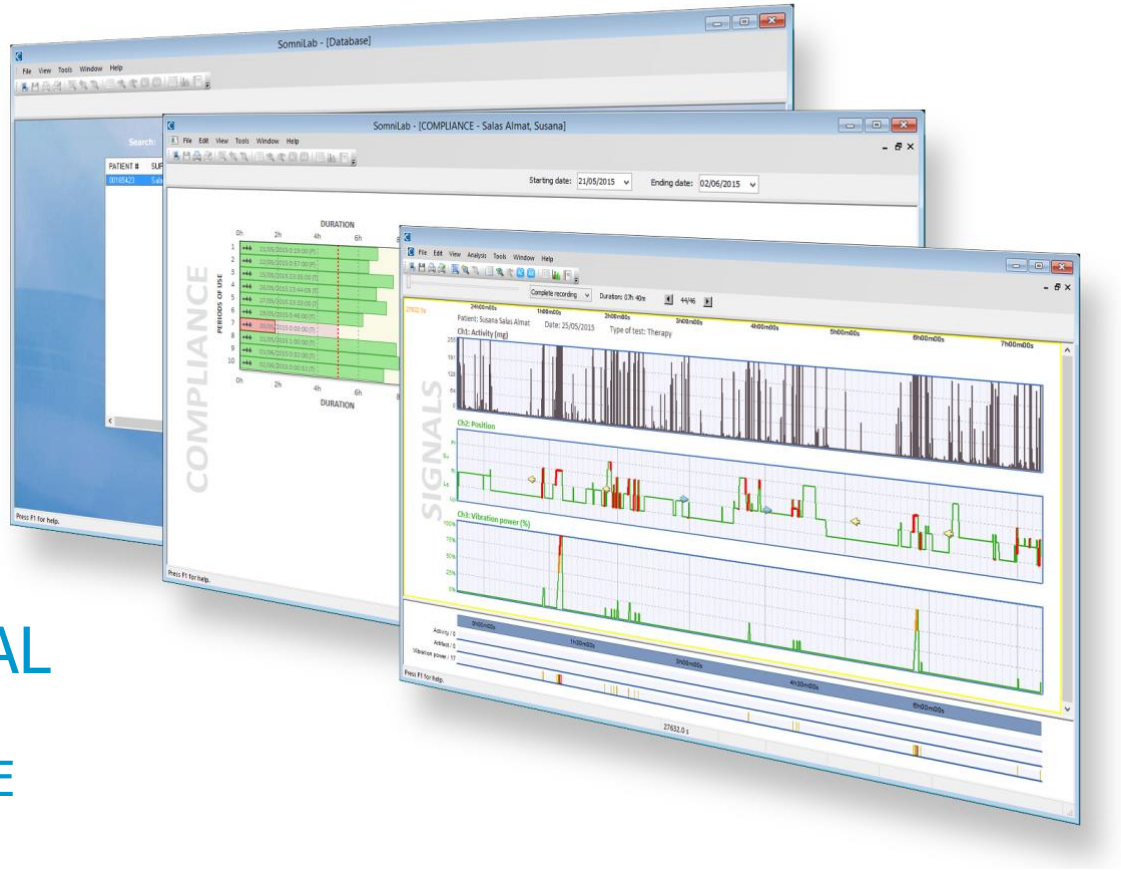
somniLab



somniLab USER'S MANUAL

POSITIONAL THERAPY SOFTWARE

534-840-MU2 · Rev 2.02 · 2024-05

CE 0318

SomniLab User's Manual

Revision: 534-840-MU2 Rev. 2.02

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DISCLAIMER

SIBEL S.A.U. is responsible for the security, reliability and performance of this equipment only if:

- The place where the system is installed or used meets the requirements for electrical installations IEC and other applicable regulations.
- The system is used by qualified staff in accordance with the recommendations stated in this User's Manual.

CE 0318 **PRODUCT IN COMPLIANCE WITH MEDICAL DEVICE REGULATION (EU) 2017/745. CLASS IIa.**

Thank you for choosing **SomniLab**!

This product has been designed by the RDI department of SIBEL S.A.U. in cooperation with the sleep units of the University Hospital Araba / Osakidetza (Vitoria, SPAIN) and of the University Hospital Arnau de Vilanova (Lleida, SPAIN). **SomniLab** is manufactured according to the European Medical Device Regulation and with the best quality standards.

Revised	Approved
Date: 2024-05	Date: 2024-05
Technical Director	Sales Director

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1 SAFETY

SomniLab is a software application running on Windows operating systems for the monitoring and follow-up of patients with Sleep-Related Breathing Disorders (SRBD), mainly the Sleep Apnea-Hypopnea Syndrome (SAHS) or habitual snoring during sleep, that are treated with Somnibel products.

SomniLab has been designed for maximum safety. The complete operating instructions should be read before proceeding to operate with the system.

Report any serious incident to the manufacturer and competent authority.

This manual describes the SomniLab software application.



Please read this manual carefully before using the SomniLab software. Pay special attention to warnings indicated with this symbol.

1.1 Intended use

The SomniLab software is intended for downloading, storage, display and analysis of signals (body position, actigraphy and stimulus power) acquired with the Somnibel Pro positional therapy device for the monitoring, evaluation and follow-up of positional treatment during sleep in patients with SAHS or habitual snoring.

The intended environments of use are hospitals, health centers and sleep clinics (not for outdoor use).

The SomniLab software is not intended for defining a diagnosis of the patient.

1.2 Intended users

SomniLab is designed to be used by a sleep physician or a technician trained in Sleep-Related Breathing Disorders and SAHS to evaluate the effectiveness of therapy in each patient. In addition to general pathology knowledge, it is not recommended to prescribe treatment with the devices or change treatment settings without prior understanding of the physiological principles of positional therapy for SAHS patients. Contact SIBEL S.A.U. about how to get additional training.

Healthcare personnel must train the patient in the use of the Somnibel Pro. The patient cannot configure the device or download data into the SomniLab software.

1.3 Indications for use

SomniLab is a software application designed to download the information recorded on the Somnibel Pro to a personal computer for viewing and analysis. SomniLab is indicated for monitoring the patient behavior during the night, evaluating the efficacy of treatment and following the therapy compliance.

1.4 Intended patient population

The Somnibel Pro device is indicated for patients older than 18 years, weighing over 40 kg and a height over 145 cm, with positional SAHS or Snoring and with a physical and mental condition that allows the understanding of the treatment aims and the correct placement of the device.

Medical personnel should inform the patient about the device use,

its cleaning and the required precautions described in section WARNINGS, before prescribing the positional therapy with the Somnibel Pro device to the patient.

1.5 Essential performance

The essential functions of the software are the configuration in therapy mode, communication between the device and the PC, storage of compliance data and presentation of therapy results through the compliance graph.

1.6 Residual risks

According to the application of the EN ISO 14971 standard, all risks related to the use of the Somnilab software have been reduced to maximum, as much as possible. It is important to read carefully all indications of use, contraindications, warnings, and recommendations provided in this manual.

1.7 Limitations of use, contraindications and side effects

No limitations in use, contraindications or side effects arising from (or related to) Somnilab software have been identified.

1.8 Warnings

The manufacturer is liable for the safety, reliability and operation of the devices and software only if the following points are observed:



- ***Read this manual before using the SomniLab software.***
- ***Use SomniLab according to the instructions included in the SomniLab user manual.***
- ***The system must be used according to the instructions of use.***
- ***The user must have a minimum computer knowledge allowing the safely operation of the SomniLab software and the Windows environment. It is important that the IT infrastructure manager trains and informs the user about the computer security measures adopted at workstation and network system level.***
- ***The computer, monitor and accessories where the software is used must meet the Low Voltage Directive (particularly EN 60950 standard) and EMC Directive (particularly EN 55022, EN 61000-3-2, EN 61000-3-3 and EN 55024 standards).***
- ***The SomniLab software must be used in a secure computing environment. It is important that you or your IT infrastructure manager establish security policies, including access control to the system, control of the installation of new software, management of backup copies, protection of the system against viruses and malware, guarantee of confidentiality and integrity of data transmission, confidentiality of personal data storage, regular system updating and installation of security patches. Using the program outside of its intended environment could result in a loss of data integrity.***
- ***Verify the hardware of your PC works properly.***
- ***To comply with Medical Device Regulation (EU) 2017/745 and for safety and reliability purposes, ensure that the Somnibel Pro and the SomniLab software are used by personnel that are adequately trained in the intended use of the system.***

- ***Contact of liquids with the flash memory drive must always be avoided.***
- ***In case of receiving the Somnibel Pro system with a deteriorated packaging, do not use the system and contact your courier agency or SIBEL's After Sales Service.***

The SomniLab software runs on PC compatible systems.



Make sure you save the changes made to signal recordings before turning off the PC.

Do not turn off the PC while the Somnibel Pro is connected and transferring data to the PC.

In no case shall Sibel S.A.U. be responsible for any losses, damages or expenses derived from incorrect use of the device, the software or the PC; or for flaws or accidents in other computer equipment.

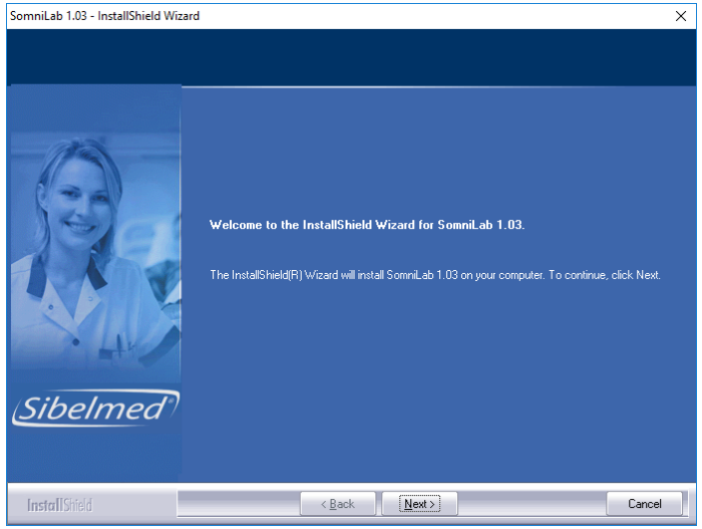


This manual is available in PDF format in the flash memory drive provided for installing the Somnibel Pro software.
Once installed, the user's manual is also available in the folder "Help", which can be found in the installation folder (usually X:/Program Files/somniLab/somniLabX.XX/Help).
A printed copy may be requested at SIBEL S.A.U.

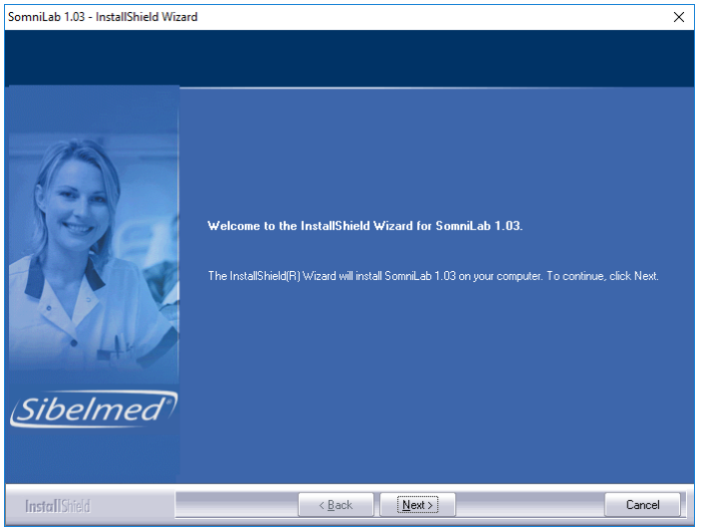
2 INSTALLING SOMNILAB

The installation wizard guides you through the whole installation process.

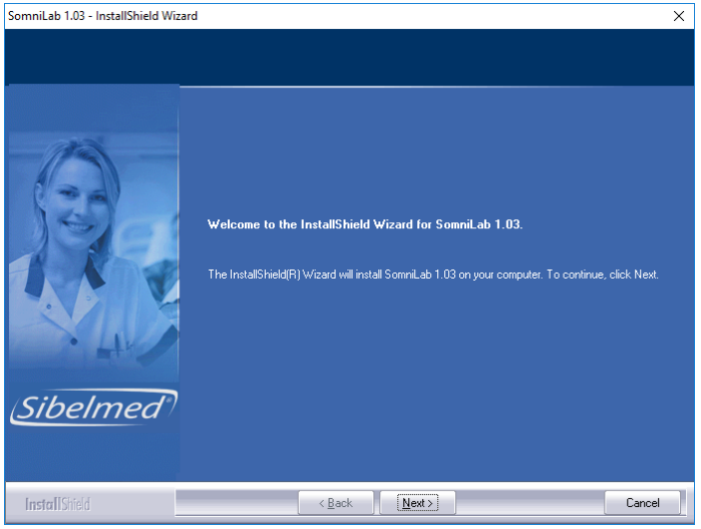
- Execute the installation wizard (setup.exe) located in the flash memory drive.
- Select the language to be installed.
- Click **Next** to start the wizard.



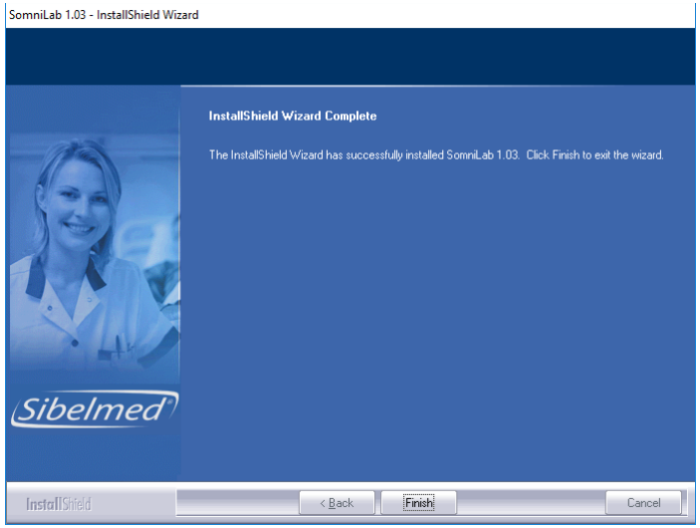
- Click **Next**.



- Select **Basic** to install the basic features. Select **Custom** to install also a PDF printer.
- Click **Next**.

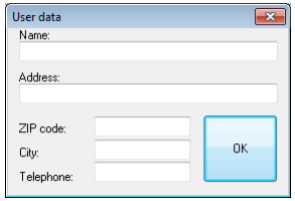


- Click **Install**.
- Wait until the wizard copies all required files to the hard disk.
- Click **Finish** to close the wizard. The SomniLab software is now ready to be used.
-

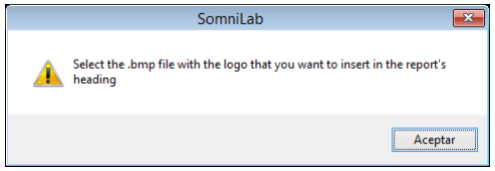


2.1 Starting SomniLab for the first time

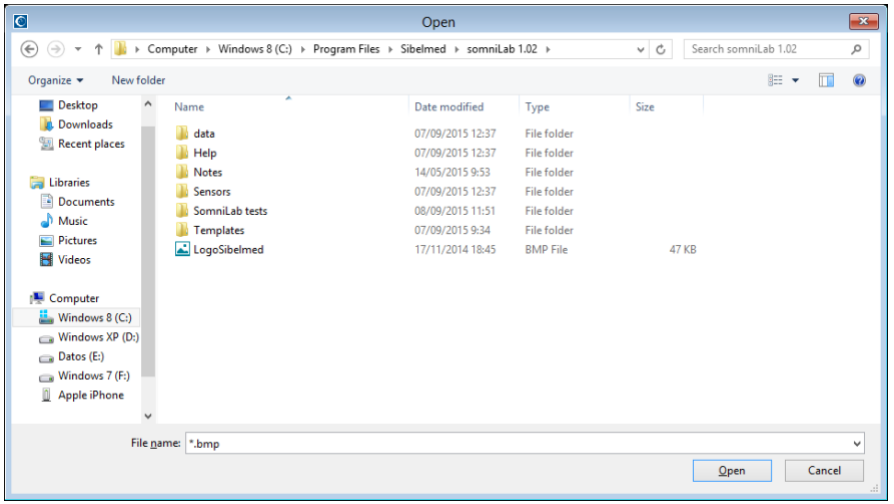
- In Windows go to **Start** and find the SomniLab folder, then click on SomniLab**.**
- The installation process places a shortcut to SomniLab in your desktop, so you can also launch the software by double clicking on it.
- After launching SomniLab for the first time, a window will be displayed for entering the user data. User data will be used in the heading of reports and printed pages.



- Enter your data and click **OK** to save them.
- Next, a new window will ask you to select a logo for being included in the heading of the reports.



- Select a BMP file for your logo and click **Open**.



- You can modify later this settings by going to the menu option Tools > Settings and selecting the User data tab.

3 INSTRUCTIONS FOR USE

3.1 POSITIONAL SAHS

It is known that more than 50% of patients with SAHS experience a worsening of the frequency and severity of respiratory events when sleeping in the supine position compared to other body positions[4, 5, 6]. This postural dependence is more prevalent in mild to moderate, young and less obese patients, who are the majority of the total SAHS patient population[7, 8, 9]. Positional SAHS is defined as an abnormal Apnea-Hypopnea Index (AHI) that is twice as high in the supine position as in other positions[7, 9]. In addition, the severity and frequency of snoring is also position-dependent in most subjects with habitual snoring[10]. When the supine position is avoided, the frequency of events is reduced in patients with positional SAHS[11] and postural therapy is considered an effective treatment for SAHS in selected patients[4, 12].

3.2 USE OF SOMNILAB WITH SOMNIBEL PRO

SomniLab allows the downloading and visualization of the signals and use periods recorded with the **Somnibel Pro** positional therapy device for the monitoring and follow-up of patients treated with this device. It has the possibility to analyze the signals, data base management and printing reports. The software provides information on the periods of use of the device and the compliance with the therapy. It also allows the configuration of the **Somnibel Pro** device and the adjustment of treatment settings for adapting the therapy to the requirements of each patient.

Somnibel Pro is a positional therapy device designed with the sleep physician in mind. Unlike the **Somnibel** model, which only generates a gentle vibrating stimulus at the right moment for applying the positional therapy, **Somnibel Pro** can additionally be programmed for adapting several Compliance Enhancement settings to the specific needs of a patient. **Somnibel Pro** is also able to record up to 36 full night signal recordings, as well as a complete year of therapy compliance.

The use of **Somnibel** devices has proven to be an effective treatment for positional SAHS, reducing AHI and time in the supine position and improving nocturnal oxygenation and sleep quality, without causing sleep fragmentation and minimizing side effects[1, 2]. **Somnibel** devices ease compliance with therapy as they are comfortable and easy-to-use devices[3]

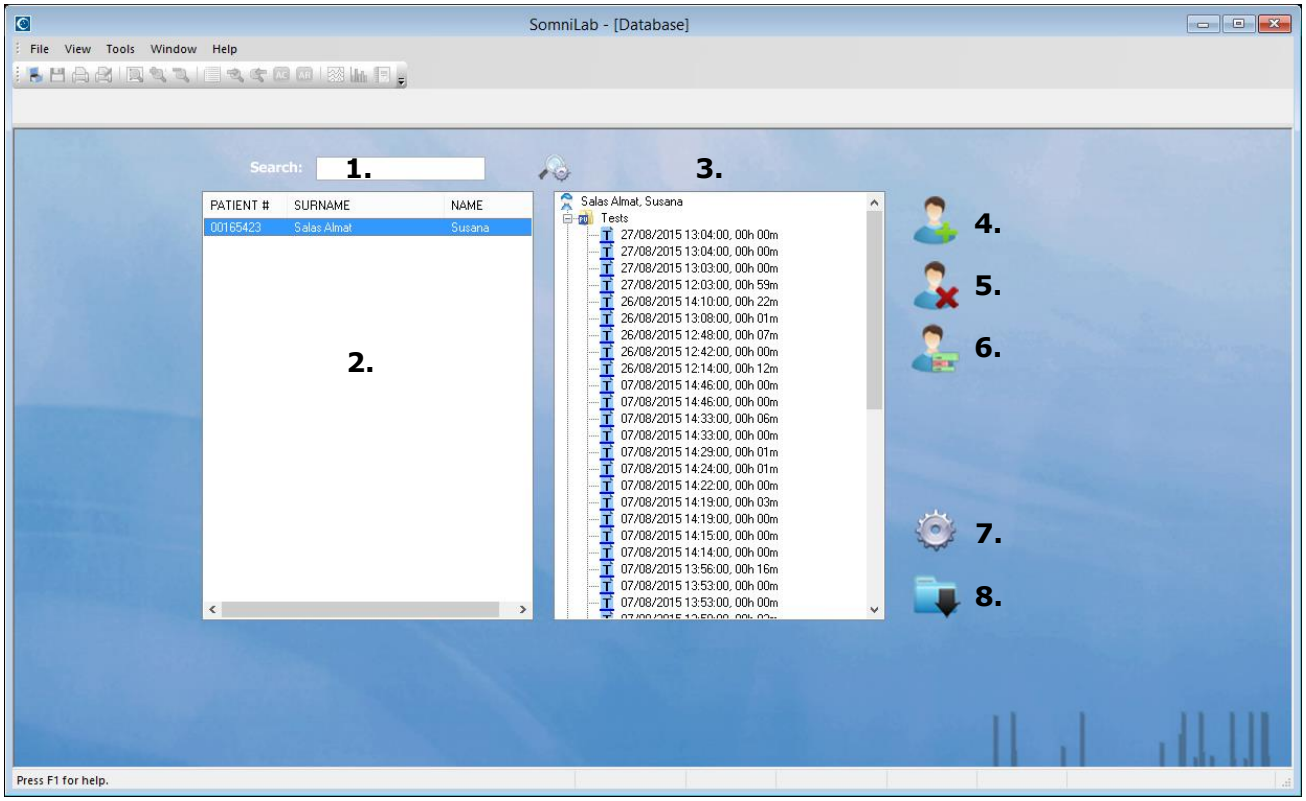
4 MAIN WINDOW

The main window (or database window) is used to manage patients and to access several functionalities, such as reviewing of therapy compliance or signals, communication with Somnibel Pro or other functions accessible through the menu bar..

1. Search field.

2. Patient list.

3.Signal recordings and associated documents of selected patient.



4. Add a new patient to the database.

5. Delete the selected patient.

6. View compliance with therapy data of selected patient.

7. Configure Somnibel Pro.

8. Download signal recordings and periods of use from Somnibel Pro.

The main window shows the list of patients in the database on the left and the list of recordings and documents associated to a specific patient on the right.

4.1 The Somnibel Pro workflow

For each new patient the following actions are usually performed:



- Create a new patient in the database.



- Configure **Somnibel Pro** settings if necessary and provide the patient with the device for several days.



- For evaluating the therapy, download the signal recordings and periods of use from the **Somnibel Pro** memory.



- Review the therapy compliance.

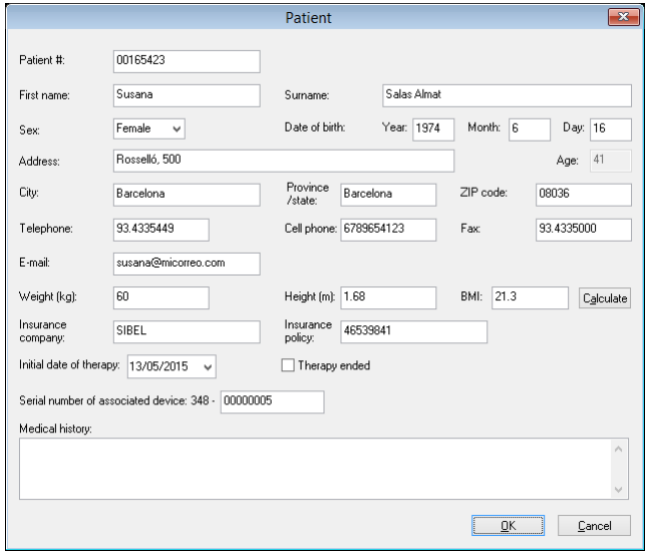


- Eventually, open some signal recordings, review the recording data window and create a report based on the data.

The first time **Somnibel Pro** is going to be used the technician will configure the device (date, time and various functioning parameters). This procedure will eventually be repeated if **Somnibel Pro** runs out of batteries (the date and time is lost in this case) or if the technician wills to change any of the functioning parameters.

4.2 Creating a new patient

- Click  to add a new patient to the database.



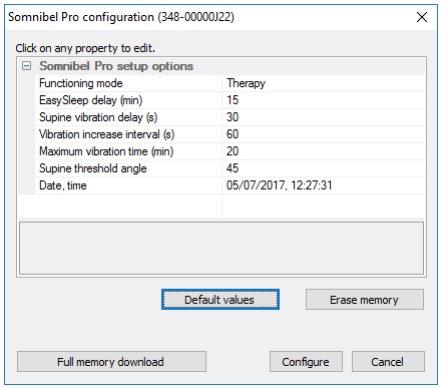
- Enter the patient's data, the Start of Therapy Date and the Serial Number of the device assigned to the patient.

- Then, click **OK**.

4.3 Configuring the Somnibel Pro

Somnibel Pro stores internally some parameters needed for its proper functioning. **Somnibel Pro** is already configured from manufacture, but you may change these parameters if needed.

- Connect **Somnibel Pro** to the PC via USB cable.
- Click . The **Somnibel Pro configuration** dialog is shown.



Somnibel Pro includes some features for enhancing treatment compliance. These features are configured by default to the settings shown in the figure. Eventually, the physician may want to change these parameters for better adapting the therapy to the specific needs of the patient.

The following parameters may be modified in the **Somnibel Pro configuration** dialog:

- **Functioning mode**:
  - *Therapy*: in this functioning mode Somnibel Pro generates a vibratory stimulus each time the patient enters in supine position. This is the default functioning mode.
  - *Placebo*: Somnibel Pro records all three signals (position, activity and vibration power), but does not apply any vibratory stimulus to the patient when in supine position. This mode is specifically designed for performing clinical studies.
- **EasySleep delay (min)**: time between device ON and activation of stimulus if patient is in supine position. Allows the patient to fall sleep at the beginning of treatment. Default value: 15 minutes (range of values between 0 and 60 minutes).(*Note 1*)
- **Supine delay (sec)**: time between detection of supine position and activation of stimulus. Allows the patient to transition between left and right positions without applying any stimulus. Default value: 30 seconds (range of values between 0 and 60 seconds).
- **Stimulus Increase Period (sec)**: Time between consecutive increases of stimulus intensity. While the patient is in supine position, Somnibel Pro applies an increasing vibratory stimulus with four different power levels. Modifies the rate of stimulus increase for adapting it to each patient's needs. Default value: 60 seconds (range of values between 30 and 300 seconds).
- **Time at Maximum Power**: maximum time with the stimulus at 100% of intensity if patient does not change position. Avoids excessive application of vibration stimulus. Default value: 20 minutes (range of values between 2 and 120 minutes).
- **Supine threshold angle**: threshold angle used to evaluate the supine position, being 0º the lateral decubitus position and 90º the supine position. Default value: 45º (range of values between 30º and 75º).

After modifying the parameters, click on **Configure** to program the settings on Somnibel Pro**.**

- Click **Default values** to return to the factory default values.
- Click **Erase memory** to erase de Somnibel Pro's memory.



Clearing the device memory will remove all therapy information stored on the device. This action cannot be undone.
Please make sure you really want to erase the device's memory before continuing.

- The button **Full memory download** should only be used when requested by the Customer Service of Sibel S.A.U.

The software automatically updates the date and time in Somnibel Pro with date and time of Windows.

Note 1: if a treatment session duration is lower than the EasySleep setting, the session will be discarded and neither the signals nor the compliance data will be recorded.

4.4 Downloading the device's memory

To evaluate the patient's therapy compliance, the data stored in the internal memory of Somnibel Pro must be transferred to the PC. Remember that Somnibel Pro is able to store up to 36 signal recordings (10 hours each) and 365 periods of use.

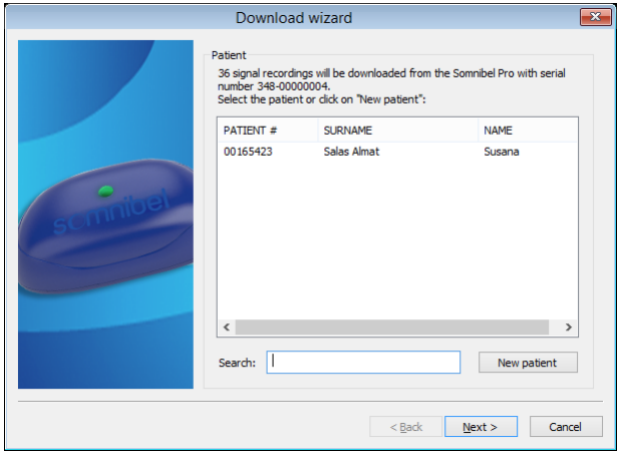
Periods of use provide information about the therapy compliance (date and duration of each use), while signal recordings store raw signals of position, activity and vibration power for each use. These signals can be reviewed in the Signals Recordings window for a more detailed analysis.

Before downloading the device's memory check that hibernation is not enabled in the PC. Otherwise, the download could be aborted if the PC goes into the hibernation state.

A wizard will guide you through the download process:

- Connect Somnibel Pro to the PC via USB cable.
- Click . The **Download wizard** is shown.
- The signal recordings and periods of use will be associated to a patient.

The program will automatically search for the patient associated to the device (by entering its serial number in the **Patient** data window), as long as the therapy is active and not complete.
Otherwise select the patient in the patient list or create a new one by clicking **New patient**. The patient number, name or surname can also be searched by entering a text in the **Search** field. Then click **Next** to start the download and wait until all data is transferred.

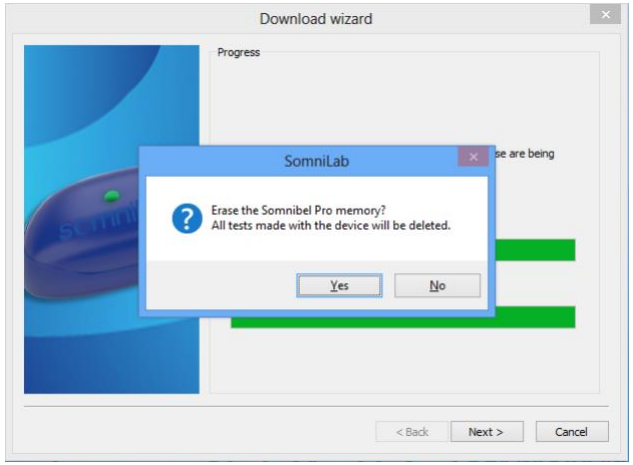


- When the process is completed the wizard gives you the option of erasing the device's memory. Select your preference.

Deleting the device's memory will erase all the therapy's information stored in the device.

This action cannot be undone.

Please make sure you really want to erase the device's memory before continuing.



- Click **Finish** to close the wizard.

4.5 Therapy compliance

To review the patient's therapy compliance, click on . The **Therapy Compliance** window will be displayed. See section THERAPY COMPLIANCE WINDOW for additional details.

4.6 Opening signal recordings

- In the main window select any patient in the patient list.
- Double click the recording to be reviewed and it will be opened. See section SIGNALS WINDOW for additional details.

4.7 Managing patients

4.7.1 Editing patient's data

- In the patient list (2) double click on the patient's name. The **Patient** dialog opens.
- Edit the patient's data and click **OK** to save the changes.

4.7.2 Deleting a patient



This action cannot be undone.

Please make sure you really want to delete the patient, the linked signal recordings and therapy information before continuing.

- In the patient list (2) of the main window select the patient to be deleted.
- Click  (5) and confirm if you want the patient to be deleted, as well as all its associated recordings.

4.7.3 Searching patients

- Enter any text in the **Search** field (1). This text will be used as filter to search within the patient's name, surname, …
- Click on . The patient list shows the patients matching the entered criteria.

4.7.4 Sorting patients

- Patients in the patient list can be sorted by any of the three column headings (**patient number**, **surname** and **name**).
- Click on any of the three column headings to sort the list by that field.

4.7.5 Linking documents to patients

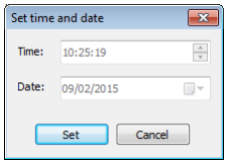
- Any external document, like a JPEG, PDF or DOC files, can be linked to a patient.
- Select the patient and right click on the **Documents** folder.
- Select **Link document**.
- In the dialog window click **Browse** and select the file to be linked.
- Click **Link** to close the dialog.
- The document appears under the **Documents** folder. Double click it to open it.

4.7.6 Modify the date/time of signal recordings

If the device runs out of battery, signal recordings may have incorrect date (the date and time in your device is automatically updated when you connect it to the PC).

If you wish to change the date and/or time of any signal recording follow these steps:

- In the database window right-click the signal recording to be modified.
- Select option **Modify date/time**.



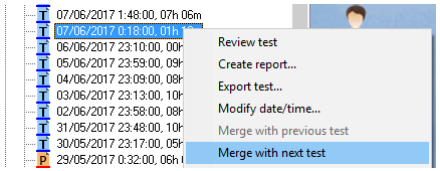
- Set the new date and/or time and click **OK**.

The new date can not be earlier than the initial date of therapy or later than the ending date, which is set in the patient data window, or the current system date.

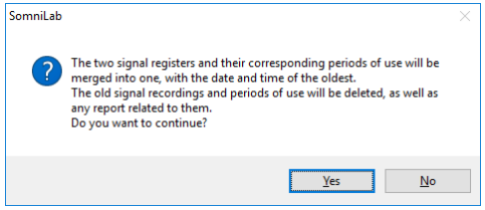
4.7.7 Merge two signal recordings

In case the patient connects and disconnects the adhesive patch several times during the same night, several separate signal recordings will be generated. The corresponding periods of use will also appear separately in the compliance window. You can merge several consecutive signal recordings into one, provided no more than 12 hours have elapsed between the start of both signal registers:

- In the database, right-click on one of the signal recordings to merge.
- Select the menu option **Merge with previous test** or **Merge with next test**.

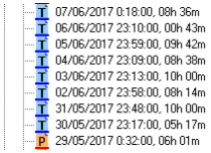


- Confirm that you want to merge both signal registers and their corresponding periods of use.

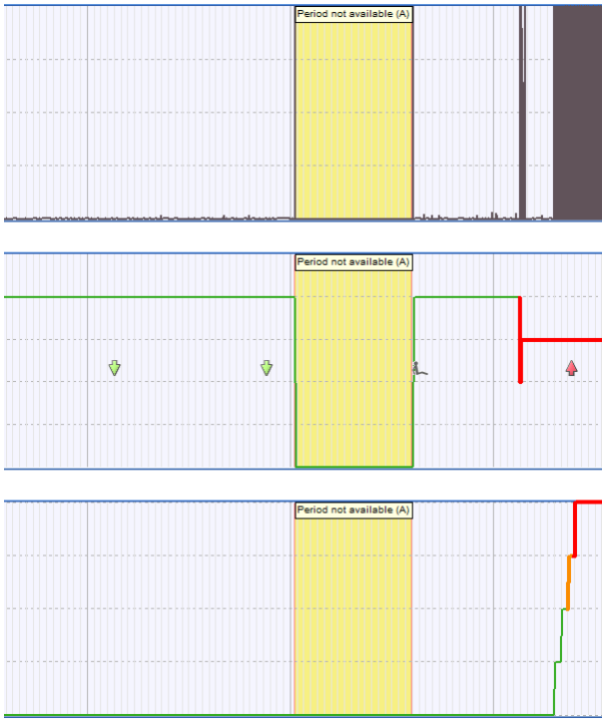


The two signal recordings and their corresponding periods of use will be merged into one, with the date and time of the oldest of them. The old recordings and periods of use, as well as any report corresponding to both records, will be deleted.

- Both signal registers will be merged into one. The same will be applied to the corresponding periods of use.



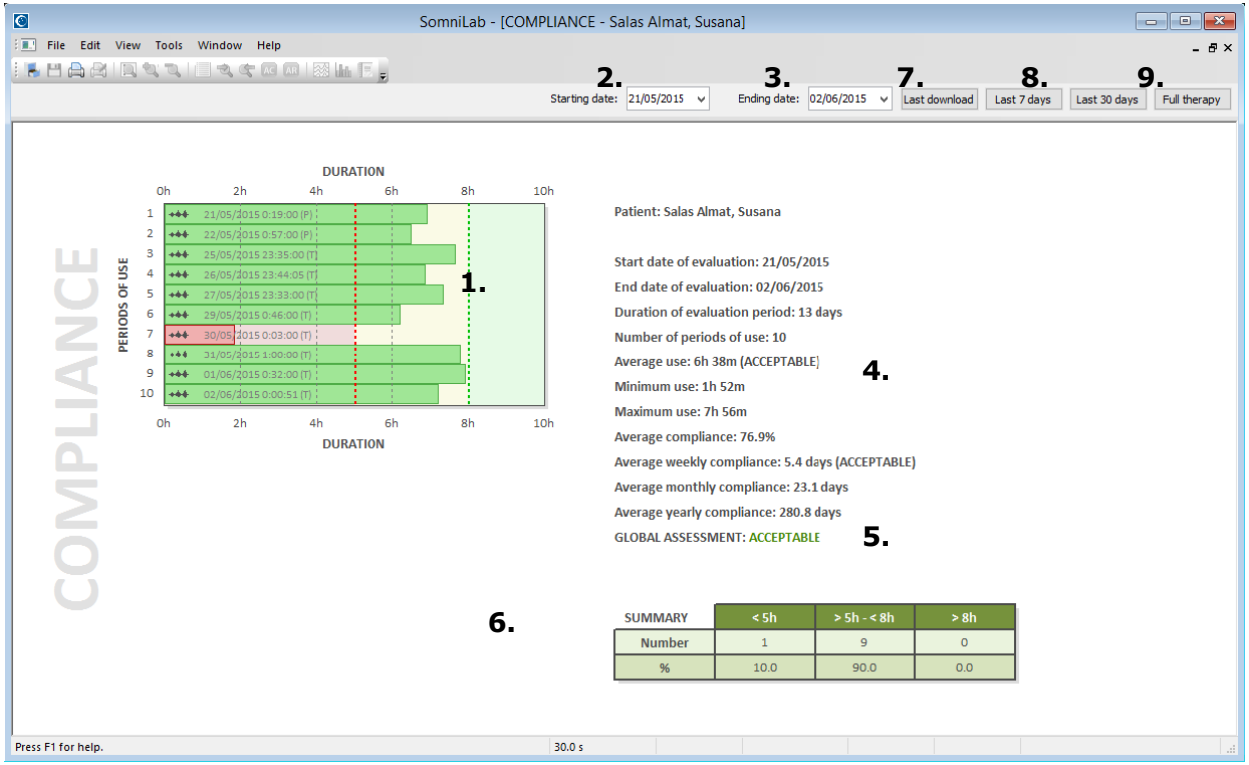
- The time gap between the end of one signal recording and the start of the next one will not have valid information and will not be taken into account when calculating data in the different program windows or reports. This period is marked in the signal recording with a yellow color as **Period not available**.



Repeat this process to merge more tan two signal recordings.

5 THERAPY COMPLIANCE WINDOW

The **Therapy Compliance** window provides information on the use of Somnibel Pro for the follow-up of positional treatment in each patient.



1. Therapy compliance graph.

2. Starting date of evaluation.

3. Ending date of evaluation.

4. Compliance statistics.

5. Global assessment.

6. Summary table.

7. Show compliance of the last Somnibel Pro download.

8. Show compliance of the last 7 days downloaded from the Somnibel Pro .

9. Show compliance of the last 30 days downloaded from the Somnibel Pro.

10. Show complete therapy compliance.

- In the main window select a patient in the patient list and click .
- The data shown in the Therapy Compliance graph and in the Compliance statistics depend on the evaluation period defined by the Starting and ending dates of evaluation.
- The default Starting date of evaluation is the Starting Therapy date set in the Patient Data window or one year back from the current date, whichever is later. The default ending date of evaluation is the current date.
- Modify the evaluation period with (2), (3), (7), (8), (9) and (10). Every time the start or end dates are changed the graph and statistics are recalculated accordingly.
- The compliance graph (1) is made of horizontal bars, each one representing one use of Somnibel Pro. The starting date and time is shown within each bar, as well as the functioning mode (**T** for therapy and **P** for placebo). The length of the bar represents how long the patient used the device. Use periods lasting less than 5 hours are considered not acceptable and are red-colored, while those above 5 hours are considered acceptable and are green-colored. Finally, a graphic symbol  is shown if there is a signal recording associated with the use period. In that case a click with the mouse over the bar opens the associated recording.
- The statistics (4) include, among other data, the global assessment on the therapy compliance (5). For the **Global Assessment** to be acceptable the **Average use time** must be > 5h and the **Average weekly compliance** must be > 5 days.
- The summary table (6) provides additional information on the use of Somnibel Pro.

6 SIGNALS WINDOW

The **Signals** window is opened by double-clicking on a recording associated to a patient in the main window. It presents the **Activity**, **Position** and **Stimulus power** data similarly to a polygraphic test.

1. Navigation slider.

2. Epoch duration selector.

3. Recording duration.

4. Previous recording.

5. Number of current/total recordings.

6. Next recording.

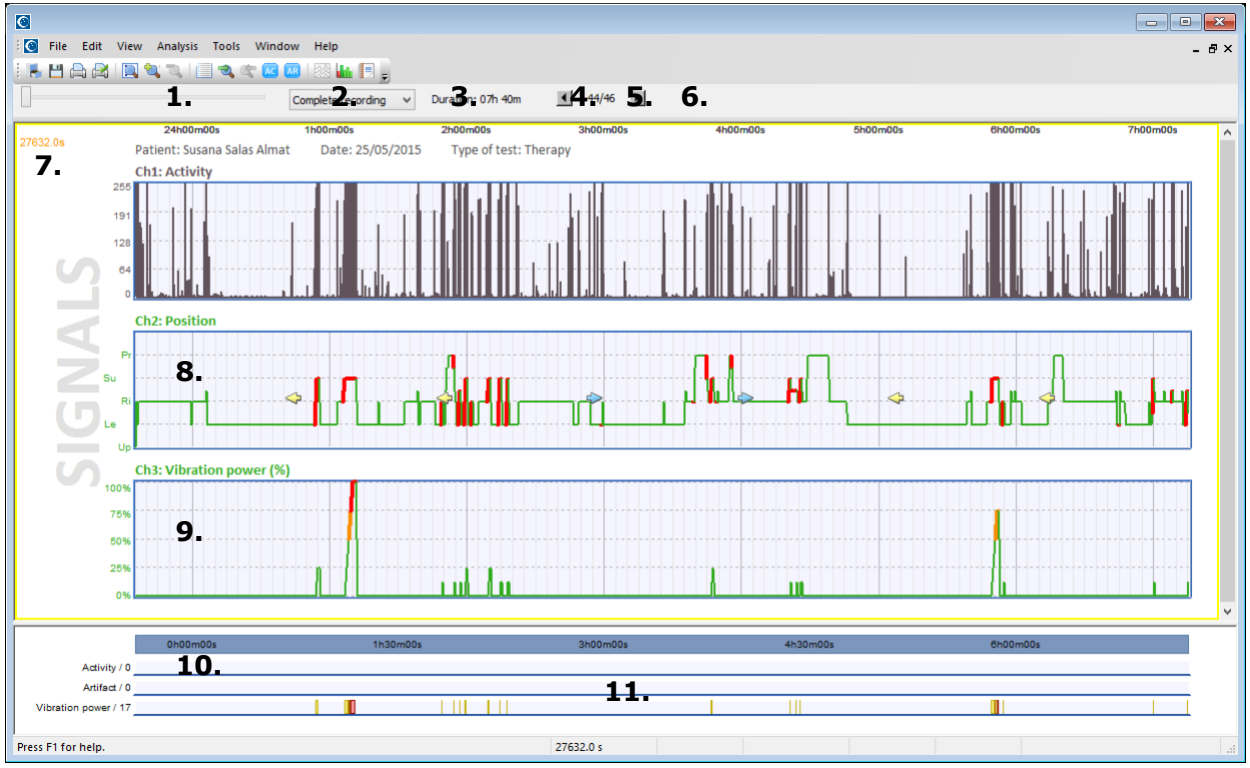
7. Epoch duration.

8. Activity signal graph.

9. Position graph.

10. Stimulus power graph.

11. Trends graph.

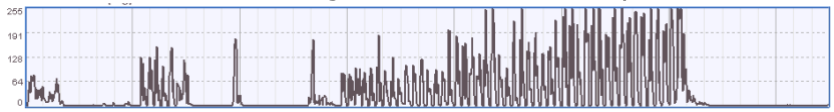


6.1 Browsing through patient's recordings

- With a recording on screen use the **Previous recording** (4) and **Next recording** (6) buttons to navigate through the recordings of the same patient.

6.2 Signals

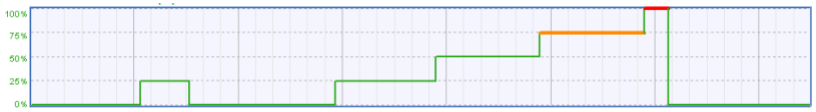
- **Activity**: activity signal derived from the device's accelerometer. The signal units are arbitrary.



- **Position**: body position of the patient. Five different positions are identified: supine, prone, left lateral decubitus, right lateral decubitus and upright position. Supine position is automatically marked in red for better interpretation.
  The arrows indicate the position of the patient and can be disabled by right clicking over the signal, selecting **Signal settings** and then deactivating the option **Show values over the signal**.

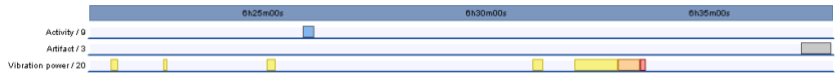


- **Stimulus power**: level of vibratory stimulus applied to the patient. There are five intensity levels: 0% (no stimulus), 25%, 50%, 75% (automatically marked in orange color) and 100% (automatically marked in red color).



6.3 Trends graph

- The trends graph shows information about scored events (position and duration). There are three different:
  - **Activity**: Users may score this event manually. See section "Scoring activity or artifact events" for details.
  - **Artifact**: Users may score this event manually. See section "Scoring activity or artifact events" for details.
  - **Stimulus power**: the software automatically analyzes the vibration power signal when a recording is downloaded and inserts marks when Somnibel Pro is vibrating at **25-50%** of power (yellow mark), **75%** (orange mark) and **100%** (red mark).



6.4 Moving through the recording

- Applies both to signals and trends windows. Just click on any of these windows to activate it (a yellow border is displayed over the active window).
- Use the **Navigation slider** to move through the recording.
- Alternatively, use the keys **Home** (goes to the start of the recording), **End** (goes to the end of the recording), **Page Up** (goes to the previous epoch), **Page Down** (goes to the

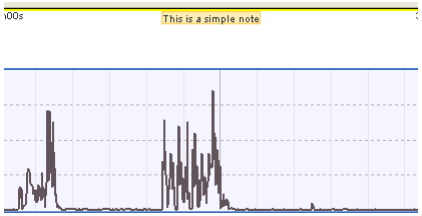
next epoch), **Left Arrow** (goes a few seconds back) and **Right Arrow** (goes a few seconds forward).

6.5 Changing the epoch duration

- Applies both to signals and trends windows. Just click on any of these windows to activate it (a yellow border is displayed over the active window).
- Use the epoch duration selector (2) to choose one of the predefined durations.
- Or use the buttons and in the toolbar or the **+** and **-** keys to multiply/divide by 2 the time on screen.
- Or use the menu option **Analysis > Viewing options** and change the parameter **Signals window** or **Trends window** under **Seconds per epoch**.

6.6 Inserting notes

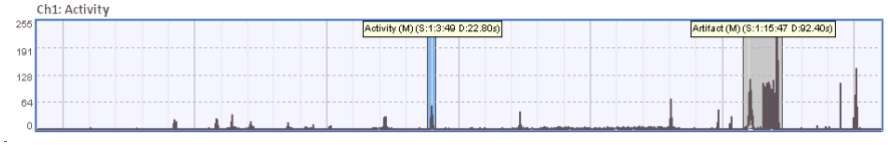
- Text notes may be added to any epoch of the recording for important observations. Notes are shown on the time scale, above the **Activity** signal.



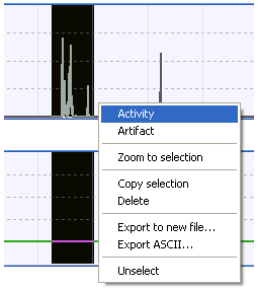
- Add a new note selecting the menu option **Analysis > Enter note** or just pressing the **Insert** key.
- Right click on the note and select **Delete** in the popup menu to delete the note or **Modify** to edit the text.

6.7 Scoring activity or artifact events

- There are two types of events that can be scored by the user: **Activity** and **Artifact**.
- Activity and artifact events are marked over the activity signal.



- Scoring an event can be done in many ways, so choose the one that better adapts to your needs:
  - Left-click on the beginning of the event, then drag the mouse and release the left button on the end of the event. Select the event to be scored in the menu.

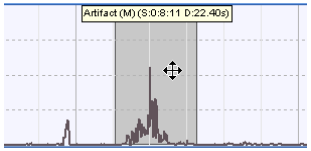


  - Or select the type of event in the toolbar: for **Activity** or for **Artifact**. Note the cursor changes to . Click and drag to score the event. When the left button is released the event is automatically scored.
  - Or press the key accelerators (**F1** for **Activity** and **F2** for **Artifact**) while making the selection to score the associated event.

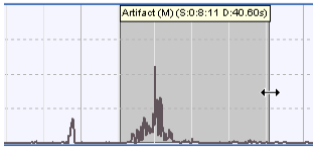
- Or press the key accelerators (**F1** for **Activity** and **F2** for **Artifact**) to score an event in the middle of the current epoch with fixed duration. This option is useful if you just need to take into account the number of events or their indexes.

6.8 Managing events

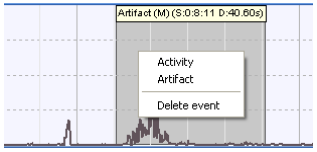
- Move an event by placing the cursor over it, then left click and move the event to the new position.



- Place the cursor over the left or right edge of the event, left click with the mouse and drag the cursor to stretch/shrink the event.



- Right click over the event to show a popup menu to delete the event or change the type of event.



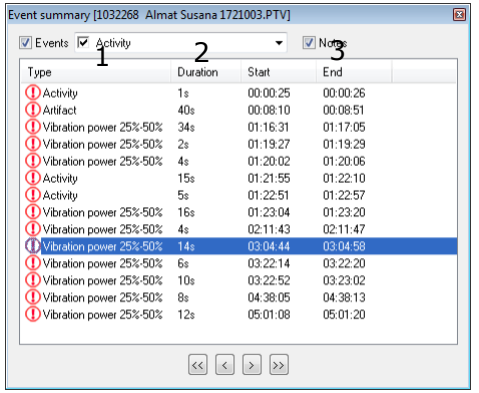
- Delete all events in **Analysis > Delete all events** or just the last scored event in **Analysis > Delete last event**.
- If you want to get a list of all events go to the menu option **Analysis > Summary window**.

1. Show/hide events.

2. Select events to be shown.

3. Show/hide notes.

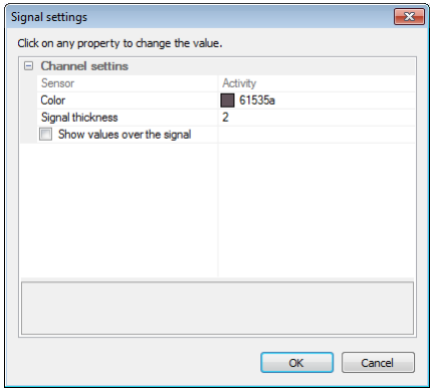
4. List of events.



- Double click on any event to show it on screen.
- Select an event and press Del key to delete it.

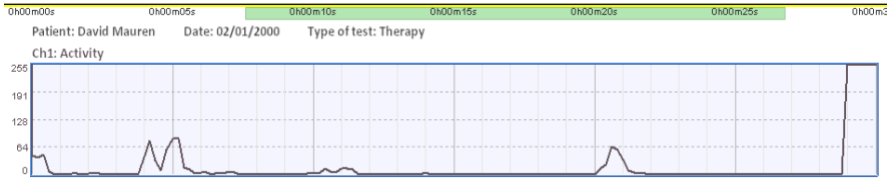
6.9 Changing the signal settings

- Right click over the desired signal and select **Signal settings** in the popup menu. From this dialog you can change the signal color and thickness, as well as show or hide the signal values.



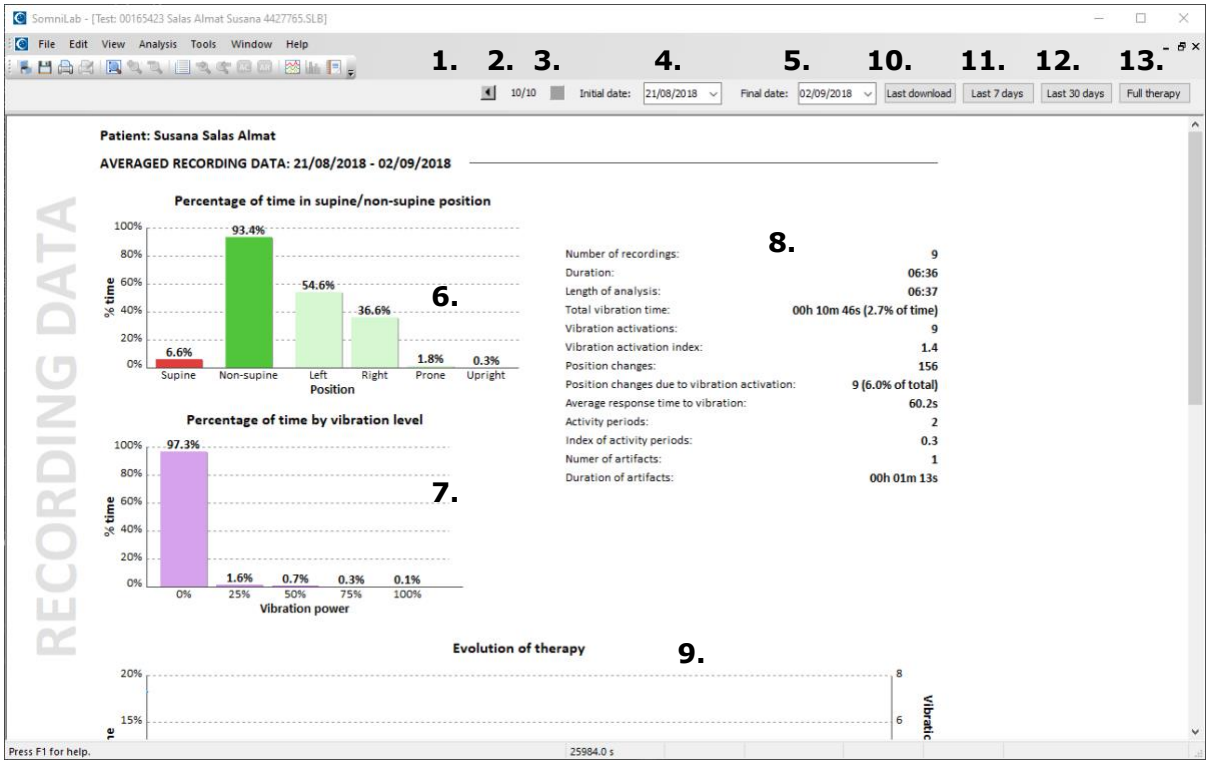
6.10 Setting the analysis period

- The whole recording is taken into account by default for the calculation of the recording data, statistics, graphs and report. However, an analysis period may be manually defined.
- Go to the position where you want the analysis period to begin. Click  in the toolbar. The cursor changes to a green arrow. Click over the time scale to set the beginning of the analysis period.
- Go to the position where you want the analysis period to end. Click  in the toolbar. The cursor changes to a red arrow. Click over the time scale to set the end of the analysis period. The analysis period is marked with a green bar on the time scale.



7 RECORDING DATA WINDOW

Use the **Recording data** window to view a summary of the current recording.



1. Previous recording.

2. Number of current/total recording.

3. Next recording.

4. Starting date of evaluation.

5. Ending date of evaluation.

6. Graph of percentage of time in each position.

7. Graph of percentage of time in each vibration power levels.

8. Statistics for active recording.

9. Statistics and graphs for the evaluation period.

10. Show data of the last **Somnibel Pro** download.

11. Show data of the last 7 days downloaded from the **Somnibel Pro** .

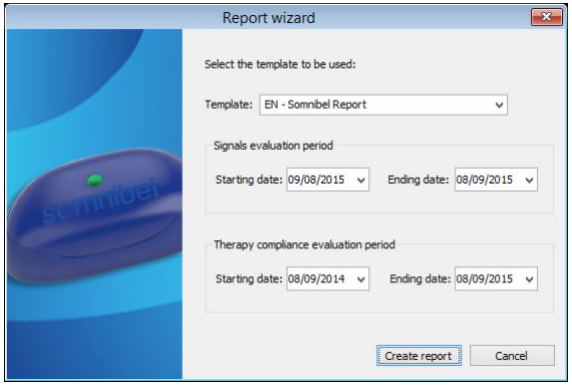
12. Show data of the last 30 days downloaded from the **Somnibel Pro** .

13. Show complete therapy data.

- In the **Signals** window click  to open the **Recording data** window.
- The software calculates a series of statistics and graphs to show the percentage of time spent in each position (6), the percentage of time of each level of vibration (7), the number of position changes and how many of them were due to the activation of the vibratory stimulus, the number of activations of the vibratory stimulus, … (8)
- Below the active signal recording data, the averaged data of last month's signal recordings are shown. The evaluation period may be changed with (4), (5), (10), (11), (12) and (13). Additionally to the graphs showing the percentage of time spent in each position and the percentage of time of each level of vibration, the Therapy Follow-up graph shows the evolution of the percentage of time in supine position and the index of vibration activation along the evaluation period.
- Use the **Previous** (1) and **Next** (3) buttons to browse the recording data of other patient's recordings.
- Click  to return to the **Signals** window.

8 CREATING REPORTS

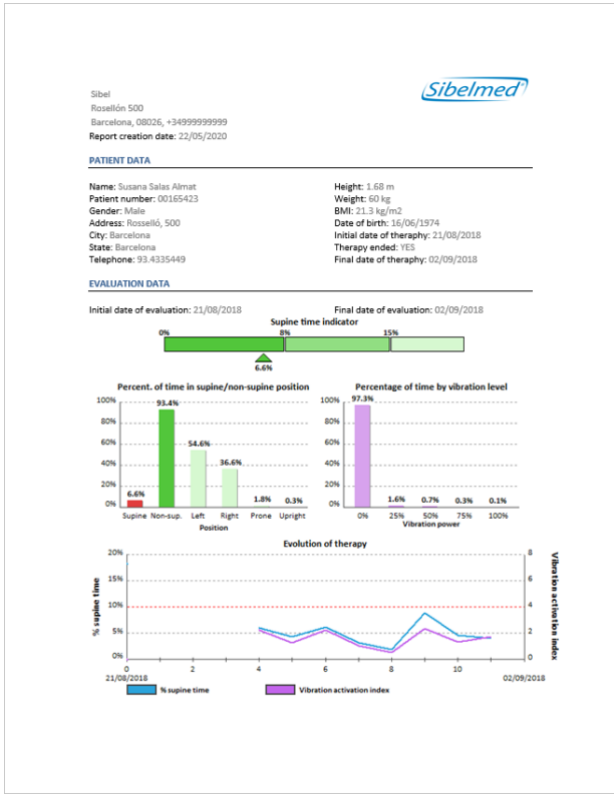
- Reports include the patient data, the statistics of the active signal recording, the averaged statistics of the evaluation period and data about the therapy compliance.
- Create a new report from the **Signals** or **Recording data** windows by clicking on  in the toolbar. In the **Report wizard** select the template to be used and the starting and ending dates for both the **Signals evaluation period** and **Therapy compliance evaluation period**. Click on **Create report**.



- By default, the report will appear in a new window into SomniLab. If you wish, the software can open the report automatically in MS Word, which provides much better editing possibilities. Go to **Tools> Settings** and enable the **Edit reports in MS Word** option in the **Program settings** tab.

- The software includes a default report templates in several languages used to generate reports. Users can customize this template or create new ones.

- Report templates are stored in the **Templates** folder of the SomniLab installation folder and use the RTF format. Any file with RTF format in this folder will be available for use as report template in the software.



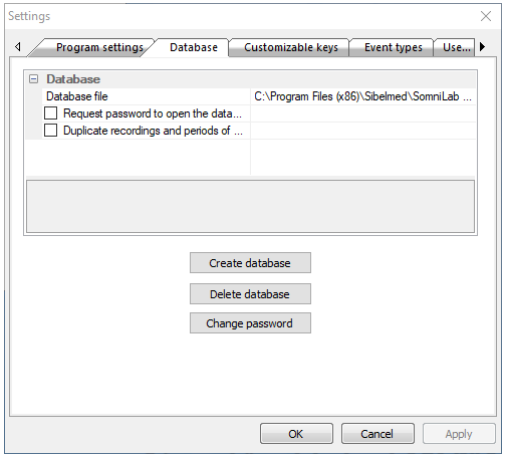
9 PROGRAM SETTINGS

9.1 Database management

The SomniLab software includes a database ready for use, so there is no need to change any of the database settings in a usual scenario. However some basic database settings might be changed if required.

9.1.1 Creating a new database

- In the main menu go to **Tool > Settings** and select the **Database** tab.



- Click on **Create database**.
- In the **Save as** dialog select the folder where the database is to be stored and enter a new one for the database file. Click on **Save**.
- Each database is given a password for security reasons. This password is required at the software's startup. It is highly recommended that you set a database access key. Assign a sufficiently complex password, including letters, numbers, upper and lower case. In case you do not wish to set a password just leave void the **Password** field and click on **Ok**.
- Repeat the password. Again, if you do not wish to set a password just leave void the **Password** field and click on **Ok**.
- In the **Settings** dialog click on **Ok**.

9.1.2 Changing the database password

- In the main menu go to **Tool > Settings** and select the **Database** tab.
- Click on **Change password**.
- Enter the current password for the database. If the current password is not entered you will not be allowed to set a new password.
- Enter the new password. In case you do not wish to set a password just leave void the **Password** field and click on **Ok**.
- Repeat the password. Again, if you do not wish to set a password just leave void the **Password** field and click on **Ok**.
- In the **Settings** dialog click on **Ok**.

9.1.3 Disabling the requirement of password at startup

- In the main menu go to **Tool > Settings** and select the **Database** tab.
- Deactivate the option **Request password to open the database**.
- In the **Settings** dialog click on **Ok**.

9.1.4 Deleting the database

Deleting the database will erase all information about patients, periods of use and therapies. However, the signal recordings are not affected.

***If you just want to delete one patient, or some of the signal recordings use the* Delete patient *or* Delete signal recording *options in the* Database Window.**

This action cannot be undone. Please make sure you really want to delete the database before continuing.

- In the main menu go to **Tool > Settings** and select the **Database** tab.
- Click on **Delete database**.
- Confirmation on deleting the database is requested. Click on **Yes** if you really wish to delete it.
- In the **Settings** dialog click **Ok**.

9.1.5 Selecting the database file

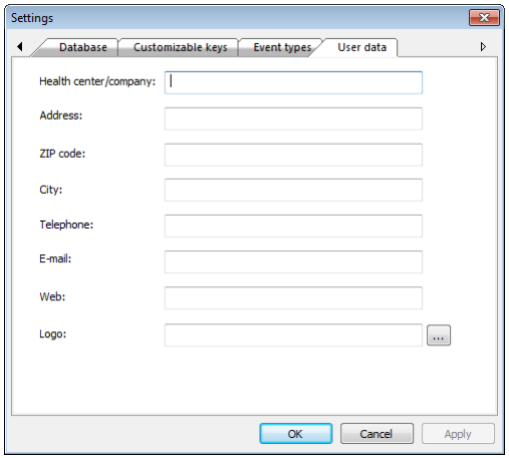
- In the main menu go to **Tool > Settings** and select the **Database** tab.
- Click on the ... button located at the right side of the option **Database file**.
- In the **Open** dialog select the database file to be used and click on **Open**.
- In the **Settings** dialog click **Ok**.

9.1.6 Selecting the storage folder for signal recordings

- By default signal recordings are stored in a separate folder named **SomniLab tests**.
- In the main menu go to **Tool > Settings** and select the **Database** tab.
- Click on the ... button located at the right side of the option **Tests storage folder**.
- In the **Open** dialog select the folder where signal recordings will be stored when downloaded from Somnibel Pro.
- In the **Settings** dialog click on **Ok**.

9.2 Entering user data

- User data will be used in the heading of reports and printed pages.
- Go to the menu option **Tools > Settings** and select the **User data** tab.
- Enter your data and click **OK** to save them.



9.3 Configuring the auto save option

- The SomniLab software includes an auto save option to backup automatically the currently opened signal recording.

- In the main menu go to **Tool > Settings** and select the **Program settings** tab.
- Under **Autosave** activate the option **Enable**.
- Enter the lapse of time (in minutes) between each automatic save.
- Click **Ok** to save the changes.

10 TECHNICAL SPECIFICATIONS

Useful life	7 years		
Physical Support	USB pen drive (> 4 GBytes)		
Available data or graphs in the report	Summary graph of all signals (activity, body position and vibration intensity) Summary of scored events Graphs of %Time in each body position Graphs of %Time in each vibration intensity level Record duration Vibration time Number and index of activations of the vibration stimulus Number of posture changes Number of posture changes due to the stimulus Number and index of activity periods Number and duration of artifacts Trend graph of %Time in supine position and index of activations. Information on the therapy compliance (number of uses; average, minimum and maximum use; average, weekly, monthly and yearly compliance; therapy compliance graph)		
Supported events (* events marked automatically by the software)	Activity Artifact Vibration intensity 25% and 50% * Vibration intensity 75% * Vibration intensity 100% *		
PC requirements		**Required**	**Recommended**
	Operating system	Windows 7 (SP1) or higher (*)	
	CPU	Intel Pentium 4, AMD Athlon > 2 GHz	Dual core processor
	RAM memory	1024 Mb	2048 Mb

PC requirements		**Required**	**Recommended**
	Free HD space	200 MB	
	USB 2.0 ports	1 Port	
	Screen resolution	1280 x 1024	1280 x 1024 or higher
Device configuration	Allows setting the device in Therapy, Placebo or Test mode and configuring the following parameters: - EasySleep delay (0 to 60 min) - Supine delay (0 to 60 sec) - Power increase period (30 to 300 sec) - Time at maximum power (2 to 120 min) - Supine threshold angle (30 to 75 º) - Time and date		
Database	Stores patients' data, signals recordings, therapy compliance data and reports. Access to data is password protected		
Customizable epoch duration	10s, 30s, 1m, 3m, 5m, 10m, 30m, 1h, whole record or user-defined.		
Storage environmental conditions for the flash memory drive	Temperature: -20ºC to +60ºC Relative humidity: <93% (without condensation)		
Other features	Comments on the test Navigation marks Customizable appearance of signals Values over the waveforms Trends window Customizable reports Data export in ASCII and EDF formats Export and import of signals		
(*) Compatible with Windows 7 (SP1), Windows 8.1, Windows 10 and Windows 11.			

The screen resolution specifications are recommended for a comfortable use of the system. Take into consideration the applicable regulations in terms of occupational safety.

11 SYMBOLS


Manufacturer (manufacturer's name and address)


Date of manufacture



CE marking, Notified Body number.


Warning, risk identified



Batch code


Waste of electrical and electronic equipment



Medical device

For the rest of the symbols see the Somnibel Pro user's manual (534-80P-MUM).

12 HOTKEYS

ACTION	KEY
Insert note	INSERT
Increase amplitude of selected waveforms	UP ARROW
Decrease amplitude of selected waveforms	DOWN ARROW
Select epoch for printing	ALT + P
Select all waveforms	CTRL + TAB
Deselect all waveforms	ESCAPE
Zoom in time axis x2	+
Zoom out time axis x2	-
Insert navigation anchor	CTRL + M
Move to the navigation anchor	CTRL + N
Move to the start of the test	HOME
Move to the end of the test	END
Move to the previous epoch	PAGE UP
Move to the next epoch	PAGE DOWN
Move one second back	LEFT ARROW
Move one second forward	RIGHT ARROW
Move half an epoch forward	TAB
Change the way text of waveforms is displayed	C
Change the way text of event marks is displayed	E

13 APPLICABLE DIRECTIVES AND STANDARDS

Directives and regulations:

- European Regulation on Medical Devices (EU) 2017/745.
- RoHS Directive: 2011/65/EU (USB Flash memory drive).
- General Data Protection Regulation (EU) 2016/679.
- Packaging and packaging waste directive 94/62/EC modified by 2004/12/EC.
- Implementing Regulation (EU) 2021/2226 regarding electronic instructions for use of medical devices
- Waste disposal according to WEEE Directive 2002/96/CE (USB Flash memory drive).
- Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (REACH) (USB Flash memory drive).

Standards:

- Quality (EN ISO 13485:2016+ A11:2021, EN ISO 9001:2015).
- Risk management (EN ISO 14971: 2019 + A11:2021).
- Safety Medical devices (EN 60601-1:2006 + AC:2010 + A11:2012 + A1:2013)
- Usability (EN 62366-1:2015+A1:2020).
- Software of medical devices (EN 62304:2006 + AC:2008 + A1:2015).
- Documentation and information (EN ISO 20417:2021, EN ISO 15223-1:2021).

14 COMPLIANCE WITH THE DATA PROTECTION REGULATION AND COMPUTER SECURITY

This section is intended to facilitate the user compliance with the legislation in force in relation to the processing of personal data that are regulated and covered by the new General Data Protection Regulation (EU) 2016/679 on the protection of individuals with regard to the processing of personal data and to the free movement of such data.

SomniLab software computer security requirements

Identification and Authentication

The processes for user identification and authentication for use of SomniLab are performed by the PC's operating system. Therefore, only Windows Operating Systems allowing these processes in a secure way are valid, i.e., Windows 7, Windows 8/8.1 and Windows 10 with an NTFS file structure. FAT file structures are not valid.

The PC administrator must create a unique and personalized identification for each user and activate authorization verification. The operating system saves the passwords in an unintelligible way.

Access control

The Operating System must be set up to control the access to data, i.e. permit or deny access to data. Likewise, the PC administrator must set up the user account lock in order to impede reiterated attempts for unauthorized access, limiting 3 incorrect attempts. Consult the manual for the operating system in order to set up said system access controls.

Access register

Accesses to the different databases are stored in one access register file.

Back-up copies (back-up and recovery)

The user must, at least once a week, make back-up copies of all data in order to guarantee full recovery of data in the case of a computer system failure. In the case of the SomniLab software, full recovery of all database data is guaranteed if the entire application folder is saved, as well as the folder where the tests and reports are stored (by default the *SomniLab tests* folder).

The back-up copy must be stored at all times in a different place from where the software is used.

Operating System Configuration

On a Windows operating system level (7, 8/8.1 or 10) and for NTFS partitions, it is possible to restrict the access to the different databases using the security characteristics of the file system. Basically, the control of access to databases is covered by the following points:

- Configuration of identification, authentication

  Each user that accesses the system must have a unique username and password, whether a local user or a network user connecting to a domain. The passwords must be changed at least once a year and, whilst a series of passwords remain valid, they will be stored in an unintelligible way.

  It is recommended to use the Windows password policy so that users use strong passwords (minimum password length, use of characters and numbers, upper and lower case, special characters) and to enable password history, so that users cannot use previous passwords. It is recommended that users do not have Administrator access level. In any case, the

Administrator is responsible for users using their identification in the ways determined both technically and by documentation, as well as for informing them of their obligations regarding the processing of personal data.It is also advisable to activate the security audit in order to register valid and erroneous accesses to the system.

- Access configuration and control. File permissions

  The following step is used to set up the access levels to the database files. The database root can be found in the <SOMNILAB_HOME>\data directory. Inside, there is a register file «log» SOMNILAB.log. One possible configuration is to provide full access to the <SOMNILAB_HOME>\data folder to all users (or at least to the application users). In any case, the owner must always have read and write rights on the database. The rest of the users may have no permissions on that database, for example. It must be taken into account that in this situation the users may only access their database from the application. With regard to the log file SOMNILAB.log, it would be advisable that users only have read rights, so that the application could register the accesses to the different databases.

  Permissions can be applied from Windows Explorer itself. Simply access the Properties of the folder or file you wish to change permissions and select the Security tab. From this tab you can select both the users who may access and the permissions (total control, read, modification, write, etc.) of each user.

Encryption of data

It is advisable to proceed with the encryption of the data. For that, the tool Bitlocker, included in the operating system (in Pro versions), can be used or some other tool available from third parties

- File audit.

  We recommend the activation of the log file audit in order to register on the security event viewer the actions performed upon it.

  To activate this option, you must first enable the audit of the aforementioned file. At this level, you must specify the users (according to the users which access the <SOMNIBEL_HOME>\data folder) and types of access to be audited. The log file audit can be activated from the Security tab of the file Properties. Using the Advanced button you can access the Audit tab. From here, simply add the users and the type of access to be audited. It must be taken into account that if all actions on the log file are audited, the security events viewer will have many entries and will complicate the monitoring of unauthorized accesses.

  The next step is to activate the audit of access to objects in the local security configuration. To do so, access the Administrative Tools icon from the Control Panel. Once there, you must select the Local Security Directive and the Local Directives branch from the directives. You must then access Audit Access to Objects. Both correct and erroneous accesses can be enabled.

  Finally, the folder where the test and report files are stored may also be audited.

Access register description

Access to the different databases is stored on the one log file (SOMNILAB.log) in the folder where the application is installed.

This file is created the first time the application is executed and cannot be deactivated The system administrator is responsible for the maintenance of this file, as well as the elaboration of a monthly report where the log is analyzed and any detected problems are reported, should there be any.

The log file saves for each line:

- User
- Time and date of access
- Database accessed
- Action carried out on the database
- Type of access (authorized or denied)
- File path of database accessed
- Reference of the register accessed

The format of each of the lines is the following:

[USER], [YYYYMMDD HH:MM:SS], [BASE], [ACTION], [ACCESS], [PATH], [REFERENCE]

The actions to be registered are divided into:

- Action on the actual database itself (open, close, delete, etc)
- Action on the registers stored on the database (insert, consult, delete, etc)

In any case, the register or access control log file, must be kept for a minimum epoch of two years.

Below, all actions registered on the log file are listed:

- Open DB
- Close DB
- Select DB
- Create DB
- Delete DB
- Modify the access password
- Consult record
- Consult all records
- Add record
- Update record
- Delete record
- Export record
- Import record

Other important issues

- Printing documents

  In the case of storage of paper prints containing patient details, it is required that these documents remain duly safeguarded in such a way that only duly authorized personnel have access to them. Likewise, in the case of a user deciding to dispose the printed documents, it will be necessary to ensure their effective physical destruction in order to avoid unauthorized access to the data.

- Exporting tests

  Once the test has been exported to a file, the software user is responsible for the security of that file, and its later deletion.

- Data transmission:

  The software permits the transmission of files with patient data via the internet. If this functionality is used, the user must configure their e-mail server so that the data is encrypted before transmission and is therefore converted into unintelligible data for any unauthorized access.

15 MAINTENANCE

The SomniLab software does not require any specific maintenance, except that for any computer program handling information.

- Make a copy of the flash memory drive in case the original gets damaged.
- Make periodical backup copies of the database, test files and report files, in order to be able to restore them if any loss of information occurs in the computer. See **13 COMPLIANCE WITH THE DATA PROTECTION REGULATION AND COMPUTER SECURITY** for more information on backups.

The software is improving continuously. Therefore, contact regularly with the Technical Assistance Service at SIBEL, S.A.U. to get the latest updates or check the website at
http://www.sibelgroup.com/en/soporte/software.
If any problem, doubt or suggestion arises while using the product or if you require additional training, please follow the next steps:

- Use this User Manual properly
- Keep the program updated. You can check your current version in "Help > About SomniLab". Check the availability of new versions at https://www.sibelmed.com/support.
- Contact with the After Sales Service of SIBEL S.A.U. at

SIBEL, S.A.U. After Sales Service
Tel. +34 93 433 54 50
sat@sibelmed.com

15.1 CLEANING

The flash memory drive should be gently cleaned with a cloth moistened with soapy (neutral) water. Then it can be wiped dry. Particular care must be taken to ensure that no liquid enters the interior of the USB connector. Abrasive substances or solvents must be avoided. Keep the flash memory drive into its package when not in use.

16 PRODUCT DISPOSAL



The device support media is a flash memory drive. The flash memory drive, as an electronic product, cannot be disposed in the household trash. Please, follow the instructions of the manufacturer.

To dispose the packaging of the device, that includes the software, consult **Somnibel Pro** user manual (534-80P-MUM).

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