Instruction manual

Stationary
Headbox

Rev. 1

12.11.2019

Inhaltsverzeichnis

Preamble

We are pleased that you chose our product. We are constantly working on updates and improvements and new releases of the Bluetooth Application are available free of charge for our customers.

Any comments and suggestions you wish to make regarding the improvement of this Instruction Manual will be much appreciated.

Our Telephone-Hotline assures daily competent help and advice from:

9:00 – 17:00   +49 (0) 9 31 / 35 90 94 994

Our Mobile-Phone-Hotline assures daily competent help and advice in case of emergency and urgent technical problems*:

7:00 –   9:00   +49 (0) 1 72 / 6 75 69 90

17:00 – 24:00   +49 (0) 1 72 / 6 75 69 90

* If due to technical difficulties our staff is not available, you will be redirected to our mail box. If that is the case, please leave your name and telephone number so that we can call you back as soon as possible.

Notice:

This manual is valid in connection with the manuals of SOMNOscreen plus and the DOMINO software. Please pay attention to the safety instructions mentioned there!

1 About the stationary headbox

1.1 Intended use

The stationary headbox is intended as a device for measuring EEG/EOG/ECG and EMG signals and recording the signals in association with the SOMNOscreen plus Tele (BT). The system is intended only for diagnostic purposes. It is not intended to be used in life-supporting situations or a monitoring device.

The headbox will typically be used for stationary routine EEGs. It can also be used as a portable device. The device must be initialized and operated by medical staff. Electrodes and sensors are applied on the patient by medical staff. The analysis and interpretation of data is carried out by a qualified physician.

1.2 Model and device number

SOMNOmedics GmbH
Am Sonnenstuhl 63
D-97236 Randersacker
Germany
KW03 2008

IP20

Type: SOMNOscreen™ plus
REF SSP704
SN 1200
FW: PSG+

3,7V 0,8W

CE 0297

📖	Read the instruction manual very carefully before you start working with the SOMNOscreen™ plus.
🧍	Protection Class: BF
⚠	Not protected against defibrillation
CE	The CE icon and the correlating number show that the headbox complies with the regulations for Medical Products.
IP20	This device complies with the **IP-Protection-Class "20".** This Classification states that the SOMNOscreen™ plus is **NOT** Waterproof.

⎓5V	This device works with a nominal 5 volts DC.
❽® ((•))	HF-transmitter with integrated Bluetooth-protocol.

2 Safety instructions

Please pay attention to the safety instructions in the SOMNOscreen plus manual!

In addition to the safety instructions in the SOMNOscreen plus manual, the following safety instructions apply:

For power supply, connect only the medical power supply provided by SOMNOmedics.

Conductive parts of the electrodes and their plug connection, including the neutral electrode, may not be in contact with other conductive parts including the ground.

On patients with cardiac pacemakers or other implanted stimulators, the active impedance analysis of all EXG channels may be affected and MUST be turned off in the Montage Editor Settings of the Domino software. Please see the instruction manual for the Domino software for details.
Avoid the use of Radio Transmitters and Receivers, High Frequency Devices, CB-Radio Systems, Cellular Phones, Microwave Ovens, etc. where the electrical field strength exceeds 10 V/m (correlating to IEC 601-1-2).
A minimal risk of injury through electric shock (limited to 3.3 volts and 180µA) may occur due to the use of defective cables when a ground lead is contacted to the patient. Check all cables and connections for damage before using this device. Damaged parts must be replaced immediately. Please contact SOMNOmedics or your SOMNOmedics Distributor.

This device complies with IP protection class "20". This means that this device is NOT waterproof.

If liquids do enter the system, DO NOT switch it on. Please send the device to SOMNOmedics Customer Services immediately.

Do not use an autoclave for cleaning the SOMNOscreen™ plus or any of its accessories, cables and sensors.

Follow the manufactures instructions when using disinfectants. Keep to the prescribed dose and contact time.

Use protective gloves when using aggressive disinfectant agents.

Only sensors supplied by SOMNOmedics and specified for use with the stationary headbox may be used with this unit.

3 Overview of functions

EKG

EMGs

EOGs

Ground

Reference

Power button of display

SOMNOscreen plus

Contact for SpO$_2$ plug
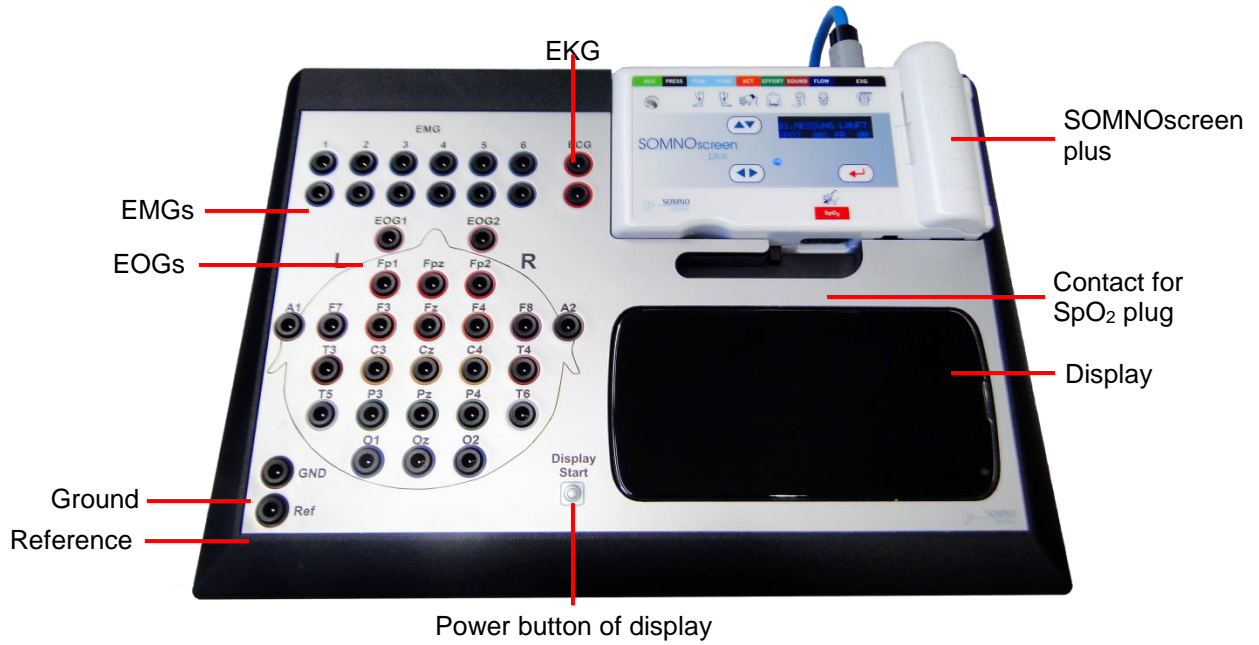
Display

3.1 Stationary Headbox - front

Contacts of SOMNOscreen

Contact for SpO$_2$

Contact for EEG cap

3.2 Stationary Headbox - back

4 Stationary and mobile use of the headbox

The display built into the headbox can be used for signal check during stationary and mobile use.

For stationary use, the SOMNOscreen plus and the SOMNOmedics app should be connected with a SOMNOmedics bluetooth receiver. This is the standard setting. The SOMNOscreen will transfer the data to the reciever, which will wire teh data to the PC and transfer them to the Bluetooth App at the same time for signal check.

Alternatively, the SOMNOmedics App can be connected directly with the SOMNOscreen plus. We recommend this setting for mobile use. In this case, the data will be stored on flashcard and be displayed on the display by the SOMNOmedics App.

Prior to using the app for signal control the following conditions are required:

1. The device/s has/have to be linked to the App.
2. The patient is fully wired, connected to the device and a <u>recording with active online-mode is running</u>.
3. To guarantee a clear presentation, please be sure to deactivate those channels in the montage, you don't need to be recorded.
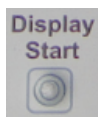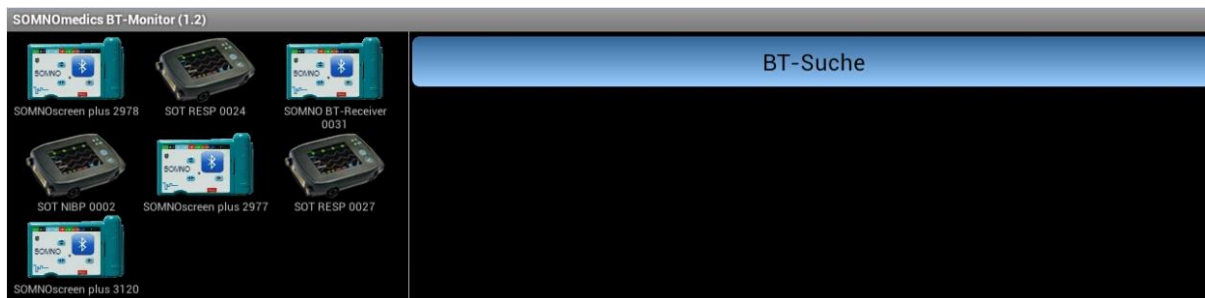
Push the button for a duration of ca. 3 seconds to activate the display. You will be shown the symbol of the SOMNOmedics app:
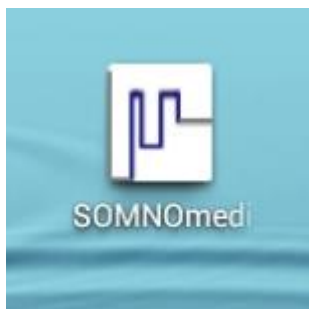
4.1 Icon SOMNOmedics App

Tap on the symbol for activating the App.

Devices that were linked to the App will be displayed on the left. Tapp on **„Search BT"**. A list of available SOMNOmedics devices with bluetooth will appear.

4.2 Start screen

## 4.1 Stationary use of the 32-channel headbox

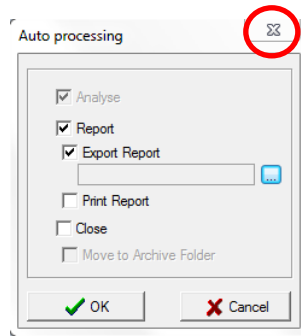## 4.1.1 Activating the SOMNOscreen plus via DOMINO

Start the online mode via the icon „Online" in the DOMINO panel. Read also the DOMINO manual for further information.

Montages can be defined in the montage editor . If you want to define an EEG montage, choose a montage for the EEG 32.

The following instructions describe a simple way of starting several short recordings in a row (e.g. for routine EEGs in the lab):

1. Start the first recording via the button „Online" in the DOMINO panel.
2. Stop the recording via Menu → File → Stop online-Mode → Yes, and stop device. The SOMNOscreen that was purchased together with the stationary headbox will stop the recording and stay in standby afterwards.
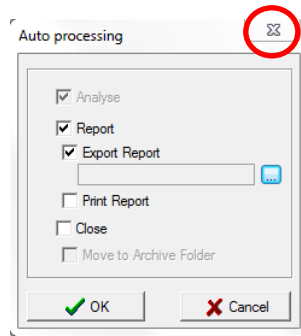
3. Close the box if you do not need a report at this time and if you would like to start another recording.

4. Click on Menu → File → Online Mode.
5. Confirm with Ok.
6. You will be automatically passed on the the start menu of the online mode.

4.1.2 Signal check on display

During stationary use, the SOMNOmedics bluetooth App should be connected to a SOMNOmedics bluetooth receiver. With this setting, you can record the data online on PC and conduct a signal check on the display in the headbox at the same time. This is the standard setting.

Configure this setting with the following steps:

Tap on the receiver with which the SOMNOscreen plus is connected.
 „Connecting…" will appear on the screen (Fig. 4.3).
As soon as the connection is established, the display will show **„Signals"** (see Fig.4.4).
Tap on **„Signals"**, the recorded channels will be displayed.
Please note that channels which are activated in the montage but where no sensor was connected will be displayed also.

Close the window of the app after signal check by tapping on .

4.2 Mobile use of the headbox

4.2.1 Manual start of the SOMNOscreen plus

If you use the headbox in a mobile setting and cannot start the recording via the DOMINO software, you can start the SOMNOscreen and headbox manually.
Connect the sensors to the Patient and then Switch on the **SOMNOscreen™ plus**.

Please Note:
The SOMNOscreen™ plus should only be turned on after the patient has been fully set up. The on button is found on the second "O" of the word SOMNOscreen™ plus.

Press the red arrow 4 times in order to manually start the recording.
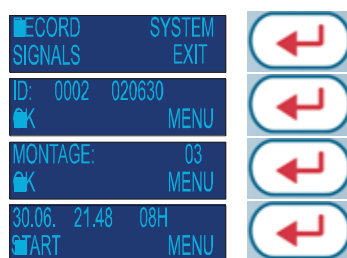
Fig. 4-1: Manual Start.

→ **A successful Start will be indicated by "01. Recording…" on the display!**

At the end of the recording, the device turns itself off automatically.

4.2.2 Signal check on display

For signal check, tap on the device (SOMNOscreen) on which the recording is running in the left-hand bar of the start screen.

"Connecting…" appears on the display.
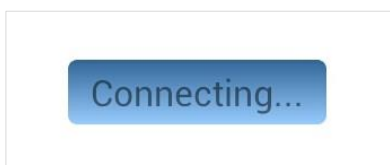
4.3 Display: Connecting

As soon as the app established the connection to the device, the display changes to **"Signals"**.

4.4 Display: Signals

Tap on **"Signals"** and all recorded channels are displayed.
Please note that all channels of the montage are displayed, no matter if you connected them or not.

4.3   Signals

Please note that the signals are displayed as raw data without smoothing.
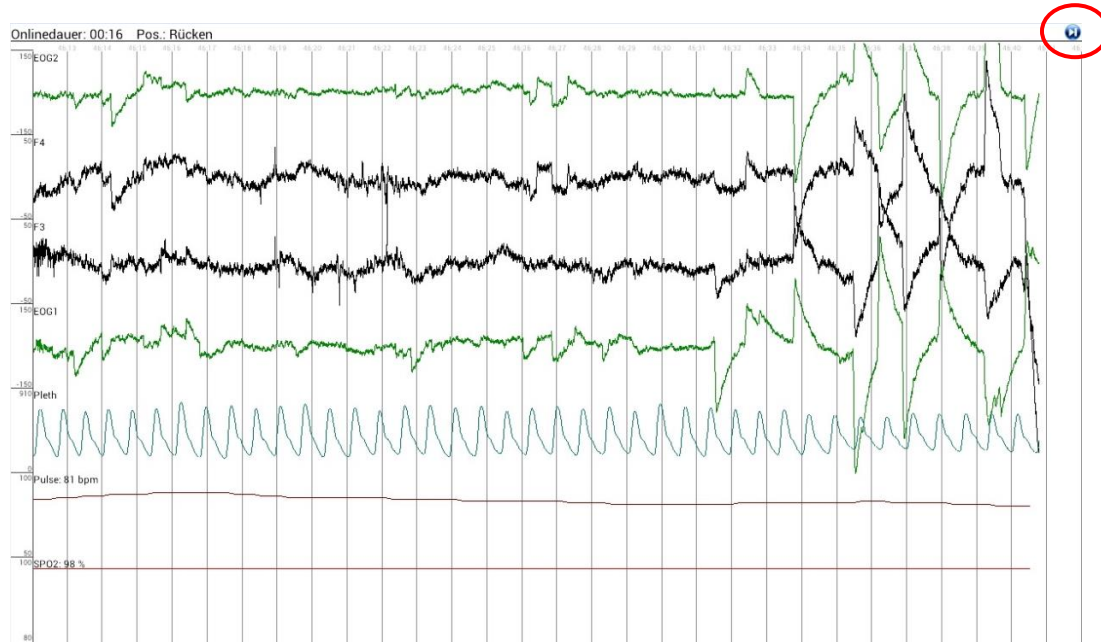
4.5 Complete signal view

The duration of the current connection between app and device is shown at the top left, as well as (if selected in the montage) the device- / patient-position, light intensity and capacity of the battery.

If you "stopped" the continuous display, you get to the end again via the blue button at the top right (red marking in Fig. 4.5).

Next to the "end" button you see the time basis of the current display.

With a short tap on a channel you get into the single- channel display where you can make several adjustments (see chapter 4.3.1 and 4.3.2).

The button on the upper right side offers the following options:

Select channels

Here you can select the channels/channel profiles to be displayed, invert signals or change the order of the channels. A tap on "Channel" de- / selects all channels. To shift a channel, tap on it until it appears shaded, then drag it to the desired position.

Time Basis

Here you can change the time basis of the display. Alternatively the time basis can be changed in the display itself: Tap on the display with two fingers side by side, keep the fingers on the display and move them apart from or towards each other to reduce or increase the time basis respectively.

Impedance Check
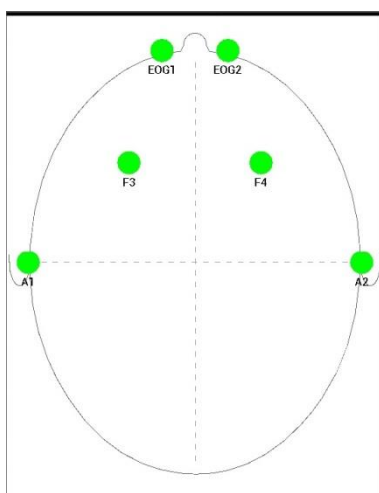
The impedance- check shows the colour coded signal quality of the EEG- channels (green = good quality ≤ 6 Ω, yellow = moderate quality, red = bad quality ≥ 15 Ω → please refit).

4.3.1 Adapt signal amplitude

If a signal exceeds the channel limits (see Fig. 4.6), you can adjust the signal as follows.
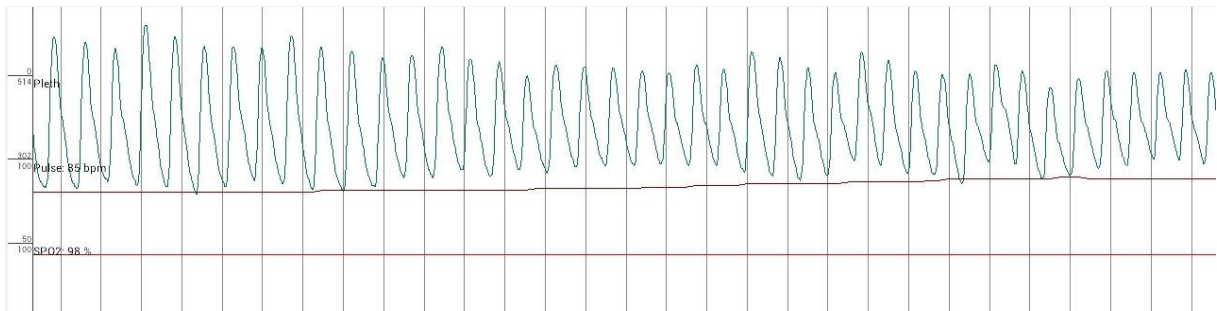
4.6 One channel exceeds limits

Tap on the according channel to get into the single-channel display.
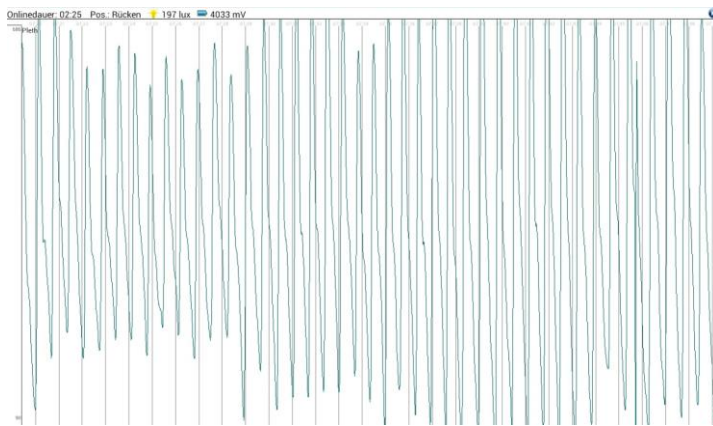
4.7 Channel where limits are exceeded

Tap on the display with two fingers, one above the other. Keep your fingers on the display and reduce the space between them to scale the signal amplitude down. At the left side you can see the scaling. For an equal scaling you can adjust the upper or lower range by moving only one of the two fingers in the respective direction.
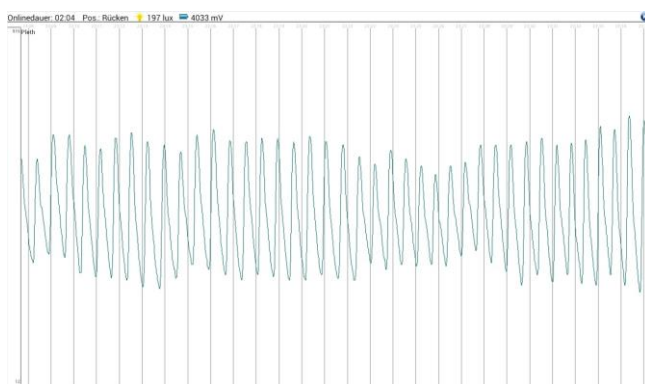
4.8 Channel with adapted limits for signal

You get back to the all-signals display with a double-tap or the "Return"- button.
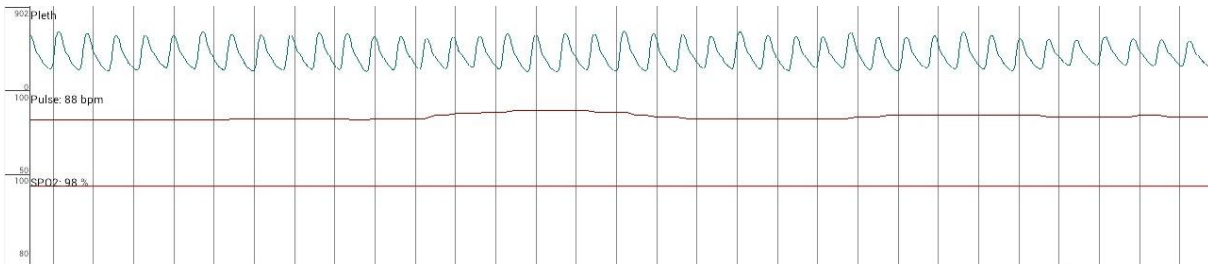
4.9 Signal adapted in channel limits

4.3.2   Adjust signal within channel display

You approach alike if a signal is beyond or at the edge of its limits (see Fig. 4.10).
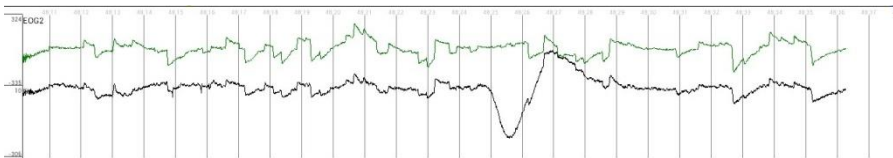
4.10 Channel with displaced signal

Tap on the according channel to get into the single-channel display.
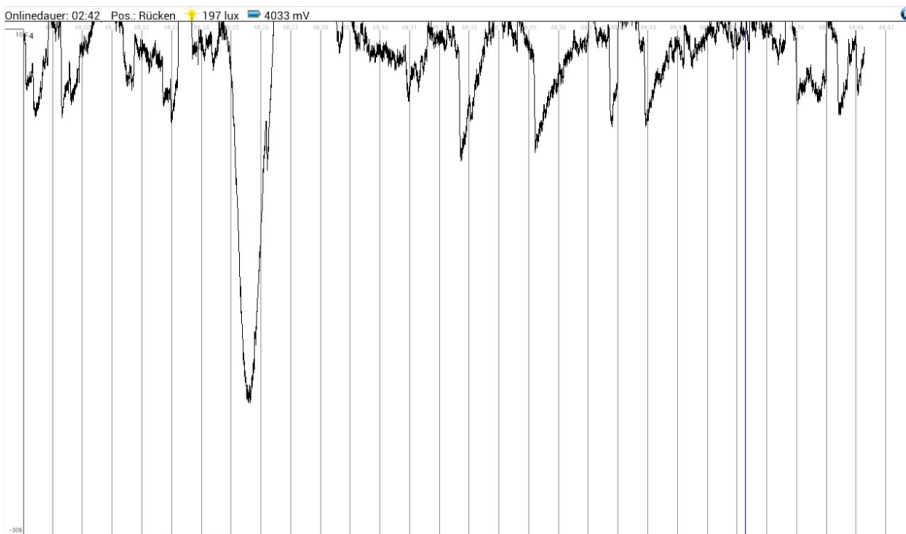
4.11 Signal displaced within channel display

Tap on the display with two fingers, one above the other. Keep the fingers on the display and move them parallel up or down to fit the signal in the channel.
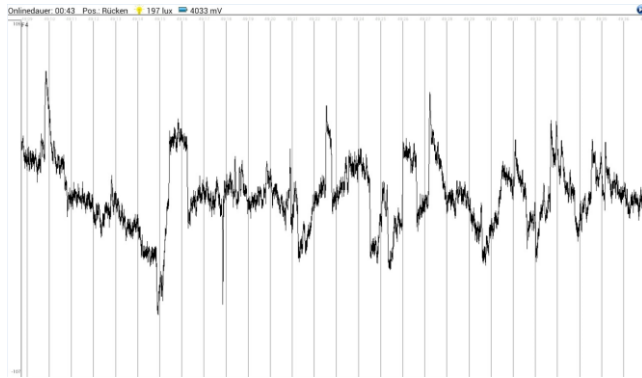
4.12 Signal positioned in the middle of channel display

You get back to the all-signals display with a double-tap or the "Return"- button.
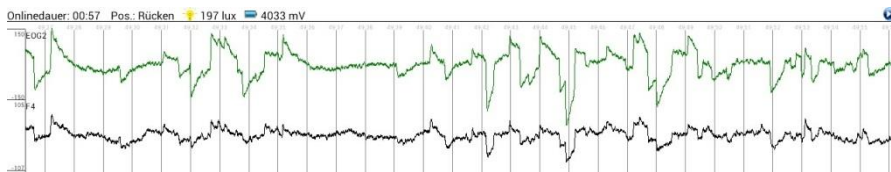
4.13 Channel with signal positioned correctly

If more than one channel has to be adjusted, you can apply the settings of one EEG-channel to all other EEG-channels when you are in the single-channel display by selecting 'Accept max/min values for all EEG channels'.

4.4   Options

When you tap on a device for about 3 seconds, the owing menu opens.

4.14 Device menu

With **"Rename"** you can change the name of the device (e.g. Room 1, SSC Room 1 etc.).

"Delete from list" deletes the device from the list. It has to be searched via **"Search BT"** before a further connection can be established, but it does not have to be linked to the app again.

The function **„<<Remote>> Check"** is not available for this device.

5   Helpful function in DOMINO: Enter station of hospital

The station or department where the recording is conducted, can be entered – in addition to prior

recording - during the online mode. Open the patient info [icon] during the online recording and enter the station or department into the field ‚Description'.

To open a recording, click on the Analysis symbol [icon] of the DOMINO panel. The following window will open:

A click on the column name sorts the recordings according to the column. They cannot be sorted by "Number" or "Source".

Saved recordings

Data volume of the recording

Video status (size and status of progress)

Status of progress

Archiving path

"Notes" information from the patient data

Edit date

Fig. 5-1 Opening a recording

When the cursor is on this field an information window opens with a list of the recorded channels.

ID of the used SOMNOscreen™

6   Power supply of the stationary headbox

The SOMNOscreen operated together with the headbox has a rechargeable battery. Recording time is 14h for online recordings. The battery status will be shown prior to a recording during initialisation in the DOMINO software. Please change and recharge batteries in time.
The built-in display has a power supply via a medical power supply with USB connector.

7 Troubleshooting / FAQ

Problem	Device	Answer to the problem
Device not listed in the BT-Search	Off	Start the recording / device manually or wait for the programmed start respectively. Start the BT-Search again.
	On	Check if the connected receiver is listed. In this case the device is probably still linked to it and cannot be found by the app.
BTMessage: Error by connect when trying to connect via the device symbol	Off	Start the recording manually or wait for the programmed start respectively.
	On	Check if the connected receiver is listed. In this case the device is probably still linked to it and cannot be found by the app. Connect the device via the receiver.
BTMessage: Error by connect when trying to connect via the BT-list	Recording	Probably the "Online-Mode" was not activated in the montage. Re-initialize the device. The list was not refreshed and the device is still listed though connected to the receiver. Start the search again and connect the device via the receiver.
BTMessage: Command timeout when trying to connect	On, but not recording	Start the recording manually.
The impedance check doesn't work.		The headbox is not connected yet. You are using the combi electrode. Re-initialize the device and select a montage with headbox instead. "Cont. Impedance" was not activated in the montage.

8 Maintenance

8.1 Maintenance rate

Return SOMNOscreen™ plus to SOMNOmedics after 3 years of usage for inspection. The inspection includes the replacement of the Internal Battery, Calibration of all the Recording Channels and visual inspection for any external damage.

8.2 Cleaning and disinfection

Regularly clean the device, accessories, cables and sensors to ensure trouble free operation. **Do not use an autoclave for cleaning.**

This device complies with IP protection class "20". This means that the device is NOT waterproof. Also, protect the SOMNOscreen™ plus from coming into contact with water, dust and dirt.

Desinfection of Headbox:

Gegenstand	Desinfektions-mittel (Handelsnamen)	Konzentration	EWZ	Häufigkeit	Sonstiges
EXG adaptor (Headbox)	Wipe disinfection: For example: Terralin Liquid Mikrozid AF Cloth	Ready to use Ready to use	5min 5 min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!

Disinfection of sensors, electrodes, elastic belts for use with the SOMNOscreen plus:

Article	Disinfectant (trade mark)	Concentration	Duration	Intervals	Other
SOMNOscreen™ plus device	Wipe disinfection: For example: Terralin Liquid Mikrozid AF Cloth	Ready to use Ready to use	5min 5 min	After use	DO NOT use a wet or fluffy cloth. Ensure that no liquids enter the device during cleaning!
Thermistor	wipe disinfection using Alcohol type chemical: For example: Mikrozid AF Liquid Mikrozid AF Cloth Isopropanol spray	Ready to use Ready to use 70%	5 min 5 min 5–10 min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!

Effort Sensor	Wipe disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
CPAP/ Pneumatic Effort Sensor	Wipe disinfection using Alcohol type chemical: For example: Mikrozid AF Liquid	Ready to use	5 min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
	Isopropanol-Spray	70%	5–10 min		
ECG (Active Electrode)	Wipe disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
PLM (Active Electrode)	Wipe disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
Activity Sensor	Wipe disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
PLM (Acceleration Sensor or Active Electrode)	Wipe disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		

Larynx microphone	Wipe disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
EEG/EMG Electrode Cables	Wipe disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
SpO2 Sensor	Wipe disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
Elastic Belts with and Without Plastic Clip/ Inductive Effort Belts	Quick disinfection on alcohol basis: For example: Mikrozid AF Liquid	Ready to use	5 min	After use	Remove adhesives if necessary. Follow manufacturer's instructions! machine washable up to 60˚ (it is recommended to use a laundry bag)
	Isopropanol-Spray	70%	5–10 min		
Gold Plated Electrodes	Quick disinfection: For example: Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Then remove all residues of EEG paste under running warm water from the electrodes. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
Pneumotachograph	Insert into e.g. Terralin Liquid	Ready to use	5min	After use	
	or				
	Cleaning in ultrasonic apparatus				

Transmitter Module	Wipe disinfection: For example:. Terralin Liquid	Ready to use	5min	After use	Remove adhesives if necessary. Follow manufacturer's instructions!
	Mikrozid AF Cloth	Ready to use	5 min		
Pneumotachograph tube/ CPAP tube	Terralin Liquid	Ready to use	5min	After use	Keep the area that has to be disinfected moist during disinfection. Fill the disinfectant into the tube with a luer-lock adapter. Do not perform immersion disinfection. Follow manufacturer's instructions!

Use protective gloves when using aggressive disinfectants!

Follow the manufactures instructions when using disinfectants. Keep to the prescribed dose and contact time!

Use cold water to prepare disinfection solvents!

9   Use and maintenance of the rechargeable battery

SOMNOmedics recommends the use of rechargeable batteries in the SOMNOscreen™ plus. We supply two Lithium-Ion (Li ION) rechargeable batteries with each system. The battery supplied offers a long life (approximately 500 charges), is not susceptible to memory effects and is ecologically friendly.

Every charging cycle will is counted as a complete charge. It is therefore recommended to only charge the battery when the display status indicates "BATTERY LOW" or the power drops below 3.7 V. The current battery status in % can be viewed on the integrated display of the SOMNOscreen™ plus under the **System** menu.

At 3.7 Volts, it takes approximately 2.7 h to charge a fully flat **battery**. The **Battery** is fully charged when the red Charging LED on the charger turns off.

Never dispose of Li ION batteries in domestic waste. It is strictly forbidden to put hazardous substances in domestic waste. Please return used batteries to your distributor or hand them in at your local municipal collecting point.

Every charging cycle, even when the battery is almost full, will be counted as a complete charge. It is therefore recommended to only charge the battery when the display status indicates that the battery is low or the power drops below 3.7 volts.

Always use the battery charger (SCC052) supplied by SOMNOmedics!

**Replace the battery for the internal clock every 3 years to ensure correct operation.
Contact your local distributor to arrange for a loan unit while the system is
returned to the factory for a complete factory test.**

10 Service

10.1 Technical specifications

Component	Channels	Resolution	Measure-ment range	Frequency range	Accuracy	Dimensions and Weight
SOMNOscreen™ plus	EXG1	16 Bit	±80mV	0,2 – 70Hz	±5%	140 x 80 x 36 mm 260 g (incl. battery)
	EXG2	16 Bit	±80mV	0,2 – 70Hz	±5%	
	EXG3	16 Bit	±80mV	0,2 – 70Hz	±5%	
	Flow-Thermistor	16 Bit	±80mV	0,1 – 1kHz	±5%	
	Aktivity	16 Bit	±240mV	0,07 – 1kHz	±5%	
	AUX-AC	16 Bit	±120mV	0,07 – 1kHz	±5%	
	AUX-DC	16 Bit	±1,2V	DC – 1kHz	±5%	
	CPAP-Pressure	16 Bit	±1,2V	DC – 1kHz	±0,2mbar	
	CPAP-Flow	16 Bit	±48mV	0,023 – 1kHz	±5%	
	Effort Abdomen	16 Bit	±170mV	0,2Hz – 35Hz	±5%	
	PLMr	16 Bit	±120mV	DC – 1kHz	±5%	
	Snore	16 Bit	±1,2V	40 – 1kHz	±5%	
	Effort Thorax	16 Bit		0,1 – 1,6Hz		
	PLMl	16 Bit	±120mV	DC – 1kHz	±5%	
	Body Position		Right, left, prone, suppine, upright			
	Accu ext.	12 Bit	0-4800mV			
	Light	12 Bit				
	Accu int.	12 Bit	0-4800mV			

Component	Channels	Resolution	Measure-ment range	Frequency range	Accuracy	Dimensions and Weight
Headbox PSG+	10 x EEG/EOG	16 Bit	±800µV	0,2 – 35Hz	3%	72 x 68 x 32 mm 120 g
	2 x EMG	16 Bit	±800µV	0,2 – 150Hz	3%	
	1 x ECG	16 Bit	±2400µV	0,2 – 150Hz	3%	
Headbox EEG 10-20	20 x EEG/EOG	16 Bit	±800µV	0,2 – 70Hz	3%	93 x 90 x 23 mm 200 g
	2 x EMG	16 Bit	±800µV	0,2 – 150Hz	3%	
	1 x ECG	16 Bit	±2400µV	0,2 – 150Hz	3%	
Headbox EEG 32	25 x EEG/EOG	16 Bit	±800µV	0,2 – 70Hz	3%	109 x 88 x 22 mm 210 g
	6 x EMG	16 Bit	±800µV	0,2 – 150Hz	3%	
	1 x ECG	16 Bit	±2400µV	0,2 – 150Hz	3%	

SpO₂-Modul

Resolution	16 Bit
Oxygen saturation	70 to 99 %
Pulse rate	18 to 300 beats per minute
Wavelength	red: 660 nanometer infrared: 910 nanometer
SpO2 (± 1 standard deviation)	70 – 100% ± 2 for adults using the finger clip sensor 70 – 95% ± 3 for neonates using the child or neonates sensors 70 – 100% ± 3 for adults using the flex or reflectance sensors 70 – 100% ± 4 using the ear clip sensor Values below 70% are not specified for these sensors.
Temperature	During operation: 0° C to +50° C Storage: -20° C to +70° C
Humidity	During operation: 10 – 90 % Non Condensing Storage: 10 – 95 % Non Condensing
Connector	DB9

Data processing	16 Bit ADC - Active Filtering Different Sampling Rates Adjustable (4/s to 512/s); optional: up to 4096/s Continuous Data Acquisition
Power supply	Diameter: 20,3 mm length: 70,4 mm Nominal voltage: 3,6V Maximal voltage: 4,2 V Nominal capacity: 2550 mAh Maximal charge current: 0,9 A Integrated protection circuit with overload protection at 4,35 V Deep discharge protection at 2,4V The battery has an operating life of approximately 500 charging cycles. **As a rule it should be changed every 3 years.**
Interactive display	Signal check at backlit Display Programmable Time Setting Keyboard for Menu Control Maximum 32 characters on 2 lines (16 characters per line) and 2 fields (8 characters per field).
Storage medium	Industrial Compact Flash memory card with up to 2 GB capacity Operating voltage: 3,3 V ±5 % Maximal current drain during writing: 50 mA Temperature range during storage/operation: 0 – 50°C Memory card has to switch to standby after every write cycle Standby current: <1 mA
Humidity	During operation: 5° C to 40° C Storage: 0° C to 50 ° C

10.2 Malfunction

In the event of a problem with the SOMNOscreen™ plus, switch it off and ensure that it is removed from use and clearly labelled.

The following are examples where this may be necessary:

- The device is visibly damaged (broken case)
- The device does is not work correctly (poor measurements)
- Components are loose or fit poorly
- Connectors are damaged (crushed or cut cables)

Please contact your local distributor for a fast response or contact SOMNOmedics directly.

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11 Notes