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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.

CAUTION! Injury or Mortal Danger!

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

WARNING! 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.

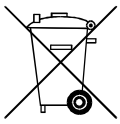
1.3 Liability and warranty

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.

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) must be made 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 used for the continuous monitoring of functional oxygen saturation and pulse frequency. It has an alarming function in case of deviations from the set 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 altered except for changing the battery.
Parts other than those pertaining to the supply scope may be used only after release by the company, Bitmos GmbH.

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.

- The pulse oximeter may not be used to monitor breathing. This may take place only with special respiratory monitoring equipment.
- A pulse oximeter shall not be used as an apnea monitor.
- 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.
- 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.
- This device is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Do not use any extensions power cords or adapters of any type. The plug-in power supply must be intact and undamaged.
- 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.
- The pulse oximeter may not be operated in a switchable power socket. Such a plug socket is unsuitable for a secured power supply.
- Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings. SpO2 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 SpO2 measurement.
- For increased COHb: COHb levels above normal tend to increase the level of SpO2. The level of increase is approximately equal to the amount of COHb that is present.

NOTE:

High levels of COHb may occur with a seemingly normal SpO2. When elevated levels of COHb are suspected, laboratory analysis (co-oximetry) of a blood sample should be performed.

- Elevated levels of Methemoglobin (MetHb) will lead to inaccurate SpO2 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 SpO2measurements. 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 SpO2 measurements.
- Severe anemia may cause erroneous SpO2 readings.
  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 electro magnetic signals, (e.g. mobile telephones, monitors, etc.) the functionality can be reduced.
- Do not use the sat801+ or sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The sat801+ may affect the MRI image and the MRI device may affect the accuracy of the Pulse Oximetry parameters and measurements.

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!

WARNING! 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.**

WARNING! Danger from Disposable and/or Rechargeable Batteries!

The unit contains rechargeable 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.**

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 enclosed 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

You can contact Bitmos GmbH as follows:

Office hours:	Mo-Fri 8.00 a.m. - 4.00 p.m.
Address:	Bitmos GmbH Himmelgeister Str. 37 D-40225 Düsseldorf Germany
Phone:	+49-211-60101030
Fax:	+49-211-60101050
Internet:	www.bitmos.de
eMail:	info@bitmos.de

3 Technical data

3.1 Unit data

Feature	Value
Unit dimensions (L x W x H)	128 x 85 x 46 mm
Weight, including batteries	230 g
External power supply	240 V ~50 Hz 5 V DC 1 A
Internal power supply	LiIonMn 2 x 3.6 V / 2250 mAh (each)
Maximum service life with battery operation	22 hours guaranteed (fully charged)
Operating temperature	+5° to + 40°C
Storage temperature	-25° to + 70°C
Classification in accordance with MDD (Medical Device Directive)	II b

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	
Resolution	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% SpO2 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 l to 2 cm and a non-repetitive motion between l to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 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.

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	75 dbA

Sensor	
Wavelengths	660 nm (red), 905 nm (infrared)
max. light intensity	0.79 mW

Notice!

Information about wavelength range can be especially useful to clinicians.

3.2 Factory default settings

Setting	Value
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
Memory configuration	Permanent, overwrite
SmartTone	On
Alarm tone volume	5
Pulse tone volume	5
Alarm tone mute time	60 sec
Averaging Time	8 sec
Perfusion sensitivity	normal
Artifact-filter	Off
Mode (access permissions)	Clinic

4 Assembly

4.1 Displays and controls

1 TFT display
2 green LED
3 red alarm LED
4 micro SD card slot
5 Navigation button right / up
6 On / Off button
7 Loud speaker
8 Alarm mute button
9 Menu / OK button
10 Navigation button left / down
11 yellow alarm LED

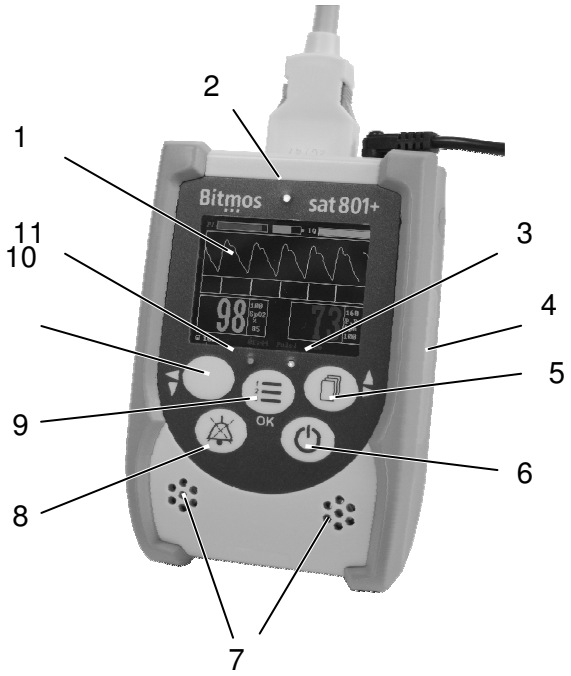


Fig. 1: Front

4.2 Connections on the unit

Connections on the upper panel of the unit:
1 USB-Interface
2 Patient cable connection
3 AC adapter socket

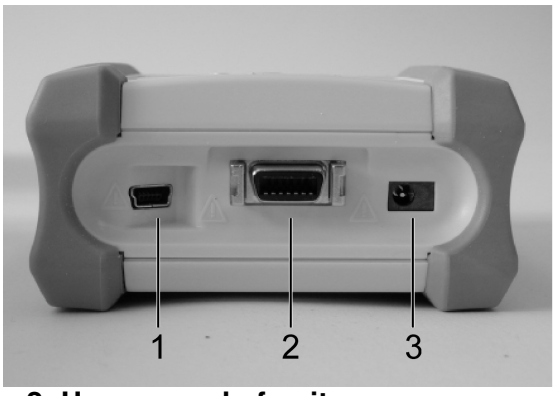
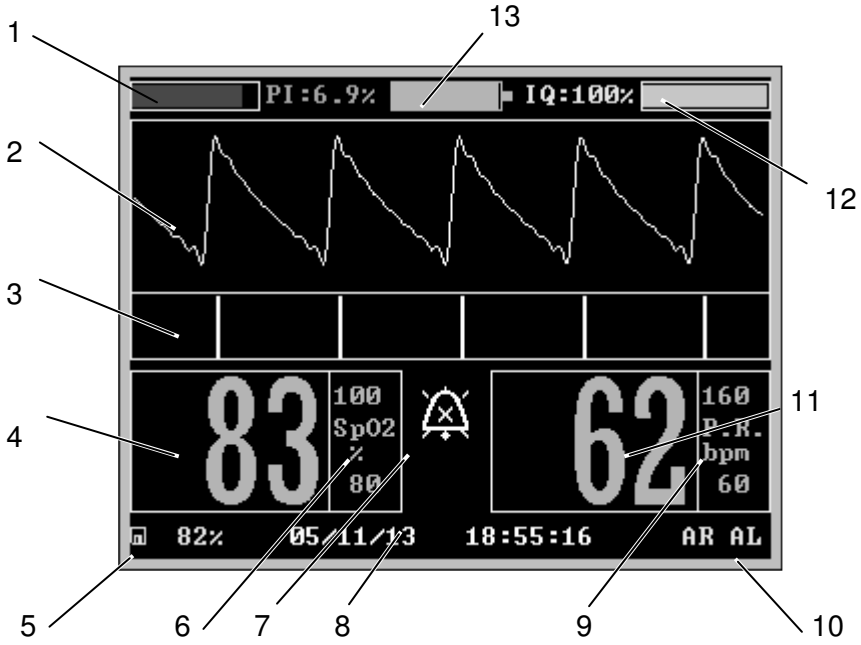


Fig. 2: Upper panel of unit

4.3 LCD display



1 Perfusion index,, graphical and numerical representation
2 Plethysmogram,
displays the actual and normalized pulse curve in standard display mode
3 Signal IQ – bouncing bar display,
displays graphically the current Signal-IQ-value; the Signal-IQ-value represents the signal inadequacy display
4 Oxygen saturation in %
5 Data storage capacity in %
6 lower and upper oxygen saturation alarm limit
7 Alarm (tone) mute symbol
if the audio alerts are temporarily suppressed (Alarm paused)
if the audio alerts are switched off (Alarm off).
8 Status line:
Alarm messages, clock and other information parameters are displayed dependent on the menu selection
9 lower and upper pulse rate alarm limit
10 AL symbol, displayed with activated **AL**arm filter and AR symbol for **AR**tifact filter
11 Pulse rate in beats per minute (1/min)
12 Signal IQ – bar graph display with numerical reading
13 battery capacity

What is signal IQ™?

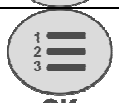
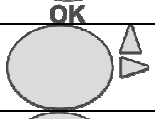
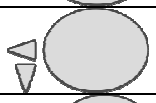
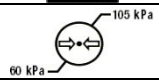
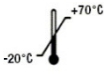
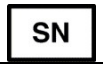
Signal-IQ™ is a measurement for Signal-Identification and Signal-Quality. Masimo developed this indicator to give the user information when a measurement is questionable. Signal-IQ™ is a visual reliability indicator for the oxygen saturation and pulse frequency measurements.

The more difficult it is to detect an arterial pulse signal the lower the presented IQ-bar. 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 Unit

Symbol	Bedeutung
	Consult instructions for use!
	On / Off button
	Menu / OK button
	Navigation button right / up
	Navigation button left / down
	Alarm tone mute
IP 22	Ingress Protection Rating
	Manufacturer
	Ambient pressure range storage condition
	Humidity storage range condition
	Temperature range storage condition
	Model number
	Serial number
	Defi-proof applied part type BF

4.5 USB-Interface

 **ATTENTION!**

To connect to the interface use only original manufactured parts. Otherwise the unit could be damaged.

For service operations, the unit has a built-in mini-USB-Interface (1).

NOTICE!

It is not possible to connect the patient connector and the USB cable at the same time.

NOTICE!

The necessary Interface software is available from the medical devise supplier or directly from Bitmos GmbH.

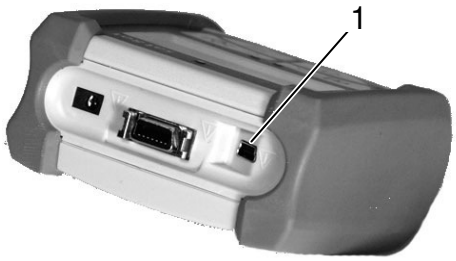


Fig. 3: USB-Interface

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 Packaging

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

 **WARNING! Risk of Suffocation!**

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

 **ATTENTION!**

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

5.3 Storage

Only store the unit under the following conditions:

- For longer periods of storage charge the battery (at least once per 6 month).
- 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 Use

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.

Before using the unit on a patient for the first time, it must be turned on and tested.

6.3 Energy supply

6.3.1 Mains connection

Electricity for the unit can be provided by the accompanying power pack plug or with batteries for mobile use.
If during use the unit is disconnected from the electrical supply, the network failure alarm activates.

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 an way that the unit can be easily disconnected from the power supply.

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

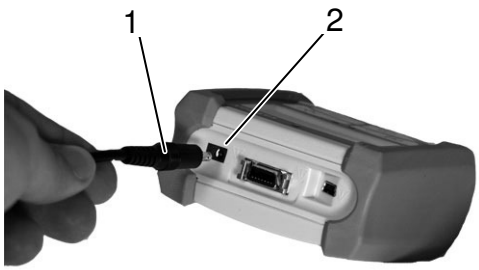


Fig. 4: Plug adapter cable into socket

The Network-LED (1) displays.

NOTICE!

The Network-LED only signals that the unit is supplied with electricity. The LED does not show the unit's operating condition (ON/OFF).

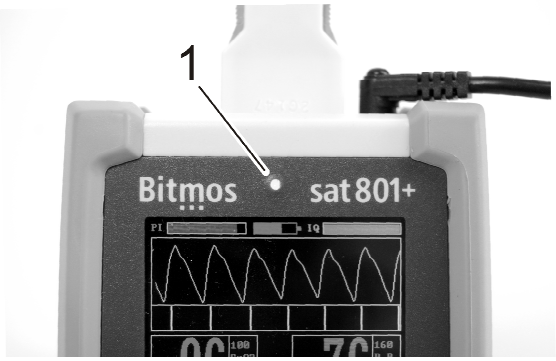


Fig. 5: Network-LED

6.3.2 Battery operation

The power supply for monitoring can be done also without the external 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 22 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.

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.

1. For charging, connect the mains adapter plug to the unit connector.
2. Plug the other end of the cable into an electric outlet.

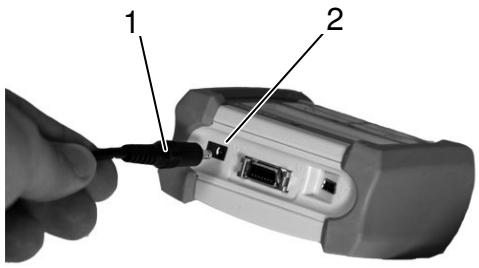


Fig. 6: DC power adapter

3 The green power LED (1) displays.

NOTICE!

The green power LED only signals that the unit is supplied with electricity. The LED does not show the unit's operating condition (ON/OFF).

4. For charging the unit, remain the unit plugged-in for 8 hours with the unit switched off and for 9 hours when switched on.

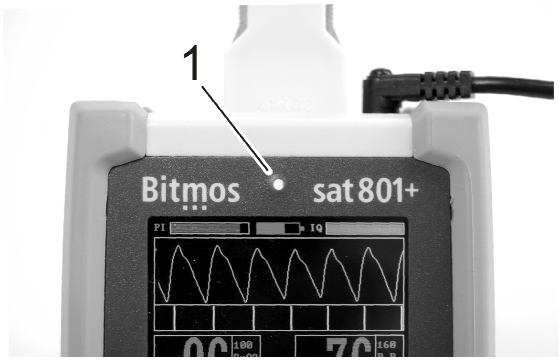


Fig. 7: Power LED

NOTICE!

When switched on, the battery capacity is displayed in the display.

6.3.3 Changing the energy supply

The unit can be supplied either by the mains network (with the power plug adapter) or by the internal rechargeable batteries.

6.3.3.1 Changing from mains to battery supply

1. Unplug the power supply from the mains network.
2. Unplug the power connector (1) from the unit (2).

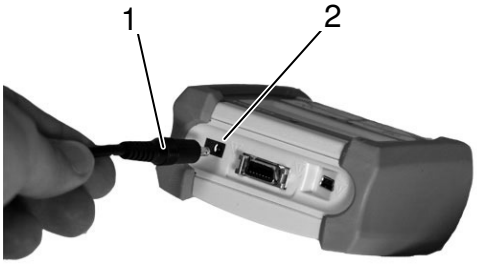


Fig. 8: DC power plug

3. The power LED (1) goes dark.

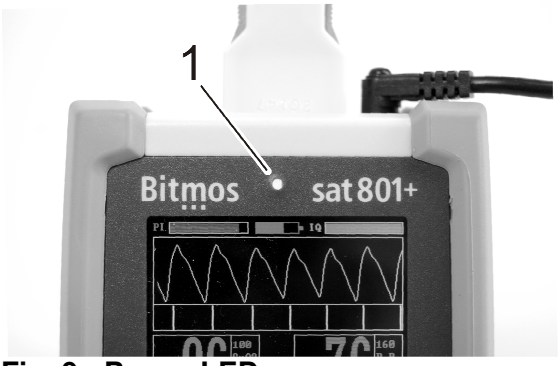


Fig. 9: Power LED

4. In case the device is switched on, for 30 seconds a mains failure alarm is triggered.
   The yellow alarm LED is triggered and the status line shows the message

   `Mains power failure`

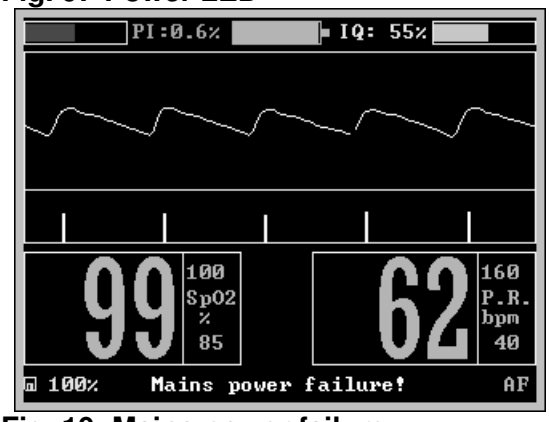


Fig. 10: Mains power failure

5. After 30 seconds the alarm will be reset and the display returns to standard mode display.
6. Now, the unit is supplied by the internal batteries.

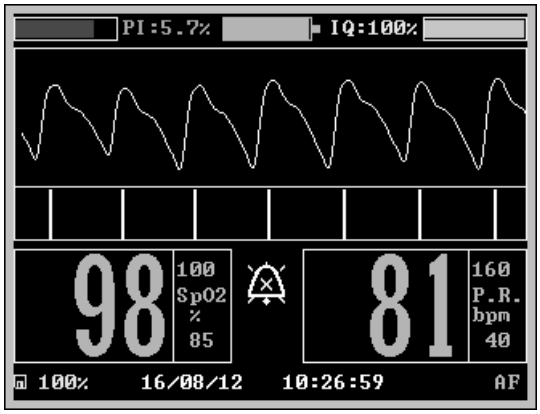


Fig. 11: Standard display mode

6.3.3.2 Changing from battery to mains supply

The device is in battery operation.

1. Connect the DC power plug to the unit connector.
2. Plug the other end of the cable into a mains electric outlet.

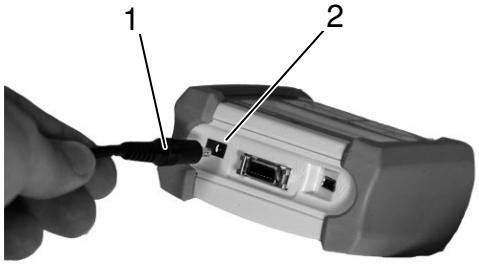


Fig. 12: DC power plug

3. The power LED (1) goes on.
4. The unit is now supplied by mains.

NOTICE!

The green power LED only signals that the unit is supplied with electricity. The LED does not show the unit's operating condition (ON/OFF).

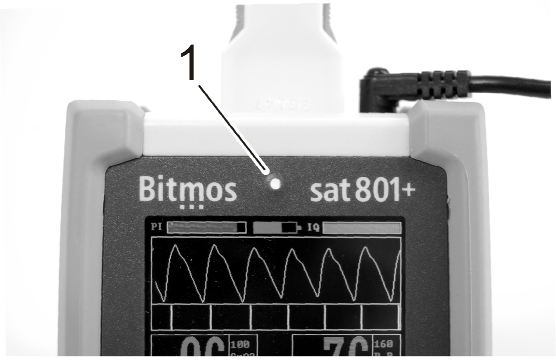


Fig. 13: Mains power LED

6.4 Connections

6.4.1 Connecting the patient cable

1. Connect the patient cable connector (1) into the unit socket (2).
   The plug only fits in one direction and audibly snaps in.
2. Select the required Masimo-Sensor.

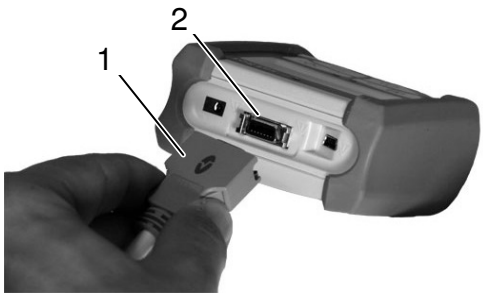


Fig. 14: Connect patient cable

3. Insert the sensor connector into the patient cable connector.

   The plug only fits in one direction and can be felt snapping in.

NOTICE!

Some Masimo sensors (e.g. type LNOP DCSC) come with an integrated patient cable. In this case connection to a separate patient cable is not necessary.

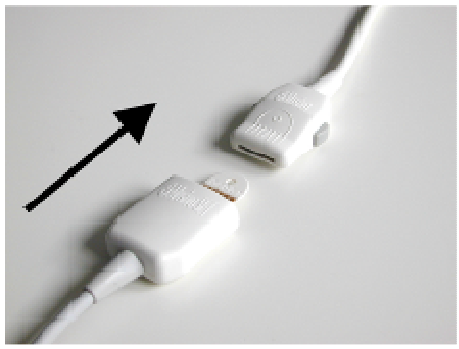


Fig. 15: LNOP sensor connection

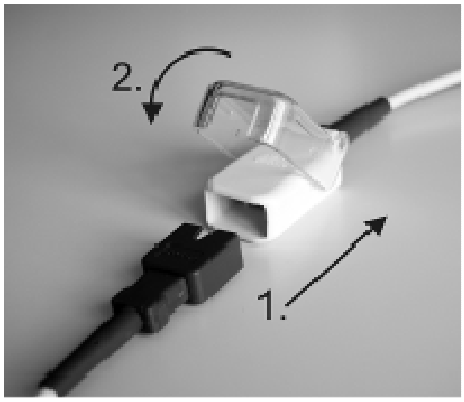


Fig. 16: LNCS sensor connection

6.4.2 Disconnecting the sensor from the patient cable

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).

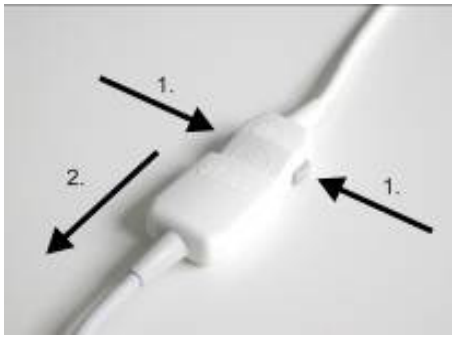


Fig. 17: LNOP sensor coupling

LNCS sensors

1. Lift the protective cover (1).

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

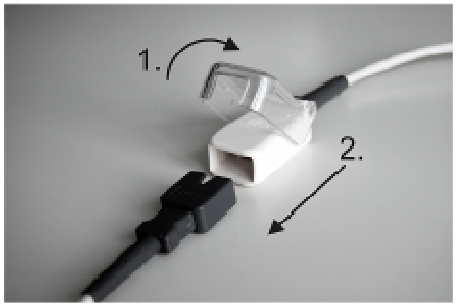


Fig. 18: LNCS sensor coupling

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.

ATTENTION!

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

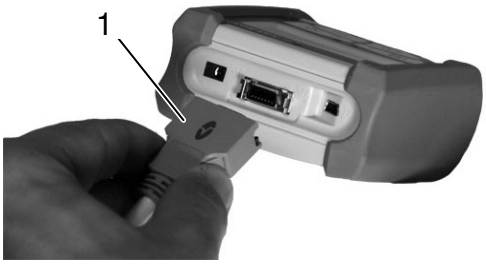


Fig. 19: Patient plug coupling

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's vicinity.

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

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

WARNING! Danger from not observing user instructions!

Pay 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. This 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 the manufacturer.

Disposable sensors

Product code	Sensor Type	Patient Type and Weight
16-1001	LNOP® Adt	Adults > 30 kg
16-1025	LNOP® Pdt	Children and Adults > 10 kg and < 50 kg
16-1002	LNOP® Neo	Newborns < 10 kg
16-1003	LNOP® Neo Pt	Newborns < 1 kg, sensitive skin
16-1798	LNOP® Neo-L	Newborns < 10 kg
16-1800	LNOP® Inf-L	Small Children > 3 kg, < 10 kg
16-1651	LNOP® NeoPt-L	Newborns < 1 kg, sensitive skin
16-1611	LNOP® Neo-Bridge	Newborns < 10 kg
16-1859	LNCS® Adtx	Adults > 30 kg
16-1860	LNCS® Pdtx	Children and Adults > 10 kg and < 50 kg
16-2328	LNCS® Inf-L	Small Children > 3 kg < 20 kg
16-2329	LNCS® Neo	Newborn, children, adults < 3 kg or > 40 kg
16-2330	LNCS® NeoPt	Neonatal Preterms < 1 kg

WARNING! Allergy Risk!

The use of Masimo LNOP® or LNCS® 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.

Reusable sensors

Product code	Sensor Type	Patient Type and Weight
16-1269	LNOP® DCI	Adults > 30 kg
16-1276	LNOP® DCIP	Children > 10 kg and < 50 kg
16-1396	LNOP® DCSC	Adults > 30 kg, Spot Check-Applications
16-1560	LNOP® DC-195	Adults > 30 kg
16-1544	LNOP® YI	Children and Adults > 1 kg
16-1794	LNOP® TC-I	Adults and Children > 30 kg, ear sensor
16-1793	LNOP® TF-I	Forehead sensor, transflective
16-1863	LNCS® DCI	Adults > 30 kg
16-1864	LNCS® DCIP	Children > 10 kg and < 50 kg
16-2258	LNCS® YI	Children and Adults, multisite > 1 kg
16-1895	LNCS® TC-I	Adults and Children > 30 kg, ear sensor
16-1896	LNCS® TF-I	Forehead sensor, transflective, adults > 30 kg

WARNING! Danger with long-term application!
The use of reusable Masimo LNOP®- and LNCS®-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.

7 Operation

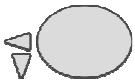
7.1 General

Control of the unit takes place on the display in combination with the control buttons.
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 menu buttons



In the menu: down or left
or
decrease settings

In the menu: up or right
or
increase settings

Confirm actions or selections

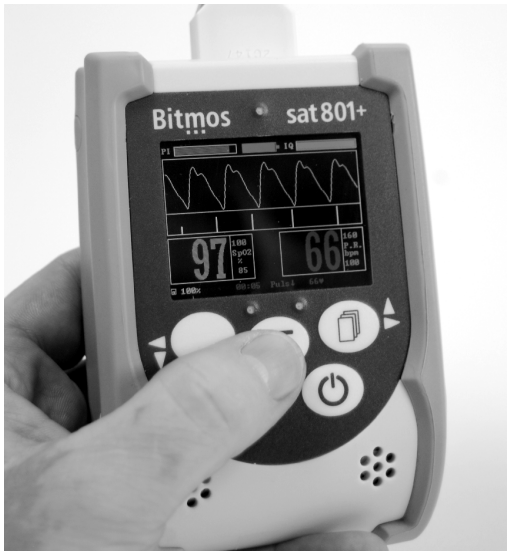


Fig. 20: Operation

Notice!

If you do not confirm or accept a menu setting within 60 seconds, the standard screen is automatically displayed.

7.2.2 Calling the main menu

1 Press the menu button 

.

2 The main menu is displayed.

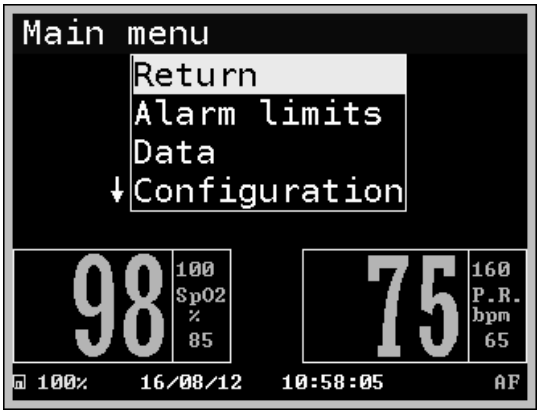


Fig. 21: Main menu

7.2.3 Menu structure

The menu structure is as follows:

Level 1	Level 2	Level 3	Remark
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		
Configuration	**Acoust. Alarms**	**Volume pulse** **Volume alarm** **Mute duration**	Configuration of the acoustical alarms
	Signal process	**Algorithm mode** **Averaging time** **Smart Tone** **Artifact filter**	Setting of pulse oximetry parameters
	Screen	**Backlight** **Mode** **Language**	Adjustment of the screen options and Access permissions
	Clock		Setting the time and date
Product Info			Information about the unit

7.3 Switching On

1. Press On/Off button .
2. An optical, audio, and internal self test is completed:
   – The LEDs are activated.
   – An alarm sound is issued.
   – The unit goes through extensive internal hardware testing.

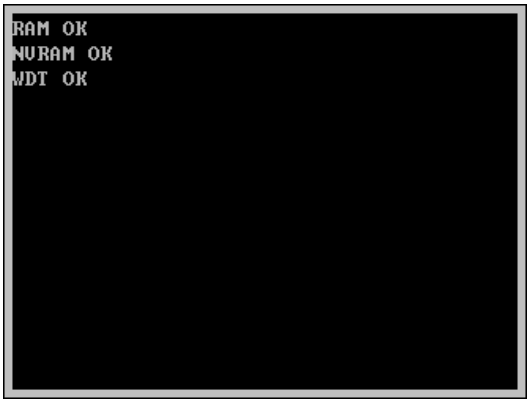


Fig. 22: Power-up screen

ATTENTION! TOO SILENT ALARMS!

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.

Fig. 23: Too silent alarms warning

ATTENTION! No alarms in SLEEP LAB MODE!

With activated SLEEP LAB MODE, there are no acoustical alarms on the unit.

If activated, the operator has to confirm this setting with OK.

Otherwise, the device will not enter the standard mode.

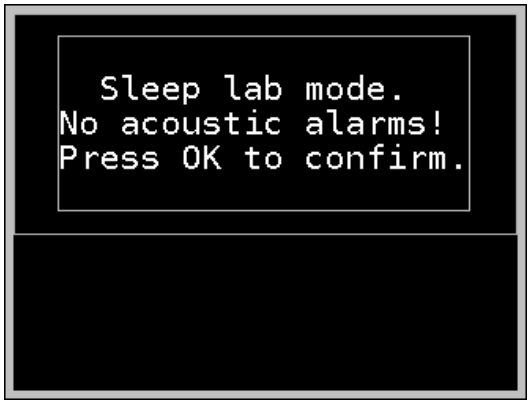


Fig. 24: Sleep lab mode

ATTENTION! Unsuccessful tests!

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

The unit can and may not be used on patients.

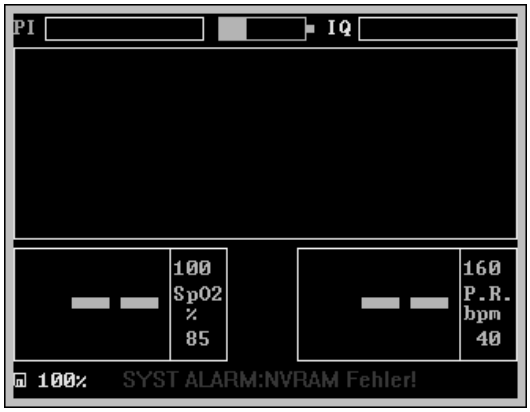


Fig. 25: Power-up error message

ATTENTION! Defective alarm loudspeaker!

The sat801+ system is equipped with a redundant alarm loud speaker system. With one defective alarm loudspeaker, the other loudspeaker is still able to alarm, but not with the standard volume.

The unit may then not be used on the patient!

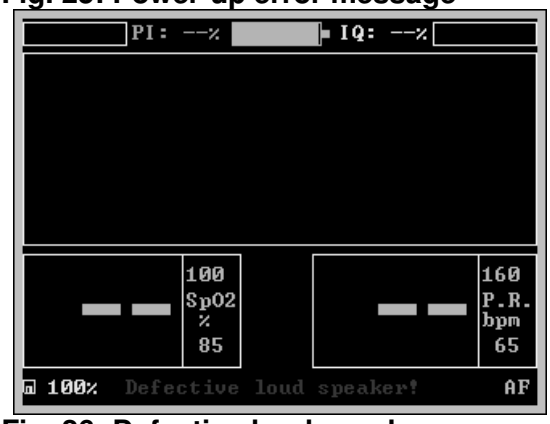


Fig. 26: Defective loud speaker.

3. After this the Normal Display appears.

   With an applied sensor, now the signal search for the pulse occurs (message "Pulse search" in the status line). With a successful pulse search the measured values for oxygen saturation and pulse frequency are displayed on the screen.

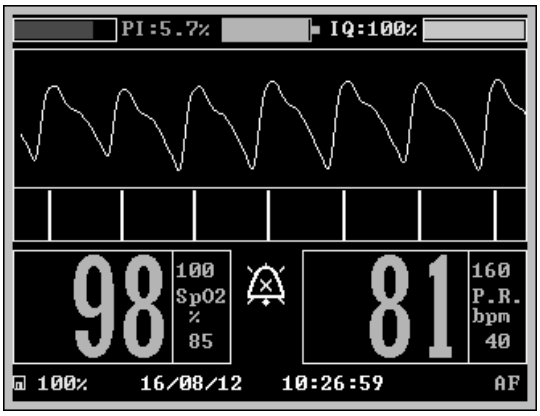


Fig. 27: Normal display

4. The unit is now 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 alarm volume = 00 and Perfusion Sensitivity (Algorithm mode). The alarm volume will be set to a

minimal non-zero value = 01. For Perfusion Sensitivity, the manufacturer's default setting will be set.

To turn the unit OFF:

1. Press the On-/Off button for approx. 2 seconds.
2. The display shows the turn-off confirmation message.
3. Press the On-/Off button again.

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.

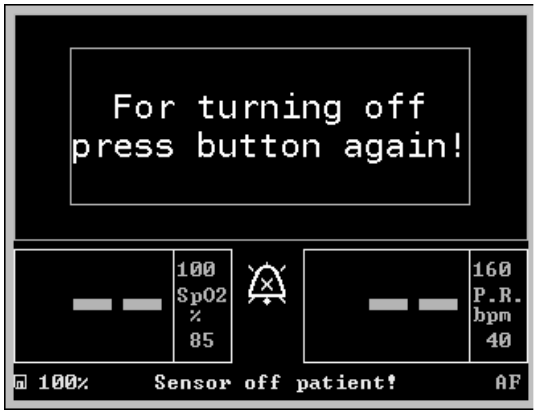


Fig. 28: Power-down screen

7.5 Alarm limits (`Alarm limits`)

CAUTION!

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.

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“ to the Accept request.
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.

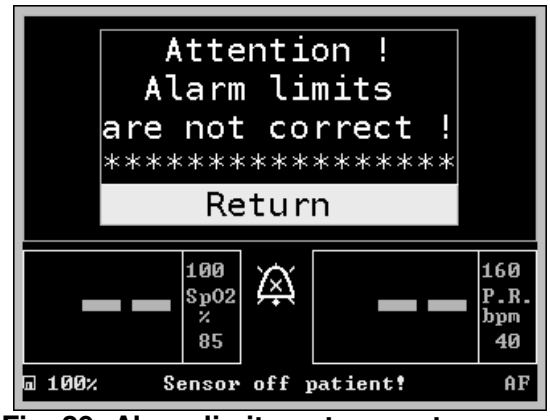


Fig. 29: Alarm limits not correct

7.5.1 Setting the alarm limits

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

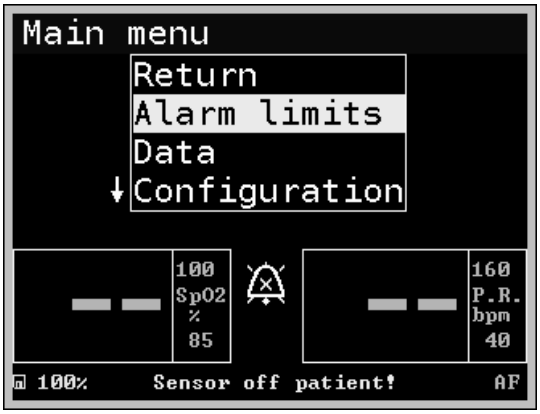


Fig. 30: Alarm limits

2. Select **SpO2 hi** , for setting the upper SpO2 alarm limits,
   or
   select **SpO2 lo** for setting the lower SpO2 alarm limit
   Select **PR hi**, for setting the upper pulse rate alarm limit,
   or
   select **PR lo** for setting the lower pulse rate alarm limit.
3. Select the alarm limits to be changed

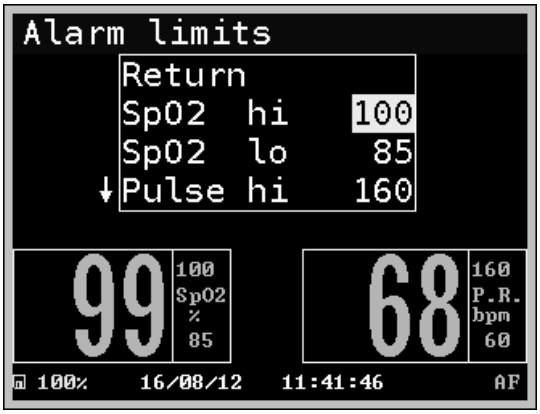


Fig. 31: Modifying the alarm limits

4. Set the new value.

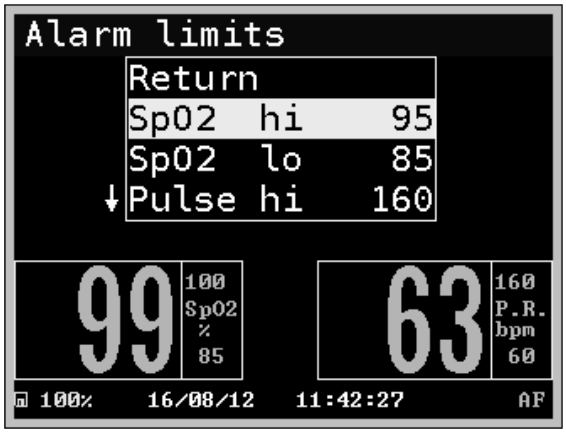


Fig. 32: Confirming the alarm limits

5. Confirm the new value.

6. Confirm the new setting by confirming the safety question **Accept? Y/N**.

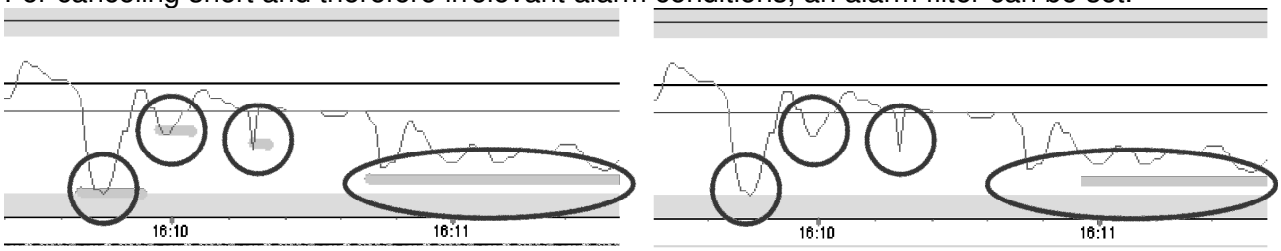
Fig. 33: Confirming the alarm limits

7.5.2 Setting the Alarm Filter

CAUTION!

Activating or changing the alarm filter settings is a serious intervention in the device functions and must never be done without first 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 occurrence 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 SpO2 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 SpO2 alarm limit,
   or
   select **`Al.F.Pulse`**↑ for setting the upper pulse rate limit

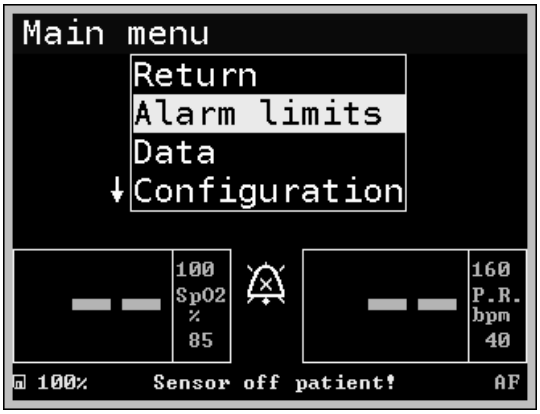


Fig. 34: Alarm limits

3. Select the alarm filter to be changed and confirm it.
4. Set the new period (in seconds) value and confirm it.

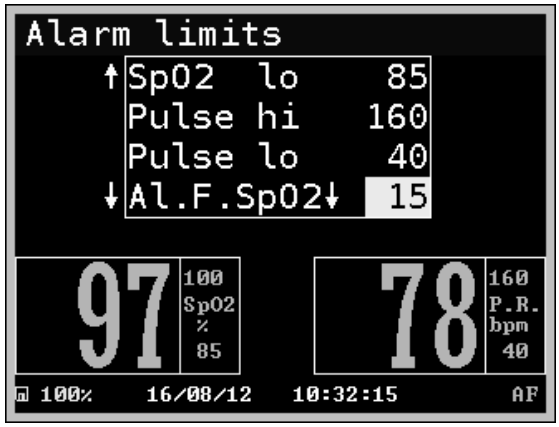


Fig. 35: Modifying the alarm filter

5. Set other values if needed.
6. Leave the menu with **`Return`**.
7. 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 “AF” in the lower right area of the display.

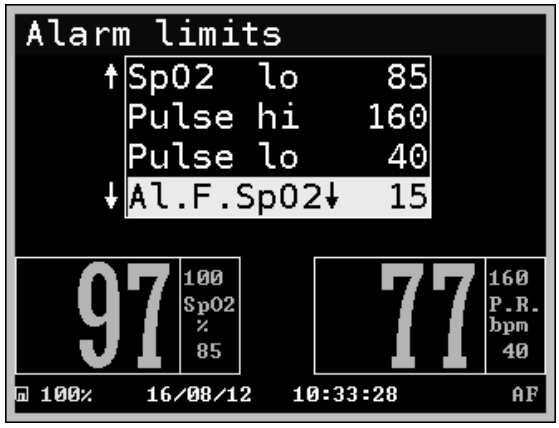


Fig. 36: Confirming the settings

7.6 Configuration (`Configuration`)

7.6.1 Screen options (`Screen`)

1. Starting from the main menu, call:
   → **`Configuration`** → **`Screen`**
2. Select
   `Backlight`, **`Mode`** or **`Language`**
3. Confirm the selection.

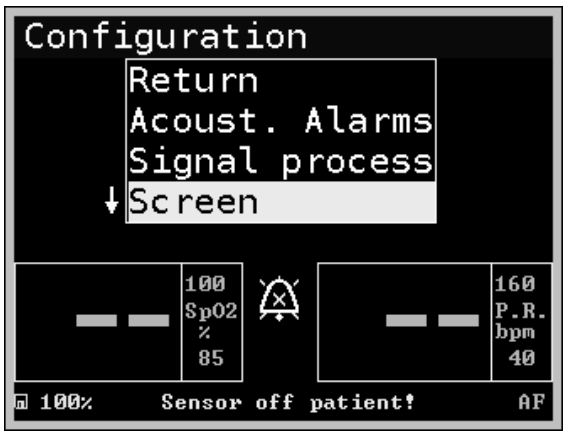


Fig. 37: Screen selection

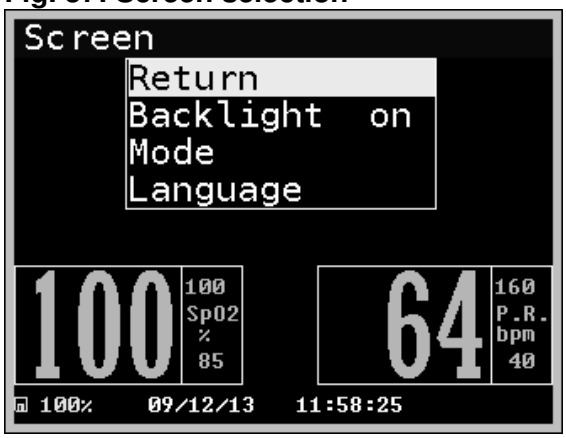


Fig. 38: Screen submenus

7.6.1.1 Backlight (`Backlight`)

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

– The ON setting switches the background lighting permanently to maximum brightness
– The AUTO setting dims the background lighting to a default minimum value. When high priority alarms are triggered, the background lighting is automatically switched to automatic. When the alarm condition goes off, the background lighting is similarly automatically dimmed to the minimum.

NOTICE!

The AUTO setting is a good idea in darkened rooms.

1. Starting from the main menu, call:
   → **Configuration** → **Screen** → **Backlight**
2. The setting options ON or AUTO can be selected with the navigation keys.

NOTICE!

The changes made will be shown in the settings.

3. Confirm the selection.

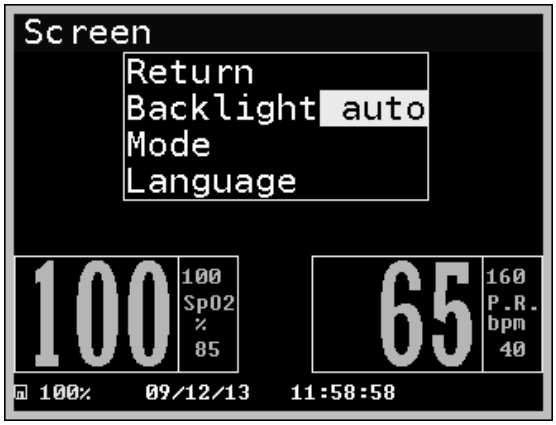


Fig. 39: Backlight

7.6.1.2 Menu language (Language)

This function sets the menu language.

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

NOTICE!

The changes made will be effective with immediate effect.

3. Confirm the selection.

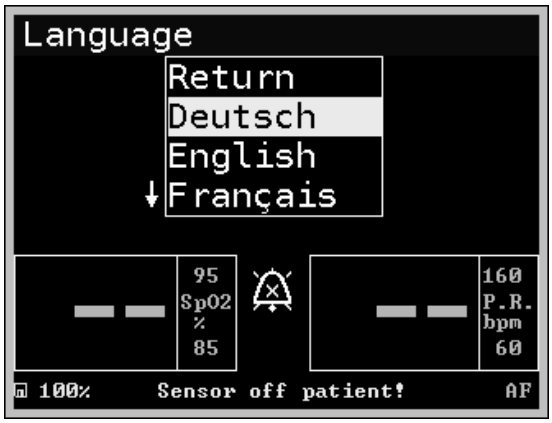


Fig. 40: Language

7.6.1.3 Access permissions (Mode)

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

Following access permissions may be either set:

– Home Care Mode (**Home Mode**)
– Clinic Mode (**Clinic Mode**)
– Sleep Lab Mode (**Sleep Lab Mode**)

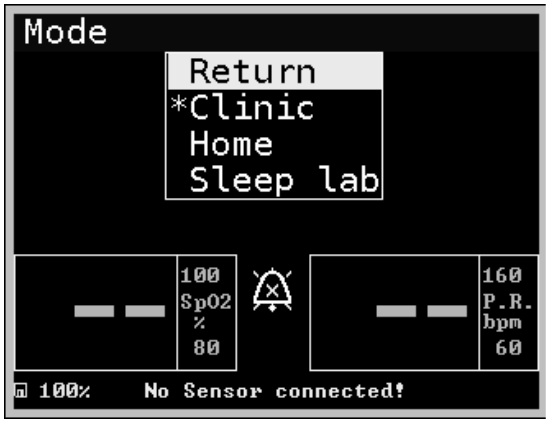


Fig. 41: Access permissions

- The “HomeCare mode” access protects the inexperienced user from modifying important monitoring parameters. These parameters are invisible.
- The “Clinic mode” access allows users to set all the configuration parameters.
- The “Sleep Lab mode” will turn off all alarms during monitoring. This is useful for overnight sleep studies.

 **CAUTION! Alarms cannot be detected!**

If in Sleep lab mode an alarm condition occurs, the operator will not be alerted by acoustical means.

Access permissions	HomeCare on	HomeCare off
Alarm limits	-	+
Alarm filter	-	+
Vital alarm list	+	+
Total alarm list	+	+
Trend	+	+
Pulse tone volume	+	+
Alarm tone volume	+/- (Off is not available)	+
Alarm tone suppression time	-	+
Erase data	-	+
Overwrite data	-	+
Masimo averaging time	-	+
Masimo perfusion sensitivity	-	+
SmartTone	-	+
Artifact filter	-	+
Backlight	+	+
Language	+	+
Access permission	+	+
Date and time	-	+
Product info	+	+

- = not allowed
+ = allowed

Setting the access permission:

1. Starting from the main menu, call:
   → **Configuration** → **Screen** → **Mode**
2. Select **Home, Clinic or Sleep lab** and confirm.
3. Enter the four-digit pin code for the respective access permission:

NOTICE!

The pin code is located in a separate document.
Call the manufacturer.

4. Select the first digit.
5. Set the correct number.
6. Repeat steps 3 and 4 until the complete code is entered.
7. Confirm the code by selecting **Accept**.

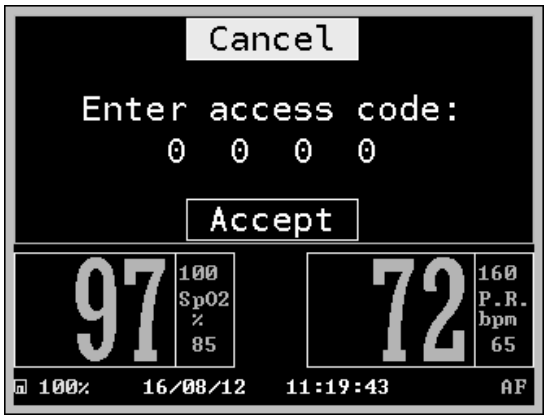


Fig. 42: PIN code entry

NOTICE!

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

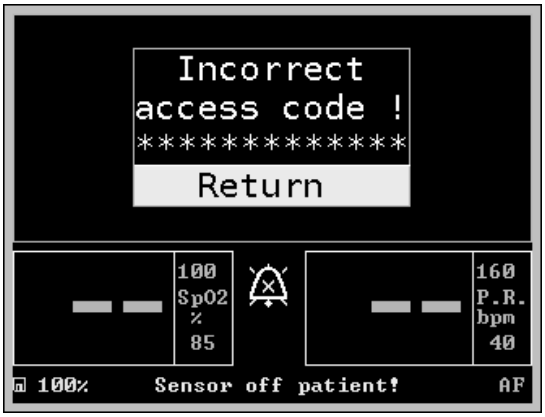


Fig. 43: Invalid access code

7.6.2 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**)

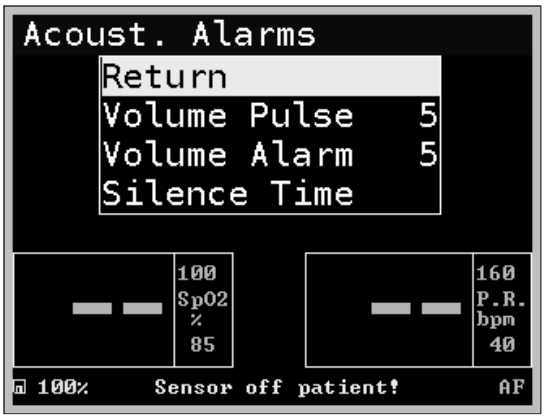


Fig. 44: Acoustical alarm

7.6.2.1 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 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 from **OFF** und loud (**10**).

NOTICE!

Every incremental change emits the actual volume strength once.

3. Confirm this setting.

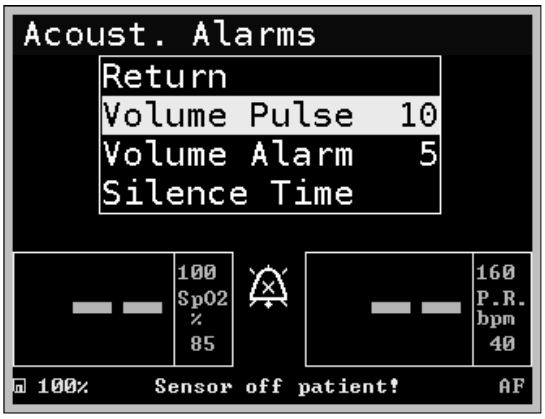


Fig. 45: Pulse tone volume

NOTICE!

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

7.6.2.2 Alarm tone volume (`Volume Alarm`)

1. Starting from the main menu, call: → **`Configuration`** → **`Acoust. Alarm`** → **`Volume Alarm`**
2. Adjust the alarm tone volume from **`OFF`** und loud (**`10`**).

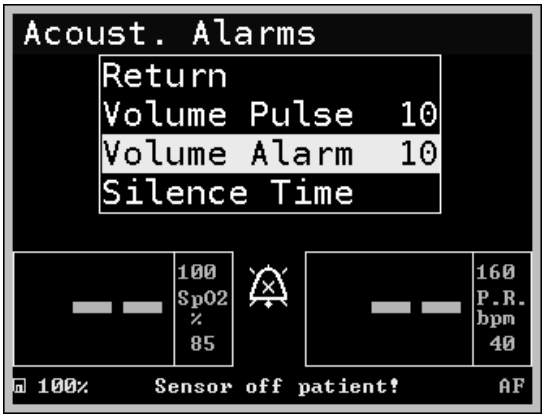


Fig. 46: Alarm tone volume

NOTICE!

Every incremental change emits the actual volume strength once.

3. Confirm this setting.

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!

In home care mode, audio mute setting (=OFF) is not possible.

7.6.2.3 Alarm mute 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**.
3. Confirm this setting with **RETURN**.

NOTICE!
During the alarm silence time, the display shows the alarm silence symbol: .

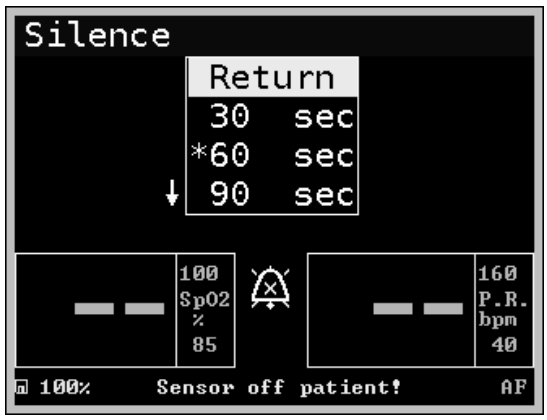


Fig. 47: Alarm tone silence time

CAUTION! 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.

7.6.3 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**)

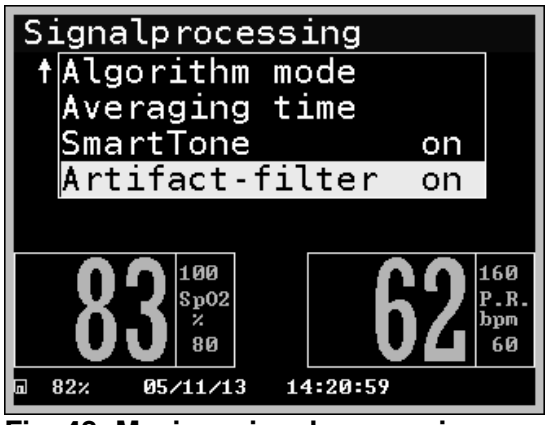


Fig. 48: Masimo signal processing

7.6.3.1 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.

CAUTION! 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 between **`2-4`** and **`16 sec`**.
3. Confirm this setting with **`RETURN`**.

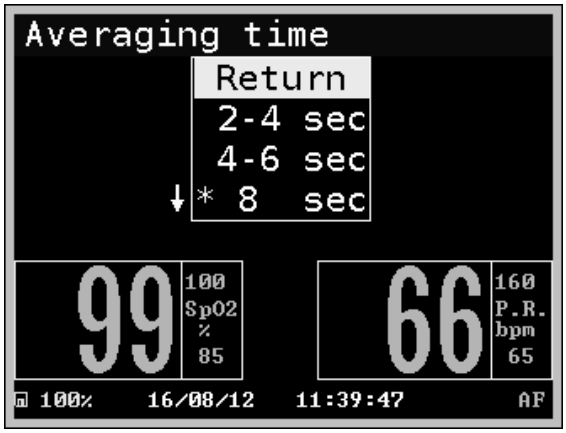


Fig. 49: Averaging time

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.

7.6.3.2 Perfusion Sensitivity (`Algorithm mode`)

The perfusion sensitivity can be set between Normal **`(Norm. perfus.)`**, 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 sat801+ 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**).
3. Confirm this setting with **RETURN**.

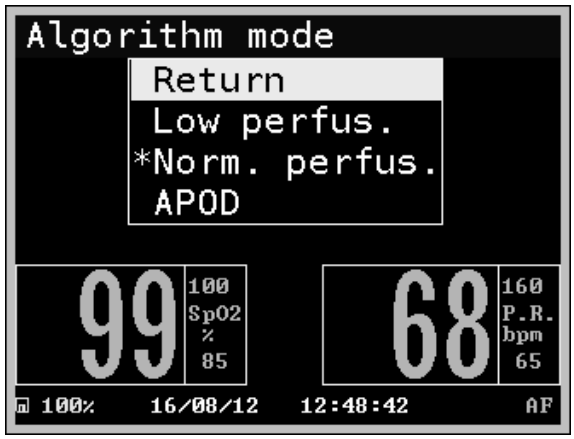


Fig. 50: Perfusion Sensitivity

7.6.3.3 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.

1. Starting from the main menu, call: → **Configuration** → **Signal process.** → **Smart Tone**
2. Select the setting (**on/off**).
3. Confirm this setting with **RETURN**.

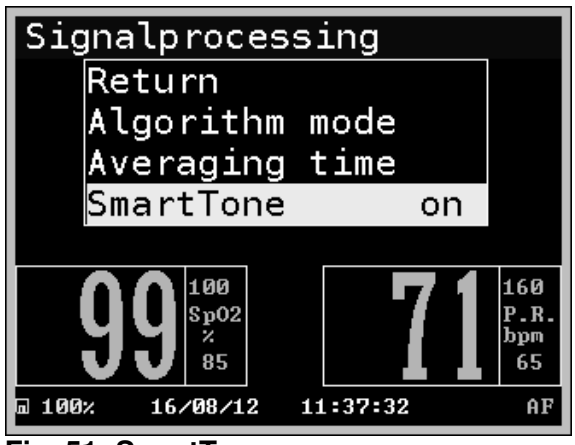


Fig. 51: SmartTone

7.6.3.4 Artifact filter (Artifact-filter)

The Artifact filter rejects sensor-related alarm messages that are shorter than 5 seconds. A sensor alarm must be at least for 5 seconds of the same type to be processed.

1. Starting from the main menu, call: → **Configuration** → **Signal process.** → **Artifact-filter**
2. Select the setting (**on/off**).
3. Confirm this setting with **RETURN**.

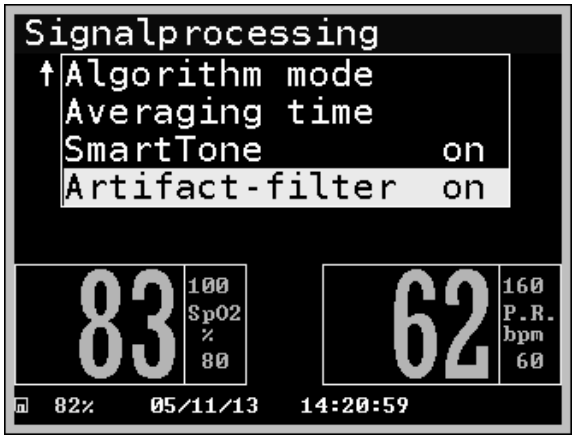


Fig. 52: Artifact filter

7.6.4 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.
3. Adjust the number.
4. Repeat this sequence for each number to be modified.
5. Confirm this setting with **`ACCEPT`**.

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 accept the time and date.

If you try to accept an invalid date (e.g. 30.02.13), the device responds with the following message: "**`Date is not correct`** ". In that case no new date or time is set.

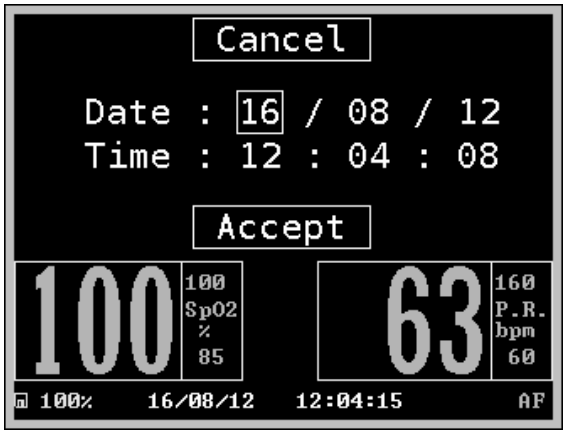


Fig. 53: Setting the system time

7.6.5 Device information (`Product Info`)

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

– device S/N and software version
– the version of the Masimo circuit board and its product identification
– the DSP and microcontroller-versions
– the perfusion sensitivity setting
– the signal averaging time setting

NOTICE!

The displayed information is read-only.

8 Alarms

8.1 In General

As a monitoring system the unit has been equipped audio and optical signals for a multiple number of alarm situations. Alarms are activated:

- When deviations from pre-set value limits occur
- In problem situations during technical monitoring
- Internal unit malfunctions

WARNING! Danger with incorrectly entered alarm limits!

Before each use test the unit on a patient to see if the configured alarm limits are patient appropriate.

If the accuracy of the displayed values is questioned, check the patient's vital parameters first using a different method. Then check the functionality of the unit.

Inaccurate measurements can be caused by:

- Incorrect sensor connection or incorrectly selected Masimo-sensor
- A significant inclusion 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 pulse
- Connection of the sensors is to a body part already connected to a blood pressure cup, an arterial catheter, or an intravenous line.

Loss of pulse signal can occur under the following conditions:

- The sensor is attached too tightly.
- There is excessive illumination from light sources such as operation or bilirubin lamps or sunlight.
- An inflated blood pressure cuff is attached on the same extremity as the sensor.
- The patient suffers from low blood pressure, serious vascular constriction and/or anemia or hypothermia.
- There is an arterial occlusion proximal to the sensor.
- The patient suffered from shock or heart failure.
- The fingernail is polished.

8.2 Alarm filter

CAUTION!

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

For canceling short and therefore irrelevant alarm conditions, an alarm filter can be set.
The alarm filter produces a “silent alarm”. During the set alarm filter time period (adjustable between 0=OFF and 20 seconds maximum), the occurrence 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 SpO2 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)

8.3 Alarm categories

There are four alarm categories:

- **High-priority alarms**
  require immediate user intervention in order to avoid possible damage to the patient.
- **Mid-level priority alarms**
  show a technical problem and require immediate user intervention.
- **Low-level alarms**
  require heightened attention from the user.

8.3.1 High Priority Alarms

WARNING! Wrong alarm limits!

Check the alarm limits each time the device is used to ensure they are appropriate for the patient being monitored.

High priority alarms require immediate user intervention in order to avoid possible damage to the patient.

With high priority alarm

– high priority alarm sound is heard,
– the red alarm indicator blinks (1) and
– the cause of the alarm blinks in the display (either numerical value or battery symbol).

These signals remain for the duration of the alarm conditions. They only disappear when the alarm conditions no longer exist.

If the alarm tone mute button is pressed during the alarm, the alarm signal remains mute for the duration of the previously entered mute time.

If ‚Sound Alarm OFF' has been selected no alarm is heard. The alarm condition is then only displayed as an optical signal.

Fig. 54: High Priority Alarm Indicator

8.3.1.1 SpO_2 alarm

Status line message	Message in the LC display	Cause
SpO_2↑	flashing SpO2 value	oxygen saturation exceeds the set alarm limit
SpO_2↓	flashing SpO2 value	oxygen saturation falls below the set alarm limit

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

8.3.1.2 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 of the current alarm is displayed on the status line.

8.3.1.3 Sensor alarms

Status line message	Message in the LC display	Cause
`Sensor not connected`	flashing sensor symbol	Sensor or patient cable became unplugged.
`Sensor not on Patient`	flashing sensor symbol	Sensor has fallen off.

Possible Cause	Description	Solution
`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.
`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.

8.3.1.4 System Alarms

WARNING! No Monitoring with System Alarm!

The monitoring function is turned off by a system alarm. For the duration of the system alarm the patient is not correctly monitored. The patient's condition must be assessed 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.

For System Alarm
– the high-level alarm sound is heard,
– the red alarm indicator blinks (1) and
– system alarm message in the status line

Fig. 55: System Alarm Indicator

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 completes 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.
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 sat801+ has 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.
Defective loud speaker!	The sat801+ has detected a defective alarm loudspeaker.

8.3.2 Mid-level Priority Alarm

WARNING! Insufficient monitoring at mid-level priority alarms.
With alarms of mid-level priority a correct signal processing 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.

Mid-level alarms display technical problems and require quick user intervention.

Mid-level priority alarm

- the mid-level alarm sound is heard,
- the yellow alarm indicator blinks (1) and
- alarm message in the status line

Fig. 56: Mid-level Priority Alarm Indicator

Mid-level Priority Sensor Alarms:

Possible Cause	Description	Solution
Sensor defect	The unit has determined the sensor does not work or only with limited capacity.	Exchange the sensor with a new Masimo-Sensor!
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.
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.
No data	The unit has determined the sensor or patient cable does not work properly.	Exchange the sensor or/and patient cable with a new one!

Possible Cause	Description	Solution
Unknown Sensor	The unit has discovered a sensor not approved for this system.	Only connect approved Masimo sensors!
Battery depleted	Remaining operation time of 15 minutes or less	Recharge battery

8.3.3 Low-level Priority Alarms

With a low-level priority alarm
– the audio sound of low-level priority is heard,
– the yellow alarm indicator lights continuously and
– alarm message in the status line

Low-level priority alarms:

Status line message	Description	Solution
`Battery low`	Remaining operation time of one hour or less	Recharge battery
`Mains power failure`	The mains power or the DC power supply is interrupted/defect.	Check the mains power and also the DC power pack.

8.4 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.

8.5 Status message

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

Possible Cause	Description	Solution
`Low perfusion`	The unit has determined insufficient circulation for reliable determination of oxygen saturation values.	Remove the sensor and connect 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.

Status messages are not alarms and there not accompanied by LED activation.
Status messages may be mask with higher ranking alarms.

9 Data

9.1 Alarm lists (`Alarm lists`)

The sat801+ continuously stores monitoring data. SpO2, 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.
On the device you have the option of analysing 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.

9.1.1 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. 89),
   - date and time when the alarm occurred (e.g. 16/08/12, 11:59 h)
   - the duration (e.g. 0 minutes 4 seconds)
   - and the extreme value during the alarm (e.g. 170 1/min)
2. Use navigation buttons to browse through the list. Press  to show a more recent alarm (i.e. higher alarm numbers) and  to show an older alarm (i.e. lower alarm numbers).
3. Leave the list by confirming **`Return`**.

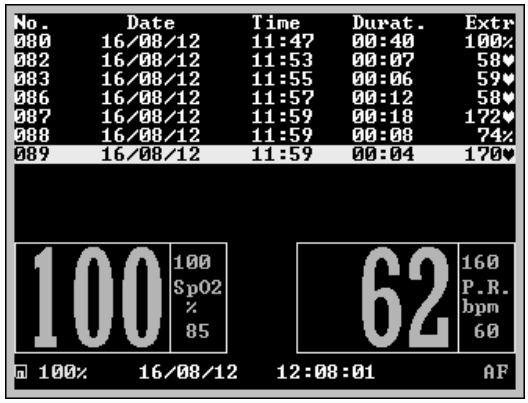


Fig. 57: Vital alarm list

9.1.2 Total alarm list (`Vital 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. 30),
   - date and time when the alarm occurred (e.g. 16/08/12, 10:56h)
   - the duration (e.g. 4 seconds)
   - and the extreme value or type of alarm event (e.g. 64 1/min)
2. Use navigation buttons to browse through the list. Press  to show a more recent alarm (i.e. higher alarm numbers) and  to show an older alarm (i.e. lower alarm numbers).
3. Leave the list by confirming **`Return`**.

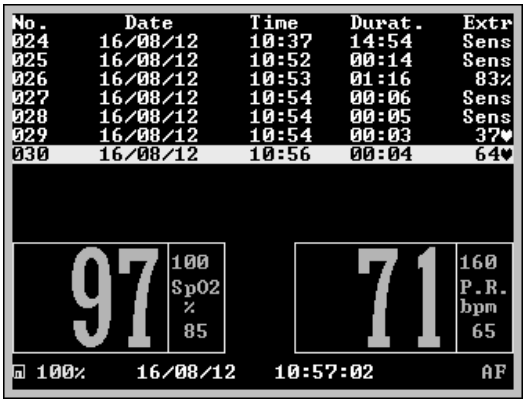


Fig. 58: Total alarm list

9.1.3 Alarm details

1. Call the alarm list.
2. Mark an alarm entry and select it.
   In the window, following information is displayed:
   - start date
   - start time
   - alarm duration
   - type of alarm (here: PR hi)
   - alarm limits
   - extreme value or type of alarm
3. Leave the window by confirming **`Return`**.

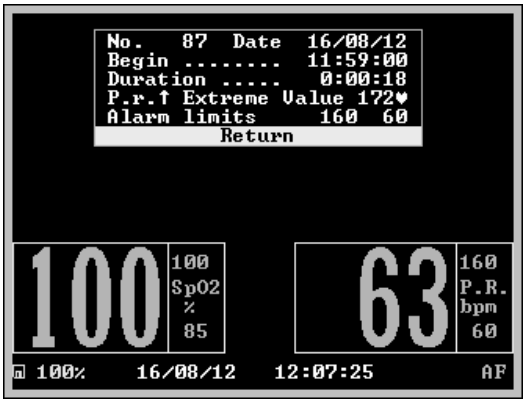


Fig. 59: Alarm details

9.2 Trend display (`Trend`)

The sat801+ stores monitoring data constantly. 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 design of the sat801+ stores 160 hours of continuous monitoring with a maximum of 4,000 alarm list entries.
The sat801+ 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 (24, 16, 12, 8, 4, 2 hours; 60, 20, 8, 4 minutes)

9.2.1 Trend display

1. Starting from the main menu, call:
   → **Data** → **Trend**
2. select the time scale (4 minutes till 24 hours)
3. select the display mode (SpO2, pulse or both)

   The most recent data are displayed in the required format.
4. Press  to move the pointer to later times and  to move to earlier times.

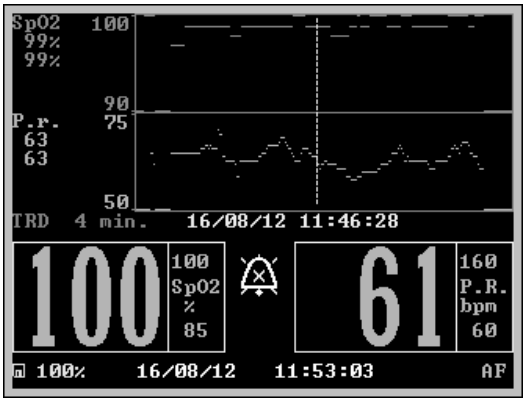


Fig. 60: Trend display

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 (4 minutes till 24 hours)
• Date (here: 16/08/12) and time (here: 11:46:28)

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 ok.

9.3 Exporting the data

9.3.1 SD-Card

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

CAUTION!

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

NOTICE!

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

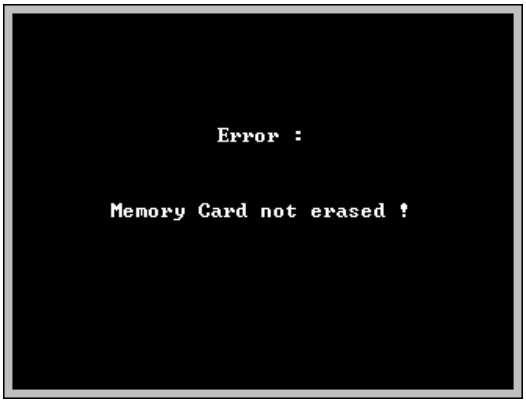


Fig. 61: Card not erased

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

Fig. 62: 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.

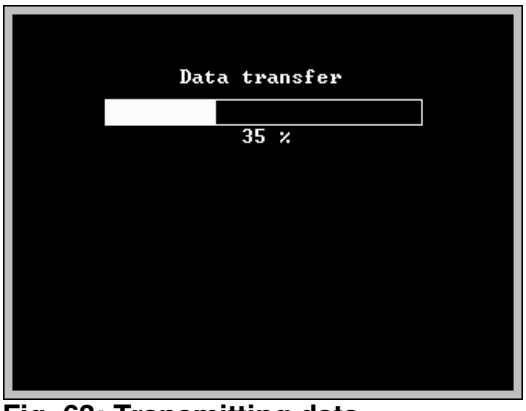


Fig. 63: Transmitting data

When transmission is complete, the message:
"**File … has been saved**!"
"**…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. 64: Removing the 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. Pull the SD card out.

The data on the SD card can then be processed with a graphics and analysis program, e.g. “Bitmos satview”.

9.3.2 USB connection

Data can also be transferred by USB.

1. Switch off the device.
2. Connect the computer to the sat801+ via a mini USB cable.
3. Switch on the device.
   The USB connection is automatically detected and displayed on the screen.

NOTICE!

The sat801+ appears in the Windows Explorer as a flash drive.

For usage of this connection, refer to the corresponding PC programs.

Fig. 65: Communication mode

10 Malfunctions

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.

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. 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.	Connect unit to electricity and charge the battery 10 min at least. Should function not occur even with a networked connection, inform medical device supplier.
When in use buttons do not work.	Internal failure.	Inform medical device supplier.
Error message after self-test run and after unit is turned on.	Internal failure.	Turn the unit ON and OFF. Inform medical device supplier.
Defective loud speaker!	Defective alarm loudspeaker.	Inform medical device supplier.
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.
`Sensor defect!`	The unit has determined the sensor does not work or only in limited capacity.	Exchange the sensor with a Masimo-Sensor!
`No data`	The unit has determined the sensor or patient cable does not work properly.	Exchange the sensor or/and patient cable with a new one!

Malfunctions

Message	Cause	Solution
Low perfusion	The unit has determined insufficient circulation for reliable determination of oxygen saturation values.	Remove the sensor and connect at a different place.
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.
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.
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.
Unknown Sensor	The unit has discovered a sensor not approved for this system.	Only connect approved Masimo-Sensors!
Signal IQ too low!	The signal strength for signal reliability is too low.	Remove the sensor and position at a different place.

11 Cleaning and Maintenance

11.1 Cleaning

11.1.1 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 area of the LCD display 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 sensors 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.

11.1.2 Cleaning of the 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.

NOTE!

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

11.1.3 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 re-use.

11.2 Maintenance

User maintenance is not required.

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 Bitmos GmbH or by a Bitmos 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.

11.2.1 Yearly Maintenance

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

11.2.2 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%.

NOTE!

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

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.

5. Reset the lower alarm limit to 70%.
The new alarm value will be accepted. The alarms stop.
6. 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.
7. 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.
8. 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.
9. Remove patient cable from the unit.
The sensor alarm will sound. The yellow LED blinks and a mid-level alarm priority will sound.
10. 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.

12 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.

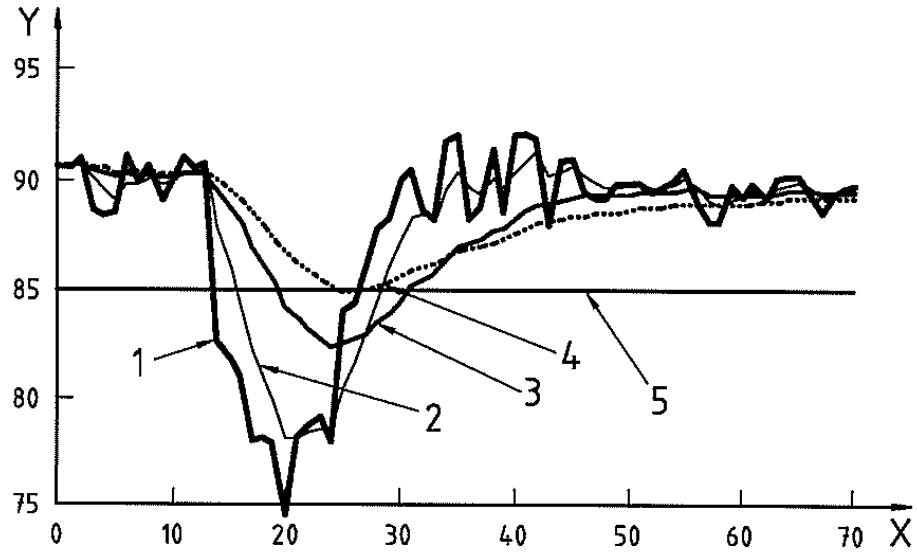
12.1 Accessories

Only use original supply parts from the manufacturer!

Order No.	Item
36-5005.XY	Plug-in power supply, XY = EU Europe XY = UK Great Britain XY = US USA XY = SAA Australia
36-1103	Universal mounting bracket, Plexi glass
36-2302	Carrying case
36-9008	Software satView
36-9002	USB cable
36-9010	Software Download801+
36-9011	Software Service801+
36-9009	micro SD memory card

13 Advanced information

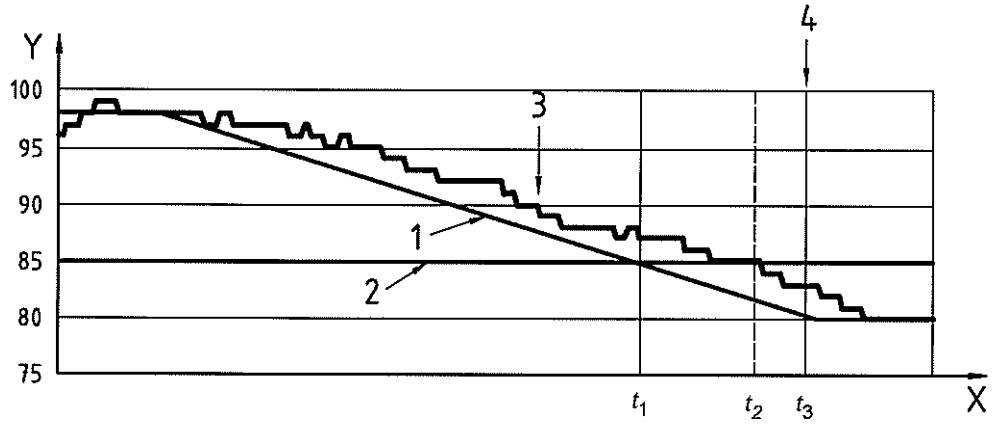
13.1 Averaging time



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.

13.2 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 $t_3 - t_1$.

14 Index

Index