

SleepDoc MiniPorti

Description and Instructions for use

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1. Introduction

The SleepDoc MiniPorti Sleep Diagnosis System is a recording system for outpatient and clinical use. It serves as a prediagnosis system for the sleep apnea syndrome. The MiniPorti unit enables continuous recording of max. 5 measurement channels for at least 15 hours without any data reduction.

It records signals for the following physiological variables:

1. Flow
2. Respiratory and snoring noises
3. CPAP pressure

optional:

4. Oxygen saturation, SpO₂
5. Pulse frequency

The MiniPorti system as a whole contains two components:

- The microprocessor controlled Porti recording device.
- PC software for measurement data presentation and analysis on a PC.

It is also equipped with the following accessories:

- Interface cable for serial data transfer between the Porti unit and PC.
- Memory card for storing the data.
- Flow prongs for obtaining the respiratory signal. The 20 cm long adapter hose is identified by a blue ring.
- Adapter hose for measurement during CPAP respiration.
- Flexible carry belt to fasten the Porti unit to the patient
- Battery recharger
- Shoulder bag for storing the Porti unit.
- Transport case.

optional:

- External reader for fast data transfer to the PC.
- SpO₂ finger sensor with cable for obtaining pulse frequency and oxygen saturation values.
- Velcro armband for securing the finger sensor cable to the wrist.

The data can be displayed and analyzed on a standard commercial PC. The measurement curves and the analysis results can be printed on all commonly available printers, such as dot-matrix, laserjet or inkjet printers.

The OR5 (Online Recording) analysis program has the following minimum configuration requirements:

- PC with Pentium processor or higher
- Microsoft Windows XP/Vista/7
- 512 MB of RAM (2 GB recommended)
- 100 MB of disk space on the hard drive
- CD-Rom drive for installation
- Mouse
- 128 MByte VGA graphics card with a resolution of at least 1024 x 768 (512 MB, 1280 x 1024 / High Colour recommended)
- 1 free serial interface or USB Port. Several graphics card manufacturers use the same interrupt as the Com1 or Com2 serial interface. This can therefore give rise to conflicts during data transfer. Ensure that the graphics card being used doesn't affect these interfaces.
- Printer with Windows driver

In this manual should be given a short description about handling the SleepDoc Porti device and an introduction in the PC program. After a few *general informations* in the following part the connections of the SleepDoc Porti and the *provision of the device for use* are described. In the next part the *PC software's* installation, structure and possibilities of representing and preparing the measurement curves are shown. Followed by a chapter for *troubleshooting* and a listing of the SleepDoc Porti's technical data. *Ordering informations*, an *index* and a *quick reference* for the patient complete this manual.

2. Informations

2.1. Safety-related informations

**Observe the instruction manual!**

Every use of the device requires exact knowledge and observance of this instruction manual. The device is only intended for the use described herein.

**Patient instruction:**

Patient instruction must only be carried out by the doctor or staff authorized by that person. The enclosed quick reference cannot take the place of instruction and warnings about possible hazards.

**Don't open the device!****WARNING:**

For online measurement it is prescribed to use an electrical or optical isolator for connection of the device to the PC (available as option)! A connection of the device to the PC without electrical or optical isolator is only allowed if all patient connections have been removed first. Only physicians or by physicians authorised stuff is allowed to perform online measurements.

**WARNING:**

Magnetic and electrical fields can impact on the functioning of the device. When operating the device, ensure that all third-party devices being operated in the vicinity are meeting their relevant EMC requirements. X-Ray equipment, HF surgical devices, tomographs, etc. can interfere with other devices because they are permitted to emit higher levels of electromagnetic interference.

**Warning:**

The device has no defibrillator protected application parts. A direct application of the device at the heart (esp. ECG!) is not allowed.

**Warning:**

Using more than one device at one patient results in summation of the leakage current, which can exceed the allowed value!

**Warning:**

Using the device together with pacemakers can result in disturbances of the pacemaker or the device.

**Warning:**

The application of the device to more than one patient at the same time is not allowed.

**Warning:**

During the fasten of the electrical sensors it is to ensure that no electrical line of the device is in contact to other electrical conductive parts or to ground.

2.2. General informations

This instruction manual should be regarded as a component of the device. It should be kept on hand somewhere near the device at all times. Exact observance of the instruction manual is a prerequisite for proper use and correct handling of the device and thus the safety of the patient and operator.

Only such accessories (e.g. patient leads, sensors, consumables, Memory cards etc.) as are listed in this instruction manual and which have been tested in conjunction with the device should be used. If third-party accessories and/or consumables are used, we cannot guarantee safe operation / safe functioning of the device.

Damages resulting from the use of third-party accessories or consumables shall render this warranty void.

The manufacturer will only assume responsibility for the device in terms of safety, reliability and function if:

- a) **assembly, add-ons, reinstallation, changes and repairs are carried out by the manufacturer or an agent expressly authorized by the manufacturer to do so;**
- b) **the device is used in accordance with the instruction manual.**

All printed material relates to the model of the device and the status of the applicable safety norms at the time of printing. All devices, switches, processes, software programs and names contained herein are subject to copyright law.

FuG shall be liable only for the functioning but not absolute error freeness of its programs.

Medical devices must only be operated by persons who, on account of their education or knowledge and practical experience, are able to guarantee correct handling of such devices.

The user should assure him or herself of the functional safety and the correct state of the device prior to every use of that device.

The operator should be familiar with the operation of the device.

You should perform a functional check at regular intervals (about once a month).

At the end of its service life, the device and its accessories should be disposed of in accordance with the relevant ordinance on electronic scrap.

If you are uncertain about this, please contact Dr. Fenýves und Gut.

2.3. Technical inspection:

Only regularly maintained devices are functionally safe. To maintain the functional and operational safety of the device, a series of technical tests should be carried out on the device every 12 months, at least every 24 months.

This testing should only be provided within the framework of a service contract and by the Dr. Fenyves und Gut customer service department, who would be happy to provide further information on this.

The following tests in particular need to be carried out:

1. Visual inspection of the device and accessories for function-impairing mechanical damage.
2. Testing the water-tightness of all hose connections.
3. Testing the thorax and abdominal sensors for leaks.
4. Checking the display LEDs.
5. Testing the pulse and SpO₂ finger sensors and carrying out plausibility test (pulse test using a watch).
6. Checking the CPAP pressure.
7. Testing the battery capacity.

2.4. Liability for functioning or damage

Liability for the functioning of the device shall transfer to the owner or operator in the event of improper maintenance or repair of the device or if it is handled in a manner for which it was not intended.

FuG shall not be liable for damages arising from non-observance of this instruction manual.

The actual guarantee and warranty conditions in FuG terms of sale and terms of delivery shall not be extended by preceding remarks.

3. Recording measurement data using the Porti unit

3.1. Sensors

3.1.1 Sensors for flow and snoring noises

A flow prong, that transmits the pressure signal to a sensitive pressure transducer in the Porti unit, serves as the sensor for respiration (flow). The flow prong can be put on easily and surely by the user and will not adversely affect the quality of sleep. It can also be used with those patients where adhesive sensors cannot be fastened reliably (e.g. persons with a beard).

Being a commonly available consumable article, this type of sensor is economical to use.

No additional sensor is required for respiratory and snoring noises. The noise is transmitted to the Porti unit by acoustic means through the flow prong hose. The arriving signal is analyzed electronically.

This makes it unnecessary to stick sensitive and expensive microphones onto the patient.

Thanks the high sensitivity of the pressure transducer in the Porti unit, it is possible to measure ultrafine pressure differences so that even those patients who breathe through the mouth can be monitored and recorded.

The flow prong should be used in accordance with the manufacturer's instructions.

3.1.2 Sensor for oxygen saturation and pulse frequency

A pulse oximeter has been integrated into the Porti device for the purpose of measuring oxygen saturation and pulse frequency. If the sensor cable is too short, then an extension can be used.

When using a finger sensor, ensure that blood circulation in the finger being measured is not affected by the manner in which the sensor has been secured.

The sensor should not be secured by winding adhesive tape around the finger. It is better to secure the cable to the wrist using the supplied velcro armband. This prevents the finger sensor from slipping and avoids annoying adhesive residues and allergic reactions.

Always remove nail polish (even clear lacquer) on the measurement finger otherwise the measurement data obtained will be unusable.

Please also observe the instructions accompanying the sensor.

3.1.2 Sensors for CPAP/BiPAP Measurement

When performing measurements on a patient undergoing CPAP respiration, an adapter hose is used instead of the flow prong.

The **blue** connection on the flow prong or CPAP hose needs to be plugged onto the **blue** connector on the Porti unit.

3.2. Preparing for measurement

To prepare the Porti unit for measurement data recording on the patient, you need to carry out the following steps:

1. Charge the battery: see 4.1 Charging the battery, (Page 6).

2. Connect the Porti cable for data transfer to the serial interface (RS 232) on the PC and the Porti unit. The Porti unit's serial connection is located at the rear of the device where you previously connected the recharger.

3. Start the Porti program on the PC.

4. Fill out the fields relating to personal data of the patient in the menu item "Porti / Initialize card" and start the transfer.

5. Switch on the Porti unit using the slider (by moving the slider to the right). For testing purposes, both LEDs will light up initially. The red LED will then go off. The green LED on the Porti unit will remain lit for the duration of the initialization process.

6. Having finished successfully, the way to proceed next depends on the type of recording mode selected:

a. timer controlled recording start:

A dialog appears which you can use to determine the start time for recording.

The Porti unit needs to remain switched on after this time!

It automatically goes into a stand-by mode and automatically switches itself on again at the selected recording start time. Never switch off the Porti using the slider.

b. manual recording start:

Both LEDs begin to blink. **The Porti unit now needs to be switched off using the slider** (by moving the slider to the left). The patient starts the measurement by switching on the Porti unit prior to going to bed (by moving the slider to the right).

7. The Porti unit is now ready for measurement. The unit can be disconnected from the PC. To do so, pull the plug out of the Porti unit (pull on the plug - **not** on the cable).

3.3. Attaching the Porti unit and starting the measurement

In order to guarantee reliable recording, you need to observe the following points when attaching the Porti unit and sensors. These steps should be demonstrated and practised with the patient beforehand in the clinic:

- Secure the Porti unit to the thorax using the elastic belt. In doing so do not wear the belt on your bare skin but instead on an undershirt. A properly fitted belt should not slip down when a standing person is in the final expiratory breathing position.
- Put the flow prong on your nose or fasten the adapter hose to the CPAP mask.
- If the sensors were not already connect to the Porti unit in the clinic, they need to be connected now (flow prong or CPAP adapter hose to the blue connection socket).
- Apply the finger sensor (SpO₂) to a finger and secure the cable to the wrist using the velcro armband. Whilst doing so, ensure that you do not squeeze the finger thereby disturbing the blood flow.
- If manual recording mode was selected at the time the card was initialized, the patient needs to switch on the Porti unit using the slider (towards the right) when going to bed. Otherwise (for timer controlled recording start) the Porti unit will switch itself on at the predefined time.
 - Both LEDs light up briefly for testing purposes.
 - The red LED will go out. The green LED blinks at regular 4 second intervals.

The patient has now been fully informed. The completely assembled case can now be given to the patient to take home along with the quick reference (at the back of this instruction manual).

When going to bed the patient needs to:

- Attach the Porti unit using the elastic belt

- Attach the flow and finger sensors.
- Check that the sensor and the connector are seated correctly.
- If manual recording start was selected: Switch on the Porti device using the slider (towards the right).

The next morning:

- End the measurement by switching off the MiniPorti unit (slider towards the left).
- Detach the Porti unit and sensor and return all parts to the case.
- Cleaning of the device will be done by the technical staff at the clinic.
- Bring the case back to the clinic.

4. Service and Maintenance of the device

4.1 Charging the battery

The Porti unit uses as its voltage supply special fast-charge capable NiMH batteries that do exhibit only a very little memory effect. The supplied ACS 110 battery recharger is specially suited for these batteries and should only be used for the aforementioned devices.

Caution: Never connect the battery charger to the Porti unit while a patient measurement is taking place! All through the charge process the Porti is to keep switched off!

Battery recharging procedure:

1. Connect the recharger to the Porti (connection socket at the rear of the device).
Make sure the Porti is switched off!
2. Plug the recharger into a power outlet.
3. The red LED of the charger will remain permanently lit
4. When fast-charging is finished (approx 2 hours) the red light will lights up. The charge process is finished as soon as the red LED lights up. The battery can remain connected to the recharger in this state for a longer period of time without suffering any damage.

4.2. Cleaning instructions

The flow prong is a single-use article and should not be used more than once or on different patients.

The finger sensor can be cleaned using a moist cloth or, if necessary, treated by spraying on or wiping it with a disinfectant.

You should however never immerse the sensor in a liquid. Any adhesive residues that may be present should be removed regularly (e.g. using alcohol swabs).

The body belt can be washed at 60°C in the washing machine. The bag can be cleaned using moist disinfectant wipes (observe the detergent manufacturer's instructions).

4.3. Maintenance

We recommend that you have the device, including all accessories, serviced once a year. The servicing should only be carried out by the manufacturer or by an agent it has authorized to do so.

Calibration of the CPAP channel (see .2.2.6. Menu item: Porti / CPAP calibration, Page 11) should be carried out once a week by the user.

5. Evaluation software for PC


5.1. Installation and configuration

5.1.1. Installing the software

Installation of the Porti PC program involves copying all the files from the supplied CD to the hard drive. This happens automatically and is managed by the installation CD.

Before carrying out the installation you need to turn on the PC and start the Windows operating system.

To install the Porti PC program, insert the supplied CD into your CD-ROM drive. In normal case the Setup-Programm starts automatically. If not you have to open the Windows-Explorer and select your CD drive. Then double-click *Setup.exe*.

By Click to the Search button  you can scan the complete computer incl. network for versions already installed. To make sure that the right version is selected, the previous version can be started before clicking to the search button. The installation software then will find the current running version.

Alternatively the setup program can be started by menu item "Tools / Update" in the Porti PC software (only for Update!).

After selecting the target drive the installation program will now automatically create the necessary directories and copy all the required files to the hard drive. The installation will automatically insert a new group containing an entry for the new software in the Programs folder of the Start Menu. Also a shortcut on your Windows desktop will be created.

After successful installation, remove the CD and store it in a safe place.

5.1.2. Configuring the serial interface

The measurement data from the Porti unit is transferred to the PC via one of the serial interfaces COM1 to COM255. After starting the program for the first time, you need to select the **correct serial interface** (see .2.2.5. Menu item: Porti / Settings, Page 10).

For faster data transfer, you also have the option to use an external card drive.

5.1.3. Selecting a printer

The curves and reports can be printed on any commonly available type of printer (inkjet, dot-matrix or laser printer) that is already installed on your Windows system. The correct printer driver can be selected using the Windows Control Panel applet.


5.2. Menu bar commands

This section will describe the menu structure and the analysis functions of the Porti software. The analysis includes the automatic recognition of apneas/hypopneas, breathing sound and artefacts.

The results and measurement curves can be printed out in the form of a report.

5.2.1. "File" menu

5.2.1.1. Menu item: File / File Manager

You can access the file management by selecting the menu item File / *File Manager* or by clicking the File Manager button . This menu offers you access to all saved measurements.

Options / *Sort* can be used to sort the list of measurements either in alphabetical order according to the name of the patient or chronologically according to the date of recording.

There is the option to print out a list of files. This list can for example be used to label the cover of an archival CD.

With Button "Backup" the measurements can be archived in different ways:

1. All non archived measurements
2. All measurement in a selected period
3. All measurements


Button "Explorer" opens the file manager with more file handling options:

To perform an action (copy, move, delete, rename or open), you first need to select one or more measurements. You can select several files at once by using the <SHIFT> or <CTRL> key.

You can use Search for / *Find* to search for the name of a patient. F4 (Find Next) can be used to display each of the surnames found in turn.


The file manager can be closed either by opening a measurement or by selecting the menu item File / *Exit*.


5.2.1.2. Menu item: File / Print

You can access the print menu either using the menu item File / *Print* or by clicking the Print button .

The following items can be printed out:

1. Report
2. Entire measurement curve

After selecting the items to be printed, you can start printing by clicking the Print button .

Notes: The Button  prints also a Screenshot while the measurement is open. It's not necessary to choose the printing menu in this case!

If the **Entire Measurement Curve** item was selected, the entire measurement curve will be outputted to the printer. In doing so the resolution (= zoom level) that was selected in the "Time Resolution" selection field on the right will be used.

The "Print Markers" selection field can be used to set whether the event markers should also be printed out along with the measurement curve. We recommend that when printing a single screen the printer markers be printed out as

well, however when printing the entire measurement curve the print markers not be printed as well to ensure readability of the output.

5.2.1.3. Menu item: File / Export

By means of the menu item File / *Export* a measurement can be exported to different formats:

- 1.) Raw data (only raw data without evaluation)
- 2.) Full measurement (all files of the measurement incl. evaluation will be compressed in one file)
- 3.) EDF (European Data Format)
- 4.) Thorax / Abdomen: Numeric output of channels Thorax and Abdomen

5.2.1.4. Menu item: File / Send via Internet

The menu item File / *Send via Internet* allows you to send a measurement via Internet. Requirement: Internet connection and a Email program installed on the computer. The following formats are available:

- 1.) Raw data (only raw data without evaluation)
- 2.) Full measurement (all files of the measurement incl. evaluation will be compressed in one file)

5.2.1.5. Menu item: File / Import

The menu item File / *Send via Internet* allows you to import raw data or full measurements, which have been exported with menu item File / *Export* or File / *Send via Internet*

5.2.1.6. Menu item: File / Close

To close a measurement that has previously been read in, select the menu item *Close* in the File menu. All changes will be saved automatically.

5.2.1.7. Menu item: File / Exit

The menu item File / *Exit* terminates program.


Important: Do not turn off the computer before exiting the program otherwise all the changes you have made will be lost!

5.2.2. "Porti" menu

5.2.2.1. Menu Item: Porti / Porti initialisation

To prepare the Porti unit for a new measurement, select the menu item *Porti / Porti initialisation*. This requires the Porti unit to be connected to the PC for data transfer by means of a serial cable.


The input window that appears can be used to input the patient data. It is not necessary to fill in all the fields.

Now make sure that the Porti unit is switched off (slider at left). After inputting the patient data you can click the Start transfer button . You now need to switch on the Porti unit (slider at right, red light on).


If "timer controlled" recording start mode has been selected (see , Page 14), you now need to specify the start time and the duration of the recording.

The transfer is complete as soon as the blue progress bar has gone away again.


If manual recording start mode is selected, you now have to switch off the device. If timer controlled recording start mode is selected, the device remains ready for operation and automatically switches to stand-by mode.

The GDT Basic Data button  can be used to request and update the personal data from a **Clinic Computer System (CCS)**.

If a suitable card reader has been connected, the patient data can also be read in from the patient's health card.

Caution: You should always click the **Health Card button**  before inserting the health card into the card reader! Should you forget to do so, if worst comes to worst the entire operating system may crash!


Procedure:

1. Select *Porti / Porti initialisation*.
2. Connect the Porti unit to the PC
3. Fill in the input fields (manually, via a CCS or via a health card)
4. Click the Start transfer button .
5. Switch on the device and wait until the blue progress bar has gone away again.
6. **For timer controlled recording start:**
Enter the time, date and duration of the recording and leave the device switched on!
For manual recording start:
Switch off the device when prompted.

5.2.2.2. Menu item: Porti / Read Measurement from device

To import a measurement from the Porti unit, select the menu item *Porti / Read Measurement from device*.

To transfer the data, connect the Porti unit to the PC using a serial cable and make sure that the Porti unit is switched off (slider at left) and connected to the PC.


Now click the Start transfer button  and switch on the Porti unit (slider to the right).

The patient data and measurement curves will now be transferred from the Porti unit to the PC.

If there is only one measurement on the card (see .2.2.5. Menu item: Porti / Settings, Page 10), it will automatically be converted, loaded, analyzed and displayed on the screen.

If there are several measurements on the card, the Select a Measurement dialog will appear allowing you to select a measurement whereupon it will be automatically converted, loaded and displayed on the screen. The other measurements that were not loaded can be loaded also at a later time using the menu item *Tools / Convert*.

Procedure:

1. Select the menu item *Porti / Read Measurement from device*.
2. Connect the Porti unit to the PC.
3. Make sure that the Porti unit is switched off.
4. Click on the Start transfer button .
5. Switch on the Porti unit.
6. If there are several measurements on the card: Select a measurement and click OK to confirm your selection.




5.2.2.3. Menu item: Porti / Online

To start online recording with the Porti unit, select the menu item *Porti / Online*. This requires the Porti unit to be connected to the PC for data transfer via a serial cable.



Select the menu item **Test** (online display only without saving the measurement values) or **Record** (online display and saving of the measurement values).


When you select the menu item **Record** an input dialog will appear in which the patient data can be entered (see 2.2.1. Menu Item: Porti / Porti initialisation, Page 9).

Make sure that the Porti unit is switched off (slide at left).


Now click the Start button  and switch on the Porti unit (slider to the right).

As soon as the connection has been established, the online measurement curves will be outputted to the screen.

Pressing 'R' or clicking the button  will enter the Scrolling Mode (only Recording!). You can exit the scrolling mode with Button .

To stop recording, click on the Stop button .

Important:

- Only when *Record* is selected (not *Test*!) are the displayed measurement values also saved and able to be analyzed afterwards.
- Always stop the measurement session by clicking the Stop button !! If the computer is turned off before the measurement session was stopped, the entire **measurement session will be lost!**

5.2.2.4. Menu item: Porti / Hot Plugin

If the screening device is equipped with the option "Hot Plugin", the online measurement can be executed without switching off the Porti device by selecting the menu item *Porti / Hot Plugin*.

Possible are Test (without storing) and Record (with storing the data to the hard disc of the PC).

Important: For performing the Hot Plugin Mode a special card has to be used (available as accessories). This card can be formatted with *Porti / Hot Plugin / Hot Plugin Generate Card*.

5.2.2.5. Menu item: Porti / Settings

To access the Porti Settings dialog, select the menu item *Porti / Settings*.

This is where, for example, you have the option to specify how the raw data of the measurements are to be analyzed and filtered when imported from the Porti unit.

The various settings provided will now be described:

- **Minimum duration for measurement:**
This is where you enter the minimum period of time (in minutes) a measurement needs to span for it to be recognized as a measurement.
- **Immediately Printing**
By Activating the option "Begin Printing Instantly after reading measurement" the Printing will start directly automatically after reading a measurement from the device. With the boxes "Report" and "Entire curve" the Printing can be configured.

- **Filter for SpO₂:**

This is where you can set the SpO₂ and pulse filter. The higher the filter value, the more the curve will be filtered and thereby smoothed. Filter 0 means no filtering.

Useful values for the filter setting are 0 to 20. Higher filter values make it difficult to diagnose desaturation and artefact events.

There are two possible ways to change the filter:


1. **New measurement:**

This setting will only affect future measurements, either when **imported** from the Porti unit or when converted. Any measurement that has already been imported will not be affected by the change but instead will retain the filter value used when it was imported.

2. **Current measurement:**

This setting will only affect the measurement that is **currently** being processed. After making the change, all SpO₂ markers will be deleted because the profile of the SpO₂ curve has changed. You therefore need to reanalyze the measurement (event recognition).

- **Com port:**

This is where you can set the interface for serial data transfer from the Porti unit to the PC. Installed COM Ports can be found with Button .

- **Send Delay:**

This parameter is used for coordination of the Porti unit with the PC. **Do not change this parameter without first consulting our technical department!**

- **Recording start:**


The Porti unit can be operated in one of two different recording modes:

- a. **Manual switch-on:**

In this case the patient starts the measurement him or herself when going to bed by switching on the Porti unit by means of the slider.

- b. **Timer-controlled switch-on:**

In this recording mode, the Porti unit automatically starts the measurement at a predefined time. This time is specified when initializing the Porti unit. In this recording mode, the Porti unit is not allowed to be switched off until after the measurement session has ended (i.e. after getting up in the morning)!

If you click on the Original values button , you will get the factory default values. You have to exit the dialog with OK however to retain the factory default values!

Tips:

- To ensure that instructional sessions with the patient will not appear as measurements, set the *Minimum measurement duration* to a high enough value (e.g. 5 min).
- If timer controlled recording is set and you mistakenly turn off the Porti unit **before** the measurement session has begun, you can still turn it on manually by means of the slider before going to bed and nevertheless obtain a problem-free measurement.
- If you operate your mouse on com1, never use com3 as the Porti interface! (The same applies for the use of com2 in conjunction with com4).

5.2.2.6. Menu item: Porti / CPAP calibration


To control or adjust the calibration of the Porti unit's absolute CPAP pressure (recommended once a week), select the menu item Porti / CPAP calibration.

Execute the CPAP calibration **before** initializing the device because only at the initialization the changed CPAP calibration data is transferred!


Note:

The Porti unit's flow sensor must not experience any pressure differences during the following procedure!

Make sure that the Porti unit is connected to the PC and is switched off (slider at left).

Now **first** click the Start transfer button  and **then** switch on the Porti unit (slider to the right).



Once a connection has been established, automatic calibration of the CPAP pressure will commence.

As soon as the displayed curve has stabilized (after approx 5 sec), you can stop the calibration by clicking on the Stop button .

If the calibration ran successfully, you can answer Yes to the confirmation prompt that follows (*Should the determined value be saved*). If you answer No to the confirmation prompt, then the result of the automatic calibration will be discarded and the previously valid value will be used again.

Next you need to switch off the Porti unit again and initialize the Porti again.

Procedure:

8. Select Porti / CPAP calibration.
9. Ensure that no air pressure acts on the flow sensor.
10. Make sure that the Porti unit is connected to the PC and is switched off.
11. Click on the Start button .
12. Switch on the Porti unit.
13. As soon as the measurement curve has stabilized (after approx 5 sec): Click the Stop button .
14. If the calibration was successful: Answer Yes to the confirmation prompt that follows.
15. Switch off the Porti unit again when prompted.
16. **Initialize the Porti with a new patient.**

5.2.3. "Evaluation" menu


The OR (Online Recording) program enables you to automatically analyze your measurements.

The recognized events are displayed as coloured markers on the measurement curve.

The menu item Options / Evaluate criteria allows you to specify yourself the criteria for the classification of events.

You can start the analysis by selecting the menu item Evaluation / Detect events.

This will delete all previously diagnosed markers (including those added manually!) and recalculate them.

At the end of the analysis, a report is generated which you can view on screen either by selecting the menu item Evaluation / Report or by clicking on the button . This is where you can also enter a commentary that will appear in the printed report.

You also have the option to export the analysis results in different formats.

Important:

The event recognition function deletes all existing markers and creates new ones.

5.2.3.1. Menu item: Evaluation / Detect events

Once a measurement has been loaded it can be reanalyzed using Evaluation / Detect events.

The menu item Options / Evaluate criteria allows you to specify yourself the criteria for the classification of events.

The following events are recognized and marked:

Flow:

- apnea
- hypopnea
- Cheyne-Stokes breathing
- artefacts

SpO₂:

- desaturation
- artefacts

Pulse:

- Pulse variance
- artefacts

Snoring:

- snoring
- artefacts

In channel Flow five User-defined events can be specified.

5.2.3.2. Menu item: Evaluation / Confirm Events

To search for and confirm events after a specified period, select the menu item *Evaluation / Confirm Events*.

For each channels either all types of event or only one event type can be selected. All detected events of this type will be displayed colour marked in sequence.

The user now has the following options:

8. Key from left column: change event type

9. Key '+': Confirms the event.

10. Key '-': Deletes the event.

11. Key 'ESC': Confirms the event and cancels the search.

After each action the next available event will be displayed automatically.

The time resolution can be changed with click to the buttons '+' or '-'.

Deleted markers can be restored again using *Evaluation / Detect events*.

5.2.3.3. Menu item: Evaluation / Delete all markings from cursor on

If the cursor is set in the raw data screen, all events can be deleted from this cursor position on either in only one single channel or in all channels.

5.2.3.4. Menu item: Evaluation / Idle running time

To enable the Porti unit to record those patients that for some reason or other cannot be expected to or relied upon to switch on the Porti unit themselves before going to bed, the Porti unit also offers an option for timer controlled starting of recording (see .2.2.1. Menu Item: Porti / Porti initialisation, Page 9 and , Page 14).

If the selected recording start time turns out to be prior to the patient actually going to bed, then the Porti unit cannot of course record any relevant signals.

To nevertheless guarantee a reliable diagnosis, this "lead time" can be specified using the menu item *Evaluation / Idle running time*. This will ensure that this period of time will be ignored in the automatic analysis.

Alternatively, the lead time can be specified in the Flow channel by dragging with the mouse (see .3.1. Editing a marker Page 19).

5.2.3.5. Menu item: Evaluation / Set evaluation period

To create separate, partial reports for different sections of the measurement, evaluation periods can be defined with menu item *Evaluation / Set evaluation period*. To define this evaluation sections the cursor has to be placed on the main screen first.

In the following dialog box an additional text can be allocated for each evaluation period, which appears while moving the mouse over the corresponding marker (red triangle) in the general view. For a quick assignment of this text 12 text storages can be configured.

To create a partial report: see .2.3.8. Menu item: Report (partial), Page 13

Evaluation periods can be edited or deleted by clicking with right mouse button on corresponding marker.


5.2.3.6. Menu item: Evaluation / Set comment

With this menu item a comment can be set in the raw data screen. To define this comment the cursor has to be placed on the main screen first.

In the following dialog box an additional text can be allocated for each comment, which appears while moving the mouse over the corresponding marker (green ellipse) in the general view. For a quick assignment of this text 12 text storages can be configured.

Comments can be edited or deleted by clicking with right mouse button on corresponding marker.

5.2.3.7. Menu item: Evaluation / Report

Once a measurement has been analysed by means of event recognition, a report is generated automatically which can then be viewed by selecting the menu item *Evaluation / Report* or by clicking the button  (to print it out, see . 2.1.2. Menu item: File / Print, Page 8).

The screen is divided in multiple parts. With menu items and mouse buttons the settings and formats can be changed for the writing area. Dynamic fields and graphics can be inserted using the sidebar.

5.2.3.7.1. Menu items in the report

a.) File:

A Template can be opened by menu item **File → Open template**. The template dialog will appear if more than one templates is available. A standard template can be assigned, which will opened in the report by default.

Every file can be stored as component (**File → save as component**) or as template (**File → save as template**).

Important: The recommended path shouldn't be changed. Otherwise the components and templates cannot be displayed in the sidebar!

File → Export as PDF creates an Adobe Acrobat® PDF file from the actual report.

File → send by E-Mail allows to send the actual report as PDF file or RTF file. After selecting the format the standard E-Mail client is started with the selected files as attachment.

File → GDT-Report is exporting the report to a Clinic Computer System

b.) Edit

The Edit menu item includes all methods to edit the text as in well-established text software.

Edit → Save selection as component (template) allows to store a selected text as a component (template).

Important: The recommended path shouldn't be changed. Otherwise the components and templates cannot be displayed in the sidebar!

c.) View

In menu item View the display of the report can be changed. For creating header and footer a double click into the area of the document is sufficient. More settings are available in the menu item **View → Header and Footer**. The start-up of the report (edit mode or read only mode) can be defined in **View → Start in Edit Mode**.

d.) Insert

Page breaks, section breaks, files, graphics, symbols, lines and page numbers can be inserted by means of the menu item Insert. Screenshots of the raw data measurement screen, which have been created by mouse drag (and pressed F2 key) can be inserted with this menu also. Formats for

single paragraphs can be defined with menu item **File** → **Page layout**.

e.) Format

Paragraphs and characters can be formatted in menu item **Format**. Also the form of the dynamic diagrams and the graphics can be changed.

f.) Table

Menu item **Table** allows to insert and edit tables. Right click with mouse is a quicker way to edit existing tables.

5.2.3.7.2. Mauspalette

Mouse buttons on the top gives a short cut for the most important and most used actions in the report builder. It allows to format the text, manage files and create or edit tables.

5.2.3.7.3. Sidebar

The side bar on the right side allows to insert dynamic fields, diagrams and raw data curves into the report. The sidebar is divided into two sections:

a.) General

In the section **General** of the sidebar the diagrams and graphics (curves) can be inserted. This objects will be updated everytime the report is opened.

Protocol Heading, **Patient Data** and **General Measuring Data** are inserted as text fields. Predefined tables for several evaluations are located in section **Components**. Additional components can be defined. They will be displayed in section **User Components**.

b.) Evaluation

All calculated values are available in section **Evaluation** in the sidebar. They can be inserted into the report as textfields. The following sections are available:

- Respiratoric
- PulsOxi and ECG
- CPAP / BiPAP
- Sleeping Analysis
- Related to position
- Miscellaneous

5.2.3.8. Menu item: Report (partial)

With menu item **Evaluation / Report (partial)** for each evaluation period, which was defined (see 2.3.5. Menu item: Evaluation / Set evaluation period, Page 12), a separate report can be created.

5.2.3.9. Menu item: Report (former)

Here the former report (until OR Version 5.07) can be displayed.

5.2.3.10. Menu item: Evaluation / Quisi

If you are performing a measurement with the QUIST® screening device in parallel to the SleepDoc Porti study, the corresponding Quisi® findings can be imported using the menu item **Evaluation / Quisi**. The following points should be noted in relation to this:

- The Porti measurement and the Quisi® measurement must always be started at the same time (instruct the patient accordingly!).

- The Quisi® analysis program must be configured to create statistics files (the checkbox "Statistics files" needs to be active in the "Options" dialog.).

Procedure:



1. Analyze the Quisi® measurement using the associated software (Quisi → Receive characteristics → Classification).
2. Read in the Porti measurement using the Porti program.
3. Import the Quisi® data via the menu item **Analysis / Quisi**:
The required Quisi® project can be opened in this dialog.

The hypnogram and the Quisi® report can be viewed using **Evaluation / Report / Sleeping stages**. These are printed out automatically along with the overall printout of the Porti report.

5.2.4. "Zoom"

You can zoom using either the **mouse** or the **keyboard**.

1. Zooming using the mouse:

- 1.1. Clicking on the zoom buttons will automatically magnify  or reduce  by one level.
- 1.2. Selecting the menu item **Zoom** will display all the available zoom levels. The currently active zoom level is indicated by a tick. A new zoom level can now be directly selected by clicking on it.
- 1.3. Move the mouse (with pressed **left** mouse button) and select "Zoom In"
- 1.4. Using mouse wheel while pressing **CTRL** and **SHIFT** Key of keyboard.

2. Zooming using the keyboard:


- 2.1. Pressing the + (plus) or – (minus) keys automatically leads to a magnification (+) or reduction (–) by one level.
- 2.2. You can select a zoom level directly by pressing the keys 0 to 9, where 1 corresponds to the highest zoom level (e.g. 30 sec), and 0 to the lowest zoom level (e.g. 8 hours).

If the cursor is not located on the screen then the left edge of the image will be maintained when zooming.

If however the cursor is located in the measurement, then the zooming occurs from the cursor onwards, i.e. the current cursor position becomes the new left edge.

Tip:

You can scroll in arbitrary small steps by placing the cursor at the new position and then reselecting the current zoom level from the menu item **Zoom**.

A click on button  shows the full measurement.


While measurement is open it's possible to increase the vertical height of all channels at once by means of "Shift"-mouse wheel (Zoom in vertical direction). With the right scroll bar or with "CTRL"+"Shift"-mouse wheel you can scroll vertical through the measurement then.

5.2.5. "Measurement" menu


5.2.5.1. Menu item: Measurement / Measurement Validated

With menu item Measurement / *Measurement validated* you can mark by mouse click a measurement as evaluated. Each modification of the system evaluation by the user will change the settings to "Yes"

5.2.5.2. Menu item: Measurement / Patient data

If you wish to view or edit the data of an existing measurement, then you can (after first opening the measurement) either select the menu item Patient Data from the Measurement menu or click the Patient Data button .

If a suitable card reader has been connected, the patient data can also be read in from the patient's health card.

Caution: You should always click the Health Card button  before inserting the health card into the card reader!

Should you forget to do so, if worst comes to worst the entire operating system may crash!

5.2.5.3. Menu item: Measurement / Measurement beginning

This input dialog can be used to edit the time or date of the measurement. This can for example be necessary if a wrong date or wrong time was set on the computer at the time of recording.

To make the change, you first need to open the required measurement.

5.2.5.4. Menu item: Measurement / Generating breathing rate by...

With this menu item the breathing rate can be calculated and displayed from the channel Flow.

5.2.5.5. Menu item: Measurement / Breathing force

For getting a very quick overview of the breathing intensity you can use the menu item Evaluation / breathing force.

A normal breathing shows a thin line over the complete measuring period. Apneas / Hypopneas resulting a wide line.

5.2.5.6. Menu item: Measurement / Channel terms

The menu item Measurement / *Channel terms* enables you to change the name of a particular channel.

This change applies **only to the current measurement** and is automatically saved with the measurement.

If you want to permanently change a channel name, then select the menu item Options / *Channel settings*

5.2.5.7. Menu item: Measurement / Range

The range of a channel for display can be increased or decreased both during the online recording and during analysis. Changing the range does not affect the raw data but only the representation on the screen or printer, i.e. the change can be undone again without any loss in quality.





The range of a channel in the currently loaded measurement can be edited using the menu item Measurement / *Range*. Also it can be changed fast and comfortable with the mouse and the left title bar (see 3.5. Adjust display of curves, page 19)

The range for all future measurements can be set using Options / *Channel settings* (Range option).

The range to be displayed can also be changed during an **online recording**:

The B key activates edit mode. The channel whose range can be changed appears in red writing at the left edge of the screen.

The range can now be changed using the following keys:

Page , Page  : Selects the channel to be set
,  : Shifts the centerline upwards or downwards
 + : Reduces the range (= increases the amplitude)
 - : Increases the range (= decreases the amplitude)

Note: Shifting the centerline will have no effect if the maximum recording range has been set!

If you wish to shift the centerline then you have to first reduce the recording range.

So that you can check the settings, a window appears at the top edge of the screen in which currently set range is displayed.

5.2.5.8. Menu item: Measurement / Numeric Output

With this menu item the numeric output of measurement values on the left border of the channel can be switched on and off.

5.2.5.9. Menu item: Measurement / Inverted Display

With means of menu item Measurement / *Inverted Display* the channels can be mirrored along the centre line of the channel.

5.2.5.10. Menu item: Measurement / Calibrate

To calibrate a channel after the measurement the menu item Measurement / *Calibrate* can be used.

5.2.5.11. Menu item: Measurement / Increase

The menu item Measurement / *Increase* can be used to retrospectively increase or decrease the amplitude of the flow, thorax, abdominal, ECG, leg and snoring values.

This allows, for example, a measurement with a nonoptimal flow recording to be corrected afterwards.

Caution: Do not amplify the channels too much otherwise the extreme values could be cut off.

It is however possible in the case of a measurement imported from a card (not an online recording!) to restore the original measurement values for this channel using the menu item Raw data.

5.2.6. "View" menu

5.2.6.1. Menu item: View / Profile

With the menu item View / Profile the design of the measurement curve display (raw data display) can be managed and configured by means of profiles.

The menu items "Profile / load", "Profile save", "Profile delete" are allowing to load, save with new name and delete predefined profiles.

With menu item "Profile / Select as default" you can define the profile, which should be the standard profile for evaluation and for validation of sleeping stages.

The menu item "Profile / Edit" starts the Profile Editor with following options:

Profile name: Selects the profile which should be adapted.

View: Defines, if the General View (upper part of screen) or the main screen (lower part of screen) should be adapted.

Available channels: Presents all available channels. **To work on a channel it has to be select first by left click with mouse.** Channels with bold font will be visible in this profile, not bold channels will be invisible. With right click on the channel term you can toggle between visible and invisible. The box "Channel visible" has the same function.

The height of a channel can be defined with "Units of height", the vertical position with "Change position".

Also the grids, background colour and channel colour can be defined in particular fields.

The default template can be selected by means of the fields "Default template" and "Default template (sleeping stage classification)" Attention: The actual profile can only be defined as default template if it has been saved before.

The control box "Show General view" defines, if the General View (upper part of screen) should be displayed. In the next boxes the Start zoom value for display can be selected.

Tip: In the measurement screen you can show and hide the channels in the General view also by right click to the General view.

5.2.6.2. Menu item: View / Visible channel settings

Show and hide channels by means of user defined channel settings can be done very quickly with the menu item View / Visible channel settings.

The settings can be managed with the menu items load, save and delete.

For each setting a short cut is available to switch quickly between the different visible channel sets of a profile.

Other settings can be done with the menu item View / Profile.

5.2.6.3. Menu item: View / Channel colour

The menu item View / Channel colour enables you to change the colour of the curve of a particular channel.

This change applies **only to the current measurement**.

To change a channel colour permanently you have to select the menu item View / Profile / Edit.

5.2.6.4. Menu item: View / Background colour

The menu item View / Background colour enables you to change the colour of the background of a particular channel.

This change applies **only to the current measurement**.

To change a channel colour permanently you have to select the menu item View / Profile / Edit.

5.2.6.5. Menu item: View / Grid

You can set contour lines for the currently loaded measurement using the menu item View / Grid.

The contour lines for all future measurements are determined by the menu item View / Profile / Edit.

5.2.6.6. Menu item: View / Show / Hide

The menu item View / Show/Hide enables you to hide or unhide channels in your measurement.

This change applies **only to the current measurement**.

If you want to show or hide the channels for a recording, then select the menu item View / Profile / Edit or menu item View / Visible channel settings.

5.2.6.7. Menu item: View / Show / Hide mark. Channels

The menu item View / Show/Hide mark. Channels enables you to hide or show the marking channels. Marking channels are channels in which only events are displayed as vertical markings. This change applies **only to the current measurement**. If you want to show or hide the channels for a recording, then select the menu item View / Profile / Edit.

5.2.6.8. Menu item: Show Videowindow

The menu item View / Show Videowindow controls the display of the video signal, if a video is available to the measurement.

5.2.6.9. Menu item: Show General view

With means of the menu item View / Show General view the upper screen of the measurement curves with the general view can be shown or hide.

5.2.6.10. Menu item: View / Cursor

With means of the menu item View / cursor the type of the cursor can be switched. A normal mouse cursor and a permanent vertical cursor are available.

Additional a crossline cursor can be used, which will display the actual cursor value separately.

5.2.6.11. Menu item: View / Numeric Values In Curve

With means of this menu item additional numeric values, which shows the maximum and minimum will be displayed in the raw data screen.

5.2.6.12. Menu item: View / Automatic Grid

With means of this menu item the horizontal grid can be adapted automatically when changing the range of the curve display.

5.2.7. "Audio / Video" menu

5.2.7.1. Menu item: Audio/Video / Settings

With menu item Audio/Video / *Settings* the video camera can be configured. Additionally the Video settings for Video cutting can be adapted.

5.2.7.2. Menu item: Audio / Video / Online recording

In this menu item the video camera which should be used for the online recording can be assigned.

5.2.7.3. Menu item: Audio / Video / Cut Video(s)

If the measurement contains a video recording, then in addition to the raw video a video channel is available. In this video channel the presence of a video is shown as a grey bar.

While creating markings (with the mouse) in the video channels video sequences can be defined. For this procedure all functions for handling markings are available.

Afterwards the video sequences can be copied out of the video signal and stored as new video sequences (blue marked). The raw data then can be deleted.

While storing only the video sequences, but not the complete raw video itself the required memory space can be reduced.

5.2.7.4. Menu item: Audio / Video / Raw Video(s) to Measurement

During the online recording the video signal can be stored on a different place than the measurement channels. With menu item Audio/Video / *Raw Video(s) to measurement* the video can be copied or moved after the recording to the place of the measurement.

5.2.7.5. Menu item: Audio / Video / Delete

With this menu item the raw videos or the video sequences can be deleted.

5.2.7.6. Menu item: Audio / Video / Export

With menu item Audio/Video / *Export* raw videos and video sequences can be exported (copied) to another place.

5.2.7.7. Menu item: Audio / Video / Video Informations

Additional video informations about the raw video and the additional video sequences can be displayed with this menu item.

5.2.8. "Options" menu

5.2.8.1. Menu item: Options / Evaluate criteria

The menu item Options / *Evaluate criteria* allows you to have an influence on the recognition of certain events (e.g. apneas) during the analysis.

You can change the following settings:

- **Threshold value of Flow:**

Threshold value *Apnea* specifies within what range the respiratory flow is allowed to vary for it to be still recognized as an apnea. The range is specified as

percentages of the maximum amplitude. The higher the value the higher the tolerance range and the greater the number of events that will be recognized as apneas.

The *Hypopnea* threshold value specifies how many percent the amplitude of the respiratory flow needs to be reduced for it to be classified as a hypopnea. The higher the value the higher the tolerance range and the greater the number of events that will be recognized as hypopneas.

The *trigger threshold* is used to recognize individual breaths. If the breathing is very shallow then the trigger threshold should be reduced somewhat.

The *Mean time* allows to determine over what period the amplitude of the breaths should be averaged when recognizing hypopneas.

Only events with a duration between *Minimum* and *Maximum* length will be detected.

The "*Combine*" parameter can be used to set the time frame in which two events are combined as one.

Cheyne-Stokes:

The criterias of Cheyne-Stokes Breathing (CSB) can be defined here: *Minimum number of breathings* and time gap between two CSB events (*Min interval*, *Max interval*). Numbers *min.* defines the minimum numbers of crescendo-decrescendo cycles. *Required follow-up events* are specifying, which events have to follow up to define a CSB.

- **Threshold value of Snoring:**

The *snoring* threshold specifies how strong a breathing sound needs to be in order to be classified as a snoring event. The higher the value set here the fewer events will be recognized. The "*Combine*" parameter can be used to set the time frame in which two events are combined as one. Only events with a duration between *Minimum* and *Maximum* length will be detected. With *Max Distance* the maximum distance between two snoring signals can be specified, to add the time between the two events to value of snoring time.

- **Threshold value of SpO₂:**

Desaturation defines by how much the oxygen saturation needs to decline (in % SpO₂) for a desaturation to be recognized.

Recovery / Follow-up event: A desaturation has ended if the SpO₂ value has again assumed its original starting value.

If however another breathing cessation arises during the recovery phase the SpO₂ value can no longer regenerate itself completely, i.e. a new desaturation has set in before the previous desaturation had ended.

The purpose of the recovery and follow-up event parameters is to ensure that these events are recorded as separated desaturations:

Recovery specifies by how many percent the SpO₂ value needs to have recovered again in order to be classified as a new desaturation event if the SpO₂ curve falls off again during the original desaturation.

The *Follow-up event* parameter determines by how many percent the SpO₂ value needs to decrease again in order to be classified as a new event. Only events with a duration between *Minimum* and *Maximum* length will be detected.

- **Threshold value of Pulse:**

Pulse threshold specifies the increase of the pulse (bpm) which defines a pulse variance. Only events with a duration between *Minimum* and *Maximum* length will be detected.

Specific Evaluation Methods

- **Apnea/Hypopnea only at desaturation :**

If this control box is activated, an apnea will only be classified as such if an associated desaturation is found in the SpO₂ channel.


In the Max. distance (in sec) Apnea – Desaturation field below you can set the maximum time that is allowed to elapse between the start of the apnea and the start of the desaturation in order for these two events to be regarded as related.

- **Snoring events only after Apneas:**

By activating this control box snoring events will only be classified after an apnea.

- **Pulse variance only during Apneas:**

By activating this control box pulse variances will only be classified during an apnea.

You can reactivate the factory settings at any time by clicking on the Original values button .

The factory-set thresholds for automatic evaluation are based on the recommendations of the German Society for Sleep Diagnostics (Deutsche Gesellschaft für Schlafdiagnostik, DGSM). Interpretation and diagnosis is the sole responsibility of the examiner or doctor. Special doctor's qualifications are a prerequisite for the use of devices such as these.

Important: The changes you have made will only take effect if you exit the dialog by clicking the OK button!

Changes to the threshold values will not automatically take effect on an already analyzed measurement! If you want to apply different threshold values to a measurement, then you need to select the menu item Analysis / *Recognize Events* again.

Tips:

- If **too few apneas** are being recognized, then increase the apnea threshold value (or vice versa).
- If **too few hypopneas** are being recognized, then increase the hypopnea threshold value.
- If **too few snoring events** are being recognized, then decrease the snoring threshold value

5.2.8.2. Menu item: Options / Channel settings

The menu item Options / *Channel settings* allows you to edit and calibrate the Porti unit's recording channels.

In the field on the left side you will find a list of all available channels, which you can use to select the channel to be edited.

The various settings and information items will now be described:

- **AD Channel:**

Specifies the actual number of the AD channel in the Porti unit (which does not have to agree with its position in the channel list!).

- **Term:**

The name of the channel as it appears in the channel representation on the left edge of the screen.

- **Unit:**

The unit of the channel's measurement values (e.g. %).

- **Protection:**

It is possible to protect channels against unauthorized editing by means of a password. To turn the protection on or off requires the password to be known.

- **Active:**

Activation or deactivation of channels. Deactivated channels are not recorded, i.e. will neither be displayed on screen nor saved. There are two possible ways to activate/deactivate channels:

Click on the "Active" control box.

Click the right mouse button on the desired channel in the channel list.

- **Measurement interval:**

The time separation between two measurement values on a channel. When the measurement interval is changed the sampling frequency value will automatically be recalculated and displayed.

- **Frequency:**

Sampling frequency of a channel. Specifies how many values per second are recorded. When the frequency is changed the measurement interval value will automatically be recalculated and displayed.

- **Required memory:**

Specifies how much disk space the measurement values require per hour of measurement time.

- **Background colour:**

This is where you set a new background colour for the recording channel.

Important: When selecting a new background colour, ensure that the coloured markers are still distinguishable on the new background!

- **Numeric output:**

If this control box is activated, the numerical measurement values will be outputted at the left edge of the screen whilst the channel is being displayed. The number of decimal places for this output can be set in the input field below.

The Cycle parameter specifies after how many measurement values a new measurement value should be outputted.

Note: If the Cycle value is set too low, the measurement values will change too quickly and you will not be able to read the numbers!

- **Time base:**

The time base specifies the smallest measurement interval that can be sampled. All measurement intervals that you set must be a whole number multiple of this time base value.

- **Save / Open channel set:**

It is possible to save all channel settings to a file and then to reload them. This allows several Porti units with differing channel settings to be managed quickly and easily.

- **Calibrate:**


This dialog allows the calibration of the channels to be edited.

- **Grid:**

This dialog allows the contour lines of the channel to be set.

- **Range:**

This dialog allows the displayed range to be set.

The factory settings can be reactivated by clicking on the Original values button .

5.2.8.3. Menu item: Options / Configuration of markings

Certain events (apneas, hypopneas, desaturations, sleep stages, etc.) are displayed on the measurement curve with the aid of coloured markers. The allocation of colours to the events can be changed using the menu item Options / *Colour of markings*.

Additional there can be changed the Hotkeys for Classify Markings.

The Original values button  reactivates the standard colour allocation to the markers.

5.2.8.4. Menu item: Options / Automatic creation of channels

Generic channels are channels, which are not recorded, but calculated from recorded channels.

With the menu item Options / *automatic creation of channels* the generic channels can be determined, which should be created automatically.

Generic channels, which are not calculated automatically, can be generated manually with the particular menu items.

5.2.8.5. Menu item: Options / General Settings

In this Menu item the following settings can be changed:

- Line Width of the curve during measurement display or printout
- Windows Control Style (Windows Classic or Windows XP - Style)
- Network - Reconnect: if this option is set, resources, which have been deactivated from Windows, will be reconnected again automatically (factory value: deactivated). Attention: If the software is not starting with this option please deactivate this setting!

5.2.8.6. Menu item: Options / Protocol heading

The menu item Options / *Protocol heading* allows you to change the header of the full printout (as a rule the address of the doctor's surgery or clinic). The header appears on the first page of the report. Four lines of 80 characters each are provided. Alignment can be used to set whether the report header is to be printed left-justified or centered on the report.

5.2.8.7. Menu item: Options / Configuration GDT-Report

The menu item Options / *Configuration GDT-Report* can be used to determine which results of the Porti report are taken over into the GDT report (for a Clinic Computer System).

Check the controll box to take over the values into the GDT report, non checked values are ignored.


5.2.8.8. Menu item: Options / Language

This is where you can set the desired language. This requires a "language file", that can be obtained from the manufacturer, to be present.

5.2.8.9. Menu item: Options / Insurance card

If a card reader is used, manual inputting of patient data can be replaced by automatic inputting (via the health card). This requires a suitable card reader.

The menu item Options / *Insurance card* allows you to set which card reader is to be used.

The Settings button  can be used to adapt the card reader to the PC.

5.2.8.10. Menu item: Options / Access to MMC

The Porti allows a measurement to be imported directly via the serial interface. In this case the data transfer rate is limited to 57,600 Baud.

When using an external card reader, the transfer speed can be increased considerably by using the parallel or USB interface. The manufacturer can supply further information on this.

5.2.9. "Tools" menu

The Tools menu contains a collection of useful functions relating to the use of the Porti.

5.2.9.1. Menu item: Tools / BDE-Version

Identifies the BDE version. You will not normally need to use this menu item.

5.2.9.2. Menu item: Tools / Card information

Information about the MMC. You will not normally need to use this menu item.

5.2.9.3. Menu item: Tools / Maintenance date

Date of the next technical maintenance.
(See 2.3. Technical inspection, Page 4)

5.2.9.4. Menu item: Tools / Delete MMC

This is where you can completely erase a memory card (independent of the actual storage space used). You will not normally need to use this menu item.

5.2.9.5. Menu item: Tools / RTC

This is where you obtain information about the RTC. You will not normally need to use this menu item.

5.2.9.6. Menu item: Tools / Filetype

This is where you register and unregister the software with several extensions. You will not normally need to use this menu item.

5.2.9.7. Menu item: Tools / Update

To make sure that during the software update the correct version of the software will be updated (if more than one version is installed on the computer), the update can now be started in two different manners:

- a.) With Tools / Update the "setup.exe" of the installation software can be started

The installation program can search for all software versions installed on the computer. Also it's possible to search for a running version. Therefore it's possible to identify the correct software version.

5.2.10. "Help" menu

The Porti software OR5 includes context sensitive online help. You can access this help in any dialog by clicking the Help button or by pressing the [F1] key.

Also the patient short manuals can be displayed with this menu item.

5.3. Additional Functions

5.3.1. Editing a marker

When you select the menu item *Analysis / Recognize Events*, the computer will **automatically recognize and highlight in colour various events (apneas, desaturations, leg movements, etc.)**. You now have the possibility to edit these markers or to insert new markers.

- **To examine an existing marker:**

Move the mouse over the marker and leave it there. After a short time a yellow information label will appear specifying the type of marker and its duration.

- **To reclassify / delete a single existing marker:**

Click on the marker using the right mouse button. A popup menu appears listing all marker types that make sense for this particular channel. The current marker type is indicated by a tick. Now click the new marker type (to delete the marker, select "Delete"). The popup menu disappears and the marker is reclassified.


- **To reclassify / delete several successive existing markers:**

Press the <CTRL> key and keep it held down. Move the mouse in front of the first marker that you want to edit and press the left mouse button without releasing it afterwards (keep holding down the <CTRL> key). Now, with the mouse button still held down, move the mouse all the way to the end of the last marker that you want to edit.

A popup menu appears listing all marker types that make sense for this particular channel.

Now click on the new marker type. The popup menu disappears and the markers are reclassified.

- **To edit the start or end of an existing marker:**

Whilst holding down the <Shift> key, move the mouse to the start or the end of the marker. The mouse cursor will change into the shape . You can now decrease or increase the size of the marker by moving the mouse whilst holding down the left mouse button.


- **To create a new marker:**

Move the mouse to the beginning of the event and press the left mouse button without releasing it right away. Now, with the mouse button still held down, move the mouse to the end of the event. As you move the mouse the selected region will be highlighted in colour and you can read the duration of the selection at the bottom of the screen. Now release the left mouse button. A popup menu appears listing all marker types that make sense for this particular channel. Click on the new marker type (to delete the marker, select "Delete"). The popup menu will now disappear and the marker will be classified.


Tip:

You can use the "To create a new marker" procedure to measure durations in the measurement.

5.3.2. "One-Click mode"

The One-Click mode can be activated by click on the button  in the top mouse palette. In the One-Click mode each Click to the measurement curve section will create a new marking with predefined length. On the right side appears a new border with the actual settings of the mode. A right click shows the "One-Click editor", where the following settings can be done:







- Type of event
- Predefined duration of the event
- Start of the event (Start, middle or end of cursor)

A second click to the button  terminates the One-Click mode.







5.3.3. Scrolling through the measurement (horizontal)

Having opened a measurement you can use the mouse or the keyboard to navigate throughout the measurement.


To scroll using the **mouse**, click on the following buttons at the top edge of the screen:

-  : Scroll half a page to the right (forwards).
-  : Scroll half a page to the left (backwards).
-  : Scroll a whole page to the right (forwards).
-  : Scroll a whole page to the left (backwards).
-  : Scroll to the end of the measurement.
-  : Scroll to the beginning of the measurement.

You also have the option to scroll using the **keyboard**:



-  : Scroll a little step to the right (forwards).
-  : Scroll a little step to the left (backwards).
-  : Scroll half a page to the right (forwards).
-  : Scroll half a page to the left (backwards).
- Page  : Scroll half a page to the right (forwards).
- Page  : Scroll half a page to the left (backwards).
- End : Scroll to the end of the measurement.
- Home : Scroll to the start of the measurement.

The cursor will automatically be removed from the screen during scrolling.

A click on the button  shows the complete measurement from the beginning with the smallest zoom level.

Tip: You can scroll in arbitrary small steps by locating the cursor at the new position and reselecting the current zoom level using the Zoom menu item.

5.3.4. Scrolling through the measurement (vertical)



While measurement is open it's possible to increase the vertical height of all channels at once by means of "Shift"-mouse wheel or with the buttons  and  on the top border (Zoom in vertical direction). With the right scroll bar or with "CTRL"+"Shift"-mouse wheel you can scroll vertical through the measurement then.



5.3.5. Adjust display of curves

Moving the mouse cursor over the left border with the channel terms shows four buttons for adjusting the display range and the vertical height of each channel.

With the buttons + and - the display of the curves can be adjusted while the measurement is open.

- + : Increase the channel display
- : Decrease the channel display

With the buttons  and  the vertical height of each channel can be changed.

-  : Increase the channel height for one unit
-  : Decrease the channel height for one unit

5.3.6. Measuring durations


To measure durations in your measurement, proceed as follows:

1. Select a channel in which markers are not possible (position, thorax, etc.).
2. Move the mouse (**in that channel**) to the start of the event and press the left mouse button without releasing it again afterwards.
3. Now, with the mouse button still held down, move the mouse to the end of the event.
As you move the mouse the selected region will be highlighted in colour and you can read the duration of the selection at the bottom of the screen.
4. Now release the left mouse button. The selection will disappear again.


5.3.7. Copy measurement curves sections

In the measurement curve screen (raw data presentation) you can copy and buffer sections of the curve as many as you want in order to insert them afterwards into the report.

To copy and buffer a section of the curve you have to mark the section with pressed left mouse button and pressed F2 key.

A click to the button screenshot  with pressed F2 key will copy the whole screen into the buffer.

In the report (Edit mode!) the sections can be inserted with menu item "Insert".

Tip: Click to the button screenshot  without pressing the F2 key will send the actual screen direct to the printer.

5.4. Quick reference for Porti unit

Performing a measurement:

1. The Porti unit can be prepared for measurement by transferring the patient data to the memory card via the menu item Porti / *Porti initialisation*.
2. The patient can now take the device with him/her.
3. When the patient has returned the device, the Porti data can be transferred to the computer using the menu item Porti / *Read measurement from device*. The measurement will then be analyzed automatically and displayed on the screen.
4. The automatically created markers can now be inspected and if necessary edited (see 3.1. Editing a marker, Page 19).
5. A commentary can now be entered using the menu item Evaluation / *Report*. The commentary can also be added to the printout by hand afterwards.
6. Finally, the report and the measurement can be printed out using the menu item File / *Print*.

It is possible to reopen a saved measurement at a later time using the File Management function.

6. Troubleshooting

Channels (e.g. CPAP) are missing in the display.

The channels are deactivated and therefore do not appear during "Test" and "Record".

Check which channels are active for recording using the menu item Options / *Channel settings*.

Channels are missing after loading a measurement.

They were not recorded or have been hidden for measurement data display.

Flow signal is missing during recording or follows the edge of the range.

The flow signal follows a straight line in the middle of the channel.

Check the flow prong on the patient and the connection on the Porti unit. When measuring during CPAP respiration, check the connection of the CPAP adapter hose to the CPAP mask and to the Porti unit.

Signal amplitudes non-existent or very small

Check the corresponding sensors on the patient and their connections to the Porti unit. Whilst doing so, check that the thin hoses and the black pressure pads of the thorax sensors are intact. A leaky sensor system in this area can cause the thorax channel to drop out. The pressure pads should be attached to the patient not too firmly but nevertheless securely in the belt. The thin hoses should be run in such a way that they cannot kink.

Check all cables and connectors on the Porti unit and the PC.

Printout not working.

The printer prints characters on the page but in no apparent format.

The wrong printer or printer driver has been installed.

The printer is not responding to the print command.

Check the printer cable and the connections to the printer and PC. The printer should be operational, i.e. the control lamps on the front should be lit, and it must be switched to "Online". If the appropriate control lamps are lit, then you should check the paper feed.

Cannot establish connection to the Porti unit.

The serial cable is not connected correctly.

Check the connection of the serial cable to the Porti unit and the PC.

Wrong serial interface has been selected or the interface is defective.

The interface can be set using the menu item Porti / *Settings*.

Battery is discharged.

Charge the battery correctly.






7. Ordering informations

Art. Nr.	Article	Art. Nr.	Spare parts / consumer material / Accessories
924 000	Porti 4 / 6 SleepDoc Sleep Diagnostic System	925 705	Manometer for quick control of CPAP pressure
926 000	Porti 4/6 microprocessor-controlled recording instrument, complete with: Finger sensor SpO2 (pulse frequency / oxygen saturation), Flow prong (breathing signal) with adapter hose, CPAP adapter hose (measurement under CPAP ventilation), Carrier belt, Interface cable for serial data transmission (Porti - PC), Velco wrist strap (to fix finger sensor to the wrist), PC software for measurements display and analysis on a PC, Memorycard for data storage, Storage battery charger, Shoulder bag, Carrying case	925 140	Thorax sensor, complete 2 pressure pads, flexible connection tubes
925 000	Porti 5 SleepDoc Sleep Diagnostic System Porti 5 microprocessor-controlled recording instrument, complete with: Finger sensor SpO2 (pulse frequency / oxygen saturation), Flow prong (breathing signal) with adapter hose, CPAP adapter hose (measurement under CPAP ventilation), Carrier belt with integrated thorax sensor (thorax effort), Interface cable for serial data transmission (Porti - PC), Velco wrist strap (to fix finger sensor to the wrist), PC software for measurements display and analysis on a PC, Memorycard for data storage, Storage battery charger, Shoulder bag, Carrying case	925 281	Carrying strap for Porti , flexible, black, Size S
	Modules	925 280	Carrying strap for Porti , flexible, black, Size M
925 060	Thorax effort module incl. Hard- and Software, only Porti 4 and Porti 6 (Already integrated in Porti 5)	925 282	Carrying strap for Porti , flexible, black, Size L
925 010	Abdomen effort module incl. Hard- and Software, Porti 4/5/6	925 395	Abdomen sensor, complete 1 pressure pad, connection hose
925 020	Leg movement module (restless leg) incl. Hard- and Software, only Porti 5	925 388	Abdomen strap for abdomen sensor, flexible, black, Size S
925 030	ECG module incl. Hardware, electrodes and Software, only Porti 5	925 389	Abdomen strap for abdomen sensor, flexible, black, Size M
925 080	Modul PTT Puls Transit Time (Modul ECG required!)	925 390	Abdomen strap for abdomen sensor, flexible, black, Size L
925 050	Neuroport Module: Automatic sleeping stage classification via frontal electrode including Hard- and Software, only Porti 5	925 400	ECG electrode cable to record the ECG signal
925 070	Modul fast data transmission: Option for extra-fast transmission of the data Porti - PC incl. Software and USB-Card reader (Porti 4 / 5 / 6), Recommended for modules Neuroport, Leg or ECG	925 025	ECG adhesive electrodes (PU=500 pieces)
	Software Options	925 425	EEG electrode cable for Neuroport module (automatic sleeping stage classification)
925 040	Software for tie-in of Quisi records into Porti records	925 046	EEG adhesive electrodes (PU=150 pieces)
925 311	Integration in doctor's office computer system with GDT interface to take over master data	925 052	Headband to fix EEG electrode cable, blue
925 312	Intagrations in a network under windows NT/2000 for findings to be obtained at several places	925 450	LEG sensor for detection of leg movements (restless legs)
925 313	Software for transmission of data via the internet	925 460	Double LEG sensor for simultaneous detection of both legs movements
Art. Nr.	Spare parts / consumer material / Accessories	925 160	Serial cable for data transmission between Porti and PC
920 102	Finger sensor SpO2 HP finger cuff with cable and Lemo plug	925 355	USB Adapter for serial data transmission via USB port
925 305	Velco wrist strap to fix finger sensor cable to the wrist (1 PU = 5 pieces)	925 356	External card reader USB for mod. fast data transmission
920 310	Flow prong nose spectacles for flow measurement (PU = 10 / 100 / 500)	244 001	Serial Switch Box with Gender changer, for connection of several serial devices to one serial port
920 307	Flow prong with O2-connector nose spectacles for flow measurement during oxygen therapie	925 043	64 MB memory card storage card for data storage
920 309	Flow prong Nasal / Oral with seperate mouth tube	925 203	Storage battery charger ACS 110
925 241	Adapter hose for flow prong for connection with Porti basic instrument, 20cm	925 302	Shoulder bag cloth bag with shoulder strap for carrying Porti
925 246	Nippel for flow prong adapter hose, blue	925 301	Carrying case gray plastic case for unit and accessories
925 220	CPAP adapter hose for CPAP mask	925 308	Patient instructions for manual or automatic recording, weld together in foil
920 221	Nippel for CPAP mask (1 PU = 10 pieces)	925 501	2-Years Inspection for SleepDoc Porti
925 233	CPAP Adapter hose for CPAP-Mask Resmed ®	Art. Nr.	Spare Parts / Accessories for use with children
925 231	CPAP Adapter hose for CPAP-Mask Respirationics ®	925 150	Thorax sensor, complete 2 pressure pads with flexible connection tubes (red marked) and lengthened tube for positioning Porti near child
925 234	CPAP Adapter hose for CPAP-Mask SleepNet ®/ Viasys ®	925 285	Thorax strap for children , flexible, black, Size XS
		925 395	Abdomen sensor, complete 1 pressure pad with flexible connection tube (black marked) and and lengthened tube
		925 393	Abdomen strap for children , flexible, black, Size XS
		920 303	Flow prong for children (PU = 10 pieces)
		920 114	Infant sensor Philips SpO2 with DSUB connector (has to be extended with Lemo-DSUB extension), infants 1 - 4kg
		920 115	Infant sensor Philips SpO2 with lemo connector (no extension required), infants 4 - 15kg
		920 116	Infant sensor Philips SpO2 with DSUB connector (has to be extended with Lemo-DSUB extension), infants 15 - 50kg
		920 112	Extension Lemo-DSUB for Porti and infant sensor

8. Technical specifications

- Dimensions : 30,5mm x 62,7mm x 140mm (H x W x L, without bag)
- Weight : 155 g including storage battery, without bag
- Housing : metallized plastic (polystyrol, UL 94HB)
- Temperature range : + 15°C...+ 45°C
- Moisture : 60 % - 80 %
- Storage media : multimedia card
- Storage capacity : min. 48 hours; several weeks if card size accordingly
- Registered parameters:
 - Respiratory activity : Differential pressure measurement via flow prong (with adapter even under CPAP-therapy)
 - Breathing sounds : Sound pressure transformer via flow prong
 - SpO₂ / Pulse : Integrated pulseoximeter
 - SpO₂ measuring range: 80 % - 99 % ± 2 % SpO₂
 - 60 % - 79 % ± 4 % SpO₂
 - Pulse measuring range: 50 1/min - 150 1/min ± 2 %
 - Finger sensor: rubber coated plug-on finger sensor
 - CPAP : Differential pressure measurement directly on CPAP mask
 - Measuring range: 0 cm H₂O - 45 cm H₂O ± 5 %
- Fault indicator : Two LEDs on instrument front
- Power supply : Rechargeable NiMH storage battery (3,6V/0.8Ah)
- with integrated Semiconductor safety
- Charger : Plug-in charger with quick charge function via Delta zero measurement with automatic changeover to charge holding power and programmable de-charging function to minimize the memory effect
- Output : Serial interface with D-sub 9-pole cable for data transmission
- Power consumption : approx 45 mA
- Online operations : In online operation with a patient, an optical waveguide to the PC is indispensable (available as an option).

9. Used Symbols

<i>Symbol</i>	<i>Meaning</i>
	Pay attention to the instructions for use!
	CE-mark: This device complies with the Council Directive 93/42/EEC concerning medical devices in 14th June 1993
	Protection class II
	Type BF
	<p>Electrical and electronic devices may not be disposed of with domestic waste. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details to this are defined by the national law of the respective country. This symbol on the product, the instruction manual or the package indicates that a product is subject to these regulations.</p> <p>By recycling, reusing the materials or other forms of utilising old devices, you are making an important contribution to protecting our environment.</p>

10. Declaration Of conformity

SleepDoc Porti

Provider: Dr. Fenyves und Gut Deutschland GmbH

Address: Lotzenäcker 9
D-72379 Hechingen
Germany

Product: Sleepapnea Diagnostic Devices
SleepDoc MiniPorti

We confirm at sole responsibility for the above mentioned products the agreement with the:

Council Directive 93/42/EEC concerning medical devices in 14th June 1993

According to the directive's Annex IX the classification follows as a:

Active medical product of class IIa

A documentation in sense of the Council Directive 93/42/EEC exists completely.
This declaration of conformity is valid until 12/2013



Andreas Faulhaber
General Manager

Hechingen, 01. March 2005

Notified Body:
Fa. MDC
Kriegerstr. 6
D-70191 Stuttgart
No: 0483

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11. Quick reference for the patient

11.1. Quick reference for manual recording

1. Fasten the device to the chest using the elastic belt. Put the belt on over your undershirt rather than on bare skin.
2. Put the flow prong on your nose and fix it in place using adhesive tape or fasten the CPAP adapter hose to the mask.
3. Connect the sensor to the Porti unit (Flow prong or CPAP adapter hose to the blue labeled connection socket)
4. Switch on the device (slider towards the right)
Both LEDs will light up. The red LED will go out. The green LED will blink at 4 second intervals during the entire night for purposes of control.
5. After going to bed: check once again that the sensor and its connection are seated properly.
6. The next morning:
 - Switch off the device using the slider (slider towards the left)
 - Detach the device, pack all parts back into the case.
 - Return the complete case to the clinic.

The sensors will be cleaned by staff at the clinic!

Caution! Caution! Caution! Caution!

The Porti unit is an highly sensitive electronic devices that need to be protected against heat and moisture. You must never bathe or shower with the device.

11.2. Quick reference for automatic recording

1. Fasten the device to the chest using the elastic belt. Put the belt on over your undershirt rather than on bare skin.
2. Put the flow prong on your nose and fix it in place using adhesive tape or fasten the CPAP adapter hose to the mask.
Connect the sensor to the Porti unit (Flow prong or CPAP adapter hose to the blue labeled connection socket)
3. The recording will start automatically at the time previously set in the clinic. The green LED will blink at 4 second intervals during the entire night for purposes of control.
4. After going to bed: check once again that the sensor and its connection is seated properly.
5. The next morning:
 - Switch off the device using the slider (slider towards the left)
 - Detach the device, pack all parts back into the case.
 - Return the complete case to the clinic.

The sensors will be cleaned by staff at the clinic!

Caution! Caution! Caution! Caution!

The Porti unit is an highly sensitive electronic devices that need to be protected against heat and moisture. You must never bathe or shower with the device.