EN Instructions for Use

SOMNO*check* micro
SOMNO*check* micro CARDIO

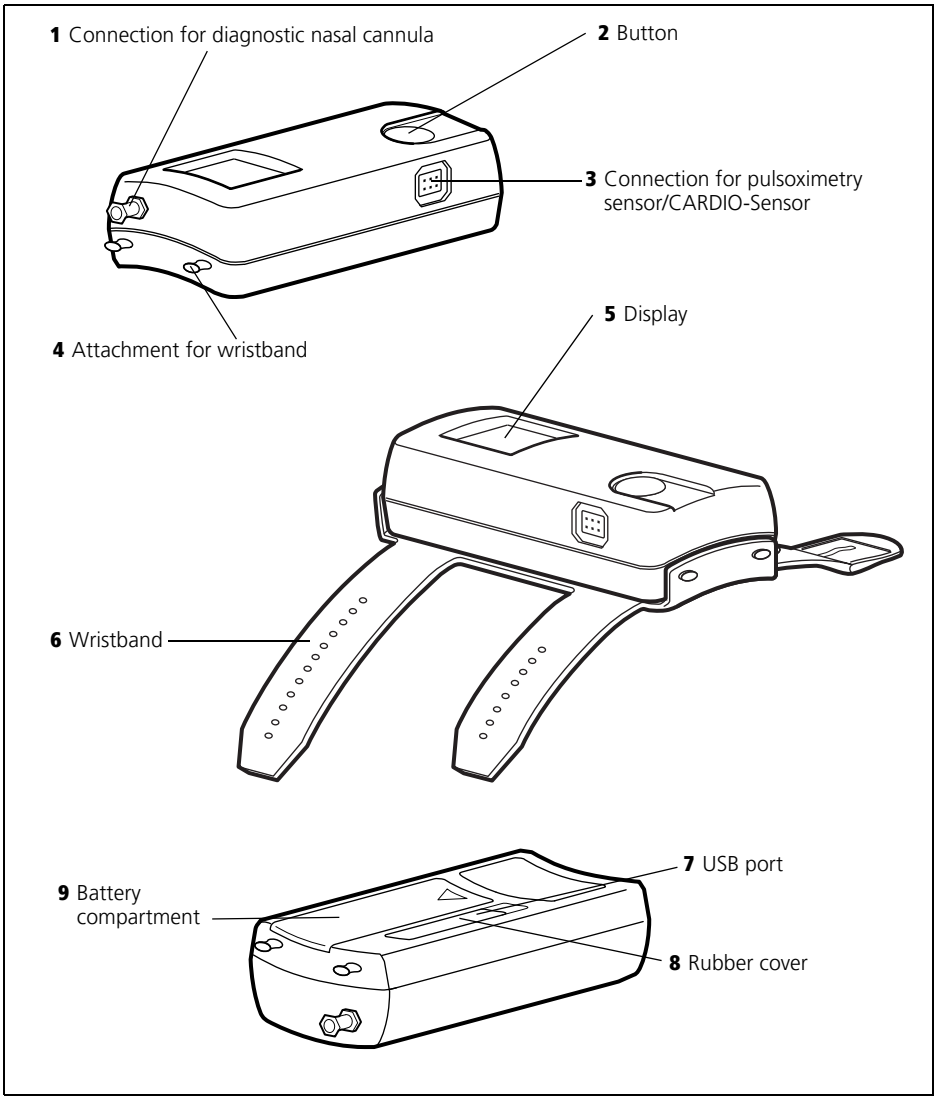
Sleep apnea diagnosis set

LÖWENSTEIN
medical

Contents

1. Overview

1.1 Device



Key

1 Connection for diagnostic nasal cannula

This is where the diagnostic nasal cannula is connected to the device. Using the Luer lock sealing cap supplied, you can seal the connection for the diagnostic nasal cannula during the hygiene treatment.

2 Button

You can use this button to switch on the device, navigate through the menu and start a measurement.

3 Connection for pulsoximetry sensor/ CARDIO-Sensor

This is where the pulsoximetry sensor is connected.

4 Attachment for wristband

You can attach the pulsoximetry sensor or the CARDIO-Sensor here.

5 Display

The display shows you the results of the recording and current measured values.

6 Wristband

You can use the wristband to attach the device to your patient's forearm.

7 USB port

The USB port is for connecting the device to a PC.

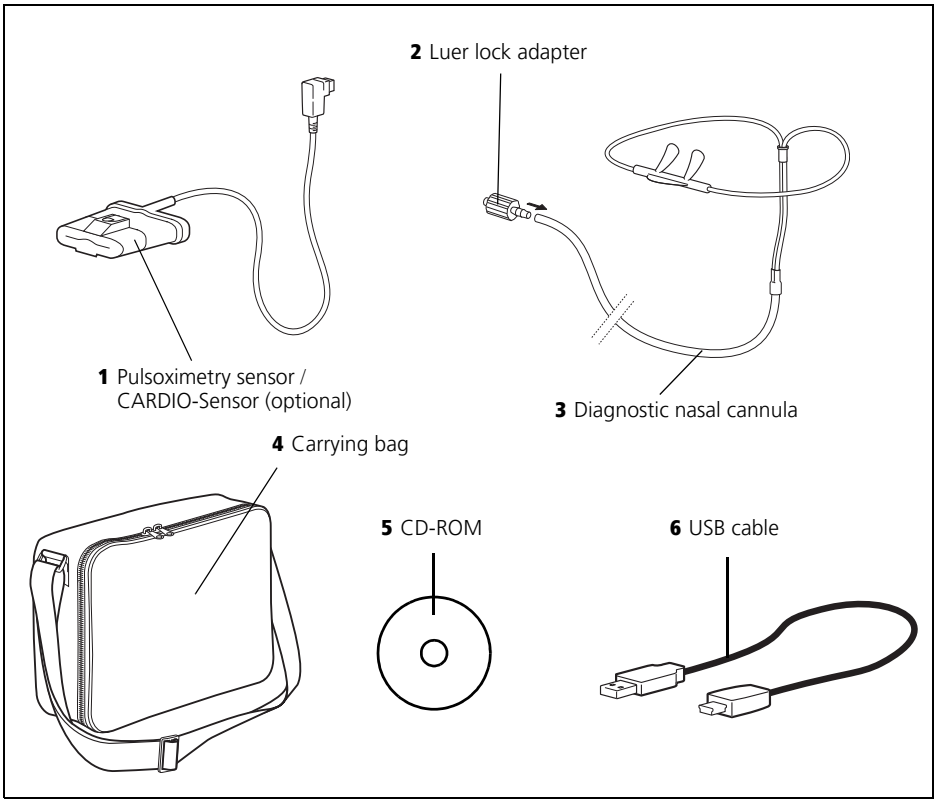
8 Rubber cover

The rubber cover protects the USB port from splashes.

9 Battery compartment

This is where batteries/rechargeable batteries are inserted.

1.2 Components



Key

1 Pulsoximetry sensor / CARDIO-Sensor (optional)

The pulsoximetry sensor is used to measure your patient's oxygen saturation, pulse frequency and pulse wave. A CARDIO-Sensor is used as an option on the SOMNO*check* micro CARDIO. The term "pulsoximetry sensor" is used for both variants in the text which follows.

2 Luer lock adapter

The Luer lock adapter is used to connect the diagnostic nasal cannula to the device.

3 Diagnostic nasal cannula

You can use the diagnostic nasal cannula to detect your patient's respiratory flow and snoring.

4 Carrying bag

You can give the patient the device and its components to take away in the carrying bag.

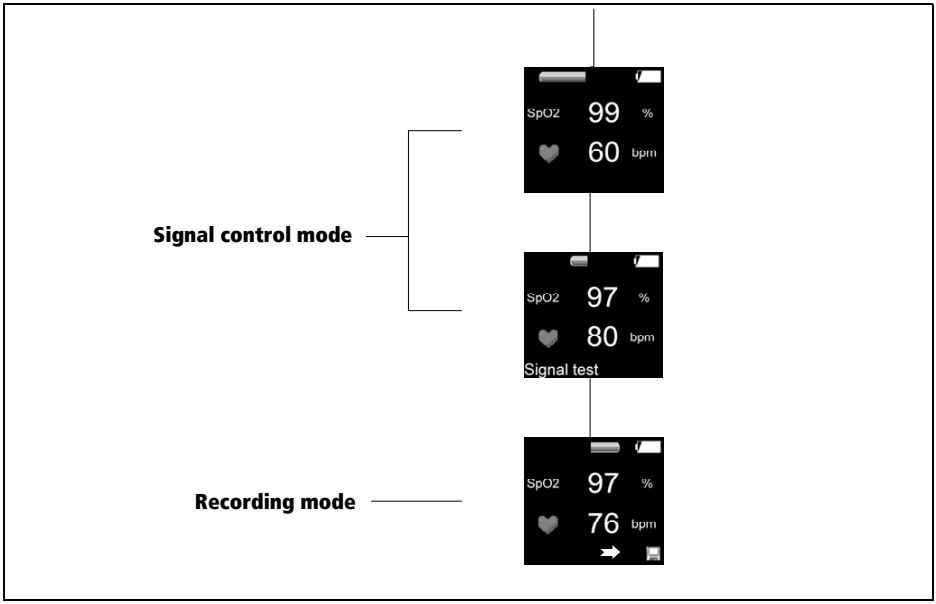
5 CD-ROM

The CD-ROM enables you to install the PC software on your PC.

6 USB cable

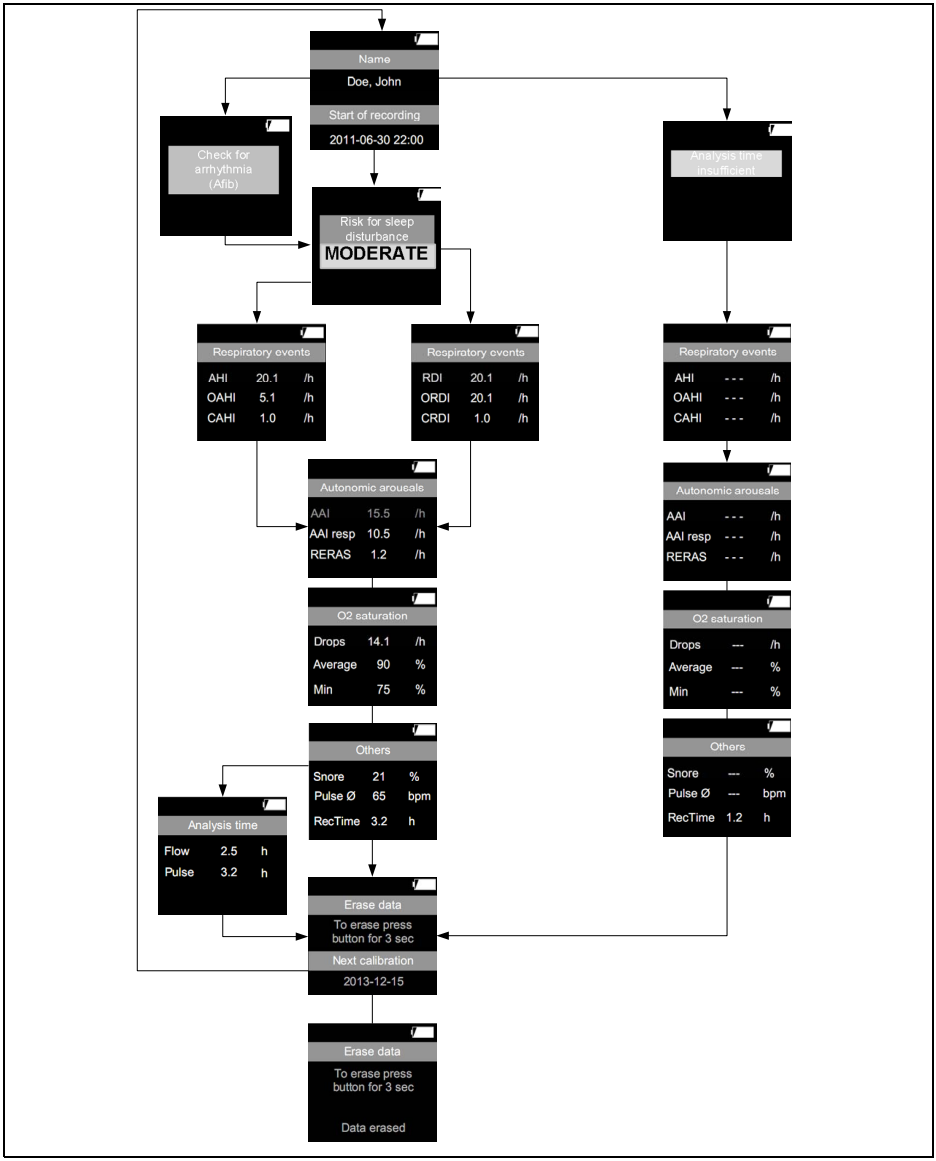
The USB cable connects the device to your PC.

1.3 Menu structure for signal control mode/ recording mode

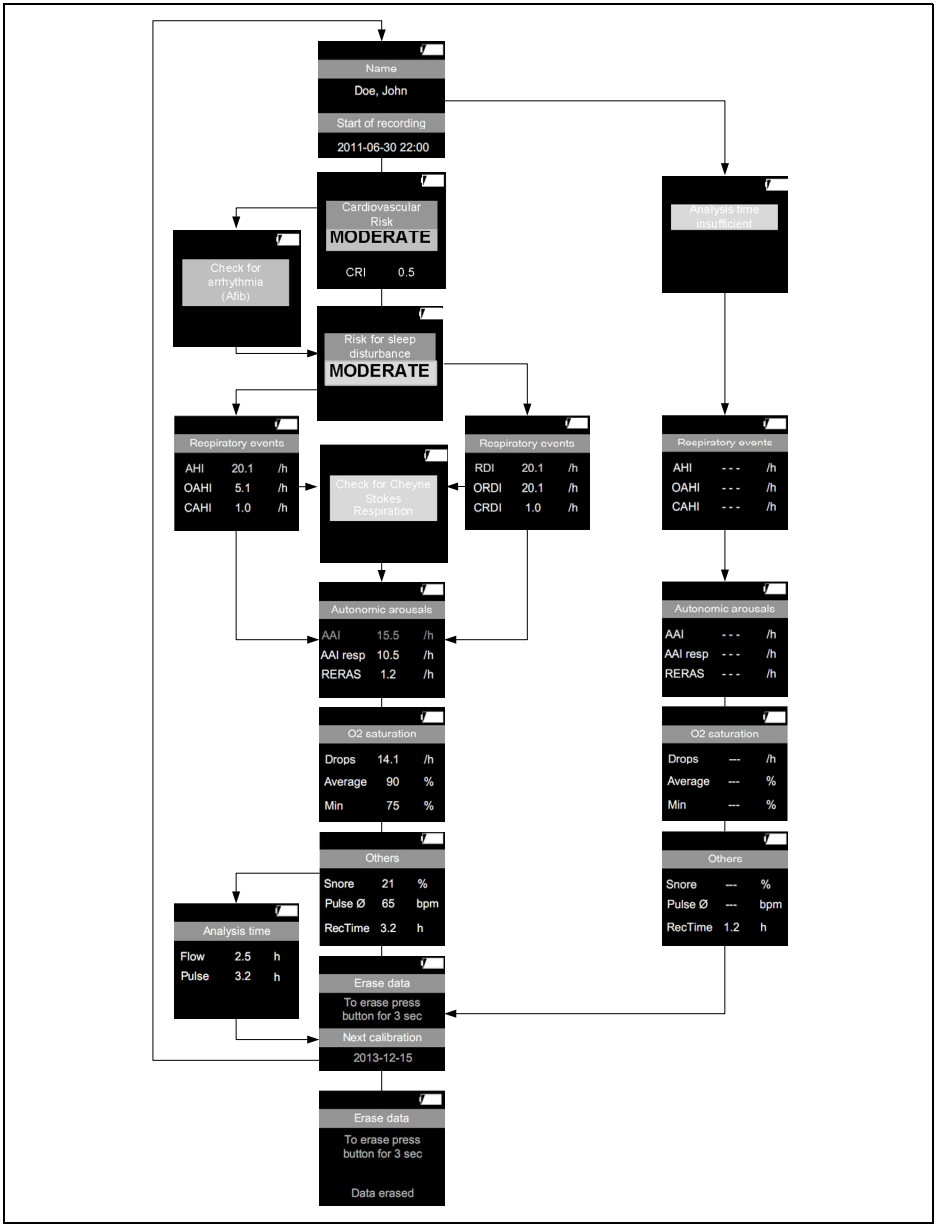


1.4 Menu structure for results display

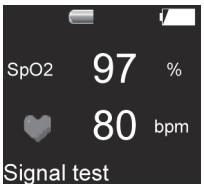
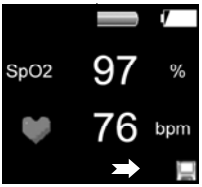
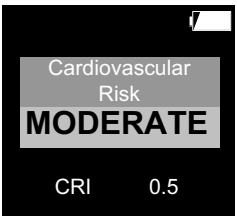
SOMNO*check* micro

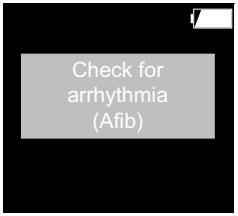
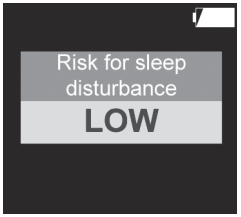
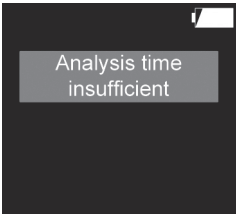
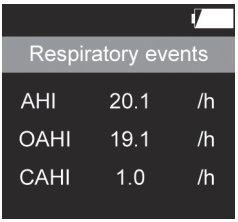


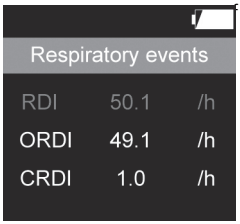
SOMNO*check* micro CARDIO

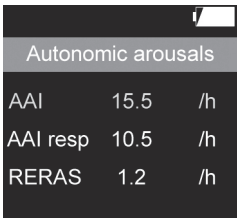
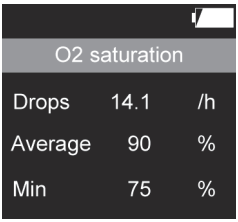


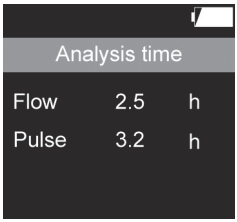
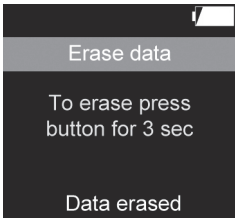
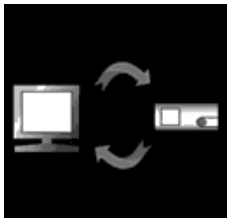
1.5 Symbols in the display

Display	Symbol*	Meaning
Signal control mode (if at least one sensor is connected)		
		Respiratory flow display: moves when there are signals
	SpO2	Oxygen saturation
		Pulse frequency display: symbol flashes at pulse frequency if there are signals
	Signal test*	Signal test in progress
Recording mode		
		Respiratory flow display: moves when there are signals
	SpO2	Oxygen saturation
		Pulse frequency display: symbol flashes at pulse frequency if there are signals
		Floppy disk symbol with arrow: indicates that a recording is in progress
Results display (if no sensor is connected)		
	**Name / Name***	Name of patient. Page is not shown if neither the name nor the recording time have been programmed using the PC software (from SOMNO*lab* Version 2.11). If the programmed name cannot be shown, a "smiley" is shown instead.
	Start of Recording*	Start time for recording. Page is not shown if neither the name nor the recording time have been programmed using the PC software.
	**Cardiovascular Risk***	Cardiovascular risk. Page shown only if recording performed using a CARDIO-Sensor.

	**Check for Arrythmia (AFib)***	Check for arrhythmia (AFib): page shown only in the event of positive findings.
	**Risk for sleep disturbance***	Risk for sleep disturbances (see "1.6 Symbols for risk for sleep disturbances" on page 14)
	**Analysis time insufficient***	Duration of recording inadequate. If the sensors were connected to the device for less than 2 hours during a recording, the recording time is not adequate for reliable results. A message appears in the display to indicate that the recording time was insufficient.
	**Respiratory events***	Respiratory events
	AHI	Apnea/Hypopnea Index: number of apneas and hypopneas per hour within the artifact-free evaluation time of the flow signal
	OAHI	Obstructive Apnea/Hypopnea Index: number of obstructive apneas and hypopneas per hour within the artifact-free evaluation time of the flow signal. The sum of OAHI and CAHI may be less than AHI, especially if there has been no differentiation between central and obstructive apneas due to arrhythmias.
	CAHI	Central Apnea/Hypopnea Index: number of central apneas and hypopneas per hour within the artifact-free evaluation time of the flow signal. The sum of OAHI and CAHI may be less than AHI, especially if there has been no differentiation between central and obstructive apneas due to arrhythmias.

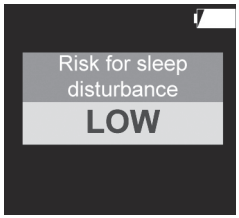
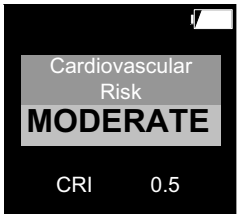
 (appears only when there is not an adequate flow signal)	**Respiratory events***	Respiratory events
	RDI	Respiratory Disturbance Index: number of apneas and hypopneas per hour within the artifact-free evaluation time of the pulsoximetry signal
	ORDI	Obstructive Respiratory Disturbance Index: number of obstructive apneas and hypopneas per hour within the artifact-free evaluation time of the pulsoximetry signal. The sum of ORDI and CRDI may be less than RDI, especially if there has been no differentiation between central and obstructive apneas due to arrhythmias.
	CRDI	Central Respiratory Disturbance Index: number of central apneas and hypopneas per hour within the artifact-free evaluation time of the pulsoximetry signal. The sum of ORDI and CRDI may be less than RDI, especially if there has been no differentiation between central and obstructive apneas due to arrhythmias.
	**Check for Cheyne Stokes Respiration***	Check for Cheyne-Stokes respiration. Page shown only in the event of positive findings and if recording performed using a CARDIO-Sensor.

	**Autonomic arousals**	Autonomic arousals
	AAI	Autonomic Arousal Index: number of autonomous arousals per hour within the artifact-free evaluation time of the pulsoximetry signal. If the warning **Check for arrhythmia (AFib)** has been issued, the device does not supply a result here.
	AAI resp	Respiratory Autonomic Arousal Index: number of autonomous arousals per hour within the artifact-free evaluation time of the pulsoximetry signals caused by a respiratory event. If the warning **Check for arrhythmia (AFib)** has been issued, the device does not supply a result here.
	RERAS	Respiratory Effort-Related Autonomic Arousal Index: number of autonomous arousals per hour within the artifact-free evaluation time of the pulsoximetry signals caused by increased respiratory effort. If the warning **Check for arrhythmia (AFib)** has been issued, the device does not supply a result here.
	**O2 saturation**	Oxygen saturation
	Drops*	Desaturation index: number of oxygen desaturations within the artifact-free evaluation time of the pulsoximetry signal
	Average*	Average: average oxygen saturation within the artifact-free evaluation time of the pulsoximetry signal
	Min	Minimum: minimum oxygen saturation within the artifact-free evaluation time of the pulsoximetry signal
	**Others***	Others
	Snore*	Snoring: proportion of snoring time within the artifact-free evaluation time of the flow signal
	Pulse Ø*	Average pulse frequency: average pulse frequency within the artifact-free evaluation time of the pulsoximetry signal
	RecTime*	Recording time: time during which it was possible to record at least one signal (flow signal or pulsoximetry signal) without artifacts

	**Analysis time**	Duration of artifact-free recording
	Flow rate	Flow signal
	Pulse*	Pulsoximetry signal
	**Erase data***	Erase measured data
	To erase press button for 3 sec*	To erase, press the button for 3 seconds
	Next calibration*	Date of next calibration (Year-Month-Day)
	**Erase data***	Erase measured data
	To erase press button for 3 sec*	To erase, press the button for 3 seconds
	Data erased*	Data erased
		Device is connected to a PC

* If the device has been configured using the PC software, these texts are displayed in the language in which the software is also displayed. English is the default language if the software is not used. The language can only be changed using the PC software. The device can be configured from SOMNO*lab* Version 2.11.

1.6 Symbols for risk for sleep disturbances

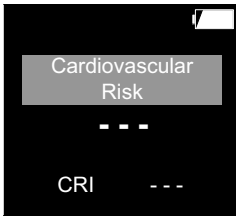
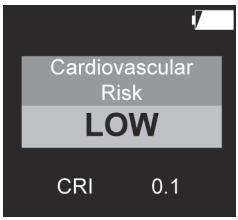
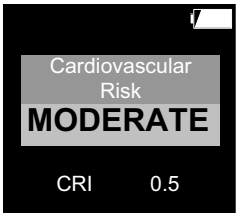
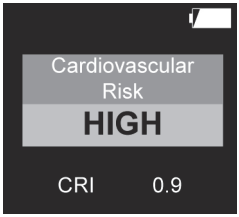
Risk level	Color	Meaning
	None	No data available
	Green	The risk is low (LOW) if all the values are in the range shown here: AHI: <10 RDI: <10 AAI: <30
	Yellow	The risk is moderate (MODERATE) if at least one of the values is in the range shown here: AHI: 10-15 RDI: 10-15 AAI: 30-40
	Red	The risk is high (HIGH) if at least one of the values is in the range shown here: AHI: >15 RDI: >15 AAI: >40

The risk for sleep disturbances is shown in three color-coded levels. The overall risk is determined by the highest individual risk in each case. Example:

AHI <10 (risk = low)
AAI >40 (risk = high)

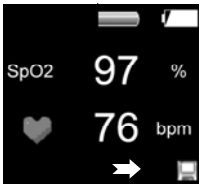
The overall risk is high (**Risk for sleep disturbance HIGH**), as the highest individual risk is red (AAI).

1.7 Display of cardiovascular risk

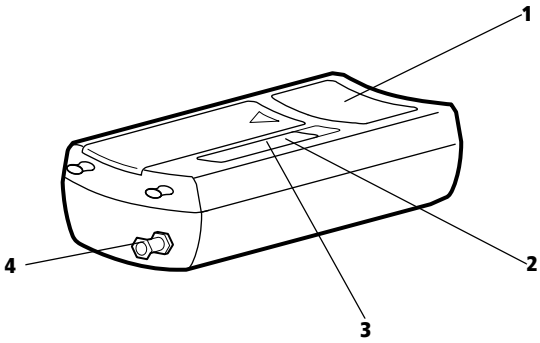
Risk level	Color	Meaning
	None	No data present because time with a good pulse signal quality was too short.
	Green	The risk is low (LOW) if the CRI is in the range 0 - 0.33.
	Yellow	The risk is moderate (MODERATE) if the CRI is in the range 0.33 - 0.66.
	Red	The risk is high (HIGH) if the CRI is in the range 0.66 - 1.

To determine the CRI, the device measures the pulse wave determined by photoplethysmography. Six parameters are recorded in the process: hypoxic variability, cardiorespiratory coupling, cardiac frequency variability, pulse wave variability, pulse wave propagation time and hypoxemic status. These data are used for calculation in a complex algorithm and the final result is a CRI between 0 (= low risk) and 1 (= high risk).

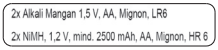
1.8 Display of charging state

	Symbol	Meaning
		100 % capacity
		75 % capacity
		50 % capacity
		25 % capacity
		<10 % capacity: symbol flashes
		0 % capacity: device switches off after 10 seconds

1.9 Markings on the device



	Symbols	Meaning
SOMNO*check* micro device ID plate		
1		Follow information in the instructions for use
		Do not dispose of the device in domestic waste
		Protection class BF
	CE 0197	CE symbol (confirms that the product conforms to the applicable European directives)
	IPX0	Protection against ingress of water
		Battery/rechargeable battery operation
		Date of manufacture
	SN	Serial number

	Symbols	Meaning
SOMNO*check* micro		
2		Follow information in the instructions for use.
3		States which batteries or rechargeable batteries can be used.
4		Connection for diagnostic nasal cannula
Pulsoximetry sensor		
		Do not dispose of the device in domestic waste.
		Date of manufacture
Diagnostic nasal cannula		
		Intended to be used once and then disposed of.

1.10 Markings on the packaging

	Symbols	Meaning
		Humidity in operation, transport and storage
		Transport and storage temperatures
		Protect from wet
		Fragile

1.11 Safety instructions

Safety instructions indicate information relevant to safety.

You will find safety instructions within instructions before a step which includes a risk to people or objects.

Safety instructions consist of

- the warning symbol (pictogram),
- a word to indicate the level of hazard
- information about the hazard and
- instructions on how to avoid the hazard.

There are three levels of warning instruction, depending on the degree of hazard.

DANGER!
Indicates an unusually large hazard. If you do not follow this instruction, severe, irreversible injuries or death will result.

Warning!
Indicates an unusually large hazard. If you do not follow this instruction, severe, irreversible or fatal injuries may result.

Caution!
Indicates a hazard. If you do not follow this instruction, slight or moderate injuries may result.

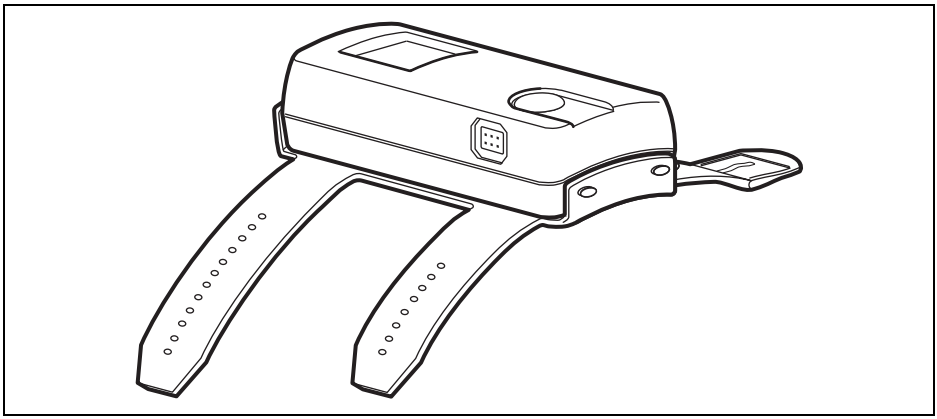
Note!
Indicates material hazards. If you do not follow this instruction, material damage may result.

2. Description of device

2.1 Intended use

SOMNO*check* micro is a data recording system for registering, recording, storing and evaluating biosignals during sleep. It is for detecting sleep-related respiratory disorders and concomitant risk factors to support diagnosis and to adjust and check therapy. Spheres of application include outpatient examinations at a patient's home or in hospital. The doctor and specialist staff instructed by the doctor provide the patient with instruction in the functions of the device and how to use it. The screening results are processed and displayed so as to support the user in detecting sleep disturbances and cardiovascular risk factors at an early stage. This allows the user to initiate patient-specific diagnosis. The data measured are stored and analyzed in the device. Analysis results are shown in a device display. Saved data can be transferred to the PC via a USB interface and analyzed there.

2.2 Description of function



SOMNO*check* micro

SOMNO*check* micro is a small screening device for sleep diagnosis which is attached to the patient's forearm by an wristband. A pulsoximetry sensor is attached to one of the patient's fingers. This pulsoximetry sensor measures oxygen saturation (SpO_2), pulse frequency and pulse wave. A diagnostic nasal cannula detects the patient's respiratory flow and snoring.

The device is switched on by pressing the button and records sleep-related parameters with the aid of the pulsoximetry sensor and the diagnostic nasal cannula. A recording generally lasts 8 hours. Other recording times can be set using the PC software from SOMNO*lab* Version 2.11 onwards. The results are shown in the display after the end of the recording.

SOMNO*check* micro CARDIO

SOMNO*check* micro CARDIO additionally analyzes the signals recorded for parameters which provide information about cardiovascular risk. The CRI (Cardiac Risk Index) is shown in the display. By downloading the data to a PC, it is possible to access further information about the cardiovascular risk and recommendations about further diagnostic procedures.

The device displays three states.

- **Results display:** the results display appears after the start screen when the device is switched on by pressing the button. If the diagnostic nasal cannula and the pulsoximetry sensor are not attached, the results display shows the results of the last recording. The individual results can be displayed if you repeatedly press the button. The display goes out after 30 seconds and can be called up again by pressing the button briefly.

- **Signal control mode:** if the device is receiving valid signals from the diagnostic nasal cannula and/or the pulsoximetry sensor outside a recording, it switches from the results display to signal control mode. The device displays current measured values, but does not store them. If the device is no longer receiving signals, it automatically switches back to the results display. A check is made in signal control mode that the sensors are attached correctly. In signal control mode, the display goes out after 2 seconds and can be called up again by pressing the button briefly.
- **Recording mode:** when the device is receiving valid signals from the diagnostic nasal cannula and/or the pulsoximetry sensor in signal control mode and the button on the device is pressed for three seconds, the device performs a signal test and then switches to recording mode. Alternatively, it is possible to use the PC software to program a recording time at which the device starts recording (from SOMNO*lab* Version 2.11). It is then only possible to start the recording manually if the PC software is used to program manual recording mode (manual recording start) or if all the data on the device have been erased (see "5.5 After the recording" on page 39).

  The recording overwrites older recordings. A floppy disk symbol with an arrow pointing towards the floppy disk symbol appears at the bottom right of the display. During recording, the device shows in the display the current oxygen saturation, pulse frequency and respiratory flow measured and stores these values. A recording generally lasts 8 hours. Other recording times can be set using the PC software (from SOMNO*lab* Version 2.11 onwards). If the PC software was used to enter a patient name, this name is retained in the device until the data in the device are erased and the software is used to configure a new recording. In recording mode, the display switches off after 30 seconds to save power. Every press of the button switches on the display for 30 seconds.

  If the device no longer receives valid signals during the recording (for example because the pulsoximetry sensor is no longer correctly attached to the finger), it stores zero values until the end time is reached and then switches off automatically.

  If the device does not receive any valid signals at the start of the recording when the recording time has been programmed, the device switches off automatically after 2 minutes. After another 20 minutes, the device tries to start another recording. The recording can be started manually during this period. If there are still no valid signals being received after the 10th attempt, the device starts a recording the next day at the programmed time. If it has not been possible to start a valid recording after a week, the device erases the patient name and start time, and recording can be started manually again.

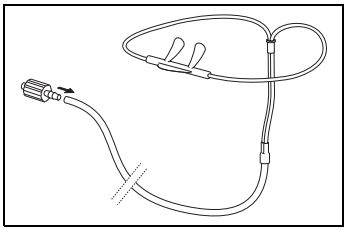
Depending on the sensor attached, the signals below may be recorded and displayed.

Sensor	Measured values
Pulsoximetry sensor	– Oxygen saturation – Pulse frequency
Diagnostic nasal cannula	– Respiratory flow

- **PC mode:** the device automatically switches to PC mode as soon as the device is connected to a PC via a USB cable. The analysis results for the recording currently saved can be imported into the PC software. The device switches off after 5 minutes if no data transfer takes place. The following settings can be programmed using the PC software (from SOMNO*lab* Version 2.11):
  - start time for the recording
  - display language
  - patient name

For software updates, contact your local specialist dealer or the manufacturer.

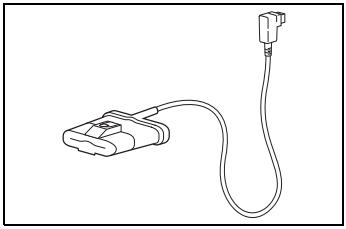
Diagnostic nasal cannula



The diagnostic nasal cannula detects respiratory flow and snoring in combination with the pressure sensor integrated in the device. Inspiration is registered by the vacuum generated, exhalation by the overpressure generated. Snoring generates pressure fluctuations in the nostrils which are likewise registered.

Signal display and automatic analysis are matched to the genuine diagnostic nasal cannula. SOMNO*check* micro may only be used in conjunction with the genuine diagnostic nasal cannula.

Pulsoximetry sensor / CARDIO-Sensor



The pulsoximetry sensor detects pulsoximetric signals, in other words, the patient's blood oxygen saturation and pulse frequency. Its primary components are two LEDs and a receiver diode.

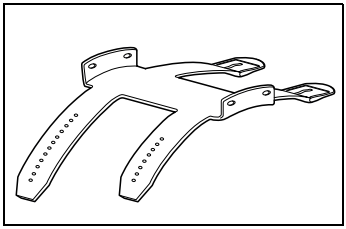
Several oxygen saturation values are determined for each pulse wave (split pulse wave algorithm). If a signal is

disrupted by movement, the number of useable measured values is reduced.

A CARDIO-Sensor can be used as an option on SOMNO*check* micro CARDIO; during the recording, this also calculates CRI parameters and checks for Cheyne-Stokes respiration. The CARDIO-Sensor is color-coded to distinguish it from the pulsoximetry sensor.

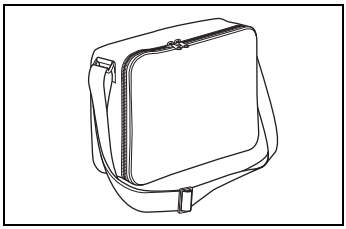
SOMNO*check* micro may only be used in conjunction with this pulsoximetry sensor or the CARDIO-Sensor.

Wristband



The device is attached to the patient's forearm with the aid of the wristband. The wristband is made of skin-friendly plastic.

Carrying bag



The device and its components can be stowed and transported in the carrying bag supplied.

2.3 Measuring conditions

General

- Follow the instructions for use for the pulsoximetry sensor and the diagnostic nasal cannula.
- Follow the instructions for attaching the sensors and components.
- Correct measurements are possible only if the system is operated properly.
- Contamination of the sensors, as a result of secretions or moisture, for example, can falsify measurement results.
- The accuracy of analysis results may be restricted and measured values may be falsified under oxygen therapy, especially if no diagnostic nasal cannula is used.

Measure using the diagnostic nasal cannula

- Use only the genuine diagnostic nasal cannula.
- Do not use a damaged diagnostic nasal cannula.
- The diagnostic nasal cannula is a disposable item and may not be reused.
- The tube of the diagnostic nasal cannula may not be pinched during the measurement.
- If the diagnostic nasal cannula is incorrectly attached, measurement results may be impaired.
- Significant movements of the tube may falsify measurement results.
- Large quantities of secretion (colds) or blood (nosebleeds) may impair the measurement of respiratory flow and snoring. Carefully wipe off all contamination, e.g. secretions after sneezing.

Measure using the pulsoximetry sensor

- Always secure the connecting cable of the pulsoximetry sensor to the patient's finger or hand using a plaster so that it is not irritating and the pulsoximetry sensor cannot slip out of position.
- Wearing the pulsoximetry sensor for too long causes pressure points. Switch the pulsoximetry sensor to a different finger at regular intervals.
- Ensure that the LEDs and the receiver in the pulsoximetry sensor are not dirty or moist.
- Varnished or artificial fingernails falsify the measurement results of the pulsoximetry sensor.

- With a high proportion of dysfunctional hemoglobins (e.g. carboxyhemoglobin or methemoglobin), measurement may deliver a normal result, even if the patient is hypoxic. This is caused by less hemoglobin being available for transporting oxygen. In such a case, there is no point using a two-wavelength pulsoximetry sensor as used with SOMNO*check* micro.
- The pulsoximetry sensor is calibrated to pulsoximetric hemoglobin oxygen saturation (assuming blood is free of dysfunctional hemoglobin) by means of referenced measurements obtained from fractional saturation measurement. Functional oxygen saturation of arterial blood is determined non-invasively with the aid of the pulsoximetry sensor on the patient's finger. A high proportion of dysfunctional hemoglobins (e.g. carboxyhemoglobin or methemoglobin) impairs measurement accuracy.
- Intravascular dyes such as methylene blue, indocyanine green or other dyes will significantly falsify the measurement result.
- Normal ambient light is compensated by the sensor. Particularly strong or fluctuating ambient light, e.g. as a result of direct sunlight or operating room lights, may falsify measurement results. The device then restricts its measuring operation and displays "0" values.
- Blood pressure cuffs, arterial catheters, arterial occlusions or excessively tight attachment of the pulsoximetry sensor have a negative impact on pulsation strength.
- The device detects movement artifacts, suppresses the majority with the aid of various algorithms and issues a message as soon as they become too high. Prolonged movement artifacts may falsify the display of measurement results.
- Arrhythmias (such as extrasystoles, sinoatrial block, atrioventricular block) generally change a patient's hemodynamics so significantly that SOMNO*check* micro is no longer able to analyze reliably the morphology of the measured pulse wave. The differentiation of respiratory events into obstructive and central, and the autonomic arousal index (AAI) calculated, may therefore be subject to errors in the event of arrhythmias.

3. Safety instructions

Read these instructions for use through carefully. They are a constituent part of the device and must be available at all times. Use the device only for the intended use described (see "2.1 Intended use" on page 20).

For your own safety and that of your patients, and in accordance with the requirements of directive 93/42/EEC, observe the following instructions.

Device

Warning!

- Do not supply any electrical power via the plug connections.
- Before using a defibrillator, remove all the components of the sleep apnea diagnosis set from the patient's body.
- Do not use the device in an atmosphere at risk of explosion.
- The sleep apnea diagnosis set may not be used to monitor vital physical functions.
- Do not touch the patient if you have the USB cable connector in your hand and the USB cable is connected to the PC.

Caution!

- Do not use the sleep apnea diagnosis set if it is damaged. Connecting cables, plugs and housing must be in perfect condition.
- Protect the device and the pulsoximetry sensor from ingress of liquids.
- Do not bring the components of the sleep apnea diagnosis set into contact with injured or infected skin. Dress any wounds with a stable dressing beforehand.
- Do not operate any devices which produce electromagnetic fields in the vicinity of SOMNO*check* micro. Faults and measuring faults can be caused by the following, among others:
  - interference with an electrical surgical unit
  - X-rays
  - MRI devices
  - radio signals (e.g. cellphones)
  - power lines
  - electrical stimulation devices

- Do not operate SOMNO*check* micro with devices which supply the body with energy – electrical stimulation devices, for example.
- Maintain a safe distance between SOMNO*check* micro and devices which emit HF radiation (e.g. cellphones), otherwise there may be malfunctions (see "11.3 Safety distances" on page 63).
- Keep the patient a distance of 1.5 m from the PC on which you are saving data and its components (e.g. printer).
- Additional equipment connected to the analog and digital ports of the device must have evidence of conformity with the corresponding EN specifications (e.g. EN 60950 for data processing devices and EN 60601 for electrical medical devices). Furthermore, all configurations must comply with the version of system standard EN 60601-1-1 in force at the time of sale. Anyone connecting additional devices to the signal input or output part is considered a system configurer and is thus responsible for compliance with the applicable version of system standard EN 60601-1-1. In the event of questions, contact your local specialist dealer or the manufacurer.
- The device may deliver incorrect measurement results if drugs which change blood color or measured physiological parameters are taken.

Note

- Do not use the device for diagnostic tests to rule out Cheyne-Stokes respiration and arrhythmias.
- A medical professional must instruct the patient in how to handle the sleep apnea diagnosis set.
- Do not connect any third-party devices to SOMNO*check* micro.
- Only use the device indoors.
- Non-medical equipment should only be positioned outside the patient's immediate vicinity.
- Operate and store the device only under the ambient conditions quoted in the technical data.
- Replace all parts which are damaged, worn or contaminated before using the device.
- Before you work with the sleep apnea diagnosis set, you must have understood how to handle it.
- The sleep apnea diagnosis set generates information signals. These are for checking the presence of signals for recording and to check the function of the device. Alarms are not generated.
- Fix the device firmly but comfortably to your patient's forearm.

- If you have questions about faults, see the section entitled "8. Troubleshooting" on page 54.
- Follow the section entitled "6. Hygiene treatment" on page 49 to prevent an infection or bacterial contamination.
- Modifications to the device and opening the device are not permitted. Any claim
- Follow the instructions in online Help for the PC software if you are using the device with the PC software.
- Ensure that the device is correctly assigned to the patient to prevent confusion.

Sensors

Caution!

- Make sure that the sensors, connecting cables and tubes are attached in accordance with specification. Incorrectly attached connecting cables and tubes may lead to injuries.
- Follow the instructions for use for the diagnostic nasal cannula and the pulsoximetry sensor.
- Do not connect the device to a PC if sensors are attached to the patient.

Note

- Plug all sensor connectors into the specified connection points.
- When handling sensors, follow the instructions in the section entitled "2.3 Measuring conditions" on page 25.

Batteries/rechargeable batteries

Note

- Replace old batteries/rechargeable batteries. Old batteries/rechargeable batteries may leak and destroy the device.
- Remove the batteries/rechargeable batteries from the device if the device will not be used for an extended period.

Replacement parts/accessories/repair

Caution!

- If third-party items are used, functional failures and restricted fitness for use may result. Biocompatibility requirements may also not be met. In such cases, please be aware that any claim under warranty and liability will be voided if neither the accessories nor the genuine replacement parts recommended in the instructions for use are used.

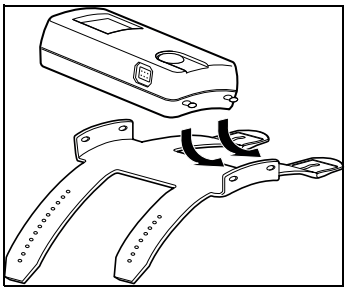
- Use of accessories, inverters and connecting cables other than those stated may lead to increased emission or to reduced immunity to interference of the device or system.

Note

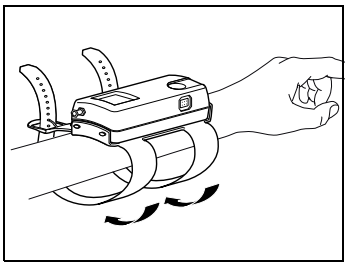
- Dispose of the components in accordance with the regulations applicable in your medical sphere.
- Have servicing and repairs carried out only by the manufacturer or by specialist staff expressly authorized by the manufacturer to do so.

4. Commissioning

4.1 Put on device

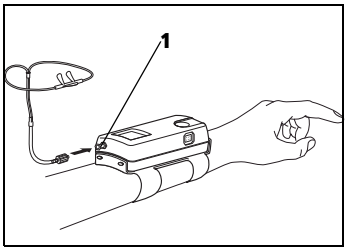


1. Insert the batteries/rechargeable batteries in the device (see "5.7 Insert batteries" on page 45).
2. Attach the device to the wristband (see illustration).
3. Ensure that the device engages fully in the holes on the wristband, otherwise the device may come loose.

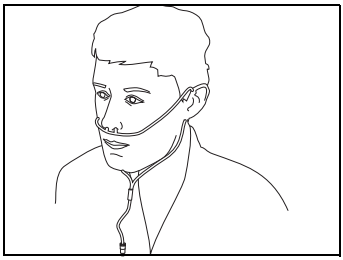


4. Place the wristband on your patient's left forearm. The shorter strap of the wristband should face the hand.
5. Tighten the wristband so that it sits firmly but does not restrict circulation in the arm.
6. Do up the buckles.

4.2 Put on diagnostic nasal cannula



1. Draw the tube for the diagnostic nasal cannula through your patient's pajama sleeve.
2. Push the Luer lock adapter onto the end of the tube for the diagnostic nasal cannula.
3. Remove the Luer lock sealing cap from diagnostic nasal cannula connection **1** on the device.
4. Screw the Luer lock adapter with the diagnostic nasal cannula attached to it onto connection **1** for the diagnostic nasal cannula (half a turn).



5. To increase wearing comfort, grease the nostrils lightly with Vaseline®, for example. This stops the skin drying out.
6. Follow the instructions for use for the diagnostic nasal cannula.
7. Grasp the double tube of the diagnostic nasal cannula to the left and right so that the cannulas point upwards.
8. Position the cannulas in the nostrils.

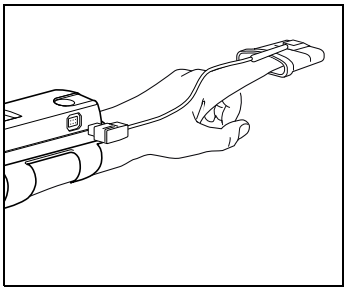
Caution!
Risk of injury if sensors and tubes are attached too tightly!
Incorrectly attached sensors and tubes may impede circulation in parts of the body and restrict breathing.

- Ensure that sensors and tubes are not impeding circulation in any part of the body.
- Ensure that your patient can breathe freely.

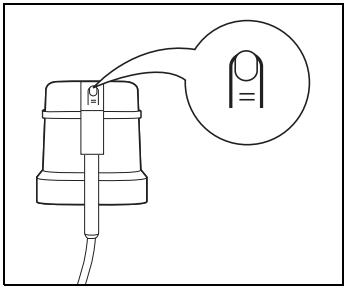
9. Pass the tubes along behind the ears and under the chin.
10. If necessary: fix the tubes to the face using adhesive tape so that the nasal cannula does not slip out of position.
11. Align the sleeve at the fork so that the tube is loose but does not slip out of position.
12. Check the diagnostic nasal cannula (see "7.3 Perform function check" on page 52) after you have put on the device and the diagnostic nasal cannula.

4.3 Attach pulsoximetry sensor

1. Put on the device (see "4.1 Put on device" on page 31).



2. Push the pulsoximetry sensor onto one of your patient's fingers.
   If you are monitoring your patient's blood pressure with a cuff on this arm, choose the other arm.

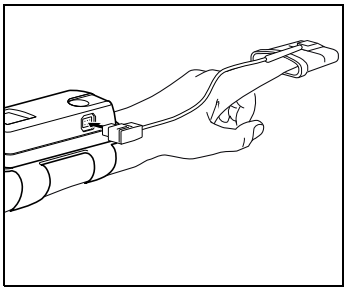


3. Ensure that the finger marking on the pulsoximetry sensor is facing upwards.
   The sensor must be comfortably and securely located and should not squeeze the finger.

Caution!
Risk of injury if sensors and tubes are attached too tightly!
Incorrectly attached sensors and tubes may impede circulation in parts of the body and restrict breathing.

   – Ensure that sensors and tubes are not impeding circulation in any part of the body.

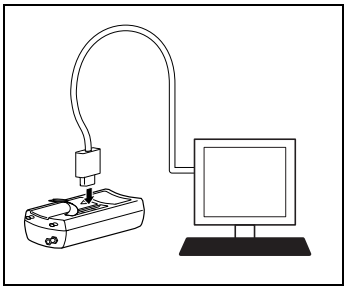
4. If necessary: fix the connecting cable for the pulsoximetry sensor to a finger or the back of the hand using adhesive tape.
   Do not affix any adhesive tape to the sensor housing.



5. Plug the connector for the pulsoximetry sensor into the socket on the device with the arrow facing upwards.
6. Check the pulsoximetry sensor (see "7.3 Perform function check" on page 52) after you have put on the device and the pulsoximetry sensor.

4.4 Make a connection to the PC

You have to connect the device to the PC via a USB cable in order to configure the device or transfer the data saved in the device to your PC. To do this, proceed as follows:



1. Install the PC software as described in the User Manual for the PC software.
   The User Manual can be found on the CD-ROM supplied.
2. If necessary: take the device off the wristband.
3. Lift the tab over the USB port on the underside of the device.
4. Connect the USB cable to a free USB port on your PC.
5. Connect the mini USB connector of the USB cable to the USB port of the device.

5. Operation

5.1 Prepare a recording

1. Take a device and a copy of the patient's instructions for use.
2. Read off the serial number of the device.
3. Enter the serial number of the device on the form on the reverse of the patient's instructions for use.
4. Enter the patient data on the form on the reverse of the patient's instructions for use.
5. Ensure that the serial number of the device and the serial number on the reverse of the patient's instructions for use match before giving the device to your patient.
6. If you are using the PC software: enter the patient data and program an automatic start time if desired.
7. Show your patient how to use the sleep apnea diagnosis set.

5.2 Give patient instructions

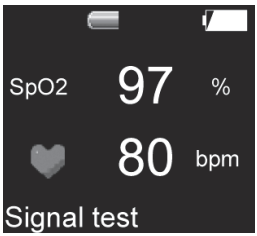
1. Put the device on your patient as a trial (see "4.1 Put on device" on page 31).
2. Check the sensors you have attached (see "7.3 Perform function check" on page 52).
3. Clearly demonstrate and explain to your patient how to put on the following without your assistance but with the aid of the patient's instructions for use:
   - device (see "4.1 Put on device" on page 31)
   - diagnostic nasal cannula (see "4.2 Put on diagnostic nasal cannula" on page 31)
   - pulsoximetry sensor (see "4.3 Attach pulsoximetry sensor" on page 33)

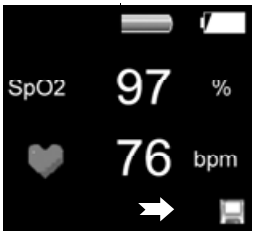
4. Ask your patient to put on the device and the sensors him or herself under your supervision.
5. Show your patient how to change the batteries or rechargeable batteries (see "5.7 Insert batteries" on page 45 and "5.8 Use rechargeable batteries" on page 46).
6. Show your patient how to perform a recording (see "5.3 Perform a recording" on page 36).
7. Give your patient a set of new batteries or charged rechargeable batteries.
8. Stow the sleep apnea diagnosis set and the patient's instructions for use in the carrying bag.
9. Give your patient the carrying bag.

5.3 Perform a recording

Manual recording

1. Put on the device (see "4.1 Put on device" on page 31).
2. Put on the diagnostic nasal cannula (see "4.2 Put on diagnostic nasal cannula" on page 31).
3. Put on the pulsoximetry sensor (see "4.3 Attach pulsoximetry sensor" on page 33).
4. Press the button on the device.
5. Wait until the start screen disappears.
6. Check whether there are any signals.
7. Press the button on the device for 3 seconds.
   The device performs a signal test (**Signal test**) for a maximum of 2 minutes.



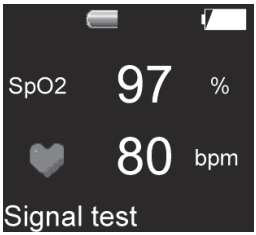


– If the diagnostic nasal cannula and/or pulsoximetry sensor are attached, the device starts recording after the signal test. A floppy disk symbol appears in the bottom right of the display. The display switches off after 30 seconds to save power. The recording ends automatically after 8 hours or the time programmed using the software.
– If neither the diagnostic nasal cannula nor the pulsoximetry sensor are attached, the display switches off after 30 seconds to save power. The device switches off completely after 2 minutes.
– In the first 15 minutes after starting recording, the data are saved but not analyzed, as it is unlikely the patient has already fallen asleep in this time.
– A manual start is not possible if the start of the recording has been programmed using the software.

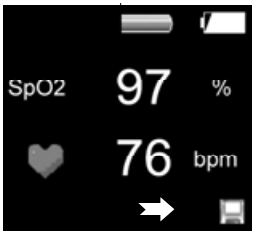
Recording with a programmed recording time (from SOMNO*lab* V2.11)

1. Put on the device (see "4.1 Put on device" on page 31).
2. Put on the diagnostic nasal cannula (see "4.2 Put on diagnostic nasal cannula" on page 31).
3. Attach the pulsoximetry sensor (see "4.3 Attach pulsoximetry sensor" on page 33).

If the device has programmed a recording time, it starts automatically at this time.



The device performs a signal test (**Signal test**) for a maximum of 2 minutes:

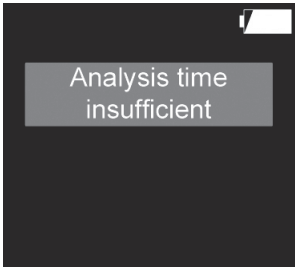


– If the diagnostic nasal cannula and/or pulsoximetry sensor are attached, the device starts recording after the signal test. A floppy disk symbol appears in the bottom right of the display. After 30 seconds, the display switches off to save power. The recording ends automatically after 8 hours or at the time programmed using the software.
– If neither the diagnostic nasal cannula nor the pulsoximetry sensor are attached, the display switches off after 30 seconds to save power. The device switches off completely after 2 minutes.
– In the first 15 minutes after starting recording, the data are saved but not analyzed, as it is unlikely the patient has already fallen asleep in this time.
– If the device does not receive any valid signals at the start of the recording with a programmed recording time, the device switches off automatically after 2 minutes. After another 20 minutes, the device tries to start another recording. The recording can be started manually during this period. If valid signals are still not being received after the 10th attempt, a manual start is no longer possible. The device starts a recording again at the programmed time the next day. If it has not been possible to start a valid recording after a week, the device erases the patient name and start time, and recording can be started manually again.

5.4 Cancel recording

A recording ends automatically after 8 hours or after the programmed recording time. If you want to cancel the recording before that, proceed as follows.

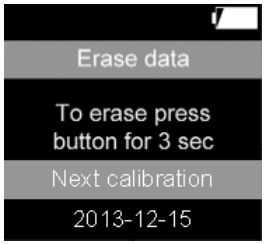
1. Press the button on the device 4 times in quick succession.
   The display switches off.
2. If you wish to view the results of the recording, press the button on the device.

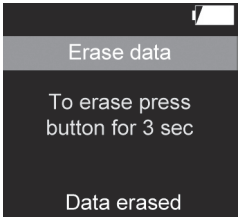


3. Wait until the start screen disappears.
   - If the sensors were connected to the device for less than 2 hours during a recording, recording time is not adequate for reliable results. A message appears in the display to indicate that the recording time was insufficient (**Analysis time insufficient**).
   - If the sensors were connected to the device for more than 2 hours during a recording, you can read off the results in the results display after the end of the recording (see "5.6 Read out results" on page 40).

5.5 After the recording

1. Check whether the serial number of the device matches the serial number on the form on the reverse of the patient's instructions for use.
2. Check whether the patient's name on the form on the reverse of the patient's instructions for use matches the name of your patient.
3. Press the button on the device.
4. Wait until the start screen disappears and the results display appears.
   The results display shows the results of the last recording.
5. Call up the individual pages of the results display by pressing the button on the device.
6. Read off the results (see "5.6 Read out results" on page 40).
7. Enter the results on the form on the reverse of the patient's instructions for use.
8. Call up the **Erase data** page by briefly pressing the button on the device, possibly several times.
   Erase data and **Next calibration** appear in the display.





9. Press the button for 3 seconds to erase the results recorded for your patient.
   The message **Data erased** appears in the display.
10. If you do not wish to erase the results, briefly press the button.
    Page 1 of the results display appears.
11. Release the Luer lock adapter from the diagnostic nasal cannula.
12. Dispose of the diagnostic nasal cannula (see "9.2 Disposal" on page 56).
13. Subject the device, the Luer lock adapter, the pulsoximetry sensor and the carrying bag to a hygiene treatment (see "6. Hygiene treatment" on page 49).

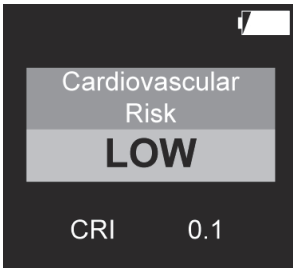
5.6 Read out results

Read out results using the PC

You can use the PC software to read out the results of recording and output the results in the form of a report.

1. Connect the device to the PC (see "4.4 Make a connection to the PC" on page 34).
2. Analyze the results using the PC software as described in the User Manual for the PC software. The User Manual can be found on the CD-ROM supplied.

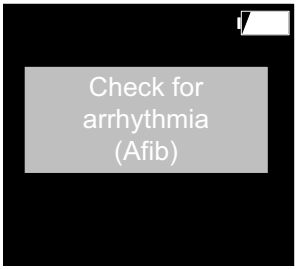
Read out results on device



1. Press the button on the device.
2. Wait until the start screen disappears.
3. Call up the individual pages by briefly pressing the button.
4. With SOMNO*check* micro CARDIO only: read off cardiovascular risk (**Cardiovascular Risk**).

The risk is shown in three color-coded levels.

Risk level	Color	Meaning
LOW (low)	Green	The risk is low (LOW) if the CRI is in the range 0 - 0.33.
MODERATE (Moderate)	Yellow	The risk is moderate (MODERATE) if the CRI is in the range 0.33 - 0.66.
HIGH (high)	Red	The risk is high (HIGH) if the CRI is in the range 0.66 - 1.



5. In the event of positive findings only: the **Check for Arrythmia (AFib)** page is displayed.

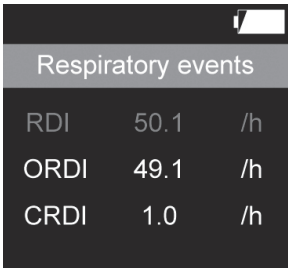
6. With SOMNO*check* micro CARDIO and in the event of positive findings only: the **Check for Cheyne Stokes Respiration** page is displayed.

7. Read off the risk for sleep disturbances (**Risk for sleep disturbance**).

   The risk is shown in three color-coded levels. The overall risk is determined by the highest individual risk.

Risk level	Color	Meaning
LOW (low)	Green	The risk is low if all the values are in the range shown here: AHI: <10 RDI: <10 AAI: <30
MODERATE (Moderate)	Yellow	The risk is moderate if at least one of the values is in the range shown here: AHI: 10-15 RDI: 10-15 AAI: 30-40
HIGH (high)	Red	The risk is high if at least one of the values is in the range shown here: AHI: >15 RDI: >15 AAI: >40

Example:
AHI <10 (risk = green)
AAI >40 (risk = high)
The overall risk is red (**Risk for sleep disturbance HIGH**), as the highest individual risk is red (AAI).



8. Read off the respiratory events (**Respiratory events**).

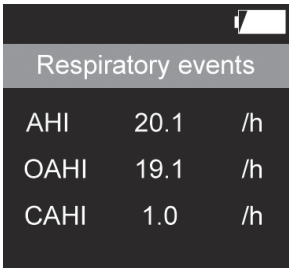
   The Respiratory Disturbance Index (RDI) is shown in the display in the following cases:

   – only the pulsoximetry sensor was attached to the device during the recording.
   – the pulsoximetry sensor and the diagnostic nasal

cannula were attached to the device during the recording. The signal for the diagnostic nasal cannula was present at an adequate quality for less than 75 % of the artifact-free time of the pulsoximetry signal.

The RDI is displayed in the color of the RDI risk determined.

RDI	Color
<10	Green
10-15	Yellow
>15	Red

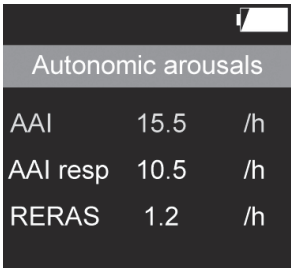


The Apnea/Hypopnea Index (AHI) is shown in the display instead of RDI in the following cases:

– only the diagnostic nasal cannula was attached to the device during the recording
– the pulsoximetry sensor and the diagnostic nasal cannula were attached to the device during the recording. The signal for the diagnostic nasal cannula was present at an adequate quality for over 75 % of the artifact-free time of the pulsoximetry signal.

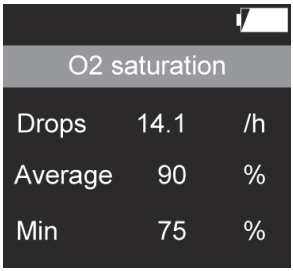
The AHI is displayed in the color of the AHI risk determined.

AHI	Color
<10	Green
10-15	Yellow
>15	Red



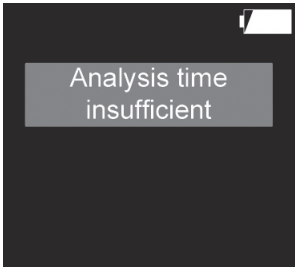
9. Read off the autonomic arousals (**Autonomic arousals**). The Autonomic Arousal Index (AAI) is displayed in the color of the AAI risk determined.

AAI	Color
<30	Green
30-40	Yellow
>40	Red



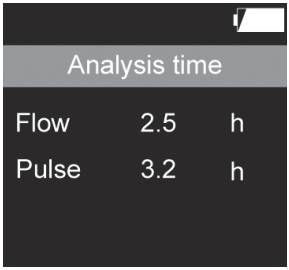
10. Read off the values for O_2 saturation (**O2 saturation**).

11. Read off the other values (**Others**) (see "1.5 Symbols in the display" on page 9).



Notes:

- If the sensors were connected to the device for less than 2 hours during a recording, recording time is not adequate for reliable results. A message appears in the display to indicate that the recording time was insufficient (**Analysis time insufficient**). Recordings less than two hours long can still be evaluated in the PC software (SOMNO*lab* from Version 2.11) after the signals have been viewed. However, a CRI is not calculated in this case either.

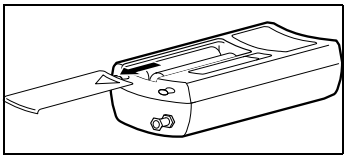


- If recording time is only 2-4 hours, the recording time (**Analysis time**) for respiratory flow (**Flow**) and pulse frequency (**Pulse**) appear in the display. If a recording lasts 2 to 4 hours, the results determined are displayed, but the recording time is comparatively short. Repeat the recording if possible in order to obtain reliable results.
- In the first 15 minutes after starting recording, the data are saved but not analyzed, as it is unlikely the patient has already fallen asleep in this time.

5.7 Insert batteries

Information

- The display of charging state has several levels (see "1.8 Display of charging state" on page 16) and tends to be inaccurate. To be on the safe side, use new batteries for every recording and always keep spare batteries to hand. If the display of charging state is displaying 75 %, a complete recording (8 hours) is guaranteed.
- Even if the capacity of the batteries runs out during a recording, the recorded data are retained.
- It is possible to change the batteries with a recording in progress. The batteries have to be changed within 10 minutes, otherwise the recording will be cancelled. However, the recorded data will be retained.
- The first time the device is used, or if no batteries have been in the device for over 24 hours, you can update device time using the PC software. This ensures that subsequent recordings are assigned the correct measuring date. The procedure is described in the User Manual for the PC software.



1. Insert new batteries:
   – before commissioning
   – before using the device
   – if the display of charging state is flashing
   – if batteries are too old
2. Open the battery compartment.
3. Ensure the correct polarity of the batteries.
4. Insert the batteries.
5. Push the lid of the battery compartment closed until it engages with an audible click.

5.8 Use rechargeable batteries

Information

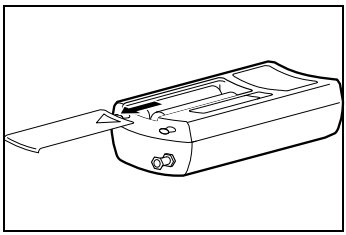
- Instead of using batteries, you can also use branded rechargeable batteries of the NiMH 1.2 V AA type with a min. of 2500 mAh. Operating the device with rechargeable batteries may lead to restrictions in operating, storage and ambient conditions. Follow the instructions for use provided by the rechargeable battery manufacturer.
- Rechargeable batteries have a finite service life. The typical service life of the rechargeable battery is quoted as approx. 500 charges or 1.5 to 2 years. However, this is heavily dependent on usage. If you use the rechargeable battery other than as described by the rechargeable battery manufacturer, overall service life may be reduced.
- All rechargeable batteries discharge with time, even if the device is switched off. A fully-charged rechargeable battery will discharge after approx. 90 days without operation. If it is not charged for a period exceeding 4 months, it can proceed to so-called deep discharge. A deep-discharged rechargeable battery no longer reaches its full capacity. It discharges

again after just a short time.

- If you do not use the device for several weeks, recharge the battery before the next recording.
- The display of charging state is based on alkaline manganese batteries and is therefore highly inaccurate when rechargeable batteries are used. The full and empty displays are much reduced in terms of time. Precise details are not possible, as there is no capacity monitoring.
- The display of charging state has several levels (see "1.8 Display of charging state" on page 16) and tends to be inaccurate. To be on the safe side, use a new rechargeable battery for every recording and always keep spare rechargeable batteries to hand. If the display of charging state is displaying at least 75 %, a complete recording (8 hours) is guaranteed.
- Even if the capacity of the rechargeable batteries runs out during a recording, the recorded data are retained.
- It is possible to change the rechargeable batteries with a recording in progress. The rechargeable batteries have to be changed within 10 minutes, otherwise the recording will be cancelled. However, the recorded data will be retained.

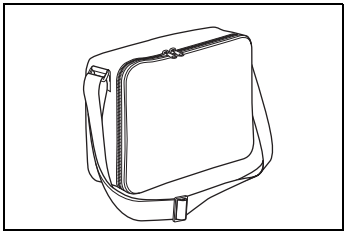
How to insert rechargeable batteries.

1. Charge the rechargeable batteries using a commercially-available battery charger. Follow the instructions provided by the rechargeable battery manufacturer for this.



2. Open the battery compartment.
3. Ensure the correct polarity of the rechargeable batteries.
4. Insert the rechargeable batteries.
5. Push the lid of the battery compartment closed until it engages with an audible click.

5.9 Transport device



1. Stow the sleep apnea diagnosis set and the patient's instructions for use in the carrying bag.

6. Hygiene treatment

Caution!
Risk of infection from pathogens!
A carrying bag infected with pathogens will cause infections on a change of patients.

– Dispose of the carrying bag in the event of potential pathogens such as MRSA, for example.

Note!
Risk of material damage as a result of ingress of liquids!
Ingress of liquids will cause short-circuiting and damage both device and pulsoximetry sensor.

– Remove the batteries/rechargeable batteries from the battery compartment.
– Before cleaning, place the rubber cover over the USB port.
– Before cleaning, seal the connection for the diagnostic nasal cannula with the Luer lock sealing cap.
– Connect the pulsoximetry sensor to the device.
– Do not immerse the pulsoximetry sensor in liquid.

Information

- You should also follow the hygiene regulations for sleep laboratories and clinical facilities.
- **This product may contain disposable items.** Disposable items are intended to be used only once. So use these items only once and do **not** reprocess them. Reprocessing disposable items may impair the functionality and safety of the product and lead to unforeseeable reactions as a result of ageing, embrittlement, wear, thermal load, the effects of chemical processes, etc.

6.1 Intervals

Clean the device and its components after every use and on change of patients.

6.2 Clean

1. Remove the labels on the connecting cable of the pulsoximetry sensor.
2. If necessary: disconnect the USB cable from the device.
3. Take a lint-free damp cloth.
4. Clean the device and its components as described in the table below.

Parts	Clean
SOMNO*check* micro	Wipe the component with a damp cloth and mild detergent. Ensure that the metal parts of the USB cable do not come into contact with moisture.
Carrying bag	
Wristband (approx. 50 uses)	
USB cable	
Diagnostic nasal cannula	Disposable component Do not subject the diagnostic nasal cannula to any treatment. Use a new diagnostic nasal cannula.
Pulsoximetry sensor / CARDIO-Sensor	Follow the manufacturer's instructions for use.
Luer lock adapter	Follow the manufacturer's instructions for use.

5. Leave the cleaned components to dry fully in air before using them again.

6.3 Disinfect

You may also disinfect some components if required, e.g. in the event of infectious diseases or unusual contamination.

1. Follow the instructions for use for the disinfectant used.
   We recommend terralin® protect for disinfecting by wiping.
2. Use suitable gloves (e.g. household or disposable gloves) when disinfecting.
3. Disinfect the individual components as described in the table below.

Parts	Disinfect
SOMNO*check* micro	Disinfect by wiping[(a)]
Carrying bag	Washing machine, 40 °C cycle, no spin, possible during cycle[(b)]
Wristband (approx. 50 uses)	Disinfect by wiping[(a)]

Parts	Disinfect
Diagnostic nasal cannula	Disposable component Do not subject the component to any treatment. Use a new component.
Pulsoximetry sensor / CARDIO-Sensor	Follow the manufacturer's instructions for use.
Luer lock adapter	Follow the manufacturer's instructions for use.

[a] After disinfecting by wiping, remove all residues of disinfectant with tap water and a mild detergent.

[b] Add a suitable disinfecting detergent to the cycle (40 °C in the washing machine, no spin). We recommend Eltra 40® for this purpose.

4. Leave the disinfected components to dry fully in air before using them again.

6.4 Sterilization

Sterilization of the device and its components is not permitted.

6.5 Change of patient

On a change of patient, clean and disinfect the device and its components as described in "6.2 Clean" on page 50 and "6.3 Disinfect" on page 50.

7. Function check

If you find faults during the function check, you may not use the device.

Try to eliminate the fault with the help of the information in Section "8. Troubleshooting" on page 54. If this proves impossible, have the device repaired by the manufacturer or by specialist staff expressly authorized by the manufacturer to do so.

A full function check includes:

- "7.2 Perform a visual inspection" on page 52
- "7.3 Perform function check" on page 52.

7.1 Intervals

Perform a function check before each use.

7.2 Perform a visual inspection

Look carefully at the device and its components.

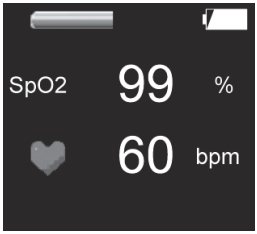
The device and its components may not be damaged, dirty or damp.

7.3 Perform function check

Check device

1. Put on the device (see "4.1 Put on device" on page 31).
2. Put on the diagnostic nasal cannula (see "4.2 Put on diagnostic nasal cannula" on page 31).
3. Put on the pulsoximetry sensor (see "4.3 Attach pulsoximetry sensor" on page 33).
4. Switch on the device.

5. Check whether the measured values shown in the display are plausible.



The device is working correctly if the measured values shown in the display are plausible.

Check display

1. Put on the diagnostic nasal cannula (see "4.2 Put on diagnostic nasal cannula" on page 31) and/or the pulsoximetry sensor (see "4.3 Attach pulsoximetry sensor" on page 33).
2. Press the button on the device.

The display is working correctly if the signals from the sensor are shown in the display.

Check sensors

1. Put on the device (see "4.1 Put on device" on page 31).
2. Put on the diagnostic nasal cannula (see "4.2 Put on diagnostic nasal cannula" on page 31) and/or the pulsoximetry sensor (see "4.3 Attach pulsoximetry sensor" on page 33).
3. Press the button on the device.
4. Check whether the measured values shown in the display are plausible.

The checked sensor is working correctly if:

- the respiratory flow display in the display is moving.
- the measured values for oxygen saturation and pulse frequency are plausible.

8. Troubleshooting

8.1 Faults in the device

Fault	Cause of fault	Remedy
No signal in flow, snore or pulsoximetry channel	Diagnostic nasal cannula and/or pulsoximetry sensor not put on	Put on the missing sensor.
	Plug connections are not properly connected	Ensure the connections are firm.
	Sensors are dirty or damp	Clean the sensors and wipe them dry.
	Sensors are defective	Use new sensors.
Results are displaying implausible values (see "2.3 Measuring conditions" on page 25)	Plug connections are not properly connected	Ensure the connections are firm. Check the sensors (see "7.3 Perform function check" on page 52) before or during the recording.
	Sensor has got dirty or has slipped out of position during the measurement	Repeat the recording with clean or new sensors.
Device displaying no signals	Plug connections are not properly connected	Ensure the connections are firm.
Display too dim	Display defective	Return the device to the manufacturer for repair.
Display dark		
Batteries/rechargeable batteries supplying no power	Contact springs have no contact	Insert the batteries/ rechargeable batteries again.
	Batteries/rechargeable batteries defective	Replace batteries/rechargeable batteries.
	Batteries/rechargeable batteries discharged	Replace batteries or charge rechargeable batteries.
Device does not switch on.	Batteries/rechargeable batteries discharged	Replace batteries or charge rechargeable batteries.
	Batteries/rechargeable batteries inserted with incorrect polarity	Insert the batteries/ rechargeable batteries with the correct polarity.
	Internal fuse has tripped	Return the device to the manufacturer for repair.

No connection can be made to the device.	Cable connection between device and PC is interrupted	Check all cable connections.
	Device has switched off. Connection has been inactive for over 5 minutes	Switch device back on at the button.
No manual recording can be started.	The device has been programmed for a certain recording time.	Erase data (see "5.5 After the recording" on page 39). If necessary, read out the data present in the device beforehand.

8.2 Error messages in the display

If a critical fault is detected when the device is switched on, the following error message appears in the display instead of the start screen:

Error message	Fault
ERROR 1	Program code
ERROR 2	RAM
ERROR 3	UART
ERROR 4	I2C
ERROR 5	SPI
ERROR 6	USB
ERROR 101	Real Time Clock
ERROR 102	EEPROM
ERROR 103	Data Flash
ERROR 104	Temperature sensor
ERROR 105	Display

In the event of one of these faults, return the device to the manufacturer to have it checked.

9. Servicing

1. Use the PC software to calibrate the pressure sensor for flow measurement every 2 years. The procedure is described in the User Manual for the PC software.
2. To read off the next calibration date: Call up the **Erase data** page by briefly pressing the button on the device several times. **Erase data** and **Next calibration** appear in the display.
3. If you are not performing calibration yourself using the PC software: send the device to the manufacturer or specialist staff expressly authorized by the manufacturer every 2 years to have servicing performed.
4. Perform a function check (see "7. Function check" on page 52).

9.1 Storage

Store the device under the specified ambient conditions (see "11.1 Specifications" on page 61).

Remove the batteries/rechargeable batteries from the device if the device is not to be used for an extended period.

If rechargeable batteries have been stored for a prolonged period, their high discharge rate may mean that they are discharged or defective (see "5.8 Use rechargeable batteries" on page 46).

9.2 Disposal

Information
You should also follow the applicable hygiene regulations for sleep laboratories/ clinical facilities.

Dispose of device and USB cable

Do not dispose of the device and the USB cable in domestic waste. To dispose of the device properly, contact an approved, certified electronics scrap dealer. You can obtain the address from your Environment Officer or your local authority. The device packaging (cardboard and inserts) can be disposed of in paper recycling facilities.

Dispose of diagnostic nasal cannula

After use, take the Luer lock adapter off the diagnostic nasal cannula and dispose of the diagnostic nasal cannula in domestic waste.

Dispose of pulsoximetry sensors

Do not dispose of the device in domestic waste. To dispose of the device properly, contact an approved, certified electronics scrap dealer. You can obtain the address from your Environment Officer or your local authority. The device packaging (cardboard and inserts) can be disposed of in paper recycling facilities.

Dispose of wristband

Dispose of the wristband in domestic waste.

Dispose of Luer lock adapter

Dispose of the Luer lock adapter in a germ-free state in accordance with the applicable legal regulations.

Dispose of carrying bag

Dispose of the carrying bag in domestic waste.

Dispose of batteries/rechargeable batteries

Used batteries/rechargeable batteries may not be disposed of in domestic waste. Contact the manufacturer or your local authority waste disposal department.

10. Scope of supply

10.1 Standard scope of supply

SOMNO*check* micro sleep apnea diagnosis set **WM 94500**

Description	Order number
SOMNO*check* micro, basic device	WM 94530
Set of 10 diagnostic nasal cannulas and 1 adapter	WM 94519
Softtip sensor, size L with Minimed connector (right-angled)	WM 94595
Carrying bag	WM 94055
Wristband	WM 94560
Luer lock adapter	WM 95221
Luer lock sealing cap	WM 94137
Battery 1.5 V AA, round-cell, LR 6	WM 5186
Instructions for use for SOMNO*check* micro, EN	WM 96621
Patient's instructions for use for SOMNO*check* micro, EN	WM 96631
CD-ROM with PC software	WM 98500
USB cable	WM 94524

SOMNO*check* micro CARDIO sleep apnea diagnosis set WM 94570

Description	Order number
SOMNO*check* micro, basic device	WM 94530
Set of 10 diagnostic nasal cannulas and 1 adapter	WM 94519
Softtip sensor CARDIO, size L with Minimed connector (right-angled)	WM 94585
Carrying bag	WM 94055
Wristband	WM 94560
Luer lock adapter	WM 95221
Luer lock sealing cap	WM 94137
Battery 1.5 V AA, round-cell, LR 6	WM 5186
Instructions for use for SOMNO*check* micro, EN	WM 96621
Patient's instructions for use for SOMNO*check* micro, EN	WM 96631
CD-ROM with PC software	WM 98500
USB cable	WM 94524

10.2 Accessories

Description	Order number
Softtip sensor, size M with Minimed connector (right-angled)	WM 94596
Set of 100 diagnostic nasal cannulas and 1 adapter	WM 94522
Softtip sensor CARDIO, size M with Minimed connector (right-angled)	WM 94586

10.3 Replacement parts

Description	Order number
SOMNO*check* micro, basic device	WM 94530
Set of 10 diagnostic nasal cannulas and 1 adapter	WM 94519
Softtip sensor, size L with Minimed connector (right-angled)	WM 94595
Carrying bag	WM 94055
Wristband	WM 94560
Luer lock adapter	WM 95221
Set, 10 Luer lock adapters	WM 95224
Luer lock sealing cap	WM 94137
Battery 1.5 V AA, round-cell, LR 6	WM 5186
Instructions for use for SOMNO*check* micro, EN	WM 96621
Patient's instructions for use for SOMNO*check* micro, EN	WM 96631
CD-ROM with PC software	WM 98500
USB cable	WM 94524
Softtip sensor CARDIO, size L with Minimed connector (right-angled)	WM 94585

11. Technical data

11.1 Specifications

	SOMNO*check* micro
Product class to directive 93/42/EEC	IIa
Dimensions W x H x D in mm	112 x 30 x 50
Weight: excl. batteries incl. 2 batteries	 79 g 145 g
Temperature range: operation storage transport	 +5 °C to +40 °C –20 °C to +60 °C –20 °C to +60 °C
Permitted humidity for operation and storage	25 % to 95 % rh (no condensation)
Air pressure for operation and storage	700 hPa to 1060 hPa
Electrical rating	2x alkaline manganese 1.5 V AA, round-cell, LR6 2x NiMH 1.2 V AA, round-cell, HR6; min. 2500 mAh
Operating time	Battery: approx. 15 hours NiMH rechargeable batt. (2700 mAh): approx. 20 h (depending on time display is operated)
Mean power consumption	approx. 250 mW without display approx. 500 mW with display in continuous operation
Max. recording period for one measurement	8 h
Classification to EN 60601-1 – Type of protection against electric shock – Degree of protection against electric shock	 Internal power supply Type BF
Electromagnetic compatibility (EMC)	Interference emission to EN 60601-1-2 Class B Resistance to interference to EN 60601-1-2 Test parameters and limit values can be obtained from the manufacturer on request.
Type of protection against ingress of water	IPX0
Read out saved data using PC software	USB 1.1 or higher

The right to make design modifications is reserved.

11.2 Pulsoximetry sensor

Parameter	Value range		Unit	Precision/calculation
	Min.	Max.		
Sensor: wavelengths	660	905	nm	
Sensor: heat output	0	20	mW	Maximum rise in temperature by 2 °C at application location
Signal quality	0	100	%	A signal quality ≥ 90 % is good - below that, SpO_2 values and pulse frequency may be unreliable.
SpO_2 measurement				
SpO_2 measuring range:	45	100	%	70 % < SpO_2 < 100 %: better than 2 % precision SpO_2 < 70 % not validated
Measuring dynamics First reaction after: Final value reached after:		 2 8	 s s	Measured at desaturation/ resaturation between 96 % and 84 % SpO_2 under favorable measuring conditions. The values may be extended in the event of poor pulse strength or movement artifacts.
First display after application:	3	6	s	Measured at default setting. The poorer the measuring conditions, the more unreliable the first value displayed.
Pulse frequency measurement				
Pulse frequency measuring range:	30	250	bpm	1 bpm to 2 % of value displayed
Measuring dynamics First reaction after: Final value reached after:	 1 1	 7 6	 s s	Maximum values measured in the case of sudden change from 40 bpm to 200 bpm and vice versa. The times for reaction and final value depend on the difference (deviation) between beats.
First display after application:	5	8	s	Measured at default setting. The poorer the measuring conditions, the more unreliable the first value displayed.

11.3 Safety distances

Recommended safety distances between portable and mobile HF telecommunication devices (e.g. cellphones) and SOMNO*check* micro			
Nominal power of HF device in W	**Safety distance depending on transmission frequency in m**		
	150 kHz - 80 MHz	**80 MHz - 800 MHz**	**800 MHz - 2.5 GHz**
0.01	0.04	0.04	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.11	1.11	2.21
100	3.50	3,50	7.00

12. Warranty

Löwenstein Medical gives the customer a limited manufacturer warranty on new original Löwenstein Medical products and any replacement part fitted by Löwenstein Medical in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase as listed below. The warranty conditions are available on the website of the manufacturer. We can also send you the warranty conditions on request.

In the event of a claim under warranty, contact your specialist dealer.

Product	Warranty period
Löwenstein Medical devices including accessories (except masks)	2 years
Masks including accessories, rechargeable batteries, batteries (unless quoted differently in the technical documentation), sensors, tube systems	6 months
Disposable products	None

13. Declaration of conformity

Löwenstein Medical Technology GmbH + Co. KG, Kronsaalsweg 40, 22525 Hamburg, Germany, the manufacturer of the devices described in these Instructions for Use, hereby declares that the product complies with the respective regulations of Medical Devices Directive 93/42/EEC. The unabridged text of the Declaration of Conformity can be found on the manufacturer's website.

WM 96621d 08/2017 EN

CE 0197

Löwenstein Medical
Technology GmbH + Co. KG
Kronsaalsweg 40
22525 Hamburg, Germany
T: +49 40 54702-0
F: +49 40 54702-461
www.loewensteinmedical.de

WM 96621d

LÖWENSTEIN
medical