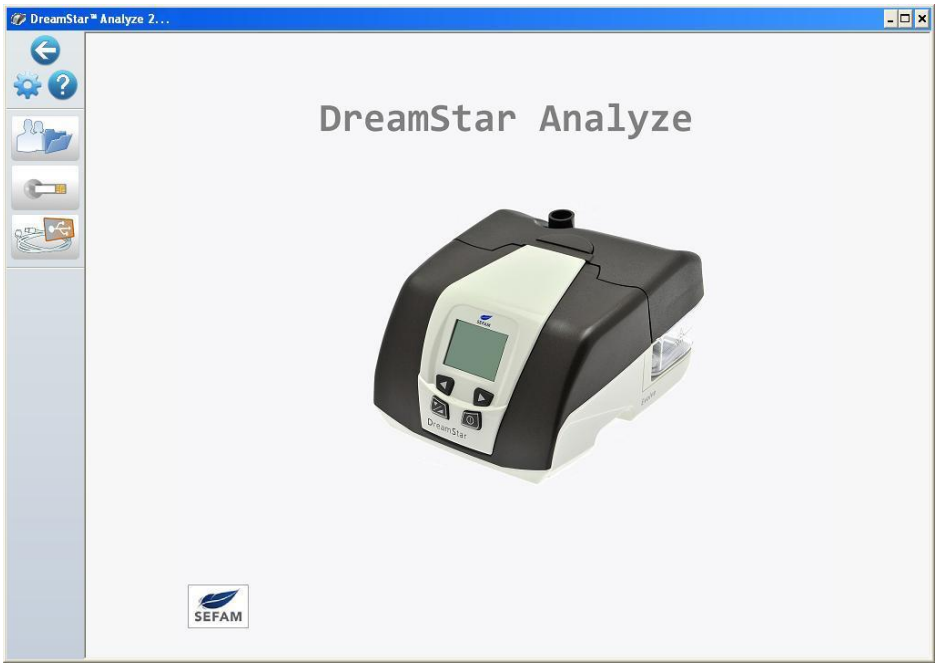
SEFAM

User manual

DreamStar™ Analyze software



DreamStar™ Intro	**DreamStar™ Intro Evolve**
DreamStar™ Info	**DreamStar™ Info Evolve**
DreamStar™ Auto	**DreamStar™ Auto Evolve**
DreamStar™ Duo	**DreamStar™ Duo Evolve**
DreamStar™ DuoST	**DreamStar™ DuoST Evolve**

DreamStar™ is a brand registered by SEFAM.

en

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Table of Contents

BEFORE YOU START 4

SOFTWARE OVERVIEW 4
INSTRUCTIONS FOR USE 5
STANDARD EQUIPMENT 5

LAUNCHING THE PROGRAM 6

THE WELCOME SCREEN 6
SOFTWARE PROPERTIES 7
SOFTWARE CONFIGURATION 7
1. *Selecting a Language 8*
2. *Configuring the serial port 8*
3. *Choosing the units of size and weight 8*
4. *Choosing analysis parameters 9*
5. *Other functionalities 9*
6. *Inserting a Home Care Provider logo 10*

PATIENT MANAGEMENT 11

PATIENT LIST 11
PATIENT INFORMATION 11
1. *Displaying information 11*
2. *Treatment history 12*
3. *Creating a patient 13*
4. *Deleting a patient 13*
5. *Adding comments 13*
OTHER UTILITIES 14
1. *Importing patient files 14*
2. *Exporting patient files 15*
3. *List of deleted patients 15*

DISPLAYING COMPLIANCE DATA 16

COMPLIANCE DATA SAVED WITH DREAMSTAR™ INTRO OR DREAMSTAR™ INTRO EVOLVE 16
1. *Patient identification for the selected patient 17*
2. *Analysis period 17*
3. *Night calendar 17*
4. *Compliance data 18*
COMPLIANCE DATA SAVED WITH DREAMSTAR™ INFO / INFO EVOLVE, DREAMSTAR™ AUTO / AUTO EVOLVE 19
1. *Patient identification for the selected patient 19*
2. *Analysis period 19*
3. *Night calendar 20*
4. *Compliance data 21*
COMPLIANCE DATA SAVED WITH DREAMSTAR™ DUO / DUOST, DREAMSTAR™ DUO EVOLVE / DUOST EVOLVE 31
1. *Patient identification for the selected patient 31*
2. *Analysis period 31*
3. *Night calendar 32*
4. *Compliance data 33*
ANALYSIS COMPLIANCE REPORT 43
1. *Printing and exporting reports 43*
2. *Using the sessions only export to a text file feature 45*

USING A MEMORY CARD 48

DOWNLOADING DATA VIA MEMORY CARD 48
FORMATTING THE MEMORY CARD 49
PATIENT CARD 49
MAINTENANCE CARD 51

CONFIGURING THE DEVICE 54

CONNECTING TO THE DEVICE 54
DESCRIPTION OF THE CONNECTION SCREEN 54
1. *Device status 54*
2. *Displayed information 55*
3. *Device setting buttons 55*
4. *Other functionalities 56*
ACCESSING DEVICE SETTINGS 56
1. *Erasing compliance data 56*
2. *Patient information 57*
3. *Inventory number 57*
4. *User configuration 58*
5. *Date and time 59*
6. *Settings 60*
OTHER FUNCTIONALITIES 67
1. *Configuring the serial port 67*
2. *Downloading data by serial link 67*
3. *Viewing the current session 68*
4. *Viewing the real time curves 72*
5. *Data for all the sessions 72*

STANDARDS COMPLIANCE 74

GLOSSARY 75

Before you start

Please read this manual carefully before using DreamStar™ Analyze software with a device from the DreamStar™ or Sandman.

Software overview

DreamStar™ Analyze is a software product that can be used with **DreamStar™** devices designed for the treatment of patients who suffer from Sleep Apnoea Syndrome (SAS). It can also be used with Sandman devices.

Before you use it with DreamStar™ Intro, DreamStar™ Info and DreamStar™ Auto, DreamStar™ Duo and DreamStar™ DuoST devices or their equivalents in Evolve configuration, or with Sandman equivalent devices, it is essential that you understand how the software operates.

When the software is launched, it automatically recognizes the device to which it is connected.

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.

DreamStar™ Analyze is user-friendly, allowing the user by means of buttons and icons:

- to view and print compliance and pressure data stored in the device, either by download via a network access or by direct connection (> 365 8-hour sessions for DreamStar™ Info, DreamStar™ Auto, DreamStar™ Duo or DreamStar™ DuoST and equivalent in Evolve configuration), or on a memory card (approximately 600 on-off sessions for DreamStar™ Intro, approximately 40 8-hour sessions for DreamStar™ Info, DreamStar™ Auto, DreamStar™ Duo or DreamStar™ DuoST and in Evolve configuration).
- to view and print compliance data from a session, along with the patient's real flow rate over the last 16 hours of use (except with DreamStar™ Intro and DreamStar™ Intro Evolve).
- to configure the device settings by direct cable connection (except with DreamStar™ Intro and DreamStar™ Intro Evolve) or by memory card, to manage a patient list which provides direct access to nominative data such as: personal information, information about the equipment used, and compliance data history.
- to print out a compliance report (Acrobat Reader or ASCII compatible PDF format) for use by the Clinician and Home Care Provider, which can then be sent by email, and/or export data to spreadsheet software programs.

User manuals for the DreamStar™ Analyze software are provided in PDF files on the software installation CD-ROM. However, paper copies of the manuals may be obtained upon request.

In the user manual, all of the screenshots are presented in English. The screens that the program displays have been translated into all available languages and may differ from that shown in this manual which are provided by way of example.

Notes:

- When some text included in the screenshots is not translated locally in the manual, it generally concerns points of detail : refer to the corresponding screenshot displayed in the language sélected.
- The dates displayed by the software are presented in day/month/year format (DD/MM/YYYY).

Instructions for use

WARNING ***This signals a risk of injury or accident to the patient.***

DreamStar™ Analyze software is only a tool to aid 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 DreamStar™ Analyze can only be used with DreamStar™ and Sandman devices.
- The device can only be connected to one device at a time and only displays compliance data for one machine at a time.
- Before using the DreamStar™ Analyze software with one of the DreamStar™ or Sandman devices, be sure to familiarize yourself with the safety instructions associated with the device, which are found in the 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.

Note:

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

Standard equipment

The **DreamStar™ Analyze** software is delivered in a clinical kit containing the following items:

- an installation CD-ROM (available separately).

  Besides the software, the CD-ROM contains the latest version of the user manuals in PDF format for each language, and the English version of Adobe® Acrobat® Reader 8 (software that is freely distributed).
- a memory card reader.
- A 6-feet mini USB cable which can be used to connect any device (except with DreamStar™ Intro and DreamStar™ Intro Evolve) to a PC.

A 6-feet or 50-feet RS 232/ mini USB cable for connecting DreamStar™ devices (except Intro models) to a PC or a 6-feet or 50-feet RS 232/ USB cable for connecting Sandman devices (except Sandman Intro™) to a PC are available in option by separate order.

CAUTION

- On receipt, confirm that the packaging is undamaged.
- Confirm that the CD-ROM and memory card are undamaged.

Protection against unauthorized data access is accomplished through the Windows® User Profile Manager. You are therefore advised to enable this management tool to ensure the confidentiality of all information.

Launching the program

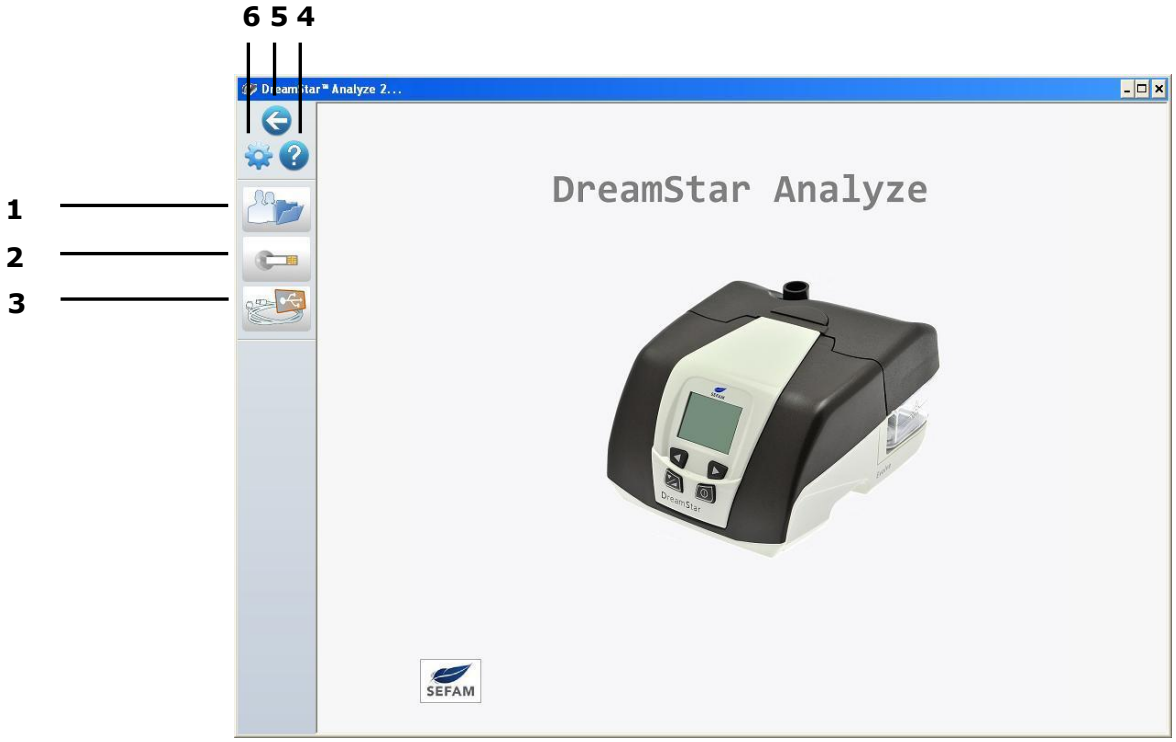
To use this software, all you have to do is double-click on the

shortcut on the desktop or select "All Programs" in the "Start" menu of your computer, then DreamStar™ Analyze.

The language is chosen the first time the program is launched after installing the application. To make your language selection, follow the instructions under, “Selecting a Language” on page 8.

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

The welcome screen



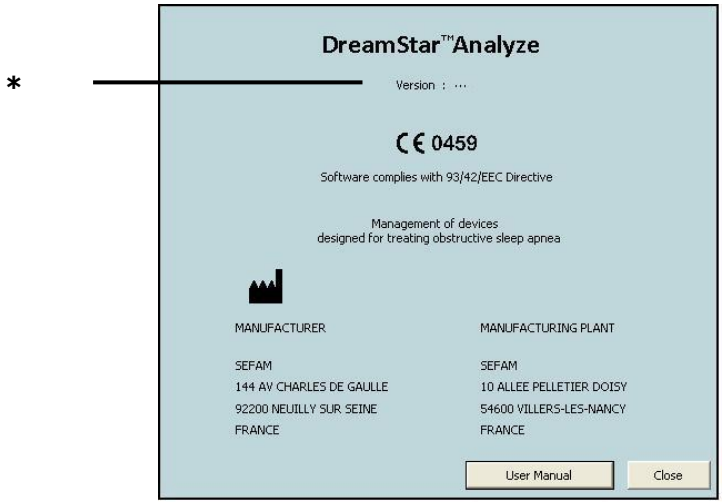
This screen is mainly used to access the following functions, allowing you to:

1. display the **patient List** and patient data histories, **view** patient compliance data and open a **patient file** containing stored treatment data.
2. **download** data from a memory card, format a memory card, program a **patient card** or a **maintenance card**.
3. establish a **serial connection** between the machine and the software using an RS-232 cable or a mini USB cable. This feature cannot be used with DreamStar™ Intro or DreamStar™ Intro Evolve.
4. software **version** and software **user manual**.
5. return to **previous screen** following the software menu hierarchy.
6. use software **configuration tools**: selection of language, serial port, etc.

You can exit the program by using Windows® button or Close menu.

Software properties

You can access the software version by clicking on the button. The following window will appear:



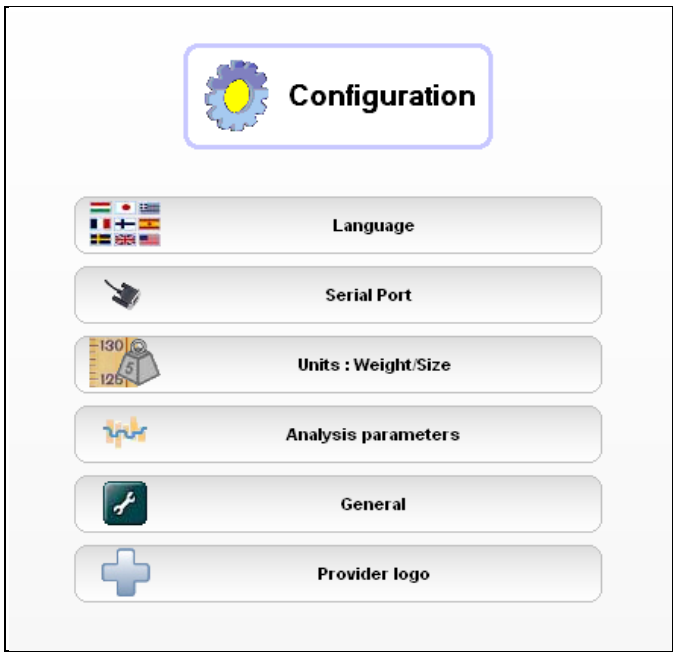
* your software version

Access the software user manual by clicking on the **User manual** button. This is then displayed in the selected language.

Click on **Close** to close the window.

Software configuration

You can configure the software by clicking on the button. The **Configuration** screen appears, from which you can access the different options (language, serial port, units of weight and size, etc.).



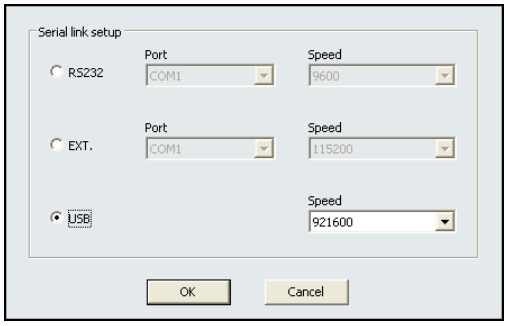
1. Selecting a Language

Select **Language**. A window opens where you can select the software language by clicking the corresponding button, irrespective of what has been chosen in the machine. The language selected then displays at the top. Only the buttons corresponding to the languages present in the software version are displayed. The screen page shown below lists all the possible languages which will be made available.

Click on to exit the window.

2. Configuring the serial port

The **Serial Port** option can be used with any **DreamStar™** and **Sandman** device except DreamStar™ Intro, DreamStar™ Intro Evolve and Sandman Intro™. The dialogue box that appears allows you to select the serial connection mode, configure the port, and set the connection speed:



You can choose an RS232 port and set a programmed speed from 1,200 to 38,400 bauds, with the programmed speed of 9,600 bauds corresponding to the device speed at start-up.

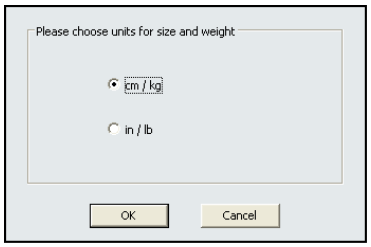
You can choose a port for a EXT. connection with a programmed speed of 115,200 bauds.

You can also choose a USB connection and set a programmed speed from 38,400 bauds to 921,600 bauds. We recommend operation at the highest possible speed except when there is a problem with the connection. The default port selection is the USB port at a speed of 921,600 bauds.

Click on **OK** to confirm your choice or on **Cancel** to cancel the selection.

3. Choosing the units of size and weight

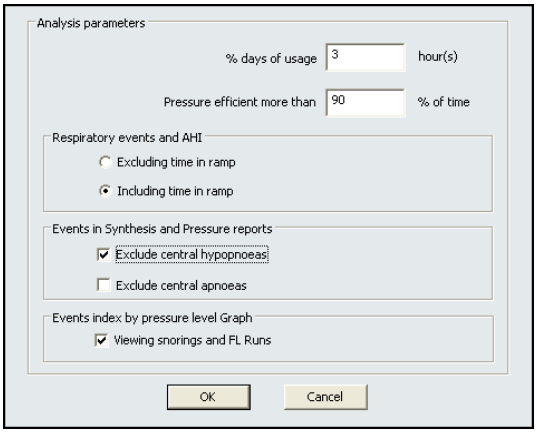
You can select the units of size and weight by clicking on **Units**: **Weight/Size**. The following window will appear.



Click **OK** after selecting cm/kg or in/lb or click **Cancel** to cancel your selection.

4. Choosing analysis parameters

By clicking on **Analysis parameters**, a dialogue box is displayed as follows:



You can modify:

- % days of usage. This is the threshold used to calculate the percentage of usage days, it is defined in number of hours per day and its value is set to 3 hours/day by default.
- Pressure efficient more than 90 % of time. This is the threshold which allows to calculate the effective pressure, it is expressed as a percentage of time and its value is set to 90% by default.

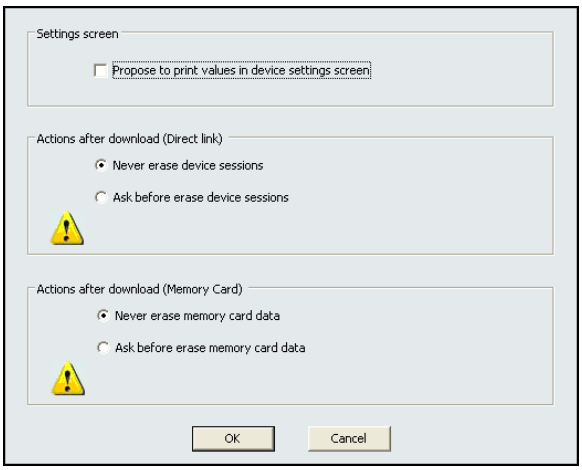
Confirm your choice by clicking on **OK** or click on **Cancel** to cancel your selection.

This dialogue box also allows you to select:

- display of respiratory events and Apnoea / Hypopnoea Index (AHI) considering or not the time spent in ramp (in CPAP mode) or in latency (in Auto-CPAP mode).
- display of respiratory events in Synthesis and Pressure reports excluding or not central hypopneas and / or central apneas (only with DreamStar™ Info and DreamStar™ Auto devices).
- view of snorings and flow limitation Runs in the events index by pressure level graph.

5. Other functionalities

Clicking on **General** displays a dialogue box as shown below:

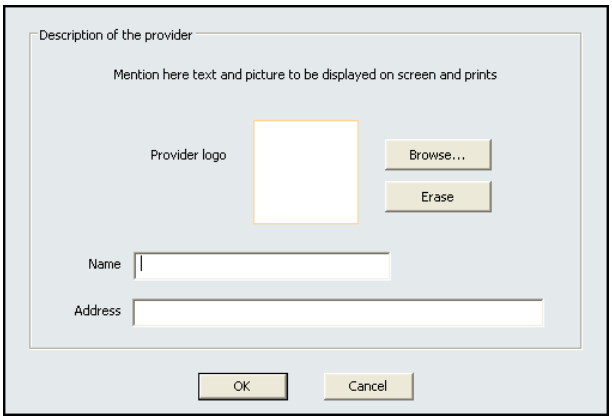


- Settings screen allows you to print the values in the device settings screen.
- After download there is an option to erase device sessions [via Direct link] or memory card data [via Memory Card].

Confirm your choice by clicking on **OK** or click on Cancel to cancel your selection.

6. Inserting a Home Care Provider logo

Provider Logo option displays a dialogue box where you select an image file and text which will appear as a logo on PDF reports. Click on Browse to select the file. Similarly, click on Erase to delete the logo.

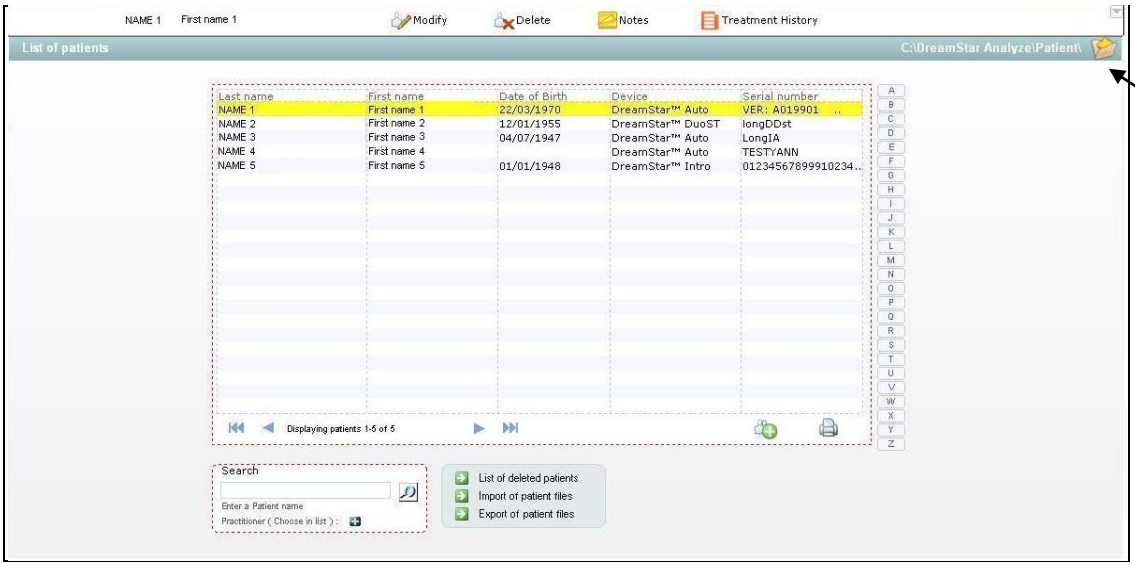


Confirm your choice by clicking on **OK** or click on **Cancel** to cancel your selection.

Patient management

Patient List

Click on the button to open the **List of patients** window which lists all the patients for whom the software keeps data (personal information, information about the equipment used, and compliance data).



You can access the patient directory by clicking on the icon located in the upper right-hand corner. By default, it is located in the software installation directory, but the window that appears when you click on the icon enables you to select another directory containing patient files.

You can scroll back and forth through the list of patients by using the ▶ and ◀ icons and you can go directly to the top of the list by clicking on ⏮ or directly to the end of the list by clicking on ⏭.

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

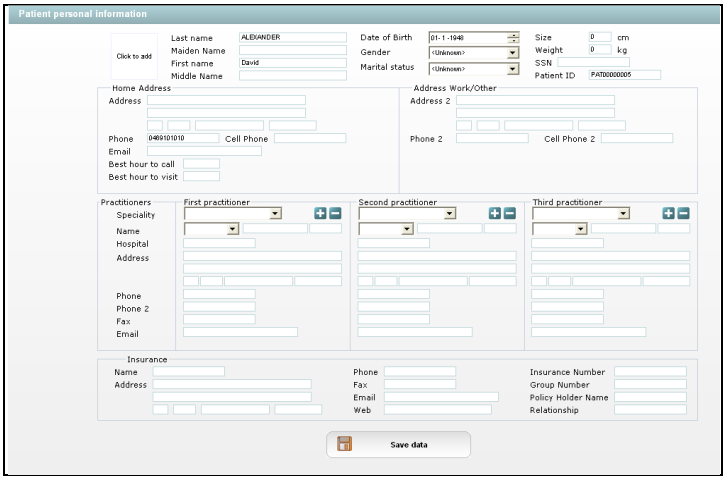
You can search for a patient by typing the first letters of the patient's name in the **Search** field then clicking on the magnifying glass icon. All patients having that name will be displayed on the screen.

If you wish to return to the whole list, click the DISPLAY ALL button in the upper right of the Patient List.

Patient information

1. Displaying information

You can select a patient by highlighting the patient's name. The patient's name will appear at the top of the window and you may consult or modify the information on file (last name, first name, contact information, physician, etc.) for that patient by clicking on the Modify icon at the top of the patient list.



From the **Patient personal information** window, you can add, change or delete data about the patient by using the Tab key on your keyboard to move from field to field.

To add a photo, click on

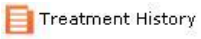
in the upper left of the window. This opens the **Open** dialogue box where you can select an image file (BMP, JPEG or GIF format) to be copied to the patient directory in question.

In addition, once you have entered the physician's name, you can click on the icon to the right of the input field to access the list of physician profiles which are on your computer hard drive. When you select a physician and click **OK**, all information about that physician (speciality, hospital, address, email, fax, etc.) is imported into the patient information record. The list is automatically updated when a new physician is entered into the patient profile.

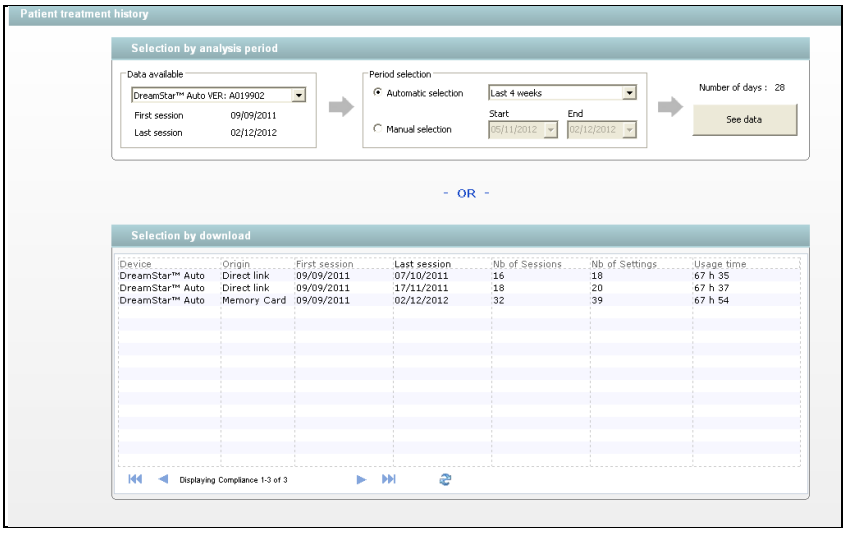
Click on the

button when you have finished making your changes. A window will appear asking you to confirm whether you want to make the changes. Click on **OK** to confirm or on **Cancel** to cancel the changes.

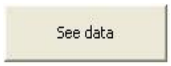
2. Treatment history

You can access a patient's treatment history by selecting the 

icon or by double-clicking on the patient. The **Patient treatment history** window that appears will identify the machine involved, the origin of recorded compliance data, the treatment period, the number of sessions recorded, the number of settings, and the total duration of use.



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.

You will then access the compliance data recorded over the period by clicking on the 

button or 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. The screen can be updated again by clicking on the button.

Click on to return to the patient list.

3. Creating a patient

You can create up to 20,000 patients.

To create a new patient, click on . A window will open in which you can enter information about the patient. You can add the information requested, moving from one line of a frame to the next by using the Tab key on the computer keyboard.

You can record information about the patient by clicking on the

button. You then return to the patient list to which the new patient has been added.

Note: When compliance data for a patient not on the list is read, the option to create a new patient file is offered automatically so that the data can be saved.

4. Deleting a patient

If you want to delete a patient from the list, select the patient and click on

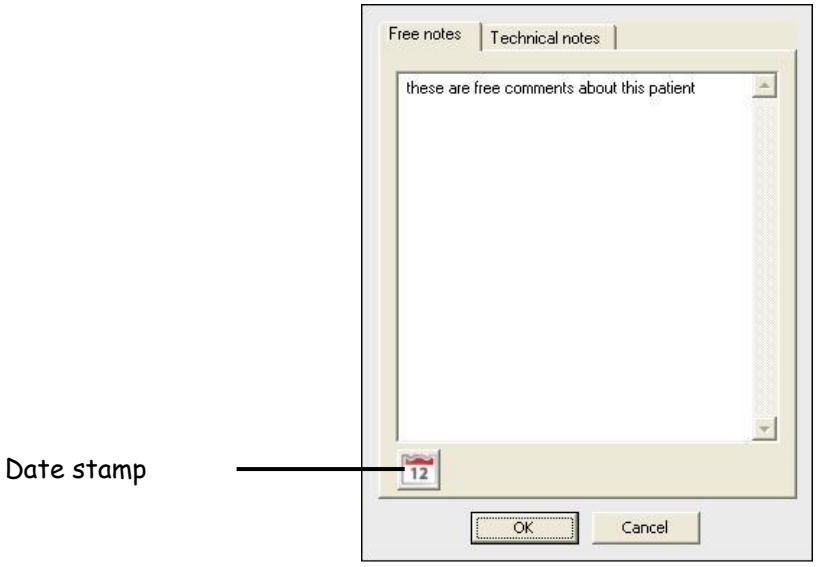
. A window will appear asking whether you really want to delete the patient. Click **OK** to confirm deletion or click on **Cancel** if you wish to keep the patient.

Note: To permanently delete a patient's data, pull up the patient ID of the patient (displayed at the top of the screen), (after clicking on in the upper right-hand corner), then using Windows® Explorer, search in the Patients root directory for a subdirectory name that is the patient's ID preceded by the characters ####. Delete this directory and all the files in it.

5. Adding comments

You can add simplified comments for a particular patient file. To do this, select the patient file and click on the

button. A window appears in which you can enter your comments: It is possible to insert the date by clicking on the date stamp.



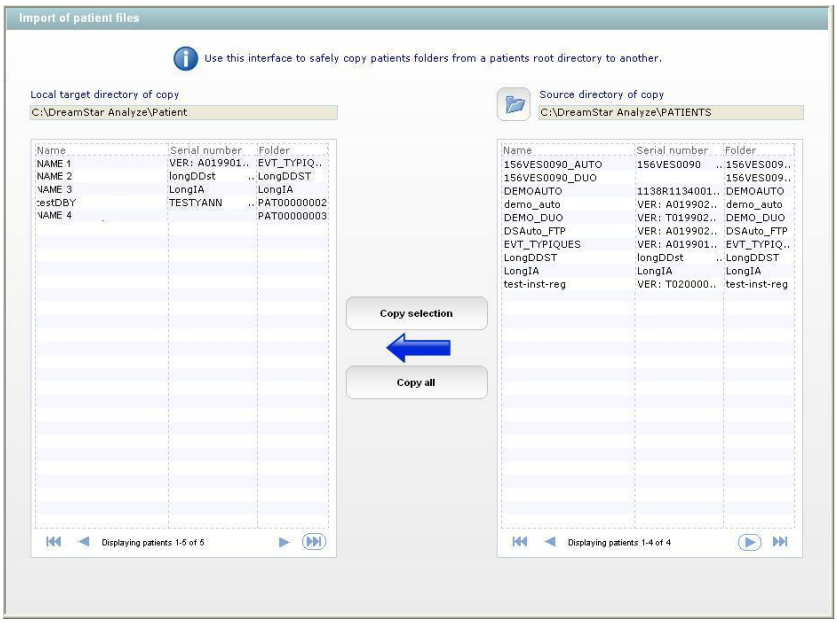
Click on **OK** to confirm or on **Cancel** to cancel.

Note: The Technical notes tab is only present if a patient card has been programmed for the patient displayed.

Other utilities

1. Importing patient files

The **Import of patient files** option enables you to copy one or more patient directories and all the compliance data files they contain to a destination directory. Click on this option and the following window will open:



This interface ensures that if you merge two patient lists you will not create more than one file per patient in the same root directory.

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

When patient files are copied into a directory that already contains files relating to that patient, a window will appear allowing you to select the patient data that you wish to keep.

Note: The patient identifier is modified between the source directory and the target directory.

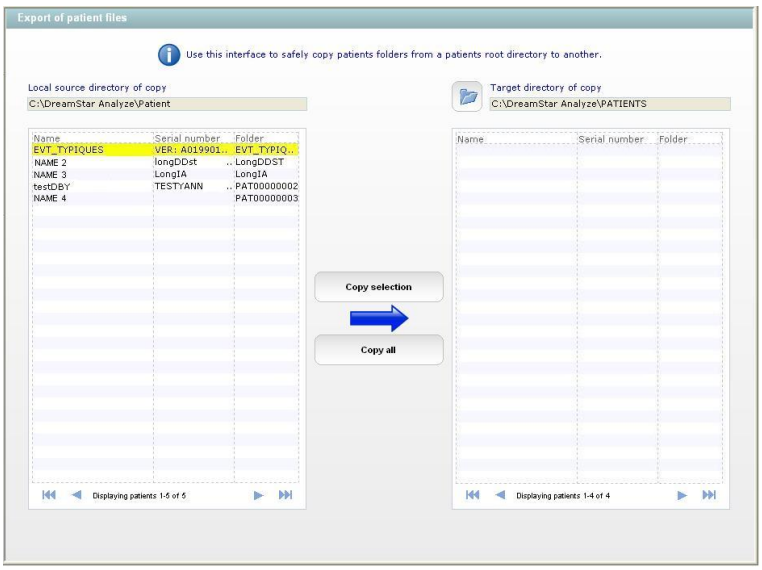
The directory paths selected are memorized for future use.

Click on to return to the patient list.

2. Exporting patient files

Similarly, the **Export of patient files** option enables you to copy one or more patient directories and all the compliance data files they contain to a destination directory.

Click on this option and the following window will open:



This option is recommended for archiving patient files in the root directory used by the software in a separate backup directory selected by the user.

Click on to return to the patient list.

3. List of deleted patients

The **List of deleted patients** option enables you to display the list of patients who have been deleted but you no longer have access to the files.

Displaying compliance data

Compliance data displays automatically after it has been downloaded to a memory card or via a direct connection to the device.

The last recorded compliance data can also be viewed directly via the Patient List. Refer to "Patient Management" on page 11.

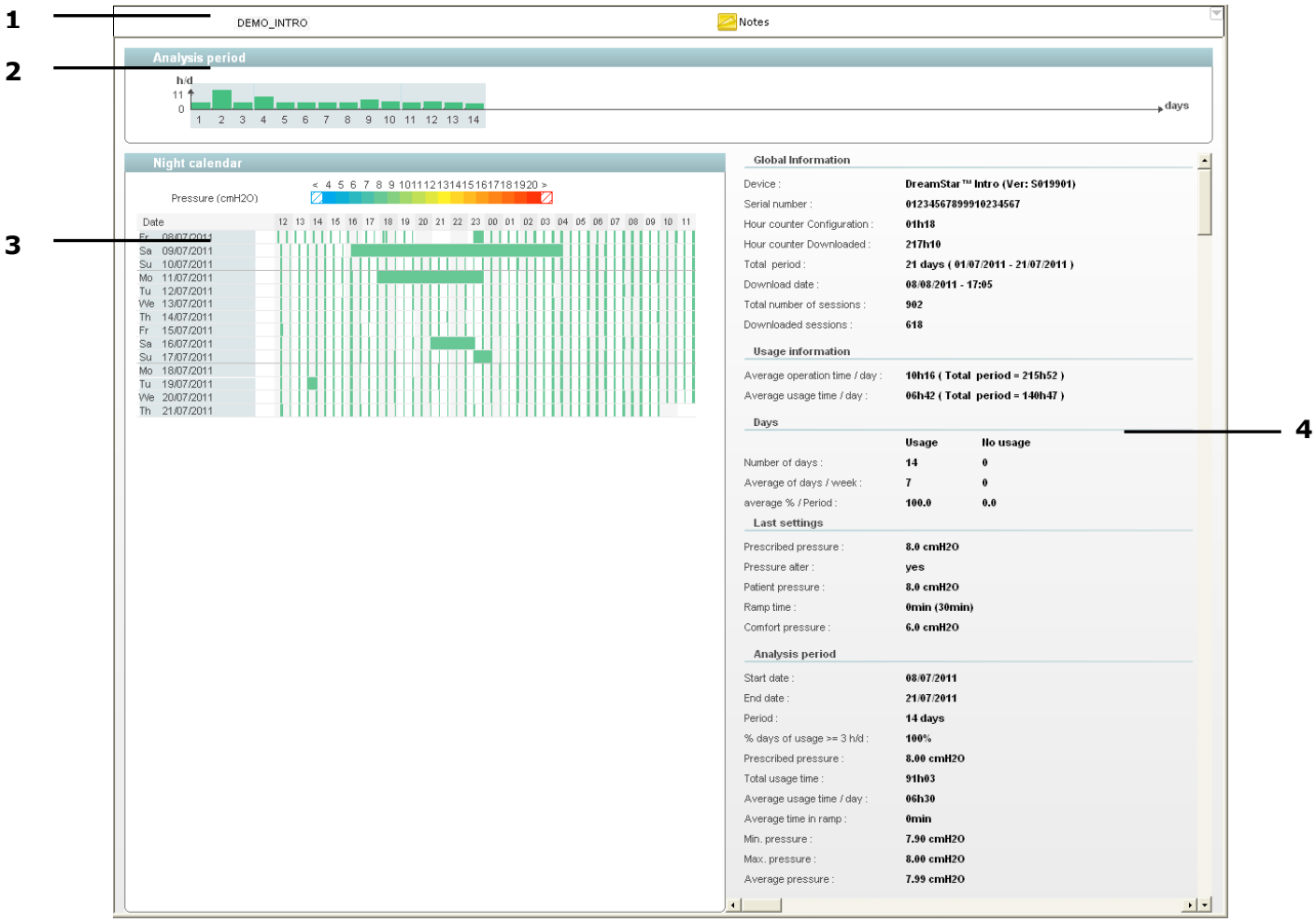
A window will appear, showing all of the information recorded for the (on/off) session.

For each session, the machine records the **useful duration**, which is the duration recorded after 5 minutes following start-up, minus the periods during which the mask was removed and the periods during which no respiration was detected.

Notes:

- To allow the patient time to properly connect to the equipment, no session data is recorded until after the device has been operating for 5 minutes. As a result, no sessions (duration of the on/off sequence) lasting less than 5 minutes are recorded.
- Sessions containing data errors are not displayed.

Compliance data saved with DreamStar™ Intro or DreamStar™ Intro Evolve



This window is divided into four sections:

1. Patient identification for the selected patient

The patient file's name appears at the top of the window. The patient's identifier and age are displayed by clicking on in the upper right corner of the screen. Other data can be displayed if available, including the patient's address and telephone number and the name(s) and telephone number(s) of clinician(s). Additional information which can be freely added to the session data by clicking on the Notes button.

2. Analysis period

The **Analysis period** section presents a **compliance summary diagram**: daily length of time during which the patient has breathed using the mask, expressed as a function of the number of days.

The value on the horizontal axis represents 24-hour periods and the value on the vertical axis represents the Duration of use (the sum of all durations of use of on/off sessions). The colour indicates the average pressure for the 24-hour period. Its value is the average of average pressures that have been weighted by the duration of use for each session.

When the compliance data record exceeds a given number of days, a Zoom button appears in the lower left corner of the graph. The icon is visible only when this feature is enabled. The Zoom button allows you to view all sessions or a subset. If you choose to display a subset of sessions, a cursor will appear, and you can move from one session to another either by clicking on the right and left arrows or by moving the cursor while keeping the left mouse button depressed.

3. Night calendar

The **Night calendar** section gives a quick overview of patient compliance across the most recent recorded sessions. A colour scale indicates pressure levels from 4 cmH_2O to 20 cmH_2O.

A 24-hour period can be selected from the calendar by clicking on the date of interest to you. The corresponding diagram will then appear in the Compliance section.

If you double-click on a session, the **Session** window will display as shown below:

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

The window indicates the following information concerning the session :

- Date – Time of the session.
- Duration of the session.
- Usage time during the session.
- Time in ramp.
- Patient pressure.
- Average pressure.

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

4. Compliance data

The compliance data is displayed as follows:

Global Information

- Device: type of machine. The embedded software version is shown in brackets.
- Serial number: serial number of the machine. This cannot be modified.
- Hour counter configuration: total operating time at configuration.
- Hour counter downloaded: total operating time at download.
- Total period
- Download date: date and time when the memory card was inserted into the device to backup compliance data.
- Total number of sessions: total number of sessions recorded by the device.
- Downloaded sessions: number of sessions downloaded to the memory card.

Usage information

- Averaged operation time/day.
- Average usage time/day.

Days

- Number of days of device use and of non-use.
- Average of days/week of device use and of non-use.
- Average % /Period : percent average use and non-use of the device during the period.

Last settings

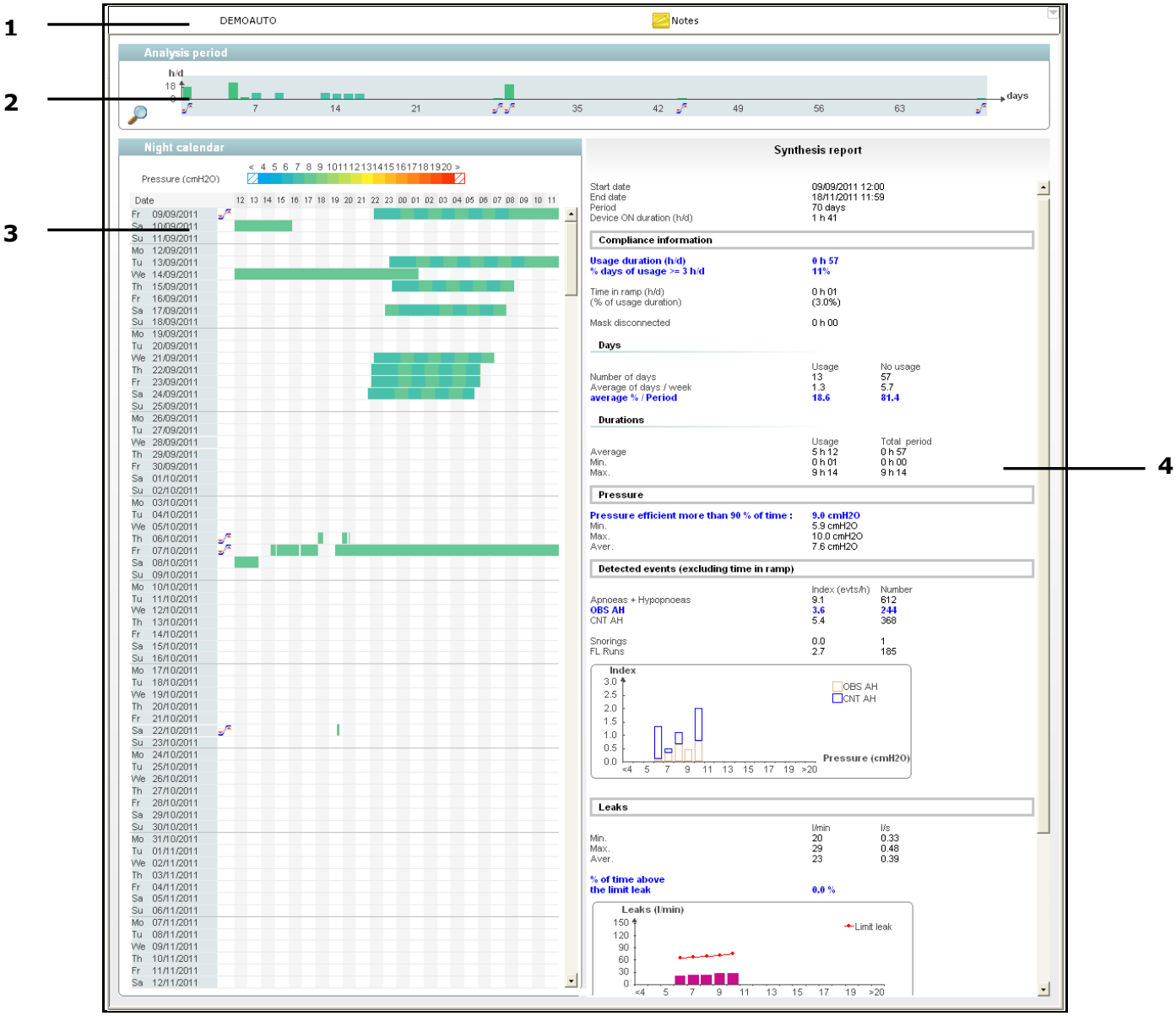
- Prescribed pressure: level of pressure prescribed for the patient.
- Pressure Alter. option for the patient to alter the level of pressure prescribed by ± 1 cmH_2O.
- Patient pressure: level of pressure set by the patient; this may differ from the prescribed pressure if the Pressure Alter feature is enabled.
- Ramp time: time the device takes to reach the prescribed pressure when starting from the comfort pressure. The ramp time and the maximum ramp time are indicated.
- Comfort pressure: level of pressure produced by the device when the ramp feature starts up (if ramp enabled) so that the patient can go to sleep comfortably.

Analysis period

- Start date: date of the first day of the selected period.
- End date: date of the end of the selected period.
- Period: number of analysis days, which is the difference between the “End date” and the “Start date”.
- % days of usage>= 3 h/d: percentage of days during which the patient has really breathed with the machine for a number of hours over the specified threshold (this threshold can be configured from the software Configuration menu, see paragraph "Choosing analysis criteria" on page 10).
- Prescribed pressure: level of pressure prescribed for the patient.
- Total usage time.
- Average usage time/day.
- Average time in ramp.
- Min. Pressure: minimum pressure measured during the analysis period.
- Max. Pressure: highest pressure measured during the analysis period.
- Average Pressure: average pressure measured during the analysis period.

Click on to return to the patient compliance list.

Compliance data saved with DreamStar™ Info / Info Evolve, DreamStar™ Auto / Auto Evolve



This window is divided into four sections:

1. Patient identification for the selected patient

The patient's name appears at the top of the window. The patient's identifier and age are displayed by clicking on in the upper right corner of the screen. Other data can be displayed if available, including the patient's address and telephone number and the name(s) and telephone number(s) of clinician(s). Additional information can be freely added to the session data by clicking on the Notes button.

2. Analysis period

The **Analysis period** section presents a **compliance summary diagram**: daily length of time during which the patient has breathed using the mask, expressed as a function of the number of days. It remains displayed, irrespective of the presentation displayed on the right.

The value on the horizontal axis represents 24-hour periods and the value on the vertical axis represents the duration of use (the sum of all durations of use of on/off sessions). The colour

indicates the average pressure for the 24-hour period. Its value is the average of average pressures that have been weighted by the duration of use for each session.

When the compliance data record exceeds a given number of days, a Zoom button appears in the lower left corner of the graph. The icon is visible only when this feature is enabled. The Zoom button allows you to view all sessions or a subset. If you choose to display a subset of sessions, a cursor will appear, and you can move from one session to another either by clicking on the right and left arrows or by moving the cursor while keeping the left mouse button depressed.

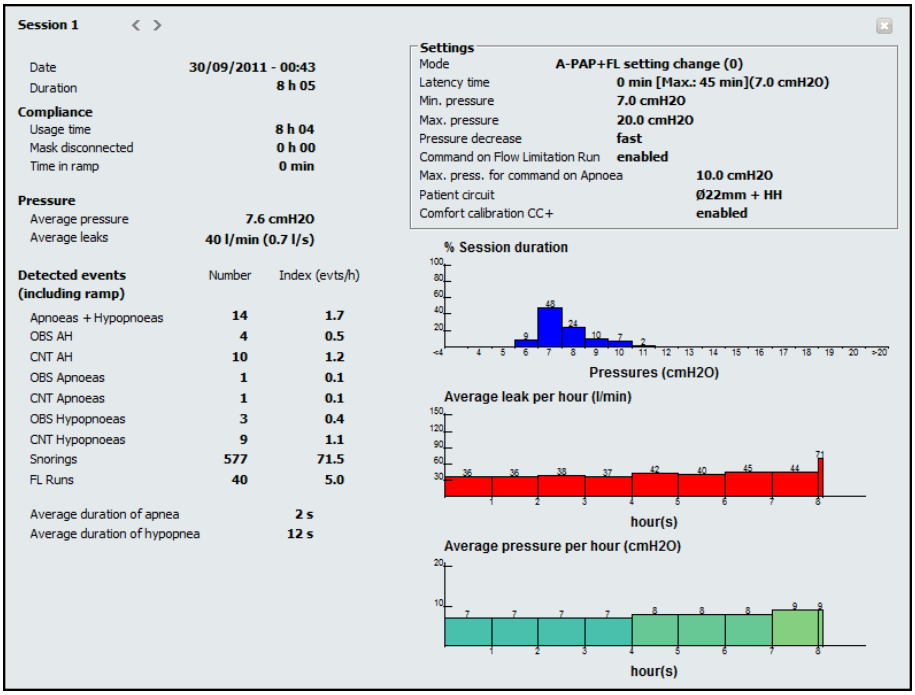
3. Night calendar

The **Night calendar** section appears by default on the left side of the window. However, the pressure graph or wave forms can be displayed there instead, depending on which tab is selected.

The night calendar gives a quick overview of patient compliance across the most recent recorded sessions. A colour scale indicates pressure levels from 4 cmH_2O to 20 cmH_2O.

A 24-hour period can be selected from the calendar by clicking on the date of interest to you. The corresponding diagram will then appear in the Compliance section.

If you double-click on a session, the **Session** window will display as shown below:



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

For further information, refer to the paragraph entitled **"Information concerning the current session"** on page 66.

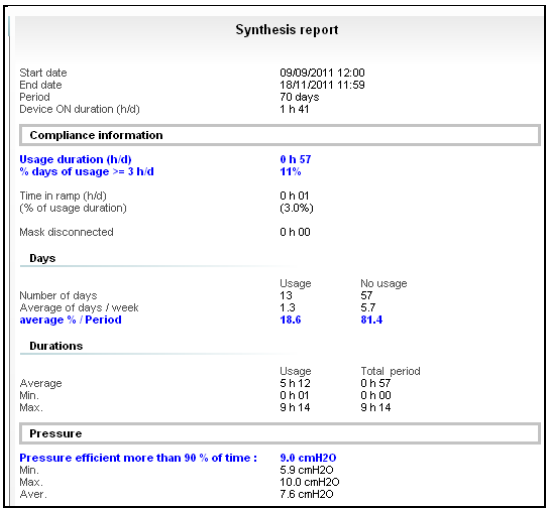
Close the window by clicking on the X in the upper right corner.

4. Compliance data

The presentation selected using one of the buttons located in the left part of the window is displayed in the right-hand section. If you right-click with your mouse on one of the first 3 presentations right (synthesis report, pressure, events and leaks report and waveforms report), the **Analysis parameters** window will be displayed and you can use the tools proposed in the dialogue box. The values shown on the right will then consider the options selected. For more information, refer to paragraph "Choosing analysis parameters" on page 9.

a) Synthesis report

The information shown in the Synthesis Report is displayed by default but also can be accessed by clicking on the button. The first part of the report contains the following information:



Synthesis report

Start date	09/09/2011 12:00
End date	18/11/2011 11:59
Period	70 days
Device ON duration (h/d)	1 h 41

Compliance information

Usage duration (h/d)	**0 h 57**
% days of usage >= 3 h/d	**11%**
Time in ramp (h/d) (% of usage duration)	0 h 01 (3.0%)
Mask disconnected	0 h 00

Days

	Usage	No usage
Number of days	13	57
Average of days / week	1.3	5.7
average % / Period	**18.6**	**81.4**

Durations

	Usage	Total period
Average	5 h 12	0 h 57
Min.	0 h 01	0 h 00
Max.	9 h 14	9 h 14

Pressure

Pressure efficient more than 90 % of time :	**9.0 cmH2O**
Min.	5.9 cmH2O
Max.	10.0 cmH2O
Aver.	7.6 cmH2O

The start and end dates for the analysis period selected in the pressure graph are shown at the top, along with the number of days and length of time during which the machine is applying pressure (**Device ON duration**)

Compliance information

- Usage duration (h/d): average duration during which the patient is really breathing with the mask, given in number of hours per day.
- % days of usage >= 3 h/d: percentage of days during which the patient has really breathed with the machine for a number of hours over the specified threshold (this threshold can be configured, see paragraph "Choosing analysis criteria" on page 10).
- Time in ramp : (% of usage duration) time spent in ramp with the % of usage duration indicated in brackets.
- Mask disconnected: length of time that the patient mask was removed.

Days

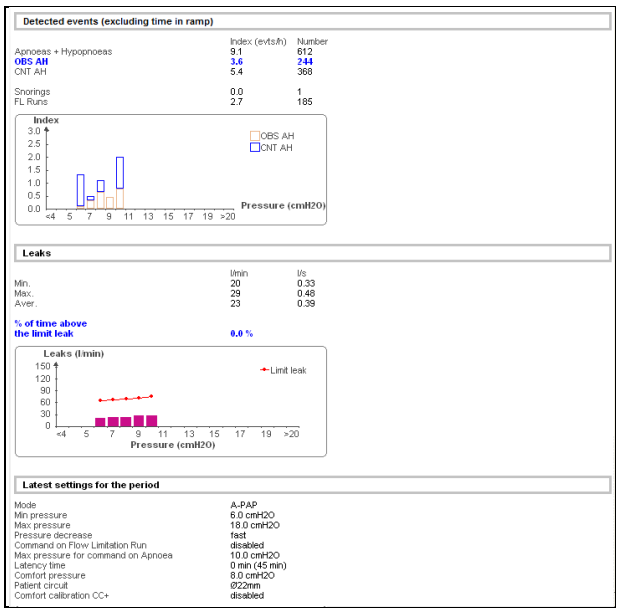
- Number of days: number of days of device use and of non-use
- Average of days/week: average number of days of device use and of non-use per week
- Average %/period: percent average use or non-use of the device during the period.

Durations

- Average: average duration of use over 24 hours for the selected period during which the the device was operating.
- Min.: minimum duration of use over 24 hours for the selected period during which the the device was operating.
- Max.: maximum duration of use over 24 hours for the selected period during which the the device was operating.

Pressure

- Pressure efficient more than 90% of time: Pressure level at which the patient spent more than a given percentage of time (this threshold can be configured, see paragraph "Choosing analysis criteria" on page 10).
- Min. (min.): minimum pressure measured over the period analysed.
- Max. (max.) maximum pressure measured over the period analysed.
- Average (moy.): average pressure measured over the period analysed.



The second part of the synthesis report contains the following information:

Detected events [excluding time in ramp]

- Apnoeas + Hypopnoeas: index (events per hour) and number of apnoeas and hypopnoeas detected over the period analysed.
- OBS AH: index (events per hour) and number of apnoeas and hypopnoeas detected and classed as obstructive over the period analysed.
- CNT AH : index (events per hour) and number of apnoeas and hypopnoeas detected and classed as central over the period analysed.
- Snorings: Index (events/hour) and number of snorings detected over the period analysed.
- FL Runs: Index (events/hour) and number of flow limitation runs detected over the period analysed.

Diagram of events index for each full pressure value.

Details of detected events depends on the options which have been selected in the Analysis parameters dialogue box (see paragraph "Choosing analysis parameters" on page 9).

Leaks

- Min.: minimum value of leaks measured in the mask hour by hour over the period analysed.
- Max.: maximum value of leaks measured in the mask hour by hour over the period analysed.
- Average: average value of leaks measured in the mask hour by hour over the period analysed.

% of time above the limit leak.

Diagram of leaks and limit leak for each full pressure value.

Latest settings for the period

- Mode: CPAP operating mode or Auto-CPAP operating mode.
- Min. Pressure: minimum pressure in Auto-CPAP mode.

- Max. Pressure: maximum pressure in Auto-CPAP mode.
- Prescribed pressure: Prescribed pressure in CPAP mode.
- Pressure Alter: option for the patient to alter the level of pressure prescribed by ± 1 cmH_2O. This feature is available only in CPAP mode.
- Patient pressure: Pressure delivered to the patient in CPAP mode, different from the prescribed pressure if Pressure Alter is activated.
- Pressure decrease: Fast or Slow in Auto-CPAP mode only.
- Command on Flow Limitation Run: enabled or disabled (when in Auto-CPAP mode).
- Max pressure for command on Apnoea: Apnoea command maximum pressure (when in Auto-CPAP mode).
- Ramp time: time the device takes to reach the prescribed pressure after the first 5 minutes when starting from the comfort pressure in CPAP mode. The maximum ramp time is indicated in brackets.
- Latency time: the wait time beyond the first 5 minutes of device operation at the set comfort pressure before Auto-CPAP is activated. The maximum latency time is indicated in brackets. This parameter only displays in Auto-CPAP mode on DreamStar™ Auto or DreamStar™ Auto Evolve.
- Comfort pressure: level of pressure produced by the device when the ramp feature starts up so that the patient can go to sleep comfortably.

  On the DreamStar™ Auto or DreamStar™ Auto Evolve device in Auto-CPAP mode, the pressure is adjusted to the comfort pressure or the minimum pressure (if comfort pressure < minimum pressure) when the device detects that there has been no respiratory cycle for more than 2 minutes or when high pressure is detected.
- Patient circuit: patient circuit used, diameter 15 mm, diameter 15 mm with water chamber, diameter 22 mm, diameter 22 mm with water chamber and SPECIFIC (other configuration).
- Comfort Calibration CC+: the Comfort Calibration + (C.C.+) feature, present on DreamStar™ Info, DreamStar™ Info Evolve, DreamStar™ Auto and DreamStar™ Auto Evolve, is designed to increase treatment pressure when the patient inhales and reduce it when the patient exhales to make breathing more comfortable during treatment.

b) Pressure Graph and Pressure, Events and Leaks Report.

You can access the information in the Pressure, events and leaks report by selecting the button. It concerns the analysis period selected in the pressure graph displayed on the left of the window.

Pressure graph

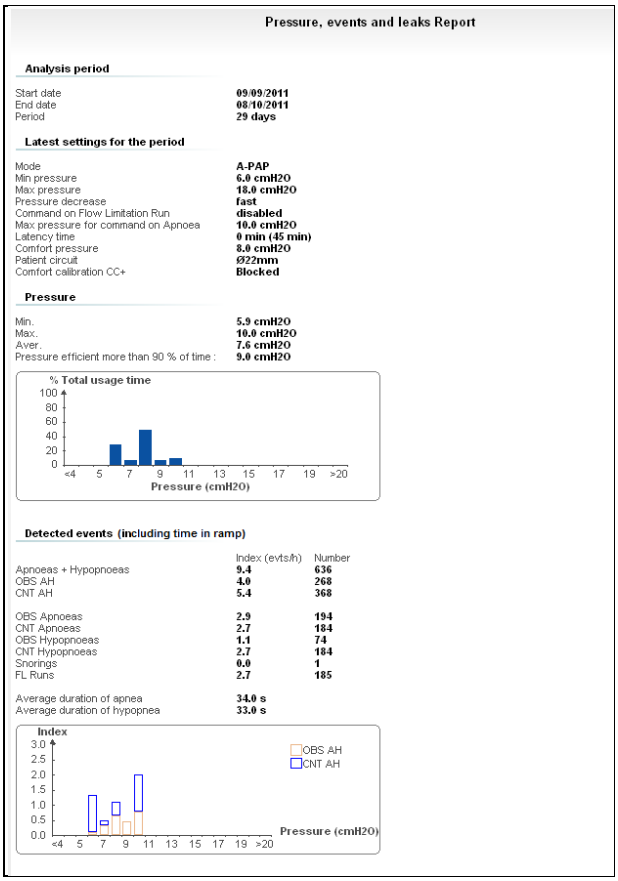
Three types of information appear on the curve displayed on the left of the screen:

- Prescribed pressure: prescribed pressure range within which the device is authorized to operate (yellow background).
- Pressure measured: estimated pressure in the mask (vertical shading).
- Average pressure: average pressure for each day of use (blue curve).

A 24-hour period can be selected from the pressure graph by clicking on the desired date or by selecting the whole period of analysis.

Pressure, Events and Leaks Report

This report only concerns the analysis period selected in the pressure graph.



Pressure, events and leaks Report

Analysis period

Start date	09/09/2011
End date	08/10/2011
Period	29 days

Latest settings for the period

Mode	A-PAP
Min pressure	6.0 cmH2O
Max pressure	18.0 cmH2O
Pressure decrease	fast
Command on Flow Limitation Run	disabled
Max pressure for command on Apnoea	10.0 cmH2O
Latency time	0 min (45 min)
Comfort pressure	8.0 cmH2O
Patient circuit	Ø22mm
Comfort calibration CC+	Blocked

Pressure

Min.	5.9 cmH2O
Max.	10.0 cmH2O
Aver.	7.6 cmH2O
Pressure efficient more than 90 % of time :	9.0 cmH2O

Detected events (including time in ramp)

	Index (evts/h)	Number
Apnoeas + Hypopnoeas	9.4	636
OBS AH	4.0	268
CNT AH	5.4	368
OBS Apnoeas	2.9	194
CNT Apnoeas	2.7	184
OBS Hypopnoeas	1.1	74
CNT Hypopnoeas	2.7	184
Snorings	0.0	1
FL Runs	2.7	185
Average duration of apnea	34.0 s	
Average duration of hypopnea	33.0 s	

The first part of the report contains the following information:

Analysis period

Shows the start and end dates for the analysis period selected in the pressure graph, and the number of days.

Latest settings for the period

Displays data concerning the settings: Operating Mode (either CPAP or Auto-CPAP), Prescribed Pressure (when in CPAP mode), Min. Pressure and Max. Pressure (when in Auto-CPAP mode), Pressure Alter if enabled (when in CPAP mode), Patient Pressure (when in CPAP mode), Ramp Time (when in CPAP mode) or Latency Time (when in Auto-CPAP mode), Pressure reduction, Command on Flow Limitation Run, Max. pressure for command on apnoea when in Auto-CPAP mode. Comfort pressure is indicated for all modes. The patient circuit is also indicated, along with enablement of the Comfort Calibration CC+ feature.

Pressure

- average minimum/maximum and average pressures measured over the period analysed.
- pressure level at which the patient spent more than a given percentage of time. This threshold can be configured, see paragraph "Choosing analysis criteria" on page 10.

The pressure histogram gives a view of the % of time spent at each pressure level.

Detected events [including time in ramp]:

- index (events per hour) and number of apnoeas and hypopnoeas detected over the period analysed.
- index (events per hour) and number of apnoeas and hypopnoeas detected and classed as obstructive over the period analysed.
- index (events per hour) and number of apnoeas and hypopnoeas detected and classed as central over the period analysed.

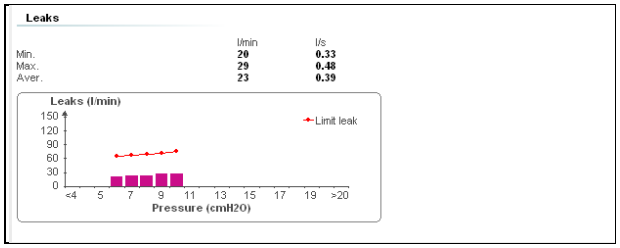
- index (events/hour) and number of detected events: obstructive apnoeas, central apnoeas, obstructive hypopnoeas, central hypopnoeas, snorings and flow limitation runs.
- average duration of apnoea
- average duration of hypopnoea
- diagram of events index for each full pressure value.

Details of detected events depends on the options which have been selected in the Analysis parameters dialogue box (see paragraph "Choosing analysis parameters" on page 9).

Leaks

Indicates min. max. and average values of leaks measured in the mask hour by hour over the period analysed.

The presentation gives a view of the leak flow level and the maximum leak in the mask for each full pressure value.



c) Wave forms, Flow rate

You can access the curves displayed by selecting the button.

This presentation first gives a summary view and then a larger view of the detected events, for measured leak level and the curve for pressure measured in the mask during recording.

You can select a duration corresponding to the page width of the larger view by clicking on the drop down list

.

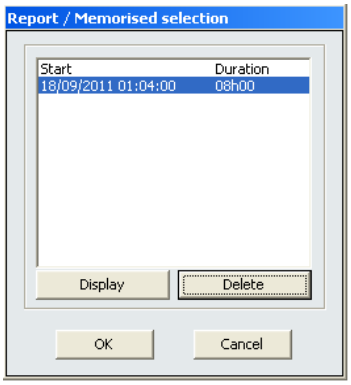
The upper section of the larger view shows the events encountered (whether they are selected for controlling the device or not):

- Obstructive events (obstructive apnoeas and hypopnoeas).
- Central events (central apnoeas and hypopnoeas).
- Patient's snoring.
- Runs indicating a breathing period with limited flow.
- Cycle state characterizing variations in resistance of the upper airways.

The central section shows the leak and maximum leak wave forms, and the pressure graph.

In the selected section of the wave forms screen, you will see a cursor, and to the right of the wave forms, values corresponding to the pressure and leak measurements associated with cursor's X-axis coordinate. If you left-click with your mouse on a wave form, the cursor will move to the address of the item clicked and the values displayed will change accordingly.

Hovering the mouse over a bar that represents one or more events in the Detected Events section causes the number of associated events to display alongside when the right button of the mouse is kept depressed.



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

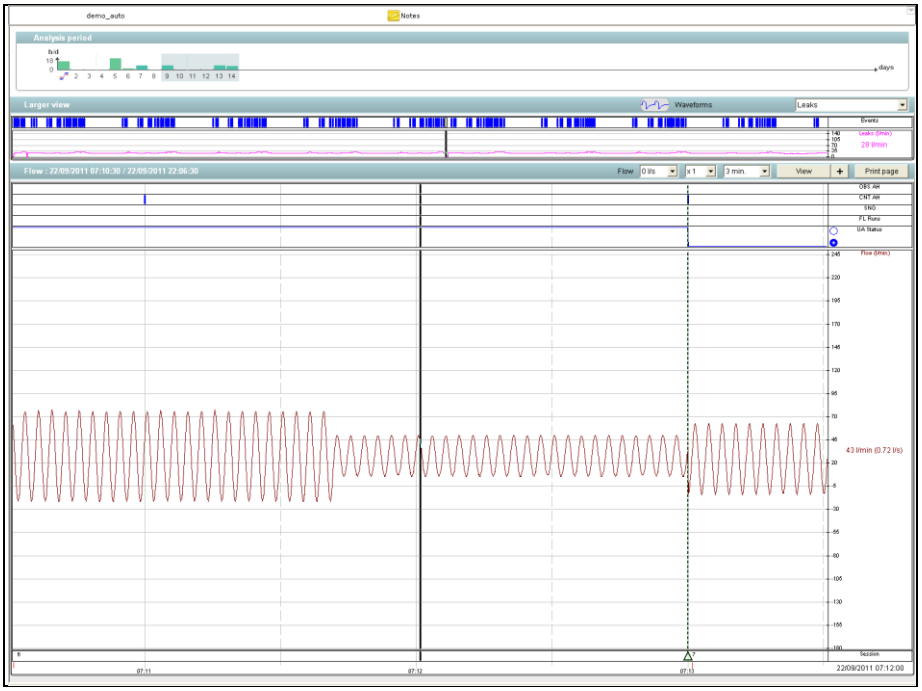
Click on the + then View buttons to open the opposite dialogue box.

The Display button allows you to display on the screen the portion of the curve and the Delete button to delete it.

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

Changes in settings are indicated in the Settings and Sessions sections. Periods during which a ramp was used are highlighted in yellow.

The **Flow** button allows you to view the 10Hz flow rate.

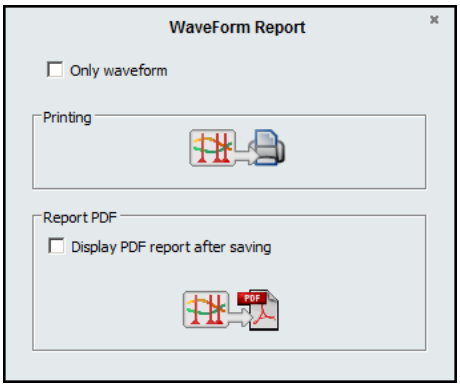


You can browse through the record using either the mouse or the left/right arrow keys.

The drop down list 3 min. or the + and – keys allow you to change the page display duration. The drop down list ×1 or the * and / keys modify the signal gain, while the drop down list -25 l/s or the ↑ and ↓ keys shift the curve.

Click on the **Waveforms** button again to return to the previous window.

The Print page button in the **Flow** and **Waveforms** window opens the following dialogue box:



The two buttons are specific to this tab and allow you to export wave forms and their reports in PDF file format and to print them with size adjustments for the space available. Only the portion of the wave form visible on the screen will be exported or printed. This dialogue box allows you to select only the curves in the report or/and view the report after saving.

To export or print an entire compliance data report, see "Analysis Compliance Report" on page 42.

A report is displayed in the right-hand part of the windows including:

Global Information

Reports information about the device and the patient reference.

Analysis period

Indicates the start and end dates for the analysis, and the analysis duration.

Pressure

Indicates the minimum pressure, maximum pressure and average pressure values for the analysis period and the Pressure efficient more than 90% of time.

The pressure histogram gives a view of the % of time spent at each pressure level.

Detected events (excluding time in ramp)

Indicates the index (events/hour) and number of detected events: obstructive and central events, snorings and flow limitation runs.

Diagram showing events index as a function of pressure.

Details of detected events depends on the options which have been selected in the Analysis parameters dialogue box (see paragraph "Choosing analysis parameters" on page 9).

Leaks

Reports the minimum, maximum and average leak values measured at the mask hour by hour during the analysis period, as well as the percentage of time spent above the limit leak.

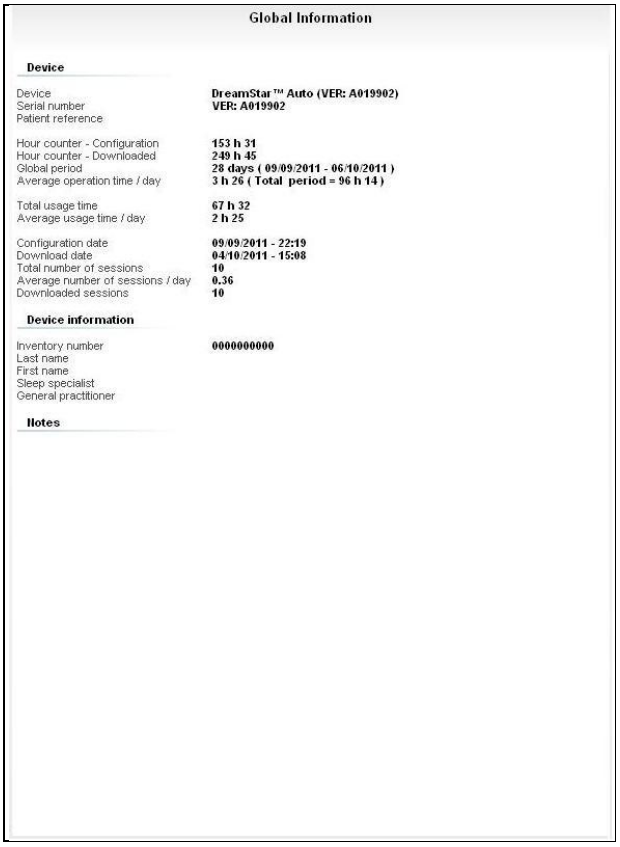
The presentation below gives a view of the leak flow level in the mask and the limit leak for each full pressure value.

Note: All of the report data is calculated based on the wave form segments displayed on the screen. Thus, the data in this report can be modified by using the zoom feature.

The case when the **Exclude Invalid Zones** feature is applied is shown beneath the report. You can enable this feature by clicking on the case with your mouse. The zones to be excluded for the case in question are defined by a measured leak level higher than the maximum leak. When Exclude Invalid Zones is enabled, those zones are excluded from the calculations which produce the data appearing in the report.

d) Global Information

You can access the information displayed by selecting the button.



Global Information

Device

Device	DreamStar™ Auto (VER: A019902)
Serial number	VER: A019902
Patient reference	
Hour counter - Configuration	153 h 31
Hour counter - Downloaded	249 h 45
Global period	28 days (09/09/2011 - 06/10/2011)
Average operation time / day	3 h 26 (Total period = 96 h 14)
Total usage time	67 h 32
Average usage time / day	2 h 25
Configuration date	09/09/2011 - 22:19
Download date	04/10/2011 - 15:08
Total number of sessions	10
Average number of sessions / day	0.36
Downloaded sessions	10

Device information

Inventory number	0000000000
Last name	
First name	
Sleep specialist	
General practitioner	

Notes

Device:

- device type of machine. The embedded software version is shown in brackets.
- serial number of the machine. This cannot be modified.
- reference assigned to the patient.
- total operating (ON/OFF) time at configuration.
- total operating (ON/OFF) time at download.
- global period
- average operation time/day
- total usage time
- average usage time/day
- date and time when the machine was configured.
- date and time when the memory card was inserted into the device to backup compliance data.
- total number of sessions recorded by the device.
- average number of sessions recorded by the device in one day.
- total number of downloaded sessions.

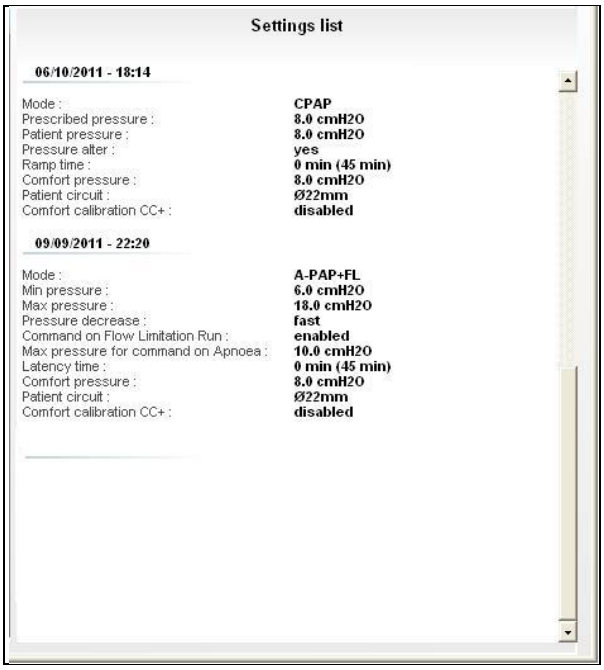
Device information:

This information is only filled in if it has been programmed in the machine.

- inventory number
- last name
- first name
- physician specializing in sleep disorders.
- general practitioner

e) Settings list

You can access the information displayed by selecting the button.



Settings list

06/10/2011 - 18:14

Mode :	CPAP
Prescribed pressure :	8.0 cmH2O
Patient pressure :	8.0 cmH2O
Pressure alter :	yes
Ramp time :	0 min (45 min)
Comfort pressure :	8.0 cmH2O
Patient circuit :	Ø22mm
Comfort calibration CC+ :	disabled

09/09/2011 - 22:20

Mode :	A-PAP+FL
Min pressure :	6.0 cmH2O
Max pressure :	18.0 cmH2O
Pressure decrease :	fast
Command on Flow Limitation Run :	enabled
Max pressure for command on Apnoea :	10.0 cmH2O
Latency time :	0 min (45 min)
Comfort pressure :	8.0 cmH2O
Patient circuit :	Ø22mm
Comfort calibration CC+ :	disabled

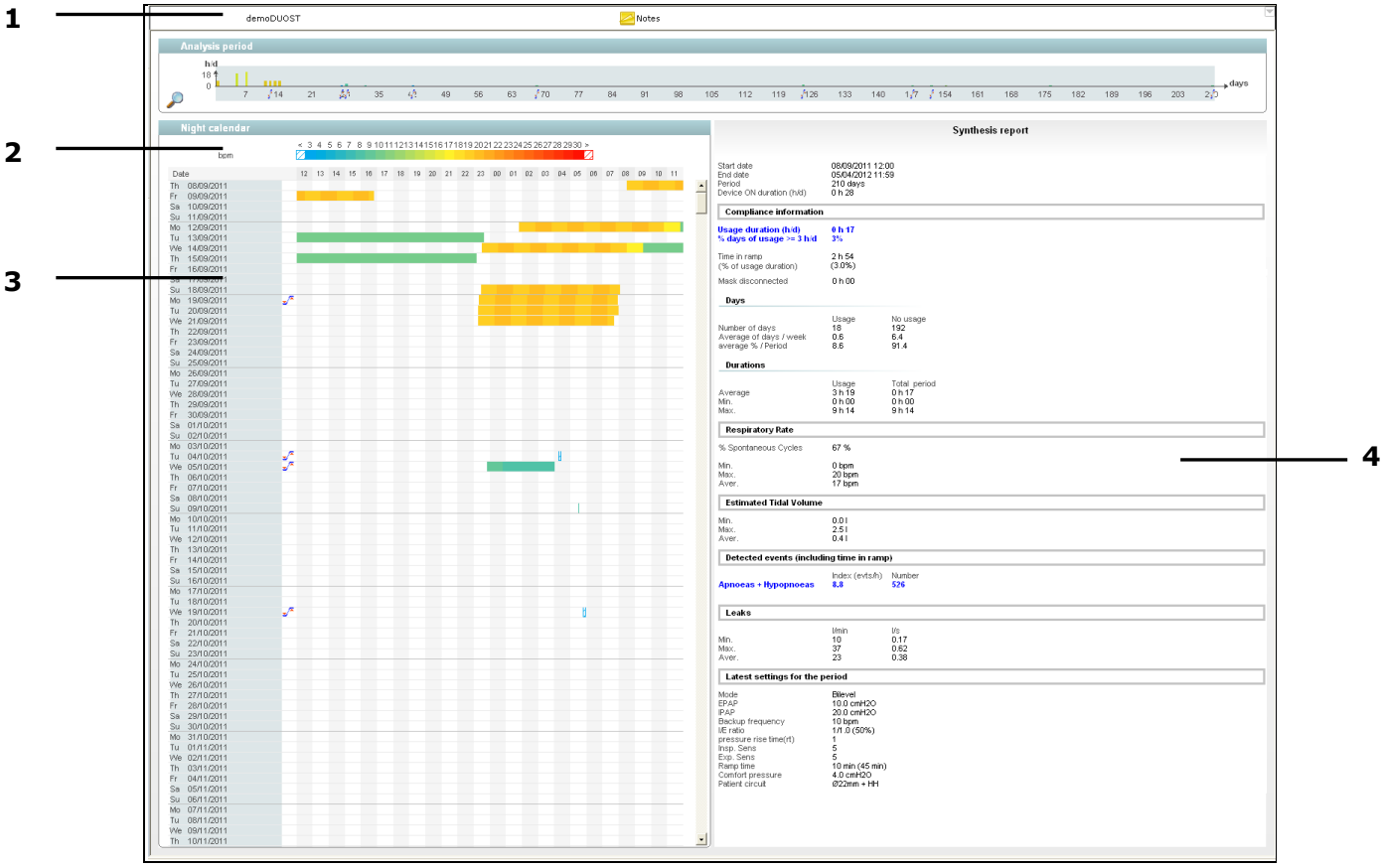
The list reflects the days selected in the calendar. The various settings driving the device are displayed in reverse chronological order (most recent to oldest). The dates and times correspond to the start of sessions affected by the new settings. The following information is displayed for each setting change:

- CPAP operating mode or Auto-CPAP operating mode on DreamStar™ Auto only.
- level of pressure prescribed for the patient in CPAP mode only.
- minimum pressure in Auto-CPAP mode only.
- maximum pressure in Auto-CPAP mode only.
- patient pressure applied to the patient in CPAP mode, different from the prescribed pressure if the Pressure Alter function is enabled.
- Pressure Alter feature which allows the patient to alter the level of pressure prescribed by± 1 cmH_2O. This feature is only available in CPAP mode.
- pressure decrease : Fast or Slow (when in Auto-CPAP mode only).
- command on Flow Limitation, enabled or disabled (when in Auto-CPAP mode only).
- max pressure for command on Apnoea (when in Auto-CPAP mode only).
- ramp time in CPAP mode or latency time in Auto-CPAP mode.
- comfort pressure indicated whatever the operating mode is.
- patient circuit used.
- Comfort Calibration CC+ feature that can be enabled with DreamStar™ Info / Info Evolve, DreamStar™ Auto / Auto Evolve.

Click on to return to the patient compliance list.

Compliance data saved with DreamStar™ Duo / DuoST, DreamStar™ Duo Evolve / DuoST Evolve

Compliance data recorded on DreamStar™ Duo, DreamStar™ DuoST or their equivalents in Evolve configuration is displayed as follows:



This window is divided into four sections:

1. Patient identification for the selected patient

The patient's name appears at the top of the window. The patient's identifier and age are displayed by clicking on in the upper right corner of the screen. Other data can be displayed if available, including the patient's address and telephone number and the name(s) and telephone number(s) of clinician(s). Additional information which can be freely added to the session data by clicking on the Notes button.

2. Analysis period

The **Analysis period** section presents a **compliance summary diagram**: daily length of time during which the patient has breathed using the mask, expressed as a function of the number of days.

The value on the horizontal axis represents 24-hour periods and the value on the vertical axis represents the duration of use (the sum of all durations of use of on/off sessions). The colour indicates the average frequency for the 24-hour period. Its value is the average of average frequencies weighted by the number of cycles in each session.

Note: Average respiratory rate is calculated with reference to the number of cycles rather than with reference to time.

When the compliance data record exceeds a given number of days, a Zoom button appears in the lower left corner of the graph. The icon is visible only when this feature is enabled. The Zoom button allows you to view all sessions or a subset. If you choose to display a subset of sessions, a cursor will appear, and you can move from one session to another either by clicking on the right and left arrows or by moving the cursor while keeping the left mouse button depressed.

3. Night calendar

The **Night calendar** section appears by default on the left side of the window. However, the respiratory rate or wave forms can be displayed there instead, depending on which tab is selected.

The night calendar gives a quick overview of patient compliance across the most recent recorded sessions. A colour scale indicates respiratory frequency levels from 0 to 30 BPM (beats per minute).

A 24-hour period can be selected from the calendar by clicking on the date of interest to you. The corresponding diagram will then appear in the Compliance section.

If you double-click on a session, the **Session** window will display as shown below:

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

For further information, refer to the paragraph entitled "**Viewing the current session**" on page 70.

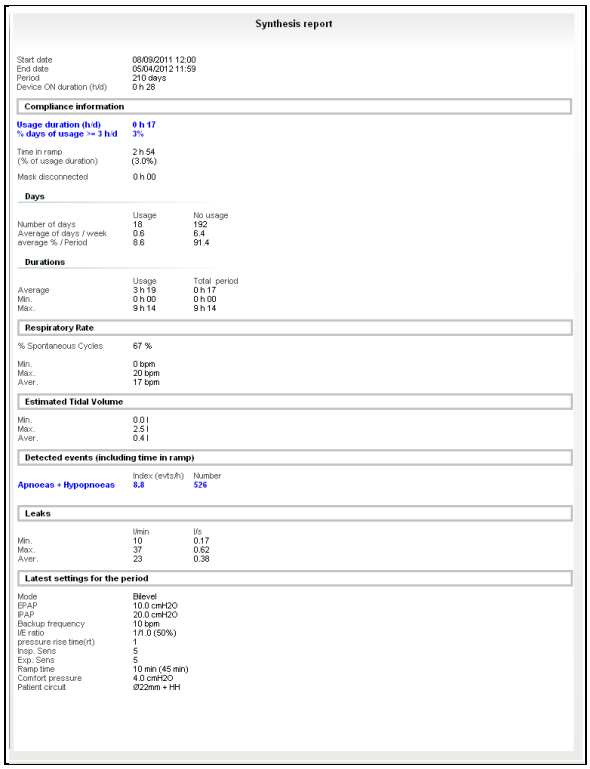
Close the window by clicking on the X in the upper right corner.

4. Compliance data

The presentation selected using one of the buttons located in the left part of the window is displayed in the right-hand section. If you right-click with the mouse on one of the first 3 presentations right (synthesis report, pressure, events and leaks report and waveforms report), the **Analysis parameters** window will be displayed and you can use the tools proposed in the dialogue box. The values shown on the right will then consider the options selected. For more information, refer to paragraph "Choosing analysis parameters" on page 9.

a) Synthesis report

The information shown in the Synthesis Report is displayed by default but also can be accessed by clicking on the button.



Synthesis report

Start date	08/09/2011 12:00
End date	05/04/2012 11:59
Period	210 days
Device ON duration (h/d)	0 h 28

Compliance information

Usage duration (h/d)	**0 h 17**
% days of usage >= 3 h/d	**3%**
Time in ramp	2 h 54
(% of usage duration)	(3.0%)
Mask disconnected	0 h 00

Days

	Usage	No usage
Number of days	18	192
Average of days / week	0.6	6.4
average % / Period	8.6	91.4

Durations

	Usage	Total period
Average	3 h 19	0 h 17
Min.	0 h 00	0 h 00
Max.	9 h 14	9 h 14

Respiratory Rate

% Spontaneous Cycles	67 %
Min.	0 bpm
Max.	20 bpm
Aver.	17 bpm

Estimated Tidal Volume

Min.	0.0 l
Max.	2.5 l
Aver.	0.4 l

Detected events (including time in ramp)

	Index (evts/h)	Number
Apnoeas + Hypopnoeas	**8.8**	**52%**

Leaks

	l/min	l/s
Min.	10	0.17
Max.	37	0.62
Aver.	23	0.38

Latest settings for the period

Mode	Bilevel
EPAP	10.0 cmH2O
IPAP	20.0 cmH2O
Backup frequency	10 bpm
I/E ratio	1/1.0 (50%)
pressure rise time(rt)	1
Insp. Sens	5
Exp. Sens	5
Ramp time	10 min (45 min)
Comfort pressure	4.0 cmH2O
Patient circuit	Ø22mm + HH

The synthesis report contains the following information:

Compliance information

- Usage duration (h/d): average duration during which the patient is really breathing with the mask, given in number of hours per day.
- % days of usage >= 3 h/d: percentage of days during which the patient has really breathed with the machine for a number of hours over the specified threshold (this threshold can be configured, see paragraph "Choosing analysis criteria" on page 10).
- Time in ramp : (% of usage duration) time spent in ramp with the % of usage duration indicated in brackets.
- Time in ramp: time in ramp when operating in CPAP or Bilevel mode.
- Mask disconnected: length of time that the patient mask was removed.

Days

- Number of days: number of days of device use and of non-use
- Average of days/week: average number of days of device use and of non-use per week
- Average %/period: percent average use or non-use of the device during the period.

Durations

- Average: average duration of use over 24 hours for the selected period during which the patient breathed in the mask.
- Min.: minimum duration of use over 24 hours for the selected period during which the patient breathed in the mask.
- Max.: maximum duration of use over 24 hours for the selected period during which the patient breathed in the mask.

Respiratory Rate

- % Spontaneous cycles : displayed with DreamStar™ DuoST/DuoST Evolve only.
- Min.: minimum frequency measured over the period analysed.
- Max.: maximum frequency measured over the period analysed.
- Average: average frequency measured over the period analysed.

Estimated tidal volume

- Min.: value of the minimum tidal volume calculated over the period analysed.
- Max.: value of the maximum tidal volume calculated over the period analysed.
- Average: value of the average tidal volume calculated over the period analysed.

Detected events (including time in ramp)

- Apnoeas + Hypopnoeas: Index (events/hour) and number of apnoeas and of hypopnoeas detected over the period analysed.

Leaks

- Min.: minimum value of leaks measured in the mask hour by hour over the period analysed.
- Max.: maximum value of leaks measured in the mask hour by hour over the period analysed.
- Average: : average value of leaks measured in the mask hour by hour over the period analysed.

Latest settings for the period

- Mode: CPAP or Bilevel operating mode.
- EPAP = Expiratory Positive Airway Pressure expiratory positive airway pressure.
- IPAP = Inspiratory Positive Airway Pressure inspiratory positive airway pressure.
- Prescribed pressure : prescribed pressure in CPAP mode.
- Backup frequency: available on the DreamStar™ DuoST or DreamStar™ DuoST Evolve device.
- I/E Ratio: available on the DreamStar™ DuoST or DreamStar™ DuoST Evolve device.
- Pressure Alter. This feature available in CPAP mode gives the patient the option to alter the level of pressure prescribed by ± 1 cmH_2O.
- Patient pressure level of pressure applied to the patient in CPAP mode, different from the prescribed pressure if the Pressure Alter function is enabled.
- Pressure rise time (RT): Pressure rise time set by the physician. Time the device takes to rise from the expiratory positive airway pressure (EPAP) to the inspiratory positive airway pressure (IPAP).

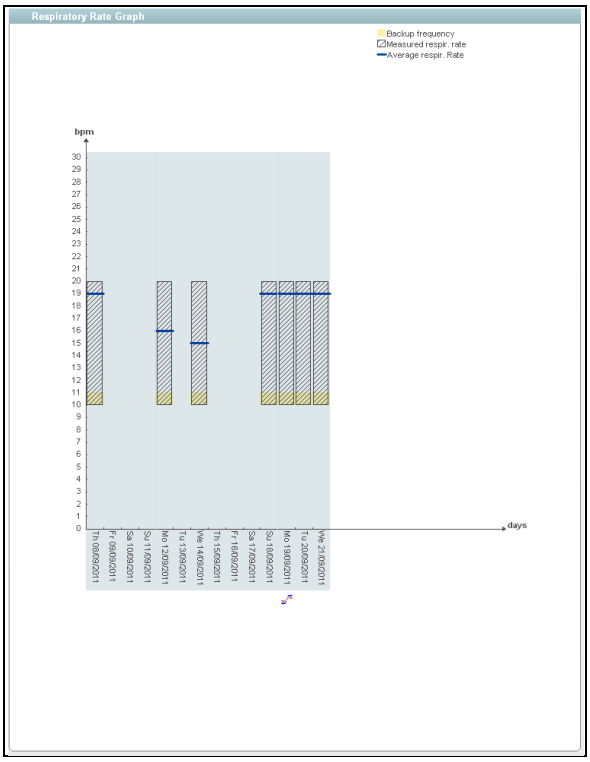
- Inspiratory sensitivity: detection sensitivity of the start of the inspiratory phase of respiration.
- Expiratory sensitivity: detection sensitivity of the start of the expiratory phase of respiration.
- Ramp time: time the device takes to reach the prescribed pressure after the first 5 minutes when starting from the comfort pressure in CPAP mode.

  In Bilevel mode, this is the time beyond the first 5 minutes that the device takes to reach the expiratory positive airway pressure (EPAP) and the inspiratory positive airway pressure (IPAP) from the comfort pressure. The maximum ramp time is indicated in parentheses.
- Comfort pressure: level of pressure produced by the device when the ramp feature starts up so that the patient can go to sleep comfortably.
- Patient circuit: patient circuit used, diameter 15 mm, diameter 15 mm with water chamber, diameter 22 mm, diameter 22 mm with water chamber and SPECIFIC (other configuration).

b) Respiratory Rate Graph and Respiratory Rate Report

The information shown in the Respiratory Rate Report can be accessed by clicking on the button.
The information is for the analysis period selected on the frequency rate wave form displayed on left of the window.

Respiratory Rate Graph

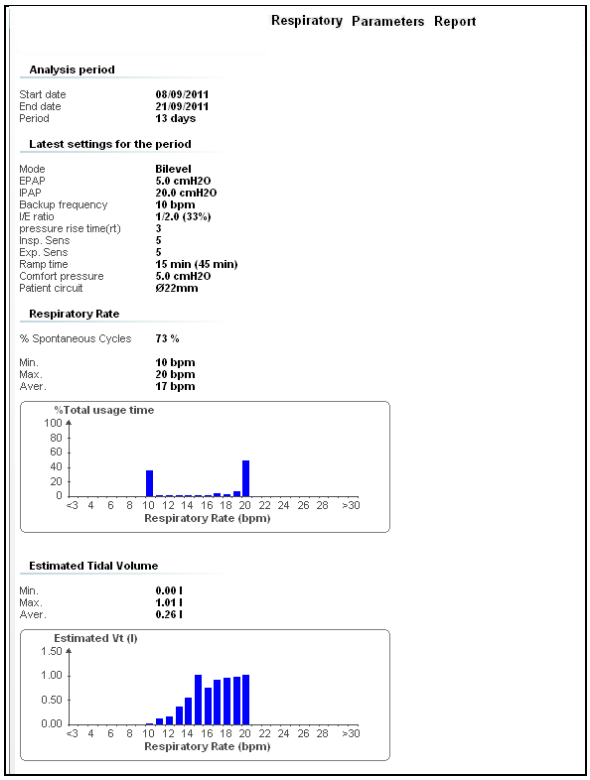


Three types of information appear on the curve displayed on the left of the screen:

- Backup frequency: periodicity of backup operations prescribed within which the DreamStar™ DuoST or DreamStar™ DuoST Evolve device is authorized to operate (yellow background).
- Measured respiratory rate: respiratory rate measured (oblique shading).
- Average respiratory rate: average respiratory rate for each day of use (blue curve).

From the respiratory rate graph, it is possible to select either a 24-hour period by clicking on the date of interest or the entire analysis period.

Respiratory Parameters Report



Analysis period

Shows the start and end dates for the analysis period selected in the respiratory rate graph, and the number of days.

Latest settings for the period

Displays data concerning the settings: CPAP or Bilevel operating mode, pressure prescribed in CPAP mode, or EPAP (Expiratory Positive Airway Pressure) and IPAP (Inspiratory Positive Airway Pressure) in Bilevel mode, Backup Frequency and I/E Ratio (which are available only on the DreamStar™ DuoST or DreamStar™ DuoST Evolve), Pressure Rise Time, Inspiratory Sensitivity, Expiratory Sensitivity, Ramp Time, Comfort Pressure and Patient Circuit used.

Respiratory Rate

- percentage of spontaneous cycles
- Minimum/Maximum and Average frequencies measured over the period analysed.

The presentation below shows the % total usage time by whole value of respiratory rate.

Estimated tidal volume

- values of the minimum, maximum and average tidal volume calculated over the period analysed.

The diagram below displays the estimated tidal volume for each full respiratory rate value.

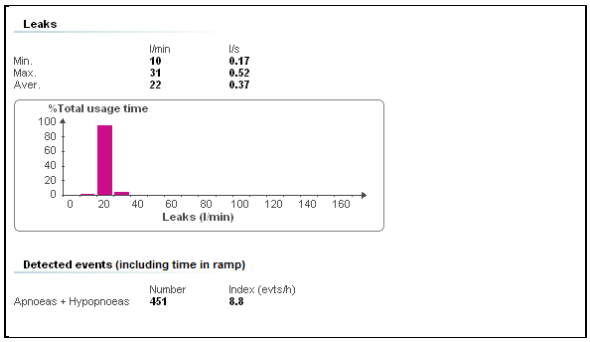
Leaks

Indicates the minimum, maximum and average leak values measured at the mask hour by hour over the period analysed.

The presentation below shows the % total usage time by leak flow level at the mask.

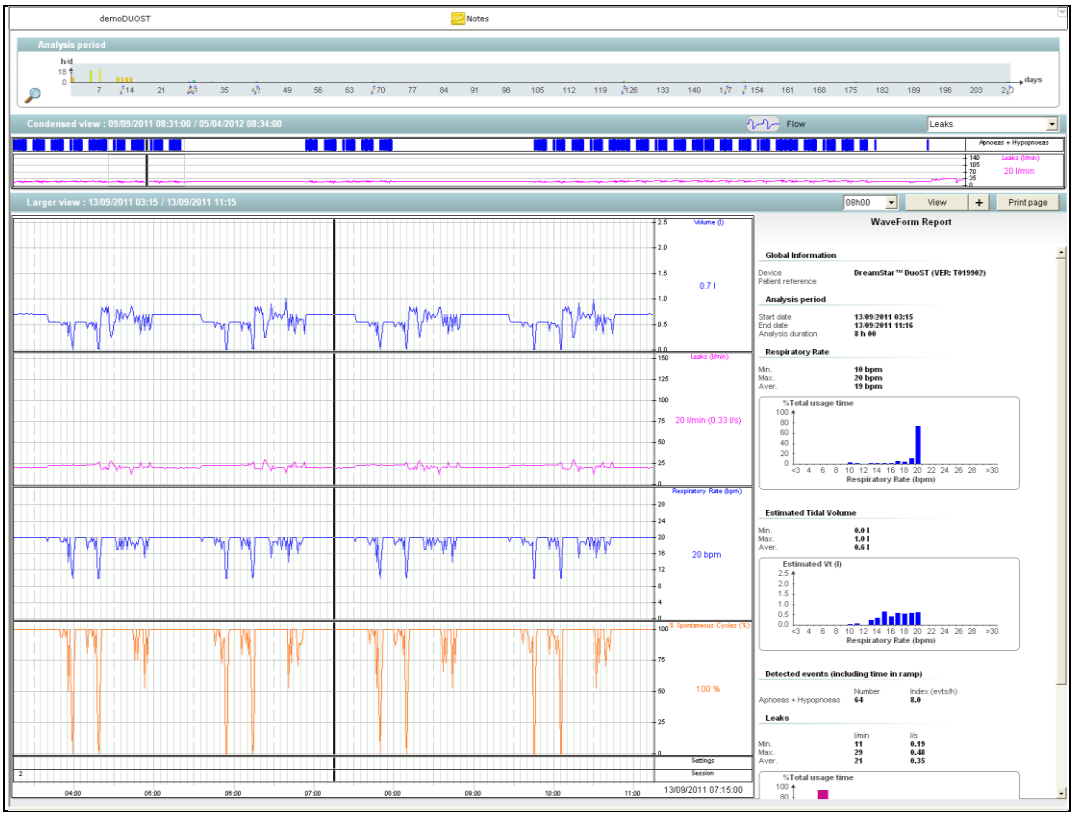
Detected events [including time in ramp]

Number and index (events per hour) of apnoeas and of hypopnoeas detected over the period analysed.



c) Wave forms, Flow rate

You can access the curves displayed by selecting the button.



This presentation first gives a summary view and then a larger view of the detected events, for measured leak level and respiratory rate during recording.

You can select a duration corresponding to the page width of the larger view by clicking on the drop down list

.

The upper section of the larger view shows the events encountered: apnoeas and hypopnoeas.

The central section shows the estimated volume, leak and respiratory rate wave forms, and the percentage of spontaneous cycles.

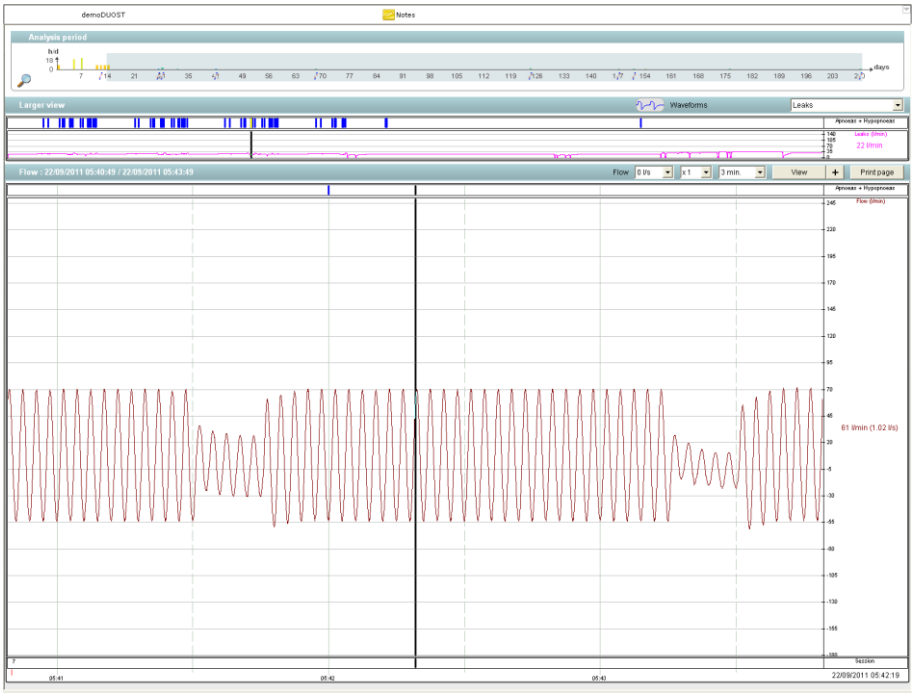
In the selected section of the wave forms screen, you will see a cursor, and to the right of the wave forms, values corresponding to the estimated volume, leak, respiratory rate and

spontaneous cycles measured on the X-axis at the cursor. If you left-click with your mouse on a wave form, the cursor will move to the address of the item clicked and the values displayed will change accordingly.

Hovering the mouse over a bar that represents one or more events in the Detected Events section causes the number of associated events to display alongside when the right button of the mouse is kept depressed.

Changes in settings are indicated in the Settings and Sessions sections. Periods during which a ramp was used are highlighted in yellow.

The **Flow** button allows you to view the 10Hz flow rate.

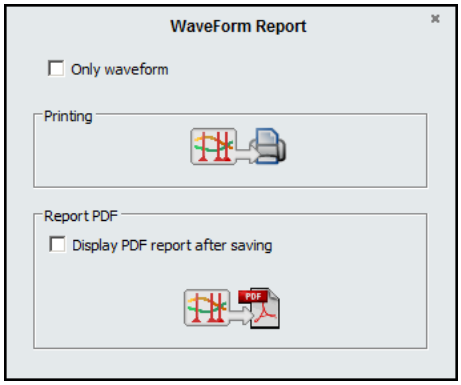


You can browse through the record using either the mouse or the left/right arrow keys.

The drop down list 3 min. or the + and – keys allow you to change the page display duration. The drop down list x 1 or the * and / keys modify the signal gain, while the drop down list -25 l/s or the ↑ and ↓ keys shift the curve.

Click on the **Waveforms** button again to return to the previous window.

The Print page button in the **Flow** and **Waveforms** window opens the following dialogue box:



The two buttons displayed are specific to this tab and allow you to export wave forms and their reports in PDF file format and to print them with size adjustments for the space available. Only the portion of the wave form visible on the screen will be exported or printed. This dialogue box allows you to select only the curves in the report and to view the report after recording.

To export or print an entire compliance data report, see "Analysis Compliance Report" on page 43. Close the dialogue box by clicking on the X in the upper right corner.

A waveform report is displayed in the right-hand part of the windows including:

Global Information

Reports information about the device and the patient reference.

Analysis period

Indicates the start and end dates for the analysis, and the analysis duration.

Respiratory Rate

Indicates the minimum, maximum and average respiratory rate values measured over the period analysed.

The histogram below shows the % total usage time by respiratory rate level.

Estimated tidal volume

Are indicated the values of the minimum, maximum and average tidal volume calculated over the period analysed.

The diagram below displays the estimated tidal volume for each full respiratory rate value.

Detected events [including time in ramp]

Indicates the number and index (events/hour) of apnoeas and hypopnoeas detected over the period analysed

Leaks

Reports the minimum, maximum and average leak values measured at the mask for each hour of the analysis period.

The presentation below shows the % total usage time by leak flow level at the mask.

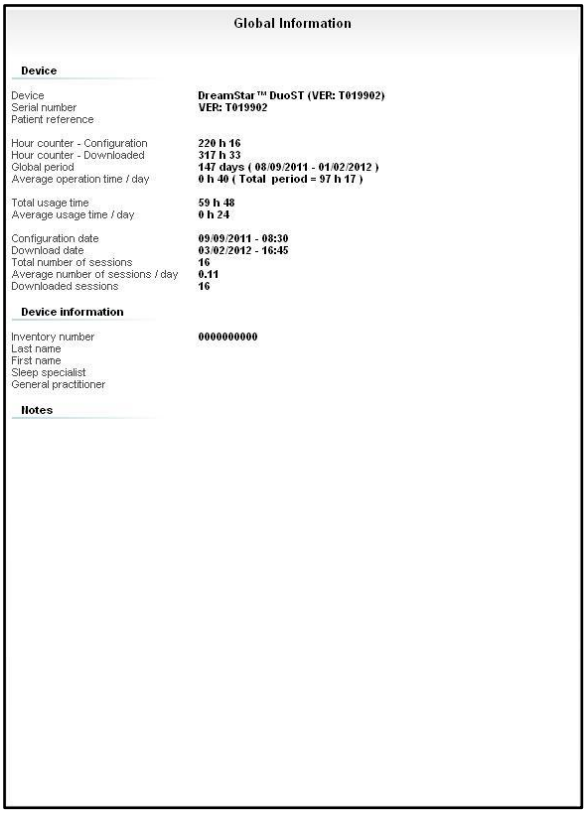
Percent of spontaneous cycles

Reports the minimum, maximum and average spontaneous cycle values.

Note: All of the report data is calculated based on the wave form segments displayed on the screen. Thus, the data in this report can be modified by using the zoom feature.

d) Global Information

You can access the information displayed by selecting the button, to display the following information:



Global Information

Device

Device	DreamStar™ DuoST (VER: T019902)
Serial number	VER: T019902
Patient reference	
Hour counter - Configuration	220 h 16
Hour counter - Downloaded	317 h 33
Global period	147 days (08/09/2011 - 01/02/2012)
Average operation time / day	0 h 40 (Total period = 97 h 17)
Total usage time	59 h 48
Average usage time / day	0 h 24
Configuration date	09/09/2011 - 08:30
Download date	03/02/2012 - 16:45
Total number of sessions	16
Average number of sessions / day	0.11
Downloaded sessions	16

Device information

Inventory number	0000000000
Last name	
First name	
Sleep specialist	
General practitioner	

Notes

Device

- device type of machine. The embedded software version is shown in brackets.
- serial number of the machine. This cannot be modified.
- reference assigned to the patient.
- total operating (ON/OFF) time at configuration.
- total operating (ON/OFF) time at download.
- global period
- average operation time/day
- total usage time
- average usage time/day
- date and time when the machine was configured.
- date and time when the memory card was inserted into the device to backup compliance data.
- total number of sessions recorded by the device.
- average number of sessions recorded by the device in one day.
- total number of downloaded sessions.

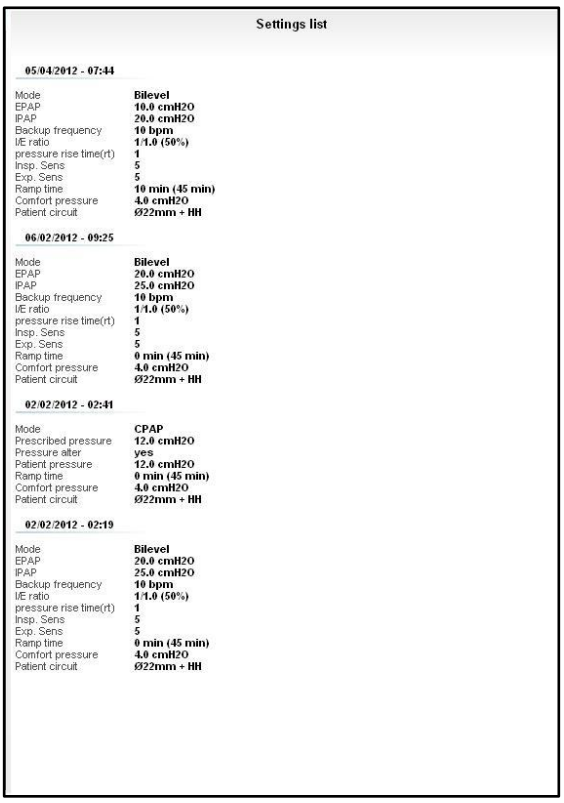
Device information

This information is only filled in if it has been programmed in the machine.

- inventory customer number
- last name
- first name
- physician specializing in sleep disorders.
- general practitioner

e) Settings list

You can access the information displayed by selecting the button.



Settings list

05/04/2012 - 07:44

Mode	Bilevel
EPAP	10.0 cmH2O
IPAP	20.0 cmH2O
Backup frequency	10 bpm
I/E ratio	1/1.0 (50%)
pressure rise time(rt)	1
Insp. Sens	5
Exp. Sens	5
Ramp time	10 min (45 min)
Comfort pressure	4.0 cmH2O
Patient circuit	Ø22mm + HH

06/02/2012 - 09:25

Mode	Bilevel
EPAP	20.0 cmH2O
IPAP	25.0 cmH2O
Backup frequency	10 bpm
I/E ratio	1/1.0 (50%)
pressure rise time(rt)	1
Insp. Sens	5
Exp. Sens	5
Ramp time	0 min (45 min)
Comfort pressure	4.0 cmH2O
Patient circuit	Ø22mm + HH

02/02/2012 - 02:41

Mode	CPAP
Prescribed pressure	12.0 cmH2O
Pressure alter	yes
Patient pressure	12.0 cmH2O
Ramp time	0 min (45 min)
Comfort pressure	4.0 cmH2O
Patient circuit	Ø22mm + HH

02/02/2012 - 02:19

Mode	Bilevel
EPAP	20.0 cmH2O
IPAP	25.0 cmH2O
Backup frequency	10 bpm
I/E ratio	1/1.0 (50%)
pressure rise time(rt)	1
Insp. Sens	5
Exp. Sens	5
Ramp time	0 min (45 min)
Comfort pressure	4.0 cmH2O
Patient circuit	Ø22mm + HH

The list reflects the days selected in the calendar. The various settings driving the device are displayed in reverse chronological order (most recent to oldest). The dates and times correspond to the start of sessions affected by the new settings.

The following information is displayed for each setting change:

- CPAP or Bilevel operating mode.
- pressure prescribed for the patient in CPAP mode only.
- EPAP : Expiratory Positive Airway Pressure in Bilevel mode only.
- IPAP : Inspiratory Positive Airway Pressure in Bilevel mode only.
- patient pressure in CPAP mode, different from the prescribed pressure if the Pressure Alter function is enabled.
- option for the patient to alter the level of pressure prescribed by ± 1 cmH_2O. This feature is available only in CPAP mode.
- Pressure rise time (RT) set by the physician. Time the device takes to rise from the expiratory positive airway pressure (EPAP) to the inspiratory positive airway pressure (IPAP).
- detection sensitivity of the start of the inspiratory phase of respiration.
- detection sensitivity of the start of the expiratory phase of respiration.
- time the device takes to reach the prescribed pressure after the first 5 minutes when starting from the comfort pressure in CPAP mode.
- In Bilevel mode, this is the time beyond the first 5 minutes that the device takes to reach the expiratory positive airway pressure (EPAP) and the inspiratory positive airway pressure (IPAP) from the comfort pressure. The maximum ramp time is indicated in parentheses.
- Backup frequency available on the DreamStar™ DuoST or DreamStar™ DuoST Evolve device.

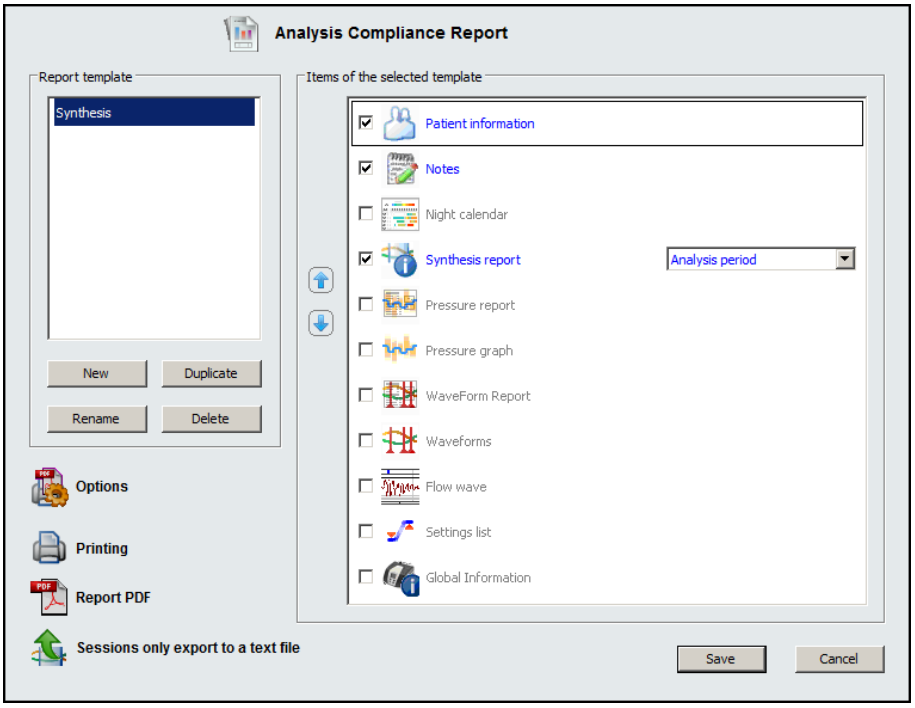
- I/E Ratio available only on the DreamStar™ DuoST or DreamStar™ DuoST Evolve device, based on the settings for backup frequency, inspiratory positive airway pressure (IPAP), and expiratory positive airway pressure (EPAP).
- comfort pressure produced by the device in CPAP mode when the ramp feature starts up so that the patient can go to sleep comfortably.
- patient circuit used.

Click on to return to the patient compliance list.

Analysis Compliance Report

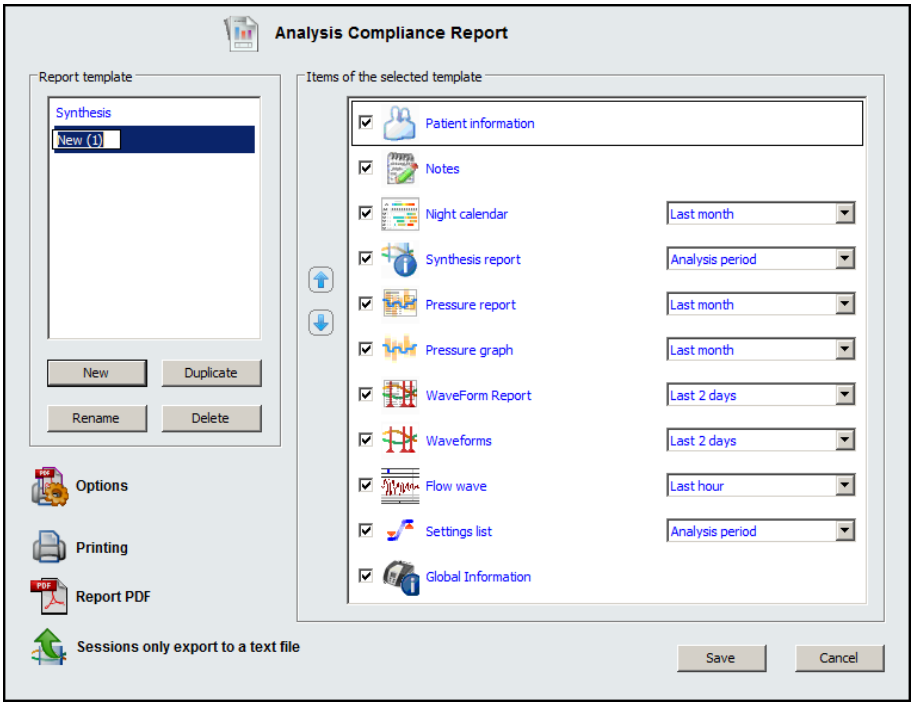
1. Printing and exporting reports

First select a analysis period. The **Analysis Compliance Report** dialogue box can be accessed by clicking on the button.



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

You can create other compliance report templates by clicking on the New... button. 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 Rename button. The new report template parameters will be set by default.



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

If in the **Waveforms** tab, you have added a portion of curve in the memorised selection, "Memorised selection" can be chosen in the drop-down list of the Waveforms or / and Flow wave item.

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.

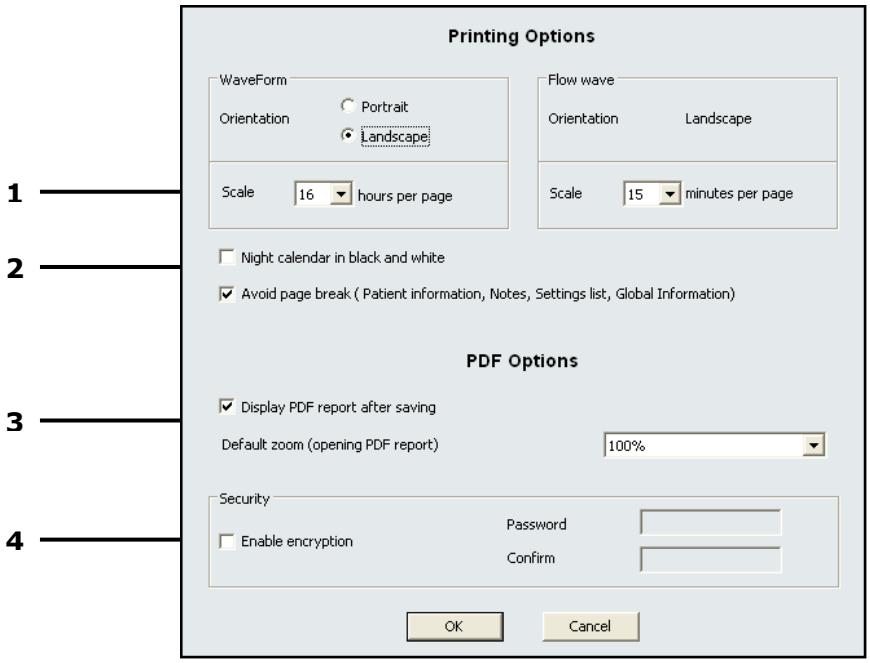
You can create a copy of an existing report template by clicking on the Duplicate button.

This copy or an existing compliance report template can be modified by selecting it and clicking on the Rename button. This option allows you to rename the report and to select or deselect the items you want to print.

It is also possible to delete a report template by selecting it and clicking on the Delete button.

The

icone allows you to access the following window in which printing options and pdf options are set by default:



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

1. **Scale** for the waveform and flow wave.
2. **Night calendar in black and white**. You can also choose to avoid page breaks for the items listed.
3. **Display PDF report after saving**. You can also set the default zoom when opening the PDF report.
4. **Enable encryption** : this option allows enabling password protection of pdf exported.

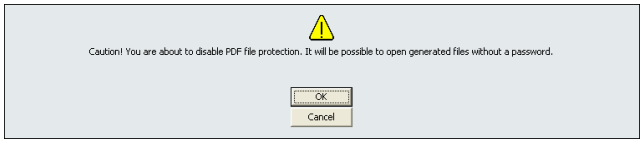
   The default password for all PDF documents generated is **SEFAM2011** (case-sensitive), but can be changed in this dialogue box. To change the password, type the new password and then confirm it.

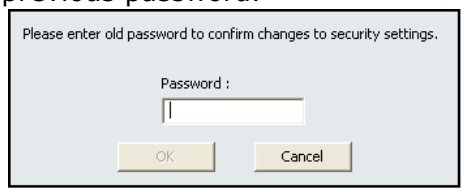
CAUTION

The password can be disabled as needed by unchecking the Enable encryption box. It is up to the user to confirm whether this setting is enabled.

Click **OK** to accept the new configuration.

A window warns you that you are going to lose password protection. Click on **OK** to confirm your choice. In this case, a dialogue box will ask you to enter the previous password.





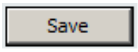
The password protection status is indicated on the Generate PDF File buttons.

You can export the compliance data report as a PDF format file. To do so, click on the

icon. The file can be saved to your computer hard drive.

You can print the report by clicking on the

icon. The compliance analysis report will resume faithfully the information presented on the screen, when only patient personal information will be printed if completed.

Click on 

to save your modifications or on **Cancel** to cancel them (in this case, only the printing options and pdf options will be saved).

2. Using the sessions only export to a text file feature

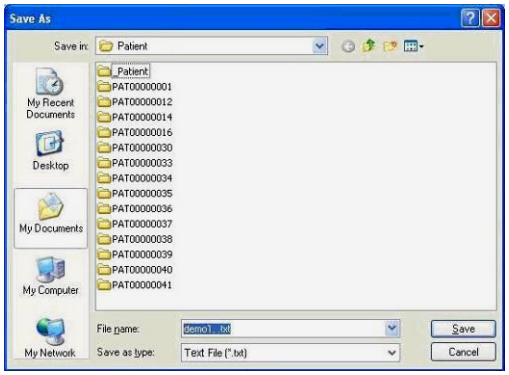
a) Launching the export

The sessions only export to a text file feature allows you to export data in file formats that can be read by spreadsheet software programmes for statistical analysis based on data formats different from the format used by **DreamStar™ Analyze**.

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

Exported file names consist of the name of the patient file in question plus an extension that specifies the file content.

Click on the **Sessions only export to a text file** icon 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.



CAUTION

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

b) File structure

Data is exported in UNICODE, with each character encoded in 2 bytes.

DreamStar™ Intro or DreamStar™ Intro Evolve

The session data exported by DreamStar™ Intro or DreamStar™ Intro Evolve is as follows:

- Session: Session number
- State: Session status: OK, Empty, Invalid data, or Checksum error
- Date: Session date
- Time: Session time
- Duration: The operating time for the machine during the session in hours and minutes
- Usage Time : The usage time for the machine during the session in hours and minutes
- Ramp time: Ramp time in hours and minutes
- Patient pressure: Patient pressure in mmH_2O
- Average pressure: Average pressure measured by the machine in mmH_2O

DreamStar™ Info, DreamStar™ Info Evolve, DreamStar™ Auto or DreamStar™ Auto Evolve

The session data exported by DreamStar™ Info/Info Evolve and DreamStar™ Auto/Auto Evolve is as follows:

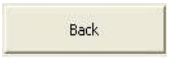
- Session: Session number
- State: Session status: OK, Empty, Invalid data, or Checksum error
- Date: Session date
- Time: Session time
- Duration: The operating time for the machine during the session in hours and minutes
- Usage: The usage time for the machine during the session in hours and minutes
- Mask disconnected: Length of time that the mask has been disconnected
- Time in ramp: Length of time in ramp while in CPAP mode, expressed in hours and minutes
- Average pressure: Average pressure measured by the machine in mmH_2O
- Average Leaks: Average number of leaks
- OBS Apnoeas: Number of apnoeas classed as obstructive.
- CNT Apnoeas: Number of apnoeas classed as central.
- OBS Hypopnoeas: Number of hypopnoeas classed as obstructive.
- CNT Hypopnoeas: Number of hypopnoeas classed as central.
- Snorings: Number of snores
- FL Runs: Number of Flow limitation runs
- Setting change: Change of settings
- Mode: Mode (CPAP or Auto-CPAP)
- Prescribed pressure: Prescribed pressure in mmH_2O
- Patient pressure: Patient pressure while in CPAP mode, expressed in mmH_2O.
- Min. pressure: Minimum pressure while in Auto-CPAP mode, expressed in mmH_2O
- Max. pressure: Maximum pressure while in Auto-CPAP mode, expressed in mmH_2O

- Max. press. for command on Apnoea: Maximum pressure for command on Apnoea (when in Auto-CPAP mode), expressed in mmH_2O
- Command on Flow Limitation Run: Command on Flow Limitation Run (when in Auto-CPAP mode)
- Pressure decrease: Pressure decrease in Auto-CPAP mode.
- Ramp time or Latency time: Ramp time in CPAP mode or latency time before Auto-CPAP mode is triggered in Auto-CPAP mode.
- Max ramp time or Max Latency time: Maximum ramp time in CPAP mode or latency time in Auto-CPAP mode.
- Comfort pressure: Comfort pressure

DreamStar™ Duo, DreamStar™ Duo Evolve, DreamStar™ DuoST or DreamStar™ DuoST Evolve

The session data exported by DreamStar™ Duo/Duo Evolve and DreamStar™ DuoST/DuoST Evolve is as follows:

- Session: Session number
- State: Session status: OK, Empty, Invalid data, or Checksum error
- Date: Session date
- Time: Session time
- Duration: The operating time for the machine during the session in hours and minutes
- Usage: The usage time for the machine during the session in hours and minutes
- Mask disconnected: Length of time that the mask has been disconnected.
- Time in ramp: Length of time in ramp while in CPAP mode, expressed in hours and minutes
- Average respiratory rate: Average respiratory rate measured by the machine in BPM
- Average Leaks: Average number of leaks
- Apnoeas: Number of apnoeas.
- Hypopnoeas: Number of hypopnoeas.
- Setting change: Change of settings
- Mode: Mode (CPAP or Bilevel)
- Prescribed pressure: Prescribed pressure while in CPAP mode, expressed in mmH_2O.
- Patient pressure: Patient pressure while in CPAP mode, expressed in mmH_2O.
- EPAP: Expiratory positive airway pressure while in Bilevel mode, expressed in mmH_2O.
- IPAP: Inspiratory positive airway pressure while in Bilevel mode, expressed in mmH_2O.
- Backup frequency: Backup frequency expressed in BPM (applies to DreamStar™ DuoST or DreamStar™ DuoST Evolve).
- I/E Ratio Average I/E ratio (applies to DreamStar™ DuoST or DreamStar™ DuoST Evolve).
- Pressure rise time (rt): Pressure rise time while in Bilevel mode
- Inspiratory sensitivity: Inspiratory sensitivity
- Expiratory sensitivity: Expiratory sensitivity
- Ramp time: Ramp time in minutes
- Max. Ramp time: Maximum ramp time in minutes
- Comfort pressure: Comfort pressure

Click on the 

button to exit the analysis compliance report.

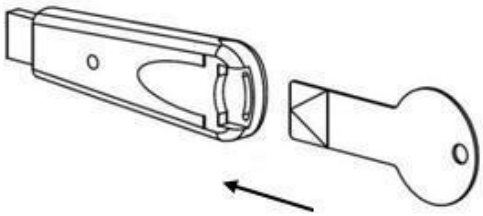
Using a memory card

Downloading data via memory card

The patient can use external memory media to download the most recent compliance data from the memory of any DreamStar™ or Sandman device by following the instructions in the Patient Manual.

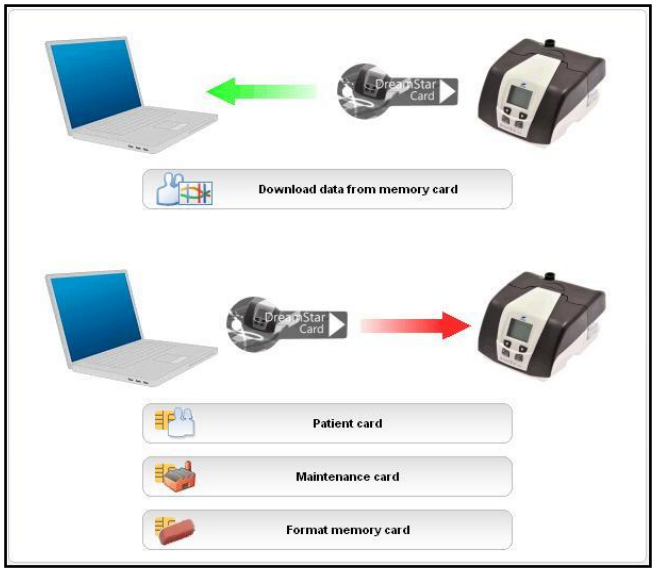
Once the data is backed up, the patient delivers the memory card to you and you can retrieve the compliance data and analyse it using the **DreamStar™ Analyze** software.

Insert the card into the memory card drive supplied with the software as shown in the diagram.



Then insert the card drive into a free USB port on your computer.

Next click on the button in the DreamStar™ Analyze software. The following screen will appear:



Click on the **Download data from memory card** option. An animation will appear until the data download is complete.

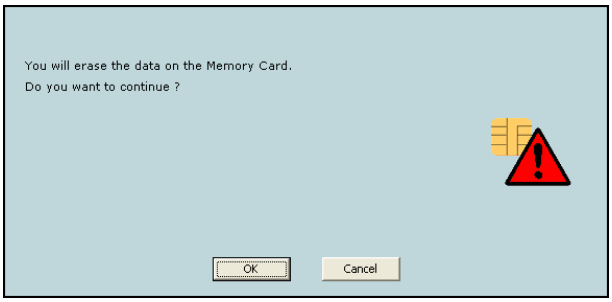
Note: Any memory card, whether it is new or has been previously used for downloads from this or another DreamStar™ device can be used to download data.

For purposes of data confidentiality, the card can be erased once it has been read. To do so, enable the corresponding option as indicated in section "Other functionalities" page 9.

Once the memory card has been read, a window will appear identical to the one described in section "Displaying compliance data" page 16 and following. Refer to this section for more information concerning the data displayed.

Formatting the memory card

The **Format memory card** button enables you to erase the data on the memory card. A dialogue box appears, reminding you that you are about to erase data:



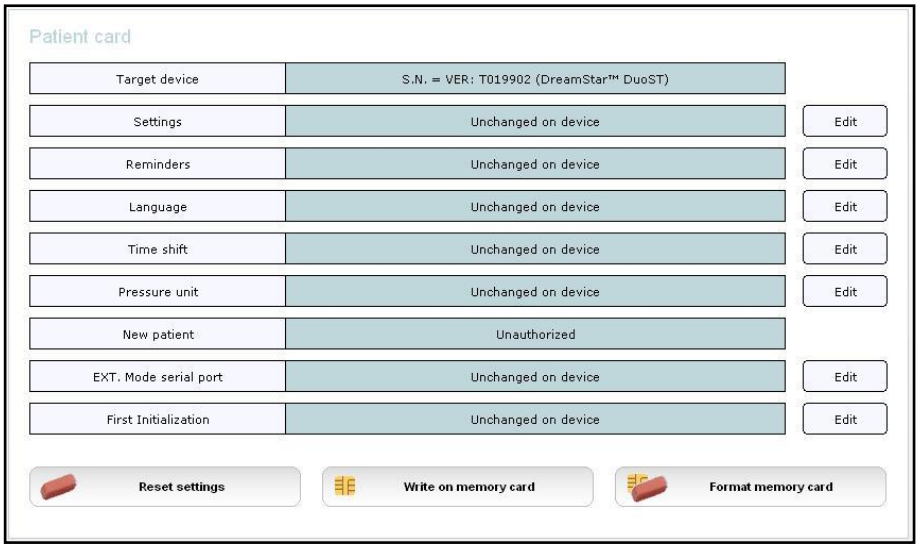
Confirm that you want to erase the data by clicking on **OK**, otherwise click on **Cancel**:

Patient card

You can prepare a memory card to be used one time only by a patient already registered in the software (for whom compliance has already been retrieved). A device/serial number combination is used to ensure the operation is secure.

A patient must first have been selected from the patient list before clicking on the **Patient card** option.

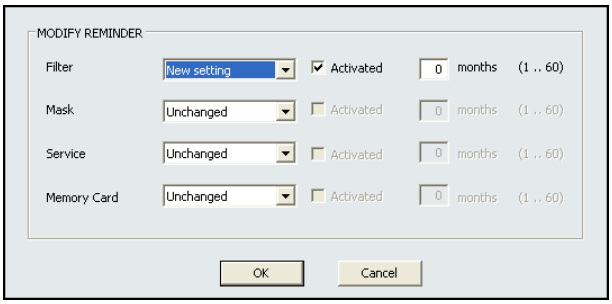
The window that appears enables you to define the following parameter settings (example of a patient card for DreamStar™ DuoST):



The **Format memory card** button has the same function as that described above.

Clicking on the Edit button to the right of each parameter displays the dialogue box relative to the setting for this parameter. This dialogue box gives you access to the device and display contrast settings, choice of language and pressure unit. For more information concerning these parameters settings, refer to the "Accessing device settings" section on page 56.

If you click on Edit next to the **Reminders** parameter, the dialogue box that appears allows you to modify the reminder activation delay.

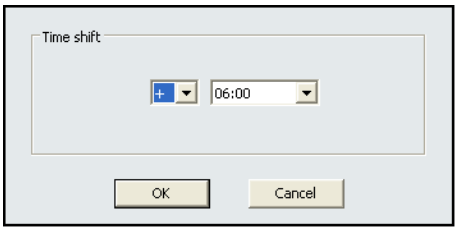


If you wish to modify a setting, select the **New setting** option next to the reminder in question in the left part of the window and then type the frequency desired in number of months in the box next to "months".

CAUTION

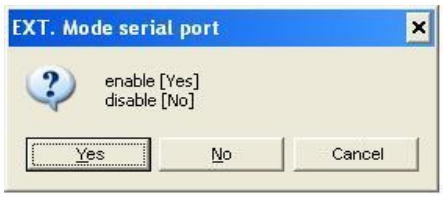
When a reminder is enabled, the reminder expiration date is recalculated whenever the memory card is inserted into the device.

If you click on Edit next to the **Time shift** parameter, the dialogue box that appears allows you to set the number of hours and minutes by changing the time with + or -.



Click on **OK** to confirm the setting or on Cancel otherwise.

The **EXT. Mode serial port** feature allows you to enable or disable connection of an external module for a wireless connection (for example Bluetooth), except with DreamStar™ Intro and DreamStar™ Intro Evolve.



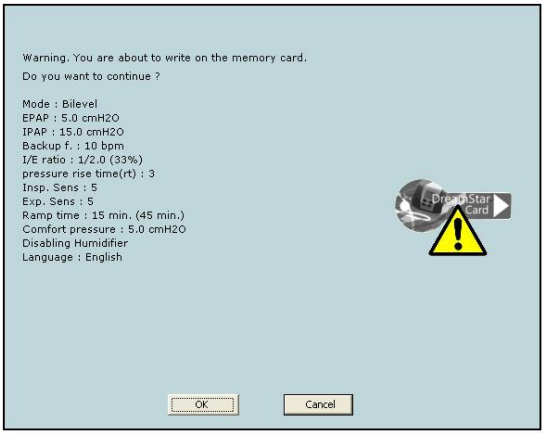
Click on **Yes** to enable connection of an external module or **No** to disable it. To cancel your action, click on **Cancel**.

The **First Initialization** feature gives the patient access to the language setting the first time the device is switched on.

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

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

Click on the **Write on memory card** button to apply settings to the memory card. A window appears indicating the settings.



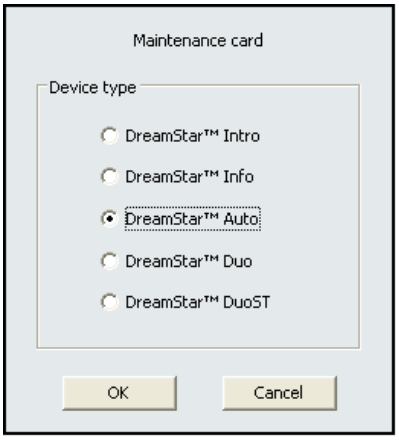
Click on **OK** to confirm or on **Cancel** to cancel if you do not wish to keep these settings. The settings written on the memory card are recorded by the software in the technical notes relative to the patient.

Note: The card needs to be inserted into the memory card reader and the memory card reader inserted into a free USB port of the computer for the patient card settings to be applied.

Maintenance card

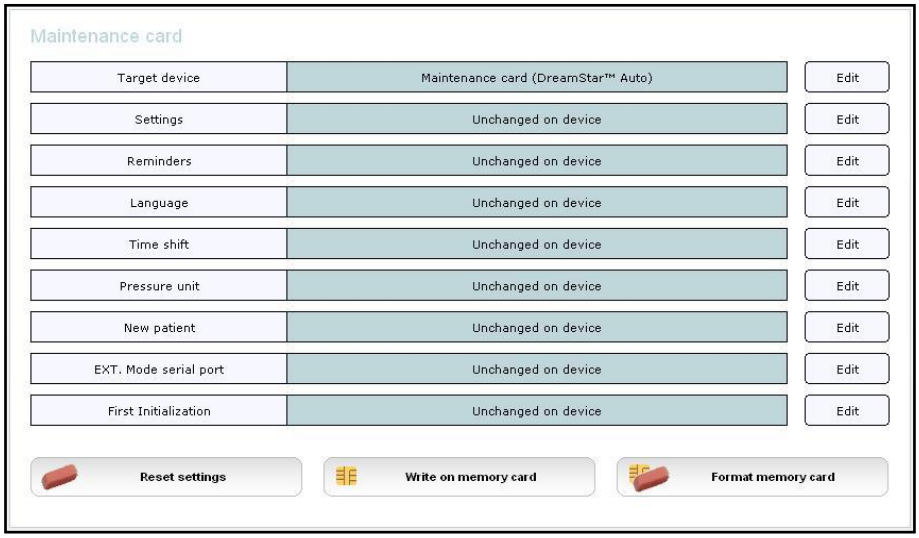
You can prepare a memory card for a device type; this allows you to configure a fleet of machines with the same settings.

The **Maintenance card** button gives you access to a dialogue box in which a device type can be selected:



Click on **OK** to confirm your choice or on Cancel otherwise.

The window that appears enables you to define the following parameter settings (example of a maintenance card for DreamStar™ Auto):



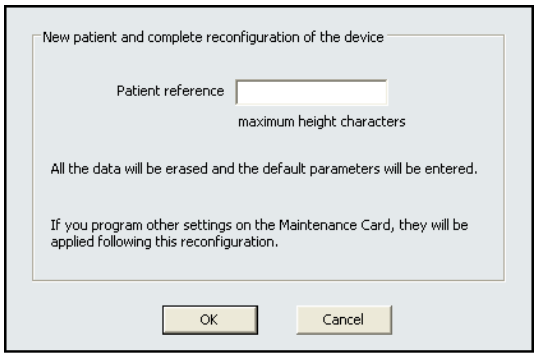
The **Format memory card** button has the same function as that described in the "Formatting the memory card" section above.

The settings available are the same as those available for the patient card (for more information, refer to the "Patient card" section).

In addition, you have the option of choosing a different target device by clicking on the Edit button to the right of the **Target device** parameter.

You can also programme a maintenance card for a new patient by clicking on the Edit button to the right of the **New patient** parameter.

A window opens asking you to enter a patient reference:



Click on **OK** to confirm your choice or on Cancel otherwise.

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

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

Click on the **Write on memory** card button to apply settings to the maintenance card. A window appears indicating the settings. Click on **OK** to confirm or on **Cancel** if you do not wish to keep these settings.

Note: The card needs to be inserted into the memory card reader and the memory card reader inserted into a free USB port of the computer for the maintenance card settings to be applied.

Click on to return to the previous screen.

Configuring the device

Connecting to the device

A computer can be connected to a DreamStar™ Info, DreamStar™ Auto, DreamStar™ Duo or DreamStar™ DuoST device (or equivalent in configuration Evolve). A computer can also be connected to a Sandman device (except Sandman Intro™).

The default port selection is the USB port at a speed of 921,600 bauds. If you want to configure a different serial port and a different communication speed, follow the instructions in section "Configuring the serial port" on page 8 before connecting.

Then connect the serial link cable as follows:

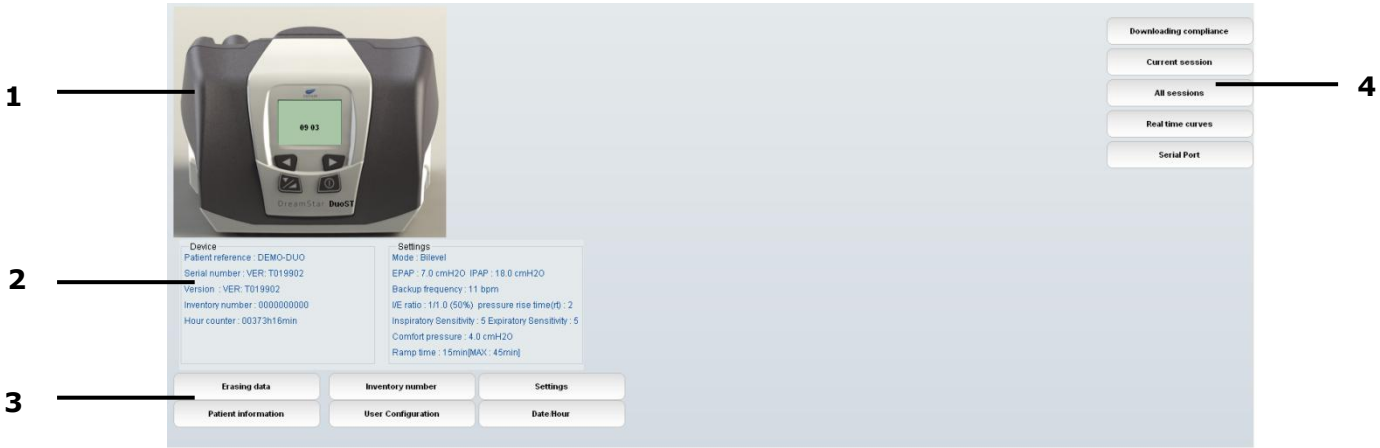
1. Place the device on a flat and stable surface.
2. Connect the RS-232 cable or USB cable to the serial/USB link connector on the device.
3. Connect the other end of the RS-232 cable or USB cable of appropriate length (6ft or 50ft) to the corresponding port on the computer.

CAUTION

- Only use the serial cables supplied with the software. Using other serial cables could damage the device.
- The welcome screen is automatically displayed if communication is lost.

Description of the connection screen

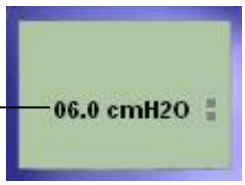
When you click on the button a window appears showing data concerning operation of the device used, settings configuration, retrieving recorded compliance data and viewing the current session or all the sessions.



1. Device status

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

Estimated pressure in the mask



Auto-CPAP operating mode (DreamStar™ Auto/AutoEvolve) or Bilevel operating mode (DreamStar™ Duo/Duo Evolve or DreamStar™

Indicates that compliance is being recorded.

The ON/OFF button is operational and allows the device to be switched on or off.

2. Displayed information

The information displayed below the machine identifies the machine and gives its settings:

a) Device:

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

This information is shown regardless of which device is connected.

b) Settings:

The information shown in this section varies with the device used and the device settings.

Information common to all devices operating in CPAP mode:

- Mode: CPAP operating mode
- Prescribed pressure with the set pressure shown in brackets
- Ramp time with the maximum ramp time shown in brackets
- Comfort pressure

Information specific to devices in Auto-CPAP mode:

- Mode: Auto-CPAP operating mode with detected event tracking
- Min. Pressure in cmH_2O
- Max. Pressure in cmH_2O
- Max. Pressure for command on Apnoea in cmH_2O
- Latency time with the maximum latency time shown in brackets.
- Comfort pressure.

Information specific to devices in Bilevel mode:

- Mode: Bilevel operating mode
- EPAP: expiratory positive airway pressure in cmH_2O
- IPAP: inspiratory positive airway pressure in cmH_2O
- Backup frequency available on DuoST or DuoST Evolve models
- I/E Ratio available on DuoST or DuoST Evolve models
- Pressure rise time (rt)
- Inspiratory sensitivity and expiratory sensitivity
- Comfort pressure is also indicated in Bilevel mode
- Ramp time with the maximum ramp time shown in brackets

3. Device setting buttons

In the connection window, the six buttons beneath the machine give access to the device settings:

4. Other functionalities

The four buttons on the right of the screen allow you to check serial port configuration, backup compliance data saved in the device and display the current session or all the sessions.

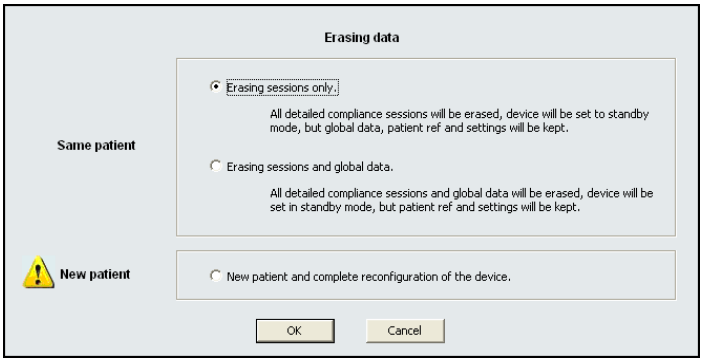
Button available only when a DreamStar™ Duo/Duo Evolve or DreamStar™ DuoST/DuoST *Evolve

Accessing device settings

1. Erasing compliance data

Clicking on the

button will cause the following dialogue box to appear:

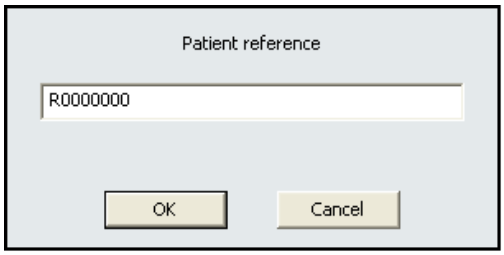


➔

- The **Erasing sessions only** option is the default setting. If you click on **OK**, a message appears alerting you that you are about to erase all sessions on the device. Click on **OK** to confirm or on **Cancel** to cancel. Clicking on **OK** will cause the session data to be erased, but the global data, the patient reference and settings will be preserved.

- You can also select the **Erasing sessions and global data** option. A message will appear alerting you that you are about to erase global data from the device. Click on **OK** to confirm or on **Cancel** to cancel. Clicking on **OK** will cause both the session data and the global data to be erased, but the patient reference and settings will be preserved.

- If you select the **New patient and complete reconfiguration of the device** option, the **Patient reference** window appears:



You can also assign the patient a new **Patient Reference**, which is the 8-character alphanumeric code associating the patient with the device. By default the patient reference will be the letter R followed by the 7 last characters from the serial number (e.g. "R8814AAA").

CAUTION

Assigning a new patient reference causes the deletion of all data stored in the device memory (i.e. all gobal data stored since the last configuration). For further information, see the technical manual for the device.

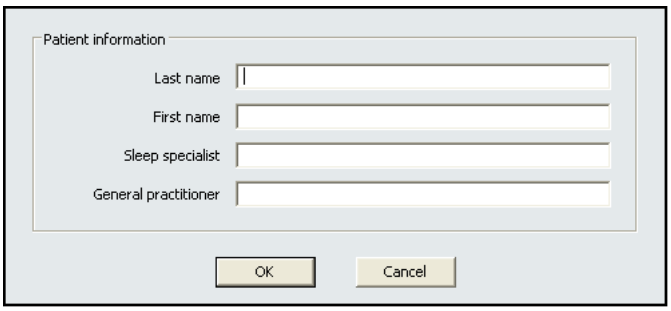
If you input a new patient reference, a dialogue box alerts you to the change and asks whether you want to continue.

Click on **OK** to confirm your choice or on **Cancel** to cancel it. The new patient reference will replace the one which was displayed.

2. Patient information

The

button allows you to view, change and enter information about the patient to whom the device has been assigned.



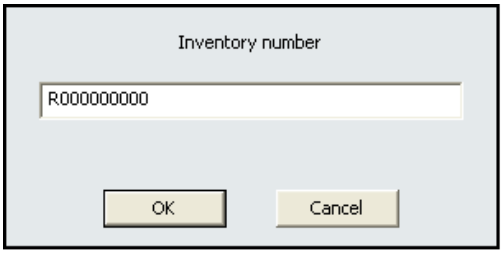
Enter the desired data and confirm your choice by **OK**. A dialogue box warns you that you have made changes and asks if you wish to continue. Click on **OK** to confirm or **Cancel** to cancel.

3. Inventory number

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

To change the inventory number, click on the

button. The following window will appear:



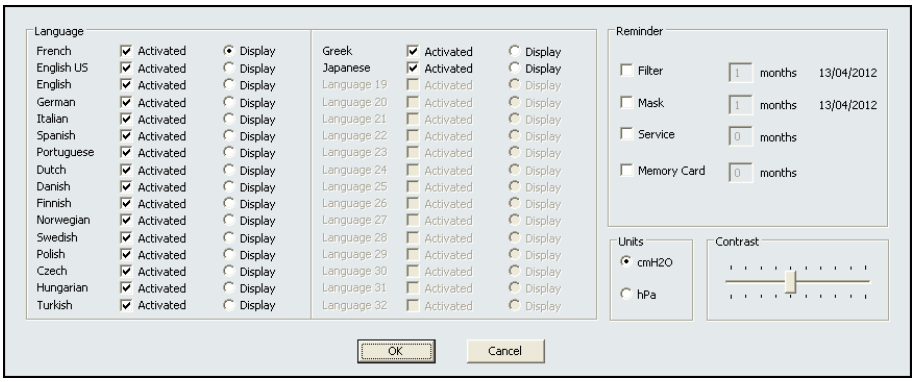
You can enter a new inventory number. Confirm your choice by clicking on **OK**.

A dialogue box warns you that you are going to make changes and asks if you wish to continue. Click on **OK** to confirm or **Cancel** to cancel.

4. User configuration

If you click on the

button, the following window appears:



You can choose the language and pressure unit, set the contrast and define reminders from this window.

a. Selecting a language

All the languages available in the device are marked "Activated" in the "Language" section. Select one of them by clicking on the "Display" box.

b. Reminders

For each type of reminder you can set the frequency with which the device will set a reminder activation date for the patient. This frequency can be set in increments of 1 month.

- **Filter**: recalls how often the filter should be changed.
- **Mask**: recalls how often the mask should be changed.
- **Service**: recalls how often the device pressure should be checked.
- **Memory Card**: recalls how often the patient should download data to the memory card and return the card to you.

This window allows you to choose a new setting for each reminder. Select the reminder by clicking on the box opposite this reminder and then enter the desired frequency in months in the box opposite "Month". The frequency can be adjusted by 1 month increments between 1 and 60 months. To suppress the reminder feature, just uncheck the box opposite the reminder in question.

c. Pressure unit

Select a pressure unit option by clicking on either cmH_2O or hPa. The pressure unit set by default is the cmH_2O which is the pressure exerted by a water column of 1 cm in height at 4°C (39.20°F). The selected unit will appear in the pressure settings display.

Note: Changing the pressure unit of measure does not affect the pressure settings in the device. It only changes the way they display (the values are calculated automatically according to the selected unit of measure).

d. LCD contrast

The contrast is set to 5 by default, but it can be set between 0 and 10 by increments of 1. The value can be increased by moving the cursor to the right and reduced by moving it to the left.

Click on **OK** to confirm all settings in the window or on **Cancel** to cancel them. A dialogue box warns you that you have made changes and asks if you wish to continue.

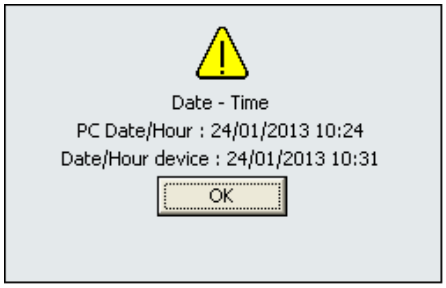
Click on **OK** to confirm or **Cancel** to cancel.

5. Date and time

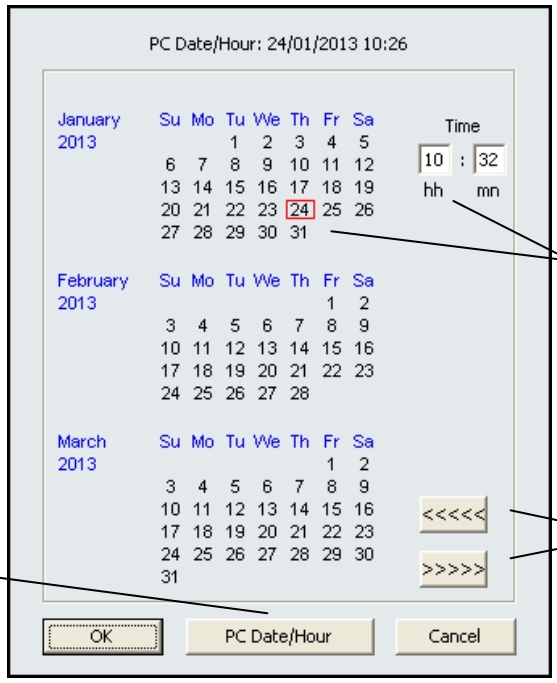
By clicking on the

button, you can access the device clock through the software.

If the device is on, the following dialogue box is displayed showing the date and time in the device, but it cannot be modified.



However, if the device is in standby, the following dialogue box is displayed allowing the date and time to be modified.



To modify the date, click on the desired day. If necessary, scroll through the months using the buttons located at the bottom right-hand corner of the dialogue box.

To change the hour and/or the minutes, place the cursor on the hh and/or mn boxes and change the values using the keyboard.

Use the **PC Date/Hour** button to synchronise the device time with that of the PC.

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 restore the original date and time.

6. Settings

Before using the DreamStar™ Analyze software to make any changes, make sure that the device and your computer are connected correctly.

CAUTION

Check the date and time in the computer before programming the device and ensure that the time in the machine is correct.

Click on

to access the device settings.

The dialogue box displays all the settings parameters and programming of 4 automatic settings changes.

The windows will vary depending on which device is connected and which operating mode is selected.

When the machine is used for the first time, or if it is reconfigured, the default settings are programmed. Otherwise the settings displayed correspond to the last settings made.

The parameter values are displayed to the left of the settings cursors. You can make the settings either by clicking on the right and left arrows or by moving the cursor while keeping the left mouse button depressed. The settings ranges are the same as those which can be adjusted on the devices.

The

button displays the original device parameters.

The settings window also allows you to programme 4 settings by clicking on the

function as explained in the section on "Programming automatic settings changes" on page 64.

a. CPAP mode

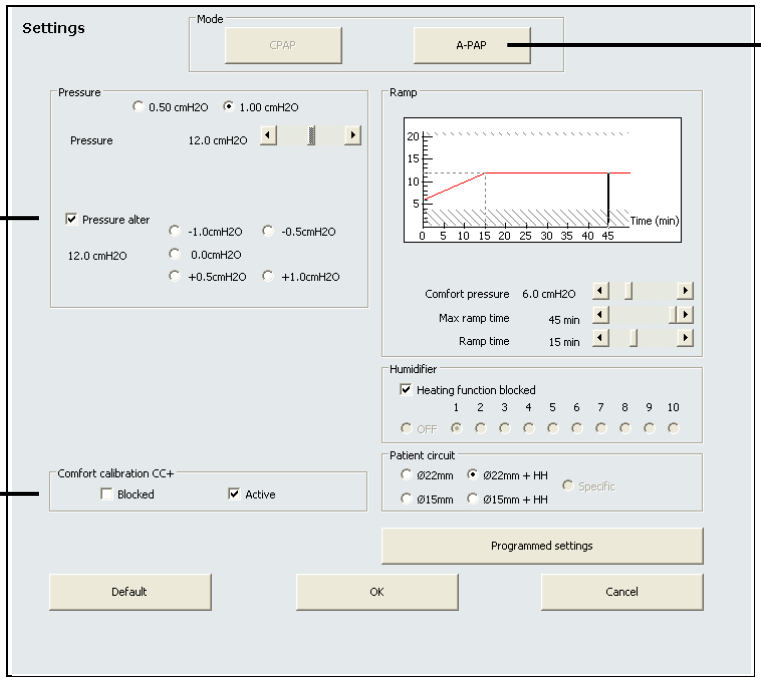
The DreamStar™ Info only operates in CPAP mode. However, DreamStar™ Auto and DreamStar™ Auto Evolve devices can operate in CPAP mode or Auto-CPAP mode, and DreamStar™ Duo, DreamStar™ Duo Evolve, DreamStar™ DuoST and DreamStar™ DuoST Evolve devices can operate in CPAP mode or Bilevel mode.

The CPAP button in the upper left of the Settings window allows you to configure the device for operation with constant pressure. If you click on this button, the following settings window is displayed:

Auto-CPAP mode with DreamStar™ Auto/ Auto Evolve, or Bilevel mode with DreamStar™ Duo or DreamStar™ DuoST (and equivalent devices in Evolve configuration)

Pressure Alter function only available in CPAP

Comfort Calibration CC+ function available on DreamStar™ Info/Info Evolve or DreamStar™ Auto/ Auto Evolve



The settings window is divided into several sections:

The **Pressure** section is used to set the pressure applied at the end of ramp time. The following parameters can be set:

- You can adjust the pressure setting **increment** to 0.5 cmH_2O or 1.0 cmH_2O. The settings are always made with the last settings increment selected.
- As pressure is constant, you can only set the value of the set **Pressure** between 4 cmH_2O and 20 cmH_2O.
- The Pressure Alter function allows the patient to modify the prescribed pressure by ± 1 cmH_2O within the limits of 4 to 20cmH_2O. This feature is available only in CPAP mode.

The **Ramp** section contains the pressure/time curve and is used to set the ramp parameters. The following parameters can be set:

- Comfort Pressure can be set to a value between 4 cmH_2O and the prescribed pressure.
- Max Ramp Time can be set in 5 minute increments between 0 and 45 minutes.
- Ramp Time can be set in 5 minute increments between 0 and maximum Ramp Time.

In the left side of the window, you can enable or disable the **Comfort Calibration CC+** function present in DreamStar™ Info/Info Evolve and DreamStar™ Auto/Auto Evolve only.

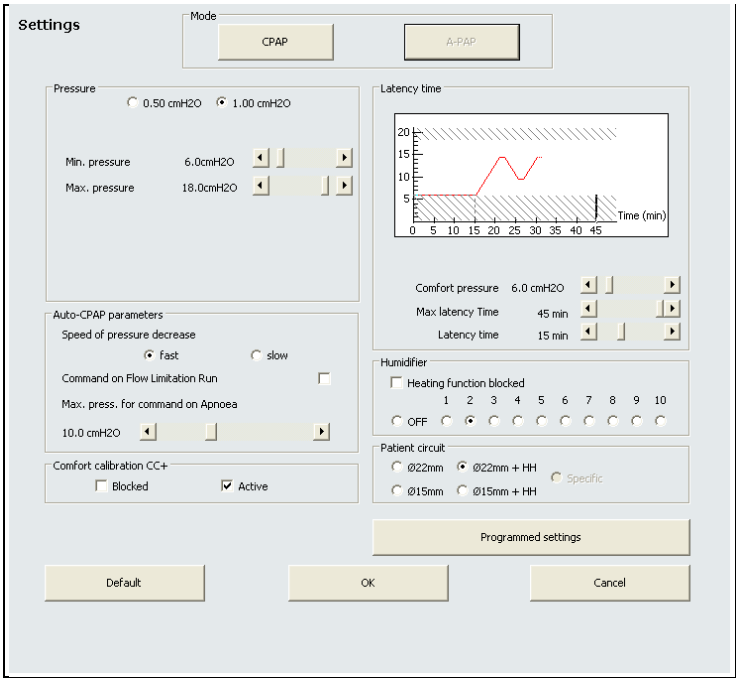
In the right side of the window, you can block the heated function by checking the box next to **Heated function blocked** or activate this function by unchecking the box. You can also set the humidifier heat level to OFF or to between 1 and 10 on the DreamStar™ device fitted with a water chamber (Evolve configuration). You can also choose the patient circuit configuration.

You can configure the DreamStar™ Auto or Auto Evolve device in Auto-CPAP mode by clicking on the **A-PAP** button. The DreamStar™ Duo/Duo Evolve or DreamStar™ DuoST/DuoST Evolve device can be configured in **Bilevel** mode by clicking on the corresponding button.

b. Auto-CPAP mode

Auto-CPAP mode is available on DreamStar™ Auto/Auto Evolve only.

The A-PAP (Auto-CPAP) button in the upper right of the settings window allows you to configure the device for operation in Auto-CPAP mode. If you click on it, a new window will appear:



The settings window is divided into several sections:

The **Pressure** section, where you can set the minimum and maximum pressure levels to be applied at the end of the latency time in Auto-CPAP mode.

The following parameters can be set:

- Min Pressure can be set between 4 cmH_2O and 20 cmH_2O (i.e. maximum Pressure).
- Max Pressure can be set between 4 cmH_2O (i.e. minimum Pressure) and 20 cmH_2O.
- You can adjust the pressure setting **increment** to 0.5 cmH_2O or 1.0 cmH_2O. The settings are always made with the last settings increment selected.

The **Latency time** section contains the pressure/time curve and is used to set the following parameters:

- Comfort Pressure can be set to a value between minimum and maximum Pressure.
- Max latency time can be set in 5 minute increments between 0 and 45 minutes.
- Latency time, which can be set in increments of 5 minutes between 0 and the maximum latency time.

The parameters which can be set in the **Auto-CPAP parameters** section are the following:

- Speed of pressure decrease. You can select a Fast or Slow speed.
- Command on Flow Limitation Run. This function can be enabled by clicking on the box opposite it.
- Max. pressure for command on apnoea**.**
  The value of this parameter can be set to a value between Minimum Pressure and Maximum Pressure using the cursor. If an Apnoea is detected, no pressure increase will occur if pressure is at the maximum pressure for command on Apnoea.

In the left side of the window, you can enable or disable the **Comfort Calibration CC+** function present in DreamStar™ Info/Info Evolve and DreamStar™ Auto/Auto Evolve only.

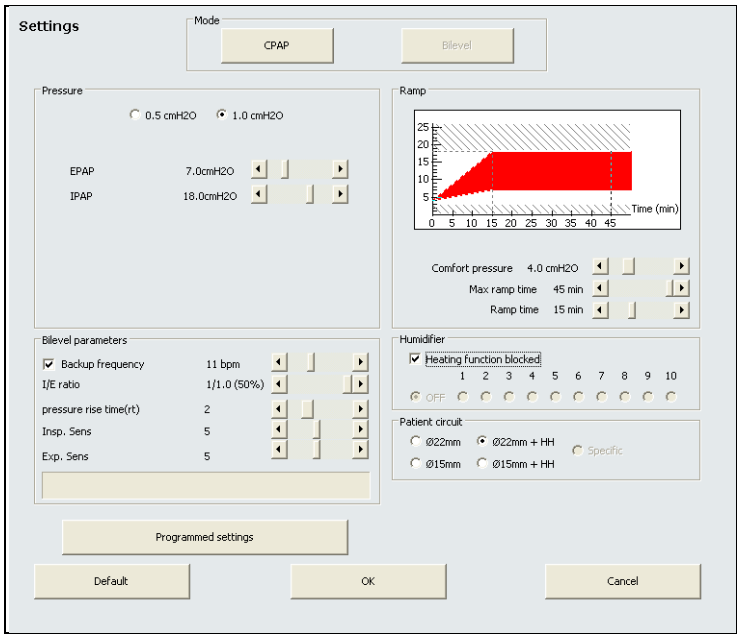
In the right of the window, you can block the heated function by checking the box next to **Heated function blocked** or activate this function by unchecking the box. You can also set the humidifier heat level to OFF or to between 1 and 10 on the DreamStar™ device fitted with a water chamber (Evolve configuration). You can also choose the patient circuit configuration.

c. Bilevel mode

Bilevel mode is available on the DreamStar™ Duo or DreamStar™ DuoST (and their equivalents in Evolve configuration) only.

The

button in the upper right of the settings window allows you to configure the device for operation in Bilevel mode. If you click on it, a new window will appear:



The settings window is divided into several sections:

The **Pressure** section, where you can set the expiratory positive airway pressure (EPAP) and the inspiratory positive airway pressure (IPAP). The following parameters can be set:

- EPAP: expiratory positive airway pressure, which can be set between 3 cmH_2O and IPAP or 20 cmH_2O.
- IPAP: inspiratory positive airway pressure, which can be set between EPAP or 3 cmH_2O and 25 cmH_2O.
- You can adjust the pressure setting increment to 0.5 cmH_2O or 1.0 cmH_2O. The settings are always made with the last settings increment selected.

The **Ramp** section contains the pressure/time curve and is used to set the following parameters:

- Comfort Pressure, which can be set at a value from 3 cmH_2O to the expiratory positive airway pressure (EPAP).
- Max ramp time can be set in 5 minute increments between 0 and 45 minutes.
- Ramp time can be set in 5 minute increments between 0 and maximum Ramp Time.

The parameters which can be accessed in the **Bilevel Parameters** section are the following:

- Backup Frequency. This parameter is available only on the DreamStar™ DuoST/DuoST Evolve, and can be set from 0 BPM to 25 BPM.
- I/E Ratio. This parameter is available only on the DreamStar™ DuoST/DuoST Evolve, and can be set from 1/4 to 1/0.5.
- Pressure rise time (rt): pressure rise time set by the physician. Time the device takes to rise from the expiratory positive airway pressure (EPAP) to the inspiratory positive airway pressure (IPAP).

The pressure rise time can be limited as a function of the values selected for the backup frequency, the inspiratory positive airway pressure (IPAP), the expiratory positive airway pressure (EPAP), and the I/E ratio.

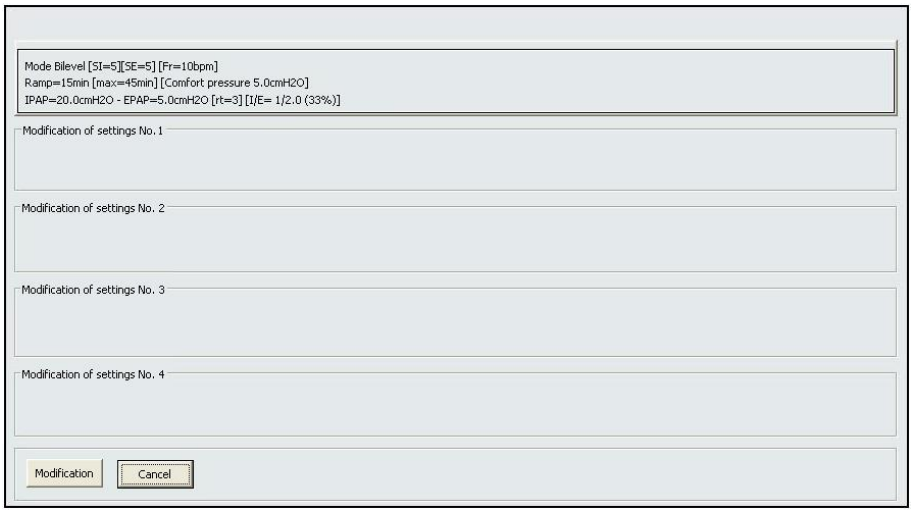
- Insp. Sensitivity can be set from 1 to 10.
- Exp. Sensitivity can be set from 1 to 10.

In the right of the window, you can block the heated function by checking the box next to **Heated function blocked** or activate this function by unchecking the box. You can also set the humidifier heat level to OFF or to between 1 and 10 on the DreamStar™ device fitted with a water chamber (Evolve configuration). You can also choose the patient circuit configuration.

d. Programming automatic settings changes

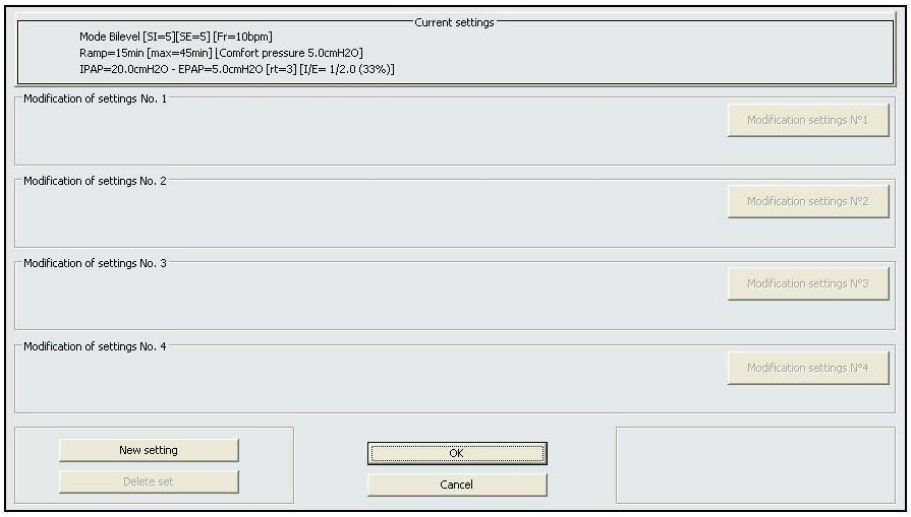
The procedure for configuring the four programmed settings into device memory is the same for all models although the settings are specific to each model. Click on the **Programmed Settings** button in the Settings window. A dialogue box appears if you have made any changes and asks if you want to save them in the machine. Click on **OK** to confirm or on Cancel to cancel.

The next window shows the current settings and allows you to programme 4 changes numbered 1 to 4.

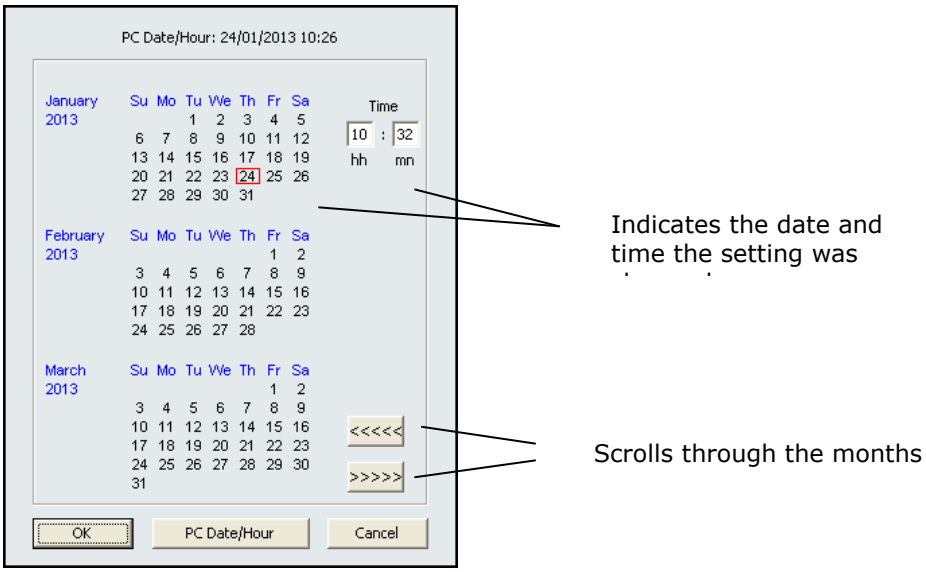


In the example, the DreamStar™ DuoST is operating in Bilevel mode, and the settings for inspiratory and expiratory sensitivity, ramp time, maximum ramp time, comfort pressure, inspiratory and expiratory positive airway pressure, and I/E ratio are shown.

If you click on the **Modification** button in the bottom left of the window, the dialogue box changes as follows:



By clicking on the **New setting** button in the bottom left of the window, a new window appears where you can select the day and time of the setting change.



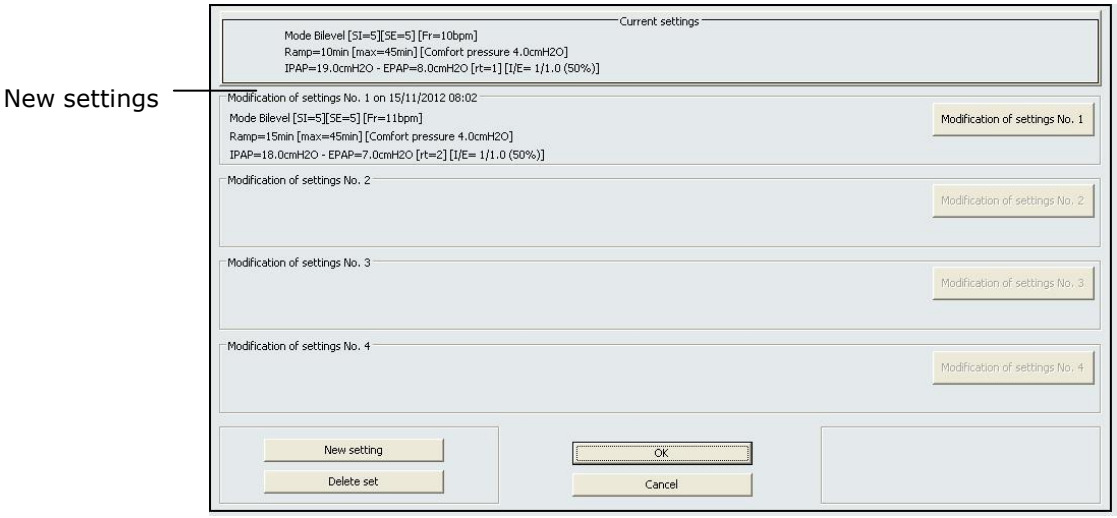
The **PC Date/Hour** allows the device time to be synchronised with that of the computer.

To programme the date you just need to click on the desired date which is then surrounded in red, and enter the hours and minutes values in the hh and mn boxes.

Click on **OK** to confirm your choice or on Cancel to cancel it.

The Settings window for the device being used appears again. Change the settings to those you want and click on **OK** to confirm the change or Cancel to cancel it.

The previous window is displayed, with the changed settings added.



The date and time of programming are displayed on the right of **Modification settings N°1** and the selected settings configuration appears below it. You can then modify the programmed settings again by clicking on the **Modification settings N°1** button.

To programme settings N°2 to N°4, follow the same procedure as for setting N°1.

You can delete the last setting programmed by clicking the **Delete set** button.

Click on **OK** to confirm programming of settings (or on Cancel to cancel). A window confirms that the changes have been programmed.

The settings changes will take place one after the other at the programmed dates and times.

Notes:

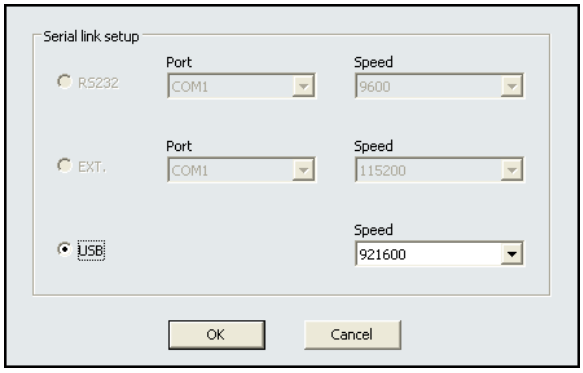
- When a settings change occurs at the programmed date and time, a new settings change can then be programmed. Therefore if you have programmed 4 settings changes, a new change can be programmed once settings change N°1 has taken place.
- The programmed settings changes will occur whether the device is on 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.

Other functionalities

1. Configuring the serial port

The

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



➔

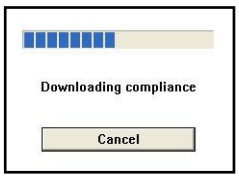
A dialogue box alerts you when you have made changes, and asks whether you want to continue.

Click on **OK** to confirm your choice or on Cancel otherwise.

2. Downloading data by serial link

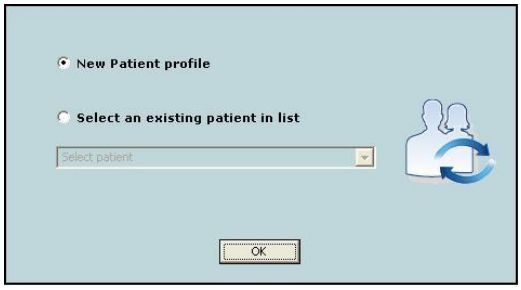
The

button allows you to download compliance data saved in the device. A window shows how the download is progressing:

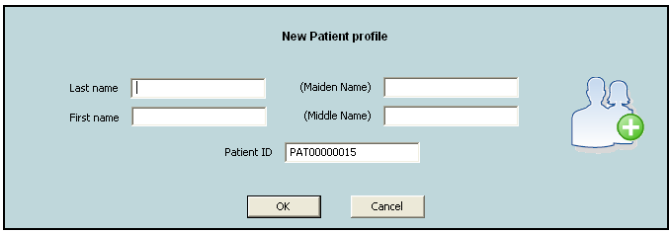


If data for a given patient reference has already been downloaded, a dialogue box will appear asking whether you want to add the data to this patient. Click on **OK** to confirm your choice.

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



- If you choose to create a new patient, a **New Patient profile** window appears where you can input the patient's data.



If the patient's data has already been entered in the device, the "Last name" and "First name" fields are already completed to help create the patient file.

The Patient ID field allows you to personalise the patient identifier which the software uses for patient management. The system offers you a default value, but you can input a custom value. Acceptable characters are: lowercase letters and symbols such as "-" and "_".

Click on **OK** to confirm or on Cancel to 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 no two patients in a given patient system have the same identifier.

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

3. Viewing the current session

The **compliance data** are only available as from when the machine begins to store them, i.e. after 5 minutes operating.

Click on the

button in the Connection screen.

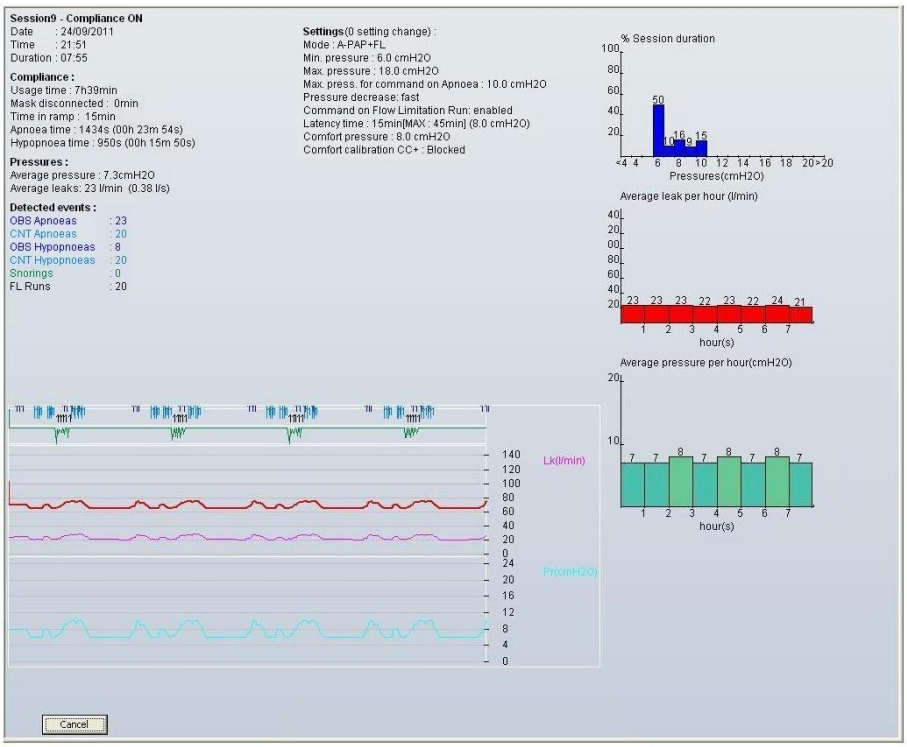
The window that appears is specific to the device being used, and contains information about a given on-off session:

The window summarises all the data relating to the current session. The session is identified by a number at the top right of the dialogue box, which corresponds to the chronological number since the last configuration.

Compliance ON is displayed next to the session number and the data displayed relates to the session currently being recorded. If no session is in progress, **Compliance OFF** is displayed at the top of the window, which does not contain any curves or values.

a) With DreamStar™ Info/Info Evolve or DreamStar™ Auto/Auto Evolve

A message informs you that the data recording has not yet started. Then, the window contains information about a given on-off session:



The data given on the left is, from top to bottom:

Session – Compliance ON:

- Date and Time: data concerning session memorisation.
- Duration: operating time during which the device has delivered pressure over the whole session.

Compliance:

- Usage time during which the patient has breathed in the mask.
- Mask disconnected: time spent with the mask disconnected.
- Time in ramp.
- Apnoea time
- Hypopnoea time

Pressures:

- Average pressure: average pressure measured in the mask during the session.
- Average leaks: average leak rate.

Detected events: number of respiratory events detected:

- OBS Apnoeas: number of apnoeas detected and classed as obstructive over the period analysed.
- CNT apnoeas : number of apnoeas detected and classed as central over the analysis period.
- OBS Hypopnoeas: number of hypopnoeas detected and classed as obstructive over the period analysed.
- CNT hypopnoeas: number of hypopnoeas detected and classed as central over the analysis period.
- Snorings: number of snores detected during the analysis period.
- FL Runs: number of flow limitation runs detected during the analysis period.

The upper central **Settings** section concerns the last settings used during the session and the number of settings changes during the session is given in brackets. The settings data is as follows:

- Mode: mode programmed during the last settings change. In Auto-CPAP mode only, the types of tracked events shown are : A (Apnoeas), SNG (Snorings), H (Hypopnoeas), FL (Flow limitation cycles)
- Pressure level in CPAP mode or Min. Pressure and Max. Pressure authorised in Auto-CPAP mode
- Max. press. for command on Apnoea: Apnoea command maximum pressure (when in Auto-CPAP mode).
- Pressure decrease: Fast or Slow (when in Auto-CPAP mode).
- Command on Flow Limitation Run: enabled or disabled (when in Auto-CPAP mode).
- Ramp time in CPAP mode (with maximum ramp time and comfort pressure indicated in brackets) or Latency time in Auto-CPAP mode (with maximum latency time and comfort pressure indicated in brackets).
- Comfort pressure whatever mode is set.
- Comfort Calibration CC+: enabled or blocked.

The four diagrams which are displayed in the window after 5 minutes device operating are:

- % Session Duration: histogram showing which percentage of the total session occurred at each pressure level.
- Average leak per hour: average leak diagram per hour.
- Average pressure per hour: average pressure diagram per hour.
- In the lower left, the Raw signal at 1 min shows the Measured Pressure (Pr), the Measured Leak (Lk), and Detected Events (in the same colours as shown in the Detected Events list).

b) With DreamStar™ Duo/Duo Evolve or DreamStar™ DuoST/DuoST Evolve

A message informs you that the data recording has not started yet and asks if you want to decrease the waiting time before the compliance beginning. Click on **Yes** to decrease it. The window contains information about a given on-off session:

The data given on the left is, from top to bottom:

Session – Compliance ON:

- Date and Time: data concerning session memorisation.

- Duration: operating time during which the device has delivered pressure over the whole session.

Compliance:

- Usage time: Usage time during which the patient has breathed in the mask.
- Time with no respiratory cycle: length of time the patient has had no respiratory cycles.
- Duration of mask disconnection: time spent with the mask disconnected.
- Average Respir. Rate for the entire session.
- I/E ratio (available on the DreamStar™ DuoST/DuoST Evolve only):
- Average leaks.
- Time in ramp.

Detected events:

- Apnoeas: number of apnoeas detected during the analysis period.
- Hypopnoeas: number of hypopnoeas detected during the analysis period.

The upper central **Settings** section concerns the last settings used during the session and the number of settings changes during the session is given in brackets. The settings data is as follows:

- Mode: CPAP mode or the last Bilevel mode that was programmed.
- Prescribed pressure when operating in CPAP mode or EPAP (Expiratory Positive Airway Pressure) and IPAP (Inspiratory Positive Airway Pressure) when operating in Bilevel mode.
- Backup frequency when operating in Bilevel mode with DreamStar™ DuoST/DuoST Evolve.
- I/E ratio when operating in Bilevel mode when operating in Bilevel mode with DreamStar™ DuoST/DuoST Evolve.
- Pressure rise time rt when operating in Bilevel mode.
- Inspiratory sensitivity
- Expiratory Sensitivity
- Comfort pressure whatever mode is set.
- Ramp time (with the maximum ramp time shown in brackets).

The five diagrams which are displayed in the window after 5 minutes device operating are:

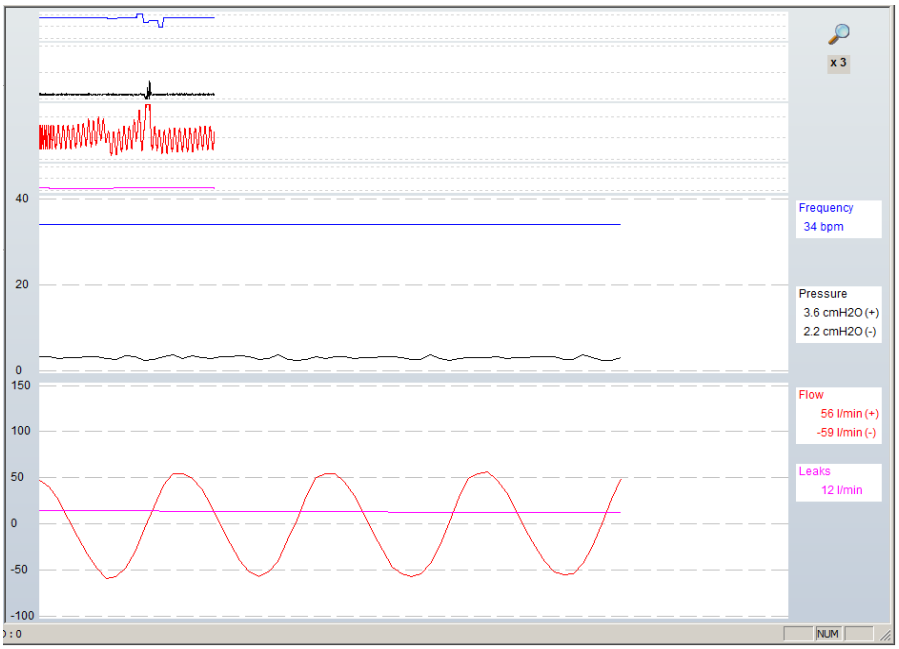
- In the lower left, the **Raw signal at 1 min** shows the Measured Frequency (Frq), the percentage of Spontaneous Cycles (C. Sp.), the Measured Leak (Lk) and the estimated volume.
- In the middle, **Percent of Spontaneous Cycles per Hour**.
- In the right of the window, histograms showing the percentage of session duration spent at each frequency level, as well as Average leak and Average respir. rate for each hour of the session.

Click on the

button to exit the current session.

4. Viewing the real time curves

This feature allows you with Dreamstar ™ Duo / Duo Evolve and Dreamstar DuoST / DuoST Evolve to display in real time a summary view and then a larger view of curves for frequency, pressure, flow and leaks.



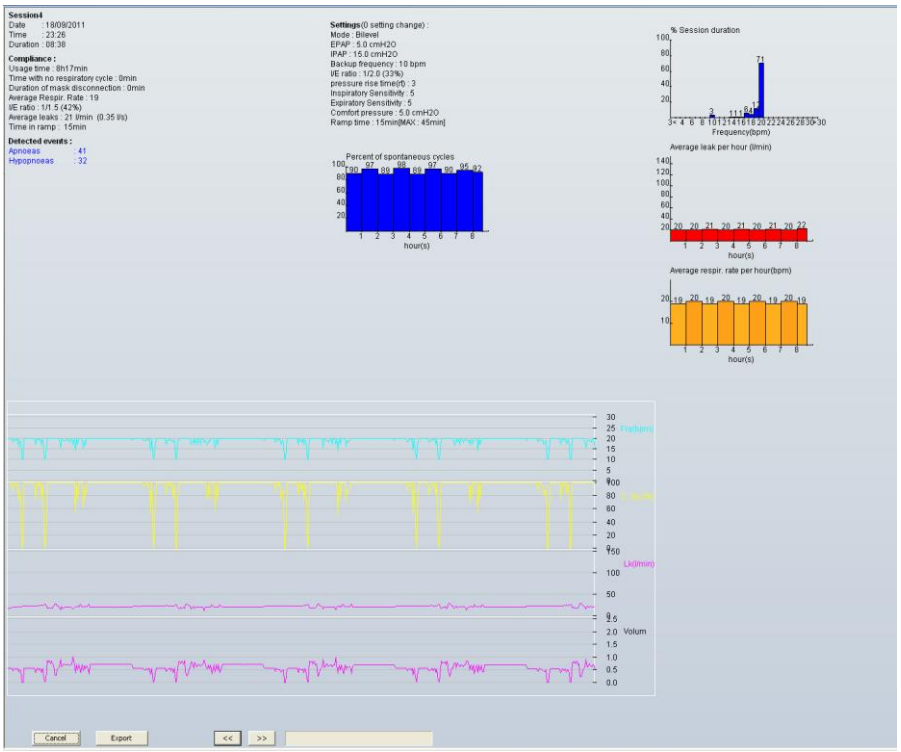
The button allows you to increase or decrease the speed of the condensed curves.

5. Data for all the sessions

Return to the main connection screen with the device by clicking on .

You can then access all the recorded sessions by clicking on the

button. A window appears with the all the data for the last on/off session (for a DreamStar™ DuoST device in the example given).



This window allows you to display data relating to each session by using the << and >> keys to scroll to the left and the right.

The session will be identified by its number shown in the title of the dialogue box and will show the compliance data and curves described in the "Information concerning the current session" section on the previous pages. The Export button allows you to export sessions in text format. For further information, refer to the "Using the **Sessions only export to a text file feature**" section on page 45.

Click on the Cancel button to exit the All Sessions view.

Standards Compliance

DreamStar™ Analyze software complies with the following standards:

- IEC 60601-1-4 :1999: Medical electrical equipment - Part 1-4 : General requirements for safety - Collateral standard : Programmable electrical medical systems.
- IEC 60601-1-6 :2004 Medical electrical equipement - Part 1: General requirements for basic safety and essential performance - Collateral Standard: Usability.
- Directive 93/42/EEC of the Council concerning medical devices.

Risks pertaining to this medical equipment were assessed in accordance with the ISO 14971:2007 standard, specifically with reference to global residual risk. (ISO 14971 :2007 : Medical devices - Application of risk management to medical devices).

CE 0459

DreamStar™ Analyze complies with the requirements of European Directive 93/42/EC on medical devices.

Glossary

Backup Frequency
If the DreamStar™ DuoST or DreamStar™ DuoST Evolve does not detect a respiratory cycle from the patient or if the patient's spontaneous respiration rate drops from the prescribed backup frequency, the device will adjust the pressure levels based on the I/E ratio and the backup frequency setting.

Comfort Calibration CC+
If it is enabled by the clinician or the home care provider, the Comfort Calibration CC + feature, present on DreamStar™ Info, DreamStar™ Info Evolve, DreamStar™ Auto and DreamStar™ Auto Evolve, is designed to increase treatment pressure when the patient inhales and reduce it when the patient exhales to make breathing more comfortable during treatment.

Comfort 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 DreamStar™ Auto or DreamStar™ Auto Evolve device is in Auto-CPAP mode, the pressure is adjusted to this comfort pressure or to the minimum pressure (if comfort 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.

EPAP = Expiratory Positive Airway Pressure
Low-level pressure prescribed for expiration.

Expiratory Sensitivity
Detection sensitivity of the start of the expiratory phase of respiration on DreamStar™ devices delivering two pressure levels.

Hour counter
Time during which the machine was in use.

I/E Ratio
Ratio of the inspiratory time and the expiratory time, used by the DreamStar™ DuoST or DuoST Evolve when operating under the backup frequency.

IFL
Inspiratory Flow Limitation

Inspiratory sensitivity
Detection sensitivity of the start of the inspiratory phase of respiration on DreamStar™ devices delivering two pressure levels.

IPAP = Inspiratory Positive Airway Pressure
High-level pressure prescribed for inspiration.

Max. Pressure
Maximum pressure that the DreamStar™ Auto or Auto Evolve can deliver in Auto-CPAP mode.

Max Pressure for command on Apnoea
Maximum pressure on the DreamStar™ Auto or Auto Evolve beyond which no rise in pressure can be applied once an apnoea has been detected in Auto-CPAP mode.

Max Ramp Time
This allows the Home Care Provider to limit the maximum ramp time value that can be set by the patient when the Ramp feature is used in CPAP or Bilevel mode.

Min. Pressure
Minimum pressure that the DreamStar™ Auto or Auto Evolve can deliver in Auto-CPAP mode.

Mode
CPAP or Auto-CPAP operating mode on DreamStar™ Auto / Auto Evolve or Bilevel mode on DreamStar™ Duo / Duo Evolve and DreamStar™ DuoST / DuoST Evolve .

Patient Reference
Reference assigned to the patient.

Prescribed Pressure
Level of pressure prescribed for the patient in CPAP mode.

Pressure Alter
Option for the patient to alter the level of pressure prescribed by ± 1 cmH_2O in CPAP mode only.

Pressure rise time (rt)
Pressure rise time set by the physician. Time the device takes to rise from the expiratory positive airway pressure (EPAP) to the inspiratory positive airway pressure (IPAP) on DreamStar™ devices delivering two pressure levels.

Ramp Time
For all devices operating in CPAP mode, when the Ramp Time feature is selected, the ramp time is the time beyond the first 5 minutes of operation that the device takes to reach the prescribed pressure from the comfort pressure.
On the DreamStar™ Duo, Duo Evolve, or DreamStar™ DuoST, DuoST Evolve when they are operating in Bilevel mode, this is the time beyond the first 5 minutes of operation that the device takes to reach the expiratory positive airway pressure (EPAP) and the inspiratory positive airway pressure (IPAP) from the comfort pressure.

Latency time
On the DreamStar™ Auto or DreamStar™ Auto Evolve in Auto-CPAP mode only, this is the time of device operation (beyond the first 5 minutes) for Auto-CPAP activation when the ramp feature is enabled.

Reminder
The DreamStar™ or Sandman device has a patient reminder function to help the patient remember key events such as changing the filter or the mask, checking the device or retrieving the compliance data on the memory card.

Session
Period during which the data is saved in the memory between device start-up and shut down. A session is recorded if the device is switched on continuously for more than 5 minutes.

Total Usage Time
Length of time during which the patient actually breathed with the mask.

CE 0459

Manufacturer:

SEFAM
144 AV CHARLES DE GAULLE
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Manufacturing plant:

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