthorized use or usage by unauthorized personnel can endanger lives.

2.3 Possible Dangers from the Equipment

The unit has undergone endangerment analysis. The construction and execution of the unit is expanded upon and is equivalent to the current state of technology.

And yet risks remain!

WARNING! Health Risk!

Particular supervision is necessary if the unit is used near children or bedridden individuals. Use with small children may never occur without additional monitoring!

CAUTION! Danger from Electrical Current!

Electrical power can cause severe injuries. Damaging the insulation or individual parts is life threatening.

Therefore:

- **Work on the unit may only take place by trained specialists.**
- **Before any work on the unit remove it from the network connection!**
- **Before each use always check network connection cables for damage.**

CAUTION! Danger from Rechargeable Batteries!

The unit contains rechargeable Lithium Ion batteries.

- **Do not throw batteries into a fire or expose them to high temperatures. Risk of explosion exists.**
- **With incorrect usage, liquid could escape from the cells. This can lead to skin irritations. Avoid contact with this liquid. If contact occurs, rinse area with plenty of water. If the liquid gets into the eyes, rinse at once for 10 minutes with water and visit a doctor immediately.**
- **If it becomes necessary to replace the batteries, please contact your medical device supplier our customer service. We assume no liability for improperly replaced batteries.**

ATTENTION! Observe High Frequency Noise Stability!

Medical instruments can be influenced by (mobile) RF-communication installations (e.g. cell phones).

Do not use cell phones in the direct vicinity of the unit.

ATTENTION! Observe Electromagnetic Compatibility!

Medical electrical equipment is subject to special safety regulations regarding electromagnetic compatibility (EMC) and must be used and installed according to directions in the EMC document.

Pay special attention to:

- **Floors should be made of wood or concrete, or covered with ceramic tiles. If the floor consists of synthetic materials, the relative humidity must be at least 30%.**
- **The unit may not be exposed to strong magnetic fields during operation.**
- **Magnetic fields in the network frequency must correspond to typical values found in business or hospital environments.**

2.4 Users

The unit may only be used by trained specialists and instructed users. The configuration of the unit (e.g. the alarm limits) in particular has to take place with corresponding medical expertise.

2.5 Customer Service

If assistance in commissioning, in operation or maintenance is needed, or you would like to report an unexpected operation or incident with sat 805, you can contact HUM Gesellschaft für Homecare und Medizintechnik mbH as follows:

Office Hours:	Monday - Thursday 8.00 a.m. - 4.30 p.m. | Friday 8.00 a.m. - 3.45 p.m.
Address:	HUM Gesellschaft für Homecare und Medizintechnik mbH Zum Pier 79 | 44536 Lünen | Germany
Phone:	+49 (0) 231 / 88 08 85 - 0
Fax:	+49 (0) 231 / 88 08 85 - 58
Internet:	www.hum-online.de
E-Mail:	sales@hum-online.de

3 Technical Data

3.1 Unit Data

Feature	Value
Unit dimensions (L x W x H)	92 x 240 x 104 mm
Weight, including batteries	900 g
Power pack	100-240 V ~50/60 Hz 9.3 V DC +/-1 % 1,29 A 12 W
Internal power supply - Lithium Ion batteries	7,2 V / mind. 3,6 Ah
Battery autonomy	20 hours guaranteed 24 hours typical
Environmental Conditions Operation: Temperature Humidity Air pressure	 +5° to +40°C 15% to 93%, non-condensing 600 mbar to 1060 mbar
Environmental Conditions Storage: Temperature Humidity Air pressure	 -25° to +70°C 15% to 93%, non-condensing 600 mbar to 1060 mbar
Classification in accordance with MDD (Medical Device Directive)	II b

3.2 Masimo Pulse Oximetry

Characteristic Data	SpO_2	Pulse
Display range	1-100 %	25-240 1/min
Accuracy – without Movement, Adults, Children and Newborns		25-240 1/min+/- 3 digits
Accuracy – with Movement, Adults, Children and Newborns		25-240 1/min+/- 5 digits
Accuracy – without Movement, Adults and Children	70-100 %+/- 2 digits 0-69% not specified	
Accuracy – without Movement, Newborns	70-100 %+/- 3 digits 0-69% not specified	
Accuracy – under Movement, Adults, Children and Newborns	70-100 %+/- 3 digits 0-69% not specified	
Accuracy	1 %	1 1/min
Data update interval	1 Hz	1 Hz

The Masimo SET Technology with LNOP Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory cooximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

The Masimo SET Technology with LNOP Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

The Masimo SET Technology with LNOP Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

Technical Data

 *NOTICE!*

A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter.

 *NOTICE!*

If there is independent demonstration that a particular calibration curve is accurate for the combination of a pulse oximeter and a pulse oximeter probe, then a functional tester can measure the contribution of a monitor to the total error of a monitor/probe system. The functional tester can then measure how accurately a particular pulse oximeter is reproducing that calibration curve.

Perfusion	
Display range	0.02-20.0 %

Setting Range of the Alarm Limits	
Upper Limit oxygen saturation	42-100 %
Lower Limit oxygen saturation	40-98 %
Upper Limit pulse frequency	27-240 1/min
Lower Limit pulse frequency	25-238 1/min
Alarm tone loudness	70 dbA

Sensor	
Wavelengths	660 nm (red), 905 nm (infrared)
max. Light Wattage	0.79 mW

 *NOTICE!*

Information about wavelength range can be especially useful to clinicians.

3.3 Factory Default Settings

Setting	Value
Alarm tone volume	5
Pulse tone volume	5
Alarm tone mute time	60 sec
Contrast	5
Averaging Time	8 sec
Perfusion sensitivity	normal
Nurse Call	N(ormally) O(pen)
Alarm limit SpO_2 high	100 %
Alarm limit SpO_2 low	85 %
Alarm limit Pulse high	160 1/min
Alarm limit Pulse low	40 1/min
Alarm filter SpO_2 low	OFF
Alarm filter Pulse high	OFF
SmartTone	ON
Artifact Filter	OFF

3.4 Life Times

Component	Value
sat 805	5 years
Batteries	3 years
Patient cable	17280 hours, X-CAL - limited
Pulse oximetry sensor, reusable	8760 hours, X-CAL - limited
Pulse oximetry sensor, not reusable	168 hours, X-CAL - limited

The Masimo X-CAL feature will prevent the use of components with an error message after the abovementioned hours. A use after this expected life could lead by faulty measurements to a possible risk for the patient. For further information on Masimo X-CAL, please refer to chapter 6.6.2.

4 Assembly

4.1 Displays and Controls

1 Green mains LEDs (behind the ON/OFF-button)

2 ON-/OFF button

3 LC Display

4 Trim knob incl. yellow/red alarm LEDs

5 Connector for patient cable

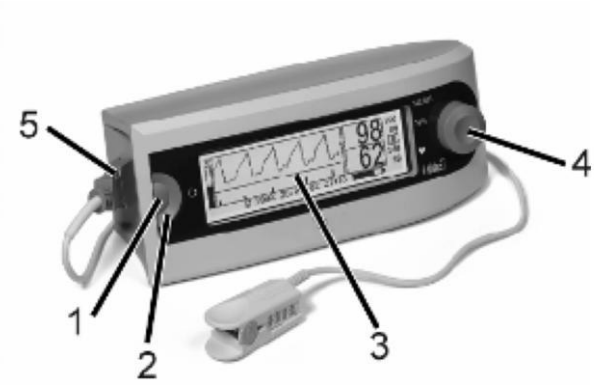


Fig. 1: Display and Controls

4.2 Connections

Connections in the rear panel:

1 Alarm loud speaker

2 Interface connector, nurse call

3 Interface connector, analogue

4 AC adapter socket

5 USB 2.0

Fig. 2: Rear Panel

Connections in the left panel:

1 Patient lead connection

2 SD Card slot

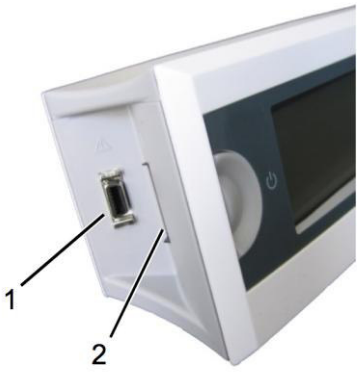


Fig. 3: Left Panel

4.3 LC Display

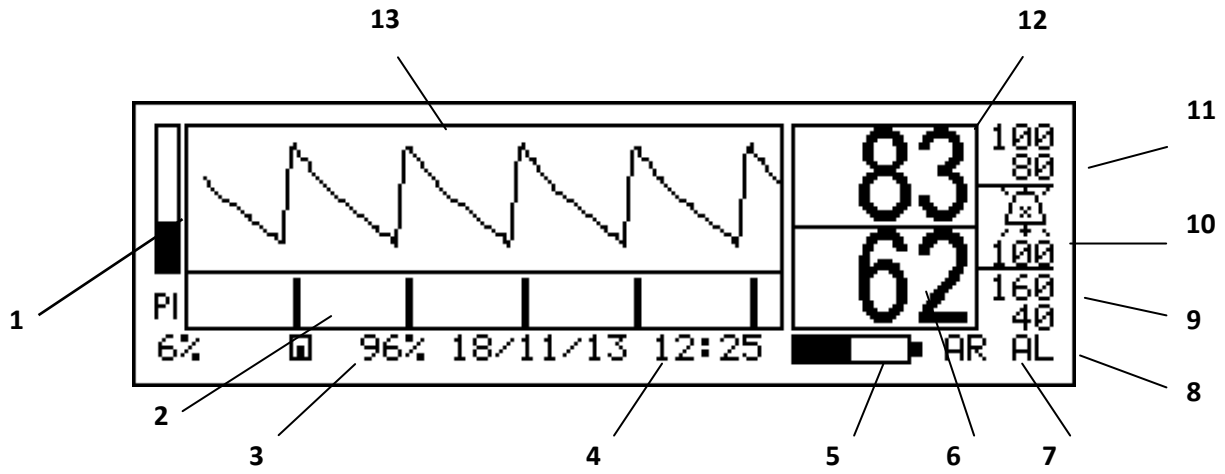


Fig. 4: LC Display

1 Perfusion index, graphical and numerical display in %

2 IQ bar, displays graphically the Signal IQ in normal operation. The Signal IQ is an indicator for signal insufficiency.

3 Remaining memory in %

4 Status line: Alarm messages, time and date, memory status and other parameters are displayed.

5 Actual battery capacity.

6 Pulse frequency in beats per minute (1/min), alarm limits high and low.

7 **AR** – symbol, is displayed when the **Ar**tifact Filter is active.

8 **AL** – symbol, is displayed when the **AL**arm filter is active.

9 Alarm limits pulse frequency.

10 Alarm tone mute symbol and remaining time in seconds.

113: if the audio alerts are temporarily suppressed.

: if the audio alerts are switched off.

11 Alarm limits oxygen concentration.

12 Current oxygen saturation in %

13 Plethysmogram, displays in normal operation the current pulse trace.

What is signal IQ™?

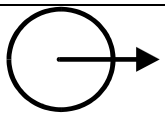
Signal-IQ™ is a measurement for Signal-Identification and Signal-Quality. Masimo developed this indicator to give the user information when a measurement is questionable. Signal-IQ™ is a visual reliability indicator for the oxygen saturation and pulse frequency measurements.

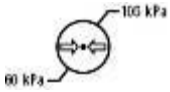
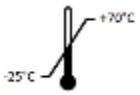
The more difficult it is to detect an arterial pulse signal the lower the presented IQ-bar (2). The Signal-IQ-figure is particularly valuable with movement, weak circulation, or environmental influences.

What is the Perfusion-Index?

The Perfusion-Index is a measurement for pulse strength at the point of sensor measurement. The Perfusion-Index varies from 0.02% (very weak pulse strength) to 20% (very strong pulse signal). The Perfusion-Index is calculated from the reflected infrared portion. The Perfusion-Index is a relative measurement and can vary at each application point and with different patients.

4.4 Pictograms on the Device

Symbol	Meaning
	ON-/OFF-Button
	DC current power connector
	USB connector
	Analogue interface Nurse call interface
	ATTENTION! Read instructions for use!

Symbol	Meaning
	The device and its components are not allowed to be discarded into normal household waste
	Manufacturer and year of manufacture
CE 0197	Notified Body TÜV Rheinland LGA Products GmbH
	Legitimate air pressure range for storage
	Legitimate air humidity range for storage
	Legitimate temperature range for storage
REF	Model Number
SN	Serial Number
	Applied part type BF
IP 22	Protection against contact with fingers and medium sized solid foreign objects, protection against slanty falling dripping water

4.5 Interfaces

The unit features following interfaces:

– Interface connectors in the rear panel of the unit (from left to right):
  – Nurse call
  – Analogue interface (right)
  – DC input
  – USB

Fig. 5: Interface Connector

ATTENTION!

To connect to the interface use only original manufactured parts.

Otherwise the unit could be damaged.

4.5.1 Analogue Interface

The analogue interface signals are output as follows:

Parameter	Pin No.	Value Range	Voltage Range
Plethysmogram	2	0 – 255	0 – 2,5 volts
Ground	3		
SpO_2	4	0 – 100 %	0 – 1,0 volts
Pulse frequency	5	0 – 240 1/min	0 – 2,4 volts

NOTICE!

The analogue voltages are constantly supplied to the interface and cannot be configured.

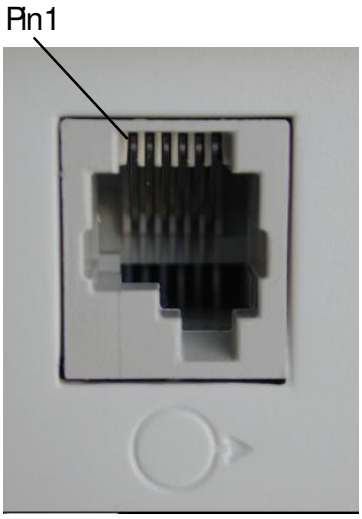
4.5.2 Nurse Call Alarm

The nurse call alarm interface can be configured for connection to a nurse call system or a remote alarm device.

NOTICE!

Even if the acoustic alarm has been silenced on the device, the acoustic alarms still always sound on the external alarm interface.

Pin assignment for the external alarm interface is as follows:



Pin no.	Signal
3	Relay terminal 1
4	Relay terminal 2

Fig. 6: External Alarm interface

CAUTION! Danger by Failure of the Alarm System!

With a failure of the alarm system, there are NO alarm signals available!

4.5.3 USB2.0 Interface

The USB interface is for service and maintenance use only.

4.6 Identification Nameplate

The nameplate is located on the bottom side of the unit.

The following information can be found there:

- Manufacturer
- Unit description
- Production year
- Serial number
- Power supply
- Type number

Fig. 7: Identification Nameplate

5 Shipping, Packaging and Storage

5.1 Shipping Inspection

Examine the delivery immediately upon receipt for completeness and possible shipping damage.

With visible external shipping damage do not accept delivery or only with reservation.

Indicate the extent of damage on the accompanying delivery document i.e. on the shipping agent's document. Start the claim procedure.

Report invisible damage immediately after discovery. Damage claims can only be processed during the valid time period for claim acceptance.

5.2 Scope of Delivery

Please check the contents of the package immediately following receipt. If the items are missing, please contact your medical equipment dealer immediately.

ATTENTION!

Never use other accessories than specified.

Scope of delivery:

1 Pulse oximeter sat 805

2 Plug-in power supply unit

3 Patient lead

4 One or several pulse oximetry sensors

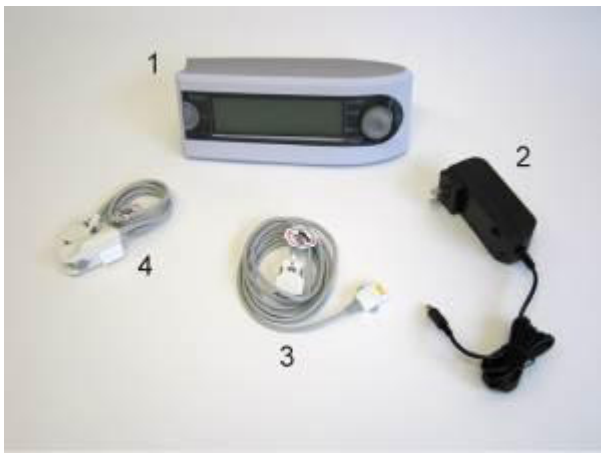


Fig. 8: Scope of Delivery

NOTICE!

With regard to the sensors the actual scope of delivery can be adjusted to the user requirements and can differ from the pictured scope of delivery!

5.3 Packaging

To minimize damage always transport or send the unit in its original packaging. We recommend you to save the packaging.

WARNING! Risk of Suffocation!

Packaging materials are not intended for children. The danger of suffocation exists.

ATTENTION! Dangerous for the Environment!

Always dispose of packaging materials in environmentally correct manner and according to local disposal regulations. If need be call the recycling company.

5.4 Storage

Only store the unit under the following conditions:

- For shorter periods of storage, store the device with batteries half-charged.
- For longer periods of storage without usage, let the batteries getting removed. Therefore, please contact your medical device supplier.
- Secure the unit before storage or turn OFF.
- Do not store outside.
- Store in dry dust free area.
- Do not expose to aggressive media.
- Prevent sunlight exposure.
- Avoid mechanical vibrations.
- Storage temperature -25 to +70 °C.
- Relative humidity maximum 93%.
- With longer storage time regularly check the general condition of all parts and the packaging.

Protect the unit from unauthorized access (theft, acquisition, and usage by unauthorized third party).

6 Operation

6.1 Environmental Conditions

The unit uses high frequency energy exclusively for its internal functions. That is why its high frequency emission is very low and it is improbable that electronic units in close vicinity can be disturbed.

The unit is intended for use in all environments including homes and those directly connected to a public service network, which also serves buildings with living spaces.

Floors should consist of wood or cement or be covered with ceramic tiles. If the flooring is covered with synthetic materials the relative humidity has to be at least 30%.

6.2 Prior to Initial Use

Before using the unit for the first time, familiarize yourself with it and its accessories. This absolutely includes reading the user manual.

WARNING! Danger to the Patient!

The unit is used to monitor patients. That is why it should only be used and configured by trained and instructed users.

Prior to the assembly check if all system components needed for a proper operation are available.

Please contact the manufacturer or your medical device supplier for help in commissioning, in operation, maintenance or any other way. You can find the address of the manufacturer in Ch. 2.5. The address of the supplier was handed over while briefing. Furthermore contact the companies as stated above in case of an unexpected operating status or incidents as well.

In application in domestic field a documented briefing is absolutely mandatory! Before using the unit on a patient for the first time, it must be turned on and tested.

6.3 Mains operation / Charging the Batteries

The power supply for monitoring can be done without a power supply unit – it can also be provided by the built-in battery. With a fully-charged battery, the power supply is guaranteed for at least 20 hours of monitoring.

When the device is switched on, the current battery capacity is permanently displayed to the user as an icon on the LCD display. If the battery capacity is no longer sufficient, in other words monitoring is guaranteed for less than 1 hour, the battery alarm is activated.

Before first use, carry out a complete charge cycle.

Operation

ATTENTION!

Never use multiple electric socket strips to supply the unit.

Never connect the unit to a switched network socket.

Only use the power pack plug supplied with the unit.

Install the unit in a way that the unit can be easily disconnected from the power supply.

1. Connect the mains adapter plug to the unit connector.
2. Plug the other end of the cable into an electric outlet.

Fig. 9: Mains Power Adapter Plug

3. The green network-LEDs (1) display.

NOTICE!

The green network-LEDs only signal that the unit is supplied with electricity. The LEDs do not show the unit's operating condition (ON/OFF).

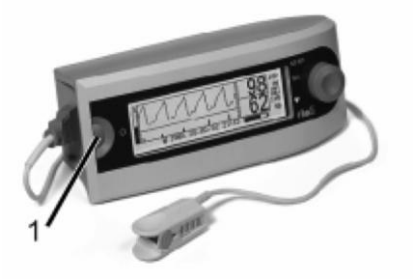


Fig. 10: Network LEDs

4. For charging the unit, remain the unit plugged-in for 6 hours with the unit switched off and for 10 hours when switched on.
5. If required now the device can be switched on.

NOTICE!

The battery capacity is displayed in the LC display.

6.3.1 Mains Power Failure Alarm

In case of a mains power failure, an alarm is triggered respectively. At the same time, the unit automatically switches from mains to battery supply without any interruption.

1. Approx. 5 sec. After mains failure, an alarm (medium priority is triggered).

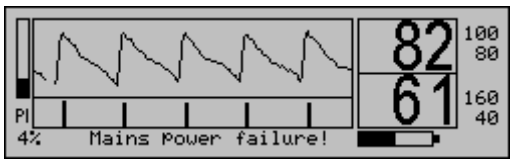


Fig. 11: Mains Power Failure Alarm

2. The mains power failure will generate a corresponding entry into the alarm list.

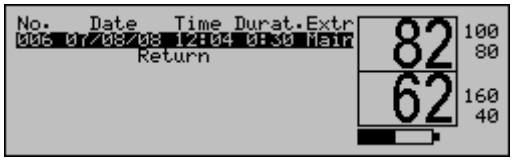


Fig. 12: Mains Power Failure in Alarm List

3. After 30 seconds, the alarm will be cancelled. The unit is now in battery operation mode.

4. If the mains power supply is re-installed in the course of the a.m. 30 seconds, the mains power alarm will be automatically reset.

NOTICE!

The Mains Power Failure condition is displayed by the dark mains power LEDs.

6.4 Connections

6.4.1 Connecting the Patient Cable and Sensor

1. Connect the patient cable connector into the unit socket.

   The plug only fits in one direction and audibly snaps in.

Fig. 13: Connect Patient Cable

2. Select the required Masimo-Sensor, see chapter 6.6.

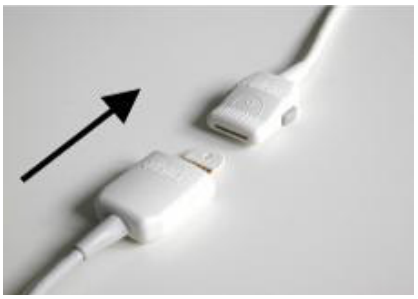


Fig. 14: LNOP Sensor Connector

3. Connect the sensor connector into the patient cable connector. The plug only fits in one direction and noticeably snaps in.

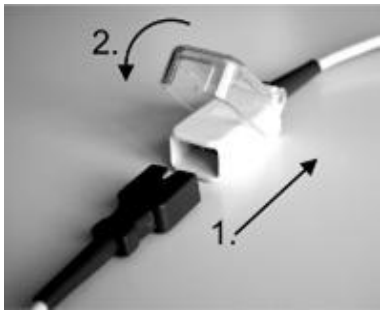


Fig.15: LNCS Sensor Connector

NOTICE!

Some Masimo Sensors (e.g. type DCSC) already have an integrated patient cable. In this case, the connection to a separated patient cable is omitted.

Fig. 16: RD SET Sensor Connector

6.4.2 Disconnecting the Sensor

LNOP Sensors

1. Press the two disconnect buttons (1) together.
   The locking mechanism unlocks the sensor plug.

2. Remove the plug from the coupling (2).

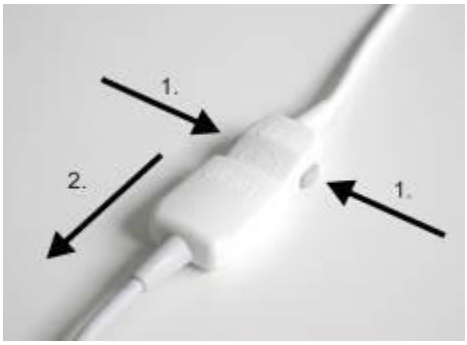


Fig. 17: LNOP Sensor Coupling

LNCS Sensors

1. Lift the protective cover (1).

2. Pull firmly in the sensor connector to remove from the patient cable (2).

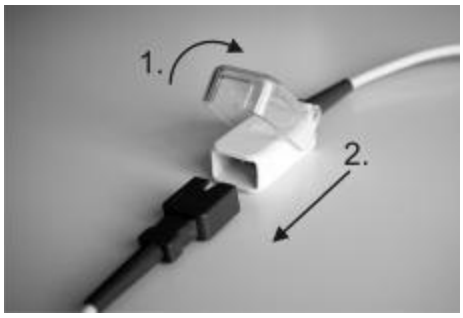


Fig. 18: LNCS Sensor Coupling

RD SET Sensors

1. Pull firmly in the sensor connector to remove from the patient cable.

Fig. 19: RD SET Sensor Coupling

6.4.3 Disconnecting the Patient Cable from the Unit

1. Press the two disconnect buttons (1) at the patient cable socket together. The locking mechanism unlocks the patient cable.
2. Remove the connector.

Fig. 20: Patient Plug Coupling

ATTENTION!

Do not apply pressure when removing the plug. It could be damaged.

6.5 Installing the Unit

Install the unit in such a way so that it interferes with the patient's mobility as little as possible. Under normal circumstances, the unit should be positioned on the night table next to the patient's bed.

WARNING! Danger from the Cable in Patient Vicinity!

When positioning the unit secure the cable line to avoid strangulation of the patient.

WARNING! Danger from Equalizing Current!

Never touch the patient and the external connections of the unit at the same time. The health of the patient can be influenced from possible equalizing current occurrence.

ATTENTION! Unit can fall!

Secure the unit's location. It can be damaged when falling or even injure the patient.
Never lift the unit by one of its connectors. They could be damaged.

Battery operation makes the unit portable.

WARNING! Connectors can disconnect during Movement!

When moving the unit during monitoring, absolutely ensure the correct position of the patient connector. Should the connector accidentally become disconnected an alarm sounds.

6.6 Using Masimo-Sensors

CAUTION! Danger from not Observing User Instructions!

These sensors were developed only for usage of pulse oximeters with MasimoSET-technology.

The responsible organisation and/or the operator has to **check the compability of the pulse oximeter, cabel and sensor before every usage, otherwise this could cause dangerous injuries of the patientPay attention to the notices in the user instruction manual for Masimo sensors. If not observed the measurement results can be false.**

Only use approved Masimo sensors with the unit. Use of other sensors can reduce the performance capacity of the unit and thus produce danger to the patient!

Tissue damage can be caused by incorrect application or use of a sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the Instructions for Use to ensure skin integrity and correct positioning and adhesion of the sensor.

Do not use damaged sensors or cables!

Do not use a sensor with exposed optical components.

The sensors as well as the patient cable connectors are not waterproof. Never immerse the sensors or connecting elements in liquid or hold under running water.

Do not sterilize sensors and patient cable by irradiation, steam or ethylene oxide.

NOTICE!

More information on the use of Masimo sensors can be found in the user instructions of the applicable sensor.

NOTICE!

A complete list of validated Masimo sensors will be provided on request by the manufacturer.

6.6.1 Selecting the (correct) Sensor

Select the sensor based on the patient's age and weight and its re-usability. The Table is a guide. The correct sensor has to be matched individually to the patient.

NOTICE!

The latest list of all sensors is directly available from HUM Gesellschaft für Homecare und Medizintechnik mbH.

6.6.1.1 Adhesive Sensors

p/n	Sensor Type	Patient Type and Weight	Application Site
HPO04-ADTX	LNCS® Adtx	Adults > 30 kg	Ring- or Middle Finger of the non-dominant Hand
HPO04-PDTX	LNCS® Pdtx	Children and Adults > 10 kg and < 50 kg	Ring- or Middle Finger of the non-dominant Hand
HPO04-INF	LNCS® Inf-L	Small Children > 3 kg < 20 kg	Great Toe or Thumb
HPO04-NEO	LNCS® Neo	Newborn, < 3 kg, adults > 40 kg	Foot, alternatively Back of the Hand
HPO04-NEOPT	LNCS® NeoPt	Neonatal Preterms < 1 kg	Foot, alternatively Back of the Hand
HPO05-ADT	RD SET Adt	Adults > 30 kg	Ring- or Middle Finger of the non-dominant Hand
HPO05-PDT	RD SET Pdt	Children and Adults > 10 kg and < 50 kg	Ring- or Middle Finger of the non-dominant Hand
HPO05-INF	RD SET Inf	Small Children > 3 kg < 20 kg	Great Toe or Thumb
HPO05-NEO	RD SET Neo	Newborn, Children, Adults < 3 kg or > 40 kg	Foot, alternatively Back of the Hand
HPO05-NEOPT	RD SET NeoPt	Neonatal Preterms < 1 kg	Foot, alternatively Back of the Hand

WARNING! Allergy Risk!

The use of Masimo and RD SET disposable SpO_2-sensors is contraindicated on patients who develop allergic reactions to the tape. The sensors must be re-positioned every 8 hours - and as soon as lack of blood circulation or skin surface injury is displayed - remove them again and attach them in another area.

6.6.1.2 Reusable Sensors

p/n	Sensor Type	Patient Type and Weight	Application Site
HPO02-DCSC	DCSC	Children and Adults > 30 kg, Spot Check-Applications	Ring- or Middle Finger of the non-dominant Hand
HPO04-DCI	LNCS® DCI	Children and Adults > 30 kg	Ring- or Middle Finger of the non-dominant Hand
HPO04-DCIP	LNCS ®DCIP	Children and Adults > 10 kg and < 50 kg	Ring- or Middle Finger of the non-dominant Hand
HPO04-YI	LNCS® YI	Children and Adults > 1 kg	> 10 kg: Ring- or Middle Finger of the non-dominant Hand. > 3 kg < 10 kg: Great Toe. < 3 kg: Foot, alternatively Back of the Hand.
HPO04-TCI	LNCS® TC-I	Adults and Children > 30 kg, Earsensor	Earlobe or Auricle
HPO04-TFI	LNCS® TF-I	Forehead Sensor, transflective, Adults > 30 kg	Forehead
HPO05-DCI	RD SET DCI	Children or Adults > 30 kg	Ring- or Middle Finger of the non-dominant Hand
HPO05-DCIP	RD SET DCIP	Children or Adults > 10 kg and < 50 kg	Ring- or Middle Finger of the non-dominant Hand

WARNING! Danger with Long-Term Application!

The use of reusable Masimo and RD SET- sensors is contraindicated with long term application. These sensors are not suitable for long-term monitoring. They must be attached every four hours - and as soon as lack of blood circulation or skin surface injury is displayed - remove them and attach them in another area.

6.6.1.3 Patient Cable

p/n	Model	Application
HPO04-K-PC04	LNC® -4	Patient Cable 1.2 m for LNCS® Sensors
HPO04-K-PC10	LNC® -10	Patient Cable 3.0 m for LNCS® Sensors
HPO05-K-PC05	RD SET MD14-05	Patient Cable 1.5 m for RD SET Sensors
HPO05-K-PC08	RD SET MD14-08	Patient Cable 2.4 m for RD SET Sensors
HPO05-K-PC12	RD SET MD14-12	Patient Cable 3.6 m for RD SET Sensors

6.6.2 Expected lifetimes of patient cables and sensors

NOTICE!

X-CAL or lifetime related alarms, messages and information might not be present in all devices.

To confirm, please check in the product info menu (see chapter 7.7.6): only devices with DSP version 5.X.X.X will support the X-CAL related alarms and messages.

Both the Masimo patient cables and the sensors are equipped with lifetime counters. If 90% of this lifetime is reached, the user is informed that the specified lifetime will be reached in the foreseeable future.

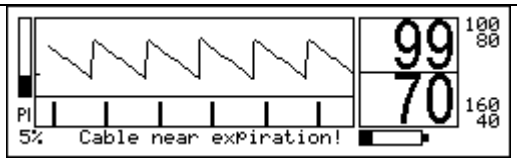
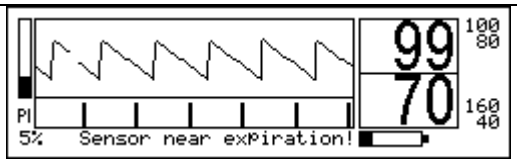
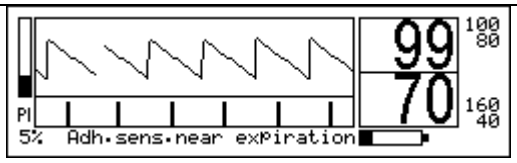
The lifetimes are defined as follows:

Sensor / Cable	Active Patient Monitoring Limit	Duration if Monitoring 24 Hours Per Day	Duration if Monitoring 12 Hours Per Day	Duration if Monitoring 8 Hours Per Day
Single-patient-use SpO2-Sensors with replaceable tape	336 hours	14 days	28 days	42 days
Single-patient-use SpO2-Sensors without replaceable tape	168 hours	7 days	14 days	21 days
Reusable SpO2-Sensors (DCI, DCIP, YI, TC-I, TF-I, and DBI)	8760 hours	12 months	24 months	36 months
Patient Cables	17520 hours	24 months	48 months	72 months

6.6.2.1 90%-Lifetime or „Near expiration“-message

Sensor / Cable	Remaining time at 90%
Single-patient-use SpO2-Sensors with Replaceable tape	ca. 34 hours
Single-patient-use SpO2-Sensors without Replaceable tape	ca. 17 hours
ReusableSpO2-Sensors (DCI, DCIP, YI, TC-I, TF-I, and DBI)	ca. 876 hours
Patient Cables	ca. 1752 hours

The following technical messages are output when 90 % of the specified service life of the patient cable or sensor is reached.

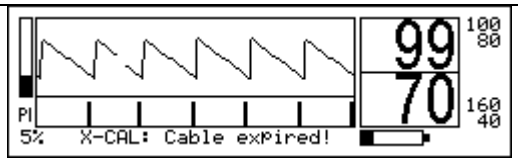
 **Fig. 21: Cable near expiration**	**Technical message:** **„Cable near expiration"**
 **Fig. 22: Sensor near expiration**	**Technical message:** **„Sensor near expiration"**
 **Fig. 23: Adh. sensor near expiration**	**Technical message:** **„Adh. sensor near expiration"**

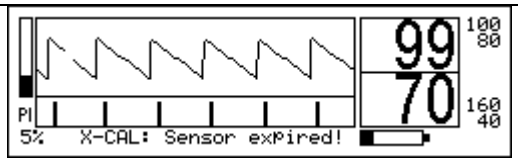
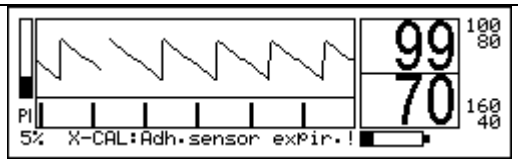
6.6.2.2 Life time exceeded

If the life time of the accessories is reached during monitoring operation, the technical message "Service life reached" is output.

Exceeding this threshold triggers a further period of time: the so-called "extension phase". This is 12 hours for single-patient adhesive sensors and 72 hours for reusable sensors.

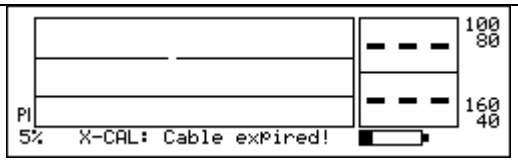
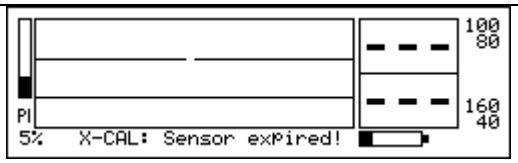
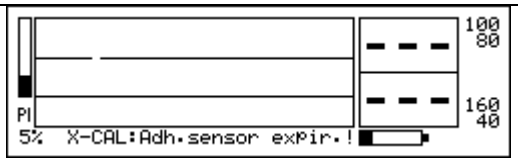
In this phase, the accessories can still be used for the current monitoring, but may be before a switch-off with a sensor-defective message.

 **Fig. 24: X-CAL: Cable expired**	**Technical message:** **„X-CAL: Cable expired"**

 **Fig. 25: X-CAL: Sensor expired**	**Technical message:** „ **X-CAL: Sensor expired**“
 **Fig. 26: X-CAL: Adh. sensor expired**	**Technical message:** „ **X-CAL: Adh. sensor expired**“

In contrast to sensors, a patient cable is never switched off after its service life has been reached.

If a sensor alarm is triggered during the extension phase (e.g. sensor not on the patient), it is displayed together with this as a high-priority alarm.

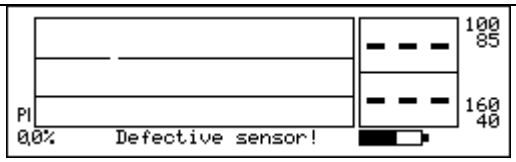
 **Fig. 27: Cable expired expiration**	**High priority alarm** **“Cable expired” & “Sensor not on patient”**
 **Fig. 28: Sensor expired**	**High priority alarm** **“Sensor expired” & “Sensor not on patient”**
 **Fig. 29: Adh.Sensor expired**	**High priority alarm** **“Adh.Sensor expired” & “Sensor not on patient”**

After the cause of the alarm has been eliminated, this alarm is downgraded again to the technical message "Sensor expired".

If, on the other hand

1. the sensor-pulse oximeter connection is disconnected or
2. longer than 2 hours the sensor would not have been on the patient or
3. a device reset (e.g. by a restart) is performed,

the sensor is immediately switched as defective (alarm: defective sensor) and further use is impossible.

 **Fig. 30: Defective sensor**	**High priority alarm** **"Defective sensor" (beyond lifetime)**

6.7 Using the Interfaces

The interfaces on the device may be operated and installed by trained personnel only. Connecting the analog or nurse call interface via the interface connector is only allowed upon instruction of these persons.

WARNING! Danger by improper Application of the Interface!

If non-specified devices are connected to the interfaces of the device, there may be health-related injuries of the patient caused by equalizing or leakage currents.
For assuring a complete patient insulation, connect electrically isolated devices only.

7 Control

7.1 General

Control of the unit takes place on the LCD-display in combination with the trim knob.

In the directional text of this user manual, the texts, appearing in the display, are highlighted to assist in understanding. In addition, the following writing format is used: "**`Display text`**."

7.2 Menu Operation

7.2.1 Using the Trim Knob

Operation of the menu by the trim knob:

1. Turning clockwise: up, page up and increase values
2. Turning counter-clockwise: down, page down and decrease values
3. Short push (< 1 sec): confirm setting or activate acoustical alarm mute function (active alarm)
4. Long push (> 1 sec): enable / disable acoustical alarm mute function (independent of active alarm)

Fig. 31: Trim Knob

NOTICE!

If you do not confirm or accept a menu setting within 60 seconds of making it by pressing the trim knob, the standard screen is automatically displayed.

7.2.2 Calling the Main Menu

1. Press the trim knob.
2. The main menu is displayed in the LC display.

Fig. 32: Main Menu

7.2.3 Menu Structure

After selecting a menu item further menu items can be selected subsequently. Therefore in some cases it is necessary to select several menu items one after the other before the final setting can be made.

The menu structure is as follows:

Level 1	Level 2	Level 3	Remark
Pleth-Display	**without pleth.**		Configuration of the LC display
	compressed		
	stretched		
Alarm limits			Setting the alarm limits and alarm filter parameters
Data	**Vital alarm list**		Alarm lists
	Total alarm list		
	Trend		On-screen data display
	Memory config.		Memory configuration
	Erase Memory		

7.3 Switching on the Unit

Level 1	Level 2	Level 3	Remark
Configuration	Acoust. Alarms	Volume pulse	Configuration of the acoustical alarms
		Volume alarm	
		Silence Time	
	Signal process	Algorithm mode	Setting of pulse oximetry parameters
		Averaging time	
		SmartTone	
		Artifact-filter	
	Screen	Contrast	Adjustment of the LC screen options
		Backlight	
		Language	
		Home mode	
	Nurse call		Configuration of the external alarm interface
	Analogue out		Calibration signals
	Clock		Setting the system time
Product Info			Overview of the device settings

Control

1. Press ON/OFF button (1).
2. A signal sound activates.
3. An optical, audio, and internal self examination is completed:
   - The LEDs are activated.
   - A dark and bright test picture appears briefly on the LC display.
   - A short alarm signal is issued.

     The unit goes through extensive internal hardware testing.

Fig. 33 Switching on

ATTENTION! Unsuccessful Tests!

If one or several tests are not successfully executed, a corresponding error message is displayed in the display.

The unit can and may not be used on patients.

ATTENTION! Defective Alarm Loudspeaker!

If the alarm loudspeaker is defective, a replacement signal generator is activated internally. This does not take over the full functionality of the alarm loudspeaker (volume, tone sequences).

The device must then not be used on the patient!

4. After this the Normal Display appears.

Now the signal search for the pulse occurs (blinking dashes and sensor symbol). With a successful pulse search the measured values for oxygen saturation and pulse frequency are displayed on the LCD screen.

Fig. 34: Normal Display

NOTICE!

In case the Masimo sensor is not connected or not correctly on the patient, a corresponding error message is displayed, e.g. **"Sensor off Patient!"**.

In addition an alarm sound is heard.

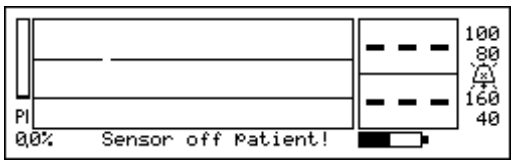


Fig. 35: Sensor off Patient!

NOTICE!

If the alarm tone volume setting is 5 or less, a warning message is displayed during the power-up cycle.

The operator has to acknowledge this setting with OK.

Otherwise, the device will not enter the standard mode but will be switched off automatically.

Fig. 36: Silent Alarm Tone!

5. Now the unit is operational.

7.4 Turning the Unit off

The turn-off process is designed so that turning it off accidentally can possibly be avoided. After turning off the unit all previously entered values and configurations are preserved.

Except for the settings „Alarm tone loudness = 0 (OFF)“ and „algorithm“ the minimum audible =1 and =“Norm.Perfus.“ is returned.

To turn the unit OFF:

1. Press the ON/OFF-button.
2. The power-down menu is displayed in the LC display.
3. With the trim knob, select **Turn off** and confirm.

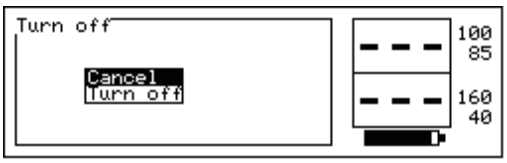


Fig. 37: Power-Down Menu

NOTICE!

Should the ON/OFF process be interrupted the last readings before the ON/OFF process appear for approx. 5 seconds. The monitoring remains intact for the entire time.

4. The unit is now being turned off.

7.5 Alarm Limits (`Alarm limits`)

WARNING! Incorrectly set alarm limits endanger risk of non-alerting!

Changing the alarm settings is a serious intervention in the device functions and must never be done without first consulting the doctor in charge of the treatment!

NOTICE!

Until the modified alarm limit value has been accepted, the most recently stored value remains in force.

If the alarm limit modification procedure is interrupted or cancelled, this value persists.

The saved limits remain also after a complete loss of the voltage.

If implausible alarm limits are set (e.g. the lower limit value is greater than the higher value), the device responds with the error message "**`Alarm limits are not correct!`**".

Fig. 38: Alarm Limits not correct

In this case, the alarm limits selected are not accepted as new values.

NOTICE!

The difference between the upper and lower alarm limit values must, to be plausible, be at least two units.

7.5.1 Setting the Alarm Limits

1. Starting from the normal display, call:
   → **Alarm limits**

2. Select **SpO2 hi**, for setting the upper SpO_2 alarm limits,
   or
   select **SpO2 lo**, for setting the lower SpO_2 alarm limit

   Select **Pulse hi**, for setting the upper pulse rate alarm limit,
   or
   select **Pulse lo**, for setting the lower pulse rate alarm limit.

3. Select the alarm limits to be changed by pressing the trim knob.

4. Set the new value by turning the trim knob.

5. Confirm the new value by pressing the trim knob.

6. Set other values if needed.

7. Leave the menu with **Return**.

8. Confirm all new values by confirming the safety question **Accept? Y/N**.

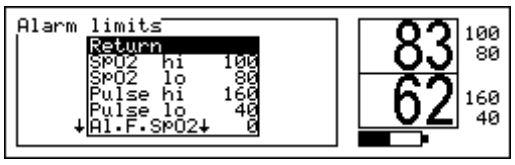


Fig. 39: Alarm Limits

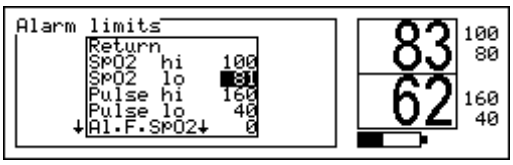


Fig. 40: Modifying the Alarm Limits

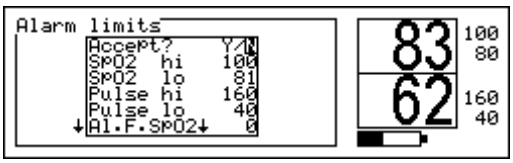


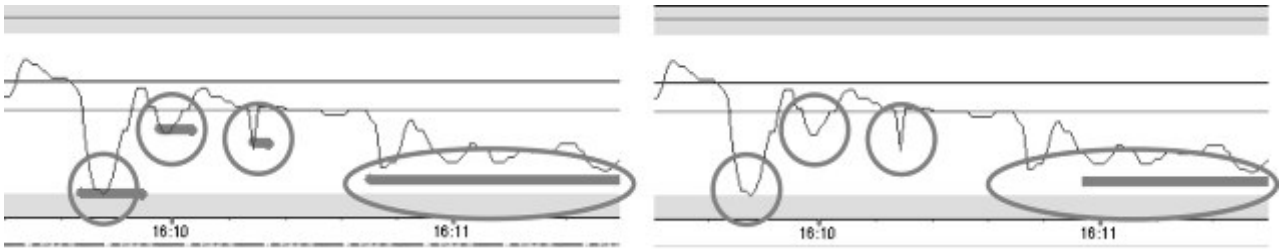
Fig. 41: Confirming the Alarm Limits

7.5.2 Setting the Alarm Filter

WARNING! Incorrectly set alarm limits endanger risk of non-alerting!

Activating or changing the alarm filter settings is a serious intervention in the device functions and may never be done without consulting the doctor in charge of the treatment!

For canceling short and therefore irrelevant alarm conditions, an alarm filter can be set.



no alarm filter **with alarm filter**

The alarm filter produces a “silent alarm”. During the set alarm filter time period (adjustable between 0=OFF and 20 seconds maximum), the occurence of an alarm condition for oxygen saturation and/or pulse rate will NOT lead to an acoustical nor optical alarm. After the above mentioned alarm filter time period, the alarm will be generated. If in the meantime the source of the alarm condition will vanish, there will be no alarm at all.

The alarm filters can be configured individually for SpO_2 low and also for pulse rate high.

This feature will increase user compliance by suppressing short alarm periods.

The alarm filters are deactivated when shipped from the factory. (0=OFF)

1. Starting from the normal display, call:
   → **`Alarm limits`**

2. Select **`Al.F.SpO2`**↓ , for setting the alarm filter period for the lower SpO_2 alarm limit,
   or
   select **`Al.F.Pulse`**↑ for setting the upper pulse rate limit.

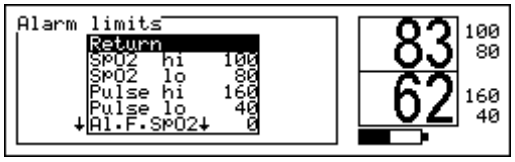


Fig. 42: Alarm Limits

3. Select the alarm filter to be changed by pressing the trim knob.
4. Set the new period (in seconds) value by turning the trim knob.
5. Confirm the new value by pressing the trim knob.
6. Set other values if needed.
7. Leave the menu with **Return**.
8. Confirm all new values by confirming the safety question: **Accept? Y/N**.
9. If the alarm filter is activated, this will be displayed by the symbol **AL** in the lower right area of the display.

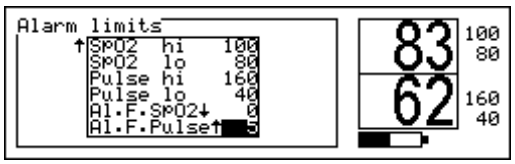


Fig. 43: Modifying the Alarm Filter

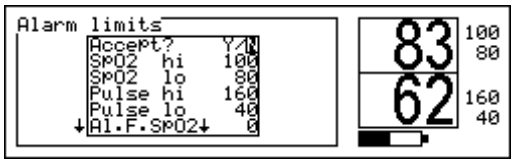


Fig. 44: Confirming the Settings

Fig. 45: Status Symbol „AL“

7.6 Plethysmogram Display (`Pleth-display`)

In this menu, the display is configured.

Following modes are available:

1. Stretched, normalized plethysmogram

Fig. 46: Plethysmogram, stretched

2. Compressed, normalized plethysmogram

Fig. 47: Plethysmogram, compressed

3. Big numbers only – without plethysmogram

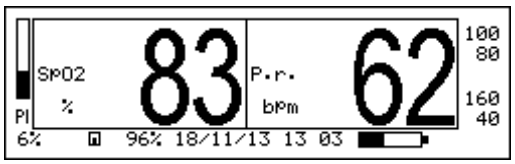


Fig. 48: Number Display

For configuration of the display:

1. Starting from the main menu, select:
   → **`Pleth-display`**
2. Select the display mode by turning the trim knob.
3. Confirm the setting by pressing the trim knob.
4. Return to the main menu by selecting **`Return`**.

Fig. 49: Plethysmogram Display

7.7 Configuration (Configuration)

7.7.1 Screen options (Screen)

1. Starting from the main menu, call:
   → **Configuration** → **Screen**
2. Select

   Backlight, Contrast, Home mode or **Language**
3. Confirm the selection by pressing the trim knob.

Fig. 50: Screen

7.7.1.1 Contrast (Contrast)

The functions adjust the contrast setting of the LC display.

The contrast can be adjusted between values of 1 and 10.

NOTICE!

The contrast setting will depend on external environmental conditions such as the prevailing amount of light and the angle when reading the device.

1. Starting from the main menu, call:
   → **Configuration** → **Screen**
   → **Contrast**
2. Adjust the contrast by turning the trim knob.

   The contrast is represented by a figure between 1 und 10.

   NOTICE!

   The changes made will be shown in the settings.
3. Confirm the selection by pressing the trim knob.

Fig. 51: Contrast Setting

7.7.1.2 Backlight (Backlight)

This function activates the LCD backlight; settings are “ON” and “OFF”.

1. Starting from the main menu, call:
   → **Configuration** → **Screen**
   → **Backlight**

2. Adjust the setting **ON/OFF** by turning the trim knob.

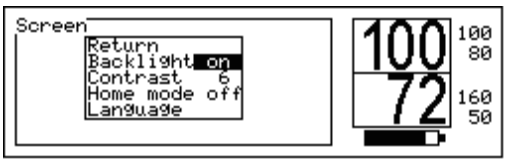


Fig. 52: Backlight

NOTICE!

The changes made will be shown in the settings.

3. Confirm the selection by pressing the trim knob.

7.7.1.3 Menu Language (Language)

This function sets the menu language.

1. Starting from the main menu, call:
   → **Configuration** → **Screen**
   → **Language**

2. Select the desired language by turning the trim knob.

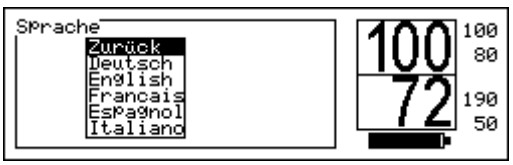


Fig. 53: Language

NOTICE!

The changes made will be shown in the settings.

3. Confirm the selection by pressing the trim knob.

7.7.1.4 Access Permissions (Home Mode)

Starting from the main menu, call:
→ **Configuration** → **Home Mode**

Following access permissions may be set:

– HomeCare Mode ON (**Home Mode ON**)

– HomeCare Mode OFF (**Home Mode OFF**)

Fig. 54: Access Permissions

– The "**HomeCare mode ON**" access protects the inexperienced user from modifying important monitoring parameters. These parameters are invisible.

– The "**HomeCare mode OFF**" access allows users to set all the configuration parameters.

Access Permissions	HomeCare ON	HomeCare OFF
Pleth-Display	+	+
Alarm Limits	-	+
Alarm Filter	-	+
Vital Alarm List	+	+
Total Alarm List	+	+
Trend	+	+
Memory Config.	-	+
Erase Memory	-	+
Volume Puls	+	+
Volume Alarm	+/- (OFF is not available)	+
Silence Time	+	+

Access Permissions	HomeCare ON	HomeCare OFF
Algorithm Mode	-	+
Averaging Time	-	+
SmartTone	-	+
Artifact-Filter	-	+
Backlight	+	+
Contrast	+	+
Home Mode (Access permission)	+	+
Language	+	+
Nurse Call	-	+
Analog out	-	+
Clock	-	+
Product Info	+	+

- = not allowed

+ = allowed

Setting the Access Permission:

1. Starting from the main menu, call:
   → **Configuration** → **Screen**
   → **Home Mode ON/OFF**

2. Enter the four-digit pin code for the respective access permission.

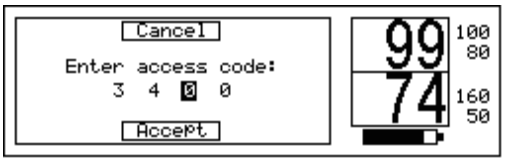


Fig. 55: PIN Code Entry

NOTICE!

The pin code is located in a separate document.
In case call the manufacturer.

3. Select the first digit with the trim knob.

4. Set the correct number.

5. Repeat steps 3 and 4 until the complete code is entered.

6. Confirm the code by selecting **Accept**.

NOTICE!

An invalid access code is answered by the error message: **"Incorrect access code!** *" Re-enter the correct code.*

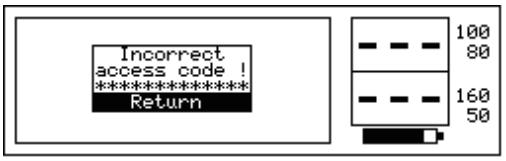


Fig. 56: Invalid Access Code

7.7.2 Acoustical Alarms (Acoust. Alarms)

Starting from the main menu, call:
→ **Configuration** → **Acoustic. Alarms**

Following settings can be adjusted:

– Pulse tone volume (**Volume Pulse**)

– Alarm tone volume (**Volume Alarm**)

– Alarm tone mute time (**Silence Time**)

Fig. 57: Acoustical Alarm

7.7.2.1 Pulse Tone Volume (Volume Pulse)

When the pulse signal tone is activated, then in monitoring mode a tone signal will be played for every detected pulse. The pitch of the tone identifies the current oxygen saturation. In other words, the higher the pitch of the tone, the greater is the measured oxygen saturation (and vice versa).

1. Starting from the main menu, call:
→ **Configuration** → **Acoust. Alarms** → **Volume Pulse**

2. Adjust the pulse tone volume with the trim knob from **OFF** to loud (**10**).

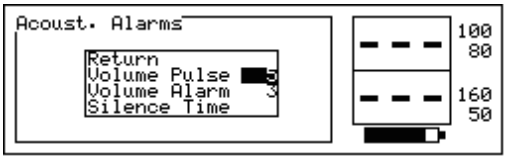


Fig. 58: Pulse Tone Volume

NOTICE!

Every incremental change emits the actual volume strength once.

3. Confirm this setting by pressing the trim knob.

NOTICE!

This de-activation of the pulse signal tone is not shown on the display.

7.7.2.2 Alarm Tone Volume (`Volume Alarm`)

1. Starting from the main menu, call: → **`Configuration`** → **`Acoust. Alarm`** → **`Volume Alarm`**

2. Adjust the alarm tone volume with the trim knob between **`OFF`** and loud (`10`).

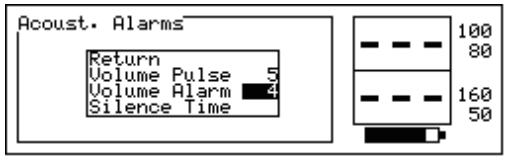


Fig. 59: Alarm Tone Volume

NOTICE!

Every incremental change emits the actual volume strength once.

3. Confirm this setting by pressing the trim knob.

NOTICE!

If you select the **`OFF`** *setting, the display shows the permanent alarm silence symbol:* .

NOTICE!

If you select a setting of less than 5, a warning message is displayed during the next power-on cycle reminding the operator at a possibly too silent setting.

NOTICE!

An alarm volume of <1 is not stored permanently. The alarm volume will be set during the next power-on cycle to a minimal non-zero value = 01.

NOTICE!

In **Home Care Mode**, *audio mute setting (=OFF) is not possible.*

7.7.2.3 Alarm Silence Time (Silence Time)

The alarm signal mute time displays the duration of the mute signal, if the alarm signal mute time has been set and acknowledged.

After expiration of this time the sound alarm is activated again, if the acknowledged alarm condition still exists.

The alarm signal mute time can be set between 30, 60, 90, and 120 seconds.

1. Starting from the main menu, call: → **Configuration** → **Acoust. Alarms** → **Silence Time**
2. Set the alarm tone silence time between **30** and **120 sec** using the trim knob (the selection is displayed by *).
3. Confirm this setting with **Return**.

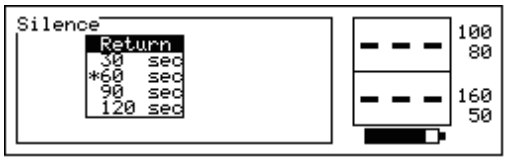


Fig. 60: Alarm Tone Silence Time

NOTICE!

During the alarm silence time, the alarm silence symbol 113 *appears to indicate that the option is active (the number below shows the remaining time in seconds).*

WARNING! New alarms cannot be detected!

If a new alarm condition occurs during the alarm tone mute duration, the new alarm will be displayed after completion of the mute duration.

7.7.3 Masimo Signal Processing (`Signalprocessing`)

Starting from the main menu, call:
→ **`Configuration`** → **`Signalprocessing`**

Following actual signal processing parameters can be set:

– Averaging time (**`Averaging time`**)

– Sensitivity (**`Algorithm mode`**)

– Smart Tone (**`ON/OFF`**)

– Artifact-filter (**`ON/OFF`**)

Fig. 61: Masimo Signal Processing

7.7.3.1 Averaging Time (`Averaging time`)

The averaging time indicates the duration, with which from several original measured values individual displays one VALUE is again computed.

The averaging time can be adjusted between 2-4 (FastSat™) and 16 seconds. 8 seconds is the default setting.

The longer the length of time, in which measured values are collected, the lower the display value varies.

WARNING! Variations in oxygen saturation cannot be recognized!

Rapid changes in oxygen saturation are not recognized with the selection of a long averaging time!

1. Starting from the main menu, call: → **Configuration** → **Signal process** → **Averaging time**
2. Set the averaging time with the trim knob between **2-4** and **16 sec**.
3. Confirm this setting with **Return**.

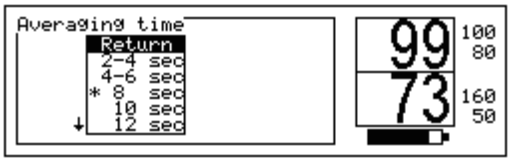


Fig. 62: Averaging Time

What is FastSat™?

FastSat™ permits the display of sudden oxygen saturation changes. In general these rapid changes in oxygen saturation are handled by the signal distribution i.e. display. FastSat™ can be especially useful for incubations or for polysomnography, where a high level of reliability in the saturation recognition process is desirable. FastSat™ is also able to stream the oxygen saturation changes from breath to breath.

7.7.3.1 Perfusion Sensitivity (**Algorithm mode**)

The perfusion sensitivity can be set between Normal **("Norm.perfus.")**, Maximum resp. high **("Low. perfus.")** and APOD **("APOD"):**

– The *normal Perfusion –Sensitivity* has been optimized for continuous long-term monitoring. Depending on signal quality the lower signal strength value lies between 0.5% and 0.02%.

– The *higher Perfusion –Sensitivity* (= lower perfusion) may only be used for supervised clinical situations. This setting is dependent on the sensor alarms, since it is only activated for signals smaller than 0.02%. The lower signal strength value lies at 0.02%.

NOTICE!

If the signal deteriorates below the configured signal strength value, the unit turns to Pulse-Search-Mode.

– *APOD* is a suite of complex and powerful signal processing algorithms that carefully analyze the incoming signal to determine if the pulse oximeter sensor is ON or OFF the patient. Adaptive Probe Off Detection (APOD) delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes detached from the patient. By providing another sensitivity level, APOD directly addresses a problem common to pulse oximetry and gives the clinician an unprecedented level of control.

  APOD may be appropriate under conditions in which the Clinician/Patient ratio is lower than in the intensive care unit and when contact between clinician and patient may be less continuous. It is recommended for "step down" and "ward" care, and nursing home care situations. APOD is appropriate where remote monitoring is employed. It is useful for patients that are at particular risk of the sensor becoming detached (pediatric, combative, etc).

How does APOD compare to Max or Normal sensitivity?

APOD is the least sensitive in picking up a reading on patients with low perfusion. Normal Sensitivity provides the best combination of sensitivity and probe-off detection performance and is recommended for the majority of patients. Max Sensitivity is reserved for the sickest patients, where obtaining a reading is most difficult. Max sensitivity is designed to interpret and display data for even the weakest of signals, and is recommended during procedures and when clinician and patient contact is continuous.

If low perfusion combined with movement inhibits the Masimo SET monitor from reading, switch from APOD to Normal or Max sensitivity.

Three sensitivity levels enable the clinician to tailor the response of the sat 805 to the needs of the particular patient situation - a truly unique and powerful capability.

1. Starting from the main menu, call: → **Configuration** → **Signal process.** → **Algorithm mode**
2. Select the setting (**Low. perfus. /Norm.perfus./APOD**) using the trim knob.
3. Confirm this setting with **Return**.

Fig. 63: Perfusion Sensitivity

7.7.3.3 SmartTone (`SmartTone`)

The SmartTone is a feature that affects pulse beep and Signal IQ waveforms and can be selected as “ON” or “OFF”.

When the SmartTone is ON, the Masimo SET algorithms will continue to provide pulse beep and Signal IQ waveforms even when the pleth is noisy due to motion or low signal conditions.

With SmartTone OFF, the pulse beep and Signal IQ waveforms will suppress beep information during periods of motion or low signal conditions.

The manufacturer’s preset for this parameter is „SmartTone ON“.

7.7.3.4 Artifact Filter (`Artifact-Filter`)

To eliminate short-term and therefore irrelevant losses of the pulse signal, an artifact filter can be applied by selecting „ON“ or „OFF“.

This filter is applied to the following sensor-related alarms only:

- No Sensor Connected,
- Defective Sensor,
- Interference Detected,
- Sensor Off Patient,
- Too Much Ambient Light,
- Unrecognized Sensor

The artifact filter rejects sporadic alarm messages (of the same kind) up to a duration of 5 seconds. After this period, the alarm will be triggered. In case the source for the alarm has vanished during the mute period, no alarm is activated.

When activated, the symbol „AR“ is displayed in the lower right corner of the screen.

The manufacturer’s preset for this parameter is „Artifact filter OFF“ .

7.7.4 System Time (`Clock`)

The function sets the date and time of the unit. For a precise analysis of the stored monitoring data, it is necessary to set the device time always correctly.

ATTENTION!

The user will need to adjust the time from summer to winter and vice versa manually!

1. Starting from the main menu, call:
   → **`Configuration`** → **`Clock`**
2. Select the first digit to be modified with the trim knob.
3. Adjust the number with the trim knob.
4. Repeat this sequence for each number to be modified.
5. Confirm this setting with **`Accept.`**

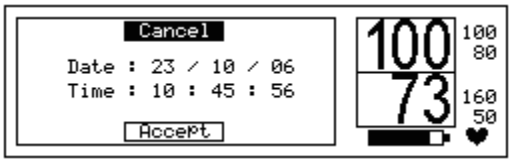


Fig. 64: Setting the System Time

NOTICE!

The clock time does not run while setting it. For that reason it makes sense to set the clock time to a later point in time, and then at precisely that point in time press the trim knob to accept the time and date.

If you try to accept an invalid date (e.g. 30.02.07), the device responds with the following message:

"**`Attention! Date is not correct!`** ".

In that case no new date or time is set.

Fig. 65: Date is not correct

7.7.5 External Alarm (Nurse Call)

WARNING! Danger by incorrect Configuration!

This setting is only allowed to be modified by experienced and training personal. A wrong setting might de-activate the external alarm.

If the unit shall be connected via the external alarm interface, this interface can be set in accordance to the respective system. For this, the relay contact can be configured as "**Norm.(ally) open**", "**Norm.(ally) closed**" or "**Remote Alarm**".

– In the **Norm. open** setting the contact is permanently closed as long as the alarm condition continues.

– In the **Norm. close** setting the contact is permanently open as long as the alarm condition continues.

– Before connecting a remote alarm device, you must select the **Remote alarm** setting. This gives a clocked transmission of coded alarm information from the device to the remote alarm device.

1. Starting from the main menu, call: → **Configuration** → **Nurse call**
2. Select the desired setting using the trim knob (**Norm.open** / **Norm.close** / **Remote Alarm**).
3. Confirm this setting with **Return**.

Fig. 66: Nurse call Interface Setting

7.7.6 Device Information (Product Info)

By selecting menu **ProductInfo** you can call up the most important device settings on to the display:

– Device S/N and software version

– Version of the Masimo circuit board and its product identification

– DSP and microcontroller-versions

– Perfusion sensitivity setting
– Signal averaging time setting

NOTICE!

The displayed information is read-only.

1. Starting from the main menu, call:
   → **Product Info**
2. Leave that window by confirming **Return**.

Fig. 67: Device Information

7.7.7 Analogue Interface (Analogue out)

If required a calibration signal can be output at the analog interface.

For calibration, a null signal (0%), a full signal (100%) or a step function can be output.

– **0 %**: On the interface, the analog voltages for 0% SpO_2, 0 1/min pulse rate and the baseline for the plethysmogram are output.
– **100 %**: On the interface, the analog voltages for 100% SpO_2, 240 1/min pulse rate and the full-scale deflection of the plethysmogram are output.
– **Steps**: In this mode, voltage steps are output, starting at 0 volts and ending at 1.0 volt, rising by incremental steps of 0.1 volt per second.

1. Starting from the main menu, call:
   → **Configuration** → **Analogue out**
2. Select the desired function (**0 %** / **100 %** / **steps**).

Fig. 68: Analogue Interface

NOTICE!

The calibration signals are immediately available on the interface.

Fig. 69: Calibration

3. Leave the menu by selecting **Return**.

7.8 Alarm lists (Alarm lists)

The sat 805 continuously stores monitoring data. SpO_2, pulse and IQ values are continuously logged on a second-by-second basis. In addition, data related to monitoring, such as alarms and device settings, are also stored. In the basic extension stage, the device stores 160 hours of continuous monitoring with a maximum of 4000 alarm list entries. Though only the last 500 are visible and displayed on the screen.

NOTICE!

Even in the case of an entire voltage loss the alarm lists remain unchanged.

Also in the state of ALARM VOLUME = 0 (=OFF) all alarms are logged.

On the device you have the option of analyzing the stored data in the form of lists and alarm event graphics:

- a list of all alarm events
- the vital alarm list
- trend displays

The stored data can be exported via various interfaces for more detailed evaluation.

7.8.1 Vital Alarm List (`Vital alarm list`)

1. Starting from the main menu, call:
   → **`Data`** → **`Vital alarm list`**

   The list of vital alarms is displayed.

   From left to right, this shows:

   – The serial alarm ID (e.g. no. 12),

   – Date and time when the alarm occurred (e.g. 23.10.06, 10:26h)

   – The duration (e.g. 0 minutes 54 seconds)

   – And the extreme value during the alarm (e.g. 99 %)

2. Turn the encoder clockwise to browse through the list.

   Turn the encoder clockwise to show a more recent alarm (i.e. higher alarm numbers), turn the encoder counter clockwise to show an older alarm (i.e. lower alarm numbers).

3. Leave the list by confirming **`Return`**.

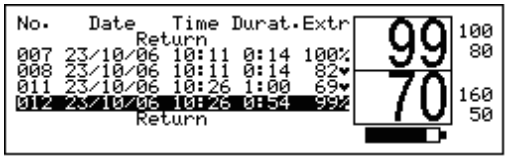


Fig. 70: Vital Alarm List

7.8.2 Total Alarm List (`Total alarm list`)

Selecting **`Total alarm list`** displays a list of all the alarm events (vital and technical alarms) as a table on the display.

1. Starting from the main menu, call:
   → **`Data`** → **`Total alarm list`**

   The total list of vital alarms is displayed.

   From left to right, this shows:

   – The serial alarm ID (e.g. no. 15),

   – Date and time when the alarm

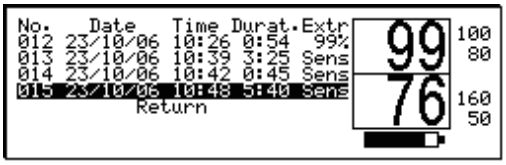


Fig. 71: Total Alarm List

occurred (e.g. 23.10.06, 10:48h)

- The duration (e.g. 5 minutes 40 seconds)
- And the extreme value or type of alarm event (e.g. Sensor failure)

2. Turn the encoder clockwise to browse through the list.

   Turn the encoder clockwise to show a more recent alarm (i.e. higher alarm numbers), turn the encoder counter clockwise to show an older alarm (i.e. lower alarm numbers).

3. Leave the list by confirming **Return**.

7.8.3 Alarm Details

1. Call the **Alarm list**.

2. Mark an alarm entry and select it by pressing the trim knob.

   In the window, following information is displayed:

   - Start date
   - Start time
   - Alarm duration
   - Type of alarm (here: SpO_2 hi)
   - Alarm limits

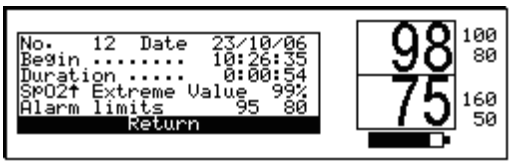


Fig. 72: Alarm Details

Extreme value or type of alarm

3. Leave the window by confirming **Return**.

7.9 Trend Display (Trend)

The sat 805 continuously stores monitoring data. The SpO_2, pulse and IQ values are recorded every second. In addition, it also stores monitoring-related data such as alarms and device settings.

The basic sat 805 model stores up to 160 hours of continuous monitoring with a maximum of 4,000 alarm list entries.

The sat 805 offers an easy and quick graphical trend display on the device.

The device records the oxygen saturation and pulse rate data every second continuously. In the Trend display, this can be shown as a trace (SpO_2 or pulse) or both simultaneously over different time as (12, 8, 6, 4, 2 hours; 60, 30, 10, 4, 2 minutes).

7.9.1 Trend Display

1. Starting from the main menu, call:
   → **Data** → **Trend**
2. Select the time scale (**2 minutes** till **12 hours**)
3. Select the display mode (**SpO2**, **Pulse** or **both**).
   The most recent data are displayed in the required format.
4. Turn the trim knob clockwise to move the pointer to later times and counter clockwise to move to earlier times.

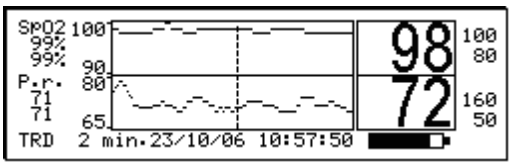


Fig. 73: Trend Display

At the current position (the position of the screen marker) are displayed:

Left:

– Minimum (lower value) and maximum (upper value) at that point in time. "---" is displayed if there are no values available.

Lower Line

– Selected display mode

– Time scale (2 minutes till 12 hours)

– Date (here: 23.10.06) and time (here: 10:57.50)

NOTICE!

When the marker reaches the left or right hand edge of the display, the area shown is moved by half a screen to one side.
The screen marker cannot move beyond the start or the end of the data.

5. For leaving the trend display, press the trim knob.

7.10 Exporting the Data

For further analysis, the stored data can be exported to a SD card.

WARNING!

Whilst the data is being exported, there is no monitoring and therefore no alarms should the patient be in a life-threatening situation!

NOTICE!

The pulse oximeter only accepts empty (erased) SD cards. All other cards will be refused, with an error message.

Fig. 74: Card not readable

1. Switch off the device.
2. With the angled edge to the top and the exposed contacts facing forwards, insert the empty SD card into the slot until it is firmly in place.

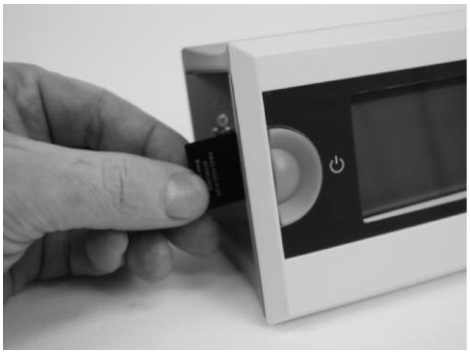


Fig. 75: Inserting SD Card

3. Switch on the device.
It automatically detects the SD card and goes into data transmission mode.

   After a short while the data transfer is complete – for the complete file about 20 seconds are needed.

   When transmission is complete, the message:

   "**File … has been saved successful !**

   Please take the Memory Card out!"

   is displayed.

   When the data has been successfully written to the SD card, the data memory in the device is automatically deleted.

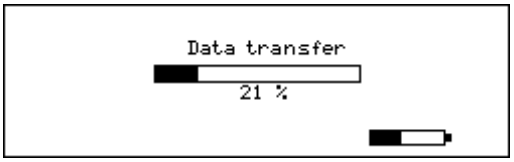


Fig. 76: Transmitting Data

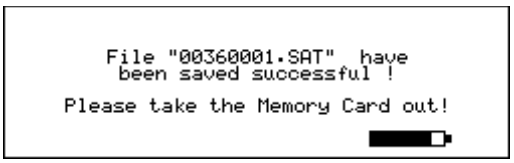


Fig. 77: Remove SD Card

NOTICE!

If the transmission is interrupted or a fault occurs, the pulse oximeter outputs an error message. No data is stored on the SD card in this event.

4. Take the SD card out.

   The data on the SD card can then be processed with a graphics and analysis program, for example "satView".

8 Alarms

8.1 General

As a monitoring system, the sat 805 pulse oximeter is equipped with acoustic and visual signals for many alarm situations. It alerts the user:

– When deviations from pre-set alarm limits occur

– In problem situations during technical monitoring

– Internal unit malfunctions

WARNING! Danger by incorrectly entered Alarm Limits!

Always check the alarm limits each time before using the pulse oximeter, in order to ensure that the current limits are appropriate for the patient in question.

If there is any doubt as to the accuracy of the values shown, first check the patient's vital parameters using other methods and then investigate whether the device is functioning.

WARNING! Danger by quiet alarm tones!

Please ensure that the openings of the loudspeaker are not covered in any way.

Inaccurate measurements can be caused by:

– Incorrect sensor connection or incorrectly selected Masimo-sensor.

– A significant proportion of dysfunctional hemoglobin (e.g. carboxyhemoglobin or methemoglobin).

– Intravascular dyes such as indocyanine green or methylene blue are present in the blood stream.

– Excessive light intrusion, such as operating lamps (especially xenon light sources), bilirubin lamps, fluorescent lights, infrared heat sources or direct sun light (excessive light intrusion can be avoided with a dark or transparent sensor shade).

– Excessive movement of the patient.

– Venous blood pulses.

- Attaching the sensor to a limb at the same time as a blood pressure cuff, an arterial catheter or an intravascular line.

Loss of pulse signal might occur under the following conditions:

- The sensor is attached too tightly.
- There is too much light from operating theatre lights, bilirubin lamps or sunlight.
- An inflated blood pressure cuff is attached to the same extremity as the sensor.
- The patient suffers from low blood pressure, severe vasoconstriction and/or anaemia or hypothermia.
- The artery is obstructed close to the sensor.
- The patient is in shock or cardiac arrest.
- The fingernail is varnished.

8.2 Alarm Categories

There are three alarm categories:

- **High priority alarms**
  require immediate user intervention in order to avoid possible damage to the patient.
- **Medium priority alarms**
  show a technical problem and require immediate user intervention.
- **Low priority alarms**
  require elevated attention by the user.

8.2.1 High Priority Alarms

High priority alarms require immediate action by the user in order to avert any possible harm to the patient.

With high priority alarms

– the high-priority alarm tone sounds,

– the red alarm-LEDs (1) flash and

– a status line message appears.

These signals remain active for as long as the condition causing the alarm persists.

If the condition causing the alarm is no longer present, then the signal goes off.

Every alarm results in an entry in the alarm list as well as the storage of the graphic alarm events.

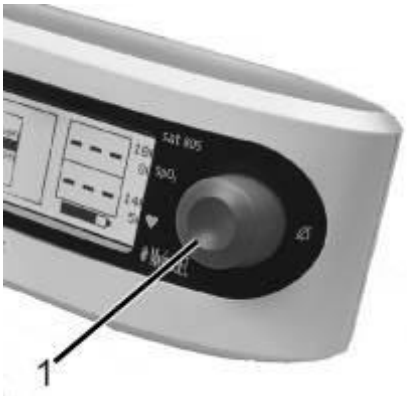


Fig. 78: Alarm LEDs

If the trim knob is pressed during an acoustic alarm signal, then the signal tone is suppressed for the duration of the pre-set acoustic alarm suppression time.

If the setting “Acoustic alarm OFF” has been selected in the configuration menu, then an alarm does not sound. Only the visual signals can notify the responsible user of the presence of an alarm condition.

8.2.1.1 SpO_2 Alarm

Status Line Message	Message in the LC Display	Cause
$SpO_2\uparrow$	flashing SpO_2 values	Oxygen saturation exceeds the set alarm limit.
$SpO_2\downarrow$	flashing SpO_2 value	Oxygen saturation falls below the set alarm limit.

The elapsed duration and the extreme value of the current alarm is displayed on the status line.

8.2.1.2 Pulse Rate Alarm

Status Line Message	Message in the LC Display	Cause
P.r.↑	flashing pulse rate value	Pulse rate exceeds the set alarm limit.
P.r.↓	flashing pulse rate value	Pulse rate falls below the set alarm limit.

The elapsed duration and the extreme value of the current alarm is displayed on the status line.

8.2.1.3 Sensor Alarms

NOTICE!

X-CAL or lifetime related alarms (*) might not be present in all devices.

To confirm, please check in the product info menu (see chapter 7.7.6): only devices with DSP version 5.X.X.X will support the X-CAL related alarms and messages.

Status Line Message	Description	Solution
No sensor connected!	The sensor is not or incorrectly connected to the unit.	Check connection between patient cable and sensor. If needed, replace sensor.
No adh. sensor connected!(*)	The sensor is not or incorrectly connected to the unit.	Check connection between patient cable and sensor. If needed, replace sensor.
No cable connected! (*)	The patient cable is not or incorrectly connected to the unit.	Check patient cable connection between unit and sensor. If needed, replace the patient cable.
Sensor off patient!	The sensor is connected to the unit, the unit is on, but no patient can be recognized.	Position the sensor correctly.
Defective sensor!	The device has determined that the sensor does not function at all or only to a limited extent.	Replace the sensor with a new Masimo sensor!
Unrecognized sensor!	The device has detected a sensor that is not approved for this system or the lifetime has been exceeded.	Only connect Masimo sensors or connect a new sensor!
"Defective adh. sensor!" (*)	The device has determined that the sensor does not function at all or only to a limited extent.	Replace the sensor with a new Masimo sensor!
"Defective cable!" (*)	The device has determined that the patient cable does not function at all or only to a limited extent.	Replace the sensor with a new Masimo patient cable!

Status Line Message	Description	Solution
„Incompatible sensor!" (*)	The device has detected a sensor that is not approved for this system.	Only connect approved Masimo sensors to the unit.
„Incompatible adh. sensor!" (*)	The device has detected a sensor that is not approved for this system.	Only connect approved Masimo sensors to the unit.
„Unrecognized adh. sensor!" (*)	The device has detected a sensor that is not approved for this system.	Only connect approved Masimo sensors to the unit.
„Check cable & sensor!" (*)	The system has detected a possible fault in the accessories or following a (no data) alarm after the next 120 seconds this alarm is triggered.	Check cable and sensor, replace if necessary or • Clean the sensor • Reposition the sensor • Exchange the sensor or/and patient cable with a new one!
„Check sensor" (*)	The system has detected a possible fault in the accessories.	Check cable and sensor, replace if necessary

8.2.1.4 System Alarms

WARNING! No Monitoring with System Alarm!

The monitoring function is turned off by system alarm. For the duration of the system alarm the patient is not correctly monitored. The patient must be monitored by other means.

A system alarm indicates that reliable monitoring is no longer being performed due to a technical error. The unit can and may no longer be used when this alarm occurs.

Alarms

Action for System Alarm Occurrence:

1. Secure monitoring of patient by other means.
2. Turn off unit by pressing the ON/OFF button.
3. Turn the unit back ON.

   If the self-test occurs without errors, the unit can be used again for monitoring.

   If an error occurs during the self-test, turn the unit OFF and take to a medical supplier for repairs.

WARNING! Danger to the Patient!

Never use a unit that indicates a system alarm.

System Alarm Messages:

Message	Source
SYST ALARM: bat low!	The battery voltage is below a level that guarantees reliable operation.
SYST ALARM: MS-FIFO!	An error has arisen in the Masimo input data memory.
SYST ALARM: MS-timeout!	The Masimo-circuit board has not responded to several queries or does not provide data for more than 60 seconds.
SYST ALARM: MS-comm.!	The Masimo-data transfer has a permanent defect.
SYST ALARM: MS-error!	The Masimo circuit board has reported an irreparable defect.
SYST ALARM: Unexp.reset!	An unexpected device restart has occurred.
SYST ALARM: NVRAM error!	The internal non-volatile memory has reported an error.
SYST ALARM: WDT error!	The integrated circuit that monitors the sat 805 has reported an error.
SYST ALARM: Reset monitor	The integrated circuit that monitors the sat 805 has

Message	Source
	reported an error.
SYST ALARM: Stack overfl.	An error has occurred in the software stack processing.
SYST ALARM: ROM-CRC!	A data security error has occurred.

8.2.2 Medium Priority Alarms

WARNING! Insufficient Monitoring at Medium Priority Alarms.

With alarms of mid-level priority a correct signal reception cannot be guaranteed. At times the patient will not be monitored correctly for the duration of the alarm. The cause of the alarm must be corrected as soon as possible.

Medium priority alarms display technical problems and require quick user intervention.

With medium-priority alarms,

– the medium-priority alarm tone sounds,

– the yellow alarm-LEDs (1) flash and

– a status line message appears.

Fig. 79: Alarm LEDs

Medium Priority Alarms:

Status Line Message	Description	Solution
MS-Comm. lost data!	Data transfer error. The device has registered this fact and has automatically restored communication.	No user intervention required.
No data!	The unit has determined the sensor or patient cable does not work properly. After 60 seconds a system alarm is triggered.	• Clean the sensor • Reposition the sensor • Exchange the sensor or/and patient cable with a new one!
Battery depleted!	Remaining operation time of 15 minutes or less	Recharge battery

8.2.3 Low Priority Alarms

With a **low priority alarm**

– the audio sound of low priority is heard,

– the yellow alarm LEDs (1) light and

– the status line message appears.

NOTICE!

With low priority alarms, the LEDs (1) do NOT blink.

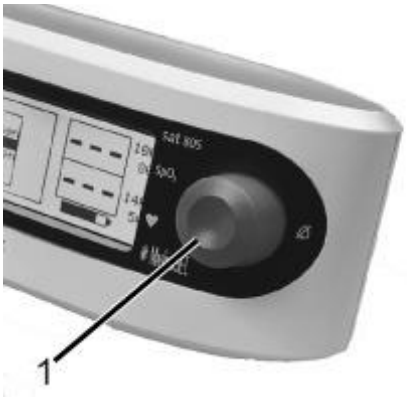


Fig. 80: No Alarm-LED

Low Priority Alarms require additional attentiveness by the user.

Low Priority Alarms:

Status Line Message	Description	Solution
`Mains power supply!`	The mains power or the DC power supply is interrupted/defect.	Check the mains power (fuses) and also the DC power pack. Is the green LED glowing?
`Loudspeaker defective!`	The sat 805 has detected a defective alarm loudspeaker and has switched over to the internal substitute signal device.	A defective loudspeaker can only be replaced by qualified personnel. Notify your medical technology dealer.

8.3 Status message

The following status messages provide information about the actual monitoring situation:

Status Line Message	Description	Solution
`Low perfusion!`	The unit has determined insufficient circulation for reliable determination of oxygen saturation values.	Remove the sensor and position at a different place.
`Signal IQ too low!`	The signal strength for signal reliability is too low.	Remove the sensor and position at a different place.
`Pulse search!`	At too low perfusion or during the initialization, the device attempts to synchronize with the detected perfusion.	If the device will remain in this state after switching on or this message is displayed during the operation, remove the sensor and position at a different place.
`Interference!`	The unit has determined influence from a second light source or a second sensor.	Remove the interfering source. Only use a new Masimo sensor.

Status Line Message	Description	Solution
`Ambient Light!`	The unit has determined a scattered or foreign light source. This can occur with particularly strong lighting from the outside (especially from xenon or similar lamps).	Do not expose the sensor to a direct light source, or shade from the outside.

Status messages are not alarms and there not accompanied by LED activation.

Status messages may be mask with higher ranking alarms.

8.4 Battery Alarms

The device warns the user in good time of low or insufficient battery capacity, and reminds the user in good time to connect the pulse oximeter again to the mains supply and to recharge the internal battery.

There are three stages in battery alarm management:

– Battery alarm low priority

– Battery alarm medium priority

– System battery alarm (high priority)

WARNING! Insufficient Monitoring!

With continued battery alarm act quickly. Monitoring of the patient can discontinue in a short time.

Reconnect to the device to mains and recharge the unit.

Once connected to the mains power supply, the battery alarm will be automatically reset.

However if the recharging is interrupted early, and the device is again run but not off the mains, the battery alarm may immediately be triggered again.

8.4.1 Battery Alarm (low priority)

Status Line Message	Description	Solution
`Battery low!`	Remaining operation time of one hour or less.	Recharge battery.

A flashing battery icon will be displayed.

8.4.2 Battery Alarm (medium priority)

Status Line Message	Description	Solution
`Battery depleted!`	Remaining operation time of 15 minutes or less.	Recharge battery.

A flashing battery icon will be displayed.

8.4.3 Battery Alarm (high priority)

Status Line Message	Description	Solution
`SYST ALARM: Bat low!`	Battery capacity is so low, that reliable monitoring can no longer be guaranteed. Signal processing and the monitoring function are disabled.	Recharge battery.

An empty battery icon will be displayed.

8.5 Combination of Alarms of Different Priorities

With overlapping different alarm conditions the latest alarm with the highest priority is activated.

With concurrently occurring alarms the highest ranking is activated. If these alarm conditions are removed, the next lower waiting alarm is immediately displayed.

A new alarm condition of higher priority immediately supersedes any lower ranking alarm.

9 Malfunctions and Troubleshooting

WARNING! Insufficient Monitoring by Malfunctions!

With the occurrence of function failure the patient cannot be correctly monitored in certain cases.

The cause of the function failure must be removed as soon as possible.

Immediately assure monitoring of patient by other means.

Action at Function Failure:

1. Secure monitoring of patient by other means.
2. Remove unit from patient.
3. Remove external interfaces.
4. Correct failure with help of Table below.

WARNING! Danger to the Patient!

Never use a malfunctioning unit.

List of possible Malfunctions / Error Messages:

Message	Cause	Solution
Unit cannot be turned on.	Batteries are empty.	Recharge batteries: connect unit to electricity. Should function not occur even with a networked connection, inform medical device supplier.
The information displayed on the LCD is difficult to read.	The display contrast is set incorrectly.	Set the display contrast that the information is easy to read.
When in use buttons do not work.	Internal failure.	Inform medical device supplier.

Message	Cause	Solution
Error message after self-test run and after unit is turned on.	Internal failure.	Turn the unit ON and OFF. Inform medical device supplier.
No function of the alarm loud speaker. Internal substitute buzzer sounds.	Defective alarm loudspeaker.	Inform medical device supplier.
Status Line Message: **"Sensor not connected!"**	The patient cable is not or incorrectly connected to the unit. The connection between sensor input and patient cable is interrupted.	Check connection between unit and sensor. If needed, replace sensor or patient cable.
Status Line Message: **"Sensor defect!"**	The unit has determined the sensor does not work or only in limited capacity.	Exchange the sensor with a Masimo-Sensor!
Status Line Message: **"Defective adh. sensor!"**	The device has determined that the sensor does not function at all or only to a limited extent.	Replace the sensor with a new one!
Status Line Message: **"Defective patient cable!"**	The device has determined that the patient cable does not function at all or only to a limited extent.	Replace the patient cable with a new one!
Status Line Message: **"Low perfusion!"**	The unit has determined insufficient circulation for reliable determination of oxygen saturation values.	Remove the sensor and connect at a different place.
Status Line Message: **"Interference!"**	The unit has determined influence from a second light source or a second sensor.	Do not expose the sensor to a direct light source. Only use a new Masimo-Sensor.

Malfunctions and Troubleshooting

Message	Cause	Solution
Status Line Message: **"Pulse search!"**	With too low perfusion or whilst the initialisation the unit tries to synchronize with the defect perfusion.	If the unit remains in this situation after turning on or if the alarm is activated while operating, remove the sensor and position at a different place.
Status Line Message: **"Sensor not on Patient!"**	The sensor is connected to the unit, the unit is on, but no patient can be recognized.	Position the sensor correctly.
Status Line Message: **"Ambient Light!"**	The unit has determined a scattered or foreign light source. This can occur with particularly strong lighting from the outside (especially from xenon or similar lamps).	Do not expose the sensor to a direct light source, or shade from the outside.
Status Line Message: **"Signal IQ too low!"**	The signal strength for signal reliability is too low.	Remove the sensor and position at a different place.
Status Line Message: **"MS-Comm. lost data!"**	Data transfer error. The device has registered this fact and has automatically restored communication.	No user intervention required.
Status Line Message: **"Unrecognized Sensor!"**	The unit has discovered a sensor not approved for this system.	Only use authorized Masimo accessories.
Status Line Message: **"Patient cable near expiration!"**	The patient cable has reached 90% of its specified life time.	Have a new patient cable ready.
Status Line Message: **"Sensor near expiration!"**	The sensor has reached 90% of its specified life time.	Have a new sensor ready.

Message	Cause	Solution
Status Line Message: **"Adh. Sensor near expiration!"**	The adhesive sensor has reached 90% of its specified life time.	Have a new sensor ready.
Status Line Message: **"X-CAL: Patient cable expired!"**	The patient cable has reached 100% of its specified life time.	Replace patient cable.
Status Line Message: **"XCAL:Sensor expired!"**	The sensor has reached 100% of its specified life time.	Replace sensor.
Status Line Message: **"X-CAL:Adh. sensor expired**	The sensor has reached 100% of its specified life time.	Replace sensor.
Status Line Message: **"Check sensor connection!"**	The system has detected a possible fault in the accessories.	Check connection between patient cable and sensor. If needed, replace sensor and/or cable.
Status Line Message: **"Check cable and sensor!"**	The system has detected a possible fault in the accessories.	Check connection between patient cable and sensor. If needed, replace sensor and/or cable.
Status Line Message: **„No adh. sensor connected"**	The sensor is not or incorrectly connected to the unit.	Check sensor. If needed, replace sensor.
Status Line Message: **„No patient cable connected"**	The patient cable is not or incorrectly connected to the unit.	Check patient cable. If needed, replace cable.
Status Line Message: **„Unrecognized cable"**	The unit has discovered a patient cable not approved for this system.	Use approved Masimo accessories only.

Malfunctions and Troubleshooting

Message	Cause	Solution
Status Line Message: **“Unrecognized adh. sensor!“**	The unit has discovered a sensor not approved for this system.	Use approved Masimo accessories only.
Status Line Message: **„Incompatible sensor“**	The unit has discovered a sensor not approved for this system	Use approved Masimo accessories only.
Status Line Message: **„Incompatible cable“**	The unit has discovered a patient cable not approved for this system.	Use approved Masimo accessories only.

10 Disinfecting, Cleaning and Maintenance

The natural aging and abrasion of certain assemblies of the unit require regular cleansing and maintenance.

10.1 Cleaning Plan

Interval	Cleaning
Daily (In the clinic)	Clean and disinfect reusable sensors
Every 14 days	Clean and disinfect patient cable
Every 14 days (In the clinic)	Dispose of disposable sensors
Weekly (In the clinic)	Clean and disinfect sat 805 & patient cable
Weekly (outside of the hospital)	Clean sat 805
Every 4 Weeks (outside of the hospital)	Dispose of disposable sensors
At change of patient	Clean and disinfect sat 805 included carrying bag, AC adapter, patient cable and reusable sensors
At change of patient	Dispose of disposable sensors
After service activities	Clean and disinfect sat 805 included carrying bag, AC adapter, patient cable and reusable sensors
After service activities	Dispose of disposable sensors

10.2 Disinfection

It has been proven, wipe disinfection is more thorough and comprehensive than spray disinfection. We recommend to use Meliseptol rapid (manufacturer B.Braun) in the same manner like for the above outlined cleaning procedure.

10.2.1 Disinfecting the Unit

ATTENTION! Danger to the Unit!

Do not use disinfectants other than those authorised. Proceed particularly cautiously in the LCD display area to avoid scratching the surface. Never immerse the unit in or under water i.e. into another liquid. The unit as well as the applicable Masimo accessories do not sustain autoclave, steam or gas sterilization.

1. Switch off the unit before cleaning and disconnect the mains and patient connections.
2. The application instructions of the disinfectant manufacturer must be followed. Disinfection takes place as part of a surface wipe disinfection. For this purpose, the disinfectant is distributed on a disposable wipe and the surface of the pulse oximeter to be disinfected is wiped off using the cross method (2 x longitudinal/2 x transverse). After the manufacturer- and disinfectant-dependent exposure time, further use can be made.
3. Allow the device to dry completely before the next use.

10.2.2 Disinfecting the Masimo sensors

NOTICE!

The single patient sensors (adhesive sensors) are only intended for use on one patient and must not be cleaned or reused.

ATTENTION: Danger to sensor functionality!

Do not use undiluted bleach 15% - 5.25% sodium hypochlorite or any cleaning solution other than those recommended here because permanent damage to the sensor may occur.

Do not immerse the sensor or connector in any liquid solution.
Do not sterilize by irradiation, steam autoclave or ethylene oxide!

Disinfect the reusable Masimo sensors as follows:

1. Disconnect the connection from both the patient and the patient cable.
2. For disinfection, use a 1:10 bleach /water solution.
3. Saturate a cloth or gauze pad with the cleaning solution und wipe all surfaces of the sensor and cable.
4. Saturate another cloth or gauze pad with sterile or distilled water and wipe all surfaces of the sensor and cable.
5. Dry the sensor with a clean cloth or dry gauze pad.

10.2.3 Disinfecting the patient cable

ATTENTION: Danger to cable functionality!

Do not use undiluted bleach 15% - 5.25% sodium hypochlorite or any cleaning solution other than those recommended here because permanent damage to the sensor may occur.

Do not immerse the cable or connector in any liquid solution.
Do not sterilize by irradiation, steam autoclave or ethylene oxide!

Disinfect the patient cable as follows:

1. Disconnect the connection from both the patient and the patient cable.
2. For disinfection, use a 1:10 bleach /water solution.
3. Saturate a cloth or gauze pad with the cleaning solution und wipe all surfaces of the sensor and cable.
4. Saturate another cloth or gauze pad with sterile or distilled water and wipe all surfaces of the sensor and cable.
5. Dry the sensor with a clean cloth or dry gauze pad.

10.3 Cleaning

10.3.1 Cleaning the Unit

ATTENTION! Danger to the Unit!

Do NOT use strong cleaning agents with petroleum base or acetone solution.

Proceed particularly cautiously in the LCD display area to avoid scratching the surface.

Never immerse the unit in or under water i.e. into another liquid.

The unit as well as the applicable Masimo accessories do not sustain autoclave, steam or gas sterilization.

1. Before cleaning turn the unit OFF and disconnect from the network and the patient.
2. Only clean the unit with a dry or slightly moist cloth. For more severe soiling use a moist cloth and all-purpose cleaner.
3. Let the unit dry completely before re-use.

10.3.2 Cleaning of Masimo-Sensors

The re-usable Masimo sensors are to be cleaned as follows:

1. Disconnect from the patient cable and also from the patient.
2. Use a cloth rinsed in 70% isopropyl alcohol to wipe the entire sensor.
3. Let the entire sensor completely air dry long enough before reusing.

NOTICE!

The single-use sensors are only intended for one patient and may not be cleaned or re-used.

10.3.3 Cleaning of Patient Cables

The patient cable is to be cleaned as follows:

1. Disconnect from the patient and also from the patient sensor.
2. Use a cloth rinsed in 70% isopropyl alcohol to wipe the entire patient cable.
3. Let the entire patient cable completely air dry long enough before reusing.

10.4 Maintenance

User maintenance is not required.

The device itself requires maintenance once every 36 months in order to work within the guaranteed specifications.

ATTENTION! Unit can be damaged!

Never correct defects on the unit, repair it or perform maintenance yourself! Corrections of defects, repairs or any maintenance should be done exclusively by HUM Gesellschaft für Homecare und Medizintechnik mbH or by a HUM Gesellschaft für Homecare und Medizintechnik mbH authorized medical device supplier!

NOTICE!

A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter.

NOTICE!

If there is independent demonstration that a particular calibration curve is accurate for the combination of a pulse oximeter and a pulse oximeter probe, then a functional tester can measure the contribution of a monitor to the total error of a monitor/probe system. The functional tester can then measure how accurately a particular pulse oximeter is reproducing that calibration curve.

10.4.1 Regular Check

The unit should be checked by the manufacturer or an authorized dealer once every 36 months. Contact the medical device supplier for the correct information.

10.4.2 User Check of Alarm Function

If difficulties occur with the unit or it is suspected the unit no longer functions properly, the following function test can be performed. This does not however replace the yearly maintenance check by the manufacturer.

To check the Unit's Alarm Function do the following:

1. Connect the sensor. Turn the unit ON.
   The unit displays the actual oxygen saturation and pulse frequency values.
2. Set the oxygen saturation alarm limit at 5% below the displayed value. The new alarm value for the upper oxygen saturation limit will display. A high SpO_2 alarm will occur. The red LED will blink and the high priority alarm will sound.
3. Reset the upper alarm limit to 100%. The new alarm value will be accepted. The alarm goes silent.
4. Set the lower oxygen saturation alarm limit at 98%.

NOTICE!

If the displayed SpO_2-value is larger or equal to 98% this test must be ignored.

5. 98 % will be accepted as the lower alarm-value limit for oxygen saturation.

   If the actual and displayed SpO_2—value is less than 98 % the alarm will activate. The red LED blinks and the high priority alarm will sound.
6. Reset the lower alarm limit to 70%.

   The new alarm value will be accepted. The alarms stop.
7. Set the upper pulse frequency alarm limit to a value of 10 1/min below the indicated pulse frequency value.

The new alarm value for the upper pulse frequency will be accepted. The alarm will activate. The red LED blinks and the alarm will sound.

8. Reset the upper alarm limit to a value of 10 1/min above the indicated pulse frequency value.

   The new alarm value will be accepted. The alarm goes silent.

9. Set the lower alarm limit to a value of 10 1/min above the indicated pulse frequency value.

   The new alarm value for the lower pulse frequency will be accepted. The alarm goes silent. The red LED blinks and a new high priority alarm will sound.

10. Remove patient cable from the unit.

    The sensor alarm will sound. The red LED blinks and a new high priority alarm will sound.

11. This completes the check of the unit's alarm function.

ATTENTION!

Should an alarm occur despite meeting the alarm conditions described above, immediately contact the appropriate medical device supplier.

The unit may no longer be used.

11 Accessories and Replacement Parts

ATTENTION!

Wrong or defective accessory or replacement parts as well as parts from secondary manufacturers can lead to severe damage to the unit.

All guarantees and service agreements are void without prior notice by the use of unapproved accessories or replacement parts.

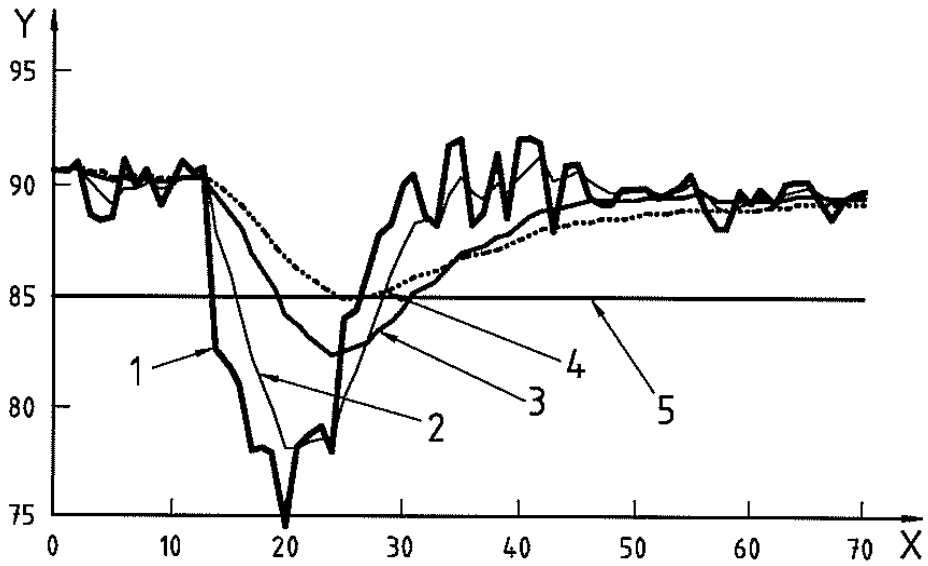
11.1 Accessories

Only use original supply parts from the manufacturer!

Order No.	Item
HPO02-805-KAF	Remote alarm/nurse call interface cable
HPO02-805-H	Mounting bracket for infusion poles and rail systems
HPO02-805-T	Carrying case
HPO02-805/816-NTEU	Euro power supply
HPO02-SW-SATVIEW-BV	Software satView, basic version
HPO02-SW-SATVIEW	Software satView, enhanced version, single user license

12 Advanced Information

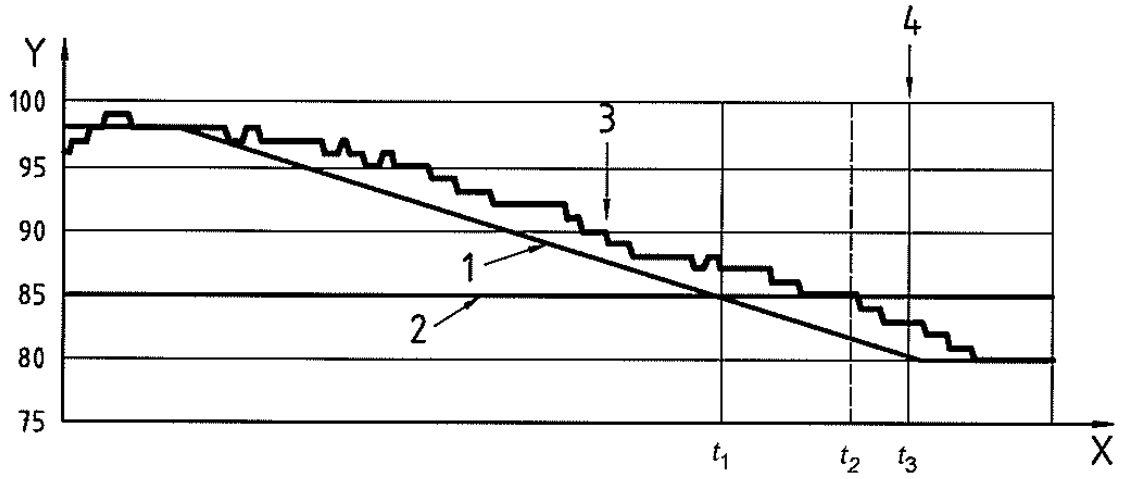
12.1 Averaging Time



This figure represents a faster desaturation slope and a more realistic, noisier saturation signal curve 1). Curves 3 and 4 underestimate the depth of the fall in saturation. Curve 2, faster averaging, can cross a low saturation **alarm limit** sooner than curve 3, normal averaging, or curve 4, slower averaging, which might not cause an **alarm condition** at all. The benefit of normal and slower averaging is to smooth out the otherwise noisy signal and reduce the number of **false positive alarm conditions**.

12.2 Alarm Signal Generation Delay

Graphic Representation of Components of Alarm System Delay:



The delay due to the pulse oximeter equipment processing and averaging is t_2 - t_1, the alarm condition delay. The interval t_3 - t_2, the alarm signal generation delay, is attributed to the alarm system strategy and the communication time to the alarm signal generation device or distributed alarm system (e.g. patient monitor or central station). Thus, the overall alarm system delay time is t_3 - t_1.

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