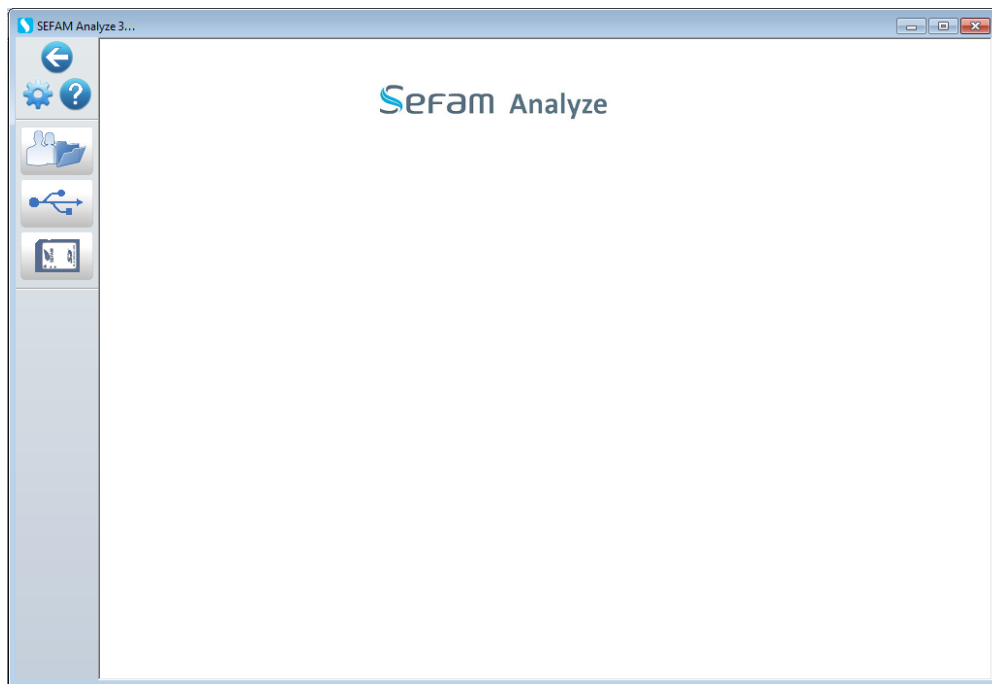


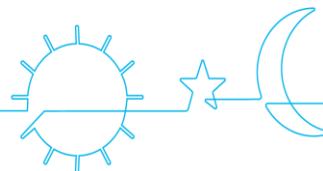
# Sefam Analyze



SOFTWARE FOR ANALYSING DATA RECORDED  
BY THE DEVICES OF THE RANGE

**Sefam**  
**S.Box**  
BY  
STARCK®

User manual



en

Manufacturer:	Manufacturing plant and technical agency:
SEFAM 144 AV CHARLES DE GAULLE 92200 NEUILLY SUR SEINE FRANCE	SEFAM 10 ALLEE PELLETIER DOISY 54600 VILLERS-LES-NANCY FRANCE TEL : +33 (0) 3 83 44 85 00 <a href="http://www.Sefam-medical.com">www.Sefam-medical.com</a>
	<b>Technical Assistance:</b> E:mail : <a href="mailto:technicalservice@sefam-medical.com">technicalservice@sefam-medical.com</a>

# TABLE OF CONTENTS

<b>Before you start</b>	<b>5</b>
Software overview	5
Instructions for use	6
Standard equipment	6
<b>Launching the program</b>	<b>7</b>
Description of welcome screen	7
Properties of the software	8
Software configuration	8
1. Selection of the language	8
2. Serial link setup	9
3. Choosing the units for height and weight	9
4. Choice of analysis parameters	9
5. General features	10
6. Provider logo	11
7. Importing or exporting report templates	11
a) Importation	11
b) Exportation	12
<b>Patient management</b>	<b>13</b>
Patient list	13
Patient information	14
1. Displaying information	14
2. History of treatment	14
3. Creating a patient	15
4. Deleting a patient	15
5. Adding comments	15
Other utilities	16
1. Import of patient files	16
2. Export of patient files	16
3. List of deleted patients	16
<b>Displaying compliance data</b>	<b>17</b>
Organization of compliance data	17
1. Identification of the selected patient	17
2. Analysis period	18
3. Night calendar	18
4. Compliance data	19
The different presentations	20
1. Statistical report	20
2. Treatment evolution profile	22
a) Treatment evolution profile	22
b) Statistical Report	22
3. Waveforms	23
4. Flow	25
5. Access HD signals	26
a) Description	26
b) Specifications of the recording when using the PolyLink kit	31
6. Global Information / Settings list	35
a) Global information	35
b) Settings list	35
7. Analysis Compliance Report	36
a) Printing and exporting reports	36
b) "Export of sessions only to a text file" feature	37
8. Send compliance data to SEFAM Connect	38
9. Patient card	38
a) Target device	39
b) Settings	39
c) Bluetooth	40

d) Modem.....	40
e) Time shift.....	40
<b>Configuring the device.....</b>	<b>42</b>
Connecting to the device .....	42
Description of the connection screen .....	42
1. Display.....	43
2. Information displayed .....	43
a) Device:.....	43
b) Settings:.....	43
3. Other functionalities .....	44
a) Downloading data by serial link.....	44
b) Viewing the current session.....	46
c) Data for all sessions .....	47
d) Settings .....	48
e) Programming of settings changes .....	50
f) Erasing compliance data.....	52
g) Inventory number .....	52
h) Configuring the serial port.....	53
i) Communicating accessory.....	53
j) Date and hour.....	55
<b>Use of the SD card .....</b>	<b>56</b>
Download data from the SD card .....	56
Maintenance card .....	58
New patient .....	58
<b>In case of problem .....</b>	<b>60</b>
<b>Definition of symbols.....</b>	<b>61</b>
<b>CE marking.....</b>	<b>61</b>
<b>Glossary .....</b>	<b>62</b>

# Before you start

---

Please read this manual carefully before using SEFAM Analyze software.

## Software overview

**SEFAM Analyze** is a medical device which can be used with the devices of the SEFAM S.Box range designed:

- For S.Box and S.Box C CPAP devices, in the treatment of Obstructive Sleep Apnea–Hypopnea Syndrome (OSAHS) of patients over 30 kg, who breathe spontaneously.
- For S.Box DuoS and S.Box DuoST bilevel devices, for Non-Invasive Ventilation of patients weighing more than 30 kg, suffering from a Ventilatory Disorder or Sleep Apnea Syndrome (SAS), but not dependent on respiratory assistance.

It is essential for you to understand the software operation before using it. When the software is launched, it automatically recognizes the device to which it is connected. It is user-friendly and allows the user by means of buttons and icons:

- managing a patient list which provides direct access to nominative data (personal information, information about the equipment used, compliance data history...)
- downloading and saving on your computer the most recent compliance data recorded by sessions in the memory of the SEFAM S.Box range device and on the SD card up to one year and 8 hours per day of operation, or via a network access, a direct connection by USB cable or Bluetooth wireless connection.
- viewing and printing of compliance data stored in the device along with the 10 Hz real flow rate over the last 8 hours of use (via direct link).
- configuring the device settings by a direct connection by USB cable, by SD card, by Bluetooth wireless connection or by S.Box modem.
- viewing the signals acquired in real time (flow, pressure, unintentional leaks, events detected, etc) from the device. You will also be able to display the signals of respiratory effort and of body position if you use the PolyLink kit and/or the signals of SpO<sub>2</sub>, heart rate and pulse wave if you use the pulse oximeter.
- printing out of a compliance report (Acrobat Reader or ASCII compatible PDF format) which can then be sent by email to the Clinician and to the Home Care Provider, and/or export of data to spreadsheet software programs.

User manuals of SEFAM Analyze software are provided in PDF files at the software installation. However, a paper copy of the manual may be obtained upon request.

In the user manual, all the screen shots are presented in English and concern mainly the software use with the S.Box device. Screenshots of the software used with S.Box C and S.Box DuoS or DuoS.Box DuoST are described when they are specific to these devices.

The software has been translated into all available languages, but the screenshots displayed may differ from that shown in this manual which are provided by way of example. The corresponding translations are given in brackets after the menus and information shown in English.

### **Note:**

The dates displayed by the software are presented in day/month/year format (DD/MM/YYYY).

If you have any questions concerning the use of this software, contact the service representative whose contact information is shown at the front of this manual.

# Instructions for use

## WARNING

It means that there is a possibility of danger risk of injuries or accident.

SEFAM Analyze software is a tool for aiding the compliance data analysis and under no circumstances does it provide an automated diagnosis.

## CAUTION

In this manual, this indicates that there is a risk of damaging the software or the hardware used.

- The SEFAM Analyze can only be used with a S.Box range device.
- The software can be connected to one device at a time and can display the compliance data of one machine at a time.
- Before using the SEFAM Analyze software with a device, be sure to familiarize yourself with the safety instructions associated with the device, which are indicated in the corresponding Patient Manual and Clinician and Home Care Provider Manual.
- Regularly run antivirus software on the computer where the software is installed.
- You are advised to keep a backup copy of the software.

### Notes:

- Before installing the software, read the installation procedure provided as well as the instructions for storing the software.
- This software requires Acrobat Reader for display of the reports. An English version is available in the \ADOBE directory.

## Standard equipment

The SEFAM Analyze software is delivered in a clinical kit containing the following items:

- a USB key for installation (available separately).  
The USB key includes the latest version of the software, the user manuals in PDF format for each language, and the English version of Adobe Acrobat Reader 8 (software which is freely distributed).
- a USB cable to connect the S.Box range device to a PC.

## CAUTION

- On receipt, check the integrity of the packaging.
- Check that the USB key and the USB cable are undamaged.

Protection of data access is carried out through the Windows User Profile Manager. You are therefore advised to activate this management tool in order to ensure the confidentiality of information.

You can also access the SEFAM Analyze software in downloading it from the SEFAM website.

# Launching the program

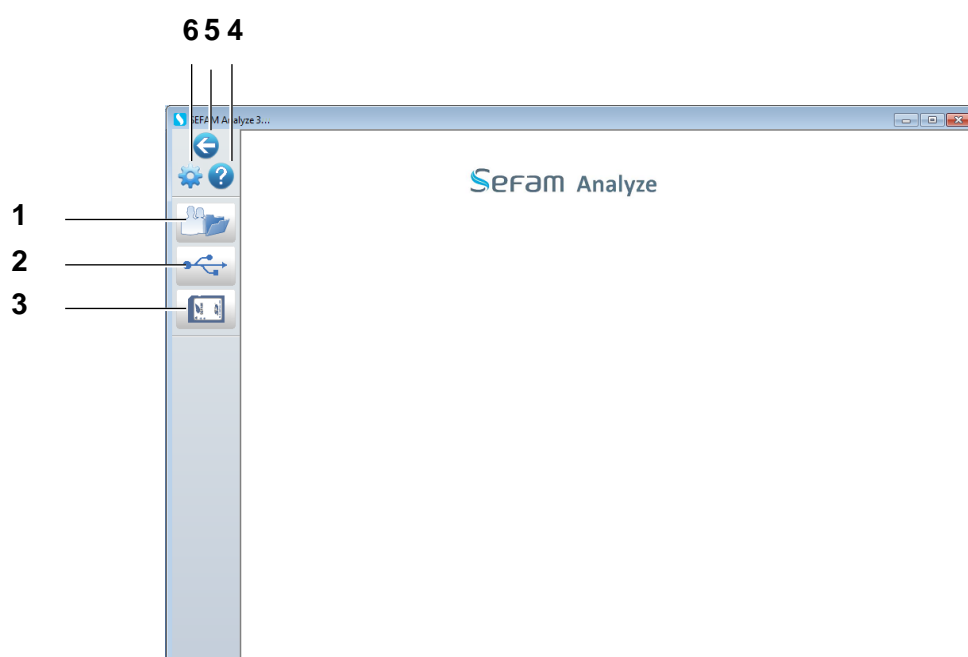


To use the software, double-click on the SEFAM Analyze shortcut on the desktop or select "All Programs" then SEFAM Analyze in the "Start" menu of your computer.








The language is chosen the first time the program is launched. To select your language, follow the instructions in "1. Selection of the language" page 8.

The welcome screen appears and gives access to the program functions.

## Description of welcome screen




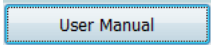
This screen is used to access the following functions:

- 1  display the patient list and history of data, open a patient file and view the compliance data stored during treatment.
- 2  establish a connection between S.Box range device and SEFAM Analyze software:
  - by a USB cable
  - or  by a Bluetooth wireless communication.The type of connection is indicated by the icon displayed.
- 3  download the data of S.Box range device saved on the SD card, program a patient card and a maintenance card.
- 4  access the software version and the user manual.
- 5  come back to the previous page according to the software menu hierarchy.
- 6  use software configuration tools.

You can exit the program by selecting  from Windows menu or by clicking on .

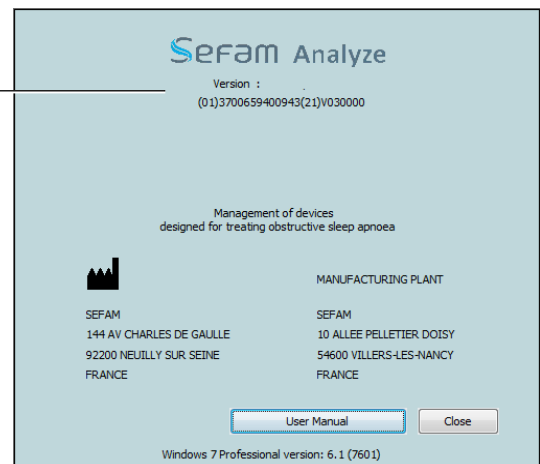
# Properties of the software

By clicking on , a dialogue box displays the software **version**.


You can also access the software user manual by clicking on . It will appear in the selected language.

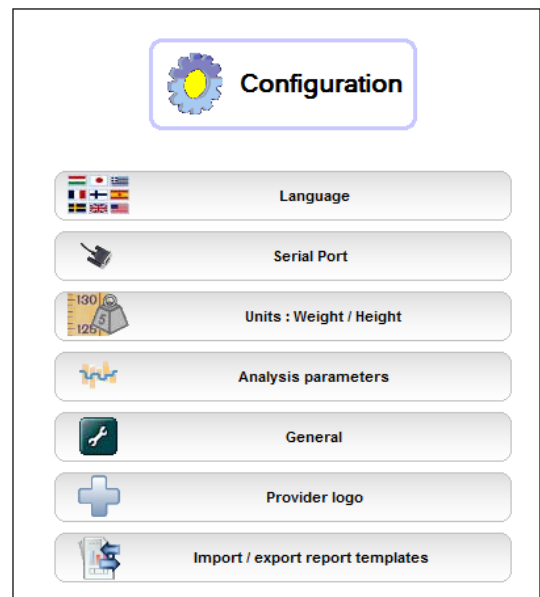
Click on  to exit the window.

Software version



## Software configuration


By clicking on , the **Configuration** screen displays and allows you selecting different parameters (language, serial port, units of weight and size, etc.).



### 1. Selection of the language

By clicking on **Language**, a window opens in which the software language can be selected by clicking on the corresponding button.

The language selected appears in header. Only the buttons corresponding to the languages available in the software version are displayed.

Click on  to exit the window.

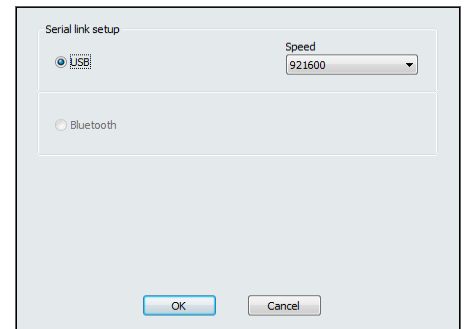




## 2. Serial link setup

By clicking on **Serial Port**, a dialogue box appears allowing you to select:

- a USB connection with a programmed speed from 38,400 bauds to 921,600 bauds. It is recommended to use the highest speed (921,600 bauds selected by default), except in case of connection problem.
- a Bluetooth wireless connection.



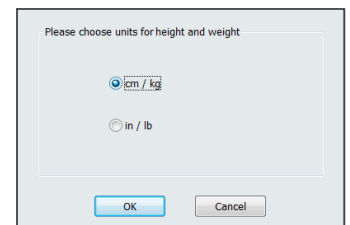
### CAUTION

The Bluetooth connection is functional only if a Bluetooth radio is installed on your computer. Click on **OK** to confirm your choice; otherwise click on Cancel.

## 3. Choosing the units for height and weight

By clicking on **Units: Weight/Height**, you can choose international or anglo-saxon units for size and for weight.

Click on **OK** to validate your selection; otherwise click on Cancel.



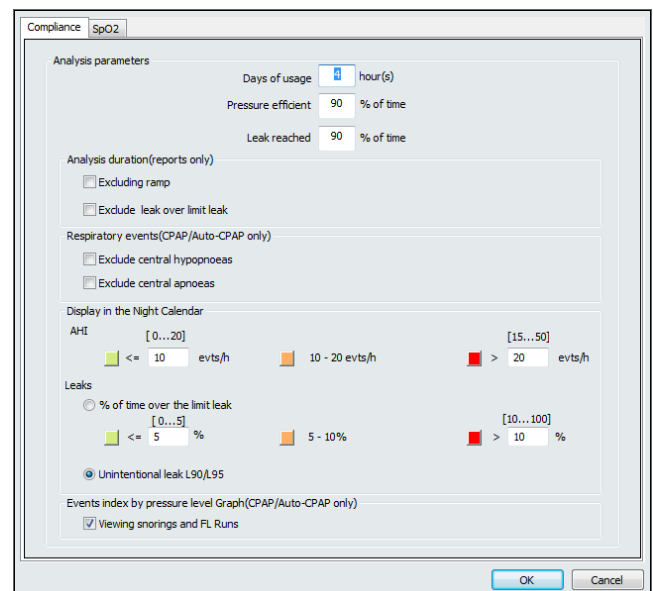
## 4. Choice of analysis parameters

By clicking on **Analysis parameters**, a dialogue box is displayed, including Compliance and SpO2 tabs.

In the **Compliance** tab, you can first choose:

- the threshold used to calculate the percentage of usage days. It is defined in hours per day (3 hours/day by default).
- the threshold used to calculate the effective pressure. It is expressed as a percentage of time (90% by default).
- the threshold used to calculate the leak reached. It is expressed as a percentage of time (90% by default).

You can configure the analysis duration by excluding or not the time in ramp and / or the time over the limit leak.

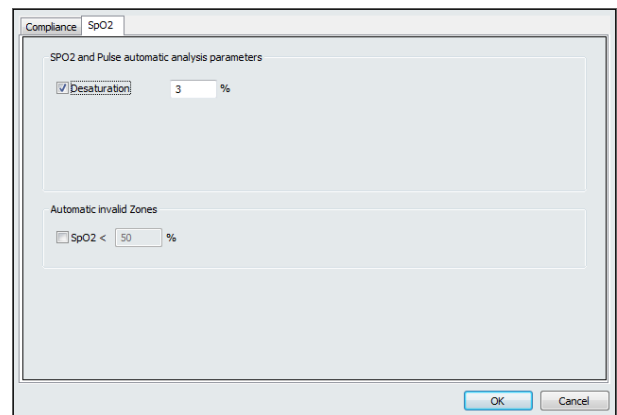


You can also select:

- respiratory events in Statistical and Pressure reports (if the S.Box or S.Box C device is used).
- Index of Apnoea / Hypopnoea (AHI) in the night calendar.
- leak indicator in the night calendar.
- viewing or not snorings and Flow Limitation Runs in the graph of events index by pressure level (if the S.Box or S.Box C device is used).

The **SpO2** tab allows you to define:

- the automatic analysis parameters used for SpO<sub>2</sub> and pulse. The desaturation parameter is set to 3% by default.
- the criteria for automatic detection of invalid zones. The SpO<sub>2</sub> saturation value is < 50 % by default.



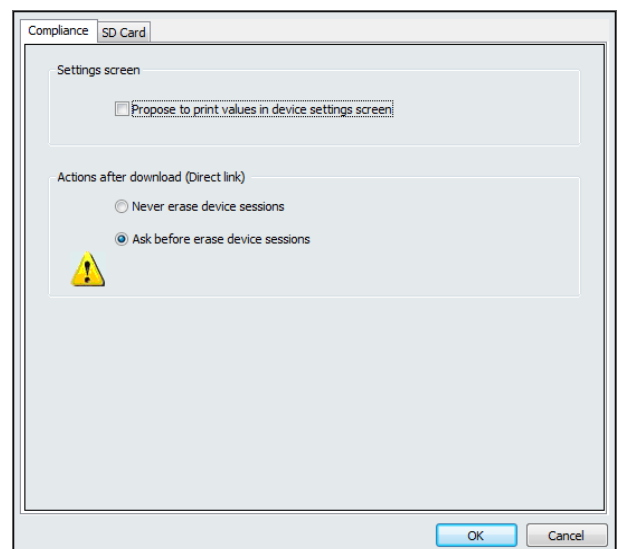
Confirm your choices by clicking on **OK**; otherwise click on Cancel.

## 5. General features

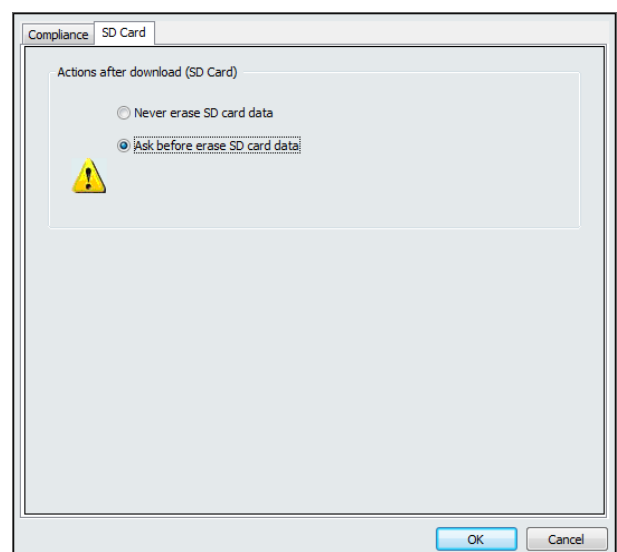
By clicking on **General**, a dialogue box is displayed, showing Compliance and SD card tabs.

In the **Compliance** tab, you can choose to print the values displayed in the device settings screen.

After download via Direct link, you can choose to never erase device sessions or to ask before erasing device sessions (option by default).



In the **SD card** tab, you can choose after download, to never erase memory card data or to ask before erasing SD card data (option by default).



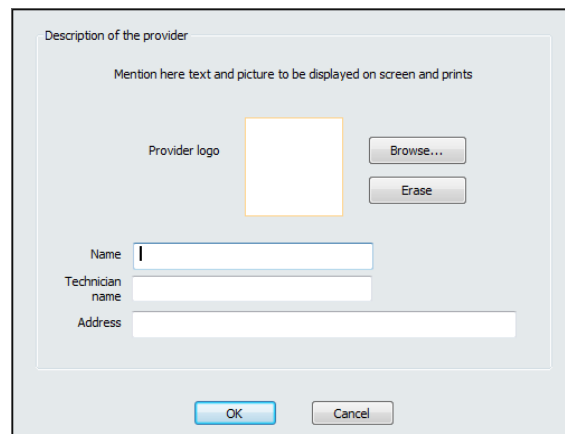
Confirm your choices by clicking on **OK**; otherwise click on Cancel.

## 6. Provider logo

By clicking on **Provider logo**, a dialogue box opens, where you can choose a logo and text which will be present on screens and prints.

Click on **Browse...** to select a file. A picture can also be deleted by clicking on **Erase**.

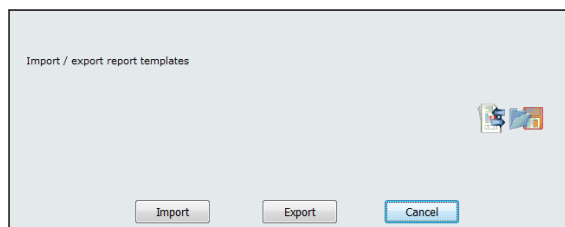
The information can be completed (names of the home care provider and of the technician, address).



Confirm your choice by clicking on **OK**; otherwise press on Cancel.

## 7. Importing or exporting report templates

By clicking on **Import / export report templates**, a dialogue box opens, which allows to import or export one or several templates of reports of compliance data.



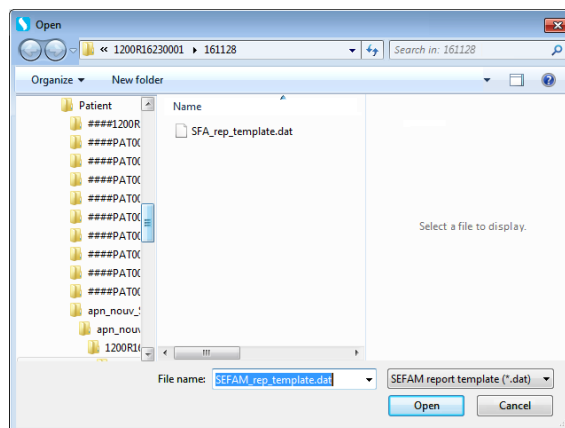
### Note:

The information included in the provider logo is imported or exported simultaneously with the report templates.

### a) Importation

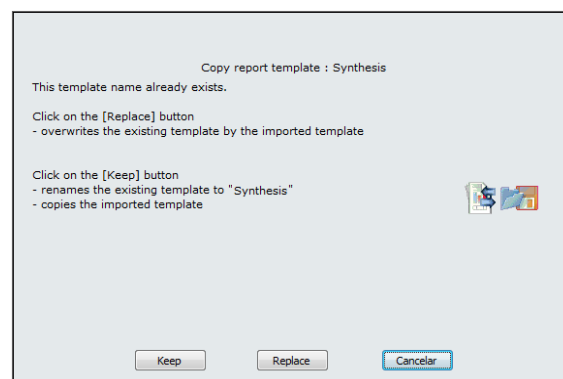
The button **Import** allows you to add one or several report templates to those already present. In the window which appears, select the file of the templates to import.

The templates will be imported directly if they are not already present in the software.



Otherwise, a dialogue box opens allowing to  or  a template by clicking on the corresponding button.

A message confirms the importation of the report templates. Click on **OK**.



## b) Exportation

The button  allows saving one or more templates present in the software. A message warns you if there is no model to be exported.

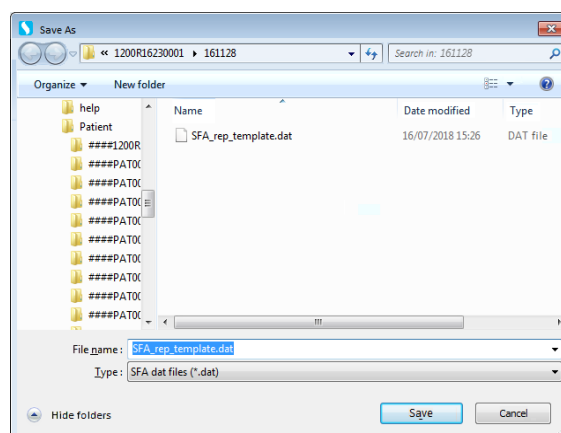
Otherwise, a dialogue box shows the number of templates to export and asks if you want to continue exporting. Confirm by clicking on **OK**.



In the window which then opens, you can select a support or a directory in which the templates file will be saved.


Click then on .

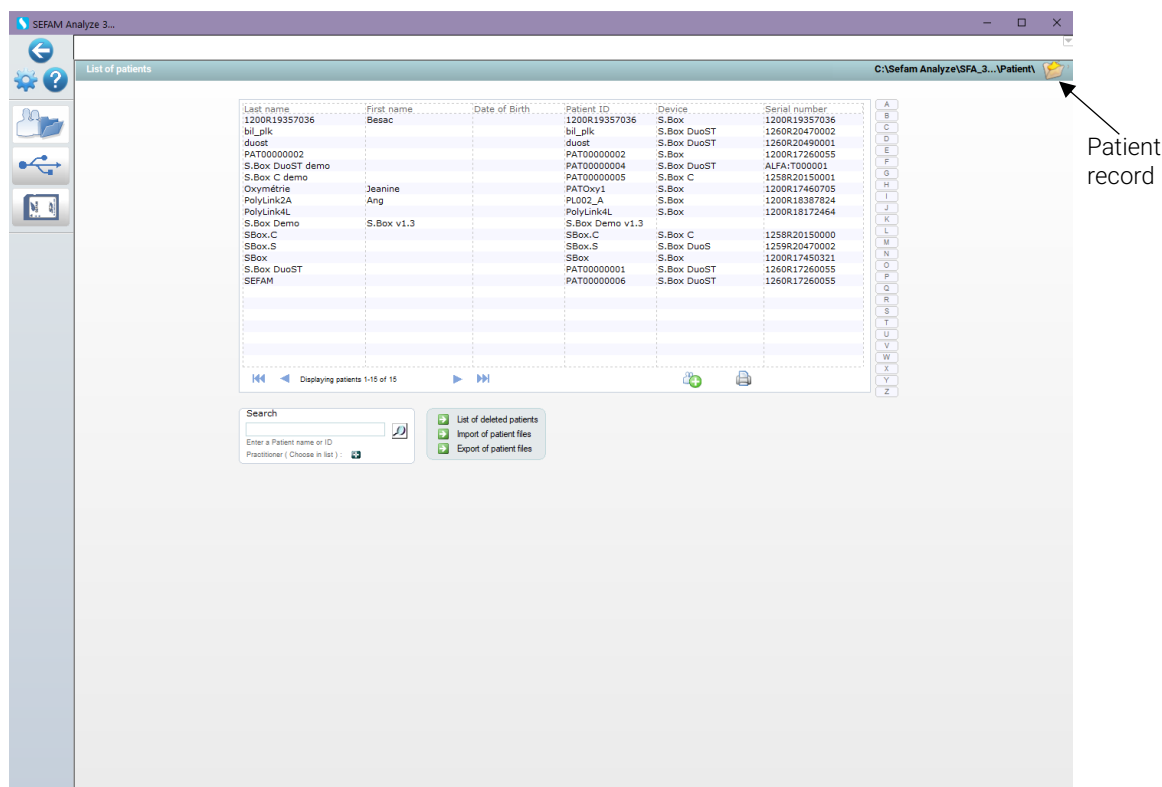
A message confirms the exportation of the report templates. Click on **OK**.







# Patient management

## Patient list


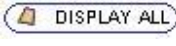
By clicking on , the List of patients opens including all the patients for whom the software keeps data (personal information and about the equipment used, compliance data).



The icon located in the upper right-hand corner allows accessing the patient record which is located by default in the software installation directory, but you can select another patient record.

You can scroll the list of patients forth and back by using  and . You can also go directly to the top of the list or directly to the end of the list by clicking on  or on .


The list of patients can be sorted alphabetically by selecting the corresponding letter on the right part; only will be displayed names beginning with the selected letter.

You can also search for a patient by his or her Identifier in the **Patient ID** column or by typing the first letters of his/her name in the **Search** field then clicking on . All the names which include these letters are then displayed on the screen. Click on  in the upper right of the Patient List if you wish to return to the whole list.

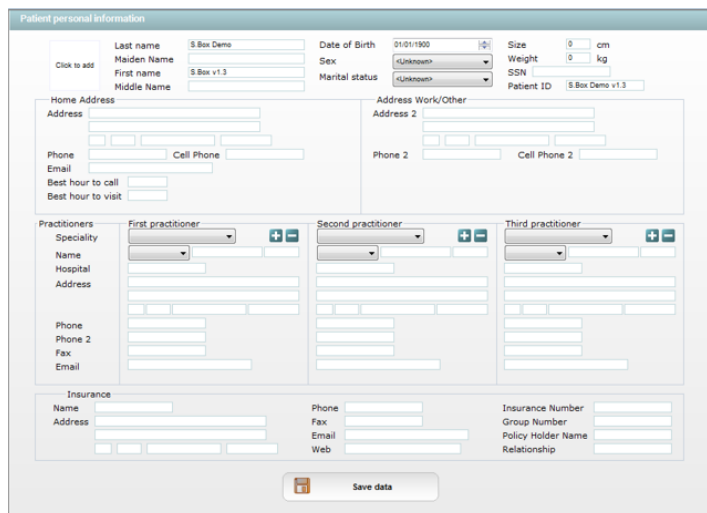
# Patient information


## 1. Displaying information



Select a patient by clicking on his/her name. The name of this patient appears at the top of the window and you can consult or modify the information recorded


by clicking on the icon  **Modify** at the top of the patient list.

From the window displayed, you can add, change or delete information by using the Tab key on your keyboard to move from field to field.




To add a photo, click on  in the upper left of the window. In the **Open** dialogue box which is displayed, you can select an image file which will be copied to the directory of the patient concerned.

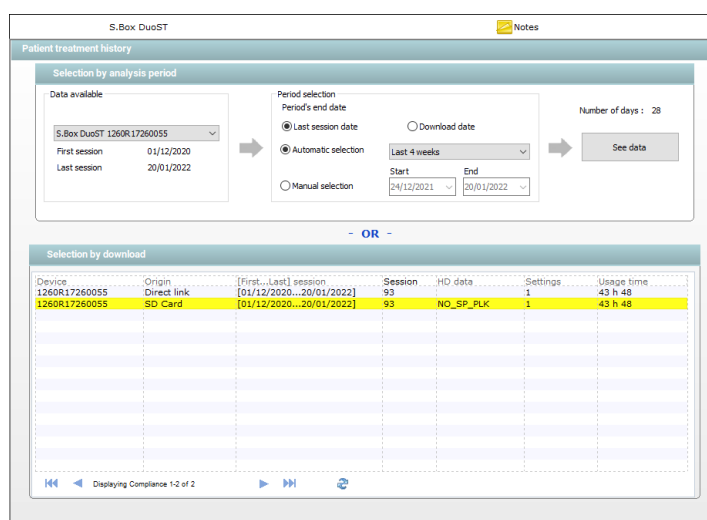
The button  on the right part of the input field of the physician's name allows to access the list of physician profiles recorded on your computer hard drive. When you select a physician and click on **OK**, all information about this physician (speciality, hospital, address, email, fax, etc.) is imported into the patient information. The list is automatically updated when a new physician is entered into a patient profile. In the same way, a physician's name can be removed from the patient record by clicking on .

When you have finished making changes, click on . In the window which appears, click on **OK** to confirm; otherwise press on Cancel.

## 2. History of treatment

You can access a treatment history of a patient by selecting the  **Treatment History** or by double-clicking on the patient's name.


The presentation which appears will give information concerning the machine, the sessions recorded, the period selected, etc. The browser of downloads available for a patient informs about the presence of data downloaded by direct link or from the SD card (curves in real time and compliance data).




Device	Origin	[First...Last] session	Session	HD data	Settings	Usage time
1260R17260055	Direct link	[01/12/2020...20/01/2022]	93	NO_SP_PLK	1	43 h 48
1260R17260055	SD Card	[01/12/2020...20/01/2022]	93	NO_SP_PLK	1	43 h 48

You can choose **Download date** which is the date of the day or prefer **Last session date** to avoid displaying a non-compliance period when the last data recovery is old.


You can either make a **manual** selection of the data analysis period or select one of the eight analysis periods proposed right of the **Automatic selection** option. By default, the software will automatically select the last 4 weeks.

By clicking on , you access the compliance data recorded over the period. You can also select a specific data file by double-clicking on one of the lines displayed.


The compliance list is automatically updated each time this screen is opened, but a new update can also be performed by clicking on .

Click on  to return to the patient list.

### 3. Creating a patient

Click on  to create a new patient; up to 20,000 patients can be created.


A new record will open, and you can enter information about the patient by using the Tab key on your computer keyboard. The information concerning this patient will be recorded by clicking on

. You will then come back to the list of patients to which the new patient will be added.


#### **Note:**

When compliance data is read for a patient not included in the list, the creation of a new patient profile is proposed automatically so that the data can be saved.

### 4. Deleting a patient


If you want to delete a patient, select his/her name in the list and click on . In the dialogue box which appears click on **OK** to confirm deletion or click on **Cancel** if you wish to keep the patient.

#### **Note:**

To permanently delete a patient's data, click on  in the upper right-hand corner of the screen and remember the patient ID displayed at the top. Then using Windows Explorer, search in the Patients root directory the name which has the patient's ID preceded by characters #####. Delete this directory and all the files included.

### 5. Adding comments

You can add simplified comments for a particular patient file.

To do this, select it and click on . In the window which appears, you can enter free notes, HD data notes or notes concerning the PolyLink polygraphy.

You can also insert the date by clicking on .

Click on **OK** to confirm; otherwise press on **Cancel**.

Date stamp

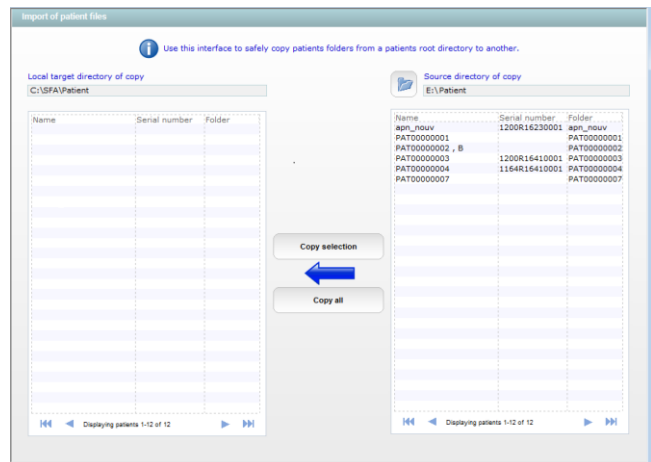



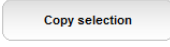
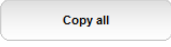
# Other utilities

## 1. Import of patient files

By clicking on **Import of patient files**, you can import one or more patient records and all the compliance data files they contain from a source directory to a local target directory.

This interface ensures that when you merge two patient lists you will not create two records per patient in the same root directory.



1. From the right-hand window, select the source directory by clicking on  and choose in the list the patient file to be copied.
2. In the left-hand window, select the target directory where you want to place the copy and click on  or  to copy the file(s).

When patient files are copied into a directory which already contains files for this patient, a window will appear which proposes to select the data of the patient that you wish to keep.

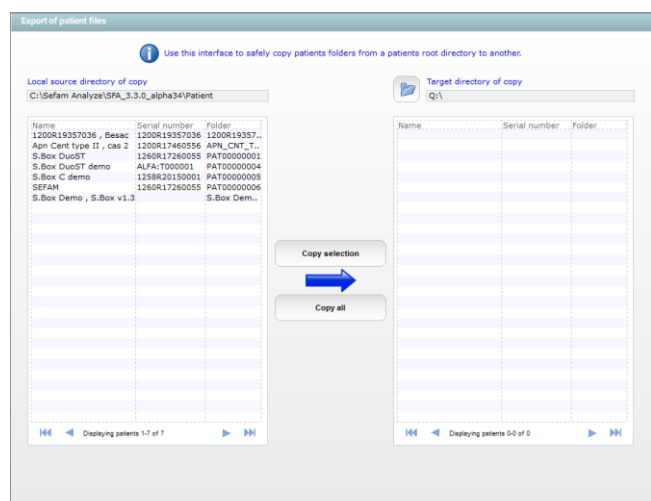
### Notes:

- The patient identifier is modified between the source directory and the target directory.
- The directory paths selected are memorized for future use.

## 2. Export of patient files


By clicking on **Export of patient files**, you can export one or more patient directories and all the compliance data files they contain from a local source directory to a target directory. Follow the same procedure as for importation.

This option is recommended for archiving patient files of the root directory used by the software into a separate backup directory which has been selected.



## 3. List of deleted patients

The **List of deleted patients** option enables to display the list of patient's files which have been deleted but you no longer have access to these files.

Each time, click on  to come back to the patient list.



# Displaying compliance data

Compliance data is displayed automatically after the download via a direct link with the device or using a SD card.

The last recorded compliance data can also be viewed directly from the patient list. Refer to "Patient management" on page 13.

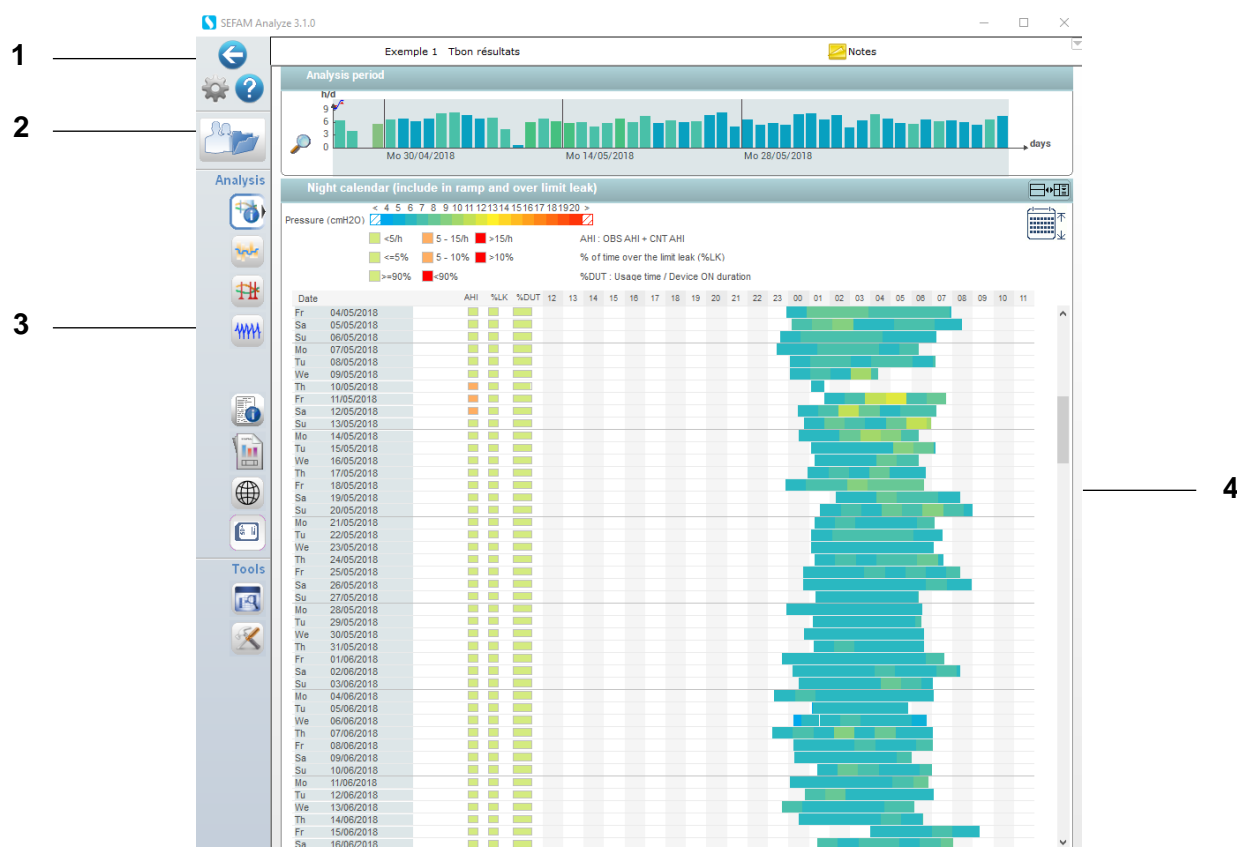
The window which appears shows all the information recorded for a session.

## Notes:



- The sessions which contain data errors are not displayed.
- The buttons of the toolbar provide access to different presentations of the compliance data. The names of the presentations to which they give access appear when positioning the mouse over the buttons.
- In all the presentations, the leak displayed is the average level of unintentional leak in the mask during the period of use.

## Organization of compliance data

The screenshot below shows the usage of a S.Box device, but the information displayed will vary depending on the device and the settings used.





## 1. Identification of the selected patient

The patient's name is displayed at the top of the window. By clicking on  in the upper right corner of the screen, other data can appear (patient's identifier and age...) if available in the patient record. Additional information can be added by clicking on  ; see paragraph "5. Adding comments" page 15.

## 2. Analysis period


The **Analysis period** section presents a compliance condensed diagram which remains displayed according to the presentation selected.

The value on the horizontal axis represents 24-hour periods and the value on the vertical axis represents the daily usage duration during which the patient breathed with the mask.


The symbol  indicates a setting change and the symbol  shows 10 Hertz flow curves in real time at the corresponding dates of the compliance condensed diagram and night calendar. If present, the symbol **HD** shows HD curves and the symbol **PL** indicates data from the PolyLink kit.

### Notes:

- there is no flow symbol if the download has been performed from a SD card.
- there is only one flow symbol if only one download has been performed by a direct connection and there are several symbols if there has been a merger of several downloads performed by direct connection.

When the compliance data record exceeds a given number of days, a Zoom button  appears in the lower left corner of the graph and the icon is visible only when this feature is enabled. It allows you to view all sessions or a subset.


## 3. Night calendar

The statistical report is displayed by default in the central part and the button  gives access to the night calendar which gives a quick overview of patient compliance across the most recent recorded sessions.

**With S.Box and S.Box C devices**, the colour scale indicates the average pressure levels for the 24-hour period.



**With the S.Box DuoS and S.Box DuoST devices**, the colour scale indicates the average respiratory rate levels for the 24-hour period.


A 24-hour period can be selected from the calendar by clicking on the desired date. The corresponding information will then appear in the Statistical report on the right part.

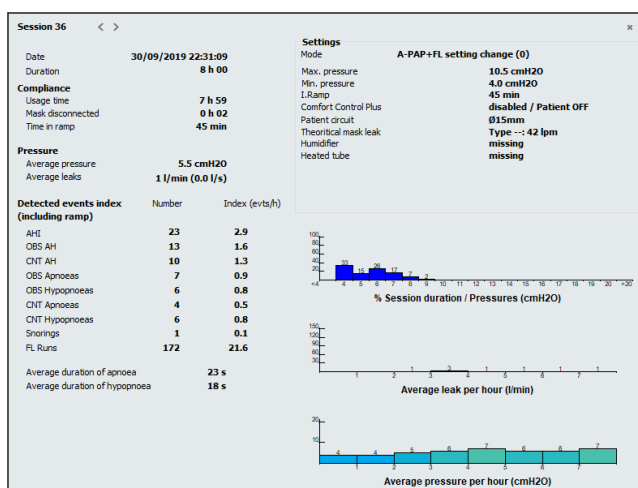
The HD curves for the 24-hour period can be accessed by double-clicking on the **HD** icon on the right side of the date concerned. Select another period if no curve displays. The button  appears when the days of the calendar cannot all be displayed on one screen, it allows by a quick scrolling down to display the most recent days.

If you double-click on a session, the **Session** window will be displayed.

The information shown varies depending on the S.Box range device used.










The previous session or the next session can be displayed by using buttons  and .

Close the window by clicking on  in the upper right corner.





















## 4. Compliance data

Each of the first 7 buttons on left gives access to a **presentation** displayed on the right side or to a specific dialogue box.


Analysis	Presentation displayed:
	➔ Statistical Report
	➔ Treatment evolution profile / Statistical Report
	➔ Waveforms
	➔ Flow: is displayed only if download by direct link.
	➔ Access HD signals: is displayed only if download is done by SD card.
	➔ Global information / Settings list
	➔ Analysis Compliance Report
	➔ Send compliance data to SEFAM Connect
	➔ Patient card

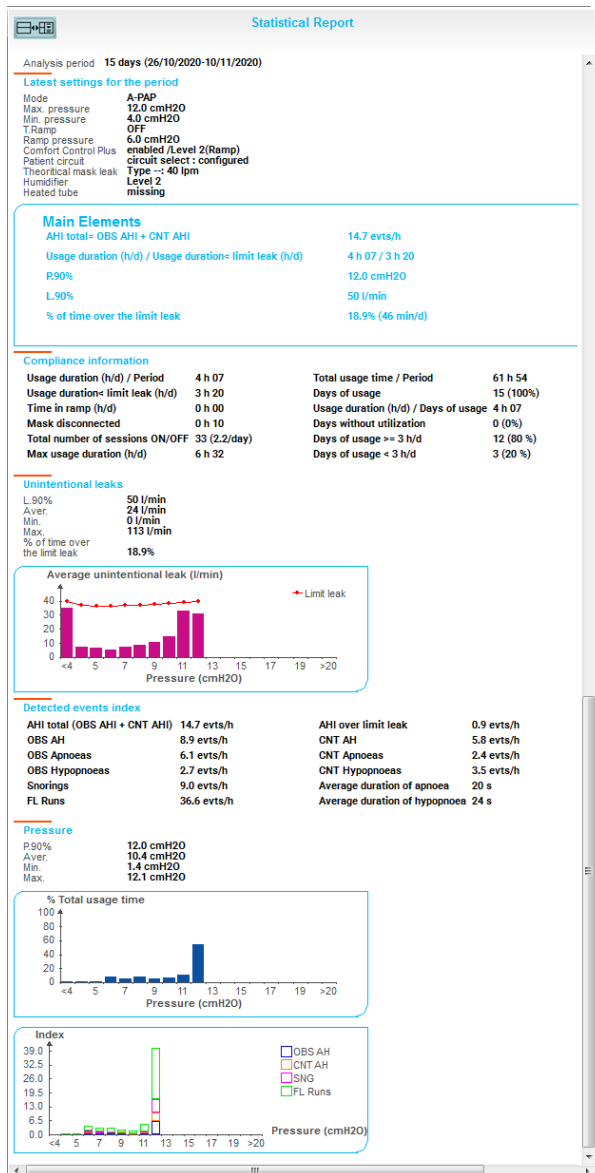
Additional buttons allow using specific **tools** according to the chosen presentation. The data displayed on the right part will then take into account the options selected with these buttons.

Tools	Available in the presentations:
➔ Period selection	 ,  ,  ,  ,  , 
➔ Add a screen copy in memory	 ,  , 
➔ View screenshots in memory	 ,  , 
➔ Direct print of screen page or Printing	 ,  , 
➔ Settings	 ,  , 

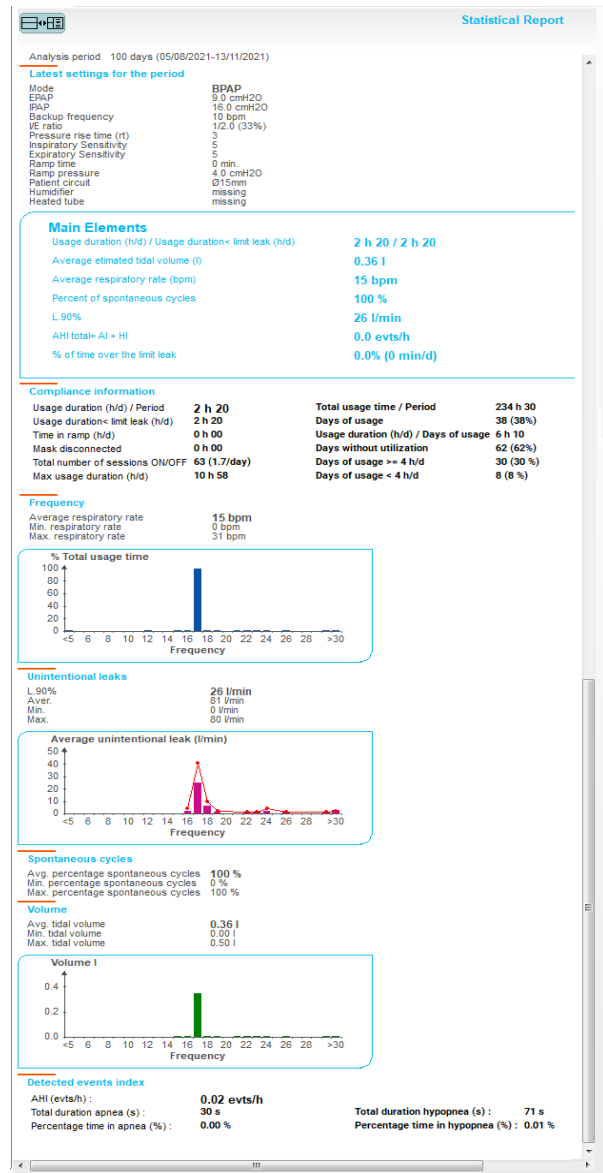
# The different presentations

## 1. Statistical report

This tab is displayed by default or can be accessed by clicking on . The information shown depends on the device used.



With the S.Box device



With the S.Box DuoST device

The header concerns the analysis period selected. Then, the information is shown in headings.

**Latest settings for the period:** operating mode, pressure values, parameters and features specific to the device, accessories used.

### Main Elements

#### Compliance information

- Usage duration / period
- Usage duration < duration over limit leak
- Time in ramp and time with the mask disconnected
- Total number of sessions ON/OFF
- Max usage duration

- Total usage time / period
- Days of usage
- Usage duration / days of usage
- Number (and %) of days without utilization
- Number (and %) of days of usage  $\geq X$  h/d and of usage  $< X$  h/d (X fixed in analysis parameters)

#### Unintentional leaks

- Leak reached Y % of time (Y fixed in analysis parameters)
- Average or min. and max. values of unintentional leaks measured in the mask
- % of time over the limit leak
- Diagram of Unintentional leak and of limit leak for each full pressure or frequency value

If the S.Box or S.Box C device is used:

#### Detected events index

- Total AHI and AHI over limit leak
- Index of the respiratory events detected over the period analysed
- Average durations of an apnoea and an hypopnoea

#### Pressure

- Pressure efficient more than Z % of time (Z % fixed in analysis parameters).
- Average or min. and max. pressures measured over the period analysed.
- Diagrams of total usage time percentage and of events index for each full pressure value.

If the S.Box DuoS or S.Box DuoST device is used

#### Frequency

- Average, min. and max. respiratory rates measured over the period analysed.
- Diagram of total usage time % for each full frequency value.

#### Percent of spontaneous cycles with S.Box DuoST only

- Minimum, maximum and average percentages of spontaneous cycles
- Percentages of spontaneous cycles above the limit leak


#### Volume

- Values calculated of the minimum, maximum and average estimated tidal volume over the analysed period.
- Diagram of the estimated tidal volume for each full respiratory rate value.

#### Detected events index

- AHI
- Average durations of an apnoea and an hypopnoea
- Time percentage in apnea and time percentage in hypopnea




The button  displays a dialogue box in which the analysis period is selected depending on the setting changes. All the settings or specific settings can be selected (or deselected) by checking the corresponding date(s).

Settings list

☐ Select all / ☐ Deselect all

Date	Mode	Prescribed pressure	Min. pressure	Max. pressure	Ramp	Ramp time	Ramp pressure	Comfort Control Plus
<input checked="" type="checkbox"/> 10/10/2020	A-PAP	-	4.0	20.0	T.Ramp	15min	4.5	0
<input type="checkbox"/> 11/10/2020	CPAP	8.0	-	-	I.Ramp	-	4.5	R.0
<input type="checkbox"/> 13/10/2020	CPAP	8.0	-	-	I.Ramp	-	4.0	R.0

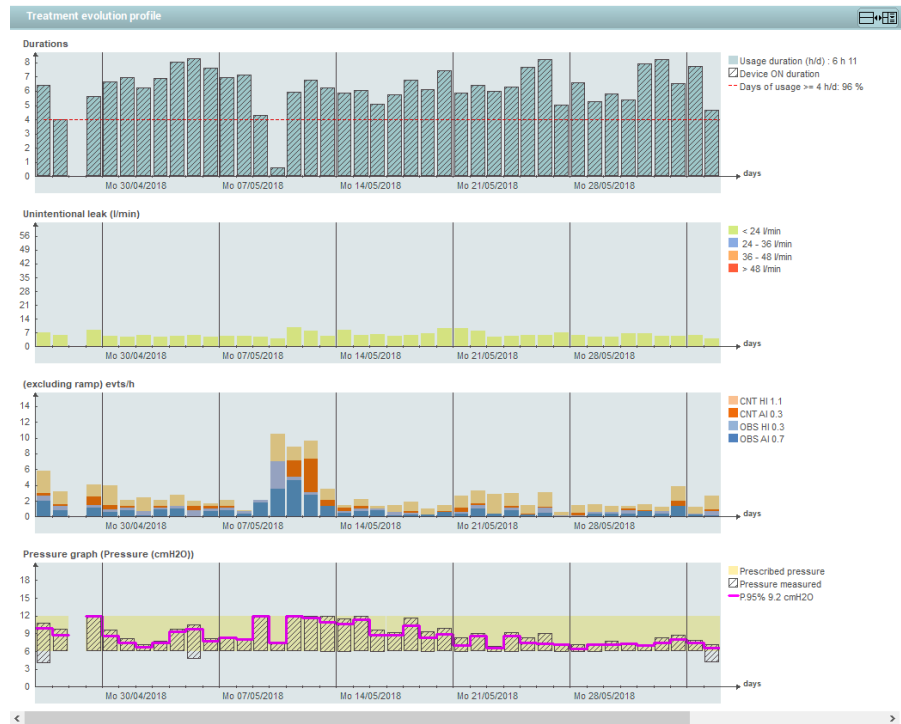
OK Cancel

The "Compliance" tab of the analysis parameters dialogue box can be opened by clicking on  or by clicking on the statistical report with the right button of the mouse (refer to the paragraph "4. Choice of analysis parameters" page 9).

## 2. Treatment evolution profile

The tab can be accessed by clicking on .

It concerns the analysis period selected in the graphs displayed on the left side of the window.



### a) Treatment evolution profile

Four graphs are displayed from top to bottom with the 24-hour periods in abscissa. The data displayed will differ depending on the S.Box range device used.


- Graph of usage duration and a dotted line which symbolizes the % of days with usage duration  $\geq$  number of hours per day selected in the analysis parameters. The usage duration is displayed in green if its value is higher than the value selected. Otherwise, it is represented in orange.
- Graph of unintentional leak

If the S.Box or S.Box C device is used:

- Graph showing index of detected events including or not the time in ramp
- Graph of pressures: prescribed pressure (yellow background), pressure measured (oblique shading) and P.90% = pressure efficient for 90 % of time (pink curve), 90 % being adjustable in the analysis parameters

If the S.Box DuoS or S.Box DuoST device is used:

- Graph of percentages of average spontaneous cycles
- Graph of respiratory rates: respiratory rate measured (oblique shading), average respiratory rate for each day of use (blue curve) and backup frequency (yellow background) with S.Box DuoST only.

The button  allows to display both the treatment evolution profile and the statistical report, or to display only the graphs, thus increasing their readability.

A 24-hour period can be selected by clicking on the desired date or the whole period of analysis can be selected, the corresponding information is displayed in the report on the right side.

Details of the parameters and events detected depend on the options selected in the dialogue box of analysis parameters (see paragraph "4. Choice of analysis parameters" page 9).

### b) Statistical Report


This report is described in the paragraph "1. Statistical report" page 20.

### 3. Waveforms

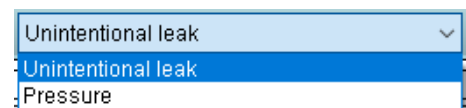
The curves can be accessed by selecting .

First, this presentation gives a summary view and then a larger view of the measured leak and of the detected events during the recording.

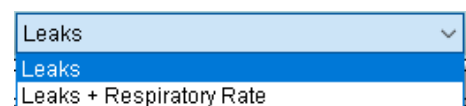



The button  allows to display both the detailed curves and the waveform report, or to display only the curves, thus increasing their readability.


With **S.Box** or **S.Box C**, the drop-down list on the right part allows you to select the display of the measured unintentional leak levels or of the pressure curve in the mask.



With **S.Box DuoS** or **S.Box DuoST**, it allows you to select the display of the measured leak levels and/or of the respiratory rate.



Enabling the command  **Remove areas over limit Leak** allows to exclude from the calculations, which produce the data in the report, the zones defined by a leak measured above the limit leak.

By clicking on the drop-down list  **08h00** or by using the mouse wheel, you can select a duration corresponding to the page width of the larger view.

If the **S.Box** or **S.Box C** device is used, you can see in the central section the events encountered and managed by different colour codes, the Runs indicating a breathing period with limited flow and UA status characterizing variations in resistance of the upper airways.

If you place the mouse over a bar which signals one or more detected events, the number of associated events will be displayed at this level by holding down the right button of the mouse.

Then are displayed the waveforms of unintentional leak and limit leak, then the curves of pressure.

If the S.Box DuoS or S.Box DuoST device is used, you can see in the central section the waveforms of tidal volume, of limit leak and of unintentional leak, of respiratory rate and of percentage of spontaneous cycles (only with S.Box DuoST).

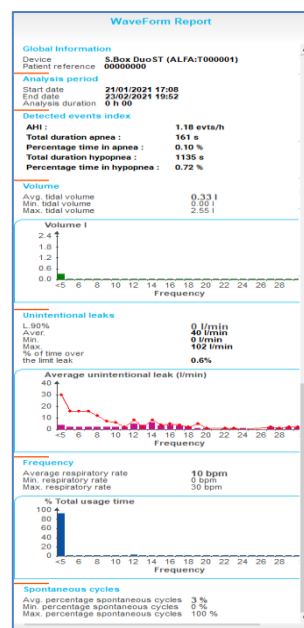
A cursor can be displayed in the selected section of the Waveforms if you click with the left button of the mouse on one of the curves and the values shown in the right section correspond to the values associated with cursor's X-axis coordinate.




Setting changes and Sessions are indicated in the lower part. The periods highlighted in yellow are those during which a ramp was used.

If present in the right-hand part, the Waveform report (enlarged view) lists all compliance data.

**Note:**


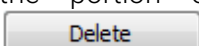
In the report, the data is calculated based on the curve portions displayed on the screen. Thus, the data can be modified by using the zoom feature.



The buttons ,  and , specific to the Waveforms, Flow and Access HD signals presentations, are described hereafter.

You can add to the report a portion of curve in the memorised selection.

Click on  then  to open the opposite dialogue box.

The button  allows you to display the portion of the curve and the button  to remove it.

If you have proceeded to modifications, click on **OK** to confirm. Otherwise, click on **Cancel**.

The dialog box is titled 'Report / Memorised selection'. It contains a table with two columns: 'Start' and 'Duration'. The first row shows '25/01/2020 15:41:24' and '3 min.' respectively. Below the table are four buttons: 'Display', 'Delete', 'OK', and 'Cancel'.





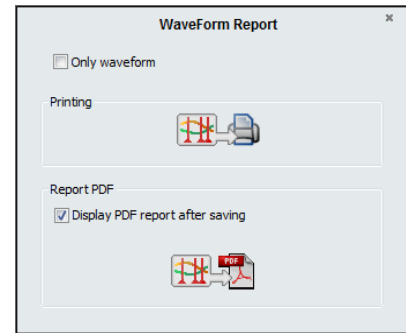
The button opens the Waveform Report print box:

The two specific buttons allow printing the waveforms and their report and exporting them in PDF file format adapting their size to the space available. Only the portion of the waveform visible on the screen will be printed or exported.

This dialogue box gives you the ability to select only the waveforms in the report or/and to display the PDF report after saving.

Close the window by clicking on the cross in the upper right corner.

To print or export the complete compliance data report, refer to "7. Analysis Compliance Report" page 36.

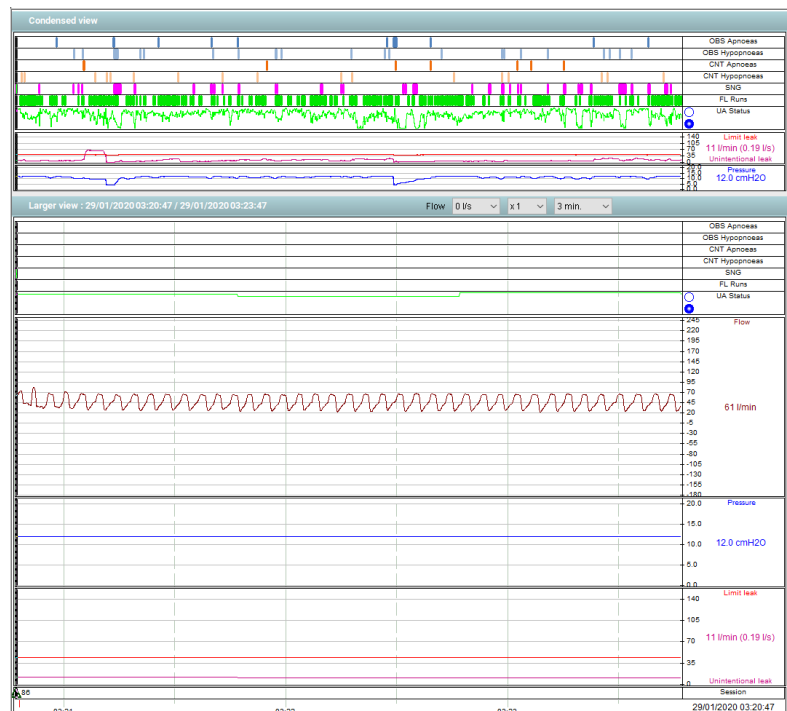


## 4. Flow



The Flow tab can be accessed by

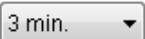
The curves are displayed only if the compliance data was downloaded by direct connection.

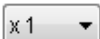
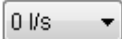





If the **S.Box** or the **S.Box C** device is used, this presentation shows first a summary view of the detected events, runs with Flow Limited, UA status, unintentional and limit leaks and pressure. In the second part, are displayed more detailed views of detected events, curves of flow, measured pressure levels and unintentional leak.

If the **S.Box DuoS** or **S.Box DuoST** device is used, the presentation shows first a summary view of the apnoeas and hypopnoeas detected, unintentional and limit leaks, and respiratory rate. In the second part, are displayed more detailed views of detected events, as well as curves of flow, tidal volume, unintentional leak, respiratory rate measured and spontaneous cycles only with S.Box DuoST.

You can browse through the record using either the mouse or the → and ← keys of the computer keyboard.

The drop-down list  or the + and – keys allow you to change the page duration. It can also be changed using the mouse wheel.

The drop-down list  or the \* and / keys modify the signal gain, while the drop-down list  or the ↑ and ↓ keys shift the height curve.

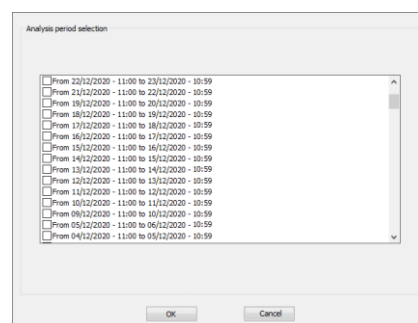
Refer to "3. Waveforms" section page 23 for using the buttons ,  and .


## 5. Access HD signals

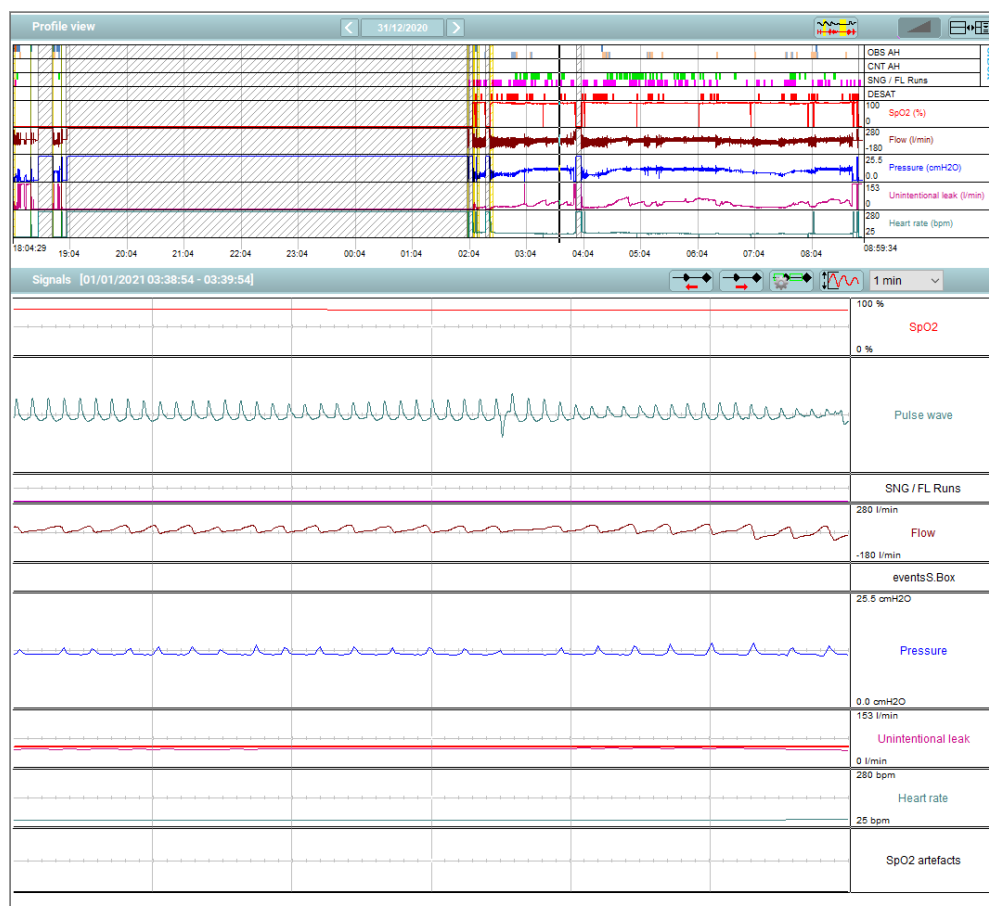
### a) Description

Access to signals downloaded from a SD card is performed by clicking on .

When you click on this button for the first time for a patient, a dialogue box proposes the available recordings of data and you can select the analysis period by clicking on the opposite box.

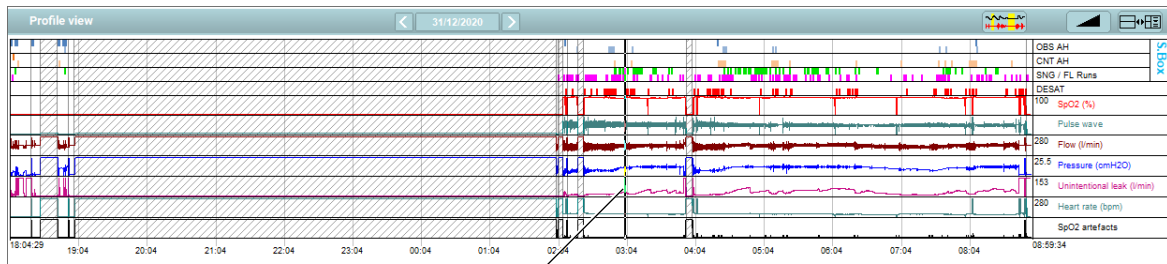


In the window which appears, the button  allows you to spread the space between the view of raw signals or/and the HD recording report. According to your choice, the recording report may be hidden.





## 1. Profile view


The profile view displays the condensed curves.



Time marker

The button displaying the current date allows to select an analysis period and the buttons  and  allow moving from a period to another.

A time marker can be displayed if you left click with the mouse on the condensed curves. It allows identifying the night period displayed in the window.

The button  allows displaying the time in ramp which appears hatched.

S.Box or S.Box C  
(without accessories)

Channel	Unit	Frequency (Hz)
<input checked="" type="checkbox"/> Flow	l/min	25
<input checked="" type="checkbox"/> Pressure	cmH2O	5
<input checked="" type="checkbox"/> Unintentional leak	l/min	1

OK All / None Cancel

S.Box DuoS or S.Box DuoST  
(without accessories)

Channel	Unit	Frequency (Hz)
<input checked="" type="checkbox"/> Flow	l/min	25
<input checked="" type="checkbox"/> Pressure	cmH2O	25
<input checked="" type="checkbox"/> Unintentional leak	l/min	1
<input checked="" type="checkbox"/> Respiratory Rate	bpm	25
<input checked="" type="checkbox"/> Tidal volume	cl	5

OK All / None Cancel


If you right-click with the mouse on the condensed curves, a dialogue box displays the list of channels acquired which can be selected. This will differ depending on the S.Box range device used.

### Note:

All the channels are selected by default.

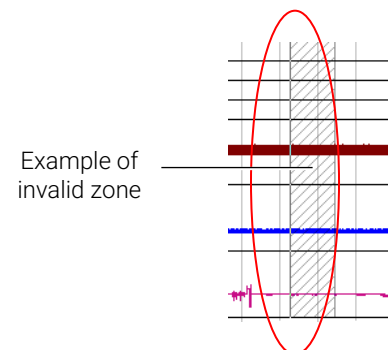
Confirm your choice with **OK**. Only the channels selected will be displayed in the order listed in the dialogue box.

The analysis profile allows to “create” manual invalid zones (for example in case of sensor loss) symbolized by a hatched background.

To create an invalid zone, press  and click in the analysis profile at the beginning of the period and slide until the end of the period, then release.

As long as the button is enabled, you can:

- change the duration of a zone by clicking on the left or right side of the area and by sliding to the desired size.
- delete a zone after having selected it by clicking once on it and by using the right mouse button.



Example of invalid zone

The duration of this (these) zone (s) will be deducted from the recording time to calculate the analysis duration.

## 2. Viewing the raw signals

This window allows you to view the signals acquired on the SD card.

As in the "Profile view", the list of the channels which can be selected displays by right-clicking with the mouse on the curves.

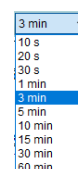




On the right-hand side of the curves, the values displayed correspond to the signals measured on the cursor's position in the abscissa: flow, pressure, unintentional leak whatever the S.Box device used and respiratory rate, tidal volume specific to S.Box DuoS or S.Box DuoST device.

If you click in one curve, the cursor will move on the item address and the values displayed will be modified accordingly.


You can select a duration corresponding to the page width of the signals by clicking on

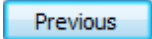
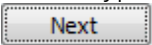
This duration can also be changed with the mouse wheel.

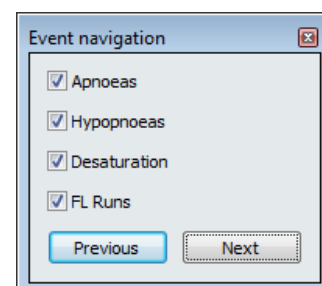



You can move a page forward or backward through the recording using the buttons  and  as well as the keys → and ← of the computer keyboard. You can also move forward or backward by ½ period pressing simultaneously the corresponding arrow and Ctrl key.

To facilitate the visualization of signals and events, you can center the page by pressing the CTRL key and by left clicking simultaneously with the mouse on a signal or on an event.

The button  allows configuring the navigation in the recordings regarding one or more event types selected in the opposite dialogue box.

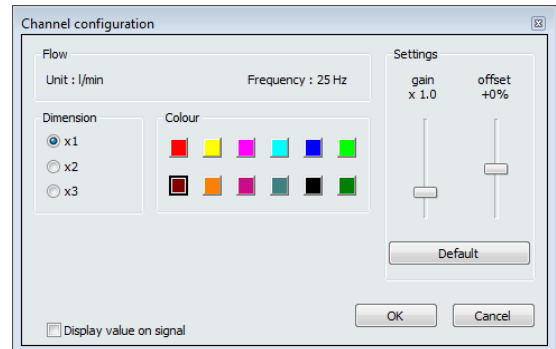
Select the types of events and if you click on  or , you move the recording of an event or several types backward or forward.



The button  allows you to automatically adjust the gain and the offset of the channels selected in the window.

The names of selected channels and a simple scale are displayed on the right part of the raw signals window.

If you left click with the mouse on the name of a channel, a dialogue box allows access to the settings:



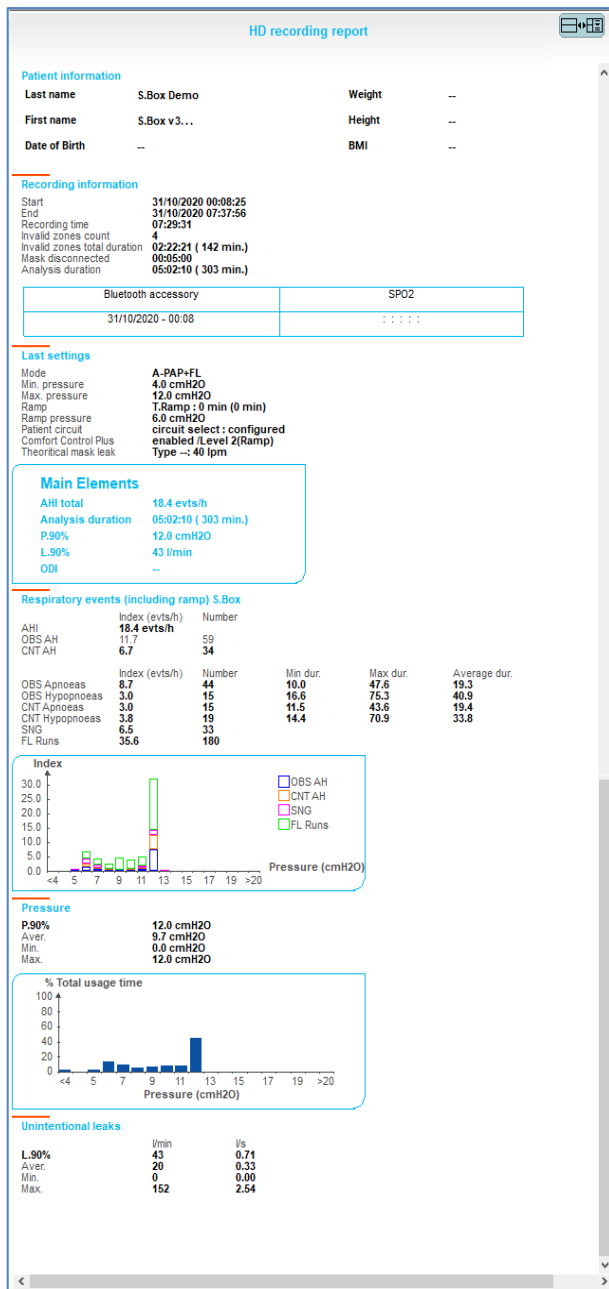
Possible settings:

- channel dimension: height of the channel considered in the window, the others share the residual space. The gain and offset values will be adjusted to the new dimension.
- colour of channel among the basic colours available.
- gain and offset of the signal. In case of change, the name of the channel displayed will be followed by "!"

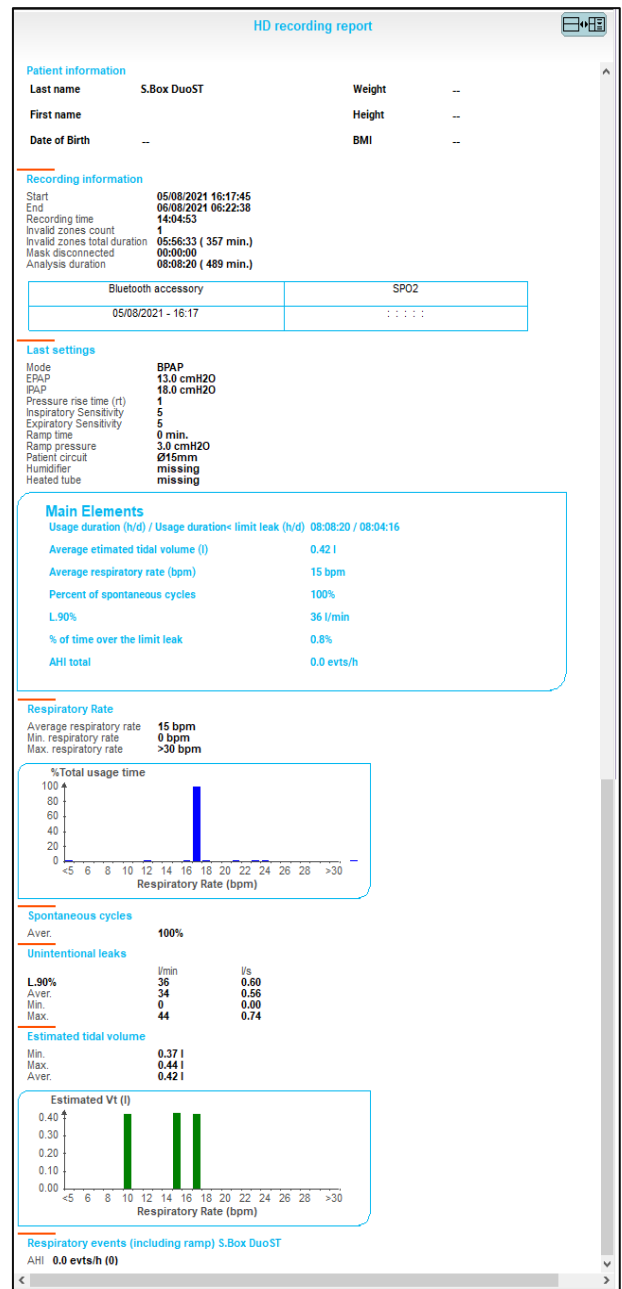
You can also choose to display the value on signal.

### 3. HD recording report

The information shown in the report is displayed on the right-hand side of the window.



With S.Box device



With S.Box DuoST device

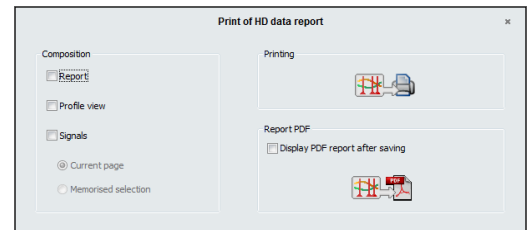
The patient information is shown in the header, followed by the recording information. The other report information is displayed, grouped in headings, and differ depending on the S.Box device used. The other report information is grouped in sections and depends on the S.Box device used:

- **Latest settings for the period:** operating mode, pressure values and accessories used.
- **Main elements.**
- **If the S.Box or S.Box C device is used,** information is then detailed regarding detected respiratory events (including or not ramp), followed by the pressure and the unintentional leaks.
- **If the S.Box DuoS or S.Box DuoST device is used,** data are detailed regarding respiratory rate, unintentional leaks and estimated tidal volume, as well as the detected respiratory events (including or not ramp) and the spontaneous cycles (with S.Box DuoST only).

For using the buttons  and  refer to 3. Waveforms" section page 23.

The data can be printed by clicking on .

In the following dialogue box which appears, the two buttons are specific to this tab and allow to export the report, the profile view, and the signals (current page or memorised selection) in PDF file format or/and to print them in adapting their size to the space available



This dialogue box allows you also to display the PDF report after saving.

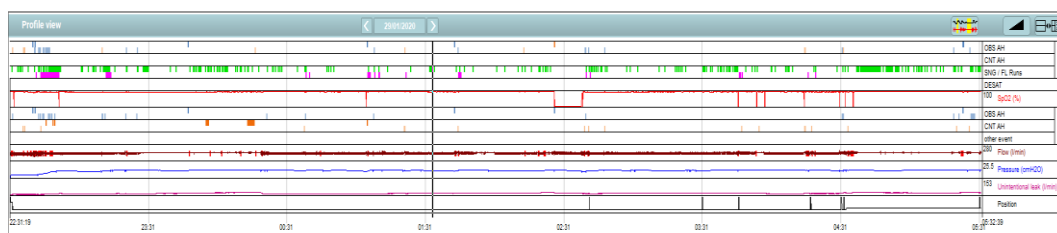
**Note:**

When selecting all pages of the signals, the number of pages printed may be important. Make sure of the availability of paper sheets in your printer.

## b) Specifications of the recording when using the PolyLink kit

When signals from the PolyLink kit have been recorded, the presentation of the HD curves is globally similar to that of the S.Box range device signals (with or without oximetry), but in addition, the interface includes modules of automatic analysis allowing the scoring of respiratory events. So, you have the ability to modify or delete the events scored automatically and to create some manually, the creation of manual events taking precedence over automatically detected events.

### 1. Profile view from PolyLink signals



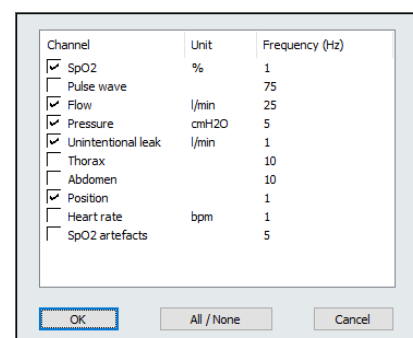
S.Box events

Events scored

The events of the polygraphic scoring from the PolyLink kit, detected automatically or manually, are displayed in addition to the events detected by the S.Box range device. To be able to differentiate them, the events are grouped in two categories identified in the header by "S.Box" and "PLK" (PolyLink).

If you right-click with the mouse on the condensed curves, a dialogue box displays the list of channels acquired which can be selected.

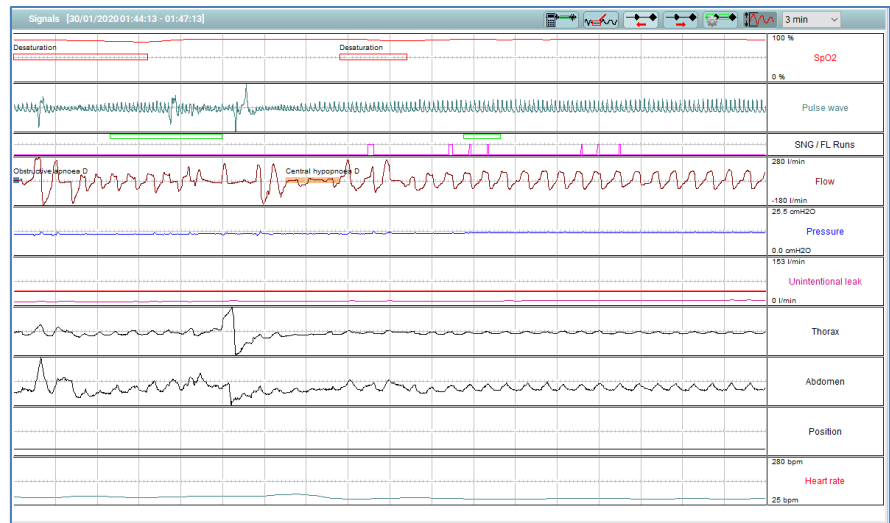
The channels "Thorax", "Abdomen" and "Position" can be displayed in addition to those of the S.Box range device and of oximetry (if it is present).



## 2. Viewing the PolyLink raw signals

The list of the channels which can be selected displays by right-clicking the signals.

Display of the selected signals from the S.Box range device, from the PolyLink kit and from oximetry (if present).



The window of the PolyLink signals analysis proposes **two specific buttons** located above the signals.



### a) Setting of the automatic analysis parameters


The button  displays a dialogue box in which you can set:

- the minimum duration of an apnoea or/and of an hypopnoea (from 2 to 20 s)
- the amplitude decrease of an hypopnoea (from 10% to 60%)
- the criterion of desaturation (from 1 to 10%)
- the time between the event end and the beginning of the desaturation in case of link between both.

The screenshot shows the 'Analysis Module' dialogue box. It contains several settings: 'Apnoea' with a checked box and 'Minimal duration' set to 10 (s); 'Hypopnoea' with a checked box, 'Minimal duration' set to 10 (s), and 'Amplitude decrease' set to 30 (%); 'Desaturation' with a checked box and a value of 3 (%); and 'Link with desaturation' with a checked box and 'Delay after event' set to 20 (s). At the bottom right, there are 'OK' and 'Cancel' buttons.



### b) Edition or modification of events manually

The button  can be used to create events manually or modify / delete existing events, automatic or manual. If you click on the button, a tool  appears at the cursor level.

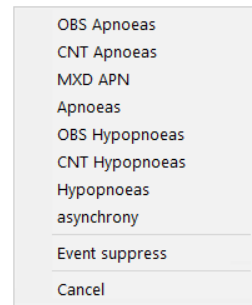
**Creation of an event:** with the mouse, position the tool  at the beginning of the event that you want to create in the selected channel. Slide the tool until the end of the event and release it. The event appears then as a coloured horizontal rectangle identified by its type and its duration.

**Selection of an event:** click on the event. A coloured strip appears vertically in the whole signals window, delimiting the event. Clear the selection by clicking elsewhere in the window.



**Modification of an event:** you can change the event duration by placing the tool  at the beginning or at the end of the event, the tool turns into . Using the mouse, you can increase or decrease the duration of the event.

You can also change the event type by selecting it and right-clicking with the mouse to access the dialogue box of manual events. You can then choose the type of event which will replace the previous one.



**Suppression of an event:** select the event. Right-click with the mouse to access the dialogue box of manual events. Then select "Event suppress".

**Notes:**

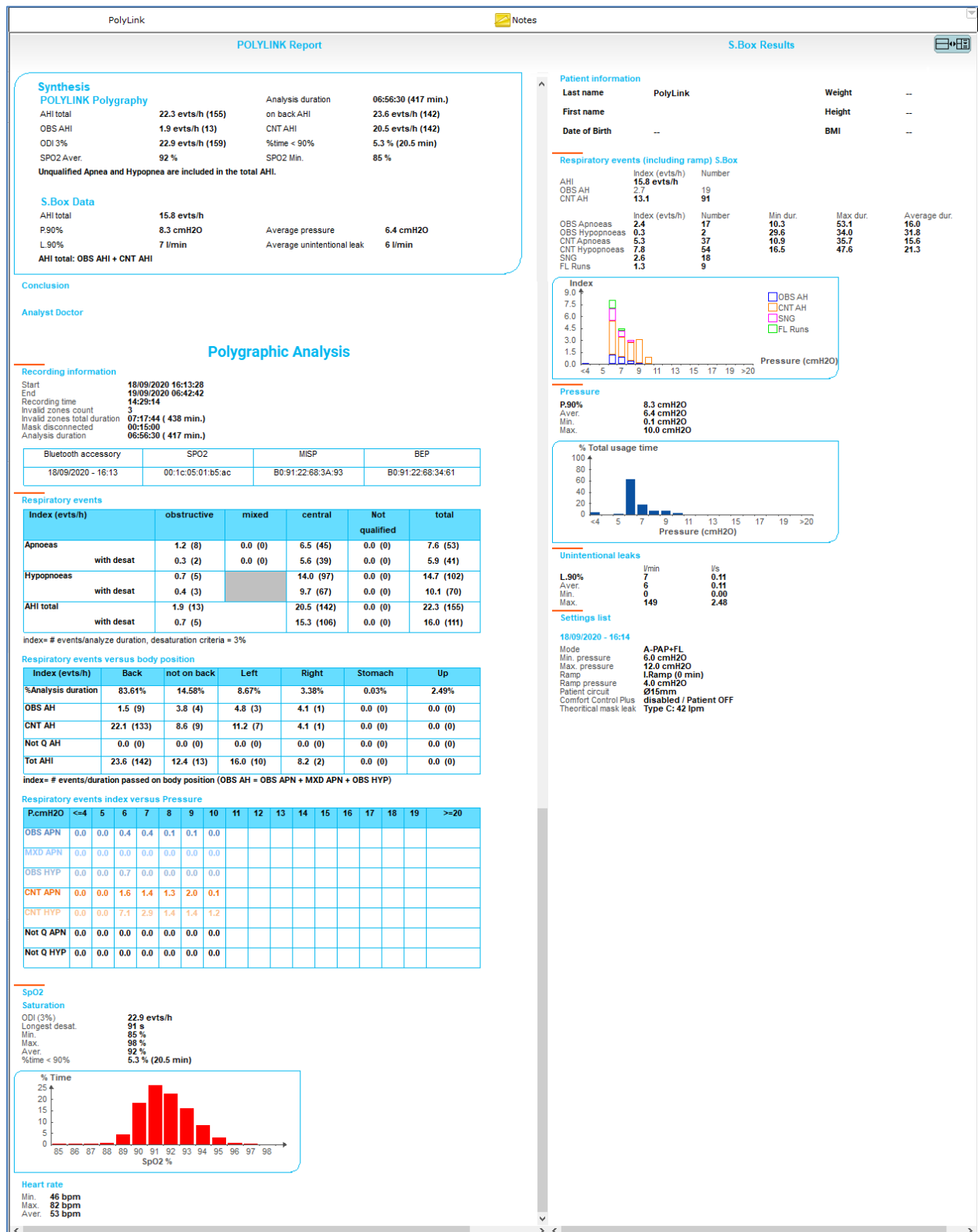
- You can create or modify an event in the "Flow", "Pressure", "Unintentional leak", "Thorax", "Abdomen", "Position" channels, as well as in the "Pulse wave" and "Heart rate" ones.
- The "SpO<sub>2</sub>" channel can be used to manually create or modify desaturation events only.

### 3. Recording report of PolyLink signals

Click on the button  to access the PolyLink recording report.

The report begins with information about the patient followed by a synthesis of the recording and the conclusion of the analyst doctor. The polygraphic analysis is then detailed, as well as the results concerning the S.Box range device and oximetry (if it is present).


## Example of PolyLink report



The PDF report can be displayed after recording and printed using the button



## 6. Global Information / Settings list

This tab can be accessed by clicking on .

Global information		Settings list	
<b>Device</b>		<b>12/09/2020 - 23:19</b>	
Device	S.Box (VER :A020000)	Mode	A-PAP
Serial number	1200R19357036	Max. pressure	10.5 cmH2O
Patient reference	R9357036	Min. pressure	4.0 cmH2O
Hour counter - Configuration	1 h 24	I Ramp	45 min
Hour counter - Downloaded	120 h 16	Ramp pressure	4.0 cmH2O
Global period	34 days ( 11/09/2020 - 14/10/2020 )	Comfort Control Plus	disabled / Patient OFF
Average operation time / day	3 h 30 ( Total period = 116 h 52 )	Patient circuit	Ø15mm
Total usage time	115 h 31	Theoretical mask leak	Type --> 42 lpm
Average usage time / day	3 h 24	Humidifier	missing
Configuration date	11/09/2020 - 20:46	Heated tube	missing
Download date	15/10/2020 - 20:19	<b>11/09/2020 - 23:03</b>	
Total number of sessions	47	Mode	A-PAP
Average number of sessions / day	1.39	Max. pressure	12.0 cmH2O
Downloaded sessions	47	Min. pressure	4.0 cmH2O
		I Ramp	45 min
		Ramp pressure	4.0 cmH2O
		Comfort Control Plus	disabled / Patient OFF
		Patient circuit	Ø15mm
		Theoretical mask leak	Type --> 42 lpm
		Humidifier	missing
		Heated tube	missing
		<b>11/09/2020 - 22:55</b>	
		Mode	CPAP
		Prescribed pressure	10.0 cmH2O
		T Ramp	OFF
		Ramp pressure	4.0 cmH2O
		Comfort Control Plus	disabled / Patient OFF
		Patient circuit	Ø15mm
		Theoretical mask leak	Type --> 42 lpm
		Humidifier	missing
		Heated tube	missing
		<b>11/09/2020 - 20:47</b>	
		Mode	A-PAP
		Max. pressure	12.0 cmH2O
		Min. pressure	4.0 cmH2O
		I Ramp	45 min
		Ramp pressure	4.0 cmH2O
		Comfort Control Plus	disabled / Patient OFF
		Patient circuit	Ø15mm
		Theoretical mask leak	Type --> 42 lpm
		Humidifier	missing
		Heated tube	missing

### a) Global information

Shows all the information concerning the device used.

- device with the embedded software version shown in brackets.
- serial number of the machine (this cannot be modified).
- reference assigned to the patient.
- hour counter at the Configuration
- hour counter at the Download
- global period
- average operation time / day
- total usage time
- average usage time / day


Are following: date and hour of machine configuration and of download, total number of sessions recorded by the device and average number of sessions per day, as well as total number of downloaded sessions.

### b) Settings list

The list reflects the days selected in the night calendar.


The different settings of the device are displayed from the most recent to the oldest, and the dates and times correspond to the start of sessions affected by the new settings.

The parameters are listed for each setting change and the information displayed depends on the device used and on the operating mode selected.


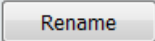
Click on  to return to the patient compliance list.

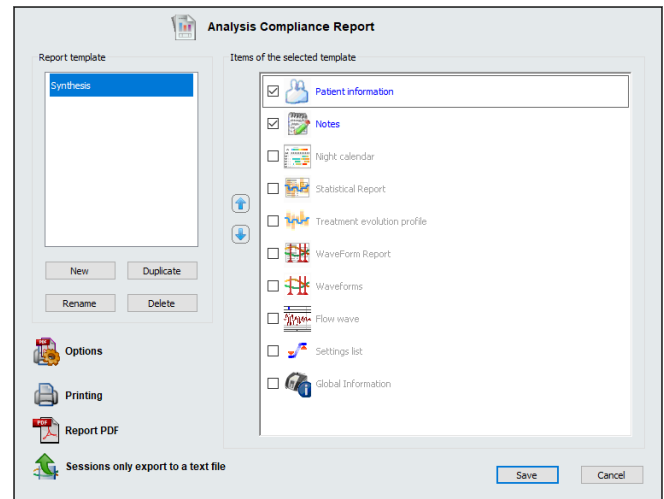
## 7. Analysis Compliance Report

### a) Printing and exporting reports

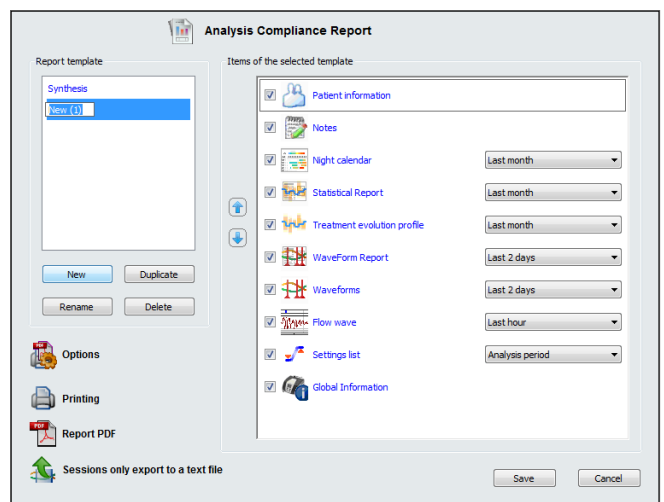
Select first a period of analysis, then click on  to display the **Analysis Compliance Report** window.

A template of analysis compliance report exists by default: **Synthesis**.

You can create other compliance report templates by clicking on . A line is added to the left part **Report template** and you can enter the name of the new template directly by clicking on it or by clicking on . The new report template parameters are set by default.





The report items can be selected in the right part **Items of the selected template** by checking the box in front of each item, then the analysis period is proposed for each of them in a drop-down list.

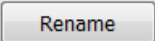



If in **Waveforms** or / and **Flow wave** tab(s), you added a portion of curve in the memorised selection, the field "Memorised selection" is proposed in the drop-down list.

#### Notes:

- The item print sequence is user-definable by using the  or  arrow to move the item forward or backward.
- The selected items are memorized for future print jobs.
- If you have chosen the "Waveforms" item with "memorised selection", you cannot choose the "Waveform Report" item.

You can create a copy of an existing report template by clicking on .

The name of this copy or of an existing compliance report template can be modified by selecting it and clicking on . This option allows you to rename the report and to select or deselect the items that you want to print. It is also possible to delete a report template by selecting it and clicking on .



The icon allows you to access the following window in which printing options and pdf options are set by default. Printing options may also have been configured when installing the software.

Besides the usual configurations common to all printers, you can select:

- **Scale** for the waveform and flow wave
- **Night calendar in black and white**
- **Avoid page break**: the items are listed in brackets
- **Display PDF report after saving**
- **Default zoom (opening PDF report)**
- **Enable encryption** by password protection of PDF exported.

#### CAUTION

If needed, you can enable the protection by a password by checking the "Enable encryption" box. It is the responsibility of the user to validate or not this possibility.

Click on **OK** to confirm the new configuration.

The password protection status is indicated on the button which generates the Report PDF

The report can be printed by clicking on **Printing**. The compliance analysis report will resume faithfully the information presented on the screen, and only will be printed the personal information which are completed for the patient.



By clicking on , you can export the compliance data report as a PDF format file,. The file can be saved to the hard drive of your computer.

## b) "Export of sessions only to a text file" feature

This feature allows you to export data for statistical analysis in file which can be read by spreadsheet softwares based on data formats different from the format used by **SEFAM Analyze**.

The export file format generated is a UNICODE text format with a semi-colon (;) field delimiter which cannot be changed.

Exported file names consist of the name of the corresponding patient file plus an extension which specifies the file content.



Click on **Sessions only export to a text file** in the Analysis Compliance Report window to launch the export module.

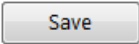
The **Save As** dialogue box appears with the name, the path where the created file will be saved, and the file type with the .txt extension. Click on **Save**.

#### CAUTION


After creating the file, it is recommended that you make a copy of the file in a separate directory before making changes in it using the spreadsheet programme.

The data exported with S.Box range device concerns a session and can be displayed in columns, as shown in the example hereafter:

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	
1	Session	State	Date	Time	Duration	Total usage t	Mask discon	Time in ramp	Average pre	Average leak	AVG_RESPI	AVG_RATIC	Percent of sy	OBS APN	CNT APN	OBS HYP	CNT HYP	Snor
2	1	OK	02/12/2020	10:47:56	00:03 0 h 02		0	3	63	153	18	39	30	0	0	1	0	
3	2	OK	21/01/2021	17:07:57	00:09 0 h 08		0	0	66	163	10	33	3	0	0	0	0	
4	3	OK	22/01/2021	16:33:10	00:12 0 h 01		0	0	79	155	25	30	100	0	0	0	0	
5	4	OK	03/02/2021	16:45:53	00:04 0 h 03		0	0	80	142	10	32	0	0	0	1	0	
6	5	OK	04/02/2021	16:15:54	00:13 0 h 12		0	0	80	148	14	35	18	0	0	2	0	
7	6	OK	04/02/2021	16:43:16	00:31 0 h 30		0	0	79	152	10	33	1	0	0	1	0	
8	7	OK	05/02/2021	14:00:04	01:00 0 h 59		0	0	80	152	10	33	1	0	0	1	0	
9	8	OK	05/02/2021	15:02:59	00:16 0 h 01		0	7	70	148	27	47	100	0	0	0	0	
10	9	OK	05/02/2021	16:19:37	00:04 0 h 01		0	0	59	136	23	40	100	0	0	0	0	
11	10	OK	05/02/2021	16:23:47	00:36 0 h 35		0	0	84	161	10	33	1	1	0	0	1	
12	11	OK	09/02/2021	16:42:03	00:08 0 h 07		0	5	72	147	10	33	4	2	0	0	2	
13	12	OK	09/02/2021	16:50:02	00:02 0 h 01		0	1	60	128	13	30	21	0	0	0	0	
14	13	OK	09/02/2021	16:51:24	00:21 0 h 20		0	2	79	152	10	33	1	1	0	0	1	
15	14	OK	15/02/2021	14:33:11	00:01 0 h 01		0	1	63	135	13	30	27	0	0	0	0	
16	15	OK	15/02/2021	14:36:12	00:06 0 h 05		0	2	81	157	10	32	0	1	0	0	1	
17	16	OK	15/02/2021	14:41:45	00:30 0 h 29		0	2	86	165	10	33	1	2	0	0	2	
18	17	OK	19/02/2021	15:31:13	00:54 0 h 53		0	2	90	164	10	33	1	2	0	0	2	
19	18	OK	22/02/2021	16:58:12	00:03 0 h 02		0	2	64	62	19	25	86	1	0	0	1	

Click on  to save your modifications or on Cancel and the analysis compliance report dialogue box will close.

## 8. Send compliance data to SEFAM Connect

If you click on , a dialogue box appears in which you can choose to send the compliance data to SEFAM Connect:


- from last session recorded on SEFAM Connect
- from a date selected
- all sessions.

**Send compliance data to SEFAM Connect**

☒ from last session recorded on SEFAM Connect  
09/02/2022



☐ from

☐ all sessions


Click on the button . A message confirms the data send success.

## 9. Patient card

You can prepare a SD card to be used by a patient already registered in the software (for whom compliance data has already been retrieved). A device/serial number association is used to make the operation secure.

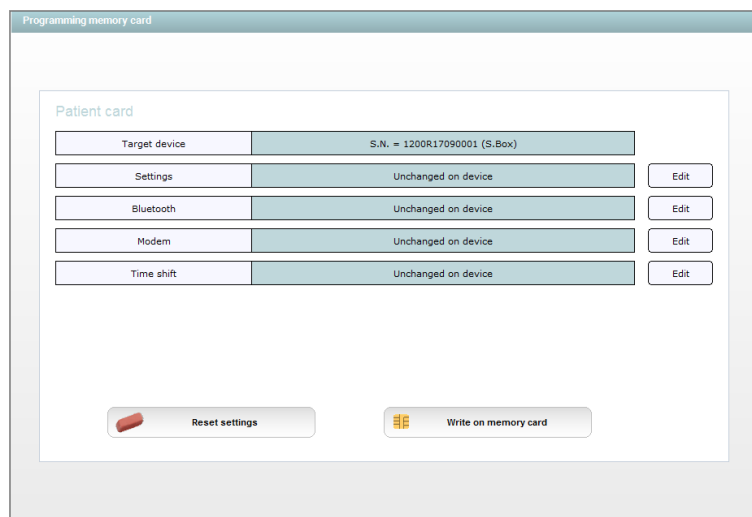
A patient must first be selected from the patient list before clicking on  or .

The window which appears allows to define settings.

The button  on the right part of each parameter allows to display the corresponding dialogue box.

Each time you modify a parameter, the new setting appears in the central strip, which changes colour.

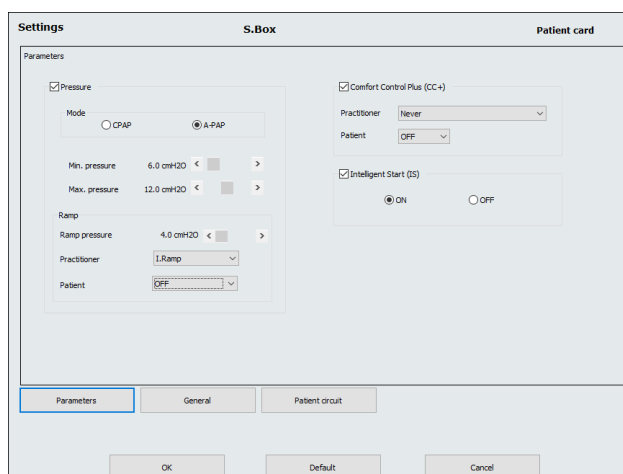
If a parameter has not been modified, the central strip displays "Unchanged on device".



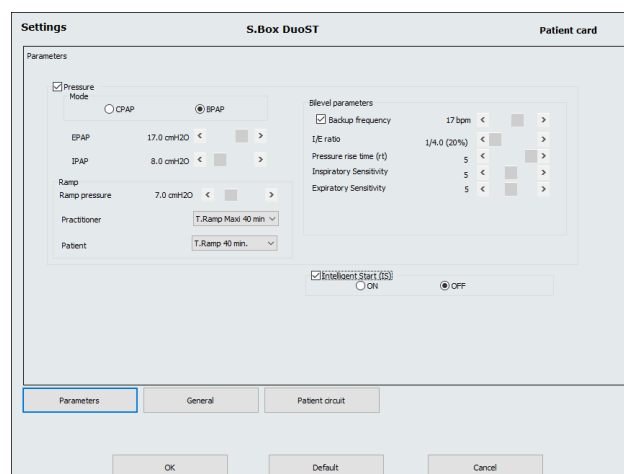
## a) Target device

The serial number of the device is displayed in the central section.

## b) Settings

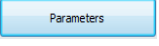


With S.Box or S.Box C




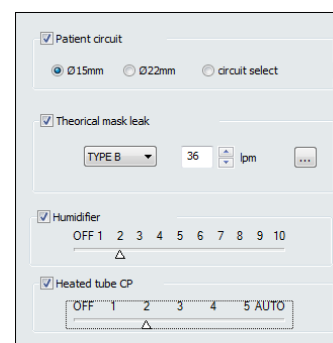
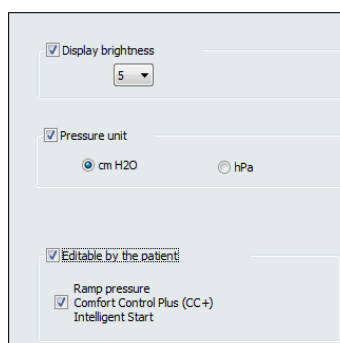
With S.Box DuoS or S.Box DuoST

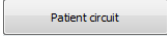

In the window which appears, the three buttons at the bottom allow activating groups of different settings.

With the  button and depending on the device used, you can access several groups of settings:

- Pressure, Comfort Control Plus (CC+) and Intelligent Start features with S.Box or S.Box C
- Pressure, Bilevel parameters and Intelligent Start features with S.Box DuoS ou DuoST.

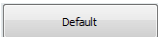
With the  button and depending on the device used, you can access device settings (brightness and pressure unit) and unlock or not the access to 2 or 3 settings by the patient (Ramp pressure, Intelligent Start and Comfort Control Plus CC+) depending on the S.Box used.



The button  allows accessing the configuration of patient circuit, humidifier and heated tube (if installed). You can also select the type of theoretical mask leak – –, A, B or C. The button  allows to view the list of masks available. Search and select the mask. Click on **OK**, the corresponding value of the theoretical mask leak will be displayed.

By checking the box next to a group, the corresponding settings appear and you can modify them. Refer to the chapter "b) Settings:" page 43 for the description of all the possible settings.

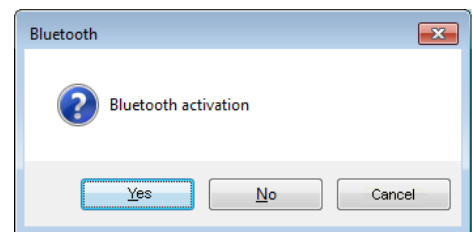
Once the settings entered, validate them with **OK**; otherwise click on Cancel. The new settings will appear in the central strip which will change colour.

You can also restore the default settings by clicking on .

### c) Bluetooth

Activate the Bluetooth feature by clicking on **Yes** in the dialogue box which opens. Otherwise, click on **No** or Cancel to withdraw your action.

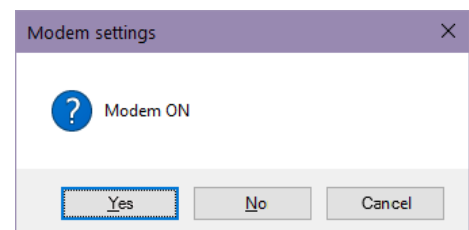
The central band will display "**Bluetooth enabled**" or "**Bluetooth disabled**" according to your selection.



### d) Modem

Activate the Modem by clicking on **Yes** in the dialogue box which opens. Otherwise, click on **No** or on Cancel to withdraw your action.

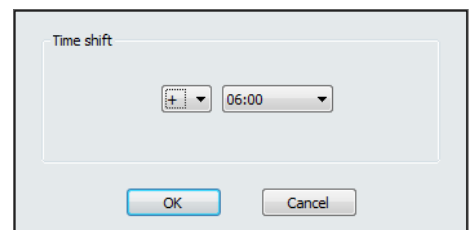
The central band will display "**Modem ON**" or "**Modem OFF**" according to your selection.



### e) Time shift

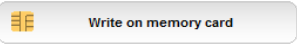
The dialogue box which appears allows you to select the number of hours and minutes in + or in - of the current time (with a setting step of 15 minutes).

Click on **OK** to confirm the setting; otherwise select Cancel.



Each time a parameter is modified, the new setting appears in the central strip, which then changes colour. If a parameter has not been modified, the central strip displays **Unchanged on device**.

The changes can be cancelled by clicking on . The central strip will display **Unchanged on device** again.

Click on  to apply settings to the SD card. A window sums up the settings.

Click on **OK** to confirm; otherwise click on Cancel. Select then the memory card reader in which the SD card is inserted.



**Note:**

The SD card needs to be inserted into the memory card reader of the computer to apply the new settings.

A dialogue box informs you that writing is done and that the memory card can be removed from the computer reader.

The settings written on the SD card can be recorded in the technical notes of the patient.

# Configuring the device

## Connecting to the device

A computer can be connected to a S.Box range device.

The USB port at a speed of 921,600 bauds is selected by default. You can configure another communication speed by following the instructions in paragraph "2. Serial link setup" page 9 before connection. Then connect the USB cable:

1. Place the device on a flat and stable surface.
2. Connect the USB cable to the USB connector of the device (see patient manual).
3. Connect the other end of the USB cable to the corresponding port of the computer.

### CAUTION



- Only use the USB cable included in the S.Box range authorised accessories. Using other cables could damage the device.
- The welcome screen is automatically displayed when the communication is lost.

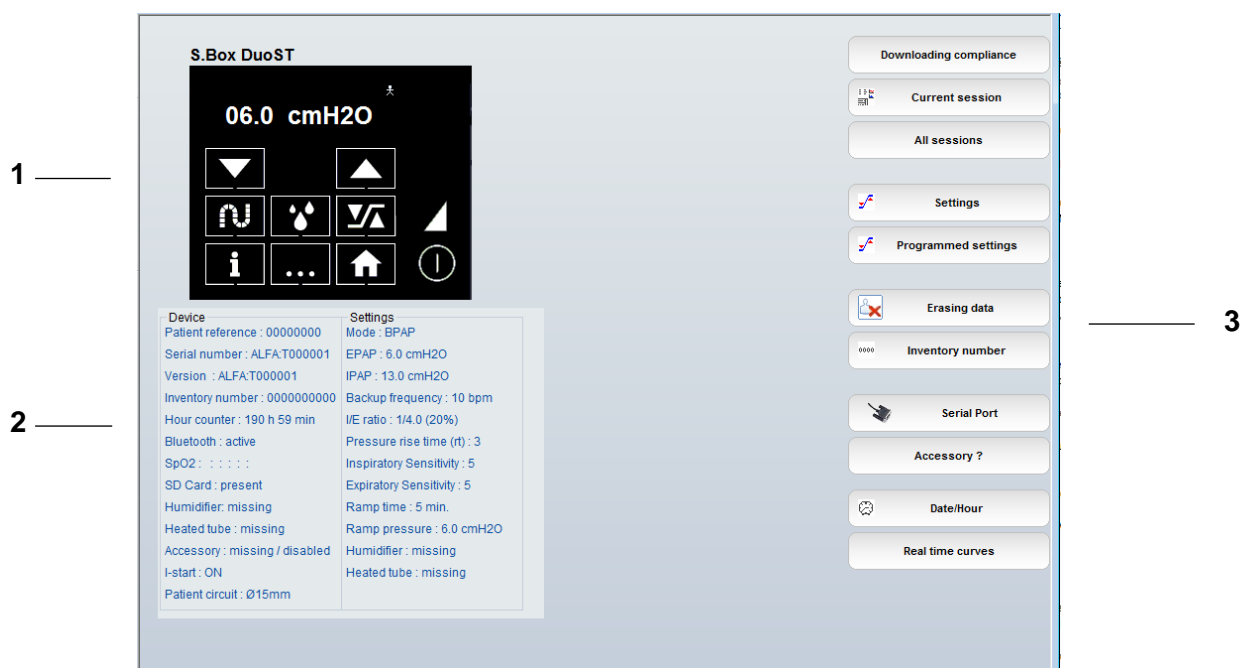
You can also access settings via a Bluetooth connection, if the corresponding feature has been enabled in the dialogue box of the serial link setup.

### CAUTION

The Bluetooth connection will be active if a Bluetooth radio has before been installed and/or enabled on your computer.

## Description of the connection screen

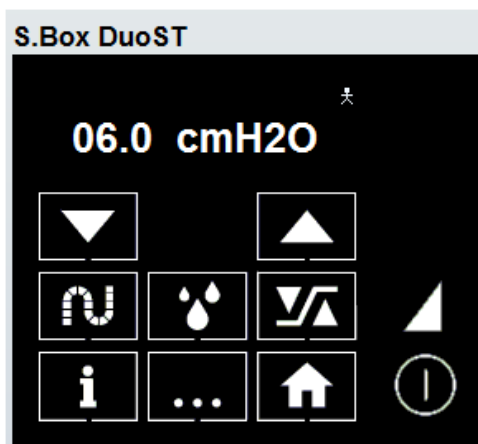
Click on the bouton  or . The window of connection which appears is divided in three parts.



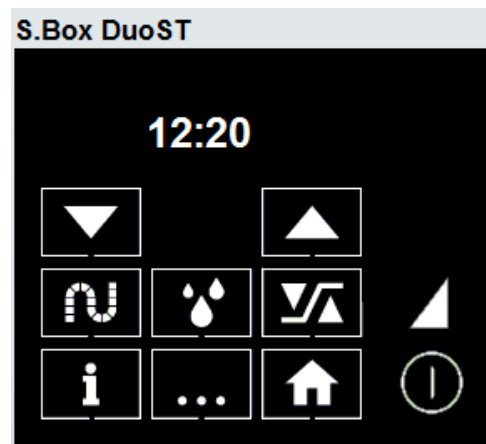
# 1. Display

The device used is identified above the display.

The display shows the status of the machine, the current time if the device is in standby mode or the pressure estimated in the mask, updated in real time, when the machine is operating.



Device in operation



Device in standby



The buttons (1.) and (2.) are operational and are used:

1. to switch the device ON or OFF
2. to enable or disable the ramp function.

The eight buttons of settings are also operational and allow to remote control the S.Box range device from the software. Their functions are described in the patient manual.

## 2. Information displayed

The information displayed under the device identifies the machine and shows the settings:

### a) Device:

- Patient reference
- Serial number
- Version
- Inventory number
- Hour counter

Are then listed: activation or not of Bluetooth and I.Start (Intelligent Start) features, presence or not of accessories (SD card, humidifier, heating tube, communicating accessory) and patient circuit diameter.

### b) Settings:

The information displayed varies depending on the S.Box device used.

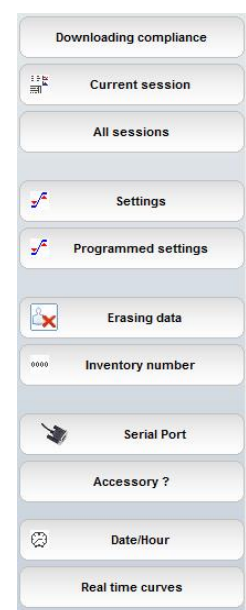
- **Operating mode:**
  - Constant CPAP available on all S.Box devices
  - A-PAP (Auto-CPAP) available only on SEFAM S.Box device
  - BPAP (Bilevel) available on S.Box DuoS or S.Box DuoST.
- **Pressures:**
  - Prescribed pressure in CPAP mode
  - Min. Pressure and Max. Pressure in A-PAP mode
  - EPAP (expiratory pressure) and IPAP (inspiratory pressure) in BPAP mode.

- **Ramp type of the S.Box or S.Box C device:** T.Ramp or I.Ramp.  
Ramp pressure and ramp time are noted for these devices in T.Ramp, as well as with S.Box DuoS or S.Box DuoST device.
- **Settings of the S.Box DuoS or S.Box DuoST device** if used in BPAP mode: pressure rise time, Expiratory and Inspiratory Sensitivities. Backup frequency and I/E ratio are mentioned only with S.Box DuoST.
- **Settings** of accessories and features used.

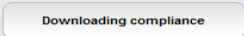
### 3. Other functionalities

The ten buttons on the right-hand side of the screen allow:

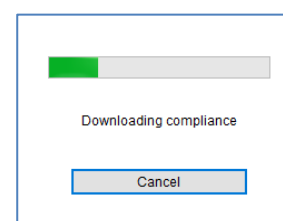
- download via USB cable, compliance data stored in the device
- display the current session and all the sessions
- access settings and program setting changes
- erasing data
- access inventory number
- check serial port configuration
- configure a communicating accessory (Wi-Fi module, 3G modem, PolyLink kit)
- set date and hour
- access real time curves.



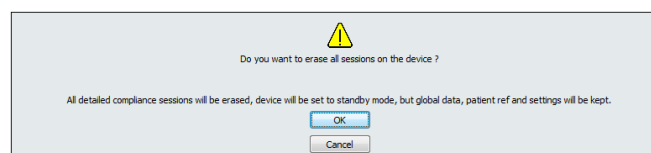
#### a) Downloading data by serial link

The button  allows you to download compliance data saved in the device.

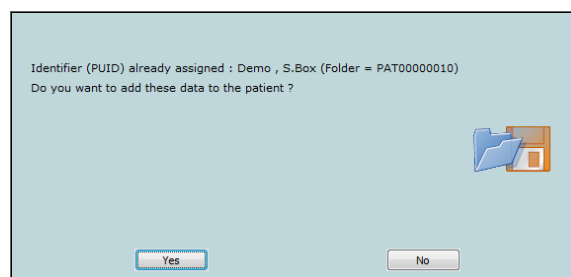
A window shows the download progress.



A dialogue box asks if you want to erase all the sessions recorded in the device. Click on **OK** to confirm or on **Cancel** if you want to keep them.



- If a download has already been performed for a referenced patient, a dialogue box will ask whether you want to add the data to this patient. Click on **Yes** to confirm. Compliance data is then displayed.



- Otherwise, a dialogue box appears allowing you to create a new patient or to select an existing patient from the list.

If you create a new patient, a window appears where you can input the patient's data.

The Patient ID field allows you to personalise the patient identifier which the software uses for patient management. The system proposes you a default value, but you can input a custom value. Acceptable characters are: lowercase and capital letters, figures and symbols such as "-" and "\_". Click on **OK** to confirm; otherwise click on Cancel.

#### CAUTION

If you wish to use a list of predefined identifiers (Patient IDs) instead of the identifiers automatically assigned by the software, you must rigorously and continually audit the list to ensure that two patients have not the same identifier in the same patient system.

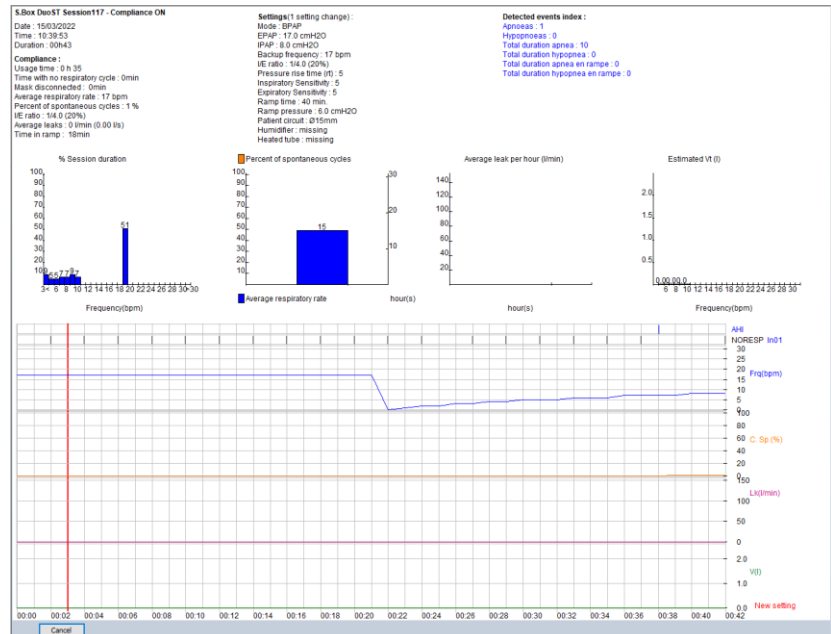
- If you choose a patient existing in the list, a message warns you that the serial number will be removed from the previous patient. Click on **OK**; otherwise click on Cancel.

## b) Viewing the current session

Click on  in the connection screen.

The window which appears shows all the data concerning the current session. The session is identified by a number at the top left, which corresponds to the chronological number since the last configuration. . If no session is in progress, **Compliance OFF** is displayed at the top of the window, which has no curve nor value. A message informs you that the data recording has not yet started.

When a session is currently being recorded, **Compliance ON** is displayed next to the session number and the data appears:



The data displayed is:

### S.Box DuoST Session – Compliance ON:

Identification of the S.Box range device used, information concerning the recorded session and operating duration during the session.

#### Compliance:

- usage time during which the patient has breathed with the mask and time spent with the mask disconnected.
- time in ramp.
- information specific to the S.Box range device used.

#### Pressures if S.Box or S.Box C is used:

- average pressure measured in the mask during the session.
- average leaks.

The section **Settings** concerns the last settings used during the session, the number of settings changes is in brackets:

- mode programmed during the last setting.
- pressure data according to the operating mode used.
- information about the ramp used.
- parameters specific to the S.Box range device used and to its accessories.

**Detected events index:** number of respiratory events detected over the period analyzed depending on the S.Box range device used.

Several diagrams are displayed in the window:



- histogram showing percentage of the session duration at each pressure or frequency level.
- diagram of average leak per hour.
- diagram of average pressure per hour if S.Box or S.Box C is used.
- Histograms showing estimated tidal volume at each frequency level (with S.Box DuoS and S.Box DuoST) and percentage of spontaneous cycles at each average respiratory rate level only when S.Box DuoST is used.
- At the bottom left, the 1-min raw curves show, depending on the S.Box range device used, the detected events in the same colours as in the list of detected events index, the measured pressure or frequency, the measured Leak and the max. Leak. The new settings are indicated, as well as the tidal volume and the percentage os spontaneous cycles with the S.Box DuoS or S.Box DuoST.

Click on  to exit the current session view.

## c) Data for all sessions

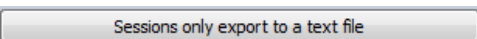
You can access all the recorded sessions by clicking on .

A window displays the data for the last session.

You can display data related to each session by using the  then  keys to scroll backward and forward.



The session is identified by its number in the title of the dialogue box and shows the compliance data and curves described in the "b) Viewing the current session" section.

The button  allows you to export sessions in text format. For further information, refer to the "b) "Export of sessions only to a text file" feature" section page 37.


Click on  to exit all sessions view.

## d) Settings

Before setting the device with the SEFAM Analyze software, make sure that the device and your computer are connected correctly.

### CAUTION

Check the date and time of the computer, as well as the hour of the S.Box range device.

Click on  **Settings** to access the device settings.

When the machine is used for the first time or when it is reconfigured, the settings are programmed by default.

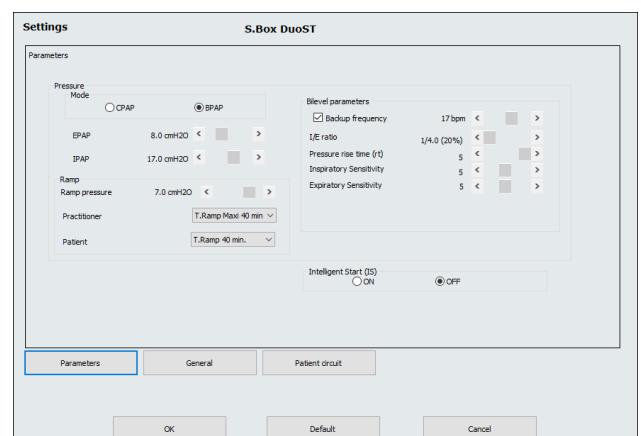
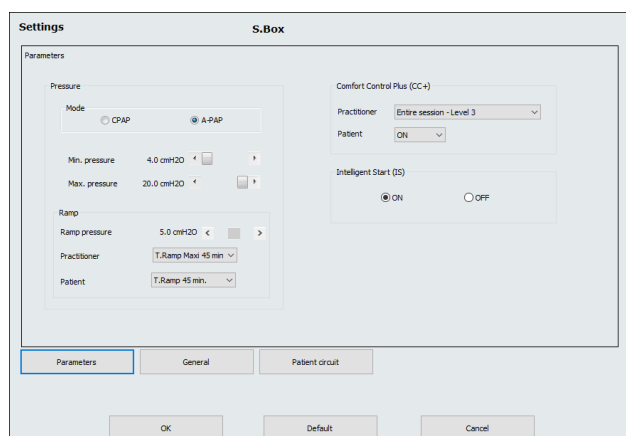
Otherwise the settings displayed correspond to the last settings made. The presentation will vary according to the button which has been selected among the three proposed at the bottom.

### 1. Parameters

The button  **Parameters** is selected by default.

The parameter values are displayed on the left of the cursors. You can set them either by clicking as many times as necessary on the right and left arrows or by moving the cursor with the left mouse button. The settings ranges are the device ones (see corresponding Home Care Provider User Manual).

The information displayed depends on the device used, as shown below .



	S.Box C	S.Box	S. Box DuoS or DuoST
<b>Mode</b>	CPAP (constant pressure)	CPAP (constant pressure) A-PAP (auto-pilot)	CPAP (constant pressure) BPAP (bilevel)
<b>Pressure</b>	Set pressure	In CPAP mode: set pressure In A-PAP mode: Min. Pressure and Max. Pressure	Set pressure in CPAP mode EPAP (expiratory pressure) and IPAP (inspiratory pressure) in BPAP mode:
<b>Ramp</b>	Ramp pressure from 4 cmH <sub>2</sub> O to the set pressure.	Ramp pressure from 4 cmH <sub>2</sub> O to the set pressure in CPAP mode. Ramp pressure from 4 cmH <sub>2</sub> O to the Max. Pressure in A-PAP mode.	Ramp pressure from 4 cmH <sub>2</sub> O to the set pressure in CPAP mode. Ramp pressure from 3 cmH <sub>2</sub> O to EPAP in BPAP mode.



	S.Box C	S.Box	S. Box DuoS or DuoST
<b>Ramp type</b>	T.Ramp (time ramp) I.Ramp (intelligent ramp) OFF.	T.Ramp (time ramp), I.Ramp (intelligent ramp), OFF.	T.Ramp (time ramp) only, OFF.
<b>Intelligent Start</b>	Activation (ON) Deactivation (OFF)	Activation (ON) Deactivation (OFF)	Activation (ON) Deactivation (OFF)

You can set the Ramp type which can be selected by the Practitioner: T.Ramp with the maximum ramp time adjustable in 5 minutes increments between 5 min and 45 min, I.Ramp (except with S.Box DuoS or DuoST) or OFF.

You can also set the Ramp type which can be selected by the Patient:

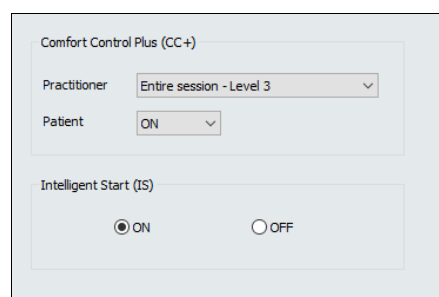
- OFF or T.Ramp with the maximum ramp time adjustable in 5 minutes increments between 5 min and the maximum ramp time set (if T.Ramp was selected by the practitioner).
- OFF or ON (if I.Ramp was selected by the practitioner except with S.Box DuoS or DuoST).
- Off no setting available (if OFF was selected by the practitioner).

**Comfort Control Plus CC+ feature specific to S.Box and S.Box C devices:** you can set its period of activation by the Practitioner

- During ramp with 3 possible levels,
- Entire session with 3 possible levels,
- Never.

**Notes:**

- If the function was enabled by the practitioner, the patient can choose to activate it (ON) or deactivate it (OFF).
- If the function was disabled, the patient will not be able to access it.

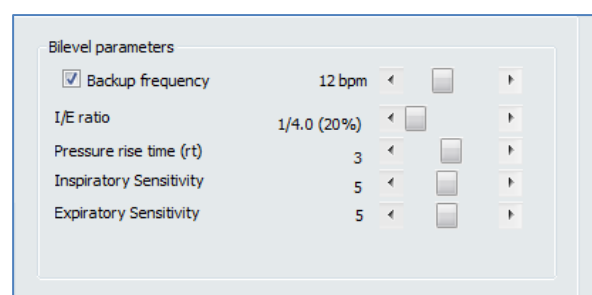


**Parameters specific to S.Box DuoS or S.Box DuoST in BPAP mode:**

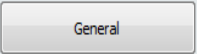
- Pressure rise time rt
- Inspiratory Sensitivity
- Expiratory Sensitivity
- Backup frequency with S.Box DuoST and I/E ratio with S.Box DuoST.

**Note:**

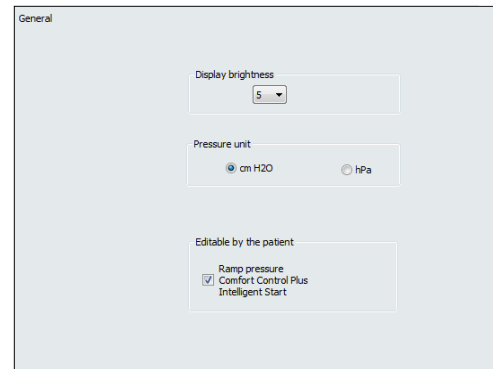
The I/E ratio can be accessed only if the backup frequency is selected.



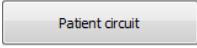
## 2. General

The button  allows to:

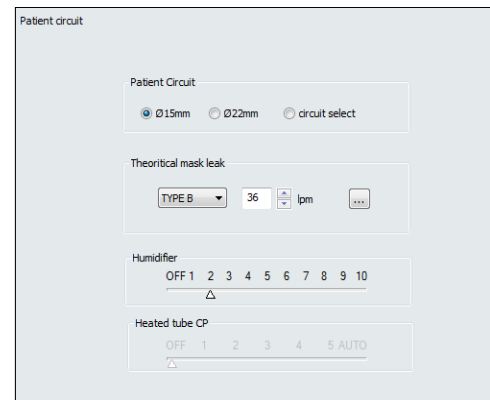
- adjust the brightness of the device display using a drop-down list
- select the pressure unit cm H<sub>2</sub>O or hPa by ticking the corresponding box
- make a group of settings editable by the patient: Ramp pressure and Intelligent Start (and Comfort Control Plus with S.Box or S.Box C).




## 3. Patient circuit

The button  allows:

- the selection of the patient circuit diameter (15 mm, 22 mm or Circuit Select)
- the selection of the type of theoretical mask leak – –, A, B or C
- the setting of the Humidification level of the humidifier (if installed)
- the setting of the Heating capacity of the heated tube (if installed).




If you do not know the type of the theoretical mask leak, choose  to display the list of masks available. Search and select the mask. Click on **OK**, the value of corresponding theoretical leak will appear.

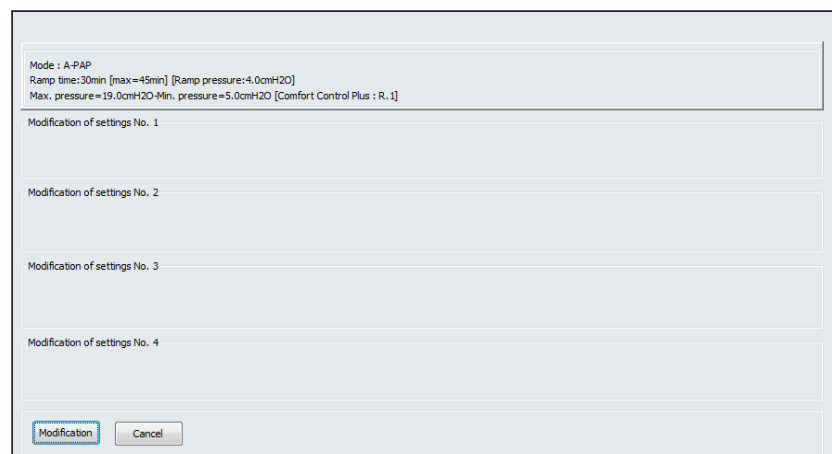
Click on **OK** to confirm the new settings; otherwise click on Cancel.


The button  restores the original device parameters.

## e) Programming of settings changes

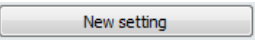
Click on .

The dialogue box appears:



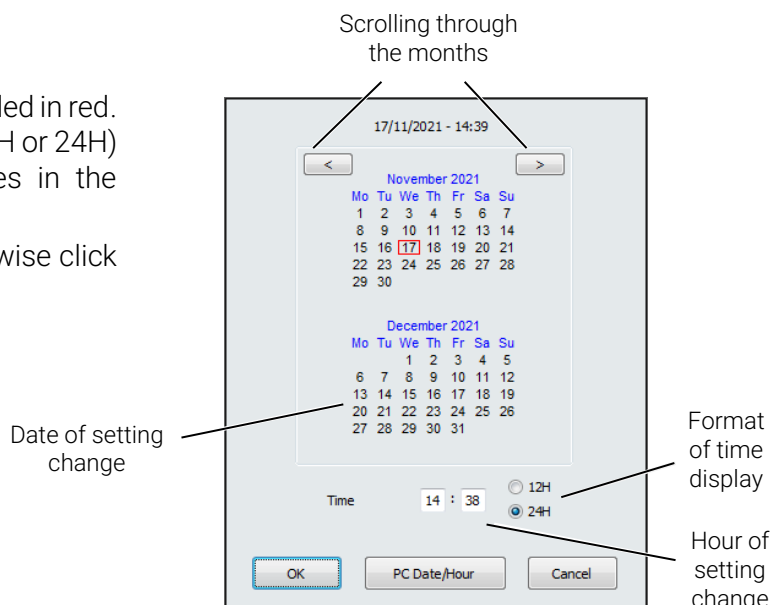
If you click on  at the bottom left, the bottom of the dialogue box changes:



Click on  to select the day and hour of the setting change.

Click on the desired date which is surrounded in red. Then select the format of time display (12H or 24H) and enter the hours and minutes values in the corresponding boxes.

Click on **OK** to confirm your choice; otherwise click on Cancel.

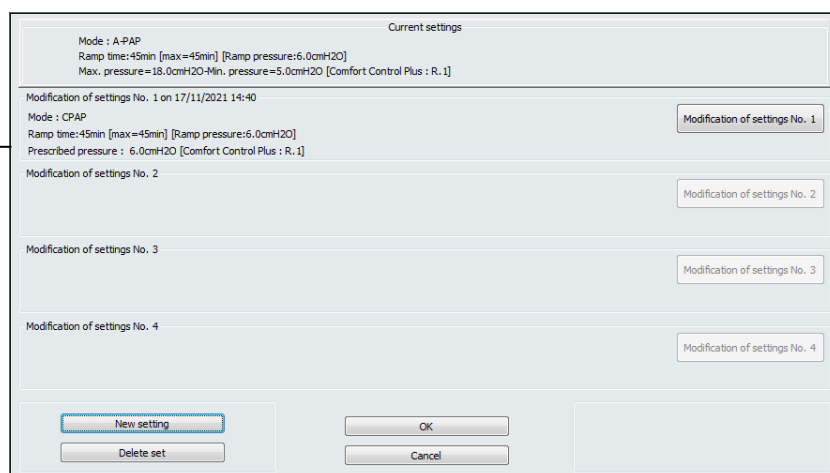


The settings window of the S.Box range device used displays. Change the parameters if necessary and click on **OK** to confirm; otherwise click on Cancel.

The previous window is displayed, completed with the new settings.

The programmed date and time are displayed on the right part of **Modification of settings N°1** followed by the new settings configuration.

New settings



You can then modify the programmed settings again by clicking on **Modification of settings No. 1**.

If you wish to programme settings N°2 to N°4, follow the same procedure as for the setting change N°1. You can delete the last setting programmed by clicking on **Delete set**.

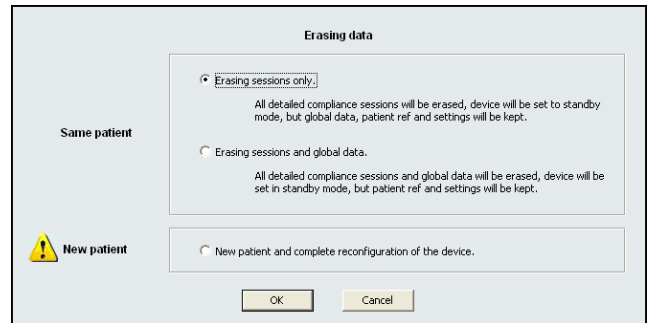
Click on **OK** to validate settings programming. A window confirms it and the settings changes will take place successively at the programmed dates and times.

### Notes:

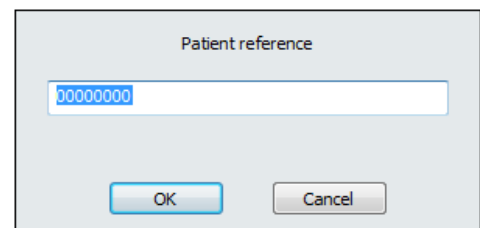
- The programmed settings changes will occur whether the device is operating or in standby. If a settings change is programmed to take place when the machine is not switched on, the settings change will become effective approximately one minute after the device is switched on.
- When a settings change occurs at the programmed date and time, a new settings change can then be programmed. Therefore if you have programmed 4 settings changes, a new change can be programmed once settings change N°1 set up.

## f) Erasing compliance data

Clicking on  will display the following dialogue box.



- The **Erasing sessions only** option is the default setting. In this case, the compliance sessions will be erased, the device will be set to standby mode, but global data, patient reference and settings will be preserved. If you select this option, a message warns you that you are about to erase all sessions of the device. Click on **OK** to confirm, otherwise click on Cancel.
- With the **Erasing sessions and global data** option, the compliance session and global data will be erased, the device will be set to standby mode, but the patient reference and settings will be preserved. If you select this option, a message warns you that you are about to erase global data from the device. Click on **OK** to confirm, otherwise click on Cancel.
- If you select the **New patient and complete reconfiguration of the device** option, the **Patient reference** window appears:



You can assign the patient a new "Patient Reference", which is the 8-character alphanumeric code associating the patient with the device. By default it will be the letter R followed by the 7 last characters OF the serial number (e.g. " R7090001").

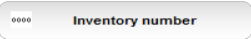
### CAUTION

Assigning a new patient reference causes the deletion of all global data stored since the last configuration. For further information, see technical manual for the device.

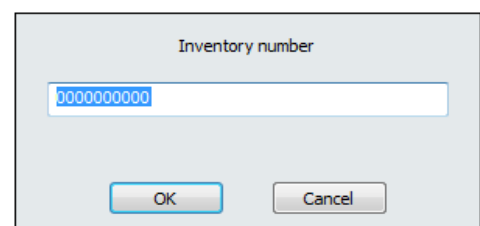
If you input a new patient reference, a dialogue box alerts you to the change and asks whether you want to continue. Click on **OK** to confirm your choice; otherwise click on Cancel. The new reference will replace the one which was displayed.

## g) Inventory number


The inventory number is a 10-character alphanumeric code specific to the machine in which it is memorised. It can be accessed only using the computer.

The inventory number can be changed by clicking on . In the window which appears, you can enter a new inventory number. Confirm your choice by clicking on **OK**.

A dialogue box asks if you wish to continue. Click on **OK** to confirm; otherwise click on Cancel.

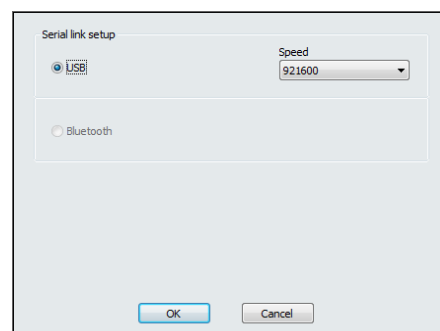


## h) Configuring the serial port


The button  allows you to check the configuration and access the communication speed of the serial port used.

In the window which appears, only the speed of the USB connection can be modified. In this case, a dialogue box asks if you want to continue.

Click on **OK** to confirm; otherwise click on **Cancel**.




## i) Communicating accessory


The  button enables a wireless communication via the communicating accessory installed in the S.Box range device (Wi-Fi module, 3G modem or PolyLink). The button will be inactive if no communicating accessory is installed in the machine.

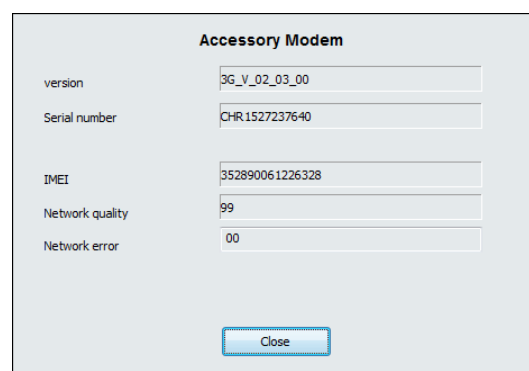
Unplug the S.Box range device from the power supply or from the electrical power grid and insert the accessory into the machine according to the instructions of the corresponding usage procedure. The button will then display the name of the inserted accessory.

### 1. S.Box modem

Click on : a window displays information about the modem and the network.

#### Note :

The modem connection must be enabled in the settings menu of the S.Box range device and the symbol  present in the status bar of the display (see S.corresponding patient manual).

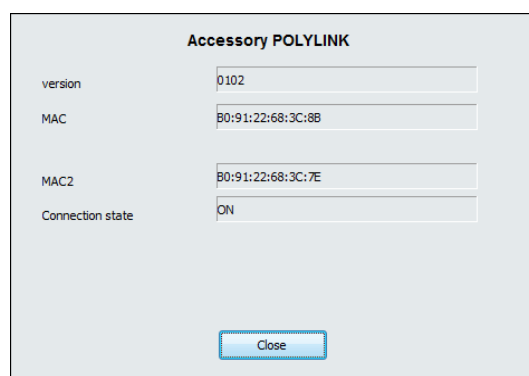


### 2. PolyLink module for S.Box

Cliquez sur : a window displays information about the PolyLink module and the connection state.


#### Note :


The BLE communication of the PolyLink module must be enabled in the settings menu of the S.Box range device (see corresponding patient manual).

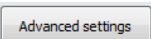


### 3. Wi-Fi module

If you use a Wi - Fi module, make sure that the Wi - Fi is available on your computer.


Click on : a window appears.

Depending on the network, you can enable the communication by clicking on  or on

.

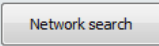
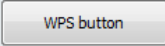
#### Note :

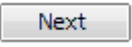
The Wi-Fi module connection must be enabled in the settings menu of the S.Box range device and the

symbol  present in the status bar of the display (see corresponding patient manual).



#### a) Quick settings

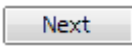
In this case, the window is changing and the buttons  and  appear:

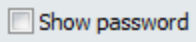
- By clicking on **Network search**, you can view the list of networks available with their SSID, Security and Quality. Select the network and click on .
- By clicking on **WPS button**, you can choose the mode of automatic configuration if your material allows it (Wi-Fi router, ADSL Box). Confirm your choice: the previous configuration will be erased and replaced by the new one.

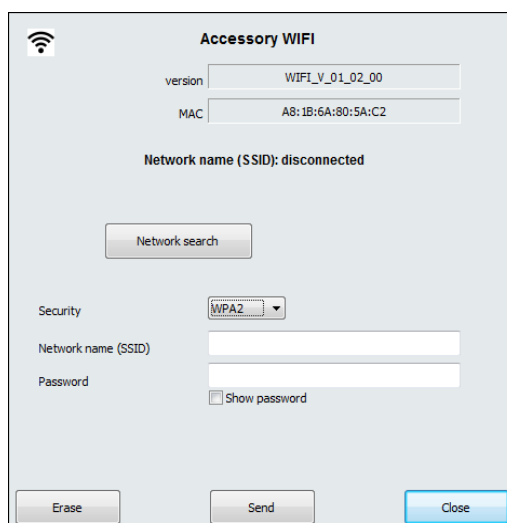


#### b) Advanced settings


In this case, the list of networks available is displayed with their SSID, Security and Quality.

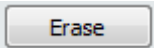
Select the network and click on . The window is changing and you can choose the **WPS** security (mode of automatic configuration) or the **WEP, WPA, WPA2** security (mode of manual configuration) or **NO..**


Then fill in the empty fields with the **SSID network name** and the **password** corresponding to the Wi - Fi network to which you want to connect. You can activate .



You will then have about two minutes for pressing the corresponding button of your Wi-Fi router and so for activating the connection to the network.

Click on  in order to send the configuration to the Wi - Fi module. A dialogue box asks you to confirm your choice. Click on **OK**: a window appears, indicating that the Wi - Fi configuration is operational.

The button  allows erasing the previous Wi-Fi configuration.

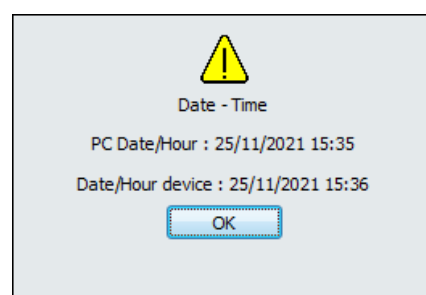
If the connection to the local network is correct, the symbol  blinks for about 30 seconds in the status bar of the S.Box range display, showing that the Wi-Fi module is operational.

Exit the window by clicking on .

## j) Date and hour

By clicking on , you access the device clock.

If the device is on, a dialogue box is displayed showing the date and time of the device, but they cannot be modified.



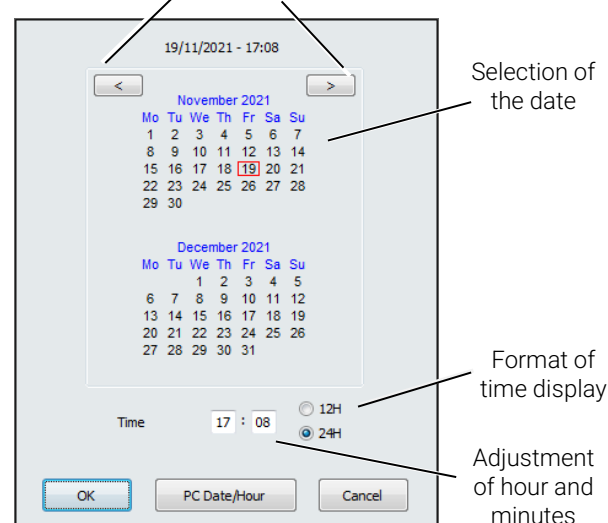
Scrolling through the months

However, if the device is in standby, the opposite dialogue box allows modifying date and time.

To modify the date, scroll through the months if necessary, using the buttons located at the top, and click on the desired day which is then surrounded in red.

To change the hour and/or the minutes, you can first if necessary, change the format of time display (12H or 24H), then place the cursor on the corresponding boxes and modify the values using the keyboard of your computer.

The button  allows to synchronise the device time with the PC's one.



### CAUTION

Before synchronising the date and time of the device with that of the PC, ensure that your computer settings are correct.

Click on **OK** to confirm your changes or on Cancel to keep the original date and time.

# Use of the SD card


## Download data from the SD card

The patient can use a SD card to save the most recent compliance data memorised in the S.Box range device by following the instructions in the Patient Manual.

Once the data is backed up, the patient sends you the SD card and you can retrieve and analyse the compliance data using the **SEFAM Analyze** software.

Insert the SD card into the SD card drive of your computer.

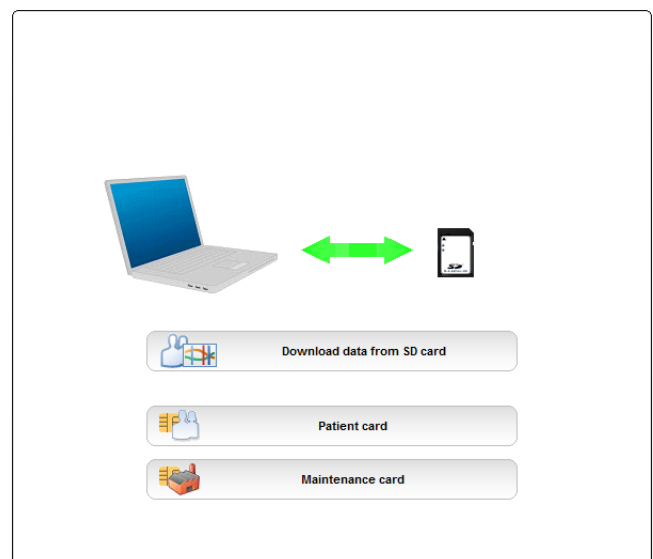



Click on  to access the recovery of the data stored on the SD card.

In the screen which opens, click on **Download data from SD card**.

**Note:**

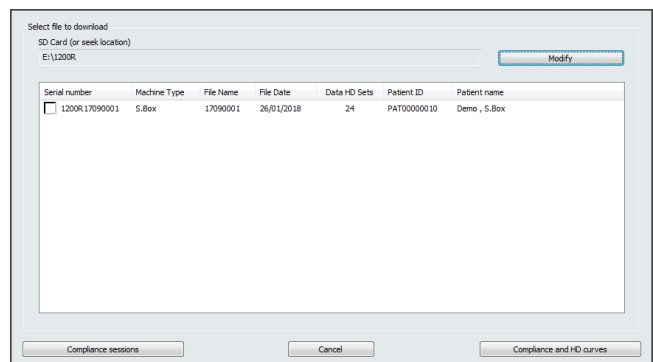
Any SD card which is new or has been previously used to save data in the device can be used.



Choose a directory on the SD card. You access a dialogue box which allows you to select a patient existing among the list. You can choose another file available on the SD card by clicking on .

**Note:**

If several files corresponding to serial numbers of different devices are on the SD <sup>TM</sup> card, the files can be assigned to different patients.



You can choose to download the **compliance sessions** or **compliance and HD curves** by clicking on the corresponding button.

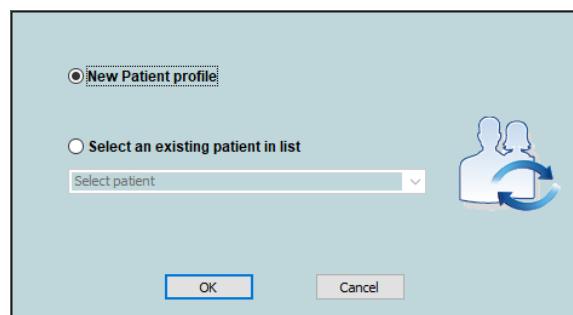
An animation appears until the data download is effective, but you have the ability to interrupt the download by clicking on the corresponding button.

For purposes of data confidentiality, the SD card can be erased once it has been read if the corresponding option has been enabled (see paragraph "5. General features" page 10).

If the option "Ask before erase SD card data" has been selected (set by default), a dialogue box appears. Click on **Yes** if you want to erase the data or click on **No** if you want to keep them.



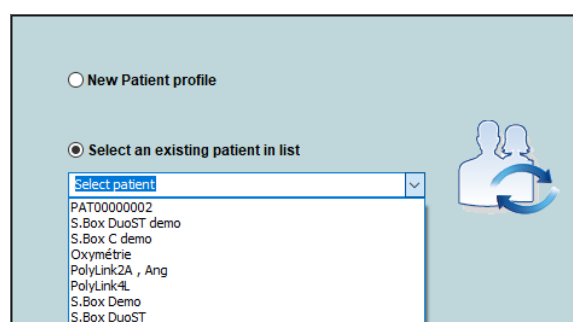
- If the identifier is already assigned, the program asks you if you want to add the data to the existing patient. Click on **Yes** to confirm.
- Otherwise, click on **No**. A dialogue box allows to create a new patient profile or to select an existing patient in the list.



If you choose creating a new patient, complete the information for this patient in the window **New Patient profile** which appears.

The "Patient ID" field allows personalising the patient identifier used by the software for patient management. A value is proposed by default which can be customized by using lowercase and capital letters, figures and characters like "-" and "\_". Click on **OK** to confirm, otherwise on Cancel. Data is displayed on the screen.

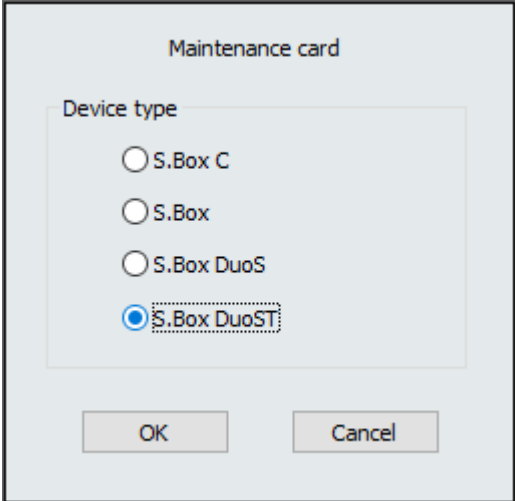
- If you choose an existing patient in the list, the corresponding information will be displayed on the screen.



# Maintenance card

You can prepare a SD card which allows you to configure a fleet of S.Box range devices with the same settings.

The button  Maintenance card gives access to a dialogue box which enables to select the type of S.Box device used:



Maintenance card

Device type

☐ S.Box C

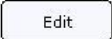
☐ S.Box

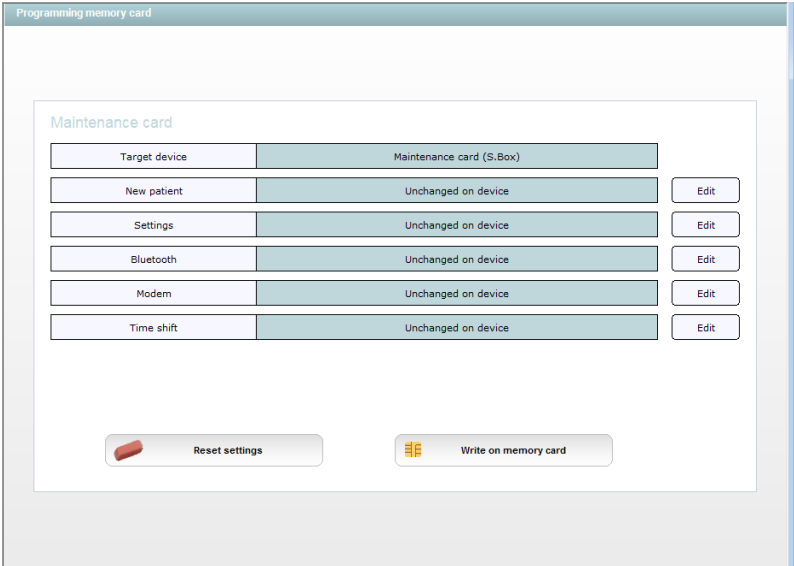
☐ S.Box DuoS

☒ S.Box DuoST

OK Cancel

The settings available are the same as those of the patient card, but you have also the possibility to create a new patient.



Using the  button located on the right of each parameter, you can display the corresponding setting box.



Programming memory card

Maintenance card

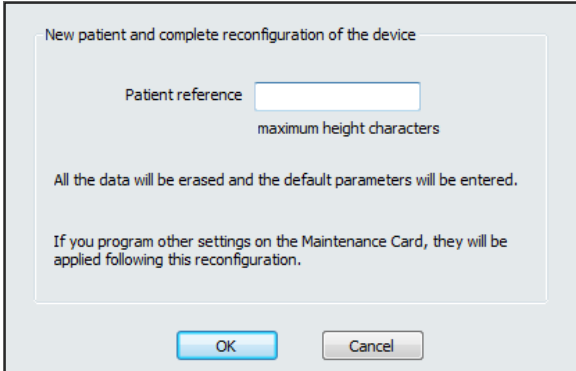
Target device	Maintenance card (S.Box)	
New patient	Unchanged on device	Edit
Settings	Unchanged on device	Edit
Bluetooth	Unchanged on device	Edit
Modem	Unchanged on device	Edit
Time shift	Unchanged on device	Edit

 Reset settings  Write on memory card

## New patient

A dialogue box appears in which you can enter a new patient reference.

Click on **OK** to approve the new reference; otherwise select Cancel.



New patient and complete reconfiguration of the device

Patient reference


maximum height characters

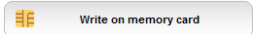
All the data will be erased and the default parameters will be entered.

If you program other settings on the Maintenance Card, they will be applied following this reconfiguration.

OK Cancel

Each time a parameter is modified, the new setting appears in the central strip, which then changes colour. If a parameter has not been modified, the central strip displays **Unchanged on device**.

You can cancel any setting changes made by clicking on . The central strip displays **Unchanged on device** again.


Click on  to apply the settings to a maintenance card. A window opens reminding the settings. Click on **OK** to confirm or on **Cancel** if you do not want to keep them. Select then the memory card reader of your computer in which the maintenance card is inserted.

**Note:**

The SD card needs to be inserted into the memory card reader of the computer to apply the new settings to the maintenance card.

A dialogue box informs you that writing is done and that the memory card can be removed from the computer reader.

Refer to paragraph "9. Patient card" page 38 pour l'utilisation du bouton .









Click twice on  to return to welcome screen.

# In case of problem

Problem	Possible cause	Proposed solution
Unable to install SEFAM Analyze software	Operating system not compatible	Choose one of the operating systems defined in the installation manual Contact technical support
SEFAM Analyze software is not working	External causes or bug	Contact technical support
Data transfer isn't functional	SD card was removed too quickly	Wait until the download is complete before removing the SD card
	SD card isn't inserted correctly	Remove and reinsert the SD card in the right way
	The SD card is either not inserted or not properly inserted in the device.	Insert the SD card properly into the SD card slot.
	The SD card is locked.	Unlock the SD card and reinsert it into the SD card slot.
	The SD card is 90% full, or more.	Delete files on the SD card and give it back to the patient. If the problem persists, Give a new SD card to the patient.
	SD card error.	Give a new SD card to the patient.
	wrong USB cable	Use the USB cable defined in the list of accessories
	USB cable was removed too quickly	Remove and reinsert the USB cable in the right way
Bluetooth function isn't functional	The USB cable isn't inserted correctly	Remove and reinsert the USB cable in the right way
	Computer's Bluetooth isn't working	Check that a Bluetooth radio has been installed/activated on the computer
Alteration of received data	Problem during the communication	Check that the normal conditions of use are respected Contact technical support
Impossibility to edit reports	PDF editor isn't functional	Refer to "Item 8 of § Software Installation" in the software installation document (M-156DFU01-50)

For any software dysfunction, contact the healthcare provider or technical support whose contact information is shown at the front of this manual.

# Definition of symbols

Symbole	Description	Symbole	Description
	Device is in accordance with the requirements of the European directive 93/42 /EC on medical devices.		Device can no longer be used, dispose separately from household garbage.
	Manufacturer.		Manufacturing date.
	Unique Identifier of device		Medical Device
	On the packaging: this symbol means "Keep dry" because the package must be protected against moisture and water.		Consult the electronic instructions for use: <a href="http://www.sefam-medical.com">www.sefam-medical.com</a>

## CE marking

Date of CE marking of the **SEFAM Analyze software**: 2017.

# Glossary

---

**AHI**

Apnoea and d'Hypopnoea Index

**Auto-CPAP**

Auto-pilot. Mode.

**BPAP (bilevel)**

Mode of operation in which the pressure varies between EPAP during the expiratory phase and IPAP during the inspiratory phase of the patient

**Bluetooth**

Low-power, short-range wireless communications technology for connecting devices.

**Circuit Select**

Specific calibration of the pneumatic circuit.

**CNT AH**

Apnoeas and hypopnoeas classed as central.

**CNT Apnoeas, CNT Hypopnoeas**

Central apnoeas, central hypopnoeas.

**Communicating accessory**

Accessory which can be inserted into the S.Box range (Wi-Fi module, 3G modem or PolyLink kit).

**Comfort Control Plus**

If it is enabled by the clinician or the home care provider, the Comfort Control Plus (CC +) feature is designed to increase treatment pressure when the patient inhales and to reduce it when the patient exhales to make breathing more comfortable during treatment. It is enabled either continuously or during the ramp, or disabled.

**CPAP**

Continuous Positive Airway Pressure mode.

**EPAP**

Expiratory pressure level

**HD (High Definition)**

Data acquired with High Definition compared to the 1 min-detailed curves.

**Heated tube**

S.Box heated tube with ATC (Adaptive Thermo Control), 15 mm in diameter.

**Hour counter:**

Device operating time.

Hour counter – Configuration: total operating time (ON/OFF) at the configuration.

Hour counter – Downloaded: total operating time (ON/OFF) at the download.

**Humidifier**

Optional accessory of S.Box range device including a heated element and a water chamber.

**IFL**

Inspiratory Flow Limitation.

**Index**

Number of events per hour.

**Intelligent Start**

This feature permits the patient to start the treatment automatically at the first breathings in the mask, without using the start / standby button.

**IPAP**

Inspiratory pressure level

**Mask disconnected**

Time during which the patient's mask was disconnected.

**Max. pressure**

Maximum pressure delivered by the device in Auto-CPAP mode.

**Max. ramp time**

This allows the Home Care Provider to limit the maximum ramp time value that can be set when the Ramp feature is used.

**Min. pressure**

Minimum pressure delivered by the device in Auto-CPAP mode.

**OBS AH**

Apnoeas and hypopnoeas classed as obstructive.

**OBS Apnoeas, OBS Hypopnoeas**

Obstructive apnoeas, obstructive hypopnoeas.

**ODI**

Oxygen Desaturation Index.

**OSAHS**

Obstructive Sleep Apnea–Hypopnea Syndrome.

**Patient circuit**

Patient circuit used: diameter 15 mm, diameter 22 mm and Circuit Select (other configuration).

**Patient reference**

Reference assigned to the patient.

**% days of usage  $\geq 3$  h/d**

Percentage of days during which the patient has really breathed with the machine for a number of hours over a specified adjustable threshold.

**Prescribed pressure**

Level of pressure prescribed for the patient in CPAP mode.

**P.x % : Pressure efficient more than x % of time**

Level of pressure at which the patient spent more than a certain percentage of time (x = adjustable threshold).

**Ramp function**

The ramp function makes it possible to gradually increase the pressure to help the patient fall asleep. There are two types of ramp: T Ramp (time ramp) and I Ramp (intelligent ramp).

**Ramp pressure**

Level of pressure produced by the device when the ramp feature starts up, so that the patient can go to sleep comfortably.

When the S.Box device is in Auto-CPAP mode, the pressure is adjusted to this ramp pressure or to the minimum pressure (if ramp pressure < minimum pressure) when the device detects that there has been no respiratory cycle for more than 2 minutes or when it detects a high pressure.

**Ramp time**

This is the time taken by the device to reach the prescribed pressure from the ramp pressure in CPAP mode or to activate the Auto-CPAP feature when the time ramp is enabled.

**Ramp type**

Type of the ramp selected, either T Ramp (time ramp) or I Ramp (intelligent ramp).

T.Ramp: the ramp time is determined by the practitioner or the Home Care Provider.

I.Ramp: the ramp time is automatically determined by the device.

**Session**

Period during which the data is saved in the memory between device start-up and shut down.

**SpO<sub>2</sub>**

Oxygen saturation of arterial hemoglobin.

**Time in ramp**

Length of time in ramp.

**Total usage time**

Total length of time during which the patient actually breathed with the mask.

**3G**

Wireless mobile telecommunication technology for connecting electronic devices.

**Usage duration**

Average daily duration during which the patient breathed with his / her machine (ON / OFF).

**Wi-Fi**

High-speed wireless transmission technology for connecting electronic devices to one another.







---

**Manufacturer:**

SEFAM  
144 AV CHARLES DE GAULLE  
92200 NEUILLY SUR SEINE  
FRANCE

**Manufacturing plant:**

SEFAM  
10 ALLEE PELLETIER DOISY  
54600 VILLERS-LES-NANCY  
FRANCE

**REF** : M-156DFU01-40 Version 9  
2023-01