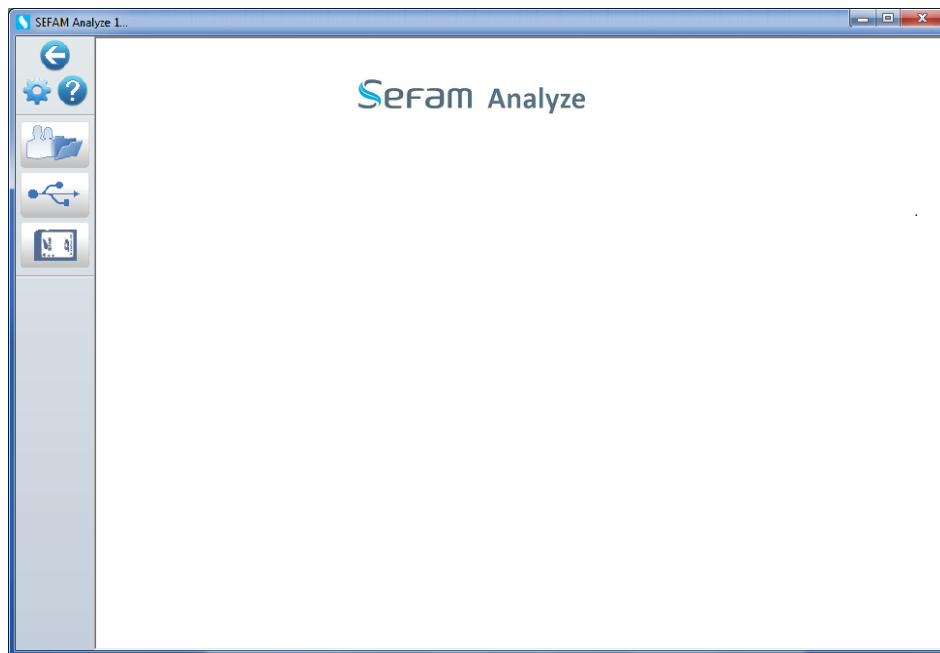


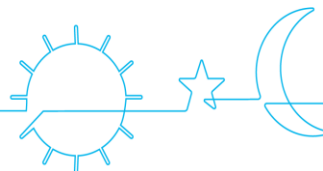
# Sefam Analyze



SOFTWARE FOR ANALYSING DATA RECORDED WITH

**Sefam**  
**S.Box**  
BY  
**STARCK®**

User manual



en

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# Before you start

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Please read this manual carefully before using SEFAM Analyze software.

## Software overview

**SEFAM Analyze** is a software product which can be used with the SEFAM S.Box device designed for the treatment of patients who suffer from Obstructive Sleep Apnoea–Hypopnoea Syndrome (OSAHS). It is essential for you to understand the software operation before using it with the device.

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 the most recent compliance data recorded by sessions in the device memory 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, and saving them on your computer
- 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 SEFAM S.Box settings by a direct connection by USB cable, by SD card, by Bluetooth wireless connection or by SEFAM S.Box modem.
- viewing the signals acquired in real time (flow, pressure, events detected., etc) from SEFAM S.Box device and 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 of the screenshots are presented in English and concern the software use with the SEFAM S.Box device. 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 to patient.

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 the SEFAM S.Box 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 SEFAM S.Box Patient Manual and in the 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 SEFAM S.Box 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 via Bluetooth wireless communication or over Internet.

# Launching the program

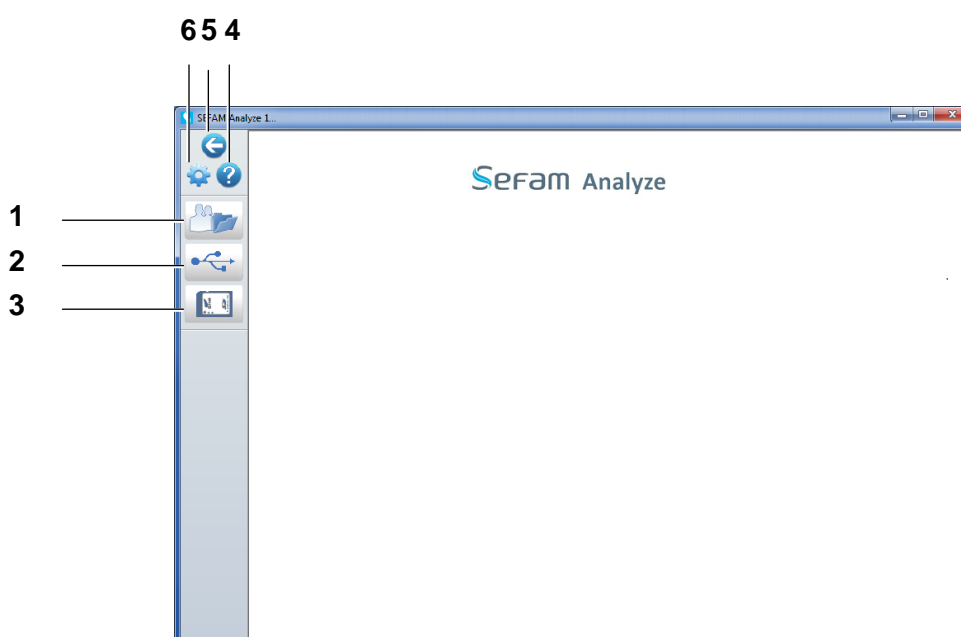


To use the software, double-click on the SEFAM Analyze shortcut on the desktop or select "All Programs" then SEFAM Analyze in the "Start" menu of your computer.








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

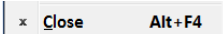

The welcome screen appears and gives access to the program functions.

## Description of welcome screen



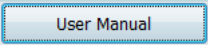
This screen is used to access the following functions:

- 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 SEFAM S.Box and SEFAM Analyze software:
  - by a USB cable
  - by a Bluetooth wireless communication.
- or 
- 3  download the data of SEFAM S.Box 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 .

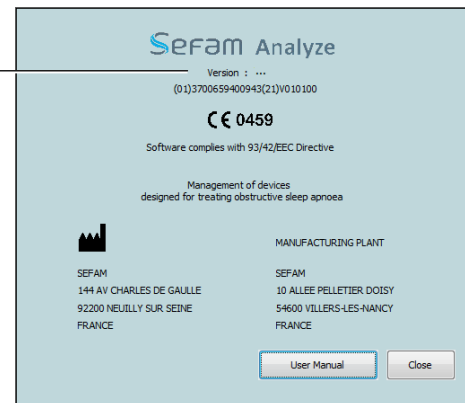
## Properties of the software

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.

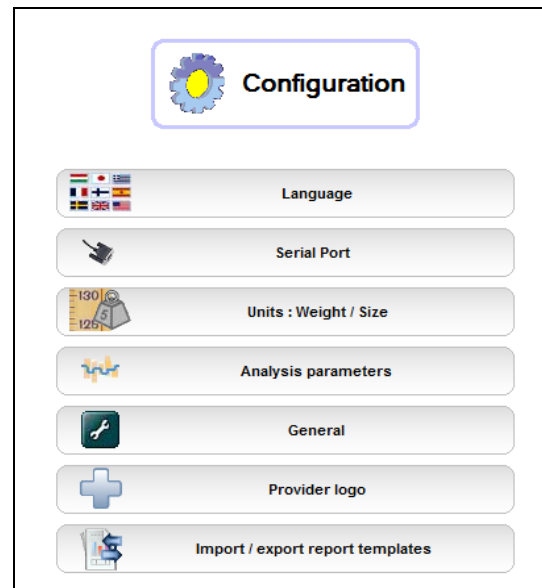
Click on  to exit the window.

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.).



## 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.

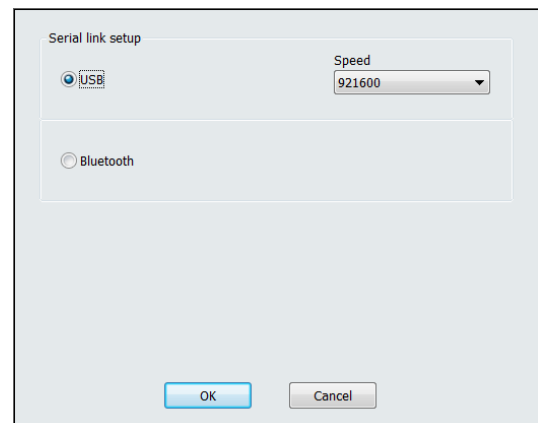




## Serial link setup

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.



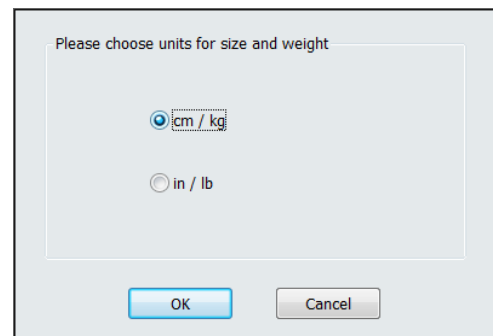
### CAUTION

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.

## Choosing the units for size and weight

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

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

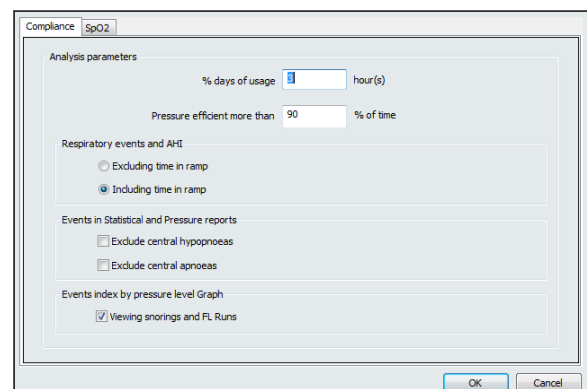


## Choice of analysis parameters

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 with a value set to 3 hours/day by default.
- the threshold used to calculate the effective pressure. It is expressed as a percentage of time with a value set to 90% by default.

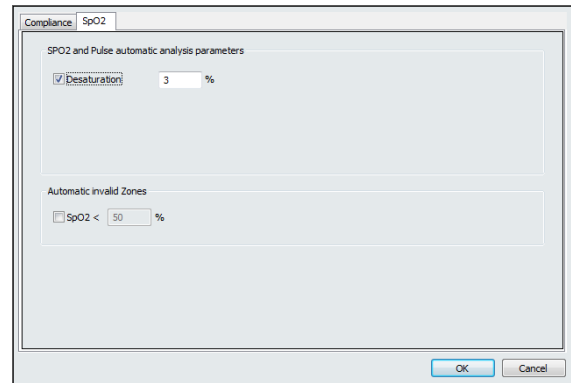


You can also select:

- display of respiratory events detected and Index of Apnoea / Hypopnoea (AHI) calculated including or not the time spent in ramp.
- display of respiratory events in Statistical and Pressure reports excluding or not the central hypopnoeas and / or the central apnoeas.
- view or not of snorings and of Flow Limitation Runs in the graph of events index by pressure level.

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.



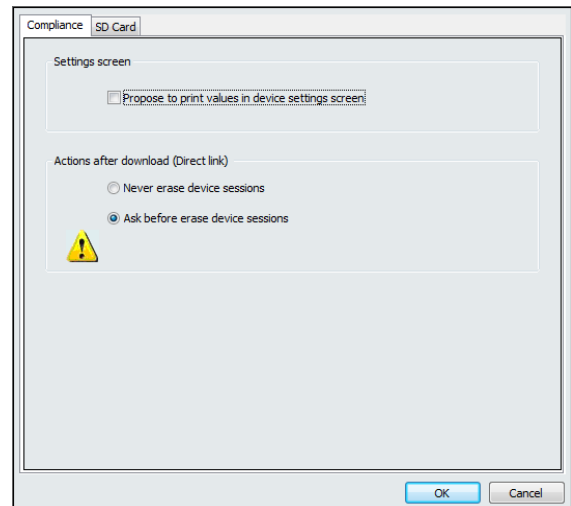
Confirm your choices by clicking on **OK**; otherwise click on Cancel.

## General features

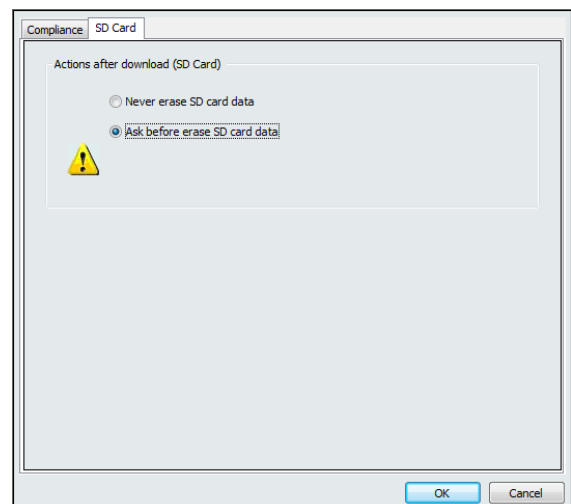
By clicking on **General**, a dialogue box is displayed, showing Compliance and SD card tabs.

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 (proposed 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 (proposed by default).



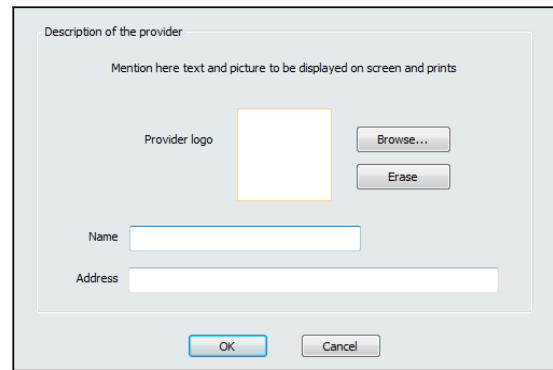
Confirm your choices by clicking on **OK**; otherwise click on Cancel.

## Inserting a Provider logo

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

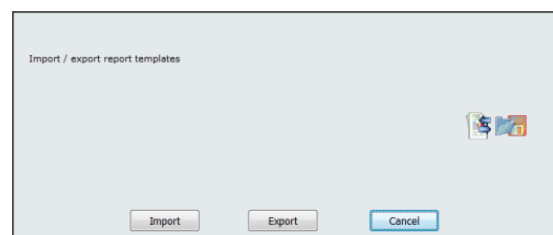
Click on **Browse...** to select a file. The picture can also be deleted by clicking on **Erase**.

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



## 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:*

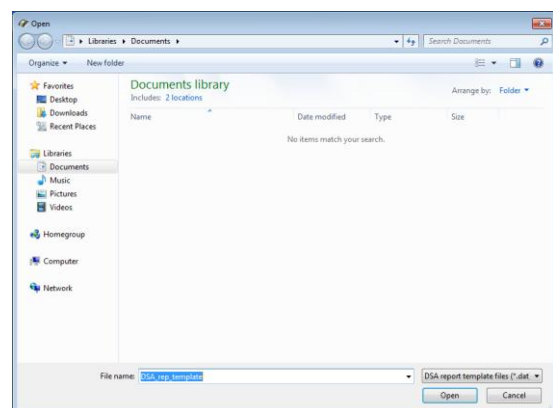
The information included in the provider logo is imported or exported simultaneously with the report templates.

### a) Importation

The button **Import** allows you to add one or several report templates to those already present.

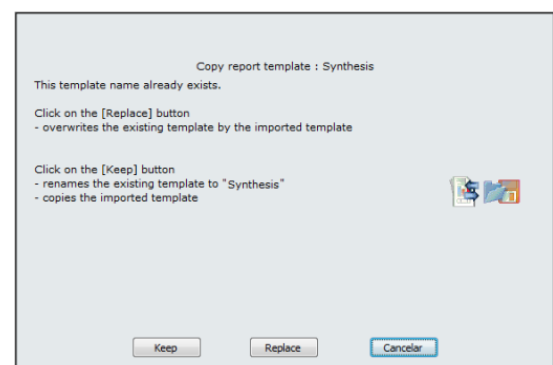
In the window which appears, you can select the file of the templates to import.

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

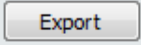


Otherwise, a dialogue box opens and allows you to **Keep** or **Replace** an existing template by clicking on the corresponding button.

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



## b) Exportation

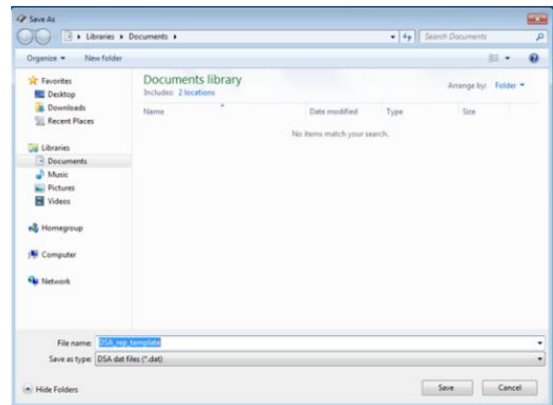
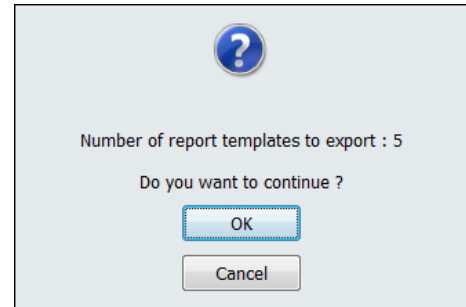
The button  allows saving one or more templates present in the software. A message warns you if there is no model to be exported.

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 .

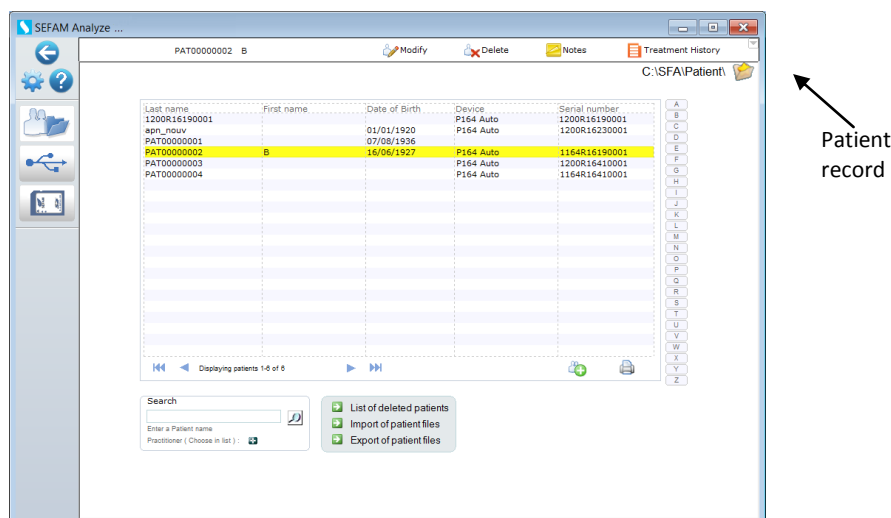
A message confirms the exportation of the report templates. Click on **OK**.







# 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.

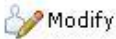
You can scroll the list of patients forth and back by using  and . You can also go directly to the top of the list or directly to the end of the list by clicking on  or on .

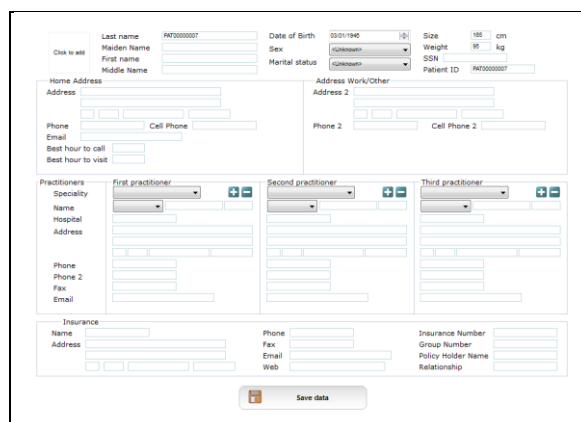
The list of patients can be sorted alphabetically by selecting the corresponding letter on the right; only will be displayed names beginning with the selected letter.

You can also search for a patient by typing the first letters of his/her name in the **Search** field then clicking on . All the names which include these letters will be 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

### 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  at the top of the patient list.



Click to edit

Last name: PAT00000007 Date of Birth: 03/01/1940 Sex:  Size: 165 cm Weight: 65 kg

Maiden Name:  Marital status:  SSN:  Patient ID: PAT00000007

First name:  Middle Name:

Home Address:  Address 2:

Phone:  Cell Phone:  Phone 2:  Cell Phone 2:

Best hour to call:  Best hour to visit:

Practitioners

First practitioner	Second practitioner	Third practitioner
Specialty: <input type="text"/>	Specialty: <input type="text"/>	Specialty: <input type="text"/>
Name: <input type="text"/>	Name: <input type="text"/>	Name: <input type="text"/>
Hospital: <input type="text"/>	Hospital: <input type="text"/>	Hospital: <input type="text"/>
Address: <input type="text"/>	Address: <input type="text"/>	Address: <input type="text"/>
Phone: <input type="text"/>	Phone: <input type="text"/>	Phone: <input type="text"/>
Phone 2: <input type="text"/>	Phone 2: <input type="text"/>	Phone 2: <input type="text"/>
Fax: <input type="text"/>	Fax: <input type="text"/>	Fax: <input type="text"/>
Email: <input type="text"/>	Email: <input type="text"/>	Email: <input type="text"/>

Insurance

Insurance	Phone	Insurance Number
Name: <input type="text"/>	Phone: <input type="text"/>	Insurance Number: <input type="text"/>
Address: <input type="text"/>	Fax: <input type="text"/>	Group Number: <input type="text"/>
	Email: <input type="text"/>	Policy Holder Name: <input type="text"/>
	Web: <input type="text"/>	Relationship: <input type="text"/>

Save data

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.

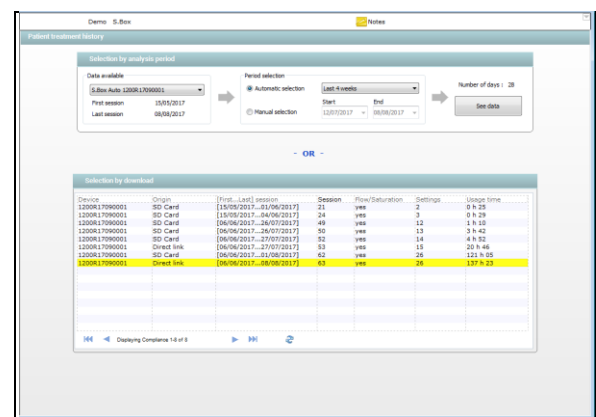
The button on right of the input field of the physician's name allows to access the list of physician profiles recorded on your computer hard drive. When you select a physician and click on **OK**, all information about this physician (speciality, hospital, address, email, fax, etc.) is imported into 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.

## 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).

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.

## 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.

## Deleting a patient



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

### Note:

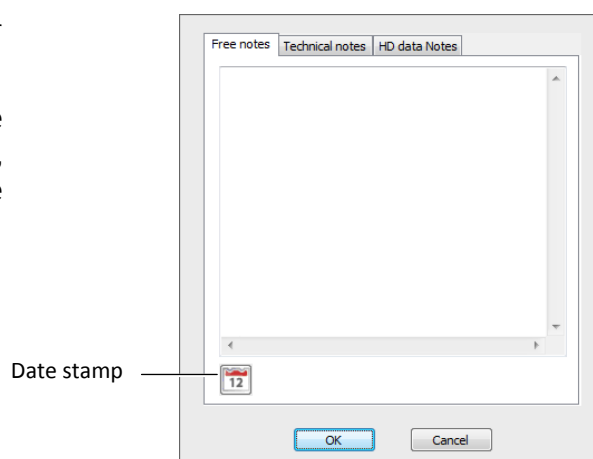
To permanently delete a patient's data, click on  in the upper right-hand corner of the screen and remember the patient ID displayed at the top. Then using Windows Explorer, search in the Patients root directory the name which has the patient's ID preceded by characters #####. Delete this directory and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

## Adding comments

You can add simplified comments for a particular patient file.

To do this, select it and click on  Notes . In the window which appears, you can enter free notes, technical notes or HD data notes and insert the date by clicking on .

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

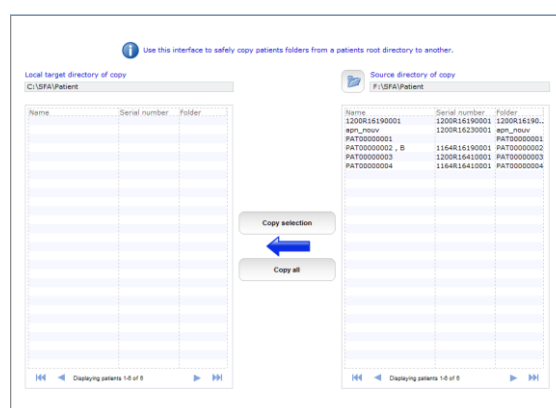



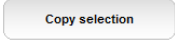
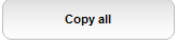
## Other utilities

### 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.

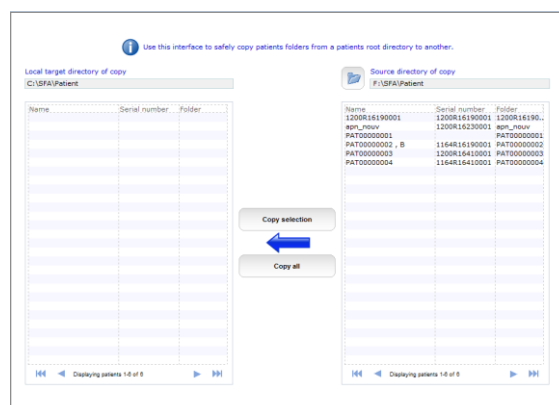
**Notes:**

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

## 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.



## 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.

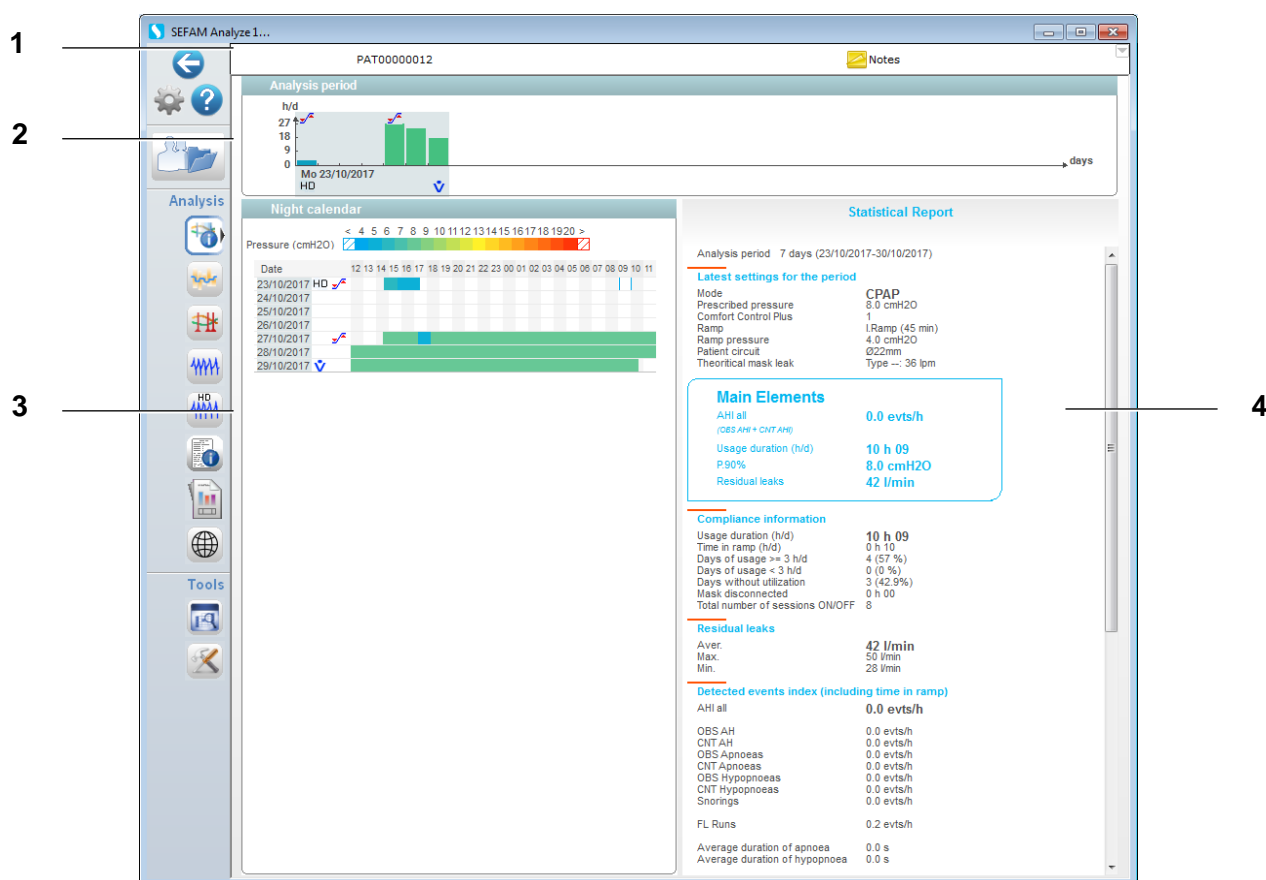
The window which appears shows all the information recorded for a session and for each session, a **useful duration** is recorded.

## 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 saved

In this chapter, the screenshots show the usage of a SEFAM S.Box device, but the information displayed will vary depending on the operating mode and the settings used.



The window is divided in four sections:


## 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, the patient's identifier and age will appear as well as other data if available in the patient record. Additional information can be added by clicking on  Notes; see paragraph "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 colour indicates the average pressure for the 24-hour period. Its value is the average of average pressures which have been weighted by the duration of use for each session.

The flow symbol  indicates 10 Hertz flow curves in real time at the corresponding dates of the compliance condensed diagram and night calendar.

### 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 **Night calendar** is displayed by default on the left of the window. It gives a quick overview of patient compliance across the most recent recorded sessions.

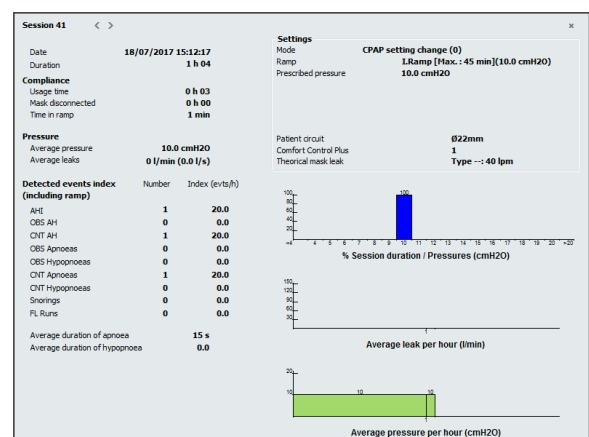
A colour scale indicates pressure levels from 4 cmH<sub>2</sub>O to 20 cmH<sub>2</sub>O.

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

If you double-click on a session, the **Session** window will open, showing data of compliance and pressure, as well as the settings adjusted during this session.









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

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

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

The different presentations are described in the following pages.

# The different presentations

## 1. Statistical report

This tab is displayed by default or can be accessed by clicking on .

The header concerns the analysis period selected in the pressure graph. Then, the information is shown in 5 headings:

### Latest settings for the period

### Main Elements

### Compliance information

- Usage duration per day and percentage days of usage  $\geq 3$  h/d (3 = threshold which can be configured)
- Time in ramp (percentage of usage duration), and time during which the mask was disconnected
- Number of days and percentage of device usage and non-usage

### Residual leaks

- % of time above the limit leak.
- Min., max. and average values of unintentional leaks measured in the mask over the period analysed

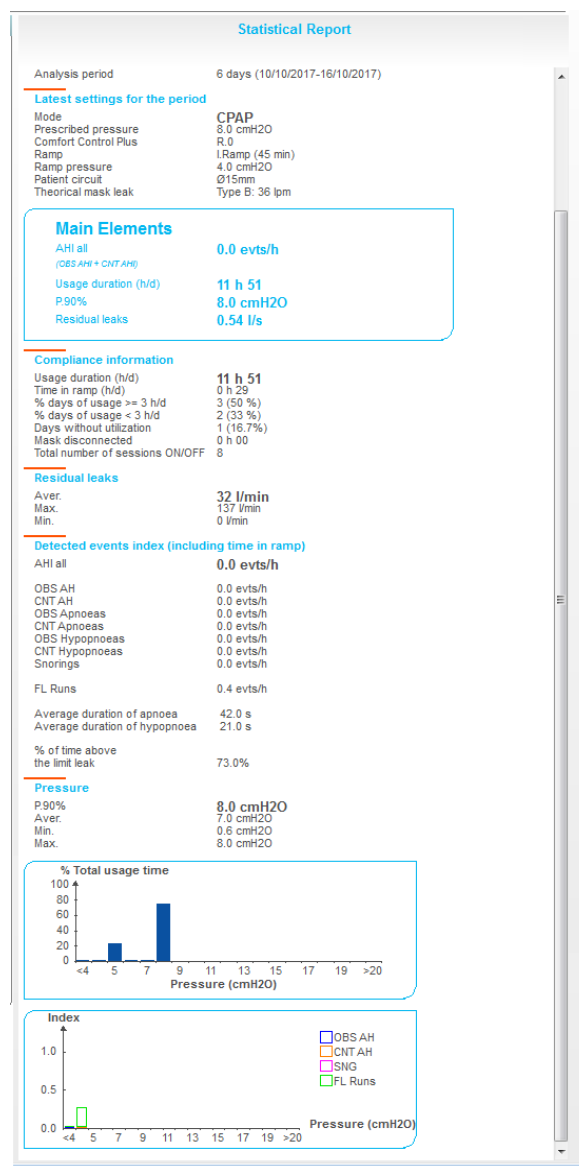
### Detected events index [including time in ramp]


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

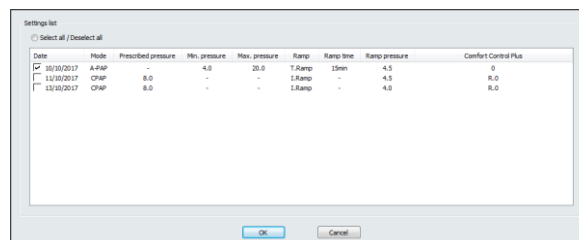
### Pressure

- Pressure efficient more than 90% of time (90 % = threshold which can be configured).
- Min. max. and average pressures measured over the period analysed.


Diagrams of % total usage time and index of events for each full pressure value.



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).




Date	Mode	Prescribed pressure	Min. pressure	Max. pressure	Ramp	Ramp time	Ramp pressure	Comfort Control Plus
10/10/2017	A-PAP	-	4.0	20.0	I.Ramp	15min	4.5	0
11/10/2017	CPAP	8.0	-	-	I.Ramp	-	4.5	8.0
12/10/2017	CPAP	8.0	-	-	I.Ramp	-	4.0	8.0

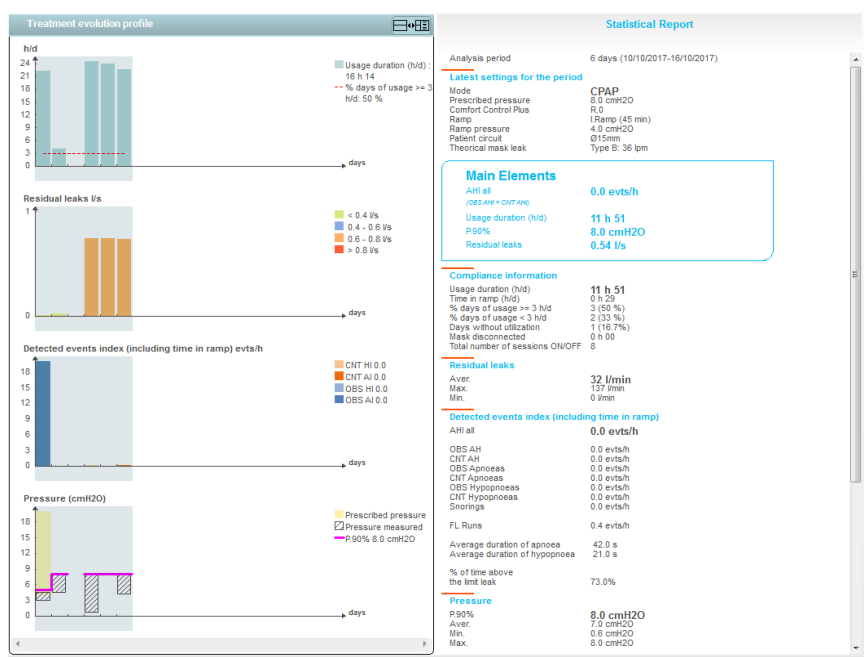
The "Compliance" tab of the analysis parameters dialogue box can be opened by clicking on  or by clicking with the right mouse button on the statistical report (refer to the paragraph "Choice of analysis parameters" page 9).

## 2. Treatment evolution profile and Statistical report

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.



### Treatment evolution profile

Four graphs are displayed from top to bottom with the 24 hour periods in abscissa.

- 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 greater than the value selected. Otherwise, it is represented in orange.
- Graph of leaks: % of time spent above the limit leak
- Graph showing index of detected events including or not the time in ramp.
- Graph of pressures: prescribed pressure (yellow background), pressure measured (vertical shading) and P.90% = efficient pressure for more than 90 % of time (pink curve), 90 % being adjustable in the analysis parameters.

The button  allows to spread the vertical space between the treatment evolution profile and the statistical report and so to increase the readability of the graphs. 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.

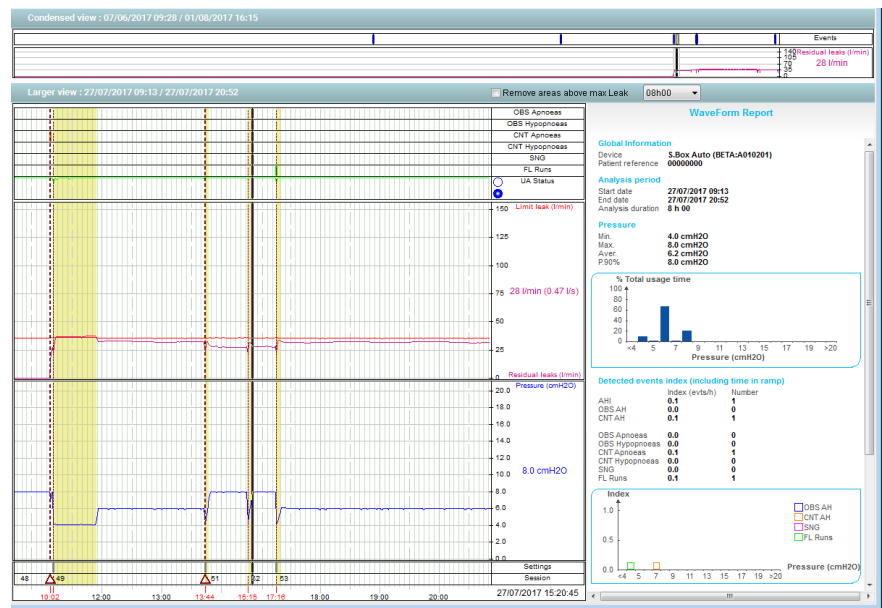
Details of the parameters and events detected depend on the options selected in the dialogue box of analysis parameters (see paragraph "Choice of analysis parameters" page 9).

### Statistical Report

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

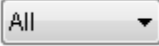
### 3. Waveforms

The curves can be accessed by selecting .



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

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

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

In the upper section of the larger view, you can see 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.

The leak and limit leak waveforms, and the pressure graph are displayed in the central section.




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 pressure and leak measurements 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.



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 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.

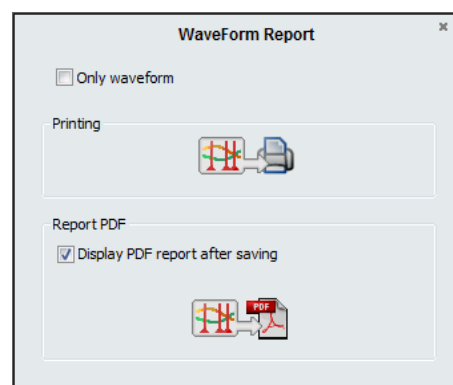
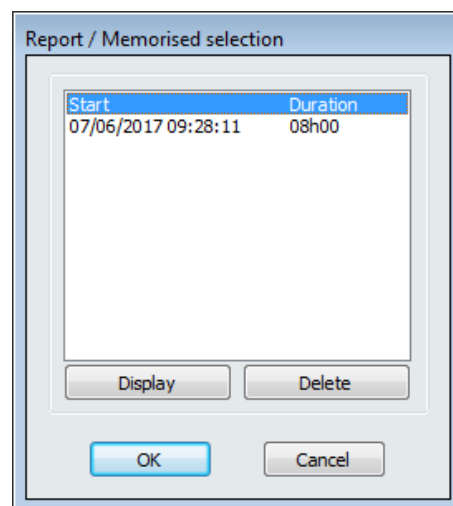
The button  allows you to display the portion of the curve and the button  to remove it.

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

The 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 curves in the report or/and to view the 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 31.

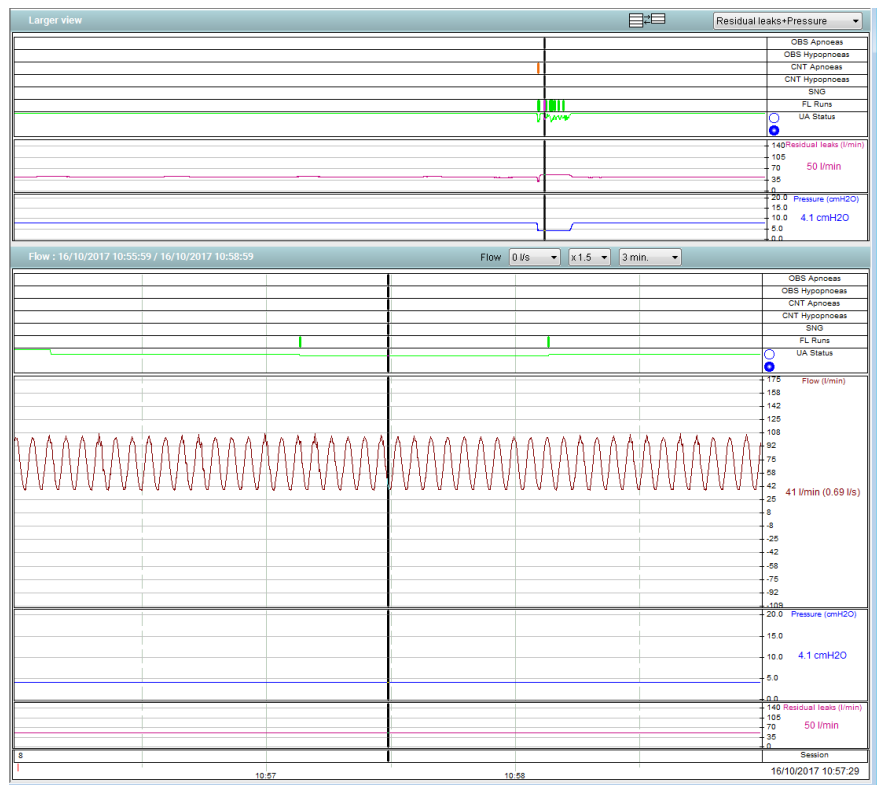
## 4. Flow

The Flow tab can be



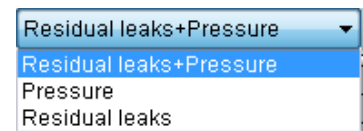
accessed by

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




This presentation gives first a summary view of the detected events.


The drop down list on the right allows you to select the display of the measured residual leak levels and/or of the pressure curve in the mask.


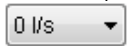





In the second part, are displayed more detailed views of detected events, of flow curve as well as of curves of measured pressure and leak levels.

The button  allows you to spread the vertical space between the summary view and the more detailed view and thereby to increase the readability of the curves.

You can browse through the record using either the mouse or the  $\rightarrow$  and  $\leftarrow$  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  $\uparrow$  and  $\downarrow$  keys shift the height curve.

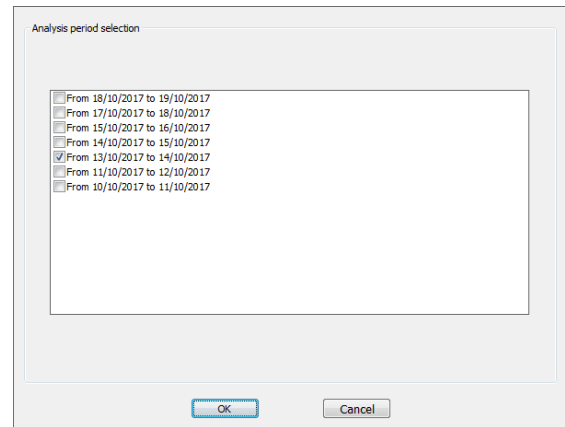
Refer to "3. Waveforms" section page 22 for using the buttons ,  and .




## 5. Access HD signals

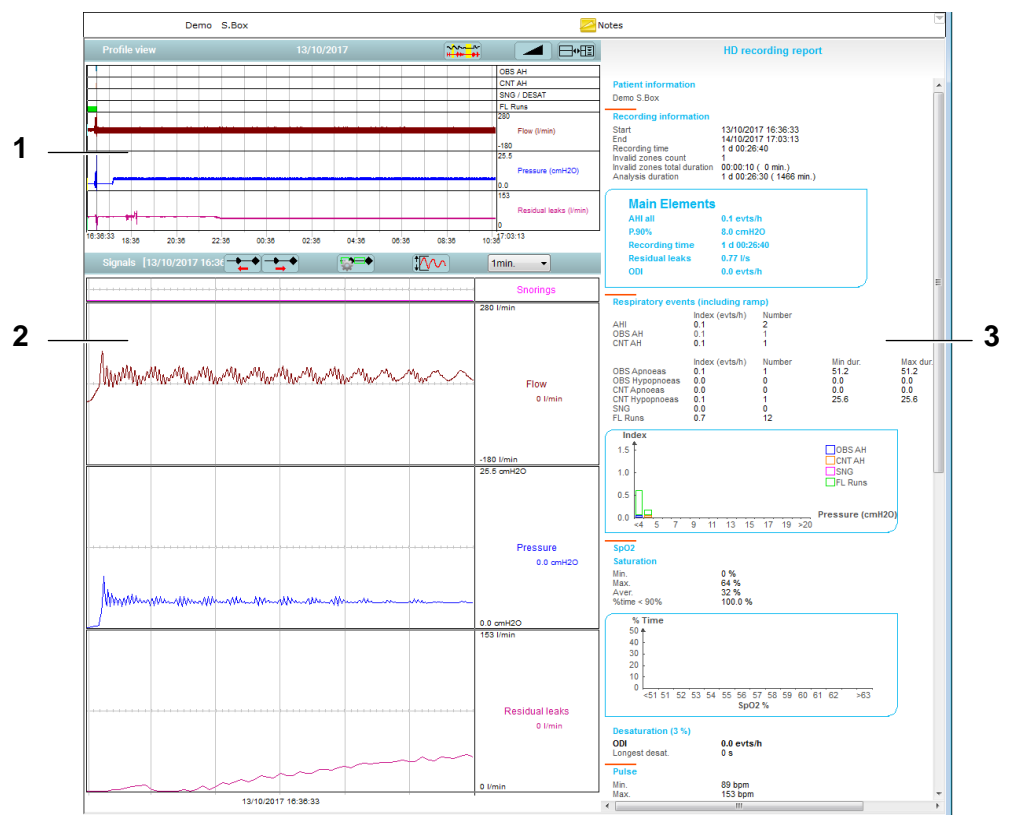
Access to signals downloaded from a SD card is performed by clicking on .

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



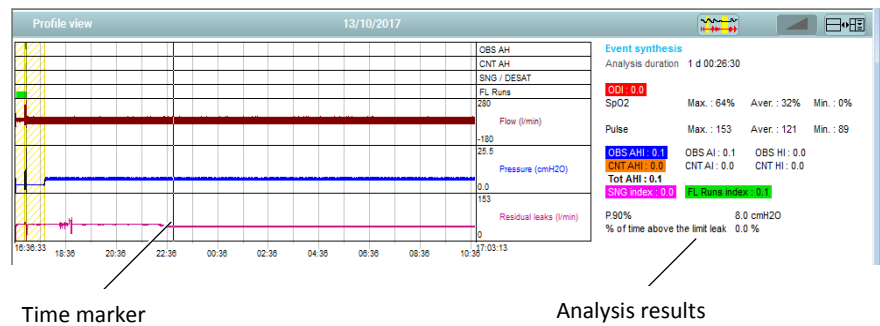
In the window which appears, the button  allows you to spread the space between the summary view, the event synthesis, the view of raw signals and the recording report. It thereby allows to increase the readability of the curves. According to your choice, the recording report may be hidden if you prefer viewing the event synthesis.

The window is divided in three parts:



## a) Profile view

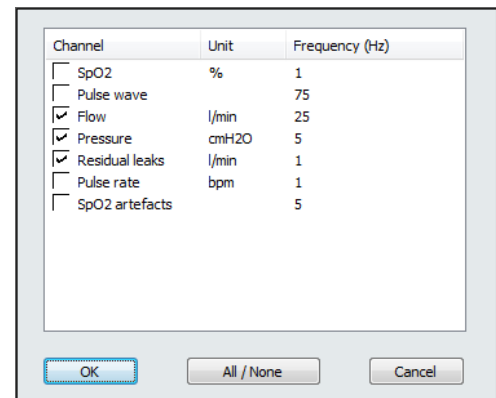
The profile view displays the condensed curves and the synthesis of detected events.



If you right-click with the mouse on the curves, a dialogue box displays the list of channels acquired that you can select.

### Note:

All the channels are selected by default.



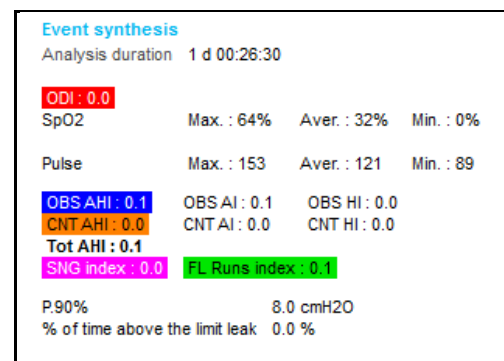
Confirm your choice with **OK**. Only the channels selected will be displayed in the order listed in the dialogue box.

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.

On the right of the analysis profile, the main results of analysis are displayed in terms of events index reported to the analysis duration.

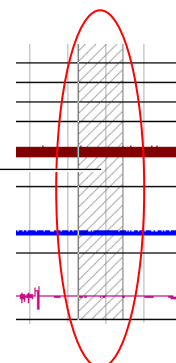
AHI obstructive and central, ODI, snoring index and FL Runs index are represented with colour codes.



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.

Example of invalid zone



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.
- remove a zone after having selected it by clicking once on it and by using the right mouse button.

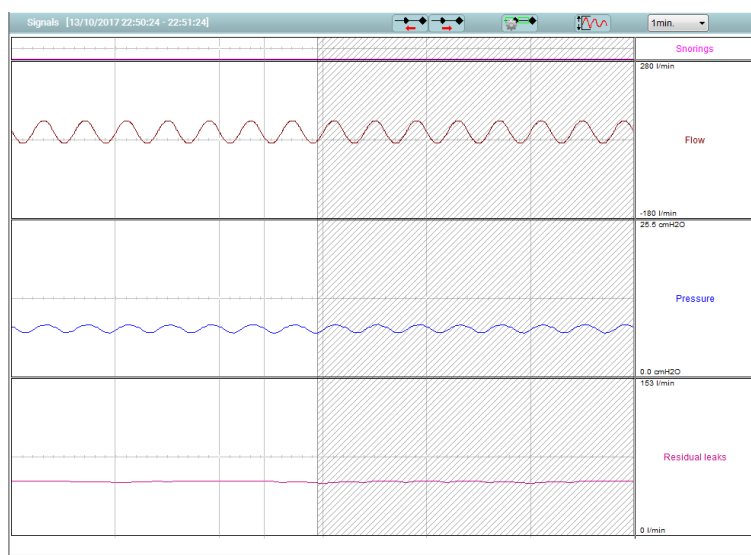
The duration of this (these) zone (s) will be deducted from the recording time to calculate the analysis duration.

## b) Viewing the raw signals

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

As in the "Profile view" part, the list of the channels which can be selected displays if you right-click with the mouse on the curves.

On the right hand side of the curves, the values correspond, to measurements of flow, pressure, leak level and so on corresponding to the cursor's position in the abscissa.



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 the drop-down list **3min.**. This duration can also be changed using the mouse wheel.

You can browse through the recording using **→** et **←** of the computer keyboard. You can also move forward or backward by  $\frac{1}{2}$  period pressing simultaneously the corresponding arrow and Ctrl key.

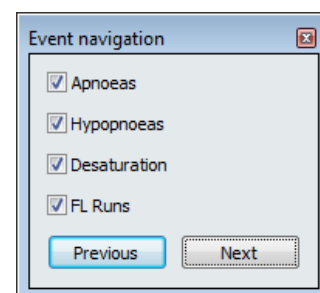


The button allows you to automatically adjust the gain and the offset of the channels selected in the window.



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

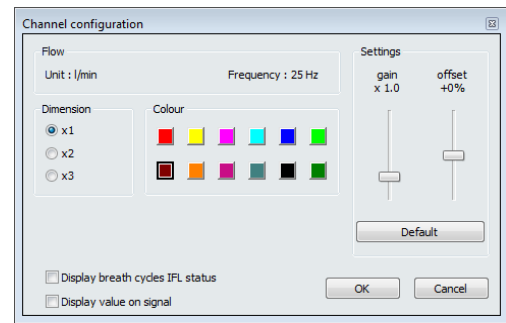
Select the types of events and if you click on **Previous** or **Next**, you move the recording of an event or several types backward or forward.



To facilitate the visualization of signals and events, you can center the page of signals by left-clicking with the mouse and pressing the CTRL key.

The names of selected channels and a simple scale are displayed on the right 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.

## c) Recording report

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

Patient Information is shown at the top and can be followed by notes.

Then the recording information is listed, as well as the invalid zones and the analysis duration.

The report information is following, grouped in headings.

### Main events

- Index of main events
- Pressure efficient more than 90 % of time (adjustable), recording time and residual leaks

### Respiratory events (including or excluding ramp)

- Index and number of detected events, min., max. and average duration of the main events
- Graph of index of respiratory events for each full pressure value

### SpO<sub>2</sub>

Saturation:

- % of min., max. and average saturation and % of time spent with SpO<sub>2</sub> < 90 %
- Histogram showing the percentage of time spent for each SpO<sub>2</sub> %.

Desaturation:

- Number of events per hour ODI and duration of longest desaturation.

### Pulse

- Min., max. and average values of frequency.

### Pressure

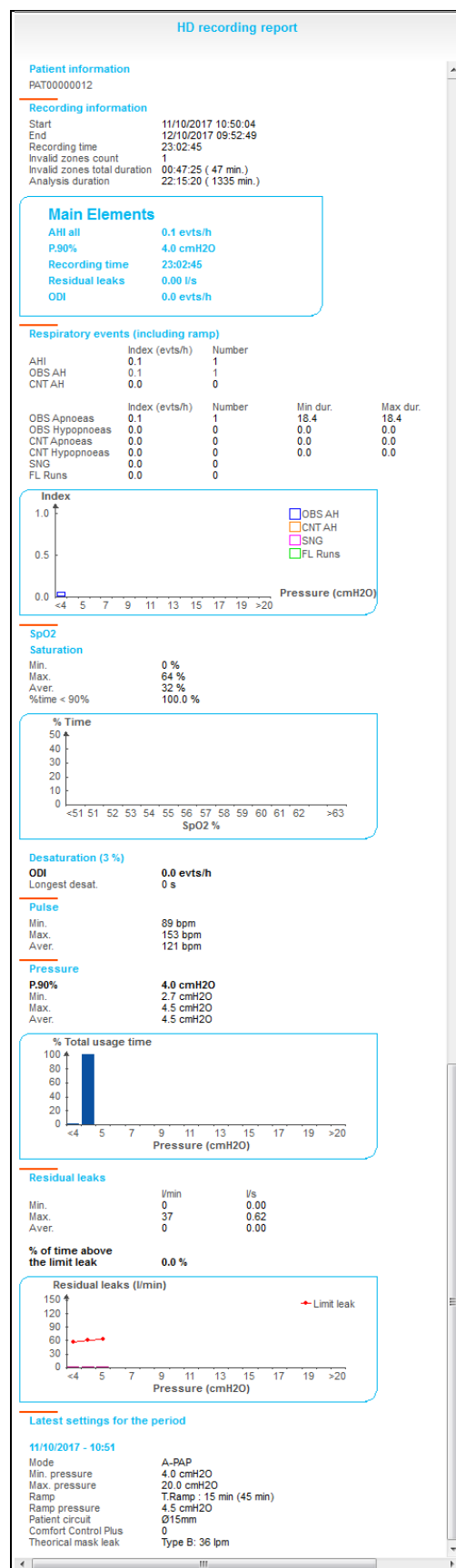
- Pressure efficient more than 90 % of time (can be set) and min., max. and average pressures
- Graph of % total usage time for each full pressure value.

### Residual leaks

- Values of min., max. and average residual leaks
- % of time above the limit leak and graph of residual leaks for each full pressure value

### Latest settings for the period

- The different settings are listed for the analysis period.



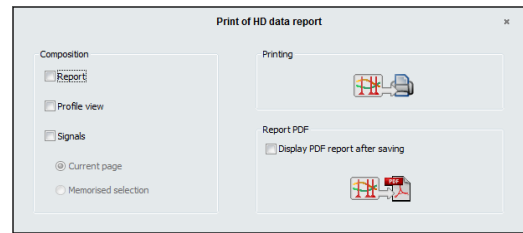
For using the buttons  and  refer to 3. Waveforms" section page 22.

## d) Printing the report



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.

## 6. Global Information / Settings list

This tab can be accessed by

clicking on

Global Information		Settings list	
<b>Device</b>		<b>31/07/2017 - 16:18</b>	
Device	S.Box Auto (BETA:A010201)	Mode	CPAP
Serial number	1200R17090001	Prescribed pressure	6.0 cmH2O
Patient reference	00000000	Ramp	T.Ramp : 30 min (30 min)
Hour counter - Configuration	0 h 00	Ramp pressure	6.0 cmH2O
Hour counter - Downloaded	900 h 32	Patient circuit	Ø22mm
Global period	64 days ( 06/06/2017 - 08/08/2017 )	Comfort Control Plus	1
Average operation time / day	14 h 54 ( Total period = 900 h 32 )	Theoretical mask leak	1 Type --36 lpm
Total usage time	137 h 23	<b>31/07/2017 - 13:58</b>	
Average usage time / day	2 h 09	Mode	A-PAP
Configuration date	07/06/2017 - 09:27	Min. pressure	4.0 cmH2O
Download date	08/08/2017 - 15:31	Max. pressure	20.0 cmH2O
Total number of sessions	63	Ramp	I.Ramp (45 min)
Average number of sessions / day	0.98	Ramp pressure	6.0 cmH2O
Downloaded sessions	63	Patient circuit	Ø22mm
		Comfort Control Plus	1
		Theoretical mask leak	1 Type --36 lpm
		<b>31/07/2017 - 09:10</b>	
		Mode	A-PAP
		Min. pressure	5.0 cmH2O
		Max. pressure	19.0 cmH2O
		Ramp	T.Ramp : 30 min (30 min)
		Ramp pressure	5.5 cmH2O
		Patient circuit	Ø22mm
		Comfort Control Plus	R.1
		Theoretical mask leak	1 Type --36 lpm
		<b>28/07/2017 - 16:38</b>	
		Mode	A-PAP
		Min. pressure	5.0 cmH2O
		Max. pressure	19.0 cmH2O
		Ramp	I.Ramp (45 min)
		Ramp pressure	5.5 cmH2O
		Patient circuit	Ø22mm
		Comfort Control Plus	R.1
		Theoretical mask leak	1 Type --36 lpm
		<b>28/07/2017 - 16:37</b>	
		Mode	A-PAP
		Min. pressure	4.0 cmH2O
		Max. pressure	19.0 cmH2O
		Ramp	I.Ramp (45 min)
		Ramp pressure	6.0 cmH2O
		Patient circuit	Ø22mm
		Comfort Control Plus	R.1
		Theoretical mask leak	1 Type --36 lpm
		<b>28/07/2017 - 16:29</b>	
		Mode	CPAP
		Prescribed pressure	6.0 cmH2O
		Ramp	T.Ramp : 30 min (30 min)
		Ramp pressure	6.0 cmH2O
		Patient circuit	Ø22mm
		Comfort Control Plus	R.1
		Theoretical mask leak	1 Type --36 lpm
		<b>28/07/2017 - 16:16</b>	
		Mode	CPAP
		Prescribed pressure	6.0 cmH2O
		Ramp	T.Ramp : 45 min (45 min)
		Ramp pressure	6.0 cmH2O
		Patient circuit	Ø22mm
		Comfort Control Plus	R.1
		Theoretical mask leak	1 Type --36 lpm

### Global information

Shows all the information concerning the device used.

- device type of machine 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
- Total usage time
- 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.

## 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 operating mode selected.


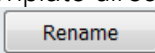
Click on  to return to the patient compliance list.

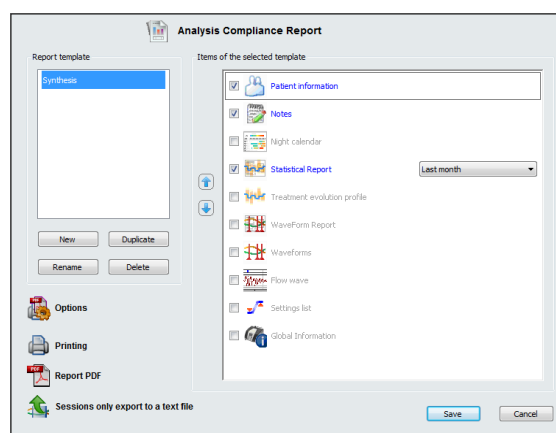
## 7. Analysis Compliance Report

### Printing and exporting reports

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

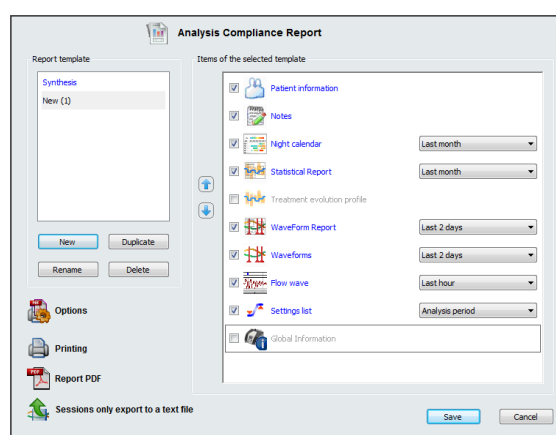
A template of analysis compliance report exists by default: **Synthesis**.

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.

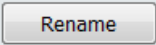

If in **Waveforms** or / and **Flow wave** tab(s), you added a portion of curve in the memorised selection, the field "Memorised selection" is proposed in the drop-down list.




#### 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 .

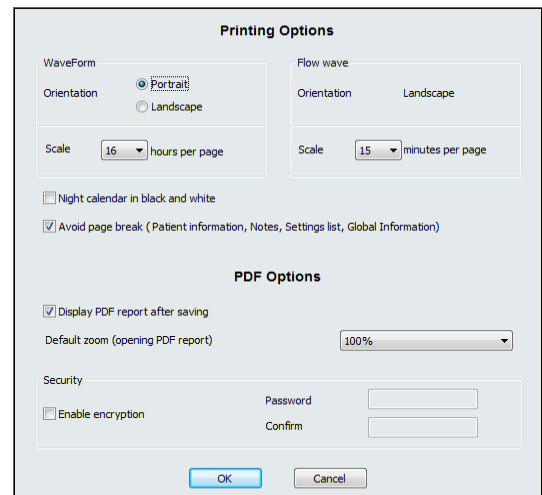
The name of this copy or of an existing compliance report template can be modified by selecting it and clicking on . This option allows you to rename the report and to select or deselect the items that you want to print. It is also possible to delete a report template by selecting it and clicking on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



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** when opening the PDF report
- **Enable encryption** by password protection of PDF exported.



The dialog box is titled "Printing Options". It contains two main sections: "WaveForm" and "Flow wave".

**WaveForm section:**

- Orientation: Radio buttons for "Portrait" (selected) and "Landscape".
- Scale: A dropdown menu showing "16" and the text "hours per page".

**Flow wave section:**

- Orientation: Radio buttons for "Portrait" and "Landscape" (selected).
- Scale: A dropdown menu showing "15" and the text "minutes per page".

**General options:**

- ☐ Night calendar in black and white
- ☒ Avoid page break (Patient information, Notes, Settings list, Global Information)

**PDF Options section:**

- ☒ Display PDF report after saving
- Default zoom (opening PDF report): A dropdown menu showing "100%".

**Security section:**


- ☐ Enable encryption
- Password: A text input field.
- Confirm: A text input field.

At the bottom are "OK" and "Cancel" buttons.


## 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 . 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.


## "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.



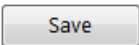
The **Save As** dialogue box appears with the name, the path where the created file will be saved, and the file type with the .txt extension. Click on Save.

## 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 SEFAM S.Box 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	R	S
1	Session	State	Date	Time	Duration	Usage	Mask disconnected	Time in ramp	Average pressure	Average leaks	OBS Apnoeas	CNT Apnoeas	OBS Hypopnoeas	CNT Hypopnoeas	Snorings	FL Runs	setting change	Mode	Prescribe
2	1	OK	07/06/2017	09:27:11	02:16	00:01	0	00:45	4.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
3	2	OK	07/06/2017	13:25:56	00:51	00:02	0	00:45	4.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
4	3	OK	07/06/2017	14:18:40	00:03	00:02	0	00:02	4.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
5	4	OK	07/06/2017	14:21:38	00:08	00:03	0	00:00	9.9	0.00	0	0	0	0	0	0	0	CPAP	1
6	5	OK	07/06/2017	14:32:42	02:21	00:02	0	00:00	10.0	0.00	0	0	0	0	0	0	0	CPAP	1
7	6	OK	07/06/2017	16:54:46	15:52	00:01	0	00:45	5.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
8	7	OK	08/06/2017	17:01:58	20:45	00:02	0	01:30	5.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
9	8	OK	09/06/2017	17:27:12	24:00:00	00:02	0	00:45	5.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
10	9	OK	10/06/2017	17:27:14	24:00:00	00:01	0	00:00	5.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
11	10	OK	11/06/2017	17:27:15	15:38	00:00	0	00:00	5.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
12	11	OK	12/06/2017	17:09:52	15:40	00:01	0	00:45	5.0	0.00	0	0	0	0	0	0	0	A-PAP+FL	
13																			
14																			
15																			
16																			
17																			
18																			
19																			
20																			

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

## 8. Sending 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 the last session recorded on SEFAM Connect
- From a date selected
- All the sessions.

**Send compliance data to SEFAM Connect**

☒ from last session recorded on SEFAM Connect  
10/11/2017

☐ from

☐ all sessions

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

# Configuring the device

## Connecting to the device

A computer can be connected to a SEFAM S.Box 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 "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 SEFAM S.Box 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.

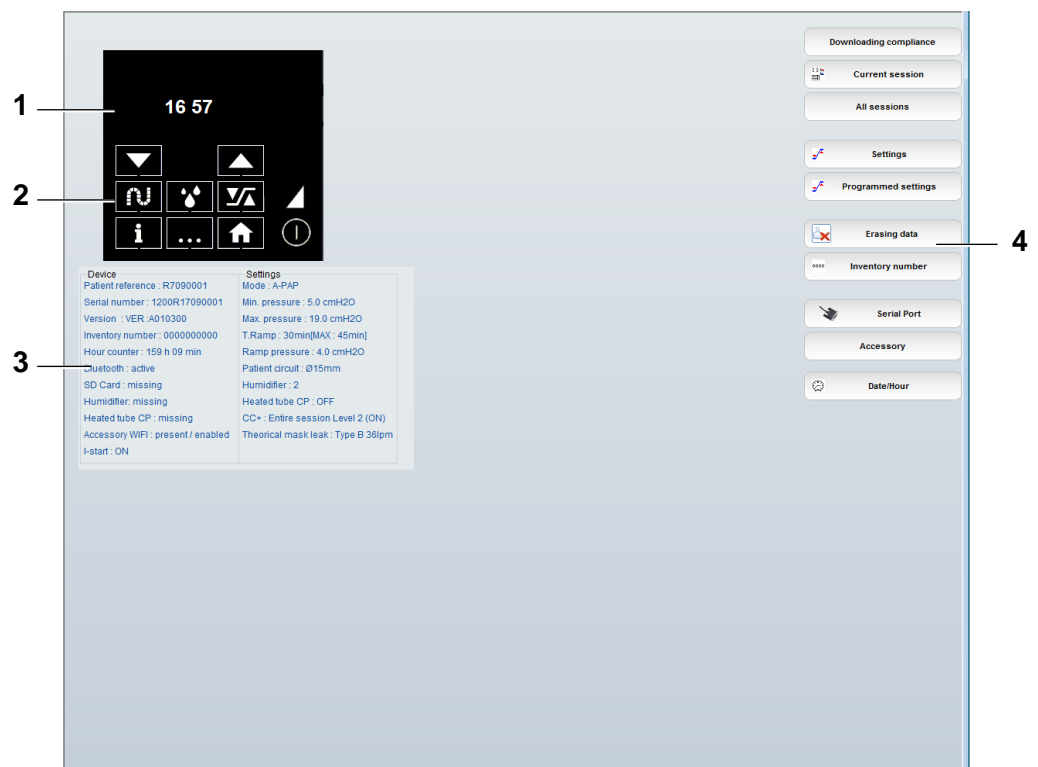
### CAUTION

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

## Description of the connection screen

Click on the bouton  or .

The window of connection which appears is divided in four parts.

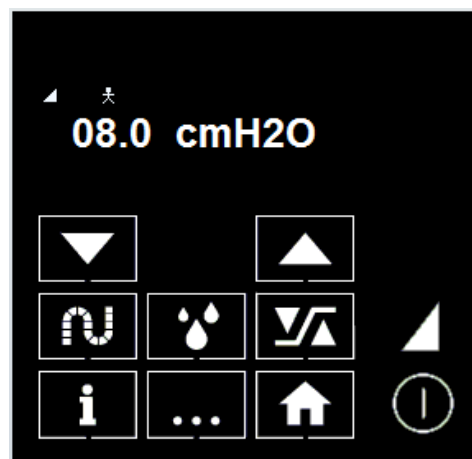


## 1. Device status

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 standby



Device in operation

## 2. Buttons

The buttons  and  are operational and are used:

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

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

## 3. 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

The activation or not of the Bluetooth and I.Start (Intelligent Start) functions is indicated, as well as the presence or not of the accessories (SD card, humidifier, S.Box heated tube with ATC, communicating accessory Wi-Fi or modem present and/or enabled or not).

### b) Settings:

The information displayed varies with the settings.

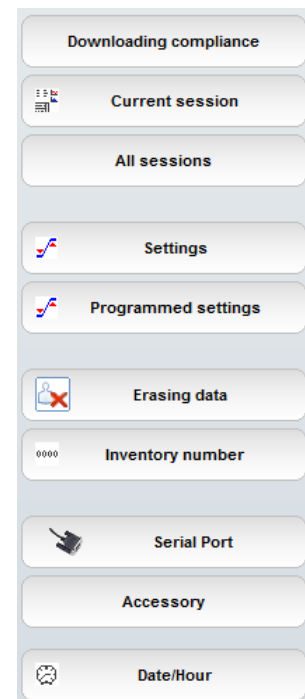
- Mode: CPAP or A-PAP (Auto-CPAP) followed by the detected events in Auto-CPAP mode
- Prescribed pressure in CPAP mode or Min. Pressure and Max. Pressure in Auto-CPAP mode
- Ramp type (T.Ramp or I.Ramp), and ramp time in T.Ramp, followed by the maximum ramp time in brackets.
- Ramp pressure (ramp start pressure).

The diameter of patient circuit is indicated, as well as the settings of the humidifier, S.Box heated tube with ATC, functions Comfort Control Plus and theoretical mask leak (Mask select feature).

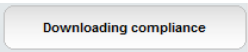
## 4. Other functionalities

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

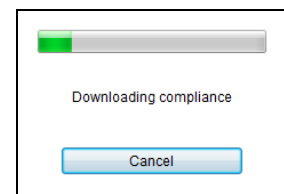
- download via USB cable, compliance data stored in the device
- display the current session or all the sessions
- access settings and program setting changes
- erase compliance data
- access inventory number
- check serial port configuration
- configure a communicating accessory (Wi-Fi module, 3G modem,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



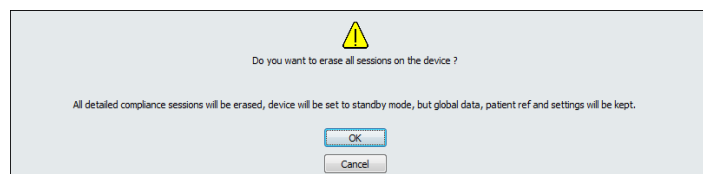
## Downloading data by serial link

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

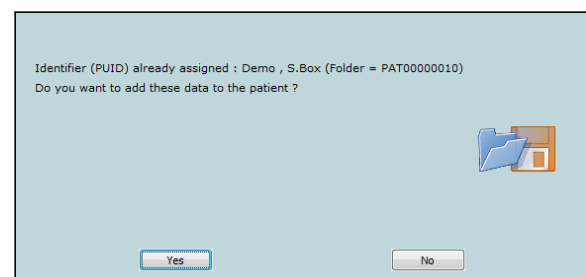
A window shows the download progress.



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 or otherwise 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.

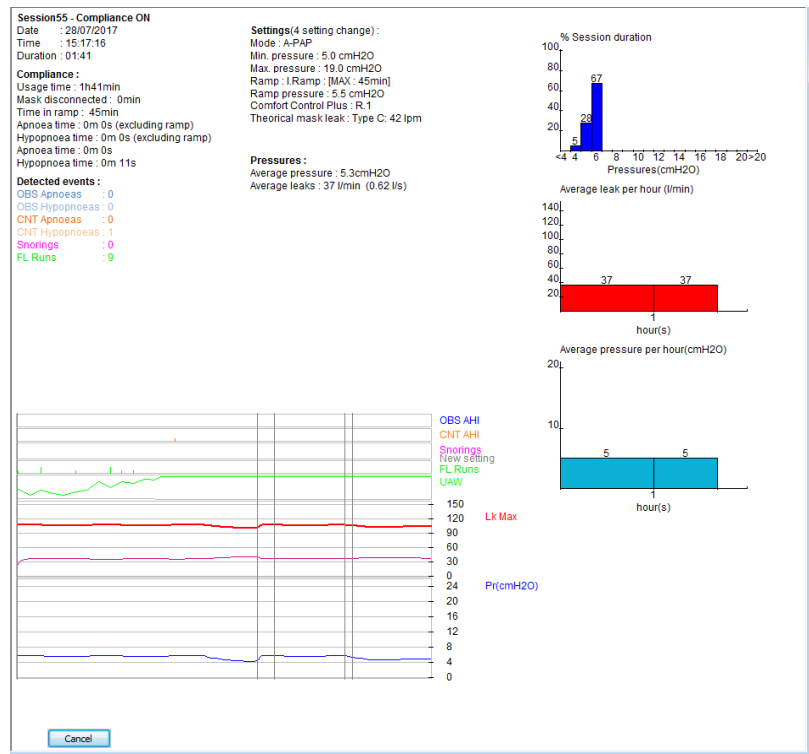
- If you choose an patient existing in the list, a message warns you that the serial number will be removed from the previous patient. Click on **OK**.

## 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:

### Session – Compliance ON:

- information concerning the recorded session and device operating duration over the session.

### Compliance:

- usage time during which the patient has breathed with the mask and time spent with the mask disconnected.
- time in ramp.
- time spent, without time in ramp, with apnoea, then with hypopnoea.
- time spent with apnoea, then with hypopnoea.

**Detected events:** number detailed of respiratory events detected over the period analyzed, obstructive apnoeas, obstructive hypopnoeas, central apnoeas, central hypopnoeas, snorings and FL Runs.

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

- mode programmed during the last setting. In Auto-CPAP mode, the types of events are following: A (Apnoeas), SNG (Snorings), H (Hypopnoeas), FL (cycles with Flow limitation)

- prescribed pressure in CPAP mode or min. pressure and max. pressure in Auto-CPAP mode
- ramp type: T.Ramp (time ramp) or I.Ramp (intelligent ramp), followed by the ramp time (in T.Ramp) with the maximum ramp time in brackets.
- ramp pressure (ramp start pressure).
- Comfort Control Plus CC+: enabled during the entire session (1, 2 or 3) or during the ramp (R.1, R.2 or R.3) or disabled.
- Theoretical mask leak with indication of the type of mask (A, B, C or \_ \_).

#### Pressures:

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

Four diagrams are displayed in the window:

- histogram showing percentage of the session duration at each pressure level.
- diagram of average leak per hour.
- diagram of average pressure per hour.
- At the bottom left, the Raw signals at 1 min show the measured Pressure, the measured Leak and the limit Leak, the detected events in the same colours as in the detected Events list, as well as the new settings.

## Data for all sessions

You can access all the recorded sessions by clicking on

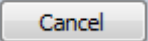
**All sessions**

A window displays the data for the last session:



The window allows to 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 "Viewing the current session" section.

The button **Sessions only export to a text file** allows you to export sessions in text format. For further information, refer to the "Export of sessions only to a text file" feature" section page 32.


Click on  to exit all sessions view.

## 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 SEFAM S.Box device.

Click on  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.

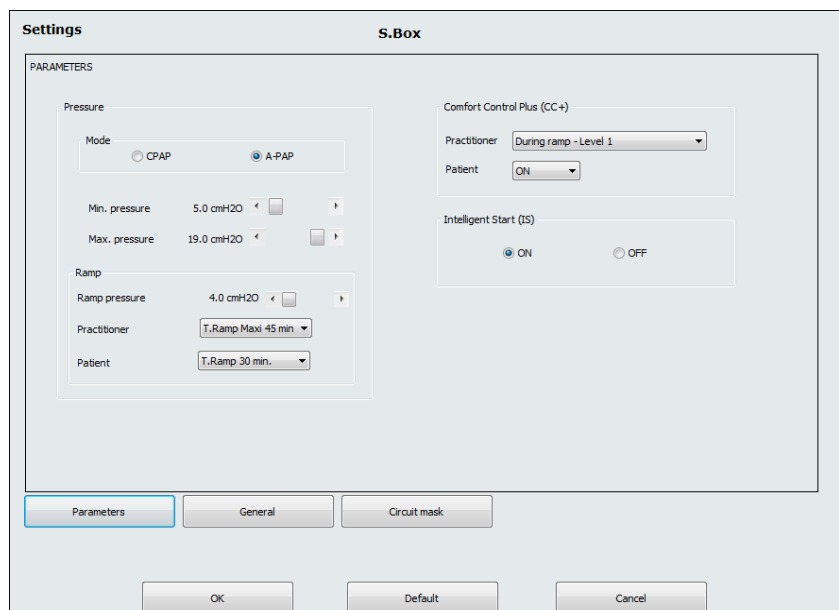
## Parameters

The button  is selected by default.

The parameter values are displayed on the left of the cursors.

You can set the parameters either by clicking on the right and left arrows or by moving the cursor with the left mouse button.

The settings ranges are the same as those of the device.



The screenshot shows the 'Settings' window for the 'S.Box' device, with the 'PARAMETERS' tab selected. The window is divided into two main sections: 'Pressure' and 'Ramp' on the left, and 'Comfort Control Plus (CC+)' and 'Intelligent Start (IS)' on the right. The 'Pressure' section includes a 'Mode' selector with 'CPAP' and 'A-PAP' options (A-PAP is selected), and two pressure range settings: 'Min. pressure' (5.0 cmH2O) and 'Max. pressure' (19.0 cmH2O), each with left and right arrow buttons. The 'Ramp' section includes a 'Ramp pressure' (4.0 cmH2O) with arrow buttons, and two dropdown menus for 'Practitioner' (set to 'T.Ramp Maxi 45 min') and 'Patient' (set to 'T.Ramp 30 min.'). The 'Comfort Control Plus (CC+)' section has a 'Practitioner' dropdown (set to 'During ramp - Level 1') and a 'Patient' dropdown (set to 'ON'). The 'Intelligent Start (IS)' section has two radio buttons, 'ON' (selected) and 'OFF'. At the bottom of the window, there are three tabs: 'Parameters' (selected), 'General', and 'Circuit mask'. Below these tabs are three buttons: 'OK', 'Default', and 'Cancel'.



The settings window is divided in several parts:

## Mode

Click on the button **CPAP** to configure the device in constant pressure mode or on **A-PAP** (Auto-CPAP) to select the auto-piloted mode.

## Pressure

In CPAP mode, the pressure being constant, the value of the pressure set can be adjusted between 4 cmH<sub>2</sub>O and 20 cmH<sub>2</sub>O.

In Auto-CPAP mode, Min. pressure can be set between 4 cmH<sub>2</sub>O and Max. pressure, and Max. pressure can be set between Min. pressure and 20 cmH<sub>2</sub>O.

## Ramp

Ramp pressure: the ramp start pressure is adjustable between 4 cmH<sub>2</sub>O and the pressure set in CPAP mode, and between 4 cmH<sub>2</sub>O and Max. Pressure in Auto-CPAP mode.

Ramp type which can be selected by the Practitioner: T.Ramp (time ramp) with the maximum ramp time adjustable in 5 minutes increments between 5 min and 45 min, I.Ramp (intelligent ramp) or OFF.

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).
- No setting available (if OFF was selected by the practitioner).

## Comfort Control Plus CC+

The feature can be enabled by the Practitioner:

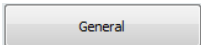
- During ramp with 3 possible levels,
- Entire session with 3 possible levels,
- Never.

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.

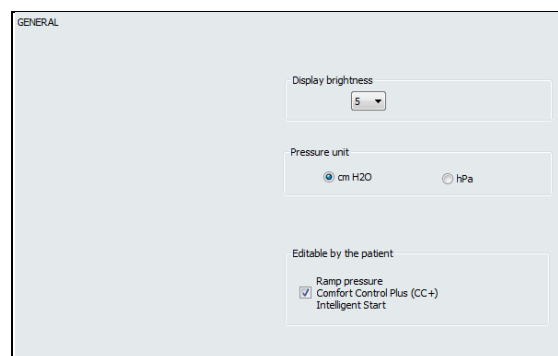
## Intelligent Start

The feature can be enabled (ON) or disabled (OFF).


## General

The button  allows to:

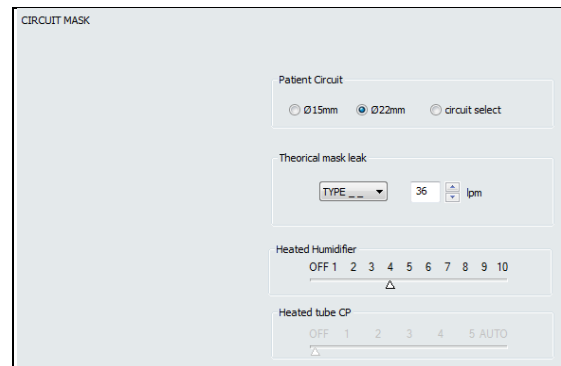
- set the brightness of the device display using the drop down list
- select the pressure unit cm H<sub>2</sub>O or hPa by checking the corresponding box
- make possible or not the access for the patient to a settings group (Ramp pressure, Comfort Control Plus [CC +], Intelligent Start).



## Circuit mask

The button  allows:

- the selection of the circuit patient 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 S.Box heated tube with ATC (if installed).




The CIRCUIT MASK window contains the following settings:

- Patient Circuit:** Radio buttons for Ø15mm, Ø22mm (selected), and circuit select.
- Theoretical mask leak:** A dropdown menu labeled 'TYPE' and a numeric input field set to 36 lpm.
- Heated Humidifier:** A slider control ranging from OFF to 10.
- Heated tube CP:** A slider control ranging from OFF to 5 AUTO.

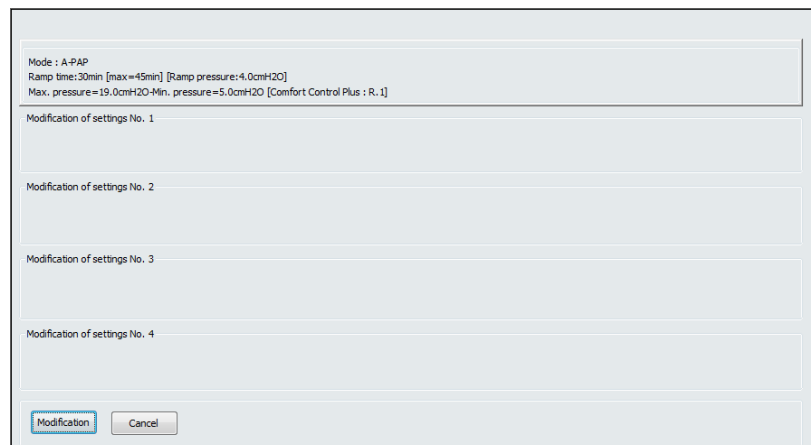
Click on **OK** to confirm the new settings; otherwise click on Cancel.

The button  restores the original device parameters.

## Programming of settings changes


Click on .


The dialogue box appears:



The dialogue box displays the following information:


- Mode:** A-PAP
- Ramp time:** 30min [max=45min] [Ramp pressure: 4.0cmH2O]
- Max. pressure:** 19.0cmH2O-Min. pressure=5.0cmH2O [Comfort Control Plus: R.1]
- Modification of settings No. 1** through **Modification of settings No. 4** (empty text areas).
- Buttons:** Modification, Cancel.

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



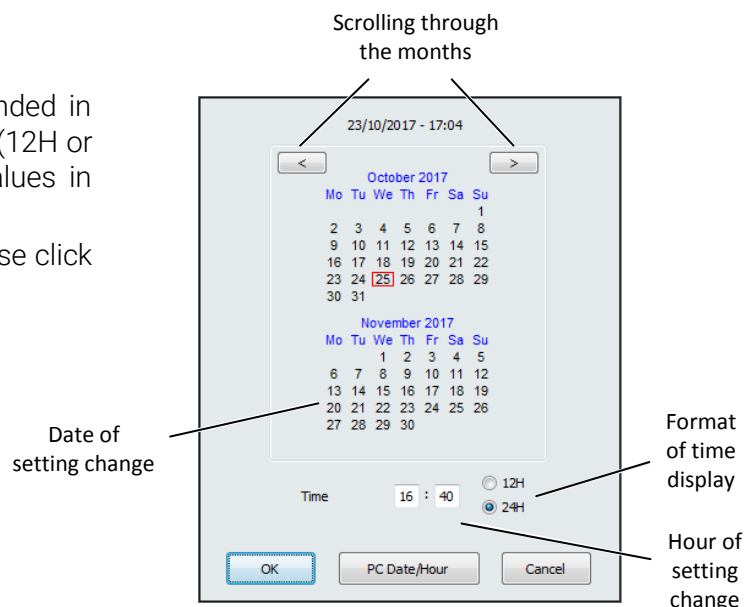
The bottom section contains the following buttons:

- New setting
- Delete set
- OK
- Cancel

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 date and time selection screen includes the following elements and annotations:

- Top status bar:** 23/10/2017 - 17:04
- Month navigation:** Left arrow (<) and right arrow (>) buttons.
- Calendar:** Displays October 2017 and November 2017. The date 25 in October is highlighted with a red box.
- Time display:** Shows 16 : 40.
- Time format:** Radio buttons for 12H and 24H (selected).
- Buttons:** OK, PC Date/Hour, Cancel.
- Annotations:**
  - "Scrolling through the months" points to the month navigation arrows.
  - "Date of setting change" points to the highlighted date 25.
  - "Format of time display" points to the 12H/24H radio buttons.
  - "Hour of setting change" points to the time input field (16 : 40).

The device settings window opens. 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.

New settings

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

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:

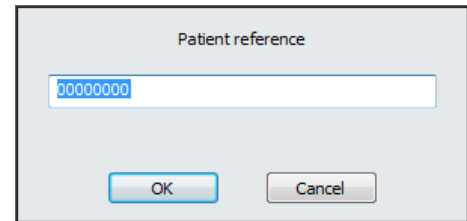
- The programmed settings changes will occur whether the device is operating or in standby. If a settings change is programmed to take place when the machine is not switched on, the settings change will become effective approximately one minute after the device is switched on.
- When a settings change 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.

## Erasing compliance data

Clicking on **Erasing data** 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:



A dialog box titled "Patient reference" with a text input field containing "00000000" and two buttons: "OK" and "Cancel".

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.

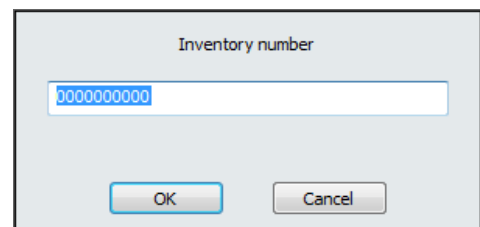
## Inventory number

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.



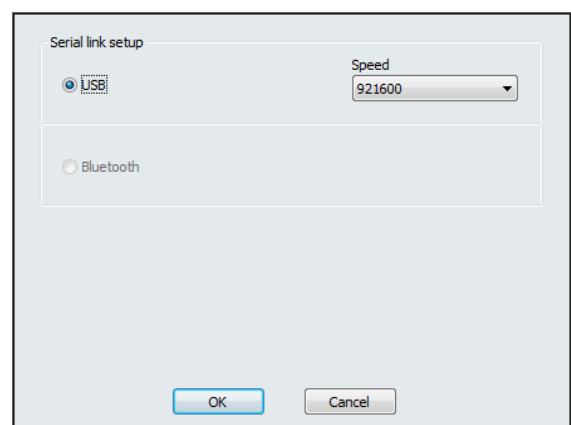
A dialog box titled "Inventory number" with a text input field containing "0000000000" and two buttons: "OK" and "Cancel".

## 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.



A dialog box titled "Serial link setup" with two radio buttons: "USB" (selected) and "Bluetooth". To the right of the "USB" button is a "Speed" dropdown menu showing "921600". At the bottom are "OK" and "Cancel" buttons.

## Communication accessory


The button  enables the wireless communication via the communicating accessory installed in the SEFAM S.Box device (Wi-Fi module, 3G modem or PolyLink).

If no communicating accessory is installed in the machine, the button will be inactive. Otherwise, a window will appear which will look different depending on the inserted accessory. Make sure that the SEFAM S.Box device is in standby, otherwise turn it off.

If you are using a Wi-Fi module, the Security, SSID, and Password fields will have to be completed, if they have not been. You can choose the WPS security (automatic configuration mode) or the WEP, WPA, WPA2 or NO security (manual configuration mode).


Then complete the SSID and Password fields with the SSID and password corresponding to the Wi-Fi network that you want to connect to.

With the **WPS** security, the connection will be automatic. You will then have about two minutes for pressing the corresponding button of your Wi-Fi router and enabling the connection to the network.

If you are using a **manual configuration** mode, click on  which appears on the screen, to transmit the configuration to the Wi-Fi module.

The button  allows erasing the previous Wi-Fi configuration.

The button  which is also displayed allows resetting the fields.

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

Exit the window by clicking on .

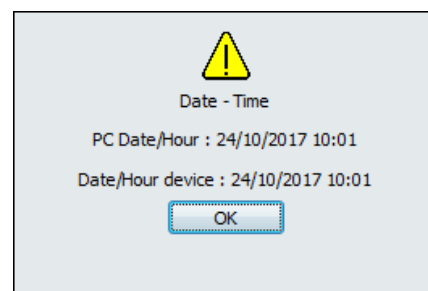


The image shows a 'WIFI Accessory' configuration window. It has a title bar 'WIFI Accessory'. Below it, there are fields for 'version' (WIFI\_V\_01\_02\_00), 'MAC' (AB:1B:6A:80:5A:C2), and 'Current settings'. Under 'Current settings', there are fields for 'Security' (NO), 'SSID', and 'Password'. At the bottom, there are three buttons: 'Erase', 'WPS', and 'Manual'. A 'Close' button is at the very bottom right.

## 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.



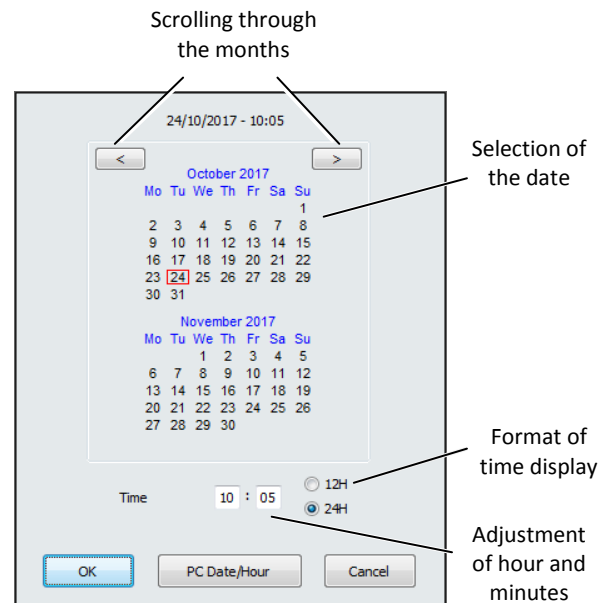
The image shows a 'Date - Time' dialog box with a yellow warning icon at the top. It displays 'PC Date/Hour : 24/10/2017 10:01' and 'Date/Hour device : 24/10/2017 10:01'. At the bottom, there is an 'OK' button.

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 SEFAM S.Box 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.

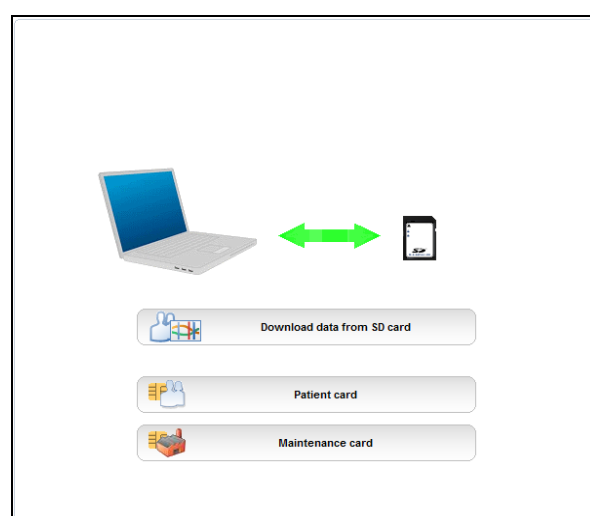
Insert the SD card into the SD card drive of your computer.

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.

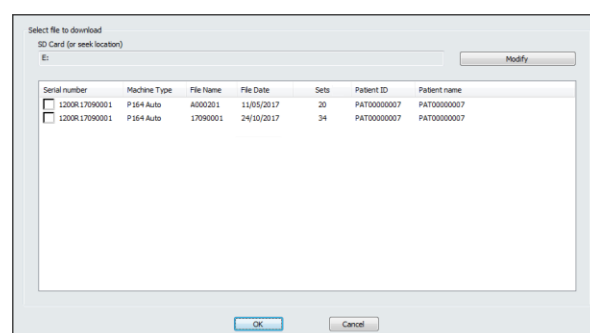


Choose a directory on the SD card. You access a dialogue box which allows you to select a patient existing among the list.

You can choose another file available on the SD card by clicking on .

**Note:**

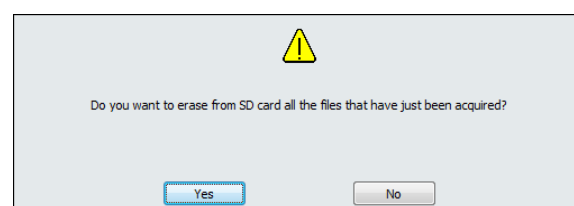
If several files corresponding to serial numbers of different devices are on the SD <sup>TM</sup> card, the files can be assigned to different patients.



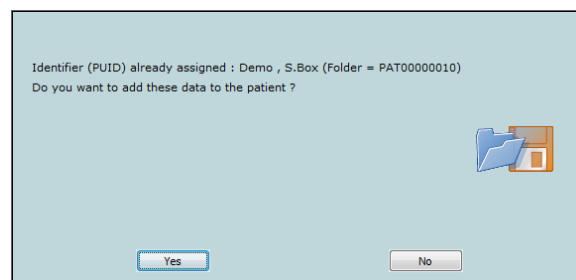
An animation appears until the data download is effective.

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

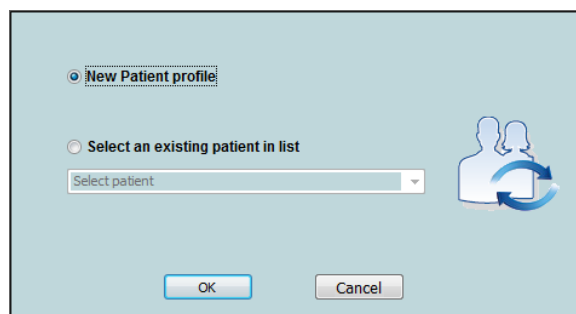
If the option "Ask before erase SD card data" has been selected (set by default), a dialogue box appears. Click on **Yes** if you want to erase the data or click on **No** if you want to keep them.



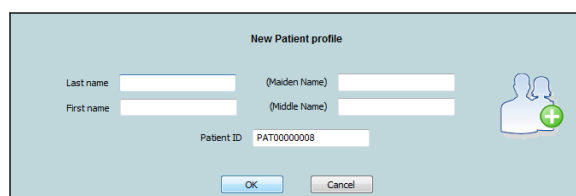
- If the identifier is already assigned, the program asks you if you want to add the data to the existing patient. Click on **Yes** to confirm.



- Otherwise, click on **No**. A dialogue box allows to create a new patient profile or to select an existing patient in the list.

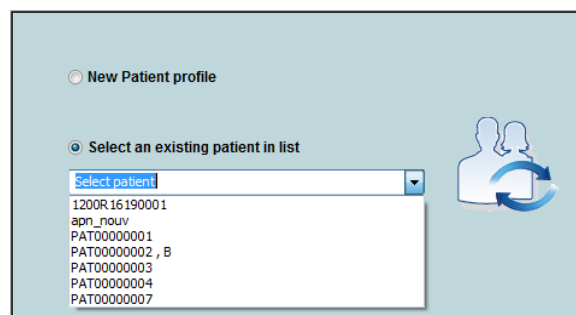


If you choose creating a new patient, complete the information for this patient in the window **New Patient profile** which appears.



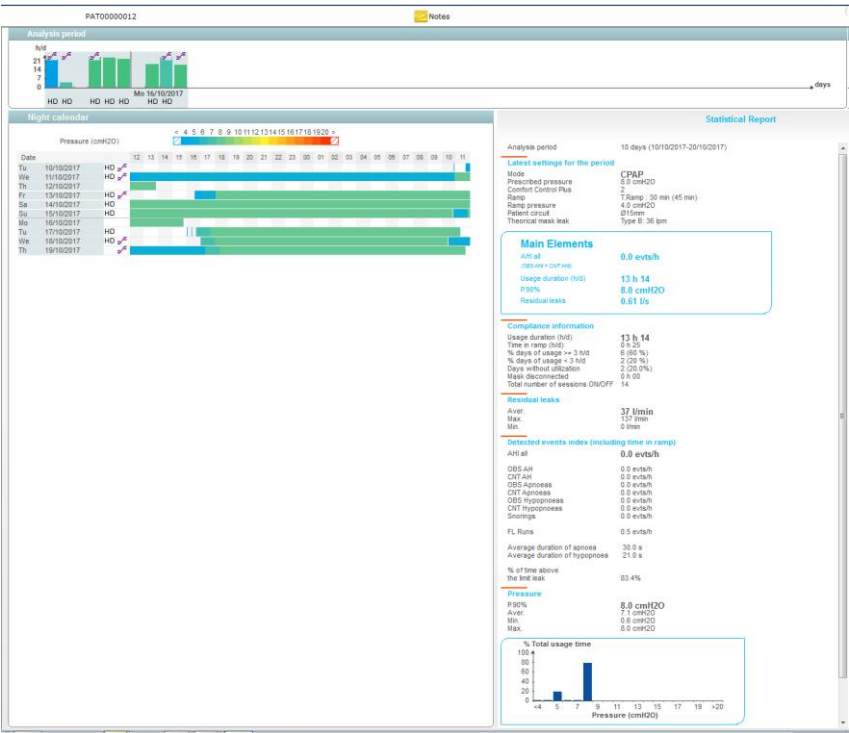
The "Patient ID" field allows personalising the patient identifier used by the software for patient management. A value is proposed by default which can be customized by using lowercase and capital letters, figures and characters like "-" and "\_". Click on **OK** to confirm, otherwise on Cancel. Data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



- If you choose an existing patient in the list, the corresponding data is displayed on the screen.





Then the window which appears shows the presence of acquisition data in real time, as in the example:




The presence of curves and compliance data in real-time is indicated by the symbol **HD** (High definition) in the graph of the analysis period and in the night calendar, in the same way as the changes of device settings  or the 10 Hertz flow curves .

## 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 **Patient card**.

The window which appears allows to define settings.

The button  on the right 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".

The 'Patient card' window displays settings for a specific patient (S.N. = 1200R17090001 (S.Box Auto)). It includes a table with parameters and their current status, along with 'Edit' buttons for each row. At the bottom, there are two buttons: 'Reset settings' (with a red pill icon) and 'Write on memory card' (with a SD card icon).

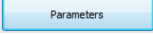
Parameter	Value	Action
Target device	S.N. = 1200R17090001 (S.Box Auto)	
Settings	Unchanged on device	Edit
Bluetooth	Unchanged on device	Edit
Modem	Unchanged on device	Edit
Time shift	Unchanged on device	Edit

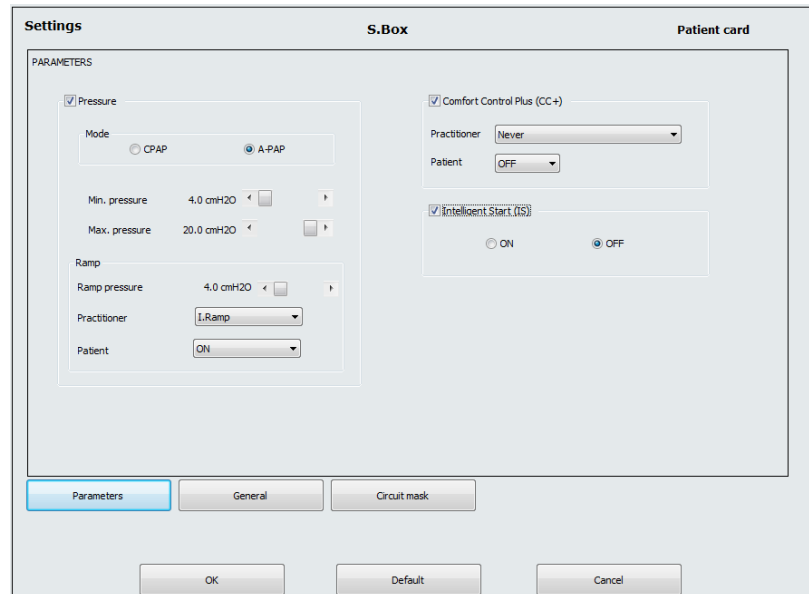
## Target device

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

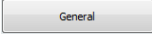
## Settings

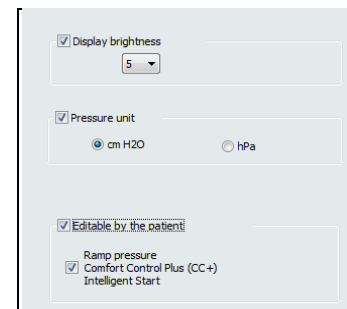
In the window which appears, the three buttons at the bottom allow activating groups of different settings.

With the button , you can access three groups of settings: Pressure, Comfort Control Plus (CC+) and Intelligent Start features.




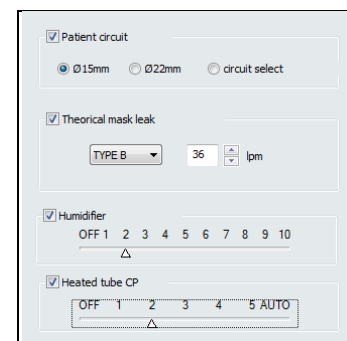
The main Settings window is titled "Settings" and "S.Box". It has a "Patient card" section at the top right. The main area is divided into two columns. The left column is titled "PARAMETERS" and contains three sections: "Pressure" (with Mode: CPAP, A-PAP; Min. pressure: 4.0 cmH2O; Max. pressure: 20.0 cmH2O; Ramp: Ramp pressure: 4.0 cmH2O; Practitioner: I.Ramp; Patient: ON), "Comfort Control Plus (CC+)" (with Practitioner: Never; Patient: OFF), and "Intelligent Start (IS)" (with ON, OFF). The right column is titled "Patient card" and contains "Display brightness" (5), "Pressure unit" (cm H2O, hPa), and "Editable by the patient" (Ramp pressure, Comfort Control Plus (CC+), Intelligent Start). At the bottom are buttons for "Parameters", "General", "Circuit mask", "OK", "Default", and "Cancel".

The button  allows accessing general device settings (brightness and pressure unit) and unlocking or not the access to 3 settings by the patient: Ramp pressure, Comfort Control Plus CC+ and Intelligent Start.



The General settings panel shows "Display brightness" set to 5, "Pressure unit" set to cm H2O, and "Editable by the patient" section with checkboxes for "Ramp pressure", "Comfort Control Plus (CC+)", and "Intelligent Start".

The button  allows accessing the configuration of patient circuit, humidifier and the heated tube (if installed). The theoretical mask leak can also be adjusted (Mask Select function).



The Circuit mask settings panel shows "Patient circuit" set to Ø15mm, "Theoretical mask leak" set to TYPE B, 36 lpm, "Humidifier" set to OFF, and "Heated tube CP" set to OFF.

By checking the box next to a group, the corresponding settings appear in the window and you can modify them. Refer to the chapter "Settings" page 40 for the description of all the possible settings.

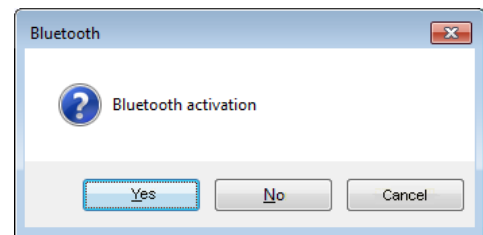
Once the settings entered, validate them with **OK**; otherwise click on Cancel. The new settings will appear in the central strip which will change colour.

You can also restore the default settings by clicking on .

## Bluetooth

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

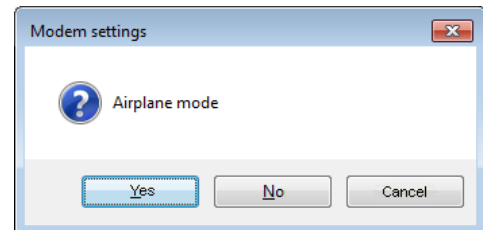
The central band will display "Bluetooth enabled" or "Bluetooth disabled" according to your selection.



## Modem

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

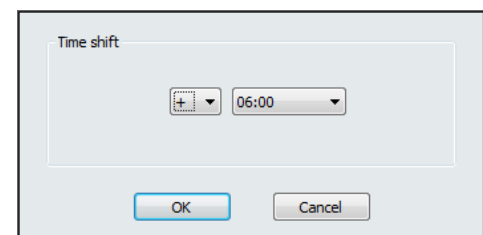
The central band will display "Airplane mode ON" or "Airplane mode OFF" according to your selection.




## 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).

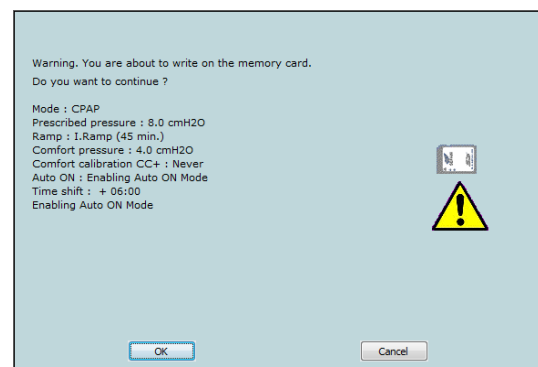
Click on **OK** to confirm the setting; otherwise select Cancel.



You can cancel any changes made 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.

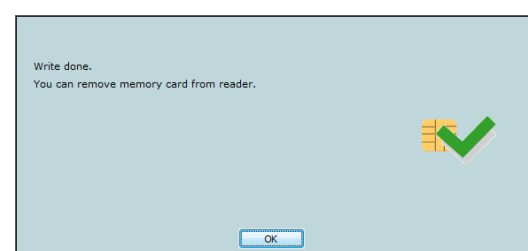


### *Note:*

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.

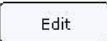


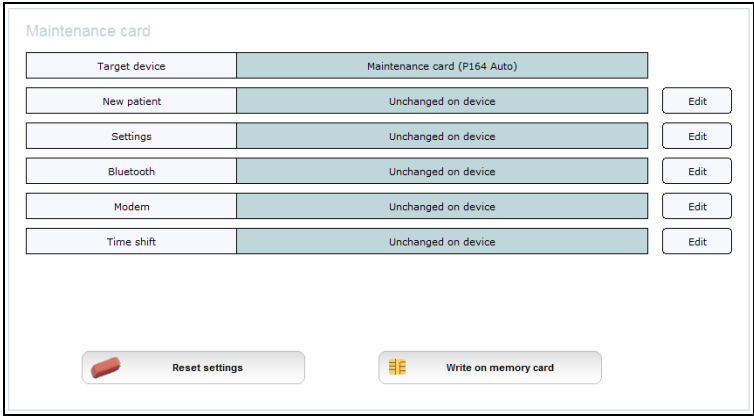
## Maintenance card

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

The button  Maintenance card gives you access to a dialogue box which enables you to define settings.



The settings available are the same as those proposed for the patient card, but you can furthermore create a new patient.

The button  on the right of each parameter allows also to display the corresponding settings box.



Maintenance card

Target device	Maintenance card (P164 Auto)	
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

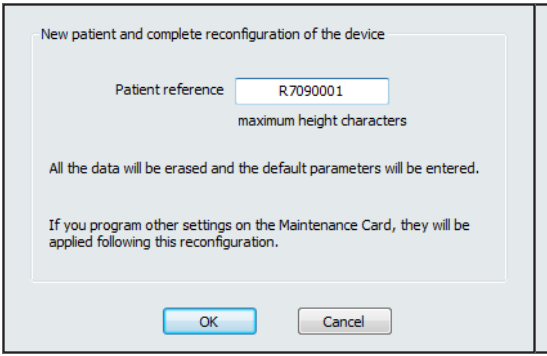
 Reset settings  Write on memory card

## New patient

A dialogue box appears in which the existing patient reference is displayed.

You can enter a new reference, but this action will erase the memorised data and result in the default reconfiguration of the device.

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  Reset settings. The central strip displays **Unchanged on device** again.

Click on  Write on memory card 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.

Click twice on  to return to welcome screen.

# Standards Compliance

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Risks pertaining to this medical equipment were assessed in accordance with the ISO 14971 standard, specifically with reference to global residual risk. (ISO 14971: Medical devices - Application of risk management to medical devices).

**SEFAM Analyze** software complies with the following standards:

- Directive 93/42/EC of the Council concerning medical devices.
- CEI 62304: Medical device software – Software life cycle processes.
- CEI 62366: Medical devices – Application of usability engineering to medical devices.

## CE marking

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

# Glossary

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**AHI**

Apnoea and d'Hypopnoea Index

**Auto-CPAP**

Auto-pilot. Mode.

**Average % / period**

Percent of average use and non-use of the device during the period.

**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 SEFAM S.Box (Wi-Fi module, 3G modem or PolyLink system).

**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.

**Device ON duration**

Time during which the machine was in use (Start / standby).

**FL Runs**

Runs of Inspiratory Flow Limitation.

**Heated humidifier**

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

**Heated tube**

SEFAM 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.

**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.

**I.Ramp: intelligent ramp**

The ramp time is automatically determined by the device.

**Mask disconnected**

Time during which the patient's mask was disconnected.

**Mask Fit & Go**

Control of the airtightness of the mask during the period of use.

**Max. pressure**

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

**Max. pressure for command on Apnoea**

In Auto-CPAP mode, maximum pressure of the device beyond which no rise in pressure can be applied once an apnoea has been detected.

**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.

**Mode**

CPAP or Auto-CPAP operating 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 SEFAM 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).

**Session**

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

**Time in ramp**

Length of time in ramp.

**Total usage time**

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

**T.Ramp: time ramp function**

The ramp time is determined by the practitioner or the Home Care Provider.

**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).

**Useful duration**

This is the duration recorded, minus the periods with the mask removed and the periods during with no respiration detected.

**Wi-Fi**

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







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**Manufacturer:**

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144 AV CHARLES DE GAULLE  
92200 NEUILLY SUR SEINE  
FRANCE

**Manufacturing plant:**

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