SOMNOlab

for

SOMNOcheck micro

WM 96741e 01/2019

Manual



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1 About SOMNOlab for SOMNOcheck micro

SOMNOlab for SOMNOcheck micro detects, visualizes and archives biosignals recorded by the SOMNOcheck micro diagnosis device during sleep.

Applications for SOMNOlab for SOMNOcheck micro are in-patient examinations in sleep laboratories and out-patient examinations in the field of sleep medicine based outside hospitals.

SOMNOlab for SOMNOcheck micro is intended only for use with SOMNOcheck micro. The relevant PC software is required to analyse biosignals recorded with other Löwenstein diagnosis devices.

SOMNOlab for SOMNOcheck micro and SOMNOlab cannot be used on one PC simultaneously.

1.1 Intended use

SOMNOlab for SOMNOcheck micro is a component part of the SOMNOlab product. SOMNOlab for SOMNOcheck micro is the complementary software for the Löwenstein screening device SOMNOcheck micro and SOMNOcheck micro CARDIO. It is for saving, editing, visualizing, documenting and archiving the data measured by the device. The SOMNOlab for SOMNOcheck micro PC software is used only with SOMNOcheck micro screening devices. The data from screening are transferred to the PC by USB cable and displayed in the SOMNOlab for SOMNOcheck micro PC software. It thus supports the user in detecting sleep disorders at an early stage. Applications are outpatient examinations in a hospital setting and outside hospitals.

1.2 Safety information

Read this Online Help/this User Manual carefully. It is a component of the PC software described and must be available at all times. Use SOMNOlab for SOMNOcheck micro only for the intended use described. For your own safety and that of your patients, and in accordance with the requirements of Directive 93/42/EEC, observe the safety instructions below.

- The system may only be used by people who have received instruction from a medical devices consultant.
- Warning! The system may not be used to monitor vital physical functions. The system is not intended for use on people weighing less than 45 kg.
- The PC on which SOMNOlab is installed, together with its peripherals (e.g. printer) and non-medical devices, may not be placed in the immediate vicinity of the patient (within 1.5 m).
- Observe the system requirements. Install the software only on a computer which meets the system requirements.

- Protect the CD-ROM from strong sunlight or mechanical effects such as bending or scratching.
- Please note that this software is a medical device. Anyone who installs medical devices on a PC, connects them to a PC or incorporates them in a network, is responsible for complying with EN 80001-1.
- · Follow the safety rules in the instructions for use for the SOMNOcheck micro device.
- Be aware that the software for detecting sleep-related respiratory disorders supplies a proposed analysis. Medical assessment may only be made by the treating doctor.
- · Do not delete the files manually using a file explorer program.
- · Do not falsify or switch recording data and do not intervene manually in program files.
- · Back up the data on your system regularly to protect it.
- Keep the date and time of your PC up to date. The date and time of your PC are transmitted to the SOMNOcheck micro device and affect the analysis.
- Ensure that during data import the device on the PC is not switched over. Under certain circumstances, this can result in data being confused.
- · Please be aware that amendments to the software configuration may affect your diagnosis results.
- Protect your PC from viruses and malicious software. If you are loading data from an external storage medium, ensure beforehand that this is not infected with viruses. Perform a virus scan on your system at regular intervals.

1.3 System requirements

In order to be able to install the SOMNOlab for SOMNOcheck micro PC software without any problems, you need administrator rights and an IBM-compatible computer with the following basic requirements:

Component	Requirement		
Processor	Pentium 4 [®] min. 1.8 GHz		
	for Windows [®] 8.1: recommended Intel [®] Core i3 or higher		
Free memory	Hard drive with min. 2 GB free memory		
RAM	Min. 512 MB RAM (depending on operating system, see operating system)		
Connection	1 free USB port		
Drive	CD-ROM drive		
Display	Supported by Microsoft® Windows®,		
	resolution min. 1024 x 768 (recommended 1280 x 1024)		
	colour quality min. 16 bit (recommended 32 bit)		
	colour monitor		
Printer	Supported by Microsoft® Windows®		
Input	Keyboard and mouse or other suitable pointing device, supported by Microsoft [®] Windows [®]		
Operating system	The operating systems listed are supported in the following languages: German, English, French, Italian, Dutch, Russian.		
	Windows® XP 32 bit SP2 or higher (if compatible) with min. 512 MB RAM (recommended 1 GB RAM)		
	Windows® 7 32 bit or 64 bit with min. 1 GB RAM (recommended 2 GB RAM)		
	Windows® 8.1 with min. 1 GB RAM (recommended 2 GB RAM)		
	For more information about compatibility with more recent operating systems, contact your local specialist dealer or Löwenstein Customer Service (e-mail: Medelo-service@hul.de)		
Software	Internet Explorer® 6.0 SP1 or higher (if compatible)		
	Adobe [®] Acrobat [®] Reader [®] 6.0 or higher (if compatible)		
Other peripherals For the peripherals which can be connected to the SOMNOch device, please see the instructions for use for SOMNOcheck			

Note:

you need administrator rights to install SOMNOlab for SOMNOcheck micro and power user rights to operate the software.

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Adobe Acrobat Reader is a registered trademark of Adobe Systems Incorporated in the USA and/or in other countries.

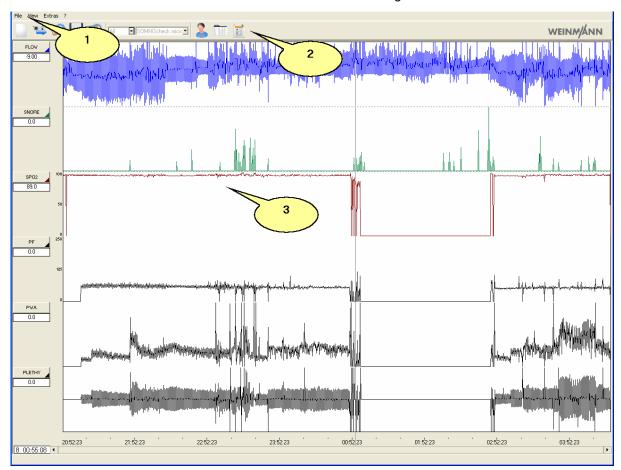
Pentium is a trademark of the Intel Corporation in the USA and in other countries.

1.4 Markings and symbols

Marking	Description
	Follow the user manual

2 User interface

The user interface of SOMNOlab for SOMNOcheck micro is arranged as follows:



- · Menu bar (1)
- · Button bar (2)
- · Channel view (3)

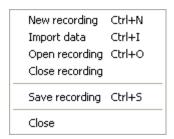
2.1 Menu bar

The menu bar is on the top left of the start screen:

```
File View Extras ?
```

Click on the menu items of the individual menu or on the hyperlinks to obtain information about topics in which you are interested.

"File" menu



In the File menu, you can perform the following actions:

- start new recording
- · import data
- open recording
- close recording
- · save recording
- close SOMNOlab for SOMNOcheck micro

"View" menu

Patient data Event list Reports

In the View menu, you can perform the following actions:

- · edit patient data
- edit events
- · create reports

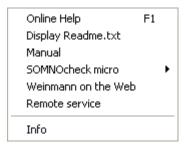
"Extras" menu

Calibration of SOMNOcheck micro Set time of SOMNOcheck micro Options

In the **Extras** menu, you can perform the following actions:

- recalibrate SOMNOcheck micro
- set time of SOMNOcheck micro
- set options

"?" menu



In the ? menu, you can perform the following actions:

- · call up Online Help
- · display the Readme file
- · call up the User Manual
- · call up instructions for use for SOMNOcheck micro
- · call up website for Löwenstein Medical
- · remote service
- · show information about SOMNOlab for SOMNOcheck micro

2.2 Button bar

The button bar is located beneath the menu bar:

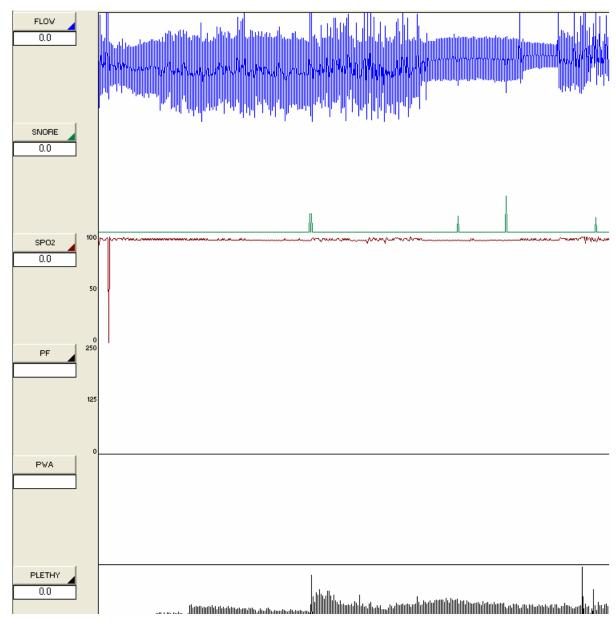


You can use it to perform the following actions:

- · Start new recording
- · import data
- · open recording
- · save recording
- · close recording
- · change time basis
- Select visualization configuration
- · edit patient data
- edit events
- · create report

2.3 Channel view

The channel view displays the individual channels recorded by SOMNOcheck micro:



The following channels are displayed

Channel	Meaning	Events displayed	Sensor	Unit
FLOW	Respiratory	Artefact	Nasal cannula	
	flow	Obstructive/central/unclassified apnoea		
		Obstructive/central/unclassified hypopnoea		
		Obstructive/central/unclassified respiratory disturbance		
SNORE	Snoring	Snoring	Nasal cannula	
SPO2 Oxygen saturation		Artefact Desaturation Symmetrical Periodic Desaturation (CARDIO sensor only) Hypoxaemia	Pulsoximetry sensor	% SpO2
PF Pulse frequency		Autonomous arousal Suspected arrhythmia	Pulsoximetry sensor	ВРМ
PWA	PWA Pulse wave amplitude Autonomous arousal		Pulsoximetry sensor	
PLETHY	PLETHY Plethysmo- gram Artefact		Pulsoximetry sensor	

Events are indicated by the abbreviations below.

Events	Abbreviation	
Artefact	Art	
Obstructive apnoea	оА	
Central apnoea	cA	
Unclassified apnoea	Α	
Obstructive hypopnoea	оН	
Central hypopnoea	сН	
Unclassified hypopnoea	Н	
Obstructive respiratory disturbance	oRe	
Central respiratory disturbance	cRe	
Unclassified respiratory disturbance	uRe	
Snoring	S	
Desaturation		

Events	Abbreviation
Autonomous arousal	AA
Flattening	Flat
Symmetrical Periodic Desaturation (CARDIO sensor only)	spd
Hypoxaemia	HY
Suspected arrhythmia	sa

Note

If SOMNOcheck micro has set events of the "Suspected arrhythmia" type, no autonomic arousals will be detected during this period and hypopnoeas and respiratory disturbances will not be differentiated into obstructive and central types.

3 First steps

This section provides information for your first steps with SOMNOlab for SOMNOcheck micro

- Install SOMNOlab for SOMNOcheck micro
- Uninstall SOMNOlab for SOMNOcheck micro
- Start SOMNOlab for SOMNOcheck micro
- Shut down SOMNOlab for SOMNOcheck micro
- · Call up the User Manual
- · Use Online Help
- · Select language
- · Use keyboard shortcuts

3.1 Install SOMNOlab for SOMNOcheck micro

Note:

if you are installing SOMNOlab for SOMNOcheck micro in a SOMNOlab or SOMNOlab 2 polysomnography system or also wish to use the SOMNOmanager patient administration system, have the installation performed by a Löwenstein Medical product specialist or a person so authorized by Löwenstein Medical.

1. Start Windows®

or

exit current programs.

Note:

you need administrator rights to install SOMNOlab for SOMNOcheck micro.

- 2. Check whether the system requirements are met.
- 3. Put in the CD-ROM.

 The installation program starts automatically.
- 4. Select the installation language.
- 5. Follow the instructions in the installation program.
- Click on Complete to exit the installation program.SOMNOlab for SOMNOcheck micro is installed on the PC.
- 7. Restart the PC to adopt the settings of SOMNOlab for SOMNOcheck micro.
- 8. If necessary: select a different <u>language</u> for the user interface.

If you have any questions or problems, the <u>Löwenstein Medical hotline</u> (0800 9600 204) is available.

3.2 Uninstall SOMNOlab for SOMNOcheck micro

- 1. In Windows®: select Start | Control Panel | Software.
- 2. Select SOMNOlab for SOMNOcheck micro in the selection list.
- Click on Remove. SOMNOlab for SOMNOcheck micro will be removed from the PC.

3.3 Start SOMNOlab for SOMNOcheck micro

1. Select Start | Programs | Weinmann | SOMNOlab for SOMNOcheck micro

or



3.4 Shut down SOMNOlab for SOMNOcheck micro

1. Select File | Shut down

or



2. If necessary: save recording. SOMNOlab for SOMNOcheck micro shuts down.

3.5 Call up the User Manual

1. In Windows®: call up Start | Programs | Weinmann | Manual | English | Manual.

or

in SOMNOlab for SOMNOcheck micro: select ? | Manual.

The content of the User Manual is identical to that of Online Help.

3.6 Use Online Help

Call up Online Help

1. Select ? | Online Help

or

press F1.

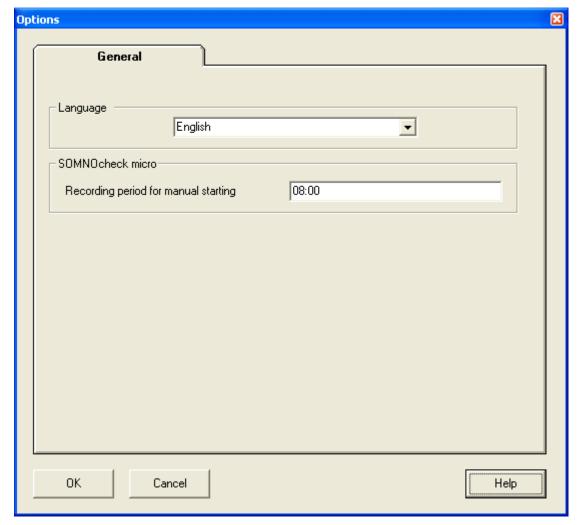
Print Help topic

- 1. Open Help text.
- 2. Click on Print in the button bar.
- 3. Select **Print selected topic** in the **Print topics** dialogue.
- 4. Click on OK.
- 5. Click on **OK** in the printer dialogue to start the print job.

The content of Online Help is identical to that of the <u>User Manual</u>.

3.7 Select language

1. Select Extras | Options.



2. Select language.

Note:

Windows Regional Options must match the selected language. The language of your operating system is set as the default.

For its display, SOMNOcheck micro adopts the language set for SOMNOlab for SOMNOcheck micro (for German, English, French and Italian).

- 3. Click on OK.
- 4. Restart SOMNOlab for SOMNOcheck micro to adopt the settings. SOMNOlab for SOMNOcheck micro starts in the selected language.

The following languages are available for the user interface of SOMNOlab for SOMNOcheck micro:

- German
- · English
- · French
- · Italian
- Russian

3.8 Use keyboard shortcuts

Keyboard shortcuts are assigned to frequently-used commands in SOMNOlab for SOMNOcheck micro.

General keyboard shortcuts

Keyboard shortcut	Function	
Alt + D	Open File menu	
Alt + A	Open View menu	
Alt + X	Open Extras menu	
Alt +?	Open ? menu	
Ctrl + S	Save recording	
Ctrl + P	Print report	
F1 Call up Online Help		

Key combinations for navigating between events

Key combinations	Function	
Alt + right arrow	Switch to next event in active channel	
Alt + left arrow	Switch to previous event in active channel	
Alt + Home	Switch to first event in active channel	
Alt + End	Switch to last event in active channel	
Alt + Page Down	Switch to next event in any channel	
Alt + Page Up	Switch to previous event in any channel	
Alt + up arrow	Switch to next event in channel above	
Alt + down arrow	Switch to next event in channel below	

4 General user information

This section provides you with the basic information you need to work with SOMNOlab for SOMNOcheck micro:

- · Start new recording
- Specify a recording duration for Manual start
- Import data
- · Open recording
- · Search for recording
- · Close recording
- · Call up recording data
- · Select visualization configuration
- Edit patient data
- · Create report
- · Recalibrate SOMNOcheck micro
- Set SOMNOcheck micro clock

4.1 Start new recording

Note

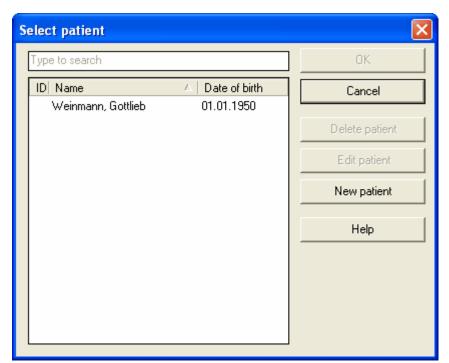
You can only configure a CARDIO-compatible SOMNOcheck micro using SOMNOlab for SOMNOcheck micro. You can see this from the heart in the Start screen of the device.

If you program a new recording, the data in SOMNOcheck micro are deleted.

Always connect only one diagnosis device to the PC when you start a recording.

1. Select File | New recording





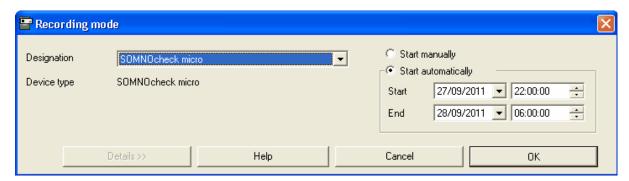
2. Select a patient in the **Select patient** window.

Note

You can use the search field above the Patient list to search for a patient with the aid of the following data:

- · patient ID
- · first name
- · last name
- · date of birth
- combination of patient ID/first name/last name/date of birth

The **Recording mode** window appears:



3. If necessary: select recording mode under **Designation**.

Note

You can create a visualization configuration for a recording mode in SOMNOlab and open it with SOMNOlab for SOMNOcheck micro.

- 4. Select start setting: Start manually or Start automatically.
- 5. With the **Start manually** function: specify a recording duration for Manual start.
- 6. With the **Start automatically** function: select the start and end of the recording.

Note

With SOMNOcheck micro, a recording lasts a maximum of 12 hours.

If you have programmed a start time using the **Start automatically** function, you can no longer start the recording on the device manually. To do this, select the **Start manually** function in SOMNOlab for SOMNOcheck micro or clear the data in the device (see instructions for use).

7. Click on OK.

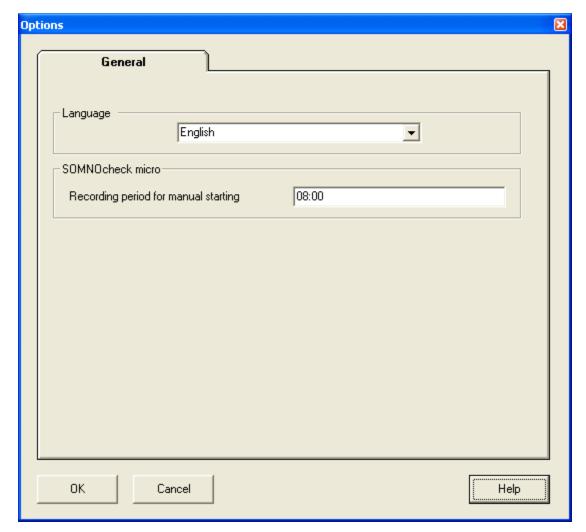
Depending on the Start setting, recording starts when you press the key on the device (**Start autmatically**) or automatically at the specified start time (**Start automatically**).

4.2 Specify a recording duration for Manual start

Note

You can only configure a CARDIO-compatible SOMNOcheck micro using SOMNOlab for SOMNOcheck micro. You can see this from the heart in the Start screen of the device.

1. Select Extras | Options.



2. Enter a recording duration for Manual start.

Note

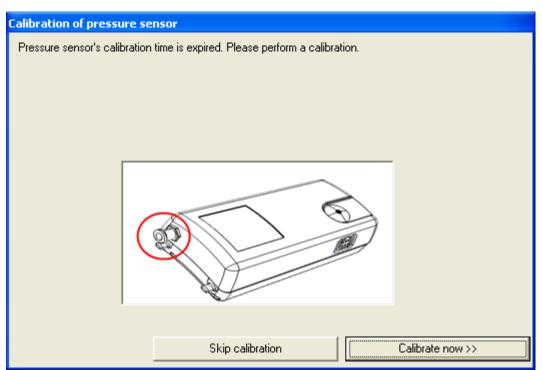
With SOMNOcheck micro, a recording lasts a maximum of 12 hours.

- 3. Click **OK**. Restart SOMNOlab for SOMNOcheck micro to adopt the settings.
- 4. Press the key on the device.
- 5. Keep the key depressed for at least 4 seconds to start recording.

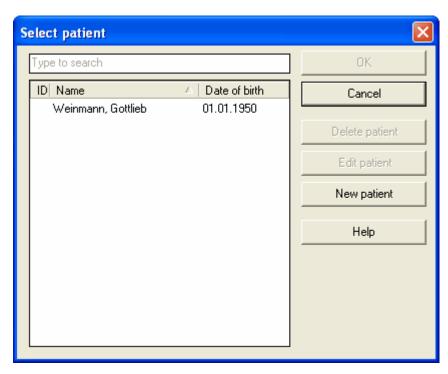
4.3 Import data

- Connect SOMNOcheck micro device to the PC using the USB cable.
 The device switches on. The drivers for the device are installed when the device is connected to the PC for the first time.
- 2. If the device is connected to the PC and has not been used for 5 minutes: switch on device.
- 3. Start SOMNOlab for SOMNOcheck micro.
- 4. Select File | Import data





5. When the Calibration of pressure sensor window appears: Recalibrate SOMNOcheck micro.



6. If the device is not personalized: select a patient in the **Select patient** window.

Note

You can use the search field above the Patient list to search for a patient with the aid of the following data:

- · patient ID
- · first name
- · last name
- · date of birth
- · combination of patient ID/first name/last name/date of birth
- 7. If necessary: click on **Delete patient** to delete the patient.
- 8. If necessary: click on **Edit patient** or **New patient** to edit patient or create a new patient.
 - 9. Click on OK.

The data are imported and the recording appears.

Note:

the first 15 minutes of a recording (time taken to fall asleep) are always marked as an artefact and shown, but not analysed.

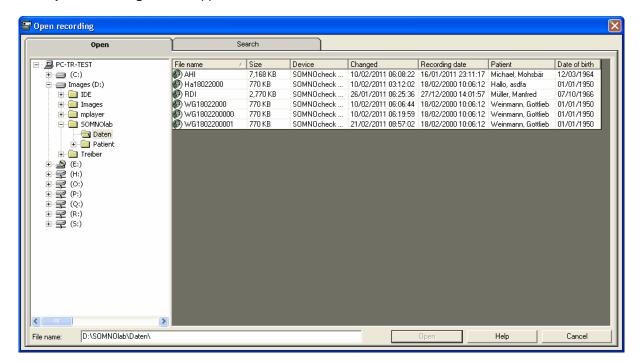
4.4 Open recording

1. Select File | Open recording

or



The **Open recording** window appears:



2. Select recording.

Note:

only files created with SOMNOcheck micro are displayed.

3. Click on Open

or

double-click on the file. The selected recording appears.

Note:

the first 15 minutes of a recording are always marked as an artefact and shown, but not analysed.

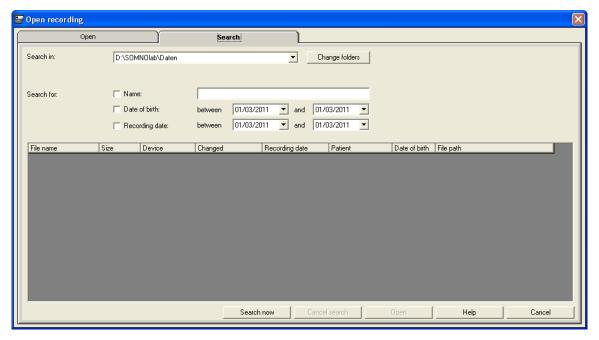
4.5 Search for recording

1. Select File | Open recording

or



The **Open recording** window appears.



- 2. Select the Search tab.
- 3. Enter information about the recording.
- 4. Click on Search now.

4.6 Save recording

1. Select File | Save recording



4.7 Close recording

1. Select File | Close recording





The recording is closed.

4.8 Call up recording data

1. Select View | Patient data

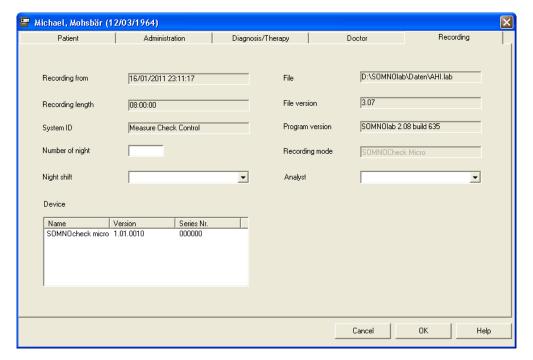
or



Note:

these patient data are saved with the recording and may deviate from the patient data in Patient Administration (on <u>data import</u>).

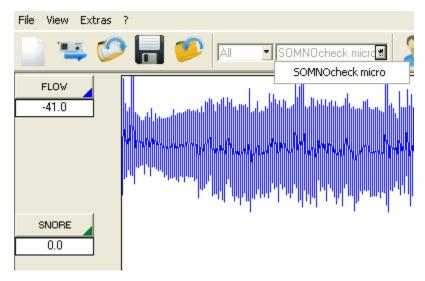
Select the **Recording** tab.The **Recording** tab displays all information about the recording:



3. Click on OK.

4.9 Select visualization configuration

1. Open recording.



2. Select Visualization configuration in the button bar.
The recording is displayed with the visualization configuration selected.

Note

You cannot edit visualization configurations in SOMNOlab for SOMNOcheck micro, but only open visualization configurations you have created using SOMNOlab.

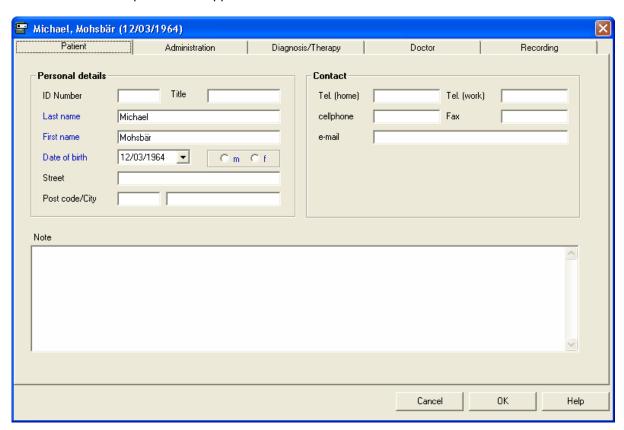
All the visualization configurations with "SOMNOcheck micro" in the name are displayed.

4.10 Edit patient data

1. Select View | Patient data

or





- 2. Enter patient data or change existing patient data on the **Patient** tab.
- 3. If necessary: enter further data on the other tabs.
- 4. Click on OK.

Restrictions for patient and recording data

Field	Max. characters	Description
Patient		
ID number	35	Identification number of patient
Title	70	Title of patient
Last name	70	Last name of patient
First name	70	First name of patient
Date of birth	10	Date of birth of patient
Sex	1	Sex of patient
Street	70	Street
Postcode	10	Postcode
City	70	Town of residence
Tel. (home)	30	Patient's home telephone number
Tel. (work)	30	Patient's work telephone number
cellphone	30	Patient's mobile telephone number
Fax	30	Fax number of patient
e-mail	70	e-mail address of patient
Note	2000	Notes
Administration	1	
Employer	70	Patient's employer
Insured party number	50	Patient's insurance number
Insured party status	50	Insurance status of patient
Insurance number	50	Number of patient's medical insurance company
Insurance company	70	Name of patient's medical insurance company
Clerk	70	Contact at patient's medical insurance company
Telephone (clerk)	70	Telephone number of contact at patient's medical insurance company
Street	70	Street
Postcode	10	Postcode
City	70	Town of residence
Telephone	70	Telephone number of medical insurance company
Fax	30	Fax number of medical insurance company

Field	Max. characters	Description		
Diagnosis/therapy				
Weight	3	Weight of patient (1 kg to 600 kg)		
Height	3	Height of patient (50 cm to 250 cm)		
BMI	6	Body mass index of patient (calculated)		
Broca Ind.	6	Broca index of patient (calculated)		
Blood pressure	10	Blood pressure of patient (10 mmHg to 300 mmHg)		
Basic saturation	10	Oxygen saturation of patient in spot test (50 % to 100 %)		
Findings	7000	Text on findings		
Code	10	Code for finding		
Medication	500	Medication		
Notes	2000	Notes		
Doctor				
Clinic	70	Hospital in which the treating doctor works		
Department	70	Department in which the treating doctor works		
Name	100	Name of treating doctor		
Street	70	Street		
Postcode	10	Postcode		
City	70	Town of residence		
Tel.	30	Telephone number of treating doctor		
cellphone	30	Mobile phone number of treating doctor		
Fax	30	Fax number of treating doctor		
e-mail	70	e-mail address of treating doctor		
Name of facility	70	Name of facility providing pre-treatment and follow-up treatment		
Referring doctor	70	Name of referring doctor		
Street	70	Street		
Postcode	10	Postcode		
City	70	Town of residence		
Tel.	30	Telephone number of referring doctor		
cellphone	30	Mobile phone number of referring doctor		
Fax	30	Fax number of referring doctor		

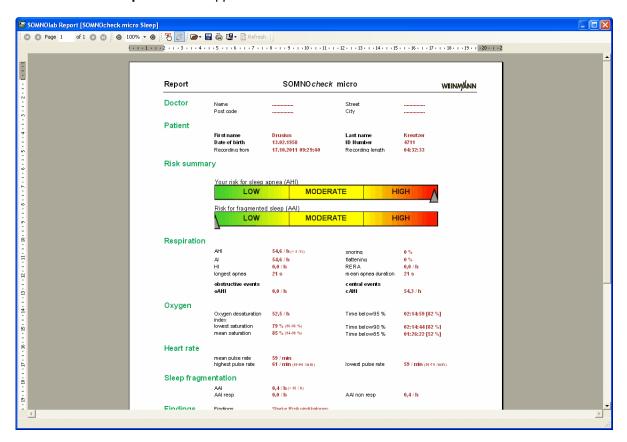
Field	Max. characters	Description
e-mail	70	e-mail address of referring doctor
Recording		
Number of night	5	Number of examination night (1 to 32000)
Night shift	30	Name of person on night shift
Analyst	70	Name of analyst

4.11 **Create report**

1. Select View | Reports



The **SOMNOlab Report** window appears:



2. Click on to select a report template from the selection list.

3. If necessary: double-click on the report with the left-hand mouse key to enlarge a section or doubleclick with the right-hand mouse key to shrink it

or

use the Zoom tools.

4. If necessary: click on to select and change elements in the report.

Note:

you can edit doctor and patient data and findings. You can save doctor data in a report template. Patient data and findings are saved in the recording.

- 5. If necessary: click on to export the report as a PDF, RTF or CSV.
- 6. If necessary: click on et to print report.

Note:

the report templates are optimized for the A4 paper format.

Create report template

You can compile your own templates with doctor data already filled in.

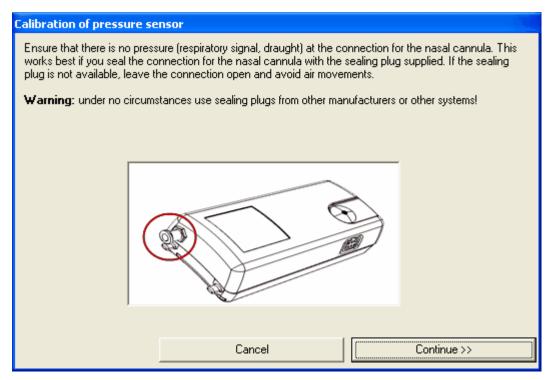
- 1. Just click once on for the first report to select and change elements in the report.
- 2. Select elements and enter doctor data.
- 3. Click on to save the new report template.
- 4. Select a name for the report template.
- 5. If necessary: repeat the previous steps to create several report templates.

Evaluation of the SOMNOcheck micro report

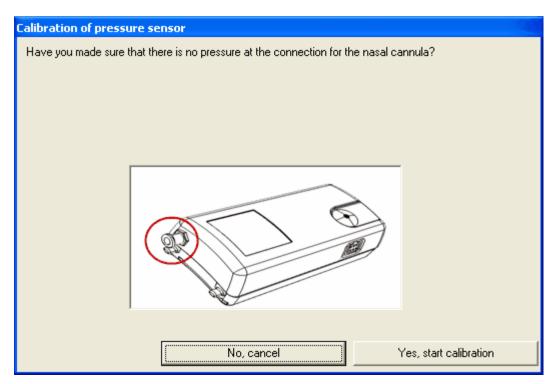
There are three types of report for SOMNOcheck micro.

4.12 Recalibrate SOMNOcheck micro

- Connect SOMNOcheck micro device to the PC using the USB cable.
 The device switches on. The drivers for the device are installed when the device is connected to the PC for the first time.
- 2. If the device is connected to the PC and has not been used for 5 minutes: switch on device.
- 3. Start SOMNOlab for SOMNOcheck micro.
- 4. Select Extras | Calibration of SOMNOcheck micro.



- 5. Seal the connection for the nasal cannula using the plug supplied.
- 6. Click on Continue.



7. If there is no pressure at the nasal cannula connection: click **Yes**, **start calibration**. The pressure sensor is calibrated. This process can take up to 30 seconds.



8. If the pressure sensor has been recalibrated successfully: click on **Continue** to exit SOMNOcheck micro recalibration.



- 9. If the pressure sensor has not been calibrated successfully: click on **Retry** to repeat the process.
- 10.If another attempt is unsuccessful: contact <u>Löwenstein Medical</u> or your specialist dealer.

4.13 Set time of SOMNOcheck micro

Note:

Always set the clock before the first recording or if you have stored the device for an extended period without batteries/rechargeable batteries.

- 1. Check PC clock time. If necessary: set PC clock time.
- Connect SOMNOcheck micro device to the PC using the USB cable. The device switches on. The drivers for the device are installed when the device is connected to the PC for the first time.
- 3. If the device is connected to the PC and has not been used for 5 minutes: switch on device.
- 4. Start SOMNOlab for SOMNOcheck micro.
- Select Extras | Set time of SOMNOcheck micro.
 The SOMNOcheck micro clock is set to current PC time.
- 6. Click on OK.

5 Edit recording

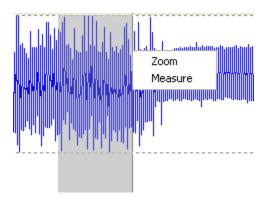
This section describes how to edit recordings.

- · Measure duration
- · Display signal parameters
- Edit events
- Change time basis
- · Change time display
- Zoom

5.1 Measure duration

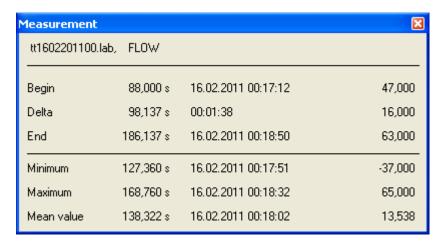
- 1. Open recording.
- 2. Mark the start of the period to be measured with the left-hand mouse key.
- 3. Hold down the mouse key and drag the cursor to the end of the period to be measured. The cursor indicates the duration of the current period marked.

4. Release the mouse key. The context menu appears:



5. Click on Measure.

The **Measurement** window appears:



The window displays the following values:

- · start time
- · end time
- · minimum/maximum of the measured data in the marked period and associated points in time
- · mean value
- · time difference (delta)

Note:

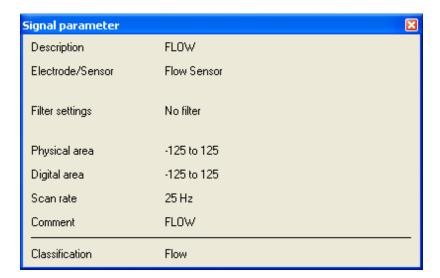
if the difference between the start and end of measurement is less than 4 seconds, SOMNOlab for SOMNOcheck micro outputs the delta value in Hz. If the difference is greater than 4 seconds, it outputs the delta value in seconds.

5.2 Display signal parameters

- 1. Open recording.
- 2. Right-click on a channel. The context menu appears:

Signal parameter...

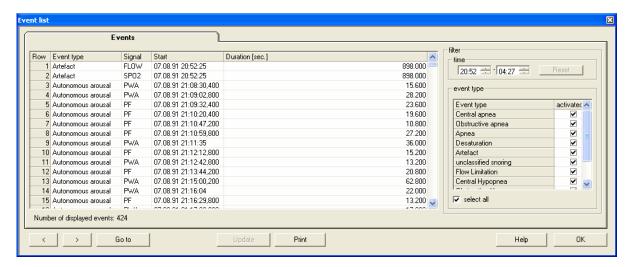
3. Click on **Signal parameter**. The **Signal parameter** window appears:



5.3 Edit events

Display events

- 1. Open recording.
- 2. Select View | Event list.
 The Event list window appears:



3. Double-click an event or mark event and click on **Go to** to display it in the channel view.

Note:

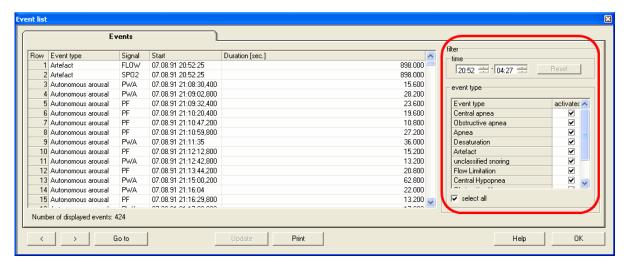
if you double-click on adjacent or overlapping events, a different event may also be marked.

Sort events

- 1. Open recording.
- 2. Select View | Event list.
- 3. Click on the heading of the column to be sorted. The column is sorted.

Filter events

- 1. Open recording.
- Select View | Event list.The Event list window appears:



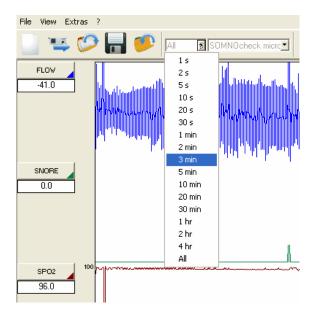
- 3. In the **time** box, enter a start and end time to show the events for a particular period.
- 4. If necessary: reset the period to the original setting using Reset.
- 5. In the **event type** box, insert or remove a tick for **activated** to display particular types of event or not.
- 6. Click on **Update** to apply the filters **time** and/or **event type**.

Events and artefacts

Events and artefacts mutually affect one another in terms of how they are displayed.

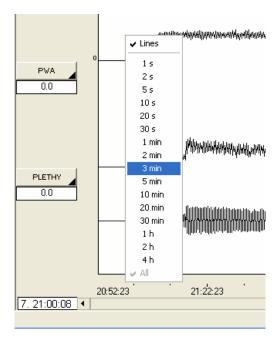
5.4 Change time basis

- 1. Open recording.
- 2. Set the time basis in the button bar



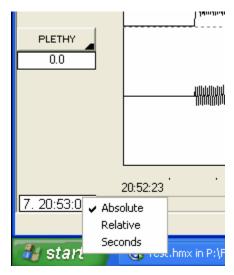
or

right-click on the time field under the channel view and set time basis there.



5.5 Change time display

- 1. Open recording.
- 2. Right-click on the time display field to the bottom left below the channel view. The context menu appears:



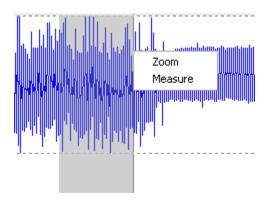
3. Change the time display in relation to the current position of the mouse pointer.

Type of time display	Explanation
Absolute	Day and time of current position of mouse pointer
Relative	Hours, minutes and seconds from start of recording to current position of mouse pointer
Seconds	Seconds from start of recording to current position of mouse pointer

5.6 Zoom

To zoom horizontally

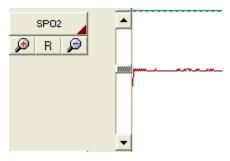
- 1. Open recording.
- 2. Mark the start of the period to be zoomed with the left-hand mouse key.
- 3. Hold down the mouse key and drag the cursor to the end of the period to be measured. The cursor indicates the duration of the current period marked.
- 4. Release the mouse key. The context menu appears:



5. Click on **Zoom**. The marked period is shown enlarged.

To zoom vertically

1. Open recording.



2. Click on the name of a channel. The zoom symbols appear.

3. Zoom channel:

Symbol	Explanation
₽	Enlarge vertical resolution of signal
	Reduce vertical resolution of signal
R	Restore default setting

6 Additional information and explanations

This section gives you additional information about SOMNOlab for SOMNOcheck micro:

- · Events and artefacts
- · Evaluating the report

6.1 Events and artefacts

From the signals measured, SOMNOcheck micro calculates further signals which SOMNOlab for SOMNOcheck micro displays in individual channels. SOMNOcheck micro measures using 2 sensors, for example, but provides 6 signals for the display: the nasal cannula measures respiratory flow (flow rate) and snoring. The finger clip measures SPO2 and plethysmogram (blood flow). The device uses the plethysmogram to calculate pulse frequency (PF) and pulse wave amplitude (PWA).

The system derives events from both measured and calculated channels. Passages in the signal which cannot be evaluated are marked as an artefact. Artefacts may be in conflict with other events. There are three options.

- Exclusion with deletion: Events such as apnoeas and hypopnoeas exclude artefacts and vice versa. If a hypopnoea is detectable in the flow channel, for example, then it must be possible to evaluate the channel, so it must be artefact-free. Conversely, a hypopnoea cannot be detectable during the period with an artefact. If a new event is marked, the old one is permanently deleted.
- Tolerance: Events such as "flow limitation" or "periodic desaturation" may extend over long periods and consequently do not contradict brief signal disturbances. They may consequently overlap or enclose artefacts.
- Masking: In order to keep the events display clear and sensible, many events are not shown in the channel from which they were obtained.

Event	Obtained from channel	Displayed in channel
Autonomic Arousal	SPO2	PWA or PF
Respiratory Disturbance	SPO2	Flow Rate
Snoring Event	Flow rate (nasal cannula)	Snore

If an artefact is detected in the channel of origin of these events, the display for the events originating from this area is deactivated. An artefact in the SPO2 channel, for example, masks the autonomic arousals in the PF and PWA channel which overlap it in time. Masked events do not contribute to the evaluation, are displayed as dotted lines and are not kept in the events list. This is reversible, however: if the masking artefact is reduced or deleted, the previously masked events are reactivated.

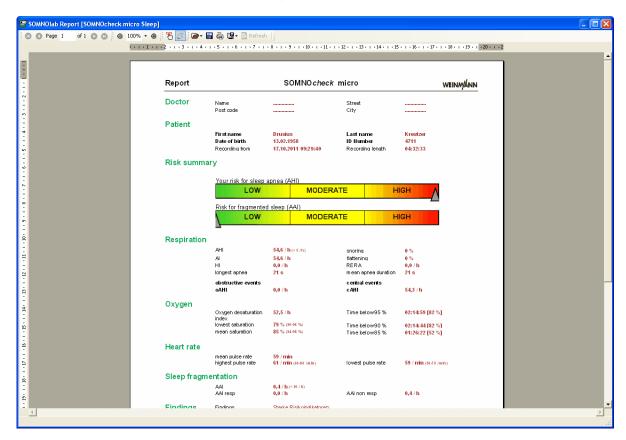
This gives you the opportunity of correcting the analysis results of the measuring device without losing the analysis results in the process.

6.2 Evaluating the report

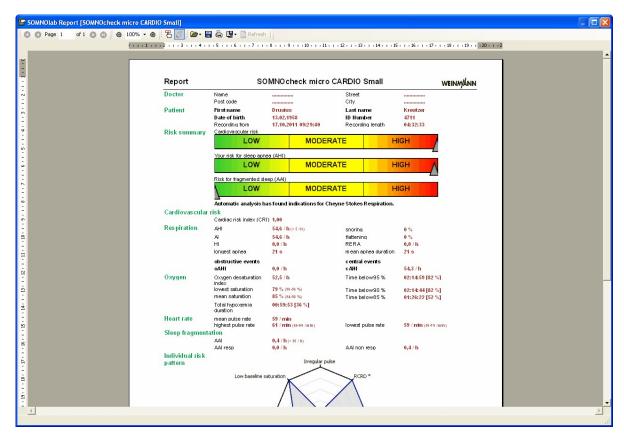
This section provides you with options to improve report evaluation. There are three types of report:

- SOMNOcheck micro report
- short SOMNOcheck micro CARDIO report
- detailed SOMNOcheck micro CARDIO report

SOMNOlab for SOMNOcheck micro report



Explanations about the individual parameters can be found in the glossary.



Short and detailed SOMNOcheck micro CARDIO report

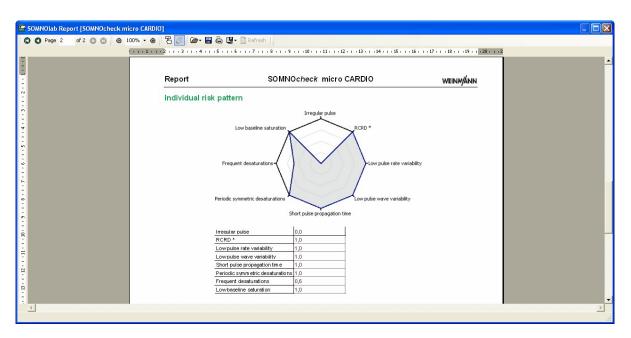
The short and the detailed SOMNOcheck micro CARDIO report contain the same information as the SOMNOcheck micro report. They also contain information about the <u>risk indicators</u> for increased cardiovascular risk which have occurred to a severe and moderate degree during a recording (see first column in the table below). Risk indicators which occurred to a slight degree are not listed in either report. The physiological background to the risk indicators and recommendations on how to proceed can be found in the table below.

Risk indicator	Pathophysiological background and possible aetiology	Recommended action
RCRD Reduced chronotropic reaction to desaturations	May be consequence of normal ageing. May indicate influence of medication, coronary artery disease, diabetes mellitus or advanced disease of the respiratory tract.	Check medication. Consider specific diagnostic procedures.
Low pulse rate variability	May be consequence of normal ageing. May accompany autonomic neuropathy (e.g. diabetes mellitus), medication (ß-blockers), coronary artery disease or hypertension.	Check medication and clinical symptoms. Consider specific diagnostic procedures.
Low pulse wave variability	May be consequence of normal ageing. May indicate vascular disease (e.g. autonomic neuropathy, diabetes	Check medication and clinical symptoms. Consider specific diagnostic procedures.

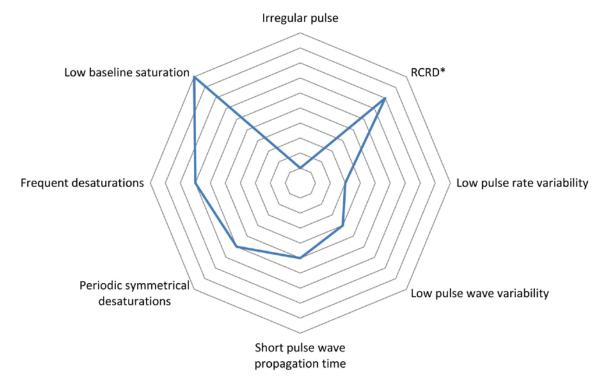
Risk indicator	Pathophysiological background and possible aetiology	Recommended action
	mellitus, advanced vascular disease) or be a consequence of drug treatment.	
Short pulse wave propagation time	May be consequence of normal ageing. Indicates high arterial stiffness (e.g. in hypertension, hyperlipidaemia, generalized atherosclerosis, PAOD).	Check specific clinical symptoms. Consider specific diagnostic procedures (e.g. for diseases such as coronary artery disease or PAOD).
Periodic symmetrical desaturations	Specific desaturation pattern indicative of central respiratory disorders such as Cheyne-Stokes respiration.	Check disease-specific symptoms such as cardiac and CNS function. Check medication. Consider specific diagnostic procedures (sleep diagnostic test).
Frequent desaturations	Obstructive and/or central sleep apnoea, nocturnal hypoventilation, advanced pulmonary disease, respiratory failure.	Check specific clinical symptoms. Consider specific diagnostic procedures (sleep diagnostic test, pulmonary function, blood gases).
Low baseline saturation	Respiratory failure due to advanced pulmonary disease (e.g. in COPD, hypoventilation syndrome, severe sleep apnoea).	Check disease-specific symptoms. Consider specific diagnostic procedures (nocturnal polygraphy, pulmonary function, blood gases).
Irregular pulse	High likelihood of arrhythmia (e.g. atrial fibrillation, ventricular extra beats), cardiac disease.	Check for artefacts in the pulse wave signal. Check disease-specific symptoms incl. cardiac function. Consider specific diagnostic procedures (diagnostic procedures from cardiology incl. ECG and/or Holter ECG).

Note:

The following parameters are not calculated in the event of an arrhythmia AFib. warning: Reduced chronotropic reaction to desaturations (RCRD), low pulse rate variability, low pulse wave variability, short pulse wave propagation time.



The risk pattern for a patient in the form of a radar chart is found only in the detailed SOMNOcheck micro CARDIO report:



The outer area of the radar chart indicates a high risk, whilst the inner area represents a low risk. The larger the circumscribed area, the greater the risk. The precise values of the individual risk indicators of the radar chart can be found in the detailed report as well as in a separate table below the radar chart.

7 Function check

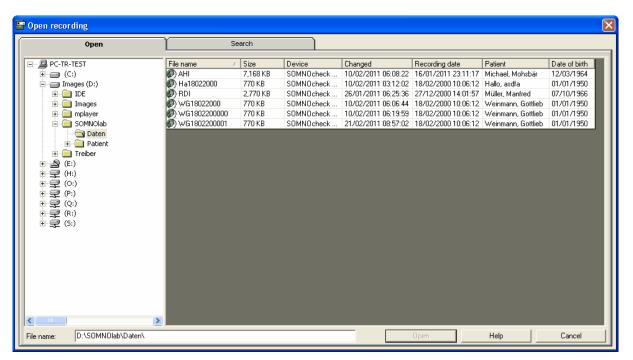
You can test the functions of SOMNOlab for SOMNOcheck micro with the aid of the demo files on the CD:

- 1. Copy the demo files to subdirectory C: | Documents und Settings | All Users | Weinmann | Daten
- 2. Decompress the demo files.
- 3. Start SOMNOlab for SOMNOcheck micro.
- 4. Select File | Open recording

or



The **Open recording** window appears:



- 5. Select C: | Documents und Settings | All Users | Weinmann | Daten.
- 6. Double-click the **Demo** file.

SOMNOlab for SOMNOcheck micro is working correctly if the file is opened and displayed.

8 Technical data

Specification	Product
Product class in compliance with 93/42/EEC	lla

9 Scope of supply

WM 98500: SOMNOlab PC software

For compatible accessories, see instructions for use for SOMNOcheck micro.

10 Declaration of conformity

Löwenstein Medical Technology GmbH + Co. KG hereby declares that the product complies with the relevant provisions of Directive 93/42/EEC pertaining to medical devices. The full text of the declaration of conformity can be found at: www.loewensteinmedical.de.

11 Glossary

Parameters	Explanation	Meaning
RDI	Respiratory Disturbance Index	Number of apnoeas and hypopnoeas per hour within the artefact-free evaluation time of the pulsoximetry signal
AAI	Autonomous Arousal Index	Number of autonomous arousals per hour within the artefact-free analysis time of the pulsoximetry signal. This parameter is not displayed in the event of an arrhythmia (AFib) warning.
АНІ	Apnoea/Hypopnoea Index	Number of apnoeas and hypopnoeas per hour within the artefact-free analysis time of the flow signal
Al	Apnoea Index	Number of apnoeas per hour within the artefact-free analysis time of the flow signal
HI	Hypopnoea Index	Number of hypopnoeas per hour within the artefact-free analysis time of the flow signal
Flattening (event)	Flow limitation	Flow limitation (also called "flattening") is a respiratory event which can be detected visually in the flow channel in the form of flattening. It is accompanied by a reduction in flow rate per unit of time.
Flattening (report)		Proportion of time with flattening in the artefact-free time of the flow signal

Parameters	Explanation	Meaning
Apnoea		Cessation of respiration
Hypopnoea		Reduction in respiratory flow
oRDI	Obstructive Respiratory Disturbance Index	Number of obstructive apnoeas and hypopnoeas per hour within the artefact-free analysis time of the pulsoximetry signal
cRDI	Central Respiratory Disturbance Index	Number of central apnoeas and hypopnoeas per hour within the artefact-free analysis time of the pulsoximetry signal
AAI resp	Respiratory Autonomous Arousal Index	Number of autonomous arousals per hour within the artefact-free analysis time of the pulsoximetry signals caused by a respiratory event. This parameter is not displayed in the event of an arrhythmia (AFib) warning.
AAI non resp	Non-respiratory Autonomous Arousal Index	Number of autonomous arousals per hour within the artefact-free analysis time of the pulsoximetry signals not caused by a respiratory event. This parameter is not displayed in the event of an arrhythmia (AFib) warning.
RERA	Respiratory Effort Related Arousal Index	Number of autonomous arousals per hour within the artefact-free analysis time of the pulsoximetry signals caused by increased respiratory effort. This parameter is not displayed in the event of an arrhythmia (AFib) warning.
Time with good flow signal quality		The diagnostic nasal cannula provided good signal quality for this length of time. If the recording lasts less than 0.5 h, some values from the report and the display, e.g. RERA and AHI, are omitted (the latter is replaced by the RDI).
Time with good pulse signal quality		The pulsoximetry sensor provided good signal quality for this length of time. If the recording lasts less than 0.5 h, the corresponding values are omitted from the report and the display. If the recording lasts less than 2 h, all CARDIO values are omitted from the report and the display.
Time with good flow and pulse signal quality		The diagnostic nasal cannula and the pulsoximetry sensor provided good signal quality for this length of time.
Time with good flow or pulse signal quality		The diagnostic nasal cannula or the pulsoximetry sensor provided good signal quality for this length of time. If the recording lasts less than 0.5 h, no analysis is possible, repeat the measurement. If the recording lasts less than 2 h, all CARDIO values are omitted from the report and the display.
Arrhythmia (AFib)		SOMNOcheck micro and SOMNOcheck micro CARDIO use pulse rhythm to detect whether there is atrial fibrillation. A corresponding warning appears in the device display and in the report. If this is the case, the pulse wave severely disrupted by the arrhythmia cannot display the following measurement results: AAI, AAI resp, AAI non resp, RERA. This parameter is displayed only in a

Parameters	Explanation	Meaning
		CARDIO-compatible SOMNOcheck micro (only if found).
Cheyne-Stokes respiration		SOMNOcheck micro CARDIO detects the presence of Cheyne-Stokes respiration and issues the appropriate warning in the report. Cheyne-Stokes respiration is a periodic breathing pattern with alternating hyperventilation and hypoventilation up to and including central apnoea. It frequently occurs in patients with cardiac insufficiency. This parameter is displayed only in a CARDIO-compatible SOMNOcheck micro (only if found).
CRI	Cardiac Risk Index	The Cardiac Risk Index shows the extent of cardiovascular risk. The CRI has values between 0 and 1 and is accordingly based on the risk SCORE as per ESC/ESH.
Risk indicator		The risk indicators in the SOMNOcheck micro CARDIO report show which measuring parameters or combinations of measuring parameters have led to an increased cardiovascular risk. If the corresponding measuring parameters have occurred to only a moderate degree, they are listed in the report under the heading "Risk factors which occurred to a moderate degree". Measuring parameters or combinations of measuring parameters which apply to a severe degree appear under "Severe risk indicators".
		The possible physiological background for all risk indicators is explained and subsequent diagnostic steps are recommended in the table with the risk indicators. This table can be found in the ? menu of the SOMNOlab for SOMNOcheck micro PC software.
Hypoxaemia		Total episodes in which an SpO2 of 90 % was undershot for at least 5 minutes. This parameter is displayed only in a CARDIO-compatible SOMNOcheck micro.
Risk pattern		The patient's risk pattern is displayed in the detailed SOMNOcheck micro CARDIO report in the form of a radar chart. This is the extent of individual measuring parameters measured directly by the device. There is a table with a more detailed explanation in the ? menu of the SOMNOlab for SOMNOcheck micro PC software.
CARDIO- compatible SOMNOcheck micro		A CARDIO-compatible SOMNOcheck micro behaves like a SOMNOcheck micro when operated with a SOMNOcheck micro sensor. In addition, several languages and arrhythmia (AFib.) are available and the device can be configured. If a CARDIO-compatible SOMNOcheck micro is operated with a SOMNOcheck micro CARDIO sensor, it has the CARDIO functions of the SOMNOcheck micro CARDIO (CRI with subparameters and Cheyne-Stokes). The CARDIO-compatible SOMNOcheck micro can be seen from the heart symbol in the Start screen when the device is switched on.

12 Contact data

In the event of questions or technical issues, please contact Löwenstein Medical Customer Service:

Löwenstein Medical Technology GmbH + Co. KG		
Address	Postfach 54 02 68, 22502 Hamburg, Germany	
	Kronsaalsweg 40, 22525 Hamburg, Germany	
Telephone (for replacement part orders)	+49 40 54702-101	
Fax (for replacement part orders)	+49 40 54702-660	
Hotline (for technical	01804 76 66 65 (24 hours, 7 days a week, chargeable)	
issues)	0800 7852190 (during office hours, no charge)	
e-mail	Medelo-service@hul.de	
Internet	http://www.loewensteinmedical.de	

If repairs are required, send SOMNOcheck micro devices and all accessories to:

Löwenstein Medical Technology GmbH + Co. KG	
Address	Postfach 54 02 68, 22502 Hamburg, Germany
	Kronsaalsweg 40, 22525 Hamburg, Germany

C€ 0197

