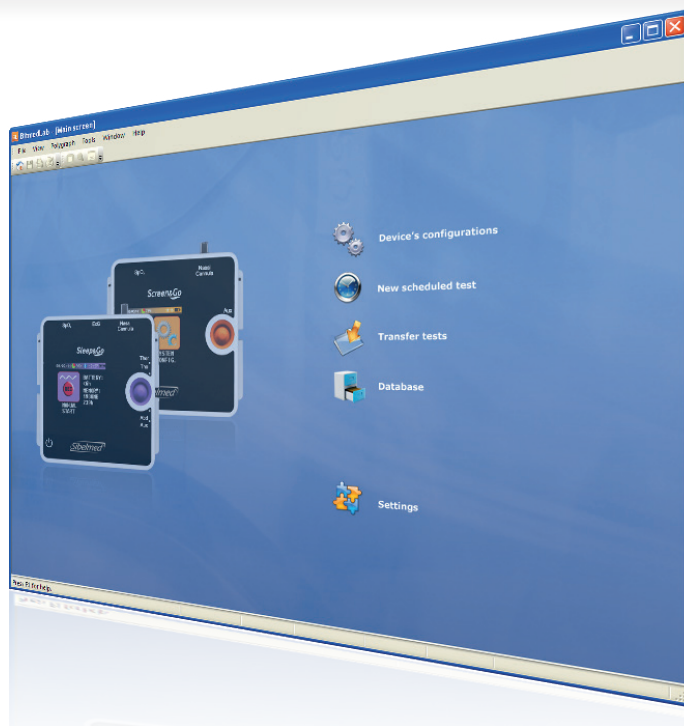


BitmedLab

SCREENING OF SAHS

CARDIORESPIRATORY POLYGRAPHY

USER'S MANUAL



BitmedLab User's Manual
Revision: 534-740-MU2 Rev. 2.03
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This manual can be purchased from the Technical Assistance Service.



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- The repairs, revisions or modifications, both within and without the warranty period are performed by SIBEL S.A.U. technical personnel.
- The product is used by qualified personnel and according to the recommendations made in this User's Manual.

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

C€ 0318

Thank you for choosing BITMEDLAB!

This product has been developed by the RDI Department of SIBEL S.A.U. with the collaboration of reference Health Centers and doctors specialized in the area of Sleep Disorders. BITMEDLAB is designed and manufactured according to the European Medical Device Regulation and with the best quality standards.

Revised

Date: 2026-04

Technical Director

Approved

Date: 2026-04

Sales Director

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1. SAFETY

BitmedLab is a software application allowing the review and analysis of sleep studies performed in holter or real time mode with Sibelmed cardiorespiratory/screening polygraphs (Sleep&Go / Screen&Go). BitmedLab is designed for the diagnosis and control of sleep related breathing disorders, mainly the Sleep Apnea Hypopnea Syndrome (SAHS). The complete operating instructions must be read before proceeding to operate with the system. Failure to do so may result in injuries to the user or patient. The BitmedLab software is the bridge between Sibelmed's sleep study systems (Sibelmed Screen&Go, Sibelmed Sleep&Go) and you as a user via a PC computer.

Sibelmed sleep diagnosis product line systems are delivered with all their accessories and with BitmedLab analysis software. This manual describes the BitmedLab software.



Please read this manual carefully before using the BitmedLab software, especially those sections marked with an exclamation mark.

Report any serious incident to the manufacturer and competent authority.

1.1 INTENDED USE

Acquisition, storage, display and analysis of biomedical sleep signals for diagnosis and control of Sleep Apnea and Hypopnea Syndrome.

Next conditions must be taken into account:

- Use in a health center.
- Not intended for monitoring vital signals.
- ECG signal can not be used for heart diagnosis purpose. It's

only intended for bradycardia and tachycardia detection during sleep analysis.

1.2 INTENDED USER

BitmedLab software is designed to be used by a physician or technician trained in SRBD and SAHS. Training in cardiorespiratory signal acquisition, data transmission and visualization on a PC, and signal analysis during polygraphic studies is also required. It is not recommended to change device settings without understanding the principles of signal digitization. Healthcare personnel can contact SIBEL S.A.U. for additional training.

1.3 INDICATIONS FOR USE

1.3.1 SLEEP APNEA AND HYPOPNEA SYNDROME (SAHS)

The Sleep Apnea and Hypopnea Syndrome (SAHS) is an sleep related breathing disorder with a high prevalence^{1, 2} and is associated with significant morbidity and mortality³⁻⁷. The standard laboratory polysomnography (PSG) for the diagnosis of SAHS is expensive, requires technical expertise and is of limited availability in many areas⁸. Cardiorespiratory polygraphy, based on recording the same biological signals as PSG except the neurological ones, is a valid method for the diagnosis of SAHS⁹.

1.3.2 INDICATIONS FOR USE OF BITMEDLAB

BitmedLab is a software application designed to be used in conjunction with the Sleep&Go and Sleep&Go polygraphs. They are indicated, together with a comprehensive sleep evaluation, for the diagnosis and control of SAHS. It can be used as an alternative to PSG in patients with both high or low pre-test probability and with or without comorbidities¹⁰, or in patients for whom inlaboratory PSG is not possible.

Sleep&Go/Screen&Go are useful tools for providing an accessible and accurate diagnosis of SAHS. They allow the acquisition, storage, display and transmission of biological signals, that can subsequently be analyzed with the BitmedLab software. BitmedLab can be used in hospitals, sleep centres or similar facilities¹¹.

BitmedLab can be used for the general screening of asymptomatic population, provided that appropriate clinical assessment is used to address potential false positives and false negatives^{12,13,14}. BitmedLab can also be used for monitoring the response to treatments for SAHS and, in selected cases, for Positive Airway Pressure (PAP) titration.

The diagnostic and therapeutic decisions taken when using BitmedLab have proved to be equivalent to decisions taken from PSG studies^{10, 14}.

The automatic analysis implemented in BitmedLab for the detection of respiratory events from the signals recorded with the Screen&Go and Sleep&Go polygraphs is useful for the diagnosis and monitoring of SAHS^{12,13,14}.

1.4 INTENDED PATIENT POPULATION

Minimum age of patients is 5 years, weighing over 15 kg and a minimum height of 95 cm. Patients must have a physical and mental condition that allow them to perform the polygraphic test.

1.5 LIMITATIONS FOR USE

The interpretation of the tests and any ensuing treatment must be carried out by a physician. The acceptability of a test is the responsibility of the health personnel.

BitmedLab is not suitable for the diagnosis of neurological sleep disorders such as insomnia, parasomnias, circadian rhythm disorders or narcolepsy.

1.6 CONTRAINDICATIONS AND SIDE EFFECTS

No contraindication or side effect has been identified for BitmedLab.

1.7 ESSENTIAL OPERATION

The real-time data transmission, data download and representation of all physiological signals is considered an essential performance (so that the specified accuracy can be met and/or the technician is able to distinguish the artifacts), and the storage and integrity of data in the computer.

1.8 RESIDUAL RISKS

According to the application of the EN ISO 14971 standard, all risks related to the use of the BitmedLab 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.

1.9 WARNINGS

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



- For correct system operation, BitmedLab software should be used only with the devices listed in this manual. Please read the user's manual of your system before using it.
- Use the software according to the instructions included in the device manual.
- Use the system, software with compatible device, according to the instructions of use.
- This manual is available in PDF format on the USB flash drive provided to install the BitmedLab software.

Once installed, the user manual is also available in the "Help" folder, which is located in the installation folder (normally C:\Program Files (x86)\Sibelmed\BitmedLab 2.xx\Help).

You can also request a printed copy from SIBEL,S.A.U. or through your authorized dealer.



- The recommended minimum duration for sleep studies to be reliably evaluated is 6 hours.
- None of the results provided by the Automatic Analyses contained in the BitmedLab software should be used as the sole criterion for medical diagnosis or patient treatment. This information should not be considered complete, nor is it to be trusted for the prescription of individual treatment. The user must understand that the results of the Automatic Analyses generated by the BitmedLab software are not exhaustive and must always be supervised and verified by medical personnel with adequate training.
- In order to comply with Medical Device Regulation (UE) 2017/745 and for safety and reliability purposes, ensure that the device and BitmedLab software are used by personnel who are properly trained in the intended use of the system.
- The user must have a minimum computer knowledge allowing the safely operation of the BitmedLab 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. These measures may include access control, software installation policy, data sharing, external access, etc.

The software BitmedLab runs on compatible PC systems.



- The computer, monitor and accessories where the software is used, meet the low voltage Directive (particularly EN60950 standard) and EMC Directive (particularly EN55022, EN61000-3-2, EN61000-3-3 and EN55024 standards).
- The BitmedLab 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 that the hardware of your PC works properly.
- Check if software updates are available.
- Make sure you save the test or changes made before turning off the PC.
- Do not turn off the PC when performing a real-time test. Stop the real-time test first.

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 computer devices (operating systems); or for flaws or accidents in other computer equipment.



1.10 DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION

The software is delivered on a USB Flash memory drive. The USB flash drive is an electronic product and therefore should not be disposed of in organic waste. Deliver to a designated recycling collection point in accordance with the legal requirements of your country.

You can obtain more information on proper disposal by contacting the SIBEL S.A.U. Technical Service or with your dealer.

2. INSTALLING THE SOFTWARE

2.1 REQUIREMENTS

	Required	Recommended
Operating system	MS Windows 7, 8/8.1, 10 or 11 (32 and 64 bits)	
Processor	Intel Pentium 4, AMD Athlon	Double core processor
Memory	1024MB	2048MB
Free space in hard disk	100MB	Several gigabytes to acquire synchronized digital video
USB Ports 1.1	Screen&Go/Sleep&Go: 2 (if a Wireless module and card reader are used)	
Screen resolution	1024 x 768	1280 x 1024 or higher
Capture of synchronized digital video	Free PCI Xpress slot (PCs) Free Xpress Card slot (Laptops)	

2.2 INSTALLING BITMEDLAB

We recommend closing all the applications running in the system before starting the installation. This reduces the possibility of conflicts between software affecting the installation.

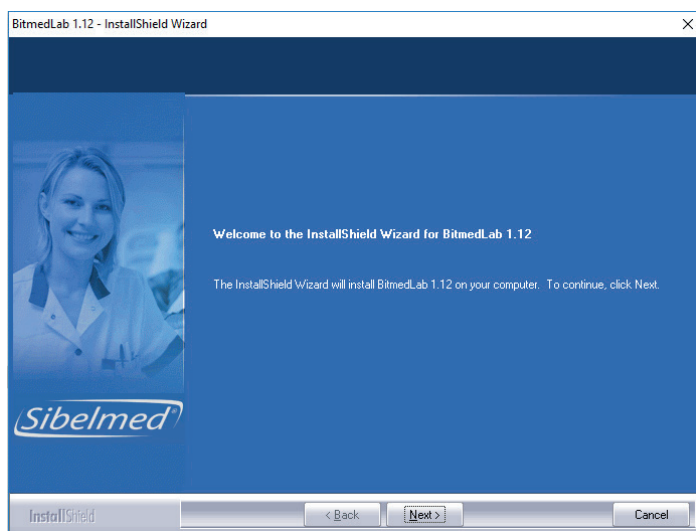
Take the following steps to install the BitmedLab software:

To install the BitmedLab software, proceed as follows:

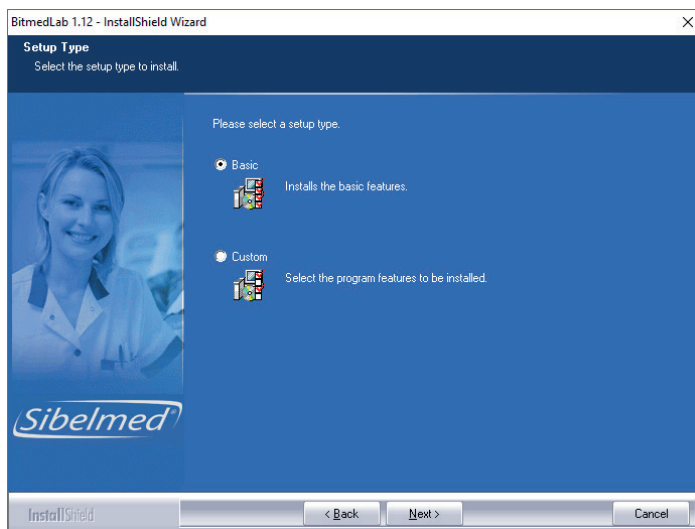
Click on Run in the Start menu of the Windows task bar. The Run dialog box will appear.

Write X:\setup.exe in the text box and click on Accept. X is the USB Flash memory unit or access path to the folder containing the installation file. Click on Browse to locate the correct files in the hard disk or in the USB Flash memory.

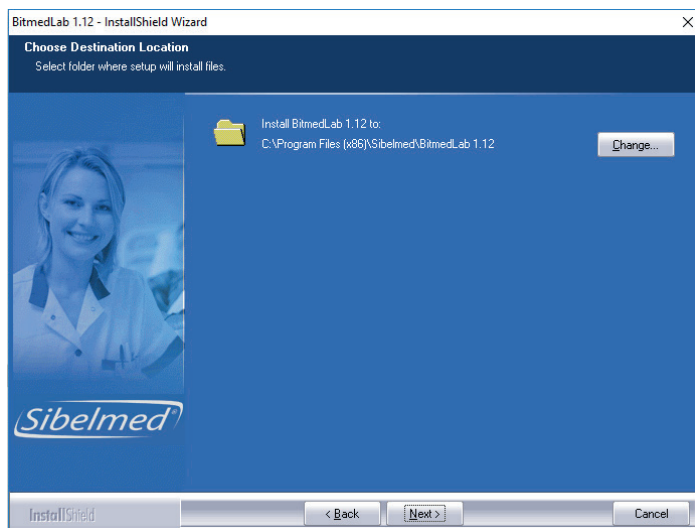
The installation program will immediately show the first panel of the installation wizard. Click on Next> to continue.



The installation program can perform a complete program installation or customize the elements of the program to be installed. Choose the option you prefer and click on Next>.

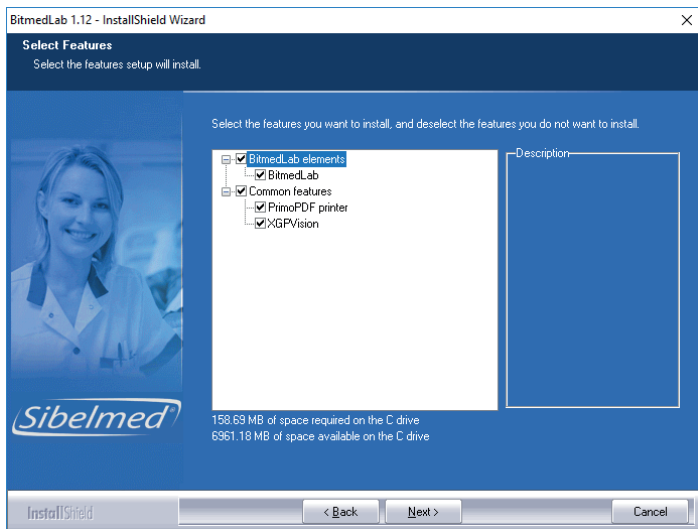


The next panel of the wizard lets you change the folder where the program files will be copied. If you want to change the default folder, click on Change. When you are finished, click on Next>.



On the next screen, choose the elements that you want to install.

Choose the modules that you want to install. The PDF printer allows you to print the reports generated by the program in PDF format, while the XGPVision module allows you to acquire synchronized video. Click on Next.



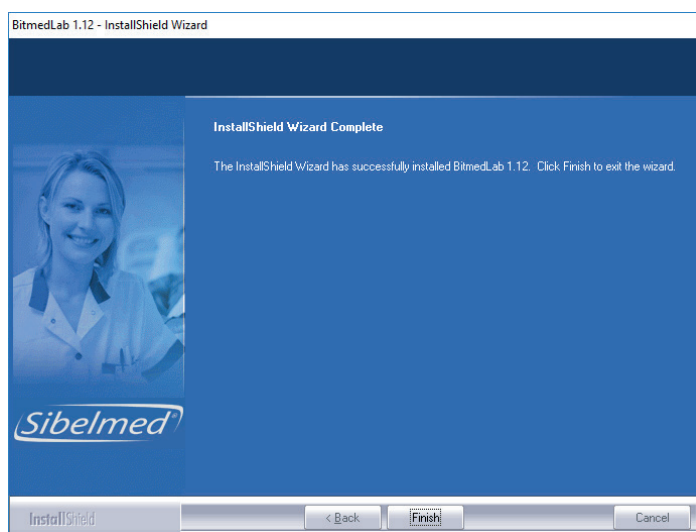
The installation program will copy the selected files. If you chose to install the PDF printer, the PrimoPDF installation program will start up automatically. Click on the Next button of all the screens until the installation of PrimoPDF has been completed.

If you chose the install XGPVision, a window will appear indicating that the software is installing hardware that has not passed the Windows logo test. Click on Continue.



If a message appears requesting confirmation to overwrite files, click on "No to all".

When the installation is complete, click on Finish. The BitmedLab software line of products is ready for use.



3. INSTRUCTIONS FOR USE

The BitmedLab software allows the review and the analysis of the tests carried out by the Sibelmed sleep study systems in Holter mode or in real-time.

BitmedLab is compatible with the systems:

- Sibelmed Screen&Go
- Sibelmed Sleep&Go

3.1 FIRST STEPS

STARTING THE BITMEDLAB

There are two ways to start the BitmedLab:

Click on the BitmedLabicon in the Windows Desktop.

In the Windows Start menu, click All the programs, go to the BitmedLab folder and click on the BitmedLabicon.

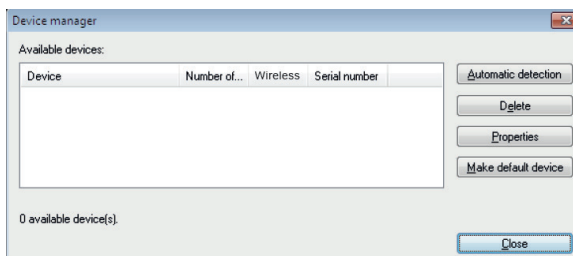
3.1.1 LANGUAGE SELECTION

You can change the language of the application at any time from the Tools > Settings menu. Select the General tab, change the language, and click OK. Restart the program to apply the changes.

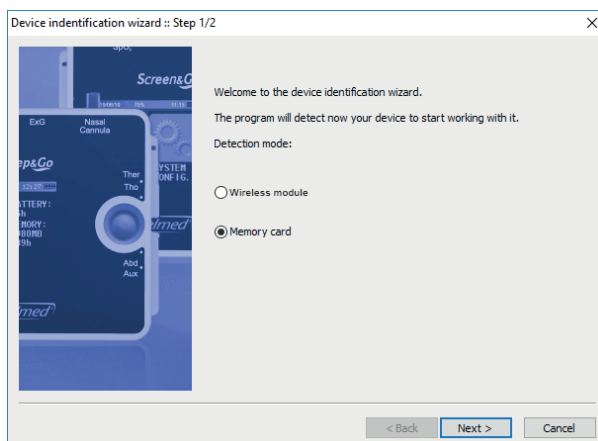
3.1.2 REGISTERING THE SCREEN&GO/SLEEP&GO IN THE SOFTWARE

Before starting to use your Screen&Go/Sleep&Go system, you must register it in the BitmedLabsoftware. This procedure is required only once and ensures that your program recognizes the characteristics of your polygraph.

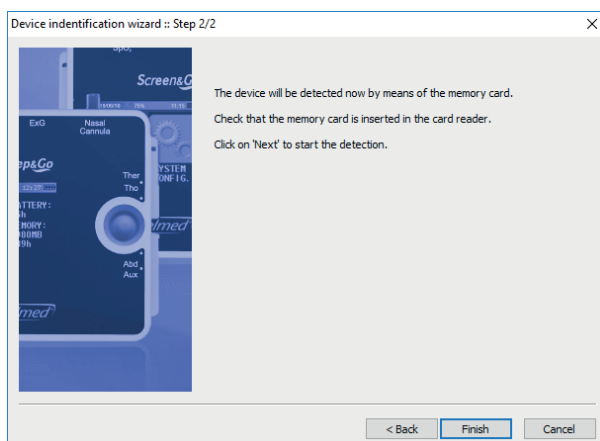
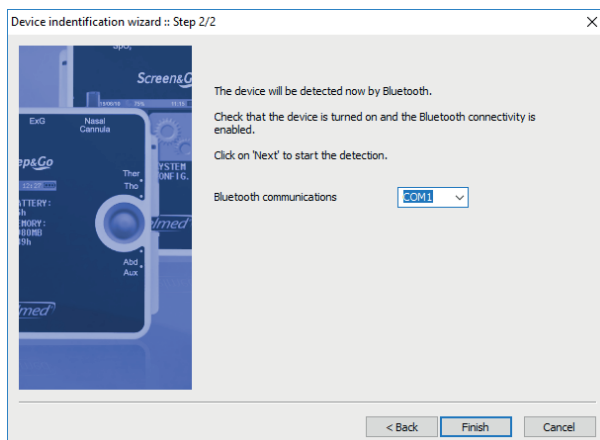
Go to the Polygraph menu > Device manager.



Click on Automatic detection. The Device identification wizard will start up. If you have a Sleep&Go system with a Wireless module select the option Wireless. Otherwise select the option Tarjeta de memoria. Click on Next.



If you have a Sleep&Go system with a Wireless module, make sure that the Wireless module is running and select the Wireless communications port that the device is connected to (you can find this in the Windows Control panel). If not, remove the memory card from the device and insert it in the PC card reader (remember to switch off the device before removing the memory card). Click on Finish.



The wizard will detect the Screen&Go/Sleep&Go.

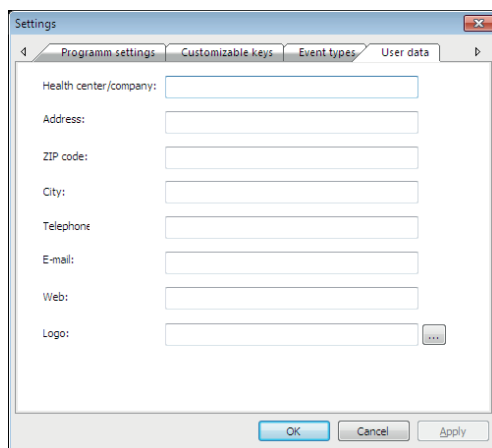
Note that the device has been registered in the software. The device is now ready to be used.

3.1.3 ENTERING USER DATA

BitmedLab lets you enter user data and an image with your logo. These will appear in the header of printed documents and in the report generated for each test.

Click on Configuration in the Tools menu.

Open the User data tab and fill in the fields with the user data.

The image shows a screenshot of the 'Settings' dialog box in the BitmedLab software. The 'User data' tab is selected, showing several text input fields for user information: 'Health center/company:', 'Address:', 'ZIP code:', 'City:', 'Telephone', 'E-mail:', 'Web:', and 'Logo:'. The 'Logo:' field has a small button with three dots to its right. At the bottom of the dialog are 'OK', 'Cancel', and 'Apply' buttons.

To select a logo, click on the "..." button of the Logotype field and choose your logo image. The image must be stored in a file with BMP, JPEG or PNG format.

3.1.4 ENTERING THE SLEEP&GO DATE AND TIME

Before starting tests with your Sleep&Go system, we recommend entering the date and time of the device. This information is used when programming tests to be performed in holter mode, in which the device starts monitoring the patient on a specific date, at a specific time.

The device date and time option can only be entered from BitmedLab software in Sleep&Go systems equipped with the Wireless communication module. In all the other systems, the date and time must be entered by using the graphics screen of the device. Refer to the device manual.

Go to the Polygraph menu > Enter date/time.

If more than one Screen&Go/Sleep&Go is available, choose one.

A window appears with the date and time of the PC. Modify the date and time, if necessary. When you are ready, click on Enter to apply the changes to your Sleep&Go.

3.1.5 DELETING STUDIES FROM THE SLEEP&GO MEMORY CARD

Each time you perform a test, whether in holter or real-time mode, a file is generated in the Screen&Go/Sleep&Go memory card. This file stores all the biomedical data compiled by the device. When the test is transferred to the PC, these files are automatically deleted. However, you may want to delete the files from the memory card. To do so, insert the card in the card reader of your PC and delete the files with .DAT extension from Windows explorer. Be sure to switch off Screen&Go/Sleep&Go before removing the memory card. You can also delete all the test files using the BitmedLab software:

Click on the Delete memory option of the Polygraph menu.

Confirm deletion of all the tests stored in your Sleep&Go memory card.

The memory card test deletion option is only available from BitmedLab software in Sleep&Go systems equipped with the Wireless communication module.



Before deleting the contents of the memory card, make sure that all test that you are interested in keeping have been downloaded to the PC.

The deletion procedure will eliminate all the tests stored in the memory card. The user will not be able to choose which tests to delete and which tests not to delete.

3.2 THE HOME SCREEN: THE BITMEDLAB WORKFLOW

The BitmedLab software home screen has been designed to facilitate the workflow of the Sleep Disorders Unit as much as possible. Only the most common tasks are shown and these can

be accessed by the following buttons:

Device configurations: this opens a wizard that allows the user to manage the device configurations used to perform the polygraph or screening studies (See Section 3.3).

New scheduled test: this opens a wizard that allows the user to program a test for a specific date and time (See Section 3.4).

Download tests: this opens a wizard that allows the user to download tests from the Screen&Go/Sleep&Go system to the PC. It also allows subsequent review of tests (See Section 3.5).

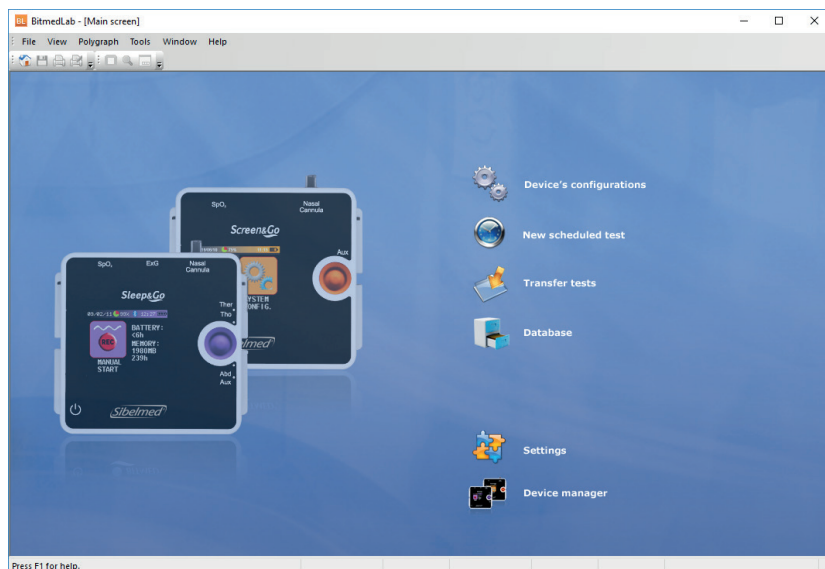
Database: open the patients and tests database. Patients and their tests can be managed from the database (new patients, discontinued patients, test reviews, consultation of work pending, etc.) (See Section 3.6).

Settings: this accesses the general options of the program (user data, type of events, custom keys, general options, etc.).

The home screen can be accessed at any time by clicking on the



icon of the toolbar.



3.3 TEST SETTINGS

Each polygraphy or screening test of the OSAS can be configured previously so the device recognizes which channels (sensors) are going to be acquired and the sampling frequencies that are going to be used. All these parameters are grouped in an "channel configuration". Each channel configuration has a name assigned by the user so it is easy to recognize.

Device manager: opens the dialog used to manage the polygraphs registered for use in the program. It is the same option of menu Polygraph > Device manager (see section 3.1.1)



During the performance of the test, check that the sensor connected to each channel corresponds to the selected channel configuration.

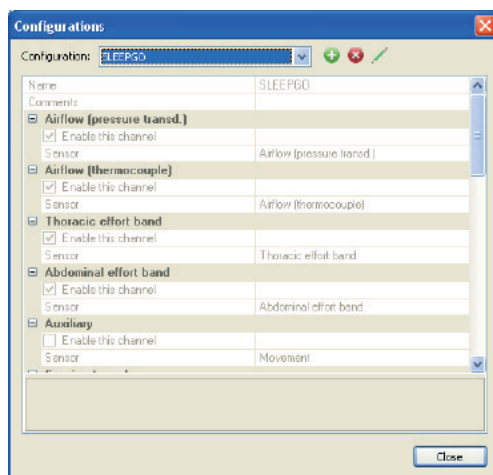
The configurations are stored in the device memory card, and a maximum of ten is allowed at the same time. The extension of

the configuration files is .CFG. The BitmedLab software module can generate, manage and store as many configurations as necessary.

Your device also has a default channel device configuration that is used when the test is started manually from the device itself. This configuration is labeled as "Internal" in the device. If you have a Sleep&Go with a Wireless communication module, the device default configuration can be set from the BitmedLab software. If not, this option will be disabled and must be done from the device itself (refer to the User's Manual of the device), by choosing from the configurations found in the memory card. Any of these configurations can be set as "Internal" from the device itself.

3.3.1 CREATING, MODIFYING AND DELETING CONFIGURATIONS

In the main menu go to Polygraph > Configurations.



The following configurations are supplied by default with the software:

- SCREEN: Screen&Go with pulseoximetry
- SLEEP_A: Sleep&Go A model
- SLEEP_B: Sleep&Go B model
- SLEEPEXG: Sleep&Go B model with ExG module

In the Configurations window, click the  button to add a new configuration. Then select the polygraph model for which the configuration will be created. Editing of channels to be acquired during the test will be enabled. Select the ones to use and configure the sensors that will be connected to each of them. You can also change the sampling rate of some of them. However, others have a fixed sampling rate and can not be changed. Do not forget to enter up to 8 characters in the Name field. When finished, click the  button to save the changes or the  button to discard them.

Use the  button to delete the configuration selected in the Configurations list.

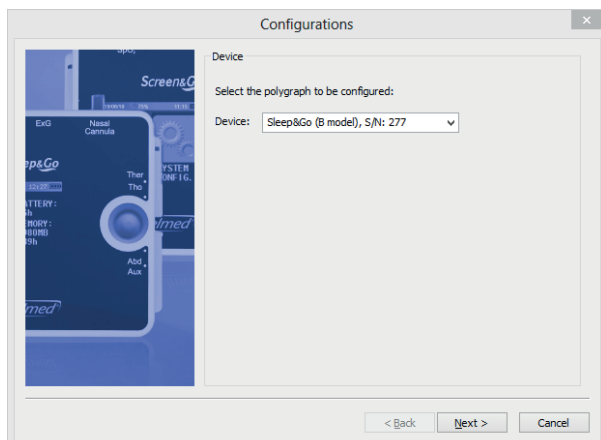
Finally, the  button allows you to modify the configuration selected in the Configurations list. Again, use the buttons  and  to confirm or discard the changes.

The following characters are available for the configuration name: letters from A to Z and digits from 0 to 9.

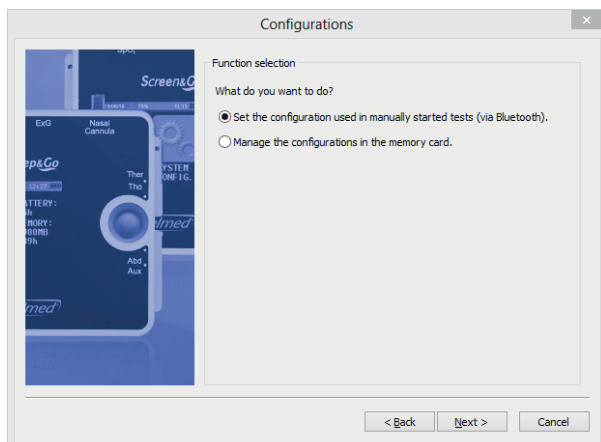
3.3.2 SETTING THE DEVICE DEFAULT CONFIGURATION USING WIRELESS (ONLY SLEEP&GO)

Click on Device configurations in the home screen.

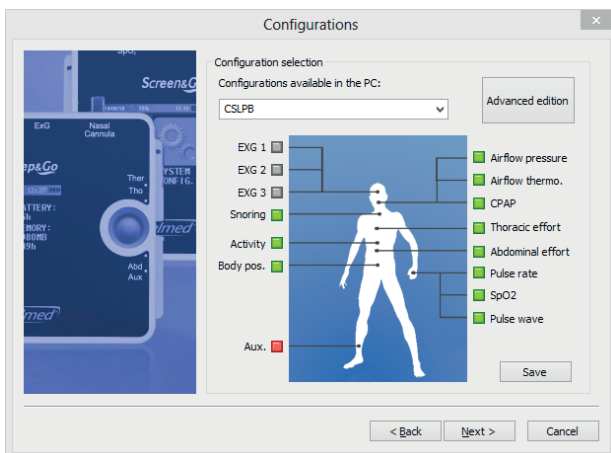
Each device configuration is associated with a Sleep&Go system by means of a specific serial number. The first step in the wizard is to choose the device that you want to establish the configurations for. Click on Next.



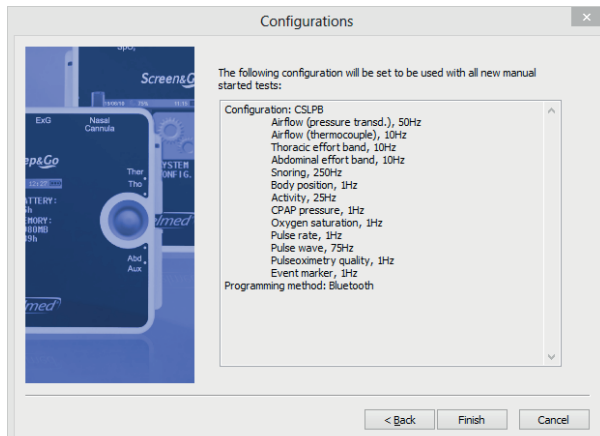
In the next screen, choose Set the manual start configuration (via Wireless) and click on Next.



Choose one of the configurations in the list. You can modify a configuration in the list or create a new one by clicking on the "Edit PC configurations" button. The graph shows the channels that will be acquired (green) or not (red), depending on the setting chosen. You can also edit a configuration in situ, activating or deactivating channels by clicking the appropriate button. If you also want to save the changes as a new configuration click the Save button and the program will ask for a name for the configuration. Click on Next.



Finally, a summary of the default configuration for the device will be shown. Make sure that Wireless communication is enabled in your device and click on Finish.

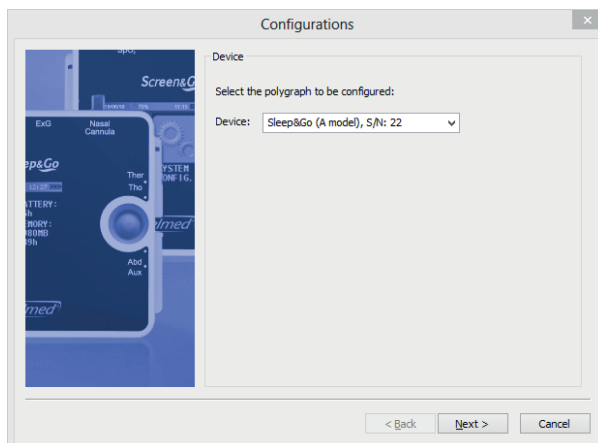


3.3.3 MANAGING THE DEVICE CONFIGURATIONS IN THE MEMORY CARD

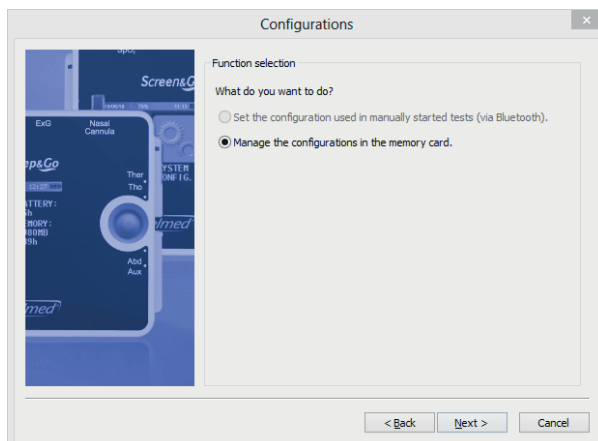
Click on Device configurations in the home screen.

Each device test setting is associated with a Sleep&Go system by means of a specific serial number. The first step in the wizard is

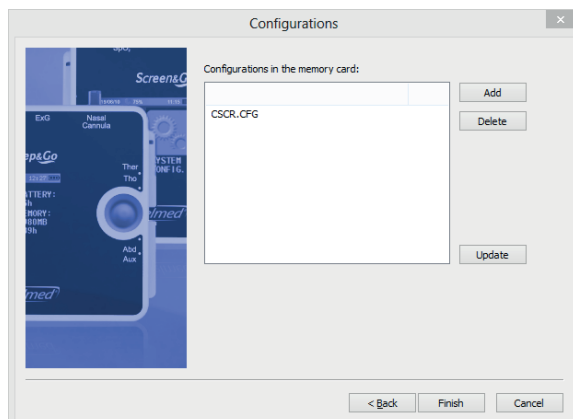
to choose the device that you want to establish the configurations for. Click on Next.



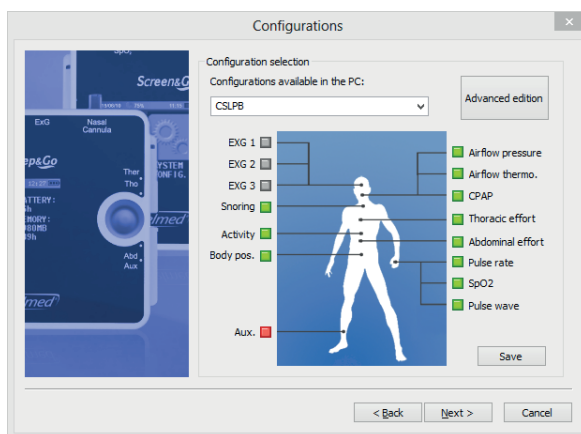
In the following screen, choose "Manage memory card configurations". Make sure you have inserted the memory card in the PC card reader and click on Next.



The following window shows a list of device configurations in the memory card. Remember that there can be no more than ten configurations in the memory card at the same time. Any of these configurations can be deleted by clicking on the Delete button.



Any of the configurations defined in BitmedLab can also be added by clicking on the Add button. In the new window, choose one of the configurations in the list. You can modify a setting in the list or create a new one by clicking on the "Edit PC configurations" button. The graph shows the channels that will be acquired (green) or not (red), depending on the setting chosen. You can also edit a configuration in situ, activating or deactivating channels by clicking the appropriate button. If you also want to save the changes as a new configuration click the Save button and the program will ask for a name for the configuration. Click on Next.



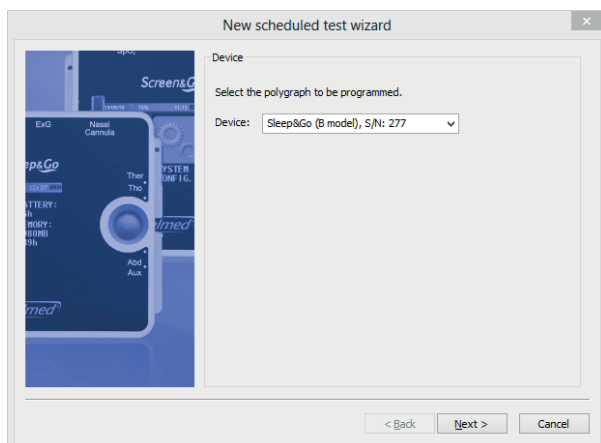
Click on Finish when you are finished.

3.4 PROGRAMMING AN AUTOMATIC TEST

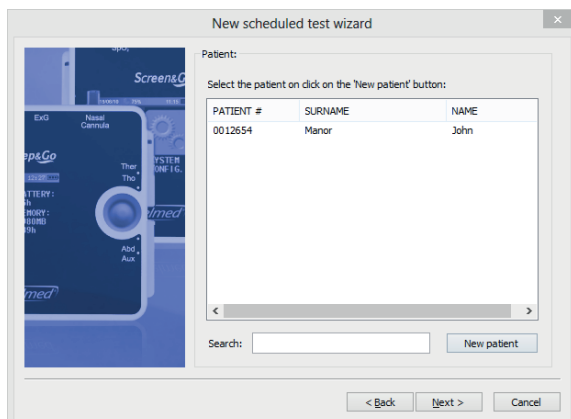
Take the following steps to set up your Screen&Go/Sleep&Go in order to start an automatic test in holter mode at a specific date and time:

Click on "New programmed test" in the home screen.

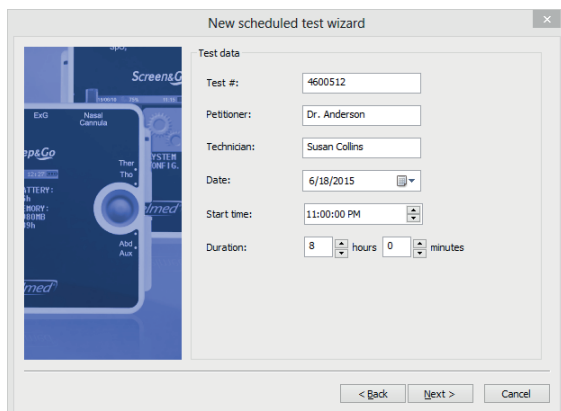
The wizard for the new programmed test will start up. Choose the device that you wish to program.



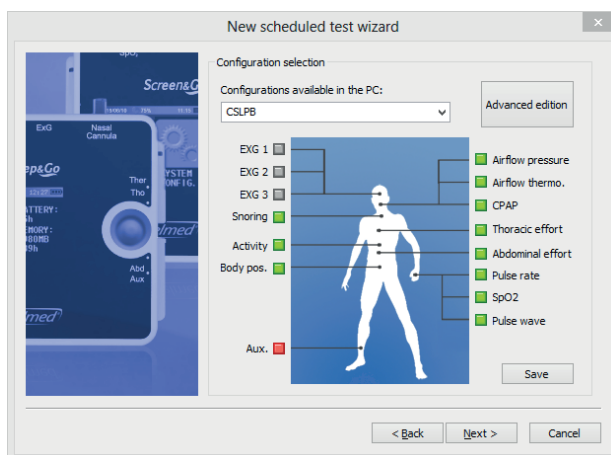
Choose the patient associated with the test. You can search for the patient by entering any of the patient's data in the Filter field. If the patient is not in the database, you can add the patient at this time by clicking on New patient. Once the patient has been selected, click on Next.



Then enter the test data, including the start date and time of the study and its duration. The device will complete the test automatically. Click on Next.

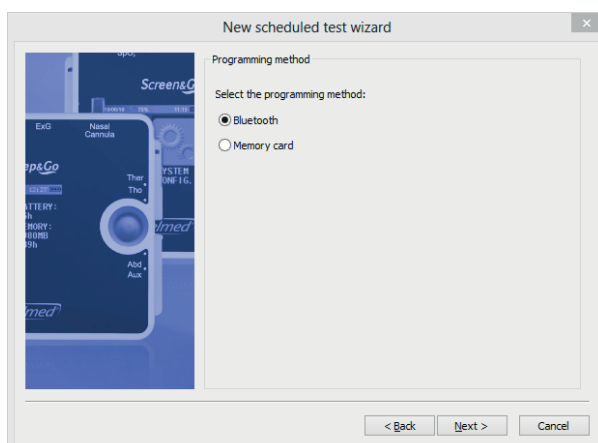


Choose the type of test to be performed. You can modify one of the available device configurations or create a new one by clicking on the "Edit PC configurations" button. The graph shows the channels that will be acquired (green) or not (red), depending on the setting chosen. You can also edit a configuration in situ, activating or deactivating channels by clicking the appropriate button. If you also want to save the changes as a new configuration click the Save button and the program will ask for a name for the configuration. Click on Next.



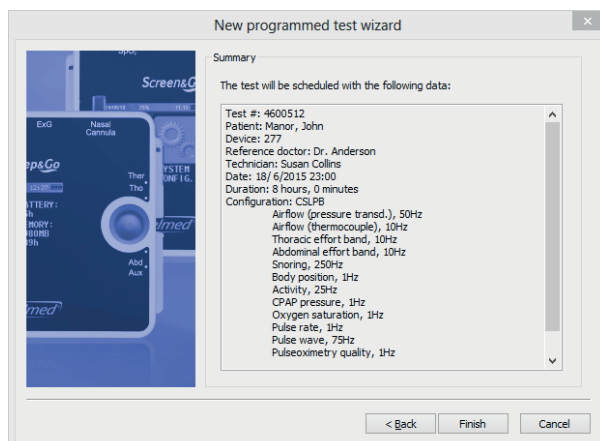
If you have a Sleep&Go system with a Wireless communication module, the test can be programmed directly via Wireless. Make sure that Sleep&Go is switched on, Wireless is enabled and choose option A via Wireless. Click on Next.

If not, remove the device memory card (remember to switch off the device before removing the memory card), insert it into the PC card reader and choose option A via the memory card. Click on Next.



Finally, a summary of the automatic test to be performed is shown.

Click on Finish.



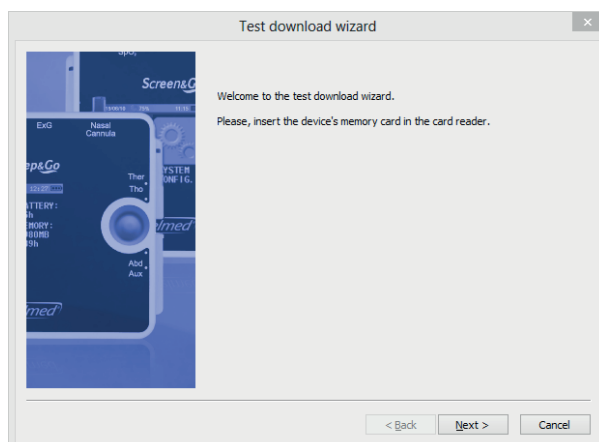
If the test was programmed via the memory card, wait until the program delivers a message indicating that programming has been completed successfully. Remove the card from the card reader and place it in the device again. Switch on the device and wait until the main screen appears (the one with the manual start option). The device will detect a new test and is now ready for use. Now you can switch off the device.

3.5 DOWNLOADING THE COMPLETED TEST

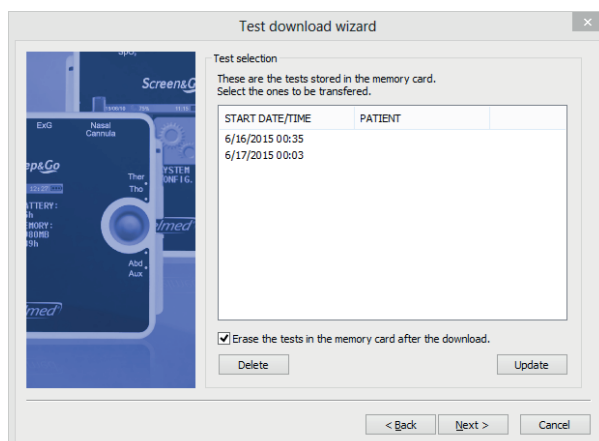
Once a test has been obtained in holter mode (whether started automatically or manually) it is necessary to download the test to the PC for review and to generate a report.

To do so, remove the memory card from the Screen&Go/Sleep&Go system and insert it into the PC card reader (remember to switch off the device before removing the memory card). Then take the following steps in the BitmedLab software:

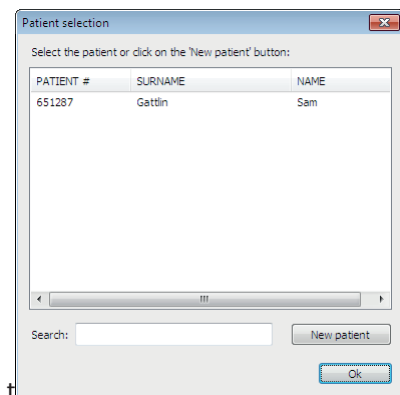
Click on "Download tests" in the home screen. The download test wizard will start up. Click on Next.



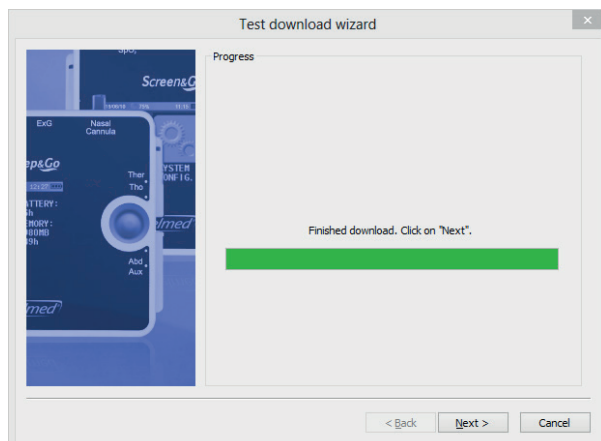
The program will list the tests available in the memory card. Choose the test you wish to download and click on Next. If you wish to delete any of the tests from the card without downloading them to the computer, choose the test and click on Delete. The test chosen for downloading will be automatically deleted from the memory card when the process has concluded.



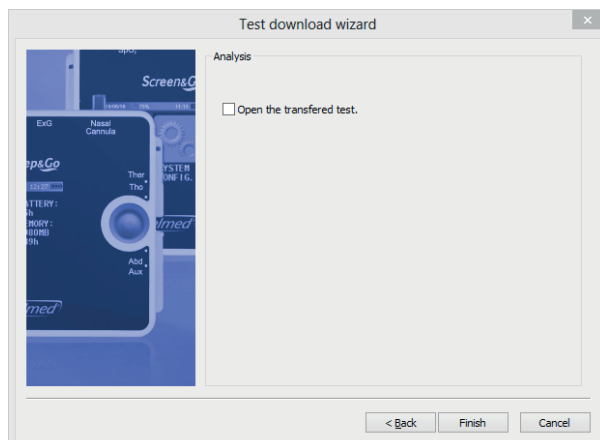
If the test was started automatically, the program will automatically associate the test with the patient selected during test programming. If the test was started manually, the patient associated with the test must be selected manually from all the patients in the database, or a new patient created.



The program will then download the test. Wait until the process has finished. When the message appears indicating that the transfer has been completed, click on Next.



Once the test has been downloaded, an option appears to open it immediately for review. In any event, the test can be opened afterwards at any time from the database window. Click on Finish.



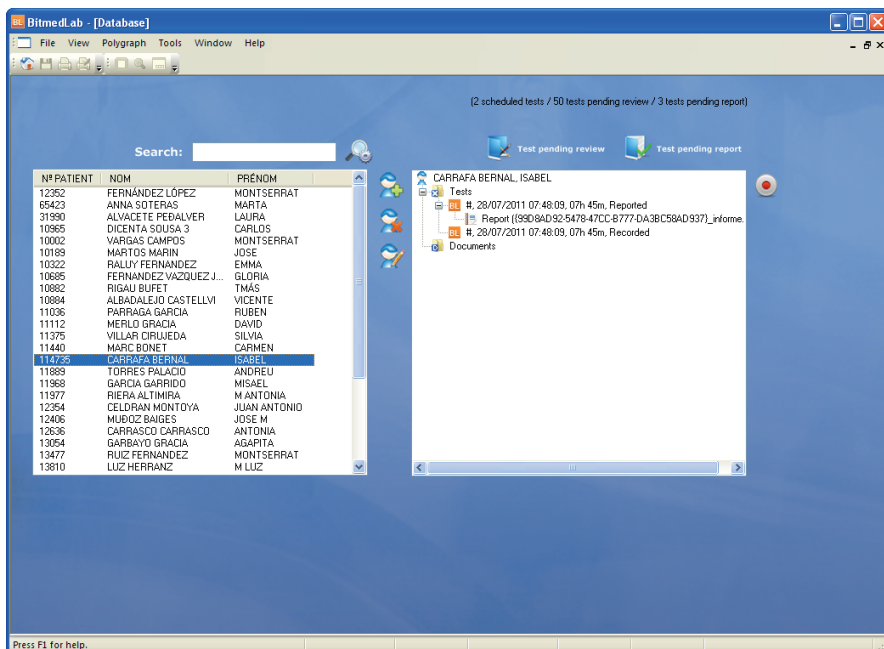
3.6 MANAGEMENT OF THE DATABASE, PATIENTS AND TESTS

The BitmedLab database provides easy management of all your patients and tests. Access it by clicking on the Database button.

The database window is divided into two highly differentiated areas. On the left is the list of patients, showing the name, last name and number of the patient. The list can be ordered by any of these fields by clicking on the field header.

On the right of the patient list are the buttons used to add, modify or delete a patient.

The area on the right is used to display a tree with the tests and documents associated with the selected patient. The information is updated every time a different patient is selected. Each test includes the start date and time, duration and status of the test. You can also associate any type of file to the patient, under the Documents branch. More information on how to do this can be found below.

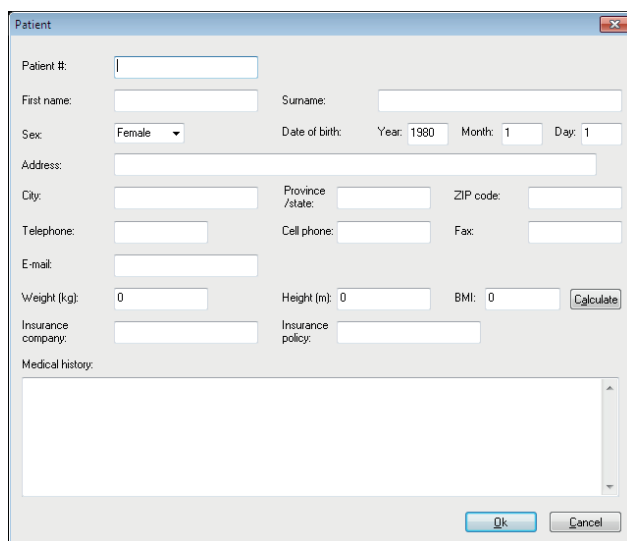


3.6.1 ADDING, MODIFYING AND DELETING PATIENTS

Adding a patient to the database

In the database window click on the New patient button .

Fill in the patient data in the Patient window and click on Ok.



The screenshot shows a 'Patient' window with the following fields and controls:

- Patient #:
- First name: Surname:
- Sex: Date of birth: Year: Month: Day:
- Address:
- City: Province /state: ZIP code:
- Telephone: Cell phone: Fax:
- E-mail:
- Weight (kg): Height (m): BMI:
- Insurance company: Insurance policy:
- Medical history:
-

Modifying patient data

In the database window select the patient to edit from the patient list and click on the Edit patient button .

Edit the patient data in the Patient edit window and click on Ok.

Deleting a patient from the database

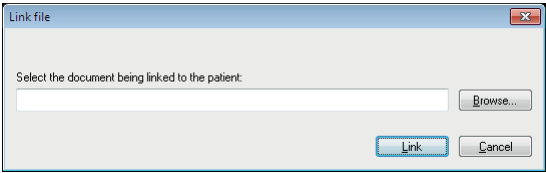
In the database window select the patient to delete from the patient list and click on the Delete patient button .

Confirm that you wish to delete the patient and the associated tests.

3.6.2 ASSOCIATING DOCUMENTS TO A PATIENT

Select the patient and right click on the Patient tree documents folder. Select the Associate document option.

Click on the Browse button in the Associate file window and choose the file that you wish to associate with the patient.



Click on Associate and confirm that the file has been associated with the patient. You can open or delete the association by clicking on the document icon.

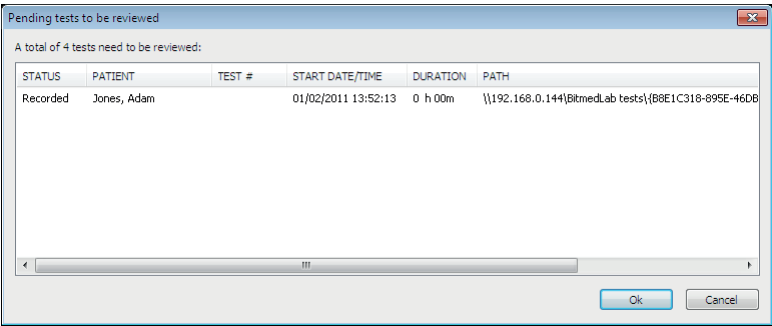


3.6.3 SEARCHING IN THE DATABASE

The Search text field can be used to filter the results shown, depending on the text that is entered. Filtering can be applied to multiple data, of both patients and tests (last name, name, patient number, insurance company, medical record, test number, doctor of reference, test date, etc.).

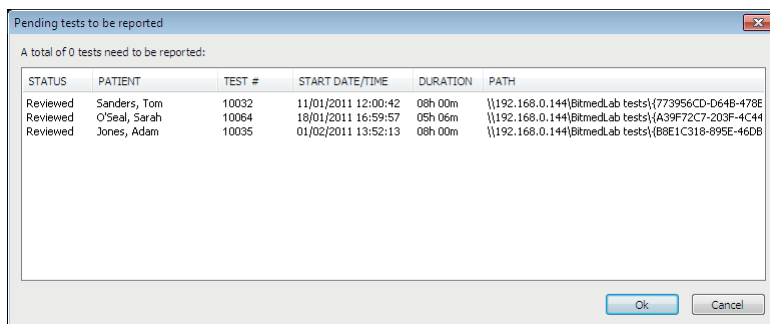
3.6.4 TESTS PENDING REVIEW OR REPORT

The Tests pending review button displays a window with the list of all the tests that have been downloaded to the PC and have yet to be reviewed.



On the other hand, the Tests pending reports button is similar to the one above, but in this case it lists the tests that have been

reviewed but for which a report has not yet been generated.



These two functionalities make it easier for the user to find work that is still pending completion. Double click on any of the tests to open them.

3.6.5 DATABASE MANAGEMENT

The **BitmedLab** software includes a ready-to-use database, so it is usually not necessary to modify the database configuration.

Create a new database

- In the main menu go to **Tools > Options** and select the **Database** tab.
- Click **Create Database**.
- In the **Save As** dialog select the folder where the database will be saved and enter a name for the database file. Click **Save**.
- For security reasons, a password is assigned to each database. This password must be entered each time the program is started. 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 don't want to set a password, simply leave the field blank and click **OK**.
- Repeat password. Again, if you don't want to set a password, simply leave the field blank and click **OK**.
- In the **Options** window, click **OK**.

Change database password

- In the main menu go to **Tools > Options** and select the **Database** tab.
- Click **Change Password**.
- Enter the current database password. You will not be able to change the password until you validate the current password.
- Enter the new password. In case you don't want to set a password, simply leave the field blank and click **OK**.
- Repeat password. Again, if you don't want to set a password, simply leave the field blank and click **OK**.
- In the Options window, click **OK**.

Disable password prompt on startup

- In the main menu go to **Tools > Options** and select the **Database** tab.
- Deactivate the option Prompt **for password when opening database**.
- In the Options window, click **OK**.

Delete the database



Deleting the database will erase all patient information and tests performed. However, test files will not be affected.

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

- In the main menu go to **Tools > Options** and select the **Database** tab.
- Click **Delete Database**.
- You will be prompted for confirmation before deleting the database. Click **Yes** if you really want to remove it.

- In the Options window, click **OK**.

Select the database file

- In the main menu go to **Tools > Options** and select the **Database** tab.
- Click the button to the right of the **Database Location** field.
- In the **Open** dialog select the database file to use and click **Open**.
- In the **Options** window, click **OK**.

3.7 IMPORTING AND EXPORTING TESTS

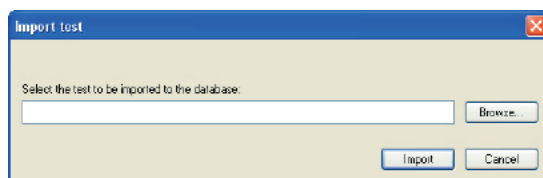
Importing tests

Select the patient to whom you want to add the test and right click the mouse on the Tests folder of the tree.

In the context menu select Import test.



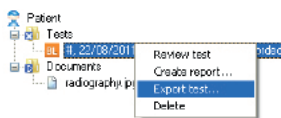
In the Import dialog box, select the test file to be added using the Browse button and click on Import. The test will be added to the patient.



Exporting tests

To export a test select it in the database and click the right mouse button.

Select Export test in the menu.



In the Save As dialog box select the name and path to the file where the file will be saved.

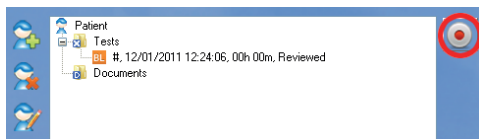
3.8 PERFORMING TESTS IN REAL TIME (ONLY SLEEP&GO)

You can perform, store and monitor tests in real time directly in the PC with all the Sibelman Sleep&Go systems including the Wireless module.

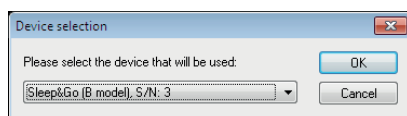
3.8.1 STARTING THE REAL-TIME TEST

Place all the sensors and electrodes required for the test on the patient, as described in the User's Manual of the device.

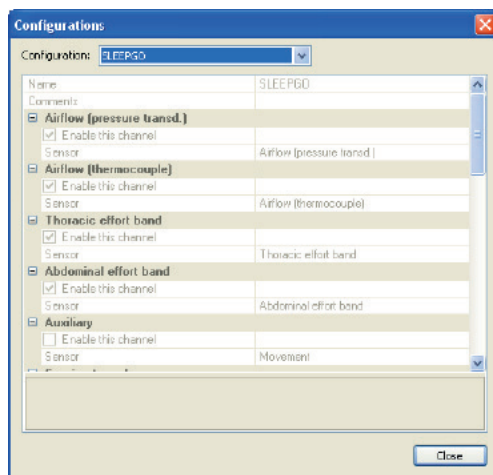
In the database window, choose the patient to whom the test will be associated and click on the Start a new real time test with the Sleep&Go button.



If more than one Sleep&Go is available, choose the one you wish to perform the test with.



The Configurations window will appear. Choose the device configuration that you wish to use.



The program will request the folder and name with which to store the test, offering a default name. Click on Save to start the test.

In the case of SpO_2 and BPM channels, a window on the bottom-right shows the values. The values are set to zero (in red) if there is no finger, the sensor is disconnected or if there is an error (and a message is displayed below the values).

If the values are correct, they appear in green.

If the power supply is interrupted for more than 30 s, turn on again the computer, connect again with the device and operate again normally.



Do not turn off the PC when performing a real-time test. Stop the real-time test first.

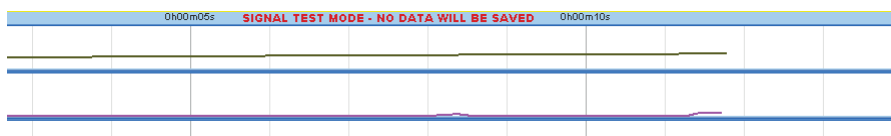
3.8.2 COMPLETING TEST ACQUISITION

Click on the Finish test button . The test acquisition will stop after a few seconds and the device will stop recording data in the memory card.

3.8.3 SIGNAL TEST

Entering and exiting the signal test mode while the test is being performed

At any time during the performance of the test, the user can use the Signal test button  on the Test toolbar to momentarily stop recording the data from Sleep&Go in the PC. However, the biomedical signals will continue to be displayed on the screen. Use this option, for example, to relocate a sensor that has moved or been placed incorrectly and to check changes in the sensor signal, without any of it being stored in the test.



To continue the test from the point at which the signal test had begun, click again on the same button.

Start all the tests in signal test mode

For starting automatically all the new real-time recordings in the signal test mode, perform the following steps:

Go to the Tools menu > Options.

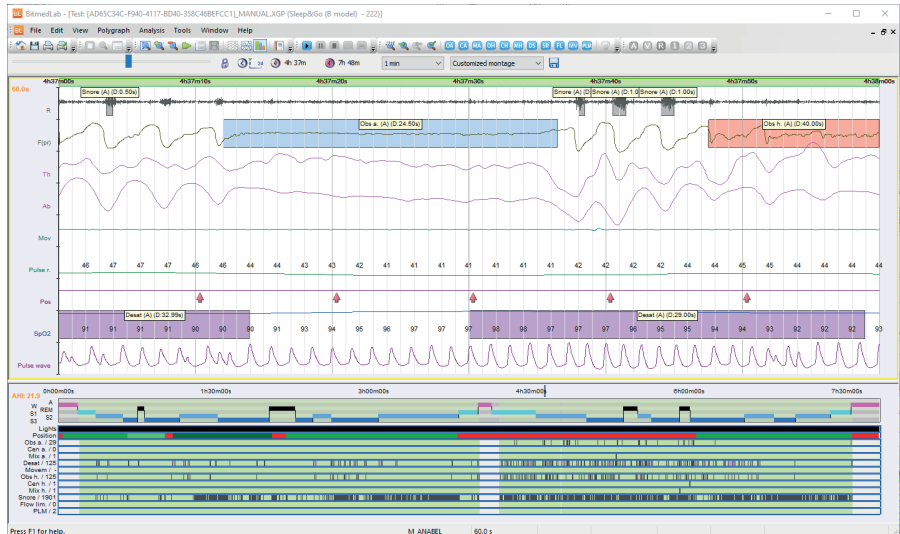
In the General tab, enable the option "Start tests in signal test mode".

Click on Accept to apply the changes.

3.9 REVIEWING THE TESTS

3.9.1 USER INTERFACE ELEMENTS DURING TEST REVIEWS

The following illustration shows the BitmedLabsoftware module during a test review:



Menu bar

Standard toolbar: used to access the home screen, save the test and printing.

Test toolbar: communication functions with Sleep&Go during performance of the real-time tests.

View toolbar: changes in the time per epoch, viewing options, report generation, etc.

Play toolbar: allows playing the test at different speeds.

Events toolbar: contains tools for sleep event analysis.

Sleep stages toolbar: tools for the manual scoring of sleep stages.

Time toolbar: provides a scroll bar to browse through the test. It can also be used to change the time per epoch, the montage used and save the changes made to the current montage.

Waveform window: this window displays the signals recorded by the Screen&Go/Sleep&Go. The screen can be customized in a

variety of ways.

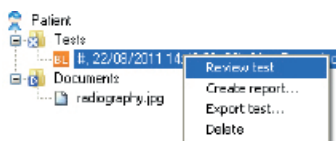
Trend window: this window provides summarized information about sleep events and light status. It provides a summary of the test at a glance.

Status bar: this provides contextual information while the program is being used.

3.9.2 OPENING A TEST

Choose the patient to whom the test is associated or search for the patient using the Search text box.

Display the Test folder in the patient tree. Locate the test to be reviewed and right click to pull down the contextual menu and choose the Review test option.



If the automatic analysis of test events has not been performed, a wizard will start automatically to guide you through the analysis process. If you do not wish to perform the automatic analysis, cancel the wizard.

3.9.3 FULL SCREEN MODE

Use the full screen mode to maximize the available screen space to review the test. The Windows task bar, the title bar of the application and the toolbars will all disappear in this mode (display them by going to the View menu > Toolbars and docking windows).

Go to View > Full screen to enter the full screen mode.

To exit the full screen mode, click on the Close full screen floating button or go to the View menu > Full screen.

3.9.4 DOUBLE WAVEFORM WINDOW

The waveform window can be divided into two parts during review. The two waveform windows can be set up with different time scales. In addition, each waveform can be displayed or hidden in either of the windows. Therefore, for example, in a sleep study the top window can be configured to view the fast channels and the bottom window to display the slow channels, each with a different time range.

The time scale used in the top window is shown in violet over the time scale used in the bottom window.

3.9.5 PLAYING THE TEST

Any of the tests that have already been performed can be played automatically at different speeds:

Place the cursor at the beginning of the part of the test that you wish to play. This can be at the very beginning or any other moment of the test.

Click on the Start playing test button on the play toolbar.



The test will start playing exactly as it was acquired. If you wish to double the playing speed, click on the ☀️ button (Increase the test playing speed). If you wish to decrease the playing speed by half, click on the 🚩 button (Decrease the test playing speed).

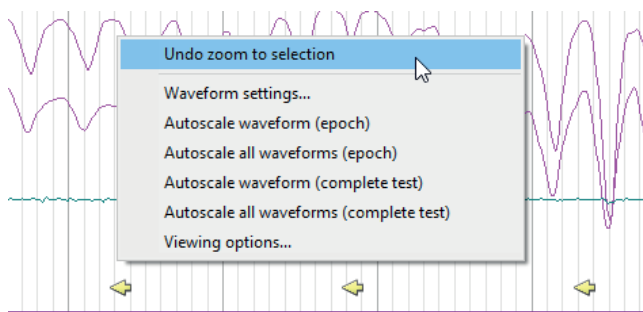
You can stop playing the test at any time by clicking on the Pause playing test button ⏸️. You can start playing the test from the same point where it was stopped by clicking again on the Start playing test.

To stop playing the test, click on the Stop playing test button ■. The difference between this button and the pause button is that when play is resumed, it does so from the beginning of the epoch on the screen.

3.9.6 SCROLLING THROUGH THE TEST

Using the time bar

The time bar allows the user to scroll through the test quickly. Simply drag the scroll bar to move to another moment in the test. Scrolling will take place in the window that is active at the time (framed in yellow). The current time and the total duration of the test is shown to the right of the scroll bar.



Using the keypad

The following keys are used to scroll through the test:

Start: moves to the beginning of the test

End: moves to the end of the test

Page down: goes to the next epoch

Page up: goes to the previous epoch

Left arrow ← : goes back a short time in the epoch

Right arrow → : goes forward a short time in the epoch

Forward half epoch

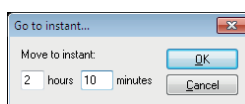
Use the Forward half epoch button of the View toolbar or the Tab (tabulator) key to move forward half a epoch. This option

is useful for a clear view of events that occur at the limit between two consecutive epochs.

Using the Go to instant option

Open the Analysis menu > Go to instant.

Specify the hour and minute of the test to go to in the box that appears.



Click on Accept for the program to automatically go to the indicated instant.

Using the browsing marks

If there is a place in the test of special interest that you wish to refer to in the future, a browsing mark can be inserted at that place from the Analysis menu > Insert browsing mark, or by pressing on the Ctrl+M key combination. The mark appears as an upside down red triangle on the time scale.



To return to the same point again, simply go again to Analysis > Browse to browsing mark or press on the Ctrl+N key combination.

3.9.7 ADJUSTING TIME ON THE SCREEN

The time scale at the top of the waveform window shows the test time and the size of the epoch. The size of the epoch also appears on the status bar.

Adjust the time on the screen with keys + and - and icons .

Use the + and - keys to multiply or divide the size of the epoch by two. This can also be done by using the toolbar icons  and .

Specifying the number of seconds per epoch

Open the Viewing options window from the Analysis menu > Viewing options.

Enable the Viewing tab. There are three text boxes under the Seconds per epoch tab to set the visible time range in each window (top waveform window, bottom waveform window, trends window). These adjustments can be applied separately to the top waveform window, the bottom waveform window or the trends window. However, the time range in the top waveform window cannot be longer than that of the bottom waveform window and the time range of the bottom waveform window cannot be longer than that of the trends window.

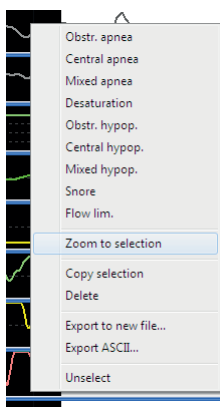
Seconds per epoch	
Top waveform window	30
Bottom waveform window	300
Trends window	3600

Zooming in on part of the test

Left click on any part of the waveform where you wish to start the enlargement.

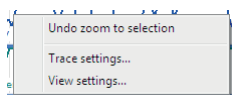
Without releasing the left click, drag the mouse to the end of the part that you wish to enlarge.

A contextual menu will appear. Select the Zoom selection option.



Undoing the zoom on an area of the test

To undo the zoom on an area of the test, right click on a waveform. Select Undo zoom selection in the menu that appears.



Modifying the time references

The program has two ways to reference time in the various windows:

Reference of the time scale to the instant 00h:00m:00s: the time line begins at instant 0.

Reference of the time scale to the time the test is performed: the time line begins at the time the test recording is started.



Changing these time baselines does not affect the test performance time data.

Go to Analysis menu > Viewing options and enable the Viewing tab.

In the Reference time section, select the instant option 00h:00m:00s or the test performance time option, depending on preferences.

Click on Accept to apply the changes.

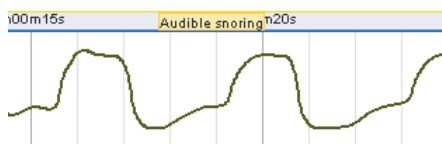
3.9.8 NOTES

The user can enter notes throughout the test for important

observations. This option can be very useful during performance of the tests in real time to record visual observations regarding the (if the patient is restless, moves or wakes up, etc.) or to record changes in the application of the CPAP, drug administration, etc. All the notes will appear afterwards in the test report, alongside the instant when they were entered.

The program enters a note automatically each time a real-time or holter recording is performed. A note is also inserted each time user events marker pulsing occurs.

These notes are shown on the time scale of the waveform window.

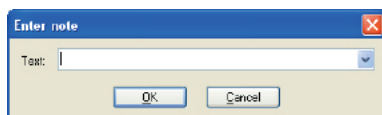


Entering a note

There are two different ways to enter notes:

Select Enter note in the Analysis menu.

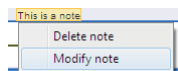
Press the Insert key on the keypad. A box will appear for the user to enter the text of the note. The user can also choose one of the predefined notes that appear. If the test is in real time, the note will appear overwritten at the instant it is being acquired. However, if a test that has already been acquired is being viewed, the note will appear overwritten at the instant corresponding to the center of the screen being viewed at that time.



Modifying a note

Right click on the note to be modified.

Select Modify note in the contextual menu that appears.

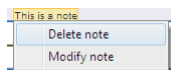


The Enter note window will appear. Modify the text and click on Accept to apply the changes.

Deleting a note

Right click on the note to be deleted.

Select Delete note in the contextual menu that appears.



Showing/hiding notes

Go to the Analysis menu > Viewing options or from the corresponding button of the Viewing toolbar.

Enable the Viewing tab. Enable the Show notes option to show the notes on the screen and disable the option to hide them.

Click on Accept to apply the changes.

Modifying predefined notes

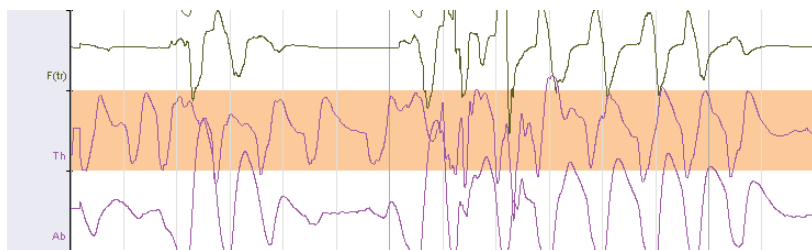
The default text provided by the program when entering notes can be completely customized to user preferences. This is done by editing the notes.txt text file in the application folder (default X:/Program files/Sibelmed/BitmedLab x.x). Remember to enter one note per line.

3.9.9 ADJUSTING WAVEFORM RANGES

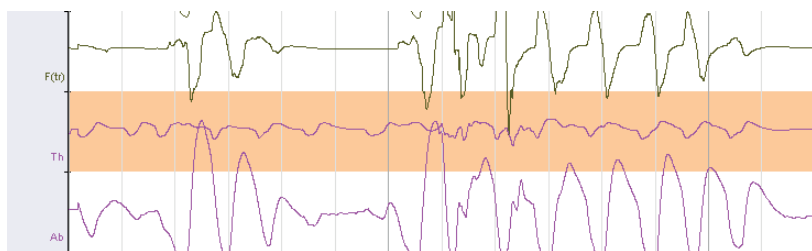
Adjusting ranges with keys ↑ and ↓ or the mouse

The simplest way to quickly adjust the range of a waveform is to place the cursor over the waveform to be changed and press the ↑ and ↓ keys to increase or decrease the amplitude.

If you want to modify the range of more than a waveform at once, then left double click on the waveforms that you wish to change the range of. The background of the waveform will change color.



Use the $\uparrow$ and $\downarrow$ keys to increase or decrease the range of the selected waveforms.

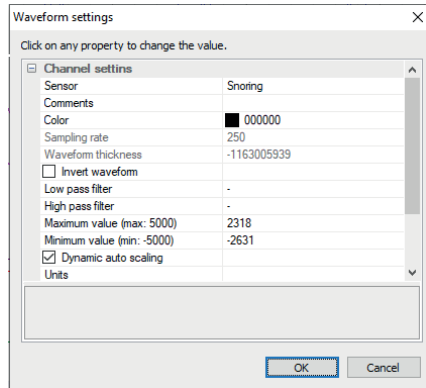


The amplitude of any channel may also be increased or decreased by clicking on it and then pressing the + and - keys, while holding the left mouse button.

Adjusting waveform ranges accurately

Right click on the waveform to be changed and select the Channel settings option.

The Channel settings window will open. Change the maximum and minimum values. The possible maximum and minimum values are specified in brackets).



Click on Close when you are done.

Autoscale waveforms

Autoscaling option adjusts the amplitude of the signal, so that it is visible throughout its envelope in the time that is displayed on the screen.

If you want a channel to change the scale automatically, open the Waveform Settings dialog and activate the Dynamic auto scaling option.

You can also set the auto scaling by clicking the right mouse button on the desired signal and selecting Autoscale waveform (epoch) or Autoscale waveform (complete test) from the context menu, depending on whether you want to adjust the waveform's amplitude for the current epoch or throughout the entire test.

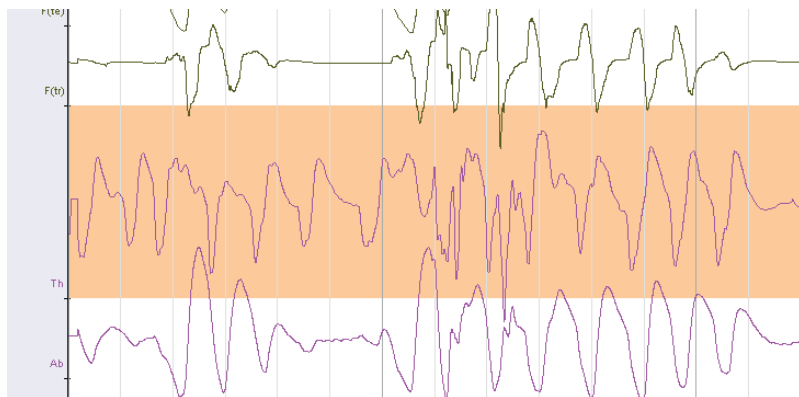
Similarly, select Autoscale all waveforms (epoch) or Autoscale all waveforms (complete test) to automatically adjust the amplitude of all waveforms.

Finally, you can use keys 8, to auto-scale the channel under the cursor, and 9, to auto-scale all visible channels.

3.9.10 ADJUSTING WAVEFORM SIZES

When the cursor passes over the separating lines of the waveforms, it changes to two arrows. This indicates the possibility of dragging

the separation line to change the height of the waveform. Pull the line up or down while left clicking to change the height of the waveform to the minimum or maximum height. This functionality can be enabled or disabled from the "Allow changes to the waveform size" option in the Viewing tab in the Viewing options window.

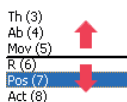


3.9.11 MODIFYING THE VIEWING ORDER OF THE WAVEFORMS

Open the Viewing options window from the Analysis toolbar button or from Analysis menu > Viewing options.

Enable the Montage tab. In the Waveform window list, select the waveform window where the changes to the waveform viewing order will be made (top or bottom).

To change the order of a channel, click on the channel and without releasing the left click, drag it to the new position. Release the left click.



When you have finished adjusting the order of the waveforms, click on Accept to apply the changes to the test.

3.9.12 NAMING THE WAVEFORMS

Changing the waveform name display from the Viewing options window

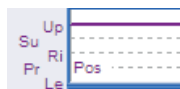
Open the Viewing options window from the Viewing toolbar button or from Analysis menu > Viewing options.

Enable the Viewing tab. Four different waveform name displays are available in the Name section of the waveforms:

Detailed: this includes the full name of the sensor and its description.



Brief: this shows only the abbreviated name of the sensor or the name of the electrode if it is defined.



Off-channel: this is similar to the previous one but shows the name to the left of the channel and hides the scale.



No description: this hides all the text on the waveforms.



When you are finished, click on Accept to apply the changes to the test.

Using the keypad to change the display of the waveform names

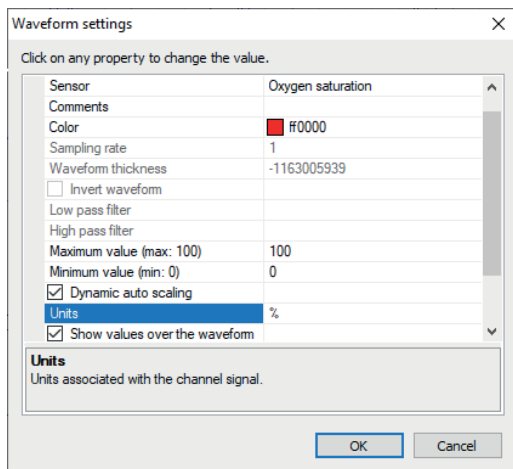
The waveform name display can also be changed by using the keypad. Use the "C" key to scroll through the four display options.

3.9.13 WAVEFORM UNITS

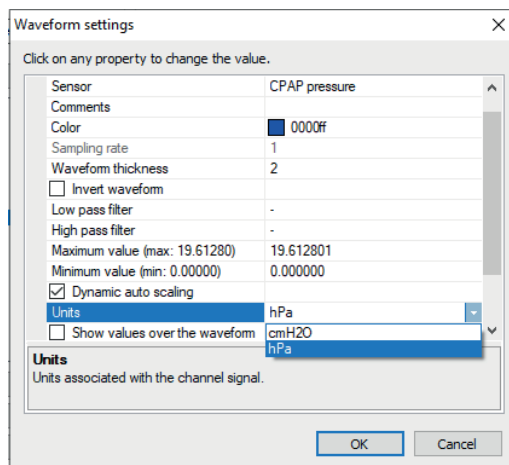
Channels measure physical quantities, such as pulse rate or oxygen saturation. Units are shown in the name of each waveform. You can change the units of waveforms in the following way:

Open the Waveform settings by right clicking the mouse on the channel to be changed and selecting the Waveform settings option in the menu.

In the Waveform settings change the Units property, enter the new text, and click on OK to apply changes.



CPAP channel behaves in a particular way. Two types of units can be selected: hPa and cmH2O. Changing the units automatically updates the minimum and maximum values of the channel. The CPAP channel units should also be changed in the polygraph, as described in the User's manual.

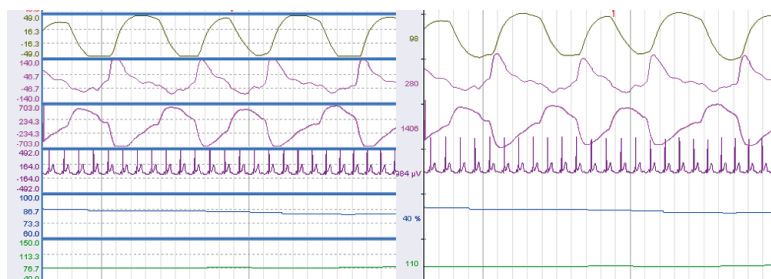


3.9.14 HIDING OR SHOWING SEPARATION BETWEEN WAVEFORMS

Open the Viewing options window from the Analysis toolbar button or from Analysis menu > Viewing options.

Open the Viewing tab and enable or disable the "View separating bar between waveforms" option.

Click on Accept to apply the changes.



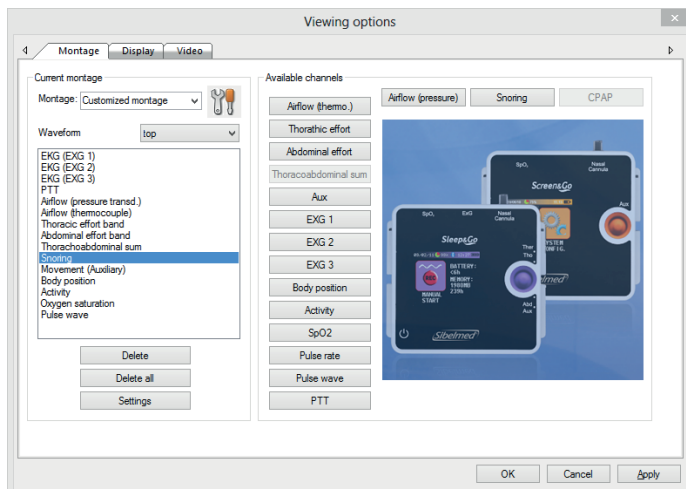
3.9.15 ADDING AND DELETING WAVEFORMS

Adding waveforms

Go to the Analysis menu > Viewing options.

Enable the Montage tab and select waveform view in the Waveform window list (top or bottom) that you wish to set up.

All the inlet channels to the device appear on the right side of the window. Click on the ones you wish to add to the list of channels.



When all the desired channels have been added, click on Accept to close the window and apply the changes.

Deleting waveforms

Go to the Analysis menu > Viewing options.

Enable the Montage tab and select the view you wish to set up from the Waveform window list.

Choose the visible waveforms that you wish to delete from the waveform list.

Click on Delete and the channel will disappear from the list of visible channels.

Click on Accept to close the window and apply the changes.

Deleting all the waveforms

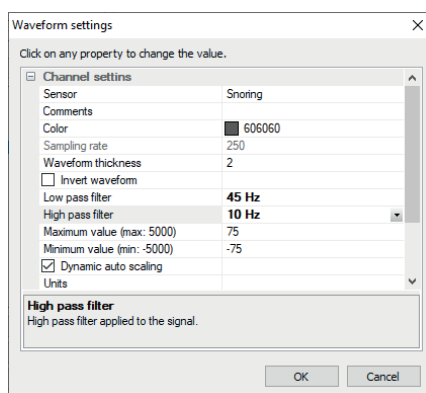
Go to the Analysis menu > Viewing options.

Enable the Montage tab and select the view you wish to set up from the Waveform window list.

Click on Delete all to delete all the waveforms at once. Click on Accept to close the window and apply the changes.

3.9.16 CHANGING THE SOFTWARE FILTERS

Right click on the waveform to be changed and select the Channel properties option.



Choose the low pass and high pass filters you wish to use and click on Accept to apply the changes. Remember that the filters that are available will depend on each channel.

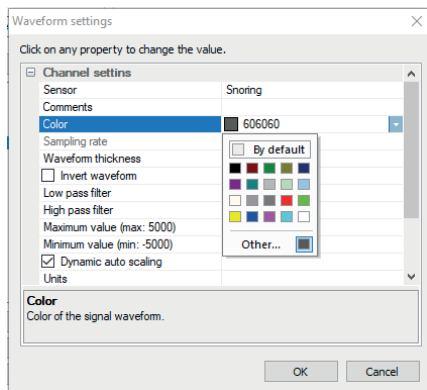
3.9.17 CHANGING THE SIGNAL WAVEFORM COLOR

The waveforms for each type of sensor are given a different color by default, but all these colors can be modified.

In the waveform window, right click on the waveform to be changed and select the Channel properties option.

The Channel properties window will open. There is a Color box with the current color of the signal waveform. Click on the color box to

open the color selection dialog and choose the new color for the signal waveform. Click on Accept when you are done.



3.9.18 MODIFYING WAVEFORM THICKNESS

The on-screen waveform thickness can be modified for all the channels at the same time or only for one specific channel.

Modifying the thickness of all the waveforms

Open the Viewing options window from the Analysis menu and verify that the "Apply the same thickness to all the waveforms" option is selected.

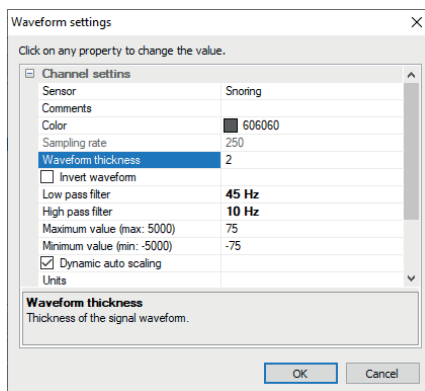
Modify the Waveform thickness option and click on Accept to apply the changes.

Modifying the thickness of a single waveform

Verify that the "Apply the same thickness to all the waveforms" option is not selected in the Analysis window > Viewing options.

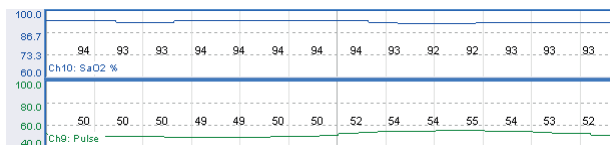
Then open the properties of the waveform you wish to modify by right clicking on it and select the Channel properties option in the contextual menu.

Change the number of thickness pixels and click on Accept to apply the changes.



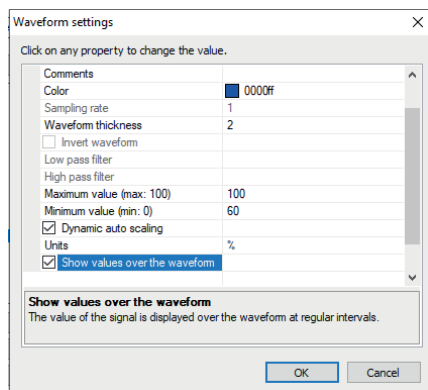
3.9.19 DISPLAYING THE VALUES OVER THE WAVEFORM

Signal values can be displayed on the waveforms at regular intervals.



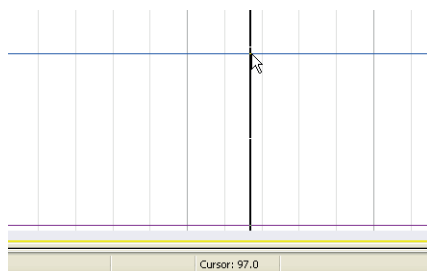
In the waveform window, right click on the waveform to be changed and select the *Channel properties* option.

Enable the *Display values over the signal* option and click on *Accept* to apply the changes.



3.9.20 NUMERICAL VALUES CURSOR

The numerical value cursor is a vertical line that the user can scroll freely across the screen. The status bar shows the value of the signal in the position and the channel that the cursor is on. To display it:

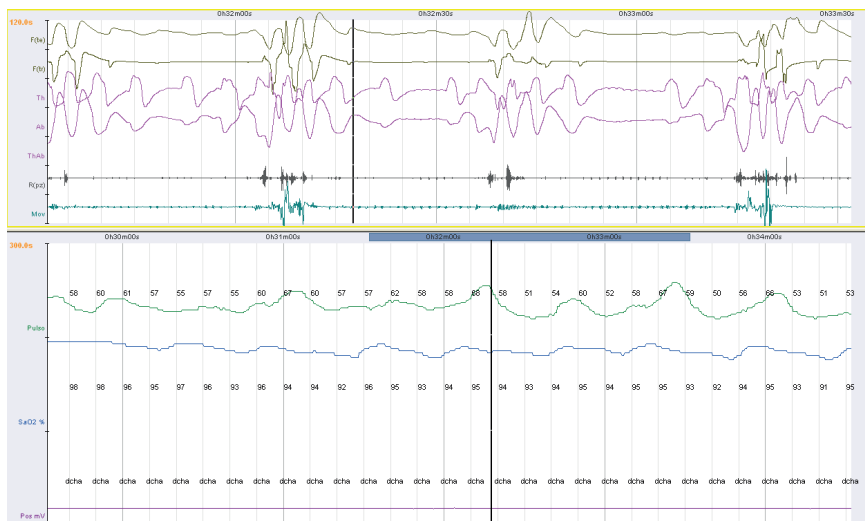


Go to the *Analysis* menu > *Viewing options*.

Enable the *Viewing* tab and mark the box of the *Display cursor* option.

Click on *Accept* to apply the changes.

Once the bottom waveform window is visible, it also displays a cursor that is synchronized with the cursor in the top window, always marking the time instant of the top waveform window.



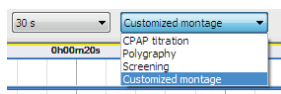
A montage stores all the settings of a test under a descriptive name. This includes sensors, filters, gains, colors, descriptions, on-screen order, epoch duration, event mark viewing, event bar viewing, channel sizes, etc. In general terms, all the parameters that can be set from the *Viewing options* window are stored in the montage. The montages are stored with a name and can then be loaded and applied to the test at any time during review.

The montages are managed from the *Montage* tab of the *Viewing options* window. The currently selected montage is shown in the *Montage* list as well as in the list of montages in the *Time bar*.

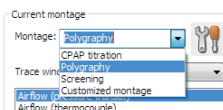
Available montages depend on the polygraph model being used. For example, if you have two different polygraphs, such as a Screen&Go and a Sleep&Go model B, the available montages will depend on the polygraph used to record the test.

Choosing a montage

The montage can be changed quickly from the waveform window by selecting it from the list in the *Time bar*.



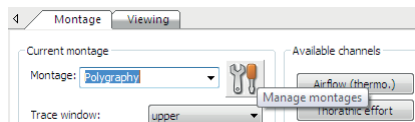
The montage can also be changed from the *Montage* tab of *Viewing options* window.



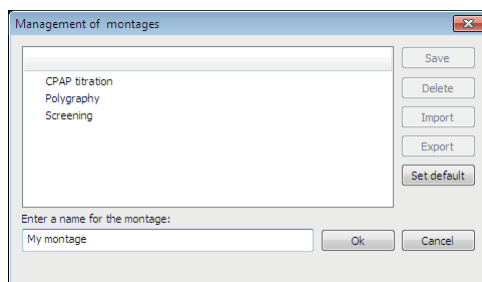
Saving a montage

Once the test has been configured as desired, go to *Viewing options* and enable the *Montage* tab.

Click on the *Manage montages* button.



Click on *Save* in the *Manage montages* window. The program will request a name for the montage. Enter the name and click on *Accept*. If there is already a configuration with the same name, the program will request confirmation to overwrite it.



If you want to save the changes made to the current montage (keeping the same name for the montage) just click the icon  in the time toolbar.

Importing and exporting a montage

BitmedLab allows the user to export any of the montages to a file, so that it can be easily imported into another computer.

Go to the *Analysis* menu > *Viewing options*.

Enable the *Montage* tab and click on the *Manage montages* button.

Choose the montage you wish to export from the list of available montages and click on *Export*.

A dialog will appear to choose the name of the file that will store the montage and the folder to save it in.

The montage will be saved in a file with extension *.xcp*

A montage can be imported in a similar manner:

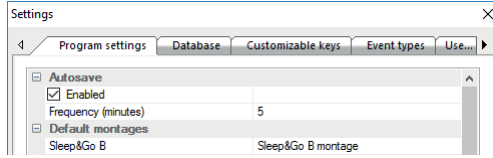
Click on *Import* in the *Manage montages* window.

A dialog will appear to choose the *.xcp* file corresponding to the montage that is to be imported. The montage will be added to the list of available montages.

Setting the default montage

Each time you download a test made with your polygraph or start a new test in real time (in case your polygraph has Wireless communication) a default montage will be applied. You can change this montage in the Settings dialog. Go to Tools > Settings and modify the Default montages option. Each polygraph model has its own default montage.

If you always use the same montage for all your tests and you do not want the Viewing options window to appear every time you start or download a test you can select Do not show this window again in the Viewing options window. Display again this dialog by activating the option Show the 'Montage' window when starting / downloading tests in Tools> Options.



Deleting a montage

Go to the *Analysis* menu > *Viewing options*.

Enable the *Montage* tab and click on the *Manage montages* button.

Choose the montage you wish to delete from the list of available montages and click on *Delete*.

3.9.22 TYPES OF EVENTS

BitmedLab defines a series of event types that the user can use in the tests. For user convenience, BitmedLab limit the available event types according to the group of event types that are enabled at a given moment. There are three groups of event types (simple, intermediate and advanced), each of which enables certain types of events, as seen in detail in the table below:

	Simple	Intermediate	Advanced
Obstructive apnea	☐	☐	☐
Central apnea	☐	☐	☐
Mixed apnea	☐	☐	☐
Hypopnea	☐	☐	☐
Desaturation	☐	☐	☐
Snoring	☐	☐	☐
Flow limitation	☐	☐	☐
Limb movement		☐	☐
PLM		☐	☐
Regular breathing		☐	☐
Cheyne-Stokes breathing		☐	☐
Undetermined breathing event		☐	☐
Hypoventilation		☐	☐
Arousal			☐

	Simple	Intermediate	Advanced
Movement arousal			☐
RERA			☐
Bruxism			☐
Tachycardia			☐
Bradycardia			☐
Sinus tachycardia			☐
Narrow complex tachycardia			☐
Wide complex tachycardia			☐
Arrhythmia			☐
Atrial fibrillation			☐
Asystole			☐

Select a group of event types, depending on the type of test to be performed. For example, the *simple* group may be enough for a screening test, while the *advanced* group may be the proper option for a cardiorespiratory polygraph.

Only one group of event types can be enabled at the same time in the program. In other words, if the *simple* group of event types is enabled and a test is opened with tachycardias marked, the latter will not appear. However, if the group is changed to *advanced*, the tachycardias will be seen perfectly.

Take the following steps to change the group of event types:

Go to the *Tools* menu > *Options*.

Choose the *Event types* tab.

Choose the group you wish to use from the list of *Group of event types*.

Click on *Accept* to apply the changes.

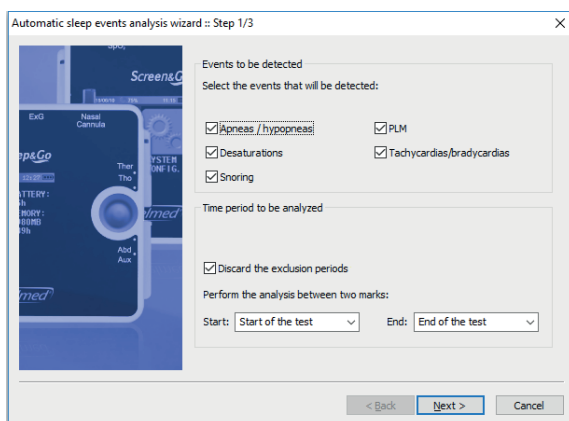
3.9.23 AUTOMATIC ANALYSIS OF SLEEP EVENTS



The results provided by the Automatic Analysis of events should not be used as the sole criterion for medical diagnosis or patient treatment. The results must be supervised and reviewed by medical personnel with adequate training.

Go to the *Analysis* menu > *Automatic analysis of events*. The *Automatic analysis of events wizard* will start up.

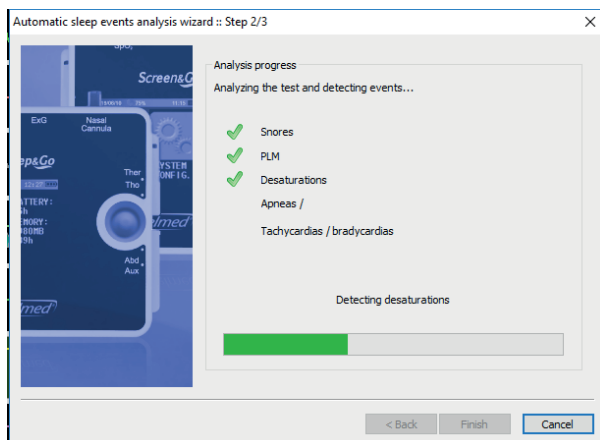
Choose the event types that you wish to detect automatically.



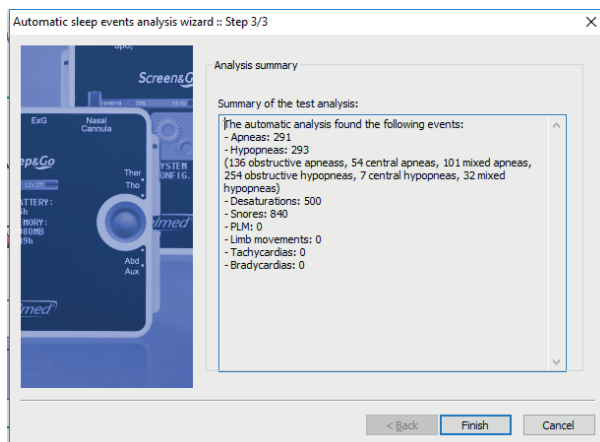
Select also the part of the test that you wish to analyze. You can discard the exclusion periods you have marked (if any) or analyze the test between two marks (see the section Notes on how to insert a note in the test). By default the program includes the marks Start of the test and End of the test to be able to perform the analysis of the whole test.

Click on *Next*.

The following window shows the progress of the analysis. When the analysis has been completed, click on *Next*.

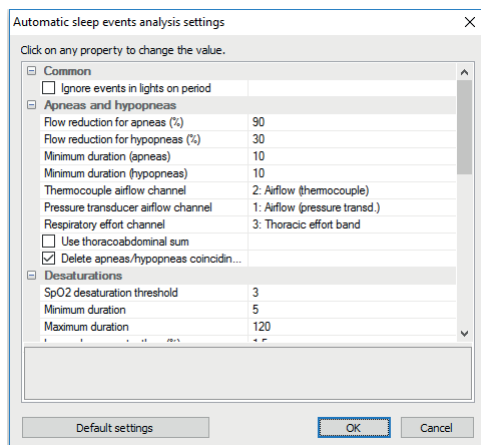


Lastly, the wizard will show a summary of the events that have been detected.



3.9.24 MODIFYING THE OPTIONS FOR AUTOMATIC ANALYSIS OF SLEEP EVENTS

Go to the *Analysis* menu > *Options automatic analysis of events*.



Make the desired changes in the criteria for automatic analysis of events. An explanation of each of these parameters is shown when you click on the parameter. To return to the program default values, click on *Reset default parameters*.

Click on *Accept* to apply the changes.

3.9.25 MANUAL MARKING OF SLEEP EVENTS

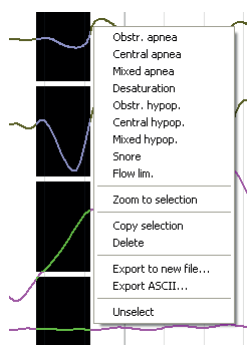
Marking events with the mouse

Place the cursor over any of the waveforms and click on the place where you wish to start the event.

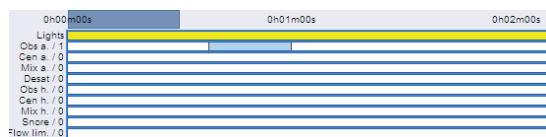
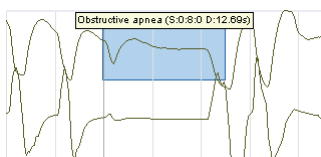
Drag the mouse to mark the duration of the event. The selected duration will appear in the status bar. If you clicked on an air flow or breathing effort waveform, the desaturation associated with the selection and the signal variation will also be shown. You can also make a selection on the oxygen saturation signal and see the signal drop percentage. These data are useful for marking apneas, hypopneas and desaturations.

Desat: 6% Var: -82.3% Sel: 16.26s

When the selection has been completed, a contextual menu will appear with all the event types. Choose the one you wish to mark.



The event mark will appear. The mark can appear over one or more waveforms, depending on the property settings of the event type. If the trends window is open, a mark will also appear on the corresponding event type bar and the length will depend on the duration of the event. Finally, the number of event occurrences will increase by one.



Marking events with the keypad

Press the key associated with the event. The program will insert a mark starting at the beginning of the epoch on the screen, with a specific duration for this type of event.

Refer to the *Customized keys* tab of the *Settings (Tools > Options)* window for the key associated to each type of event.

The hotkeys are also listed in Annex 3 in this manual.

Marking event with the mouse and the keypad

Press on the key associated with the event that you wish to mark.

The cursor changes to an arrow with the sign +. 

Do not release the key and select the part of the test where you want to mark the event.

Release the key to mark the event.

There is another way to mark events with the keyboard and mouse: Press the key next to the event you want to dial, and then click the mouse in the place where the event starts. The program inserts a predetermined duration event

Use the event marking toolbar

Choose the type of event that you wish to mark.



The cursor changes to an arrow with the sign +. Unless you click again on the event type icon, all the events that are marked will be of the same type. 

Do not release the left click and select the part of the test where you wish to mark the event.

Release the left click to mark the event.

3.9.26 WORKING WITH EVENTS

Modifying the default duration for events inserted with the keypad

Open the window *Tools > Options > Event types*.

Choose the event type you wish to customize and click on *Properties*.

Enter the desired duration with all the occurrences of the event entered with the keypad in the text box *Default duration of events entered with the keypad*.

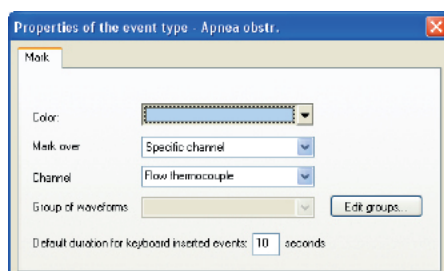
Click on *Accept* and close the *Event types* window.

Changing the color of the event marks

Open the window *Tools > Options > Event types*.

Choose the event type you wish to customize and click on *Properties*.

Click on the *Color* section and choose the desired color for the mark.



Click on *Accept* to apply the changes.

Hiding/showing the event marks on the waveforms

The events are marked with a color rectangle over the signal waveform. The mark also includes the event type, the time instant of the start of the event and its duration. These marks can be shown or hidden by the user.

Open the *Viewing options* window from the *Analysis* menu and enable the *Waveforms* tab

To hide the marks, disable the option *Show event marks on waveform*. Enable the option again to show the marks.

Click on *Accept* to close *Viewing options* and apply the changes.

Hiding/showing the trends window

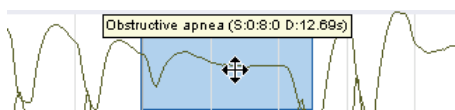
The trend window displays a bar for each type of event. The occurrence of each event is marked with a color rectangle on this bar. The number of occurrences of each event type appears on the

left of each bar.

These bars are normally used to get a general idea at a glance of the trend of events over a long epoch of the test or the complete test. The trends window can be shown or hidden by clicking on the  button of the *Viewing* bar or by clicking on the *See > Trends* menu.

Moving events

Place the cursor over the event to be moved. The cursor changes as shown in the illustration.

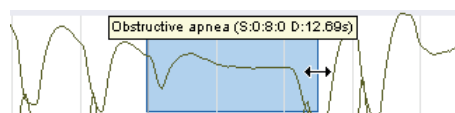


Click on the event and drag it while left clicking.

Release the left click when the event mark is in the desired position.

Changing event duration

Place the cursor over the left or right end of the event. The cursor changes as shown in the illustration.

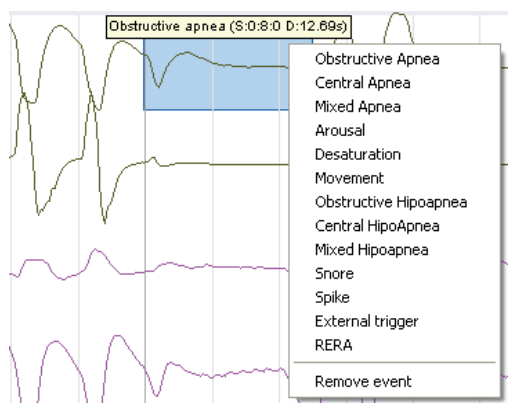


Click and move the cursor to the left or right, while maintaining the left click.

Release the left click when the event mark is in the desired position.

Changing event types

Place the cursor over the event you wish to change and right click. A menu will appear with all the event types defined in the application.



Choose the type of event to assign to the event.

Deleting events with the mouse

Press the *Control* key. The cursor changes to an arrow with the mouse icon.

Do not release the *Control* key and click on the event to be deleted.

Deleting events from the event mark

Place the cursor over the event you wish to delete and right click. Choose the Delete event option in the contextual menu. You can also place the cursor over the event to be deleted and press the Delete key.

Deleting all the test events

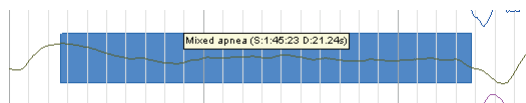
Choose the Delete all events option in the Analysis menu. Confirm that you wish to delete all the test events.

Changing the way the event marks appear on the screen

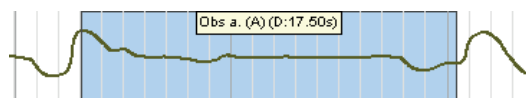
The event marks on the channel waveforms can be viewed in different ways:

Detailed: a legend appears on the mark that includes the event

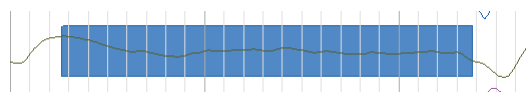
type, the initial instant and its duration.



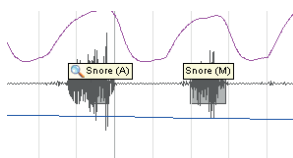
Brief: a legend appears on the event mark only with the short name of the event type and the duration.



No description: no text appears. The event type is distinguishable only by the color of the mark or the waveform on which it appears.



Events inserted manually show the mark (M), while events detected by automatic analysis show the mark (A).



Toggle between the three views by using the "E" key or from *Viewing options*:

Open *Viewing options* from *Analysis > Viewing options* and enable *Waveforms*.

Choose the option you wish to use in *Event mark descriptions*.

Click on *Accept* to close the window and apply the changes.

3.9.27 SCORING OF SLEEP STAGES

The program displays the hypnogram in the trend window. When viewing a test, the hypnogram can be displayed or hidden from the Display tab of the Analysis > Viewing Options menu.



Depending on the time setting of the trends window, the hypnogram will display the stage corresponding to the current epoch, the trends behind and ahead of the current epoch, the sleep structure of the entire night, etc.

Manual scoring of sleep stages

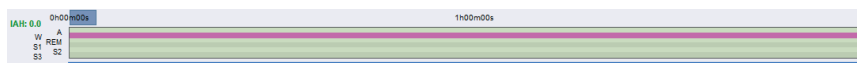
BitmedLab has two different ways of marking sleep stages manually.

First method:

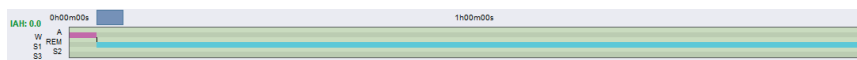
In Tools > Options, enable the General tab and make sure the Advance epoch when stage is entered is disabled. Close the window.

Place the cursor at the beginning of the test.

Enter the stage corresponding to the first epoch. To do so, use the corresponding button in the sleep toolbar or the key associated with the stage. The software will introduce a mark from the beginning of the test to the end.



Use the PgDn key to review all the epochs until the beginning of the next sleep stage and mark it. The new mark will go from the beginning of the current epoch to the end of the test.



Repeat the point above until you reach the end of the test.

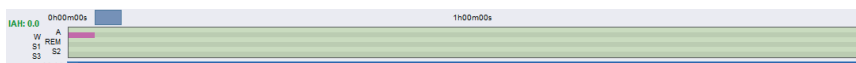
Second method:

In Tools > Options, enable the General tab and make sure the

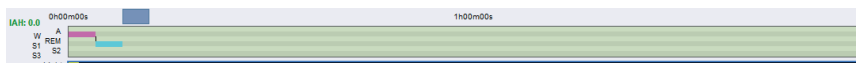
Advance epoch when stage is entered is enabled. Close the window.

Place the cursor at the beginning of the test.

Enter the stage corresponding to the first epoch. To do so, use the corresponding button in the sleep toolbar or the key associated with the stage. The software will introduce a mark for that epoch and advance automatically to the second epoch.



Enter the sleep stage corresponding to the epoch on the screen. The software will automatically go to the next epoch.



Repeat the point above until you reach the end of the test.

Keys associated to each of the sleep stages

Each sleep stage has an associated default key:

Artifacts: A

Waking: V

REM: R

Stage 1: 1

Stage 2: 2

Stage 3: 3

The associated keys can be changed by going to Tools > Options > Custom keys.

3.9.28 CALCULATING THE PTT

The Sleep&Go polygraph allows acquisition of the ECG signal (using the optional ExG channel module) and pulse wave (optional

in model A and serial in model B). These two channels generate a third, calculated channel: the PTT (Pulse Transit Time). This channel shows the time it takes the pulse wave to travel between two arterial points, in this case between the place of acquisition of the ECG signal to the tip of the finger, where the pulse oximeter is placed. This is a calculated channel that displays 0 during performance of real-time tests and that the program has to calculate once the test has finished.

Perform the test, making sure to correctly place a pair of ECG electrodes, the patient's ground electrode and the pulse oximeter. Remember to acquire the ECG and pulse wave channels.

Once the test is finished, go to *Analysis > Calculate PTT*. The program will calculate the PTT data and update the PTT waveform.

To perform the calculation, the program uses the ECG channel selected in the automatic analysis options (*Analysis > Automatic analysis options*).

If the PTT waveform is not visible on the screen, it can be shown as any other waveform by going to *Analysis > Viewing options*, enabling *Montage* and clicking on the *PTT* button.

In the report, the program will show a series of data associated with the PTT, such as the number and rate of increases, decreases, maximum and minimum values, etc.

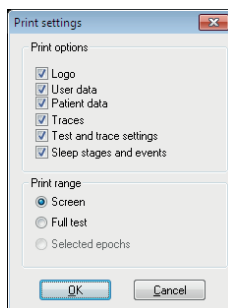
3.9.29 PRINTING

The BitmedLabsoftware module allows the user to print both the epoch being viewed on the screen and a selection of several epochs (consecutive or not) or the entire test.

Printing the on-screen epoch, the entire epoch or a selection of epochs.

Browse to the epoch you wish to print and go to *File > Print*.

Choose the printed items to include in the dialog. For example, a header with user data and/or logo can be added.



Choose the printing range and click on *Accept*.

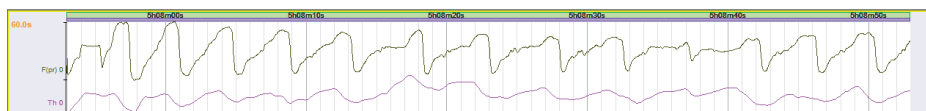
Direct printing

The epoch on the screen can be printed directly by simply clicking on *Direct printing*  in the *Standard toolbar*. The epoch will be printed with the last settings used to print from *File > Print*.

Choosing epochs for future printing

While reviewing the test, a series of epochs can be selected to be printed at the same time.

Choose the epoch on the screen by clicking on *Select for printing* . The epoch is selected and distinguished from unselected epochs by a purple mark in the time scale area.



When you have finished choosing the epochs, go to *File > Print* and when the *Printing options* window appears, choose *Selected epochs* in *Printing range*.

Preliminary printing view

Go to *File > Preliminary presentation*.

Choose the items you wish to include in the preliminary view. This window also provides the option of obtaining a preliminary view of

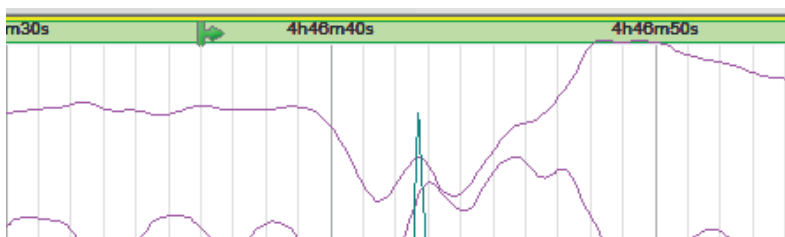
the entire test, only the epoch viewed on the screen or the epochs selected for printing.

The preliminary view can be used to print what is being viewed on the screen.

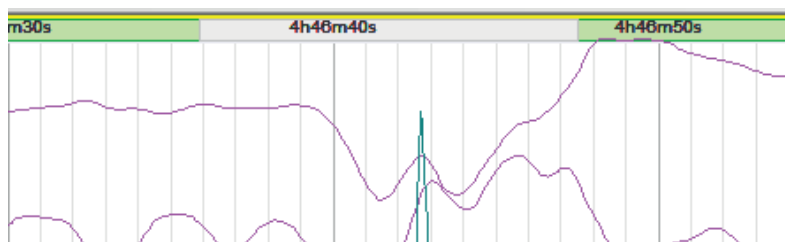
3.9.30 EXCLUSION PERIODS

If during the review of the test you detect periods that you want to discard for the analysis / report, you can mark them and they will not be taken into account. An example would be a period of artifacts or the time it takes the patient to fall asleep.

Use the button  in the toolbar to insert the beginning of the exclusion period.



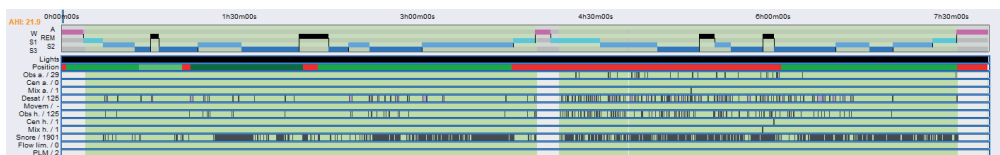
Use the button  in the toolbar to insert the end of the exclusion period.



You must insert the marks in the time zone, just above the first visible signal on the screen.

You can mark as many exclusion periods as you want throughout the test and delete them by right-clicking on them.

If the trend window is showing the complete test, all of it is marked in green, except for the exclusion periods, which are marked in gray. Periods are also marked in a similar way on the report charts.



For information on how to exclude these periods from the analysis / report see sections 3.9.23 and 3.10.1.

3.10 GENERATING REPORTS

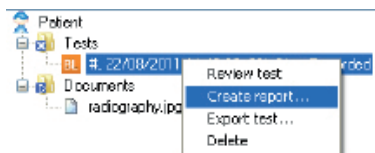
Once the doctor has reviewed the test, he can issue a complete report with all the test data, including statistical information of the sleep events that have been detected.

The software includes a series of default templates that can be used to generate reports. The user can customize these templates or create new ones, as described below.

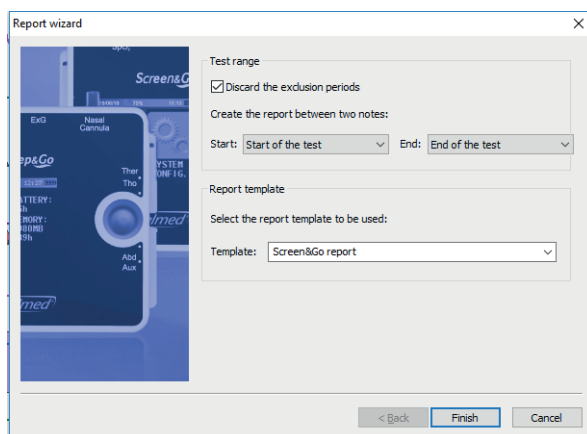
3.10.1 GENERATING A REPORT

To generate a report from the database:

Choose the patient, right click on the test from which to generate the report and choose *Create report*.



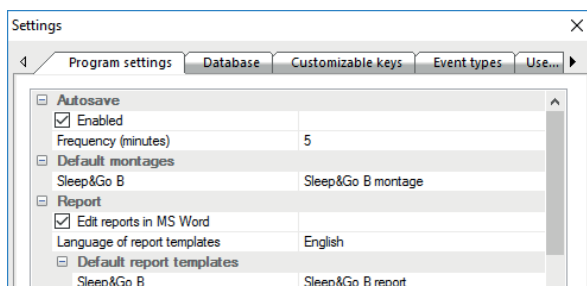
The report generation wizard will start-up. The user can choose the range of the test to take into account for the calculation of all the statistical data of the test. The user can discard the marked exclusion periods or perform the calculations between two marks (notes).



Choose the report template to be used. Any new template generated will be added automatically to this list.

You can define the template that will be used by default in Tools>Settings. Each polygraph model has a different default report template, so if you have several different devices you can select the most appropriate report for each type of test.

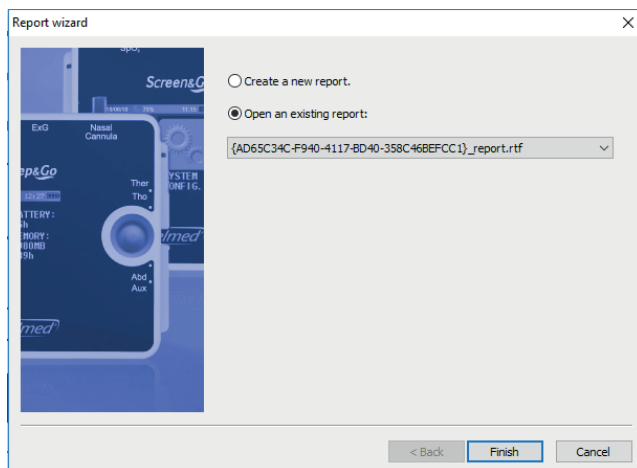
Users can also choose if reports are to be opened directly in the software or in the MS Word text editor (if it is installed in the system).



To generate a report when the test is open on the screen: Choose *Report* in the view menu. You can also use the  button. The *Report creation wizard* will be launched. Follow the steps indicated previously.

If the test is edited after generating the report, the report will have to be generated again for the changes to appear.

If there is a report previously created, at the beginning of the wizard you will be able to open it or create a completely new report.



3.10.2 PRINTING A REPORT

With the report open and activated on the screen, go to *File > Print*.

Choose the printer, printer properties, printing interval and number of copies.

Click on *Accept* to start printing.

3.10.3 SAVING A REPORT

Go to *File > Save*.

In *Save as*, enter the name of the report file, choose a folder to save it in and click on *Save*.

3.10.4 CHOOSING THE REPORT EDITOR

By default, the report will appear in a window in BitmedLab. If you wish, BitmedLab can open the report automatically in MS Word, which provides much better editing possibilities.

Take the following steps to change the report editor:

Go to the *Tools menu > Options*.

Enable the *Edit reports in MS Word* in the *General* tab.

Click on *Accept* to close the window and save the changes.

3.10.5 GENERATING AND MODIFYING REPORT TEMPLATES

The program is provided with several different report templates, designed for different types of tests. However, the user can generate new templates or customize the existing templates to adjust them to his needs.

Report templates for each language are stored in a specific folder within the folder in which the program is installed (e.g., report templates in English language are to be found at: C :/ Program Files / Sibelméd / BitmedLab X.XX / Templates / BitmedLab/ EN).

Report templates are in RTF format. RTF is a universal file type for text formatting. The WordPad program, supplied with Windows or MS Word, two common programs, can work with this type of file.

Any of the templates saved in this folder can be used to generate a new report. All that is required is to create a new template and save it in the *Templates* folder, where it will be available for the generation of a new report.

The report templates are based on the use of a series of labels that are later interpreted by BitmedLab to generate the reports.

For example, if a line in the template is:

Name: #name_pat#

the program will replace the #name_pat# label with the real

name of the patient so the report shows something similar to the following:

Name: Paul Garralda

If, on the contrary, the template has:

Total recording time: #TRT# min

the generated report will replace the #TRT# label with the total recording time:

Total recording time: 182 min

Any of the report templates supplied by default with the program can be opened in your usual text processor to verify its appearance.

Refer to the CD supplied with the software to familiarize yourself with the complete list of available labels to customize your reports.

Briefly, the steps to create a report template are as follows:

Open a word processor, such as WordPad or MS Word.

Create a new document or edit any of the report templates in the *Templates* folder.

Customize the report. You can use, tables, format the text (bold, various fonts, colors), insert images, etc. The text entered will appear the same in the report, while the labels with the #name_label# format will be automatically replaced with a value calculated by the program.

When you have finishes, save the file with the .RTF extension in the *Templates* folder.

The new template will appear in the list of available templates for the generation of reports.

3.10.6 CHANGING THE LANGUAGE OF REPORT TEMPLATES

To change the language of the report templates go to *Tools > Options*.

On the *General* tab, locate in the list the report options and select the language you want to use under *Language of report templates*.

4. ACQUIRING DIGITAL VIDEO

XGPVision is a software module that allows the user to acquire synchronized digital video and audio in sleep studies.

The audio and video are stored in a file different than that of the test file, in the same folder and with the same name, but with an .AVI extension. The video acquisition process is a demanding process for the computer, so video compression during capture is minimum. This generates large files (these can occupy several gigabytes) and they will need to be compressed after acquisition in order to be saved alongside the test. Video compression used an MPEG4 standard compressor that significantly reduces the size of the file. Audio compression uses a standard MP3. Compression significantly reduces the size of the file without affecting the quality.

XGPVision is completely integrated into BitmedLab and is very easy to use.

4.1 ACQUIRING VIDEO DURING PERFORMANCE OF REAL-TIME TESTS

Start recording a new test in real time. When you are in *Viewing options* select *Video*.

The screenshot displays the XGPVision software interface with the following sections and settings:

- Video properties:**
 - ☒ Acquire video
 - Frames per second: 10
 - Video capture device: IF Camera [JPEG/MPEG]
 - Buttons: Source, Format, Inputs
- Audio properties:**
 - ☒ Acquire audio
 - Audio device properties button
 - Audio capture device: Realtek AC97 Audio
 - Sampling:**
 - ☐ Mono
 - ☐ 8 bits
 - ☐ 11kHz
 - ☒ Stereo
 - ☐ 16 bits
 - ☐ 22kHz
 - ☒ 44kHz
- Save video:**
 - ☒ Save the video file with the same name than the recording file
 - ☐ Ask me for the video file name before the recording starts
- Compression:**
 - ☐ Compress the video file when I stop the recording
 - Compress video button
- Preview:** A large empty box labeled "Preview" with a "Preview" button above it.

Enable *Acquire video* and select the name of the video capture card from the list of *Video capture devices*. This list includes all the devices installed in the system capable of capturing video.

If you also wish to acquire audio, enable *Acquire audio*. As in the point above, select the audio device from the corresponding list.

Enable the *Ask me for the file name before starting recording* option if you want the program to request a name for the file that will store the video at the beginning of the test recording. If not, the video file will have the same name as the recording, but with the extension *.AVI*, and it will be saved in the same folder (we recommend this option).

Use *Preview* to preview the video source currently selected in *Previewing*.

Click on *Accept* to start the test and video capture.

A video viewing window will appear on the top right of the screen. The video is acquired at the same time as the signal data.



Once video acquisition has started, it can be paused and resumed at any time, which will also pause and resume the test recording. To do so, click on *Pause/resume direct communication*. Remember that when the recording is paused, you can move freely through

the test acquired up to that time, although the video will not synchronize with the time instant that is being viewed in the waveform window.

If, on the other hand, you stop the recording using *Stop direct communication*, you will not be able to add any more data to the test, but the video will synchronize with the time instant indicated by the waveform window.

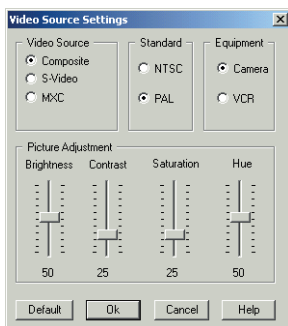
4.2 MODIFYING THE CAPTURE PROPERTIES

The audio and video capture properties can be changed from the Video tab in Viewing options.

The capture properties can only be changed before starting the test.

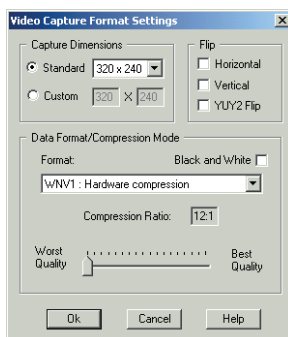
Frames per second: the number of video frames that will be captured per second. Remember that a high rate per second will generate a much larger file, which may reach several gigabytes in long tests. For example, a test with 9 hours of compressed video at a rate of 5 frames/second occupies approximately 600 Megabytes.

Controls: these are used to change the capture properties of the card (brightness, contrast, saturation, etc.). Select the input source and the input signal type (camera, video). The available properties will depend on the model of the capture card in the system, and some of the options mentioned may be in another menu. Normally, the values needed are *Composite video* and *PAL system*.



Format: this establishes the size of the capture window, the format

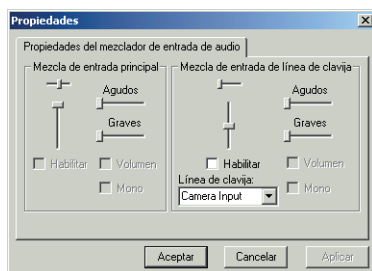
of the images to be recorded, etc. If you have a Winnov Videum 1000 Plus capture card, we recommend using the Hardware compression format with a window size of 320x240 and selecting the desired compression quality. If you do not have a Winnov Videum 1000 Plus card, possible settings could be a similar window size but an image format of 24-bit RGB.



Inputs: this button is only available in certain card models (those with several inputs for video signals). A dialog appears for the user to select the input that the video source is connected to.

Video capture device: a list of the devices installed in the system capable of capturing video. Select the video capture card.

Audio device properties: this shows a new dialog where the user can select the input line from which to perform audio capture (camera Input, line Input, etc.). These options will vary depending on the sound card model or the video capture card, if the latter has an option for capturing audio.



Audio capture device: a list of the devices installed in the system

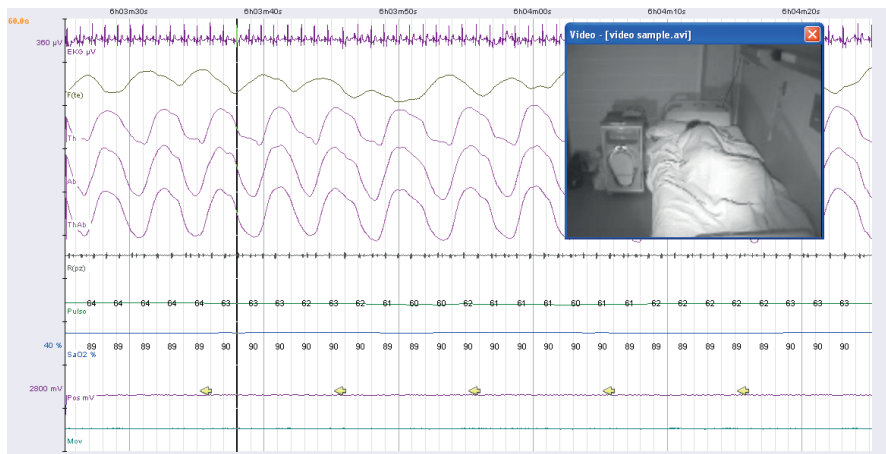
capable of capturing audio. Choose the device that you wish to use in the tests.

Sampling: several audio recording features can be chosen in this block. Recording in stereo or mono, 8 or 16-bit coding (the higher the bit coding, the better the sound will be but this will also increase the space occupied by the file in the hard disk). You can also choose the capture sampling frequency, 11, 22 or 44 KHz. The higher the frequency, the larger the resulting file will be.

4.3 REVIEWING THE TEST

When the video recording of a test has been completed or a test with video is opened, the video window will be on the top right of the main window of the program.

The window can be hidden by clicking on the X and shown again from *See > Video*.



If the numerical data cursor is enabled, you can verify whether the video window is displaying the frame that corresponds to the time instant on which the cursor is placed.

If the cursor is not enabled, the video window will display the frame corresponding to the left end of the waveform window or the position of the pointer if a selection is being performed on the test.

The video will play automatically when you enable the play test function at the selected speed.

If any part of the test is deleted, the corresponding video will not be deleted, so it will cease to be synchronized with the biomedical signals.

4.4 COMPRESSING THE VIDEO FILE AUTOMATICALLY AFTER COMPLETING THE TEST

We recommend compressing the video file to significantly reduce its size. If you want the program to compress the video automatically once the test has been completed, choose the *Compress video after completing the test* option in the *Video* tab of *Viewing options*. Nonetheless, the program will request confirmation before performing the procedure, since the procedure is quite time-consuming for long tests.

4.5 COMPRESSING THE FILE AT ANY TIME

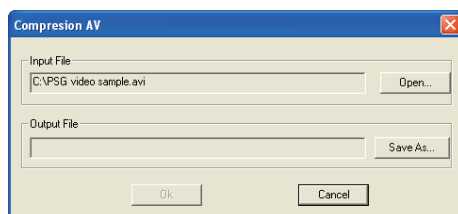
Open the test that you wish to compress the video of.

Open the *Viewing options* window from *Analysis > Viewing options*.

Enable the *Video* tab.

Start the video compressor by clicking on *Compress video now*.

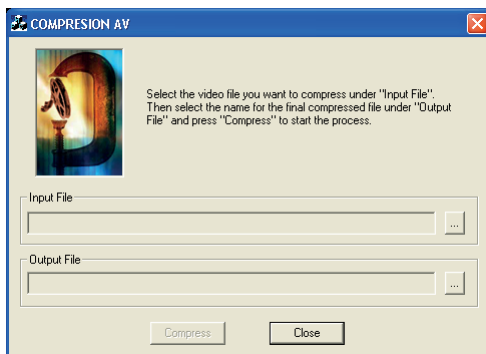
The *AV compression* dialog will open where you can choose the file to compress (the default file is the one associated with the active test) and the name of the compressed file. Click on *Accept* to start compression.



4.6 COMPRESSING A VIDEO FILE USING THE COMPRESORAV TOOL

The BitmedLab software includes the installation of a tool called Compressor AV that can be used to compress video files without needing to start any of the software.

In the Windows *Start* menu, go to *All programs > BitmedLab* and open *Compressor AV*.



Choose the video file to compress in *Input file*.

Choose the name for the compressed video file in *Output file*. You can choose the same file if you wish.

Click on *Compress* to start compression.

4.7 CHANGING THE VIDEO FILE ASSOCIATED WITH A TEST

This option only appears once test acquisition has been completed and allows the user to associate a video file other than the original one. This is useful when the test file is moved from one folder to another or to another computer and the location of the video file does not coincide with the original.

Open *Viewing options* from *Analysis > Viewing options*.

Enable the *Video* tab.

Click on *Video file associated with the test* to choose the video file you wish to associate with the test.

Click on *Accept* to apply the changes.

ANNEX 1. APPLICABLE STANDARDS

The BitmedLab is manufactured by SIBEL and the software meets the following standards and regulations:

Recommendations:

- National consensus document on the apnea-hypopnea syndrome (SAHS). Spanish Sleep Group (GES), September 2005.
- The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, Version 2.6.

Medical Device Regulation (EU) 2017/745:

- CE marking Class II a

Software:

- EN 62304:2006+AC:2008+A1:2015 Medical device software - Software life-cycle processes

Usability:

- EN 62366-1:2015 + A1:2020 Medical Devices – Application of usability engineering to medical devices

Safety:

- EN 60601-1:2006+AC:2010+A11:2011+A1:2013+A12:2014+A2:2021+A13:2024: Electrical safety (3rd edition)

Pulse oximetry:

- EN ISO 80601-2-61:2019 Special requirements for basic safety and essential operation characteristics of pulse oximeters for medical use.

Symbology:

- EN ISO 15223-1:2021 + A1:2025 Symbols to be used with medical device labels, labelling and information to be supplied.

Information supplied by the manufacturer:

- EN EN ISO 20417:2021 Information supplied by the manufacturer of medical devices
- Implementing Regulation (EU) 2021/2226 regarding electronic instructions for use of medical devices.

System quality:

- Manufactured according to the SIBEL S.A.U. Quality Manual, which is compliant with EN ISO 13485:2016+A11:2021 and EN ISO 9001:2015

Risk Management:

- EN ISO 14971:2019 + A11:2021

The user of the software must comply with:

- General Data Protection Regulation (EU) 2016/679

ANNEX 2. COMPLIANCE WITH THE GENERAL DATA PROTECTION REGULATION AND PROTECTION MEASURES

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 General Data Protection Regulation (EU) 2016/679 on the protection of individuals with regard to the processing of personal data personal data and to the free movement of such data.

Next, a brief description of the fundamental points of such legislation is given, and also, the details about what must be done with the Software **BitmedLab** and/or the operating system in order to meet the requirements of the General Data Protection Regulation.

IMPORTANT WARNING

- According to current legislation, the software's user is solely responsible for the storage and treatment of their patient data in accordance with the law.
- Observance of the recommendations included in this section does, in no case, guarantee the full adaptation of user activity to the standards relating to data protection.

Requirements which specifically affect the use of the BitmedLab.

Identification and Authentication

The processes for user identification and authentication for use of the SOFTWARE BitmedLab are performed by the PC's operating system. Therefore only Windows Operating Systems which allow the performance of said processes in a secure way are valid, i.e. Windows XP, Windows 7, Windows 8.1, Windows 10 and Windows 11 with NTFS file structure. Windows 9x systems or 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 on the 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. the case of the Software, full recovery of all database data is guaranteed if the entire DATA directory of the application directory is saved.

Said back-up copy must be stored at all times in a different place to where the equipment on which the software is used is located.

Operating System Setup

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

Setup of Identification and 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 setup and control: File access grants

The following step is to set up the access levels to the files which form the databases in relation to the previous users. The database root can be found in the <BitmedLab_HOME> \ Data directory. Inside, there is a subdirectory per database, as well as the register file «log» BitmedLab_UTF16.log. One possible setup is to provide full access to the <BitmedLab_HOME> \ Data directory to all users (or at least to the application users) and to restrict access to each of the subdirectories according to the user that they belong to. In any event, the owner must always have read and write access for their subdirectory and the files that make up the subdirectory. The rest of the users may have access to said database totally denied, for example. It must be taken into account that in this situation the users may only access their database from the application. On the log file BitmedLab_UTF16.log level, it would be advisable for the users to only have read access 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 directory of file to which you wish to establish 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 said file. At this level, you must specify the users (according to the users which access the <BitmedLab_HOME> \ Data directory) 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 upon the log file are audited, the security events viewer will have many more 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 setup. 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.

Access register description

Access to the different databases are stored on the one log file (BitmedLab_UTF16.log) in the DATA folder of the directory where the application is installed.

This file is created the first time that the application is executed and cannot be deactivated. The system administrator is responsible for the maintenance of said file with regard to size, and the preparation of a monthly report where the periodic reviews carried out are analyzed and any problems detected are reported, should there be any.

The log file is saved by line:

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

The format of each of the lines is the following:

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

The database comprises a directory and a data file, as well as auxiliary files. The actions to be recorded are divided into:

- Action on the actual database itself (open, close, delete, etc.)
- Action on the records stored in the paciente.dbf and pruebas.dbf data files (insert, find, delete, etc.)

In any event, the register or access control «log» file, must be kept for a minimum period of two years.

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

- Opening a db file
- Closing a db file
- Selecting a db
- Creating a db
- Creating a db file
- Deleting a db
- Deleting a db file
- Re-indexing a db file
- Compacting a db file
- Changing password
- Finding a record
- Adding a record
- Marking a record
- Recovering a record

- Changing a record
- Deleting a record
- Exporting a record
- Importing a record

Other important subjects

- Printing documents:

In the case of storage for paper prints containing patient details, it is required that said 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 of the printed documents, it will be necessary to ensure their effective physical destruction in order to avoid unauthorized access to data.

- Exporting tests

The software allows for tests to be exported only if the user is identified and authorized to read the database. Once the test has been exported to a file, the software user is responsible for the security of said 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.

ANNEX 3. HOTKEYS

Insert note	Insert
Delete selected waveforms / event under the cursor	Delete
Increase amplitude of selected waveforms	Up arrow
Decrease amplitude of selected waveforms	Down arrow
Start/pause playback	Ctrl + Espace
Select epoch for printing	Alt + P
Select all waveforms	Ctrl + Tab
Deselect all waveforms	Escape
Increase time per epoch x2	-
Decrease time per epoch 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
Automatic scaling of the waveform under the cursor	8
Automatic scaling of all channels	9

ANNEX 4. BITMEDLAB SPECIFICATIONS AND REQUIREMENTS

Useful life	7 years
Available data or graphs in the report	Pulse rate, SpO2 and body position summary graphs and histograms Events summary graphs Apnea-hypopnea index Indexes of all type of events Indexes of events by body position Time in each body position Mean and maximum duration for each type of event Sleep stages summary graph and related parameters PTT increases; decreases; mean, minimum and maximum PTT values CPAP graph and related parameters

Supported events (events supported by the automatic analysis module are marked with *)	Apnea (obstructive, central and mixed) * Hypopnea * Desaturation * Limb movement * Periodic limb movement (PLM) * Snore * Arousal Movement arousal Respiratory effort related arousal (RERA) Flow limitation Hypoventilation Bruxism Periodic respiration Cheyne-Stokes respiration Undetermined respiratory event Tachycardia * Bradycardia * Asystole Sinus tachycardia Narrow complex tachycardia Wide complex tachicardia Atrial fibrillation Arrhythmia
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ANNEX 5. SYMBOLS

	MANUFACTURER (MANUFACTURER'S NAME AND ADDRESS)
	MANUFACTURING DATE
	TEMPERATURE LIMITATION
	ATTENTION ADDITIONAL WARNINGS IN THE ACCOMPANYING DOCUMENTATION
	ATTENTION, RISK IDENTIFIED
	MEDICAL DEVICE
	BATCH NUMBER
	REFERENCE
	FOLLOW THE INSTRUCTIONS FOR USE
	DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC ACORDING TO THE WEEE DIRECTIVE
	HUMIDITY LIMITATION
	PREASURE LIMITATION

PC requirements		Required	Recommend.
	Operating system	MS Windows 7, 8/8.1, 10 or 11 (32 and 64 bits)	
	CPU	Intel Pentium 4, AMD Athlon	Dual core processor
	RAM memory	1024 MB	2048 MB
	Free HD space	100 MB	Several gigabytes are needed to acquire synchronized digital video
	USB 1.1 ports	Screen&Go/ Sleep&Go: 2 (if a Wireless module and card reader are used)	
	Screen resolution	1024 x 768	1280 x 1024 or higher
	Synchronized digital video capture	Free PCI Xpress slot (Desktop PCs) Free Xpress Card slot (Laptops)	
User-defined Screen&Go and Sleep&Go configurations	Unlimited in the software, up to 10 configurations at the same time in the device		
Scheduled tests	Unlimited in the software, up to 5 scheduled tests at the same time in the device		
User-defined montages	Unlimited		
Database	Stores patients' data, tests and reports. Access to data is password protected		
Customizable on screen time	5s, 10s, 15s, 20s, 30s, 1m, 2m, 3m, 5m, 10m, 30m, 1h or user-defined		

Filters	Low pass filter: 3, 5, 10, 15, 25, 35, 45, 70, 100 Hz High pass filter: 0.1, 0.5, 1, 2, 10 Hz
Environmental conditions for USB Flash memory drive	Transportation and storage: Temperature: -25°C to +70°C Relative humidity: <90% (without condensation)
Other features	Annotations on the test Customizable channel amplitudes Customizable thickness of waveforms Values over the waveforms Trends window Customizable reports Digital video capture (supported only by the Sleep&Go with Wireless module)



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

ANNEX 6. CLEANING AND MAINTENANCE

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

- Make a backup copy of the installation program in case the original gets damaged.
- Make regular backup copies of the Data Base, test files and report files, in order to be able to restore in case of loss of information on the computer. See Appendix 2 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.

If any problem, doubt or suggestion arises while using the product or if you require additional training, please follow the next steps:

1 Use the help windows available in the program

2 Use this User's Manual properly

3 Keep the program updated. You can check your current version in "Help > About BitmedLab". Check the availability of new versions at <https://www.sibelmed.com/support>

4 Contact with the After Sales Service of SIBEL S.A.U. at

You can also check the "Known abnormalities report" (534-741-MU2) available to the user from SIBEL S.A.U.

SIBEL, S.A.U.

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CLEANING

The USB flash drive must be carefully cleaned with a cloth dampened with water and a mild (neutral) soap. You can then dry it with another cloth.

Pay special attention so that no liquid comes into contact with the inside of the USB connector. Abrasive substances or solvents should be avoided.

Keep the USB Flash memory drive in its packaging when you are not using it.

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