Instruction Manual

SOMNOscreen Eco

Caution: Federal law restricts this device to sale by or on the order of a physician.

SOMNO medics

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Inhalt

1. Getting started – Quick Guide

Control and display elements of the main device

Control elements which are active and selectable are backlit.

1 Power button: with this button the device can be turned on and off. The button is illuminated continuously red if the device is on. The button is flashing red if the device is recording and green if in wait mode.

2 Button for starting a recording. Until serial number 76 the button is not illuminated. From serial number 77 onwards the button is backlight with a green and a red LED. The button is illuminated in green if a recording with manual recording start is initialised or the device is ready to start the recording. If the button is illuminated in red this is a warning for the user that there is an untransferred recording on the device. The recording can be started anyway.

3 Marker button for indicating events. Backlit with a red LED. If connection between device and PC is active the LED is flashing red quickly.

4 Light sensor: detects ambient light

5 Battery status:

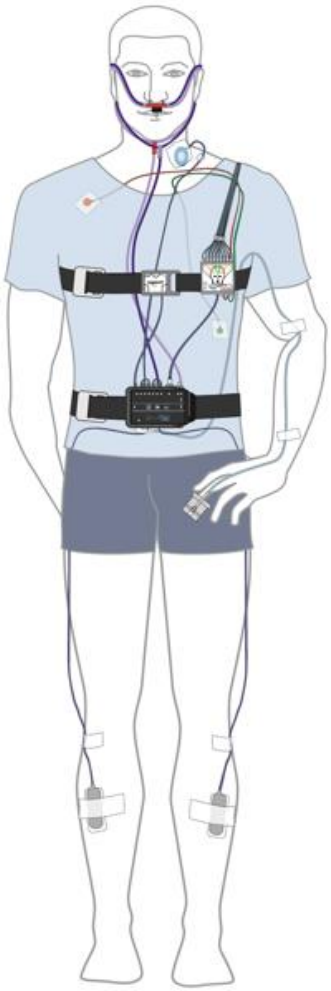
- yellow → battery is being charged
- green → battery is fully charged, docking station is connected to the power supply
- switched off → docking station is not connected to the power supply

6 Bluetooth: blue light indicates connection with the paired receiver

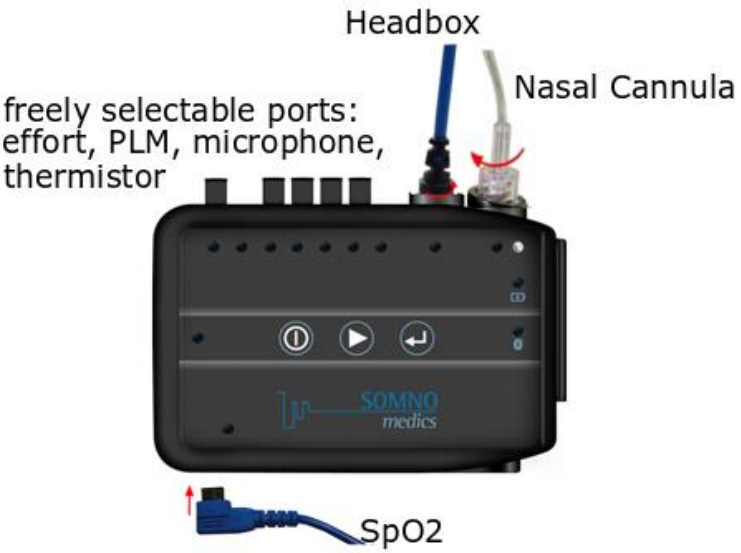
7 LEDs for sensor ports: either green or red. LEDs are indicating missing/connected sensor during start of the recording and during the recording. When switching on the device all LEDs light up shortly and indicate the operational state and battery capacity of the device. Afterwards, the LEDs turn red and show which sensors are needed for the next recording. All LEDs turn off after 5 minutes after the recording has started. If a sensor is accidentally removed during the recording the LED next to the port turns red and stays red until the sensor is re-connected again. LEDs for flow (**9**) and abdomen (**10**) are green all the time (as soon as they are part of the montage).

8 LED for headbox connector. Functionality identical to **7**.

Application Plan



Plug in of Sensors



1. Apply device to the abdomen with abdomen belt. Adjust belt.
2. Plug in all further sensors.
3. Switch on the device

Switch on device

Press power button (1).
LEDs are turned on and off signalling device activity.
Afterwards device is off again.

Switch off device

Press power button (1).
Marker button (2) is flashing red.
Press marker button and confirm shutdown of device.

2. Introduction

Thank you for purchasing the SOMNOscreen™ Eco from SOMNOmedics. Please read the following instruction manual carefully before installing and using the device. We gratefully accept any feedback and helpful suggestions to improve our product or instruction manual.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Please find the safety instructions and important information in the chapter “Safety instructions”, as well as in the individual chapters where they are labelled as follows:

Note: This is an example.

Warning: Take care in arranging patient and sensor cables to avoid risk of patient entanglement or strangulation. To minimize the risk of patient strangulation, the sensor and electrode cables must be carefully placed and secured. Medical tape can be used to additionally secure the sensors in place if necessary.

Technical Specifications are subject to change without notice.

The Initialization of the System and Analysis of the Data must be performed by Trained Operators. Measurements can be performed in professional healthcare facilities or at the Patients’ home. When used at the Patients’ home, the Patient should be carefully instructed on how to use and care for the system.

Please also hand out to the patient a copy of the enclosed Patient Instruction Manual. The initialized device will **automatically** start recording the measurement at the pre-set time. The data transfer and the analysis must be performed by the doctor or qualified physiologist.

The device should be programmed by the physician/medical staff to start recording automatically at a pre-set time. Therefore, there is no need for the patient to start the device manually. Once the patient returns the device, the data transfer and analysis must be performed by the doctor or a qualified physiologist.

The SOMNOscreen™ Eco may not be worn during swimming and showering.
Please refer to the safety instructions in chapter 2.6.

2.1 Intended use

The SOMNOscreen™ Eco is a mobile device for recording, displaying and saving biophysical parameters. The device is used as polysomnography system (PSG) for assisting in the diagnosis of sleep related disorders. The device is used in hospitals, medical offices, sleep centres, clinics or other research facilities where adults and/or infants are observed. The system may also be used in ambulatory settings.

The software DOMINO is part of the system and offers the opportunity to record video signals or signals of external devices. Those signals are displayed synchronously with the SOMNOscreen™ Eco signals.

DOMINO is not providing full, automatic diagnosis. The software is supposed to be used by trained medical experts. DOMINO generates reports of the recorded and manually scored data (number, index, average values, maximum and minimum, ranges). All values displayed within the software and on the device itself must be checked and evaluated by trained medical stuff. Diagnosis must be given after visual evaluation of all recorded data.

The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home.

This device is not intended to be used as a life support system or together with other systems in life support applications. The device does not provide an alarm. The device is not designed to be used as an automatic apnoea monitor. The device is not designed for use with HF surgical equipment.

2.2 Patients

The SOMNOscreen™ Eco and its components may only be used as follows:

- The AASM rules indicate that the respiratory screening setting for adults can be used for patients >18years, but an individual sleep specialist can choose to use adult setting and scoring for children ≥ 13years.

- Excluded are monitored and intensive care patients

2.3 About this instruction manual

It is essential that you read each paragraph carefully when you see this icon on the left of that paragraph. This instruction manual is a part of the device and it must be available at all times.

2.4 Explanations of Symbols used in this Manual

	This **Warning** Symbol indicates potential danger to Patients, Property or Data Loss.

2.5 Essential performance features of the device

According to DIN EN 60601-1:2013-12 (Edition 3.1) SOMNOscreen™ Eco does not have any essential performance features if used as polysomnography device. The basic safety of the device must be ensured without the presence of essential features.

For extension of the intended use of the device to neurological applications then the DIN EN 60601-2-26 is applicable. The following essential performance features are defined:

- Accuracy of signal reproduction 201.12.1.101.1
- Input dynamic range and differential offset voltage 201.12.1.101.2
- Input fault 201.12.1.101.3

- Frequency response 201.12.1.101.4
- common mode rejection 201.12.1.101.5

Electromagnetic influences, caused by other devices or device with radio equipment, may affect the essential performance feature or could lead to a loss of the essential performance features. The waveforms of EEG signal can be affected by an increased noise level, peaks, offset or other noise.

2.6 Safety instructions.

This instruction manual is regarded as part of the instrument and should always be kept on hand.

The SOMNOscreen™ Eco system may not be used in the course of life support monitoring, surgical rooms, intensive care units, or in emergency vehicles.

The SOMNOscreen™ Eco must be applied only under instruction of a physician. Cleaning and disinfection also has to be done by a physician or medical professional with recommended chemicals and not by 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. If the device is damaged (e.g. broken case) it has to be taken out of service. If any sensor cable or the device housing itself is damaged, a low risk of injury to the patient may occur through a direct connection to the ground lead. The maximum voltage generated by the device is 3.3 V. Please check the device housing, all wires, sensor cables and plug connections for damage before every use. **Damaged parts** should not be used and must be repaired or replaced by trained experts or by persons authorized by SOMNOmedics.

In order to guarantee the correct interpretation of the recorded data the operator should hold suitable qualifications recognised in their local country.

We recommend that patients with a cardiac pacemaker should wear the main device on the abdomen rather than on the thorax. We recommend placing the main device at least 16 cm away from the pacemaker. When following these instructions, no signs of interference of the cardiac pacemaker with the main device are expected. Additionally, a safe distance needs to be maintained between the Bluetooth data receiver and patients with cardiac pacemakers or other implanted stimulation devices.

It is important to deactivate Continuous Impedance Measurement for all EXG channels in patients that have a **cardiac pacemaker** or other implanted stimulation devices. Please find a detailed description regarding this topic in the instruction manual of the DOMINO software, in the section called “Continuous impedance measurement”.

Do not use Radio Transmitters and Receivers, High Frequency Devices, CB-Radio Systems, Cellular Phones, Microwave Ovens, etc. where the electrical field strength exceeds 3 V/m (in accordance with IEC 60601-1-2) close to SOMNOscreen™ Eco.

All sensors are provided unsterile and should never be sterilized.

This device is not to be used on broken skin. If this device comes in contact with broken skin/blood, do not reuse this device and discard.

Only accessories/sensors designed or recommended by SOMNOmedics are allowed to be connected to or used with the SOMNOscreen™ Eco.

When using the 4-channel analogue optocoupler to record signals from several external devices, medical devices and non-medical devices should not be connected at the same time as there is no galvanic separation between the 4 signal inputs.

The main device is not designed to be used in a potentially explosive or combustible **environment**.

This device is not designed for use in an MRI (Magnetic Resonance Imaging) environment.

The main device is not designed for outdoor use and thus must be protected against temperatures below 0°C and above 50°C. Ingression of dust, dirt and water may damage the device.

Regarding ingression of humidity and water, the main device complies with protection class IP 22. Consequently, the device must be protected against humidity and water. Small amounts of water are tolerated by the device. Do not expose the device to huge amounts of water. Do not wear the device during showering or bathing. Prevent the device of rain.

Should any **liquids** enter the device, the device must be cleaned immediately by SOMNOmedics customer service personnel. Following this, the device will undergo a safety-related examination. Do not switch on the device if any liquids have entered.

Cleaning should only be conducted with a lint-free and damp cloth. Do not use a steam autoclave.

Please refer to the information about **disinfection** (see chapter 6.1 Cleaning and disinfection). Adhere to the indicated dosages as well as to the application time. Use disposable protective gloves when using aggressive disinfectants.

Chemicals required for maintenance have to be stored, prepared and kept ready in appropriate containers to avoid confusion.

When **stored** for a longer period, the main device should be kept in a closed room to avoid water condensation caused by temperature fluctuations at high humidity.

Avoid using the main device in close proximity to radio devices, e. g. high frequency operation devices, wireless (mobile) phones, CB radio devices, microwave ovens etc. where the **electrical field** may exceed 10 V/m (according to norm IEC 60601-1-2).

If a **battery change** is required, only batteries specified by SOMNOmedics may be used. SOMNOmedics cannot guarantee error-free operation if different batteries are used.

Refrain from removing the battery while the device is running as this can result in data loss and damage of the storage media.

Insert the battery always with the imprinted arrow pointing up and to the back of the device.

Check on the battery regularly. **Do NOT use batteries that appear severely swollen**.

Please note that the internal time and date will not be saved when **storing** the device without a battery. If the device is stored without a battery, it must be initialized before use via the DOMINO software in order to synchronize time and date.

Repairs, modifications and opening of the main device must be carried out in the factory. Otherwise, this will lead to immediate loss of warranty.

Any damage of the warranty seal “Warranty void, if seal is broken”, located on the side of the device case, will lead to immediate loss of warranty.

The main device should only be used with **micro SD cards** specified by SOMNOmedics. SOMNOmedics cannot guarantee error-free operation if third-party memory cards are used.

The memory card must not be removed during recording as this may lead to data loss.

Note: Since 1st October 1998 portable batteries must no longer be disposed of in household waste after use. Consumers are obliged to hand over used batteries to the manufacturer, authorized dealers or to the local collection point.

When recharging a partly-charged Li-Ion battery, this counts as one whole **recharging cycle** and shortens the durability of the battery.

Always **recharge** the battery with the SOMNOmedics docking station as the battery can otherwise be damaged. The **docking station** of the main device should only be used with the supplied power supply.

SOMNOscreen™ Eco should only ever be used with **sensors and electrodes** specified and approved for usage with this device by SOMNOmedics.

Connect the **docking station** to a freely accessible socket. In case of a fault it should be possible to unplug it easily.

When using SOMNOmedics equipment with an external plug-in power supply unit, the power supply unit should not be placed in direct proximity to the patient.

There was no testing conducted to demonstrate the moisture retention filter for nasal cannula used is effective in preventing cross-contamination.

Opening the case, repairing or modifying the SOMNOscreen™ Eco in any way will void the guarantee and might affect the safety of the device. Only SOMNOmedics and its authorised distributors may repair the unit.

The body strap is made of material commonly used in clothing and non-medical watchbands, however if redness or swelling of the skin occurs where the band is in contact, please discontinue use immediately and consult your physician.

Pulse Oximeter and sensor related Warnings and Cautions:

The SOMNOscreen™ Eco has no audible alarms for monitoring Pulse and SpO2.

The SOMNOscreen™ Eco must be able to measure the pulse properly to obtain accurate SpO2 measurement. Verify that nothing is hindering the pulse measurement before relying on the SpO2 measurement.

Fingernail polish may reduce light transmission and thereby affect SpO2 accuracy.

Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity to sensors may vary due to medical status or skin condition. Avoid excessive damage to the skin beneath the sensor.

Do not use damaged SpO2 sensors. If the sensor is damaged in any way, discontinue use immediately and replace the sensor.

Misuse of the pulse oximeter sensor with an increased pressure over a prolonged period can lead to a barotrauma.

Follow local governing ordinances and recycling instructions regarding disposal or recycling of the sensor and any components.

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

Factors that may degrade pulse oximeter performance include:

Excessive motion and low perfusion may affect the accuracy of the SpO2 measurement.

Cardiogreen and other intravascular dyes, depending on the concentration, may affect the accuracy of the SpO2 measurement.

Excessive ambient light, artificial nails, excessive motion, Incorrect sensor type, poor pulse quality, electrosurgical interference, Venous pulsations, cardiovascular dyes, sensor not at heart level, Dysfunctional haemoglobin, fingernail polish, moisture in the sensor, Improper applied sensor, carboxyhemoglobin, methemoglobin, Residue (e.g. dried blood, dirt, grease, oil) in the light path, Anemia or low haemoglobin concentrations , Aterial catheters, blood pressure cuffs on same arm, infusion lines, etc.

The pulse oximetry device integrated in SOMNOscreen™ Eco is calibrated to determine the percentage of arterial oxygen saturation of functional haemoglobin. Significant levels of dysfunctional haemoglobin such as carboxyhemoglobin or methemoglobin may affect the accuracy of the measurement.

2.7 System components & accessories

Main Device

Internal channels: body position, movement, flow/snore, CPAP-pressure, RIP effort abdomen, ambient light, patient marker, battery status

Additional Sensors

PSG Headbox

EEG32 Headbox
RIP effort sensor thorax
SpO2 sensor (SpO2, pulse, pleth)
Limb EMG sensors left and/or right (for paediatric applications and adults)
Microphone
Thermistor
Pneumotachograph
Dual pressure sensor

Accessories

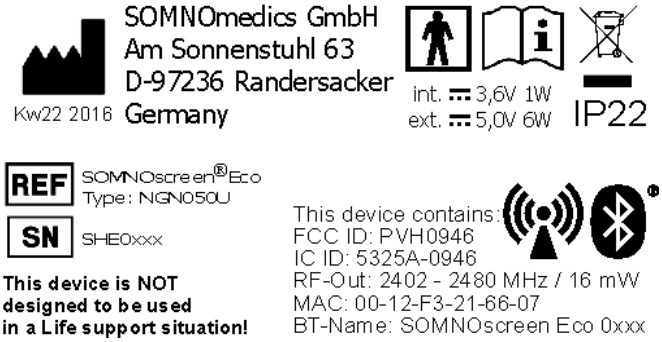
Nasal cannula
RIP effort belt abdomen
RIP effort belt thorax

--- Check the current price list for all available options ---

Cable length

Item	Article number	Cable length
USB cable for docking station (1-port)	NGA102	180cm
USB cable for docking station (3-port)	NGA103	180cm
Network cable for Bluetooth receiver	Komp90	200cm
Network cable for Camera	Komp90	200cm
Electrode cable Gold cup	SEN710	75 cm
Electrode cable snap fastener	SEN018	80 cm

2.8 Labels/Symbols



Information, Symbols, Icons and Classifications on the Type Label of SOMNOscreen™ Eco and its accessories:

	HF-Transmitter with integrated Bluetooth Protocol.
	Read the instruction manual very carefully before you start working with the SOMNOscreen™ Eco.

	Protection Class: BF
CE	The CE icon shows that the SOMNOscreen™ Eco complies with the applicable regulations of the EU and that the conformity was declared by the manufacturer.
IP22	This device complies with the **IP-Protection-Class 22.**
	Regulatory Compliance Mark (Australia)
	Do not dispose electronic devices in the domestic waste.
	The power supply meets the requirements of protection class II and does not need any additional protective conductor connection.
	The power supply is intended for indoor use only.

3 Preparing the patient: applying main device, sensors and electrodes

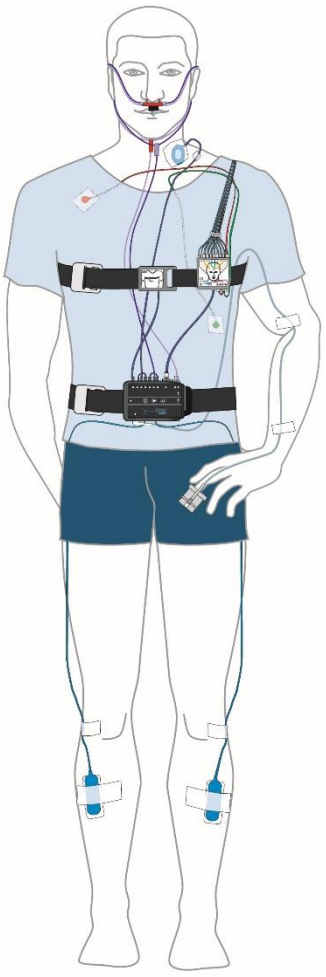
Note: The main device should be placed on top of light clothes (nightshirt, pyjamas) and should not be in direct contact with the skin.

Note: If applying the main device and the sensor in a different way then shown in the figure this could lead to wrong results.

Note: Attach the belts and sensor/electrode wires securely to the patient to avoid strangulation. Fix the sensor cable with adhesive tape if needed. Recordings with children may only be performed while under continuous observation.

We recommend placing the main device in the abdominal region of the patient. Alternatively, you can place the device in the thoracic region.

Please take note of the following images in order to place the main device and the sensors correctly on the patient's body. If the main device and the sensors are placed differently to that shown in the images, invalid data may be generated.



Main device and sensors on the patient's body

For home sleep tests it is highly recommended that the physician/medical professional either attach the device and the accessories before the patient leaves the office or the physician explain and demonstrate the attachment and use of the device and sensors face-to-face.

The physician/medical professional should go through the following points with the patient:

1. Attaching device and sensors.
2. Testing of correct sensor connections.
3. Patient marker on the device and status indications.

It is important to remind the patient to follow the instructions given, prior to the recording. A detailed instruction sheet for attaching the device and sensors is available and can be sent home with the patient to remind them how to properly attach the device and sensors.

The decision as to whether an examination at home is possible must be made by the physician on a case by case basis.

When making this decision the physician should take the following items into consideration:

- Physical size, mobility, coordination, flexibility, strength and stamina
- Range of vision and hearing abilities and tactile sensitivities.
- The abilities to process information and literacy levels, as well as some type of cognitive impairment (feedback about e.g. comfort; follow instructions and tolerating the attached sensors must be given by the patient).
- The emotional state of the user.

After evaluating the characteristics of the patient, the physician should determining that a home sleep test is appropriate, the physician should then choose and provide the appropriate informational material and individual training.

All cables should be routed and fixed carefully as described in the attachment information to reduce the possibility of entanglement or strangulation.

The size of the sensors has to be chosen according to the individual patient to ensure a correct fit. If the sensors do not fit correctly the measurement should not be performed.

3.1 Connecting the sensor plug to the main device

Please insert the sensor plugs into the main device as shown in the following image:

Inserting a sensor plug into the main device

The device automatically recognises the connected sensors.

The Luer-lock plug of the nasal cannula is screwed directly into the sensor port:

Connecting the luer-lock plug to the main device

Insert the headbox plug into the designated port and position. Turn the safety screw as indicated by the arrows in the image and indicated on the plug/device.

Connecting the headbox plug to the main device

Insert the SpO2 plug into the bottom as shown in the image.

Connecting the SpO2 plug to the main device

Note: In order to prevent damage of the sensor, patient should take off SpO2 sensor while washing hands or splashing water.

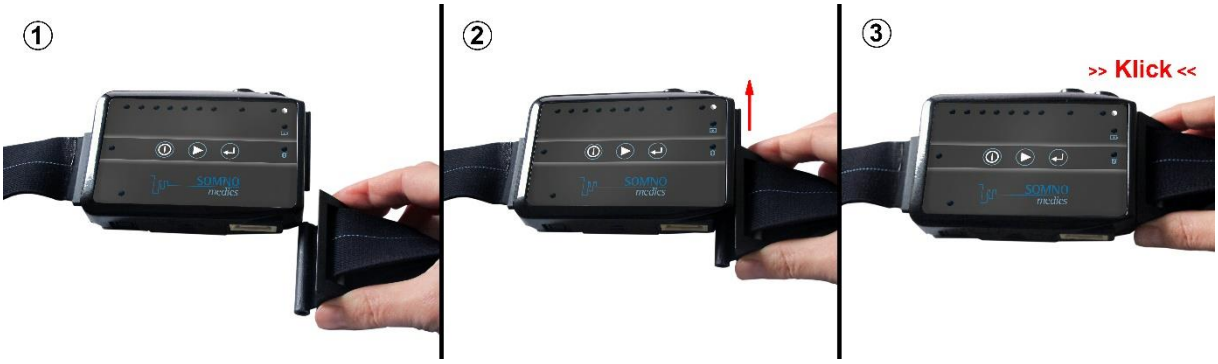
3.2 Sensors for Polysomnography

3.2.1 Attaching the effort belts

Insert the thin end of the effort belt into the slot on the left side of the main device (seen from the front). Follow the steps shown in the following image:

Connecting the effort belt to the main device using the thin end

Wrap the belt around the patient. Insert the wider side of the effort belt to the right side following the guiding rail.



Connecting the effort belt with the main device using the wider end

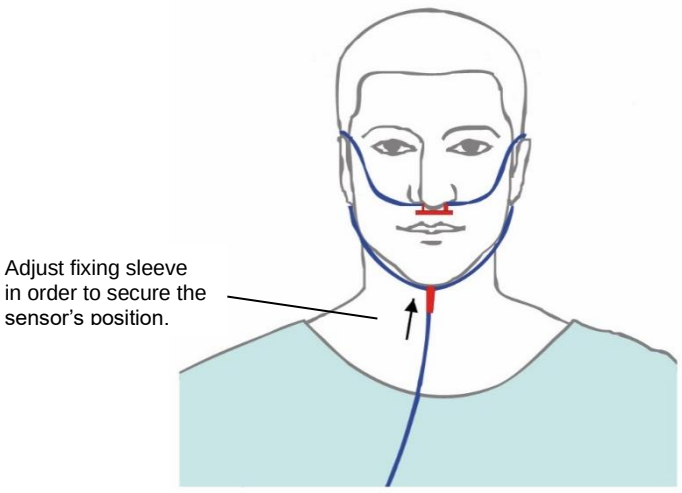
Thread the belt into the sensor.

Attaching the effort belts to the patient

3.2.2 Nasal Cannula

Attach the nasal cannula to the patient's nose. Make sure that the holes of the sensor elements (highlighted red in the following image) are placed directly below the nostrils.

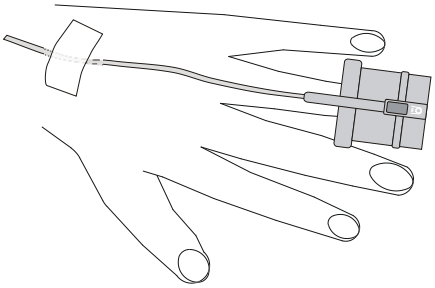
Note: Nasal cannulas are single-use items.



Attaching the nasal cannula

3.2.3 SpO2 sensor

The finger sensor should be attached to the most suitable finger. The upper side of the sensor is marked by the embossing of a finger as shown in the following image. You can use adhesive tape to secure the cable.

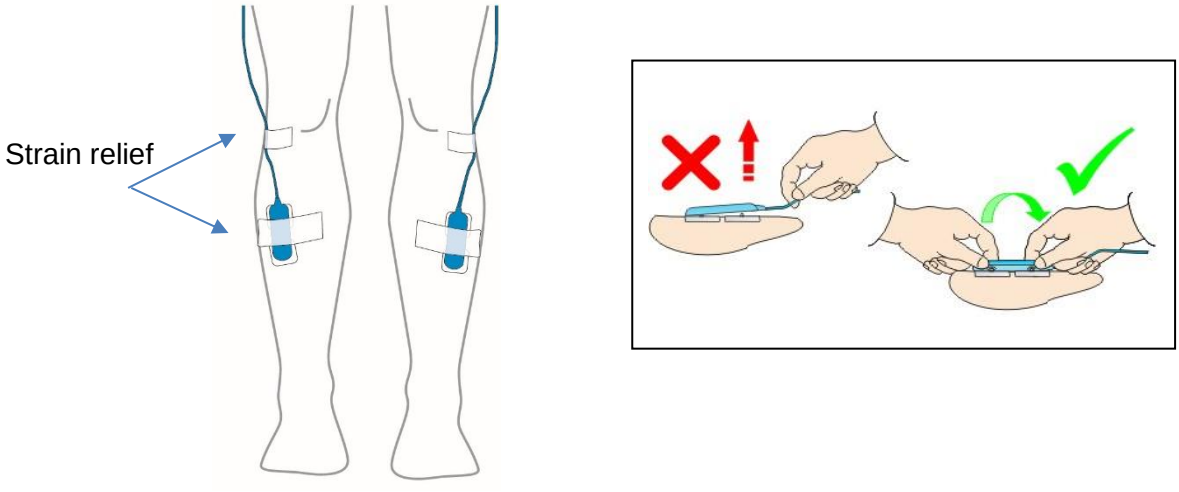


Attaching the finger sensor

3.2.4 Leg EMG sensor

The active electrodes (EMG) should be attached to the skin in the area of the anterior tibialis muscle of each leg between the knee and ankle (see the following image). Use two adhesive disposable snap electrodes to place it in the correct position. Connect the electrodes with the sensor before attaching it to the patient. Use adhesive tape to secure the cable to ensure an accurate measurement and for strain-relief.

The sensors are labelled L and R and should only be applied to the corresponding leg.



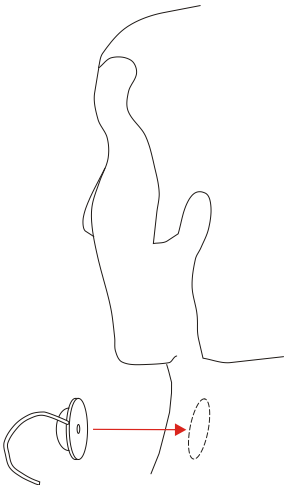
Attaching the PLM electrodes to the legs

Note: Do not use dried-out adhesive snap electrodes. Only use electrodes provided by SOMNOmedics to ensure the best signal quality.

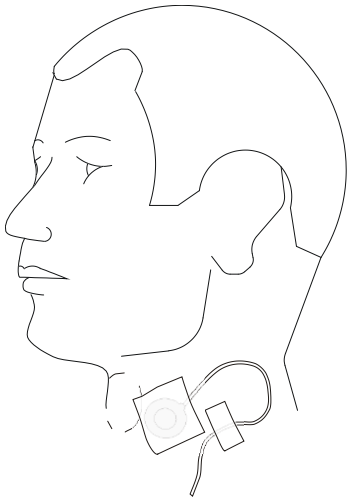
Note: When using the leg EMG sensors, always use a ground lead electrode to ensure optimal signal quality. You can use the following sensors: PSG-headbox, ECG sensor, combi electrode EEG/EOG.

3.2.5 Mikrophone

Attach the microphone between the larynx and carotid artery to record the snoring sounds. (DO NOT place the sensor directly on the larynx and not too close to the carotid artery). Ensure that the cable does not restrict the patient's breathing or endanger the patient in any way. Attach the sensor with the flat side of the microphone towards the skin. The patient's head should be as straight as possible (looking straight ahead) when attaching the microphone to prevent discomfort. Check to make sure the patient can turn their head to the left and right before applying the securing tape.



Attaching the microphone

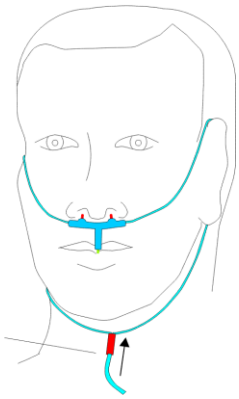


Fixation of the microphone

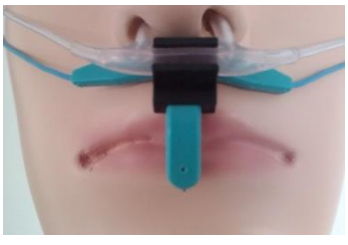
3.2.6 Flow sensor (Thermistor)

The thermistor measures the air flow via temperature changes and can be worn like a nasal cannula. See the following image to fit the sensor to the patient's face. Make sure that both upper sensor elements (highlighted red in the following image) are located directly below the nostrils and that the lower element is located directly in front of the mouth. Adjust fixing sleeve (small rubber sleeve) along the tube in order to ensure the sensor's position during the whole measurement. The sensor can be adjusted to the contour of the patient's face by bending it gently. When using the nasal cannula and the thermistor simultaneously, they can be connected by using the nasal cannula adapter. Use adhesive tape to attach the cable to the cheeks for an optimal fit.

Adjust fixing jacket in order to secure the sensor's position.



Attaching of the thermistors



Adapter for thermistor and nasal cannula

3.2.7 ECG

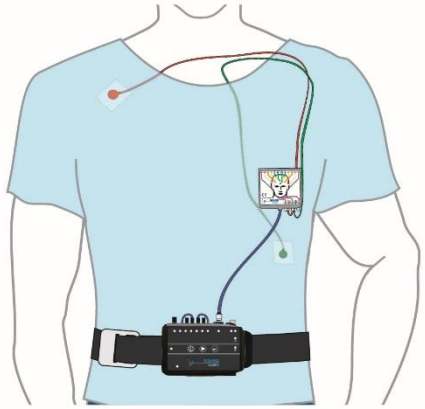
Attach the red electrode to a disposable snap electrode and attach it to the patient at ICR 4. Attach the green electrode to a disposable snap electrode and attach it to the patient at ICR 2.

Note: Use disposable snap electrodes only. Clean the skin before attaching the ECG electrodes.

Note: The main device must not be placed directly on the skin. The cables of the ECG electrodes should run under the pyjamas/nightshirt. The connecting cable of the corresponding ECG sensor should run on top of the pyjamas/nightshirt to the main device.

The ECG is applied using the PSG or EEG32 channel headbox.

Please use two snap electrode cables similar to the following figure. Insert the two ECG cables into the ports labelled “ECG” on the digital headbox.



Attaching the ECG cables to the headbox (similar for EEG32 channel headbox)

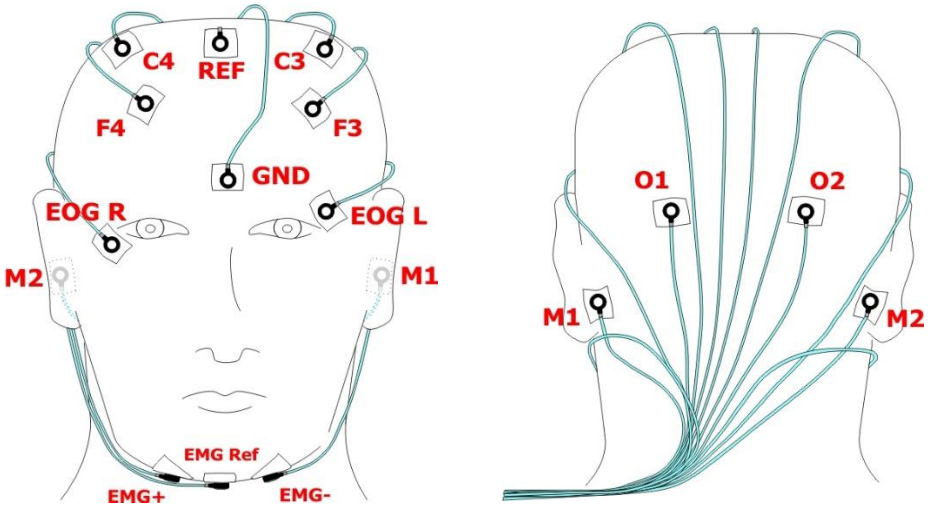
3.3 EEG/ EOG

Previous to the application clean all skin areas with Nuprep abrasive gel.

Connect the EEG electrodes in accordance to the labelling and colour-coding to the headbox.

Make sure you are using the same type of electrodes for all derivations (e.g. only Ag/AgCl or only gold cup).

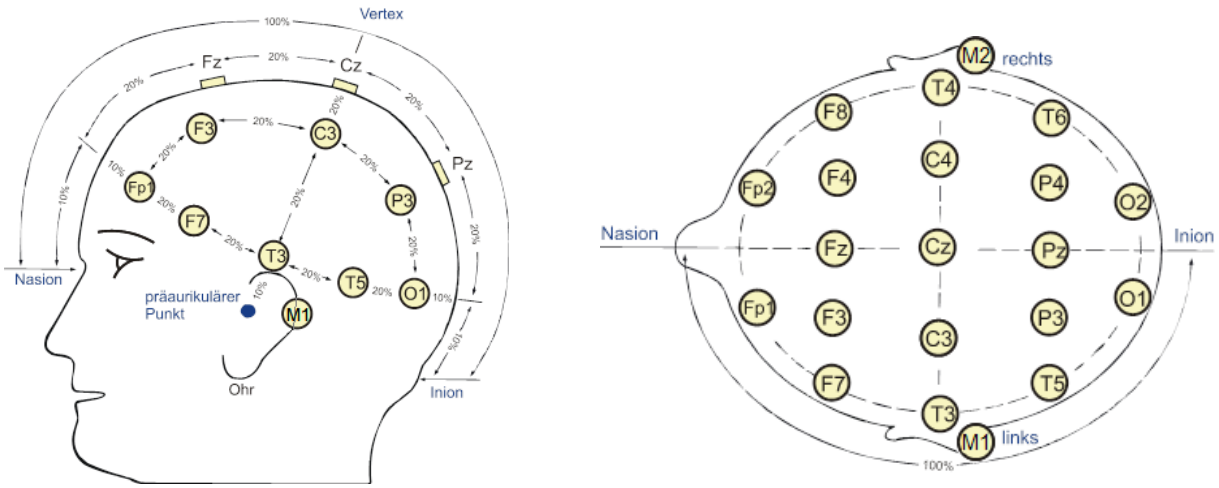
3.3.1 Attaching the PSG headbox according to AASM Guidelines



Position der Elektroden (PSG nach AASM)

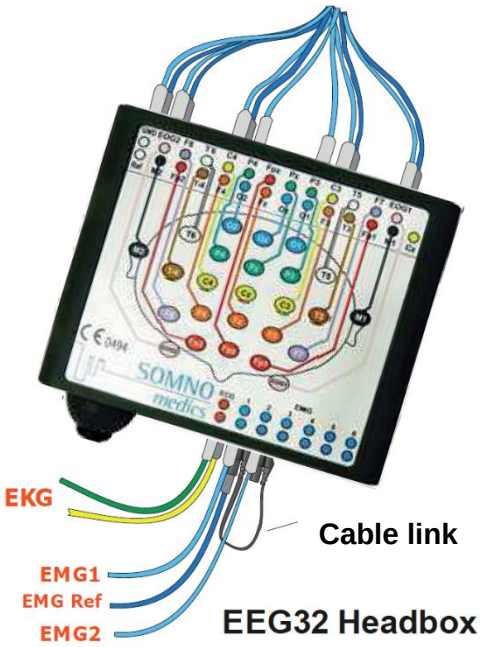
GND: Centre of forehead
REF: Applied to Cz, see 10/20 system
EOG l: 1cm above outer canthus of left eye
EOG r: 1cm below outer canthus of right eye
F3/4: See 10/20-System
C3/4: See 10/20-System
O1/2: See 10/20-System
M1/2: Behind left/right ear (mastoid; select boniest area)
EMGref: centred 1 cm above the inferior edge of the mandible
EMG1/2: 2 cm below the inferior edge of the mandible and 2 cm to the left/right of the center.

3.3.2 Application for 32-channel headbox according to 10-20 System



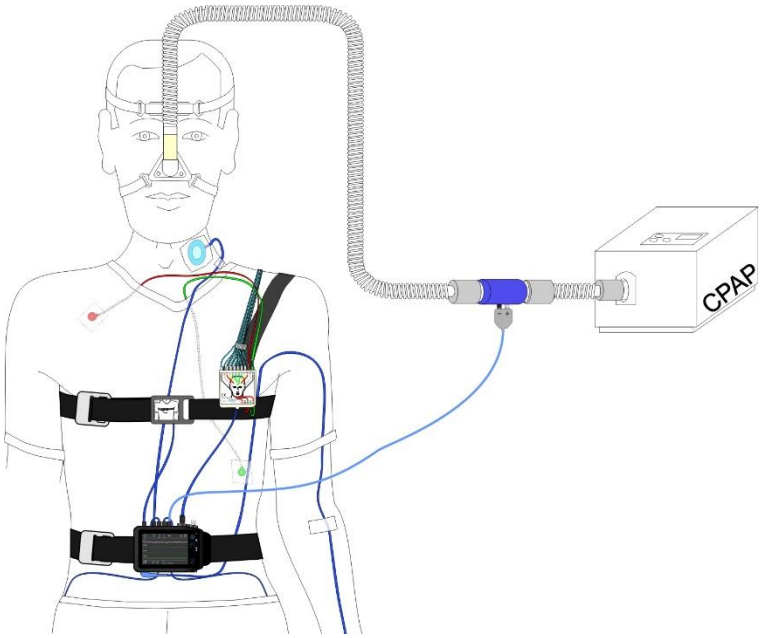
Electrode positions (10-20)

Use the cable link between the reference electrode and the second free EMG port for application of EMG electrodes according to AASM rules



3.4 CPAP sensor and CPAP device

The PAP device is connected via the dual pressure sensor. Therefore, you need the following items: dual pressure sensor, pneumotachograph (blue) and connecting tube. The pneumotachograph is connected directly to the dual pressure sensor. Make sure that the white Luer-Lock of the pneumotachograph is connected in the direction of the end of the CPAP tube and the also connected with the positive pole of the dual pressure sensor. Use the small connecting tube to connect the pneumotachograph to the dual pressure to the PAP device. To the other end of the pneumotachograph connect the end of the masks' tube. Afterward, connect the cable of the dual pressure sensor with the main device.



Connecting the pressure sensor to the mask via an oxygen adaptor

4 Operating the main device

4.1 Control Elements

Control and display elements of the main device

Control elements which are active and selectable are backlit.

1 Power button: with this button the device can be turned on and off. The button is illuminated continuously red if the device is on. The button is flashing red if the device is recording and green if in wait mode.

2 Button for starting a recording. Until serial number 76 the button is not illuminated. From serial number 77 onwards the button is backlight with a green and a red LED. The button is illuminated in green if a recording with manual recording start is initialised or the device is ready to start the recording. If the button is illuminated in red this is a warning for the user that there is an untransferred recording on the device. The recording can be started anyway.

3 Marker button for indicating events. Backlit with a red LED. If connection between device and PC is active the LED is flashing red quickly.

4 Light sensor: detects ambient light

5 Battery status:

- yellow → battery is being charged
- green → battery is fully charged, docking station is connected to the power supply
- switched off → docking station is not connected to the power supply

6 Bluetooth: blue light indicates connection with the paired receiver

7 LEDs for sensor ports: either green or red. LEDs are indicating missing/connected sensor during start of the recording and during the recording. When switching on the

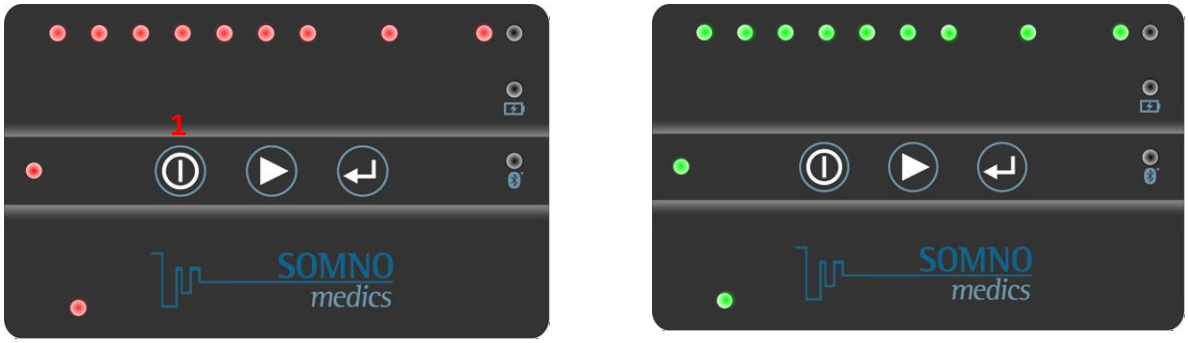
device all LEDs light up shortly and indicate the operational state and battery capacity of the device. Afterwards, the LEDs turn red and show which sensors are needed for the next recording. All LEDs turn off after 5 minutes after the recording has started. If a sensor is accidentally removed during the recording the LED next to the port turns red and stays red until the sensor is re-connected again. LEDs for flow (**9**) and abdomen (**10**) are green all the time (as soon as they are part of the montage).

8 LED for headbox connector. Functionality identical to **7**.

4.1.1 Switch-on /-off of the device

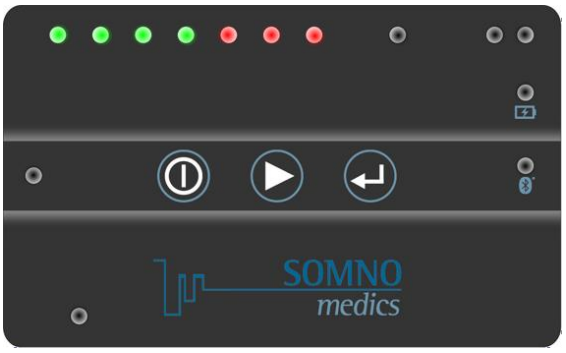
Switch-On

Press the power button (**1**) to switch the device on. All LEDs are turned on to signal the device is active. The LEDs turn red first and then green.



During the start-up process of the device the LEDs of the sensor ports are used to indicate the battery capacity. Each LED is reflecting a capacity of 14 %. Green means charged, red empty.

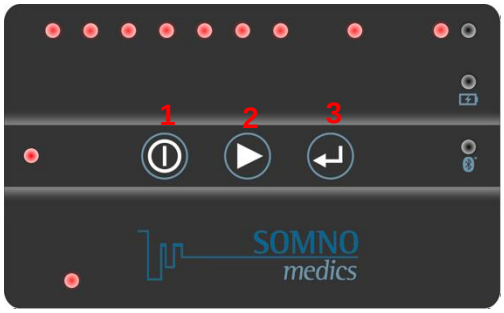
The device in the following figure has four green and three red LEDs. So the battery capacity is four times 14 %. The available battery capacity is 56 %.



Afterwards all LEDs flash twice before turning off. Then, the device is then ready to record. All LEDs next to a port that is expecting a sensor for the initialised montage will be red. All of the other LEDs are off.

Switch-Off/Termination of a Recording

To terminate a recording before the programmed end/duration time is reached wake the device first by pressing the power button (**1**). All LEDs turn on again. Now you need to press the power (**1**) and the play button (**2**) together until the marker button (**3**) turns on as well. Then, let the power and play button go and confirm the shutdown with the marker button. Afterwards all LEDs are on (red) before the device fully shuts down.



4.1.2 Patient markers/event markers

Patient and event markers can be set when the device is in measuring mode. Just press the marker button. You will hear a beep sound which indicates the marker has been noted in the recording.

4.2 Initialisation of a recording

A measurement can be initialized via the DOMINO software or directly on the device. An active connection between the DOMINO software and the device is indicated by a fast flashing marker button for approximately 30 seconds. During this time all buttons are inactive. Afterwards, the initialised montage is displayed by the LEDs at the sensor ports.

4.2.1 Initialisation via DOMINO Software

If initialising a recording with the DOMINO software you can enter the patient's name, ID and further information such as date of birth, height and weight. This data is saved together with the measurement.

The device can be programmed for manual or automatic start or for an online recording.

4.2.1.1 Pre-programmed automatic start

For initialisation of the device please place the device in the docking station.

Main device in docking station

Virtual Docking Station when the main device is not connected

If the docking station is connected to the PC, a connection between the device and the PC is initiated automatically. A virtual docking station is displayed on the PC monitor. It shows relevant information on the device status.

Virtual docking station, main device connected

Click on “Initialise” to enter the patient data etc. (alternatively use icon 1 of the DOMINO panel). After successful initialization the status is displayed (patient data, start, montage).
You can change the initialization by clicking “change”. The initialization dialogue will re-open.

After initialisation the device enters wait mode automatically. The power button is flashing green. All sensor ports expecting a sensor are indicated with a red LED. The LED is red until the expected sensor is connected. Then the LED is turned green. The device starts recording at the programmed start time.

Please see further information about the initialization process in the DOMINO software instruction manual.

4.2.1.2 Pre-programmed manual start

For programming of a manual start proceed as described for automatic start time. Place the device in the docking station and start initialisation process. Enter the patient data. In the tab Date tick the box for “manual start”.
Then, remove the device from the docking station. All LEDs expecting sensors are red, all other LEDs are off. If you do not start the recording immediately the device enters standby mode after 15 minutes. All LEDs are turned off again to save battery capacity. If you start the device again, the LEDs are turned on again.
For actual start of the recording press the play button.

4.2.1.3 Online recording

An online recording can be started via symbol 4 of the DOMINO panel.

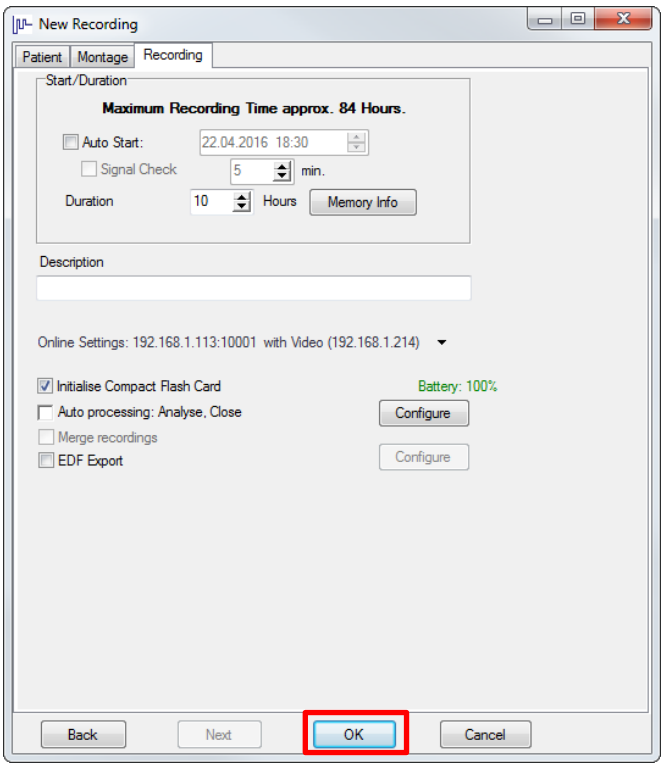
DOMINO panel

Enter the patient’s data on the “Patient” tab and select a montage on the “Montage” tab. The recording duration is set on the “Recording” tab. On the “Recording” tab, you will also see if a connection to the Bluetooth receiver has been made and that the recording device is connected and turned on (“initialize card” and battery status are displayed).

A recording can only be started when the battery status is green. If you have to exchange the battery, refresh the display clicking the “back” button followed by the “next” button.

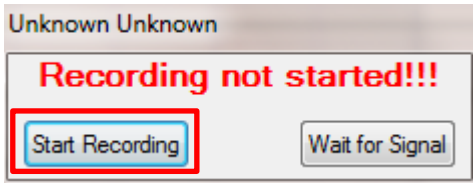
If there is an active connection between your computer and the main device all buttons are disabled. Power button and marker button flash red alternating.

Press “OK” to enter the online display.



Online recording tab "Recording"

To start recording data, click on the "Start recording" button in the signal view mode (window has a yellow background).



Online recording "Start recording"

If the recording was started via DOMINO the power button at the device is flashing red.

If a problem occurs during the online recording, the data can be retrieved from the mSD card of the device afterwards (see chapter 4.5.1).

Within the online recording missing sensors are indicated. The DOMINO software is displaying an information message if sensors are missing.

4.2.2 Direct initialisation of the device

As an alternative to the above, you can start a measurement directly on the device. When Bluetooth is active, the data can be displayed in an online recording or with the SOMNOmedics app on a tablet.

Please perform the following steps for starting the device:

1. Switch on the device with the power button.
2. Connect all sensors.
3. Start the recording with the play button.

If the recording is started successfully the power button is flashing red and the marker button is active. During the recording it is possible to mark events with this button.

Please keep in mind that for direct start of the device the last montage is still remembered by the device. The device is expecting the sensors of the last montage and the recording is running with the previous sampling rates and duration. Due to intelligent connect you can add whatever sensor you need for the recording and the sensor will be recognised and added.

To identify the patient correctly after the recording a unique ID is generated by the device. During transfer of the recording you can change this ID into a patient name and add further patient information as size, weight and birth.

4.3 Functionality of the LEDs/buttons during the recording

During the recording the power button is flashing red and the marker button is active. Marking of an event is confirmed with a beep sound. The backlight LED of the marker button is switched off during the recording.

Approximately 5 minutes after the measurement start all sensor LEDs are turned off.

If a sensor is removed during the recoding the LED at the corresponding port is continuously red until the sensor is plugged in again.

A sensor which is not part of the montage can be added during the recording. Then, the LED at the corresponding port is flashing green five times to indicate that the sensor was recognised. In the online recording the raw data channel of the sensor is added automatically.

If a faulty or not programmed sensor is added the LED at the corresponding port is flashing red until the sensor is removed again. During this time all other functionalities of the device are locked.

A recording can be terminated earlier by pressing the power and play button together and afterwards the marker button. With pressing the marker button the termination is confirmed.

4.4 Signal view via tablet

During the recording you can check your data at the tablet.

The following parameters are shown as numerical values on the display: SpO2, heart rate (HR), pulse transit time (PTT).

If a sensor is not included in the montage or if the sensor is not plugged in, no values for the parameter are displayed.

Swipe vertically ↕ on the display to see further channels of the same signature group. Swipe horizontally ↔ on the display to see previous data.

A vertical ↕ zoom movement (stretching and pinching two fingers on the display) changes the signal amplitude; a horizontal ↔ zoom movement changes the temporal resolution of the signal. The time scale is shown on the bottom right on the display.

4.5 Impedance check and biocalibration

Impedance check and biocalibration can be performed either with the bluetooth app or the DOMINO software (online recording). For further information about this please read the instruction manual of the DOMINO software and the Bluetooth app.

4.6 The docking station

Make sure that the docking station is connected to the power supply system via the power plug and to the PC via USB cable.

The upper LED displays that the docking station is connected to the power.
The lower LED displays yellow if the inserted battery is charging and green if it is fully charged.

4.6.1 Data transfer via docking station

When the main device is plugged into the docking station and a measurement is on the device, the virtual docking station displays the following:

Virtual docking station, main device is connected, measurement ready for transfer

Click “Transfer” if you want to transfer the measurement to the PC. If you want to delete the measurement, click on the trash icon.
Please find further information regarding data transfer in the DOMINO software instruction manual.

4.6.2 Recharging of the battery

For charging of the battery keep the battery in the SOMNOscreen™ Eco and place the device into the docking station. The LED on the device shines orange during charging and green as soon as the battery is fully charged.

4.6.3 Firmware Update

When the DOMINO software is updated, an update of the firmware may be required. This update will be carried out automatically after accepting the notification. It is necessary for the

SOMNOscreen™ Eco device to be put into the docking station and left there until the update is fully completed.

If your PC does have an internet connection you will be notified if a new firmware version is available. The update will be performed during the next transfer of a recording. Please confirm the notification about the update. Then, it will be performed automatically.

5 Troubleshooting

If battery capacity is below 15 % during start up of the device three short beeps will sound and the device is automatically shut down again. Start of a recording is not possible.

In general, always have a look at the battery capacity when switching on the device.

If the device is started without a memory card there are two long beep sounds and the device is automatically shut down again.

If the configuration file on your memory card is faulty five short beep sounds will inform you. The device is shut down afterwards.

The similar five beep sounds will sound if the configuration file is broken.

Is a faulty or not programmed sensor connected to the device the corresponding LED at the port is flashing red until the sensor is removed again.

Logbook entries:

Code	Description	Short description in logbook	Further actions at the device
1	Measurement was finished as scheduled	Terminated correctly	
4	Performance Problem	Performance Problem	Restart of the device necessary.
5	Measurement was stopped due to low battery voltage.	Stopped, low batt.	
6	Device cannot access the memory card. Recording cannot started.	SD-card inaccessible	Check orientation of the memory card. If orientated correctly replace with a different card.
7	Not enough storage capacity on memory card.	SD-card full	
9	Online measurement was finished in DOMINO. The device switches off by itself.	Online stopped by PC	
11	The device was connected to the PC while the recording was running. Recording was paused. If the pause is too long the recording is terminated.	Paused, rec. Missed.	
13	Measurement was terminated manually at the device.	Stopped by user	Only possible with several manual confirmations on display
14	The battery was discharged to fast.	Batt. Worn out	Change battery.

15	Non-programmed or defective sensor is connected.	Defective sensor	Notification on screen: Non-programmed or defective sensor connected.
16	Waiting mode was stopped manually on the device.	User aborted Wait mode	Only possible with several manual confirmations on display
18	Battery was removed during the measurement and inserted again. Measurement continues.	Stopped, batt. removed	
19	Measurement was deleted manually on the device.	User deleted Rec.	Only possible with several manual confirmations on display
21	A sensor was removed during the measurement.	Sensor pulled while Rec.	1 long beep (if sound is activated)
22	The recording was transferred successfully to PC.	Rec. transferred	
23	The same sensor is connected twice.	Duplicate sensor	Sensor must be removed to continue.

6 Cleaning and maintenance

6.1 Cleaning and disinfection

Preface: The nasal cannula and the nasal cannula filter are single-use components and have to be disposed after usage for one sleep session (see section disposal).

Clean the device frequently to ensure trouble-free operation.

Even when used in home environments, cleaning and disinfection is done by qualified healthcare professionals at the professional healthcare facility. The reprocessing of the reusable device components is not done in home environments. Cleaning and Disinfection is all done at the professional health care facility by qualified professional staff.

The device and the reusable accessories (e.g. SpO2 sensor, effort sensor, etc.) has to be cleaned and disinfected everytime after usage with a patient to reduce the risk of cross contamination and in addition when visibly soiled.

Wipe the case of the main device with a lint-free, soft cloth slightly moistened with a mild detergent. We recommend Terralin Liquid for cleaning.

Note: This SOMNOmedics device complies with protection class IP 22 regarding ingression of humidity and water. Cleaning should be performed with a lint-free and damp cloth.

Note: Ensure that no liquids seep into the device during cleaning!

Note: Other surface disinfectants listed by the DGHM are permitted as long as the surface of the device or sensor will not be damaged.

Note: The device and the sensors cannot be sterilized or autoclaved.

Please follow the instructions thoroughly:

You can use adhesive tape for strain relief on the SpO2 sensor cable (please see Patient Instruction “Attaching the sensors”). After usage, remove the adhesive tape. If necessary, please remove remaining adhesives from the cable with Citrace Hospital Germicide, EPA REG No. 67619-29.

The SOMNOscreen™ HD recording unit, the SpO2 sensor, the thoracic sensor and the transport bag are to be cleaned and disinfected after usage with Citrus II Germicidal Deodorizing Wipes, Beaumont Products Inc., EPA REG. NO. 1839-223-68939.

Visually inspect all components to ensure cleanliness and integrity of the components (no cracks, defects). Repeat the cleaning on any item that is not clean.

Components may be air-dried or dried by hand with a clean, lint-free towel.

Dry the device and components before next use and store it at a clean place.

Use protective gloves when using aggressive disinfectants!

Do not allow any liquids to enter any openings on the device! Do not use liquids or wet wipes.
Please just use moist cloth/wipes and dry device and components afterwards!

Follow the manufacturer’s instructions when using cleaning agents and disinfectants. Keep to the prescribed dose and contact time!

Do not use an autoclave for sterilizing the SOMNOscreen™ HD or any of its accessories!

6.2 Maintenance interval

After 3 years of use, send the main device to SOMNOmedics for validation and inspection. The inspection includes an examination for damage, a function test and a firmware update.

6.3 Usage and maintenance of the rechargeable battery

An accumulator is a rechargeable battery. The storage of electrical energy is carried out by an electrochemical process. The supplied battery is a lithium ion accumulator (Li ION). This battery type has the highest charge capacity and the longest durability (approximately 500 charging cycles). Furthermore, this battery type has no memory effect and is ecologically friendly.

The battery can be recharged in the docking station. The charging time increases when the battery is in the main device during the charging process. If the device is required to be ready again for immediate use, replace the empty battery with a charged one.

Note: Even if you recharge a nearly full Li-Ion battery or a battery with 3.7 volt for 15 minutes (for example), it counts as a whole charging cycle which shortens the durability of the battery.

Note: Never recharge the battery using a different docking station than the one provided by SOMNOmedics as the battery could be damaged.

Always use the Docking Station sent with the SOMNOscreen™ HD to charge the internal battery. Otherwise the battery could be damaged.

Remove device and sensors from the patient before starting the recharging process.

7 Technical Data

Component	Sensor	Resolution	Measurement range	Frequency range	Accuracy	Measurements and weight
	Thermistor	16 Bit		0.07 – 15 Hz		115 x 78 x 25 mm 190 g incl. battery 145 g without battery
	Activity external	16 Bit	± 1 g	0.5 – 10 Hz	± 30 %	
	CPAP pressure	16 Bit	0 – 30 mbar	DC – 8 Hz	± 2 %	
	CPAP flow	16 Bit	± 2 mbar	0.007 – 1 kHz	± 5 %	
	RIP Effort Abdomen	16 Bit		0.1 – 15 Hz		
	RIP Effort Thorax	16 Bit		0.1 – 15 Hz		
	PLMr	16 Bit	± 1200 µV	1 – 100 Hz	± 5 %	
	PLMl	16 Bit	± 1200 µV	1 – 100 Hz	± 5 %	
	Snore	16 Bit		30 Hz – 5 kHz		
	Body position		right, left, supine, prone, upright			
	Light	16 Bit	0 – 2700 lx	DC – 1 Hz		
	Battery voltage	10 Bit	2.6V – 4.5V		± 25mV	
Component	**Channels**	**Resolution**	**Measurement range**	**Filtering**	**Accuracy**	**Measurements and weight**
Headbox PSG	10 x EEG/EOG	24 Bit	± 1465 µV	HP 0.3 Hz, LP 35 Hz	5%	66 x 60 x 12 mm 80 g
	2 x EMG	24 Bit	± 1465 µV	HP 0.3 Hz, LP 110 Hz	5%	
	1 x ECG	24 Bit	± 5860 µV	HP 0.03 Hz, LP 110 Hz	5%	
Headbox EEG32	25 x EEG/EOG	24 Bit	± 1465 µV	HP 0.3 Hz, LP 75 Hz	5%	100 x 110 x 25 mm 193 g
	6 x EMG	24 Bit	± 1465 µV	HP 0.3 Hz, LP 110 Hz	5%	
	1 x ECG	24 Bit	± 5860 µV	HP 0.03 Hz, LP 110 Hz	5%	

SpO_2 module

Resolution Plethysmogram	16 Bit
Oxygen saturation	70 to 99 %
Pulse rate	18 to 300 pulsations per minute
Wave length	Red: 660 nm; Infrared: 910 nm
SpO2	70 – 100% ± 2 for adults when using the finger clip sensor 70 – 100% ± 3 for new-borns when using the sensor for new-borns or infants 70 – 100% ± 3 for adults when using the flex or reflectance sensor Accuracy of all sensors less than 70% is not specified.
Temperature	While in use: 0° C to +50° C When storing: -20° C to +70° C
Humidity	While in use: 10 – 90 %, not condensing When storing: 10 – 95 %, not condensing

SOMNOscreen™ Eco

Data processing	Active filtering of the signals Recording rate adjustable individually up to 1024Hz, High sampling Microphone up to 4096/s
Bluetooth module	Transmission power: 16mW Frequency range: 2402 – 2480MHz
Electricity supply of battery:	Measurements 53.5 mm x 36 mm x 12 mm Nominal voltage 3.6V Maximum charging voltage : 4.2 V Nominal capacity: 2350 mAh Maximum charging current: 1.5 A Integrated protective circuit with overcharge protection at 4.3V, deep discharge protection at 2.4V The duration is 15 months in use or 500 loading cycles. **Experience has shown that the battery should be replaced after 3 years at the latest.**
Docking station	Connect to PC via USB connection Status and charging LED
Touch Display	480 x 320 Pixel Signal control on the display Programmed starting and ending time Menu navigation via touch control
Storage medium	Industrial Grade µSD card, 1 GB in standard version Temperature range storage 0 – 50 °C, In use: -20 – 70 °C Only use memory cards authorised by SOMNOmedics
Humidity	While in use: 10 – 90 %, non-condensing When stored/transported: 10 – 95 %, non-condensing
Environmental temperature	While in use: 0°C to 50°C When stored/transported: -20°C to 70°C
Atmospheric Pressure	700 hPa – 1060 hPa

8 Service

8.1 Interference

If safe and proper operation is no longer possible, the device must be put from operation and securely stored to prevent inadvertent operation.

This applies:

- If the device is visibly damaged (broken housing).
- If the device is no longer functional (incorrect measurement results).
- If parts of the device are loose.
- If connectors are damaged (damaged cables).

Please call our service department if any of the above occurs. We will provide quick and competent help and service. Please find our contact information in the chapter service hotline and contact

8.2 Product life cycle

The expected product life cycle is 7 years.

Therefore, we highly recommend to stick to the suggested maintenance intervals of 3 years. Otherwise we cannot guarantee the expected product life cycle.

With each maintenance or repair, the firmware will be updated and the flash memory refreshed.

8.3 Storage and transport

Store the device and its sensors in the supplied transportation bag.

Pack the products in antistatic bubble wrap and in the device specific protection bags. The bag should be placed in a suitable shipping carton for transportation.

8.4 Storage and usage conditions

During operation, ensure an ambient temperature of 0°C to 50°C and a non-condensing humidity of between 10% and 90%.

During storage conditions, ensure an ambient temperature between -20°C and 70°C and humidity between 10% and 95%, non-condensing.

8.5 Warrenty

Warranty of security, reliability and functionality of the device is only provided by SOMNOmedics if:

- add-ons, modifications and repairs are carried out exclusively by persons authorised by SOMNOmedics or made by SOMNOmedics personnel.
- the device is only handled by instructed persons and skilled workers.
- transportation of the device is only carried out with original packing.
- the operation site complies with the ambient conditions of the device.
- the device is used according to the instruction manual (consider the safety instructions)

The warranty only refers to the main device SOMNOscreen™ Eco and includes a period of 24 months.

Note: If you use accessories which are not authorised by SOMNOmedics and it comes to service provision, this will be invoiced.

Note: It is not permitted to open the device. Repairs, opening the device and modifications are carried out exclusively in the factory. **All kind of repair and warranty procedures must to be performed by SOMNOmedics.**

8.6 Accessories and replacement parts

Should you wish to receive our catalogue, we will be pleased to send it to you. Please contact SOMNOmedics.

8.7 Disposal of application parts and batteries and/or the device

Used or replaced parts are not to be disposed of in the household waste.

Please consider the regional environmental regulations regarding disposal of used electronic devices and electronic parts.

Patient data saved on the memory card of the main device must be deleted for data protection reasons.

Note: Since 1st October 1998 portable batteries must no longer be disposed of in household waste after use. Consumers are obliged to hand over used batteries to the manufacturer, authorized dealers or to the local collection point.

8.8 EMC declaration

Bluetooth® information

The SOMNOscreen™ Eco device uses Bluetooth® wireless technology which is based on radio link that offers fast and reliable transmission of data. Bluetooth® radio uses globally available frequency range in the ISM band, intended to ensure communication compatibility worldwide and a fast acknowledgement and frequency hopping scheme to make the link robust, even in noisy radio environments. Please refer the technical specification section for details on RF specifications.

EMC information

The product emits radio frequency energy, but the radiated output power of this device is below the FCC radio frequency exposure limits. Nevertheless, the device should be used in such a manner that the potential for human contact with the antenna during normal operation is minimized.
The application of the device is within the EMC home health care environment.

Caution: Exposure to radio frequency radiation.

Portable and mobile RF communications can affect the performance of the device.

The device should not be used adjacent, or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Electrostatic discharge (ESD) may cause artefacts in the signal from the device. Avoid conditions where electrostatic charge can build up because of low humidity and friction against carpets, clothing and sheets made from artificial fibres.

The use of accessories, sensors, and cables other than those provided by SOMNOmedics GmbH and specified in chapter 2.5 may result in increased emission and/or decrease immunity of this device.

Cables with ferrite must not be substituted or replaced by cables without ferrite.

This system may be interfered with by other equipment, even if that equipment complies with CISPR emission requirements.

For patients with pacemakers we recommend placing the SOMNOscreen™ Eco on the abdominal region rather than the thoracic region. We recommend placing the device at least 7 inches away from the pacemaker. Following these placement guidelines, there is no indication for complications in patients with a pacemaker.

Do not use Radio Transmitters and Receivers, High Frequency Devices, CB-Radio Systems, Cellular Phones, Microwave Ovens, etc. where the electrical field strength exceeds 3 V/m (in accordance with IEC 60601-1-2) to SOMNOscreen™ Eco.

Refer to the tables below in this section for specific information regarding the compliance to the standard IEC60601-1-2.

In accordance with the EMC-regulations for medical products we are obliged by law to provide the following information.

Guidance and manufacturer's declaration — electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions, CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	N/A	Only for devices with power consumption > 75 W
Voltage fluctuation/flicker emissions, IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration — electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.		
Immunity test	**IEC 60601- test level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD), IEC61000-4-2	±8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment. Input/output not applicable. All cable shorter than 3 m.
Surge, IEC 61000-4-5	± 0,5 kV, ±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment. Common mode not applicable. Power supplies protection class II.
Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11	0 % U_τ for ½ cycle at 0, 45, 90, 135, 180, 225, 270, 315 degree 0 % U_τ for 1 cycle at 0 degree 70% U_τ for 25 / 30 cycles at 0 degree 0 % U_τ for 250 / 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery. Note: U_τ is the a.c. mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
		Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF, IEC 61000-4-6	3 V, 6V in ISM and amateur radio bands 150 kHz to 80 MHz, 80 % AM @ 2Hz	$d=1,2\sqrt{P}$
Proximity Field from Wireless Transmitters, IEC 61000-4-3	385 MHz PM @ 18 Hz, 27 V/m 450 MHz FM ± 5 kHz @ 1 kHz, 28 V/m 710 MHz PM @ 217 Hz, 9 V/m 745 MHz PM @ 217 Hz, 9 V/m 780 MHz PM @ 217 Hz, 9 V/m 810 MHz PM @ 18 Hz, 28 V/m 870 MHz PM @ 18 Hz, 28 V/m 930 MHz PM @ 18 Hz, 28 V/m 1720 MHz PM @ 217 Hz, 28 V/m 1845 MHz PM @ 217 Hz, 28 V/m 1970 MHz PM @ 217 Hz, 28 V/m 2450 MHz PM @ 217 Hz, 28 V/m 5240 MHz PM @ 217 Hz, 9 V/m 5500 MHz PM @ 217 Hz, 9 V/m 5785 MHz PM @ 217 Hz, 9 V/m	Do not use Radio Transmitters and Receivers, High Frequency Devices, CB-Radio Systems, Cellular Phones, Microwave Ovens, etc. within a distance of 30 cm (in accordance with IEC 60601-1-2) to SOMNOscreen™ Eco.

Radiated RF, IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz, 80 % AM @ 2Hz	d=1,2√P for 80 MHz to 800 MHz d=2,3√P for 800 MHz to 2,5 GHz
		Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.

Rated power of the transmitter (W)	**Separation distance according to the transmission frequency (m)**		
	150 kHz to 80 MHz d=1,2√P	**80 MHz to 800 MHz d=1,2√P**	**800 MHz to 2,5 GHz d=2,3√P**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

8.9 Service hotline and contact

If you have any questions, problems or suggestions, our phone and fax service will be available. We will provide a quick and competent service.

Our service hotline will provide expert help and advice at:

866 361 9937 (toll free)*

Send us a message by fax at any time.

+49 (0) 9 31 / 35 90 94 49

Send us your query by email any time.
service@somnomedics.de

Get free access to current software updates via service login on our website **www.somnomedics.com**

* 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.