

Patient Manual

DreamStar[™] Product Range



Upgradeable Humidifier Option

DreamStar™ Intro

DreamStar[™] Info

DreamStar™ Auto

DreamStar[™] Intro Evolve DreamStar[™] Info Evolve DreamStar[™] Auto Evolve

DreamStar[™] is a brand registered by Healthc'Air.

TABLE OF CONTENTS

BEFO	DRE YOU START	4
SA	VETY PRECAUTIONS	4
RE	COMMENDED USE	5
Co	DNTRA-INDICATIONS	5
AD	DVERSE EFFECTS	5
VE	ERIFICATION OF THE ELEMENTS OF THE SYSTEM	5
DEVI	ICE DESCRIPTION	6
VIE	EWS OF THE DEVICE	6
Syr	MBOLS ON THE DEVICE	7
INST	ALLATION	8
St	ANDARD INSTALLATION OF THE DEVICE	8
INS	STALLATION FOR USE WITH BATTERY POWER OR (OPTIONAL) CIGARETTE-LIGHTER CABLE	9
OPER	RATION	10
Fil	LLING THE WATER CHAMBER (IF INCLUDED)	10
St/	ARTING TREATMENT	
Sto	OPPING TREATMENT	
Ac	CCESSING THE DEVICE MENU	
Av	/AILABLE FEATURES	
TR	RANSPORTING THE DEVICE	
Us	SING A MEMORY CARD	14
ном	V TO SET THE DREAMSTAR™ INTRO OR DREAMSTAR™ INTRO EVOLVE DEVICE	15
1)	HEAT LEVEL (IF THE WATER CHAMBER IS INCLUDED)	
2)	Settings	
3)	Set Parameters Display	
4)	Set Patient Reminders display	
5)	Setting the clock	
6)	Setting the date	
7)	Miscellaneous Settings	
ноw	V TO SET THE DREAMSTAR™ INFO OR DREAMSTAR™ INFO EVOLVE DEVICE	
1)	HEAT LEVEL (IF THE WATER CHAMBER IS INCLUDED)	
2)	Settings	
3)	Set Parameters Display	
4)	Set Patient Reminders display	
5)	Setting the clock	20
6)	Setting the date	20
7)	Miscellaneous Settings	20
ноw	V TO SET THE DREAMSTAR™ AUTO OR DREAMSTAR™ AUTO EVOLVE DEVICE	21
1)	HEAT LEVEL (IF THE WATER CHAMBER IS INCLUDED)	21
2)	Settings	
3)	Set Parameters Display	
4)	Set Patient Reminders display	24
5)	Setting the clock	24
6)	Setting the date	24
7)	Miscellaneous Settings	25
OTHE	ER INFORMATION	26
Ge	ENERAL INFORMATION	26
Re	MINDERS ABOUT TO EXPIRE	27
ном	V TO USE WHEN ADDING OXYGEN (OPTIONAL)	28
Ins	STALLING AN OXYGEN ADAPTER (OPTIONAL)	

STARTING AND STOPPING THE TREATMENT	
CLEANING AND MAINTENANCE	29
Daily	
WEEKLY	
MONTHLY	
TROUBLESHOOTING	
Helpful hints	
DEVICE MESSAGES	
TECHNICAL CHARACTERISTICS	
Performance of the device	
INTEGRATED HUMIDIFIER PERFORMANCE	
DEVICE ELECTRICAL CHARACTERISTICS	
TRANSPORTATION AND STORAGE CONDITIONS	
OPERATING CONDITIONS FOR THE DEVICE AND HUMIDIFIER	
Physical characteristics	
STANDARDS COMPLIANCE	
END-OF-LIFE DISPOSAL OF DEVICE	

Please read this manual carefully before using your **DreamStar**[™] device so that you fully understand the limitations of this device.

Safety precautions

WARNING

This indicates in this manual a risk of injury or accident to you or to others.

- The DreamStar[™] product range devices cannot be used without a medical prescription. Under no circumstances should you attempt to adjust prescribed settings without agreement of the medical team.
- Use the device only for the recommended use as described in this manual. Advice contained in this manual should not supersede instructions of your health professional.
- This device is not intended to provide assistance for vital functions.
- The DreamStar[™] product range devices must only be used with the circuits, masks, fittings and accessories recommended by a physician or provided by your health care provider. Make sure the 'Directions for Use' instructions for each accessory are in the package and read them carefully.
- If you suspect that the device or one of its accessories is defective or damaged or not working properly, please contact your health care provider.
- Do not try to open the device (risk of electric shock). Maintenance of this equipment is to be performed by skilled personnel only. Please contact your health care provider.
- Place the device on a stable horizontal surface in a clean environment. Do not use the device if it has been set next to or on top of another device.
- Be careful not to obstruct the air outlet, or any other opening of the device or respiratory circuit, either accidentally or intentionally. Avoid placing the unit too close to a wall. Do not introduce liquids or objects into the air outlet.
- Please hold the device and the power cord away from any water source (electrocution hazard). Use the device and its accessories (power cords) only if they are dry and in working order.
- Keep the cord away from heated surfaces.
- If supplemental oxygen is to be introduced, carefully follow the instructions and safety precautions for using oxygen.
- Do not use this device near flammable vapors and in particular do not use the integrated heated humidifier near flammable anesthetics, whether they are present alone or in combination with other gases (explosion hazard).
- Once the mask is in place, make sure that the device produces an air flow. Never block the mask exhalation vent, which allows air to be expelled continually. When the device is operating, the air produced flushes the exhaled air out through the mask vent hole. When the device is not operating, insufficient fresh air is produced in the mask, presenting a risk of re-breathing exhaled air, which under certain circumstances could risk patient safety within several minutes.
- If the operation of the unit is defective and if the patient uses a nasal mask, the device resistance is low enough that the patient can exhale through the machine or even open his mouth. If a full face mask is used, the mask must have an anti-asphyxia valve.
- In case of power failure or malfunction, remove the mask.
- Do not leave long lengths of tubing on the bed. They could twist round your head or your neck while you are sleeping.

If your device is equipped with a water chamber:

- When using the water chamber, take precautions to eliminate the risk of introducing water into the device since this can cause irreversible damage. The device must be placed on a stable horizontal surface and must not be tilted.
- The humidifier has a plate that, like the base of the water chamber, may become hot during normal operation. Avoid touching them.
- The water chamber must be cleaned before the first use, after any technical intervention, and regularly thereafter, following the instructions provided under "Cleaning and Maintenance", on page 29.
- Always empty the water chamber before moving or transporting the device.
- Fill the water chamber away from the device to prevent water from flowing over it.
- Do not use the device if leakage is detected in the chamber, due for example to the deterioration of the gasket.
- The heated humidification feature must not be used where the ambient temperature is higher than 35°C (95°F) because the temperature of the air delivered to the patient could exceed 43°C (109.4°F), which could pose a risk of scalding the upper airways.
- There is a risk of air leakage if the water chamber or the cover is not reassembled correctly, which could cause the applied pressure to deviate from the prescribed pressure.

CAUTION

This indicates in this manual that there is a possibility of material damage to this device or any other device.

- If your device is equipped with a cover where the water chamber should be, the heated humidification feature must be disabled. Otherwise, the heating element of the device could continue to provide heat to the device, although it would not reach dangerous temperatures. However, if it is enabled, set the heat level to the minimum value, and alert your home care provider.
- Be sure to position the device in order to prevent anyone stumbling into or tripping over the power cord.
- If the device is placed on the ground, ensure it is in a place free from dust, bedding, clothing or other objects that could block air intake.
- Like all medical electrical devices, the DreamStar[™] product range device is vulnerable to interference from mobile and portable radiofrequency communication equipment (mobile phones, Wi-Fi...).

Recommended use

The DreamStar[™] product range devices are intended to treat patients suffering from Obstructive Sleep Apnea Syndrome (OSA) in patients over 30 kg (66 lbs.) and breathing spontaneously. They can be used at home or in a sleep center.

Contra-indications

Studies have shown that the use of positive pressure is contra-indicated in some patients with one of the following pre-existing conditions:

- Severe bullous emphysema or emphysema previously complicated by pneumothorax.
- Pneumoencephalus, trauma or recent surgery with sequela of cranio-nasopharyngeal fistula.
- Decompensated cardiac insufficiency or hypotension, particularly in case of decreased blood volume or cardiac arrhythmia.
- Dehydration.
- Massive epistaxis or history of massive epistaxis. Acute sinusitis, otitis media, or perforated tympanic membrane.
- Derivation of the upper airway.

Adverse effects

Please contact your health care professional if while using this DreamStar™ product range device, the following symptoms appear: dry airways or nose, skin sensitivity, runny nose, ear pain, discomfort sinus, daytime sleepiness, mood changes, disorientation, irritability or memory loss.

Verification of the elements of the system

The DreamStar[™] product range device is delivered with the following components:

- carrying case
- tubing
- reusable filter
- cover (optional)

- detachable power supply cord
- memory card
- patient manual
- water chamber (optional)

The DreamStar[™] product range devices can be used with the following optional accessories. Contact your home care provider for additional information on available accessories. During use, follow the instructions provided with the accessories.

- battery cable
- filter holder kit

- cigarette-lighter cable
- optional high-efficiency filter (disposable)

DEVICE DESCRIPTION

This DreamStar[™] product range device is equipped with custom accessories and includes an integrated electrical power supply.

Views of the device



Allows viewing the information.

- 1 Screen
- 2 Left control button
- 3 Right control button

4 Ramp and selection button

This allows the selection of the symbol displayed at the lower right of the screen. Provides access to ramp functions. It is also used to select the next parameter in

the displayed menu during the device-settings.

5 On/off button

Turns the device on or off. It is used also to exit the device-setting menus.

This allows the selection of the symbol displayed at the lower left of the screen.



6 Power port

This is where the power cord is connected.

power cable.

- 7 External battery port
- 8 Air intake filters
- 9 Heating element
- **10** Serial cable/USB connector
- The base of the heated humidifier is used to heat the water chamber. Available on Info and Auto devices, it is used by your physician or home care provider. Do not connect anything to it.

This allows the device to be powered by an external battery or a cigarette-lighter

- 11 Memory card connector
- Connector into which you can slide the memory card.

Prevent dust in the airflow from entering the device.



12 Outlet connector (indicated by 🗥) Air outlet to which the tubing will be connected.

13 Water chamber (if included) Wate

Water chamber in case of humidification, which is marked to show the maximum fill level for water.

- 14 Cover (if included)
- 15 Air inlet (indicated by 🗥)

Symbols on the device

Symbol	Description	Symbol	Description
0	Symbol of On/off button.		Symbol of Ramp and selection button.
	Symbol of Left control button.		Symbol of Right control button.
IP11	Device protected against solid objects up to 50 mm (e.g. accidental touch by persons hands) and against vertically falling drops of water (e.g. condensation).	X	Waste device to be eliminated separately from the household waste. For further information, refer to the paragraph "Waste device elimination", page 36.
	Class II device.	Ŕ	Type BF device.
⊖ <u>C</u> ⊕ 13V === 3A	DC power supply.		Consult use instructions before using this device.
C E 0459	Device complies with the requirements of European Directive 93/42/EC on medical devices.	₽	Recording and play back.

Standard installation of the device

The device is delivered with either a cover (configuration A) or with a water chamber (configuration B).

1. Installation of the cover or the water chamber



2. Connecting the patient circuit



- 3. Prepare the mask according to the instructions provided in the operating instructions that came with the mask. Connect the mask to the other end of the patient circuit.
- 4. Plug the end of the power cord into the power input of the device and the other end into the power source.

5. At the first power-on, the screen lights up and displays the language setting screen:



Press the right control button \checkmark or the left control button \checkmark as many times as necessary to display the desired language.

After the language is selected, press the on/off button (\underline{O}) to return to the page header, then press this button a second time to exit the menu.

6. The display shows the time and date. The device is ready to operate.

WARNING

There is a risk of air leakage if the water chamber or the cover is not installed correctly, which could cause the applied pressure to deviate from the prescribed pressure.

Installation for use with battery power or (optional) cigarettelighter cable

The DreamStar[™] product range device can be powered by a rechargeable 12 volt optional special battery by connecting the battery cable to the inlet of the external battery of the device (item 7 of Figure 2 page 6).

The device can also be powered from a cigarette-lighter socket using an optional cable specially designed for this purpose. For this configuration, replace Step 4 of the standard installation procedure with the following step:

• Connect the power cable to the input of the external battery of the device (Item 7 of Figure 2 page 6) and the other end of the cable directly to the cigarette lighter socket.

Continue with steps 4 through 6 of the standard installation procedure.

CAUTION

- Do not use a battery power cable other than the one supplied with the battery.
- Do not connect the battery power cable to a 24 volt cigarette-lighter cable.
- Do not use a 24 volt battery.
- Do not connect to the DreamStar[™] product range device a 12-volt power supply plugged in the mains.
- *Note:* When the device is battery-powered, the heated humidification feature (if included) cannot be used and the following screen page is displayed after the settings button has been pressed:



Filling the water chamber (if included)

- 1. Switch off the device and remove the patient tubing. Press with your fingers at the "Push" marking on the top of the unit to separate the water chamber from the device.
- 2. Tip the tank back and remove the tank from the device.
- 3. Fill the water chamber (through the upper orifice) to the maximum level mark.
- 4. Reattach the water chamber to the rear of the device.









CAUTION

- Be careful not to exceed the maximum fill level.
- Do not add any other product to the water in the water chamber.
- Do not use alkaline solution (physiological saline solution).
- Use only room temperature water; do not fill the water chamber with hot or chilled water.

Starting Treatment

- 1. Put your mask on as described in the user instructions.
- 2. To start treatment, press the on/off button ①. The device screen displays the delivered pressure.
- 3. If the message "MASK UNPLUGGED" displays on the screen, this means that the mask is not connected properly. Reposition your mask correctly to eliminate the leaks, and press any of the four buttons on the front of the device. The device will restore the pressure set and the message "MASK UNPLUGGED" will disappear. Otherwise, the device will stop after 30 minutes.
- 4. Lie down and place the tubing so that it can follow your movements while you sleep.
- 5. The symbols that may be displayed on the screen are summarized in the table entitled "Description of symbols displayed on the screen" on page 12.
- 6. In the event that the humidification function has been activated on your device, the heated humidifier turns on automatically.
- *Note:* Following a power supply interruption, the device is in the same mode it was in (on/off) when it was disconnected.

Stopping Treatment

- 1. Remove the mask.
- 2. Turn off the DreamStar[™] product range device by pressing the on/off button (①) for several seconds.

Accessing the device menu

The four buttons on the front of the device allow you to access the device settings menu, scroll through different pages, or possibly modify the value of certain parameters within these pages.

The parameters are accessible when the machine is in standby or operating mode.

The parameters that are accessible are grouped on several screen pages indicating:

- device settings related to prescribed treatment
- general device settings, such as date and time
- recorded compliance data
- reminders

Description of a screen page

Each screen page includes:

- a first line or page header
- up to 4 parameter lines with associated values
- a final line showing the various symbols used for such features as changing a parameter value, moving about a page, or moving from page to page (see table entitled "Description of symbols displayed on the screen").



Description of symbols displayed on the screen

Symbol	Description	Symbol	Description
(i)	Access to device information.	T / A	Access to device settings.
·>	Provides access to the next page available for display on the screen.	 ←	Provides access to the preceding page displayed on the screen.
+	Allows the value of the parameter displayed on the screen to be raised.		Allows the value of the parameter displayed on the screen to be lowered.
	The heated humidification feature is		Heated humidification feature enabled with heat.
	activated without heat or on a device connected to a battery.		The symbol blinks if the heated humidifier has a problem.
	Parameters displayed on the screen can be changed.		Parameters displayed on the screen are for information and cannot be changed.
\checkmark	Feature enabled.		Feature disabled.
\checkmark	YES.	×	NO.
G	Ramp feature in CPAP mode. The symbol blinks when the ramp feature is selected but still disabled.	ව	In Auto-CPAP mode, wait time. The symbol blinks before the Auto-CPAP is activated.
С	CPAP operating mode, on the DreamStar™ Auto or DreamStar™ Auto Evolve.	А	Auto-CPAP operating mode, on the DreamStar™ Auto or DreamStar™ Auto Evolve.
۲	Comfort Calibration feature enabled on DreamStar™ Info or DreamStar™ Auto (or equivalent in Evolve configuration).	→	Indicates that compliance is being recorded.
\bowtie	The symbol blinks when one or several patient reminders are about to expire.	C	Memory card present. The symbol blinks if the memory card is not operational.
DD/MM/YYYY	The dates displayed by the device are in the format day/month/year.	÷-	Indicates that a battery is connected.
SERVICE	The device has detected an operating error. The symbol displays alternately with the error code	♦	Indicates that a remote control is connected.

For settings specific to the **DreamStar™ Intro** or **DreamStar™ Intro Evolve** device, see "How to set the DreamStar™ Intro or DreamStar™ Intro Evolve device", on page 15.

For settings specific to the **DreamStar™ Info** or **DreamStar™ Info Evolve** device, see "How to set the DreamStar™ Info or DreamStar™ Info Evolve device", on page 18.

For settings specific to the **DreamStar™ Auto** or **DreamStar™ Auto Evolve** device, see "How to set the DreamStar™ Auto or DreamStar™ Auto Evolve device ", on page 21.

The General Information menu for the devices is described on page 26.

Available features

The DreamStar[™] Intro and DreamStar[™] Info devices (and equivalent in Evolve configuration) operate in continuous mode (CPAP), i.e. the device delivers a constant pressure level throughout the night. The DreamStar[™] Auto or DreamStar[™] Auto Evolve device operates in either constant mode (CPAP) or in automatic mode (Auto-CPAP), the device monitors your breathing while you sleep and adjusts the pressure to suit your needs.

The device includes an integrated power supply and can be equipped with a humidification function (Evolve configuration), which can be enabled or disabled by the home care provider.

The patient reminder feature can help you remember events, such as filter and mask changes, device inspections, and memory card compliance data downloads on the memory card. This feature, which is identical on all of devices in the product range, is described under "Reminders about to expire", on page 27.

Ramp feature

If enabled by your home care provider, the Ramp feature allows for a gradual rise in pressure to help you go to sleep: the treatment begins at a reduced pressure called comfort pressure, then the pressure increases to treatment pressure. In Auto-CPAP mode, the Ramp feature allows you to delay the commands to raise or lower the pressure.

Pressure Alter

If it is enabled by the physician or home care provider, this feature provides the option to change the prescribed pressure by \pm 1 cmH₂O.

Note: This feature is only available in CPAP mode.

Comfort Calibration +

If enabled by the physician or home care provider, the Comfort Calibration + feature (C.C.+) available on DreamStar[™] Info and DreamStar[™] Auto (and equivalent in Evolve configuration), aims to increase the treatment pressure during inspiration and to decrease it during expiration to make the breathing more comfortable during the treatment.

Transporting the device

Unplug the device and disconnect the accessories from the device. Store them in the carrying case.

DreamStar[™] or DreamStar[™] Evolve device with cover

You must separate the cover from the device. Detach the cover from the machine by pressing on "Push" at the top of the device. Then, lift the cover back and remove it from the device. Place the cover and the device in the separate compartments of the carrying case.

DreamStar[™] Evolve device with water chamber

You must remove the water chamber from the device and drain it. Detach the water chamber from the machine by pressing on "Push" at the top of the device. Then, lift the water chamber back and remove it from the device. Disassemble it by following the instructions under "Cleaning and Maintenance", on page 29 and empty the water chamber completely. Place the chamber and the device in the separate compartments of the carrying case.

CAUTION

To eliminate any risk of introducing water into the device and thereby causing irreversible damage, the water chamber must be completely emptied before moving or transporting the device.

Using a memory card

An external storage medium can be used either to store the most recent compliance data stored in the device, or to update your device's setting parameters. Refer to the instructions given by your home care provider to use this card.

If the device is running, turn it off before you insert the memory card into the memory card connector: the symbol *e* appears to the right of the display header. If this symbol flashes, the card is inserted incorrectly, or inserted upside down, or it is not operational. Reinsert it correctly, and if the symbol is still flashing, contact your home care provider.

Updating Settings

If the care provider has configured the memory card to update the settings of the machine, the device will start automatically when inserting the card into it. Once the update is complete, a message appears asking to remove the card. Remove it. This operation can be performed only once.

Data Backup

Data backup starts automatically when inserting the card into the machine. An indicator allows the progress of the data downloaded to be monitored. Once the data has been recorded, a message displays on the device "DOWNLOAD FINISHED. REMOVE MEMORY CARD." The memory card can then be given to your home care provider.

Notes:

- The backup data and update settings functions are only accessible if the device is in standby.
- If the card is left inside the device, the machine cannot be turned on and no feature can be accessed.

How to set the DreamStar[™] Intro or DreamStar[™] Intro Evolve device

To access the device settings, press the right control button \checkmark to select the symbol \checkmark displayed on the screen. In the Settings page display:

- The symbol 🗖 at the bottom of the screen indicates that it is impossible to change the parameters displayed.
- The symbol **b** at the bottom of the screen indicates that the parameters displayed can be changed:
 - \circ Select the parameter to change by pressing the ramp button as many times as it is necessary \swarrow .
 - Increase or decrease the parameter value by pressing the control buttons.

To return to the page header, press the ramp button \swarrow at the bottom of the page or the on/off button 0.

To move from one settings page to another, select the symbol siplayed on the screen by

pressing the right control button . To return to the previous page, select the symbol symptotic by pressing the left control button .

To exit the settings menu, press the on/off button \bigcirc or wait 30 seconds.

Note: In the following pages, the values displayed are given by way of example.

1) Heat level (if the water chamber is included)

This page displays only when your home care provider has enabled the device's heated humidification feature.



 $^{\circ}$ 6 Press $\stackrel{\checkmark}{2}$ at the bottom of the page or $\stackrel{\frown}{2}$ to return to the page header.

 \odot Press \smile to move to the next page.

Note: When the device is battery-powered, the heated humidification feature cannot be used (see paragraph "Installation for use with battery power or (optional) cigarette-lighter cable page 9).

2) Settings

This page displays only if the ramp feature and (or) the Pressure Alter feature were activated by the home care provider.



 \bigcirc Press \checkmark at the bottom of the page or \bigcirc to return to the page header.

6 Press by to move to the next page.

Comfort pressure: Level of pressure produced by the device when the ramp feature starts up. **Ramp time:** Time the device takes to reach the prescribed pressure when starting from the comfort pressure.

Set pressure: Level of pressure prescribed, which may be altered by \pm 1 cmH₂O.

Note: Adjusting the ramp time is also accessible by pressing the ramp button when the device is in standby only.

3) Set Parameters Display



^② Press by to move to the next page.

4) Set Patient Reminders display

This page displays only if the home care provider has activated a reminder to remind you for example to replace the filter or the mask.

0	
The page dis	plays:
REMINDER	
FILTER	15.05.2012
M.ASK	15.09.2012
MAINTENANCE	10.03.2013
MEMORY CARD	10.06.2012
+	+

The reminder activation date is shown opposite the corresponding reminder.

^② Press **D** to move to the next page.

5) Setting the clock

The time can be set when the device is in standby only.



S Press at the bottom of the page or O to return to the page header.
Press to move to the next page.

6) Setting the date

The date can be set when the device is in standby only.



[©] Press by to move to the next page.

7) Miscellaneous Settings



How to set the DreamStar[™] Info or DreamStar[™] Info Evolve device

To access the device settings, press the right control button by to select the symbol select the symbo

- The symbol 🗖 at the bottom of the screen indicates that it is impossible to change the parameters displayed.
- The symbol **b** at the bottom of the screen indicates that the parameters displayed can be changed:
 - \circ Select the parameter to change by pressing the ramp button as many times as it is necessary \bigotimes .
 - Increase or decrease the parameter value by pressing the control buttons.

To return to the page header, press the ramp button \swarrow at the bottom of the page or the on/off button 0.

To move from one settings page to another, select the symbol **mass** displayed on the screen by

pressing the right control button . To return to the previous page, select the symbol symptotic by pressing the left control button .

To exit the settings menu, press the on/off button \bigcirc or wait 30 seconds.

Note: In the following pages, the values displayed are given by way of example.

1) Heat level (if the water chamber is included)

This page displays only your home care provider has enabled the device's heated humidification feature.



© Press 🖾 at the bottom of the page or 🙆 to return to the page header.

⑦ Press by to move to the next page.

Note: When the device is battery-powered, the heated humidification feature cannot be used (see paragraph "Installation for use with battery power or (optional) cigarette-lighter cable page 9).

2) Settings

This page displays only if the ramp feature and (or) the Pressure Alter feature and (or) the Comfort Calibration + feature were activated by the home care provider.

0	2	3		(4)
The page displays: SETTINGS C.C.+ OFF COMFORT PRESSURE 6.0 cmH20 RAMPTIME 15 min PRESSURE 8.0 cmH20 I**** 6	Press as many times as necessary to access the desired parameter setting.	The page cha SETTINGS C.C.+ COMFORT PRESSURE RAMPTIME PRESSURE	0 0 6.0 cmH20 15 min 8.0 cmH20 ₽	If the Comfort Calibration (C.C.+) is disabled (OFF), you can enable it (ON) by pressing the left or right parameter settings button. Then press to access the next menu parameter. Increase •• or decrease •• the
				parameter value with the right or left parameter settings button.
	·	6		· · · ·

⑤ Press 🖾 at the bottom of the page or 🔘 to return to the page header.

6 Press by to move to the next page.

C.C. +: Comfort Calibration +.

Comfort pressure: Level of pressure produced by the device when the ramp feature starts up. **Ramp time:** Time the device takes to reach the prescribed pressure when starting from the comfort pressure.

Pressure: set pressure, level of pressure prescribed, which may be altered by $\pm 1 \text{ cmH}_2O$.

Note: Adjusting the ramp time is also accessible by pressing the ramp button when the device is in standby only.

3) Set Parameters Display

\bigcirc				
The page displays:				
SETTINGS	CPAP			
PRESCRIBED P	8.0 cmH2O			
PRESSURE ALTER	V			
C.C+	✓			
MAXRAMPTIME	45 min			
l ≪ ==== 8				

Prescribed P.: Level of pressure prescribed by your physician.

Pressure Alter: The **v** symbol shows that the feature has been enabled by the home care provider.

C.C. +: Comfort Calibration +. The \checkmark symbol shows that the feature has been enabled by the home care provider.

Max ramp time: Maximum ramp time set by the home care provider.

② Press to move to the next page.

4) Set Patient Reminders display

This page displays only if the home care provider has activated a reminder to remind you for example to replace the filter or the mask.

0		
The page displays:		
REMINDER		
FILTER	15.05.2012	The reminder activation date is shown expected the corresponding
MASK	15.09.2012	reminder
SERVICE	10.03.2013	reminuer.
MEMORY CARD	10.06.2012	
⊷ 8	+	
<u>ر</u>		

^② Press by to move to the next page.

5) Setting the clock

The time can be set when the device is in standby only.



[©] Press by to move to the next page.

6) Setting the date

The date can be set when the device is in standby only.



 \bigcirc Press at the bottom of the page or \bigcirc to return to the page header.

© Press 🕑 to move to the next page.

7) Miscellaneous Settings



⑤ Press 🖾 at the bottom of the page or 🙆 to return to the page header.

 $^{\odot}$ Press 0 to exit the menu.

How to set the DreamStar[™] Auto or DreamStar[™] Auto Evolve device

To access the device settings, press the right control button \smile to select the symbol \checkmark displayed on the screen. In the Settings page display:

- The symbol 🗖 at the bottom of the screen indicates that it is impossible to change the parameters displayed.
- The symbol **b** at the bottom of the screen indicates that the parameters displayed can be changed:
 - \circ Select the parameter to change by pressing the ramp button as many times as it is necessary \swarrow .
 - Increase or decrease the parameter value by pressing the control buttons.

To return to the page header, press the ramp button \swarrow at the bottom of the page or the on/off button 0.

To move from one settings page to another, select the symbol displayed on the screen by pressing the right control button. To return to the previous page, select the symbol the symbol by

pressing the left control button

To exit the settings menu, press the on/off button \bigcirc or wait 30 seconds.

Note: In the following pages, the values displayed are given by way of example.

1) Heat level (if the water chamber is included)

This page displays only your home care provider has enabled the device's heated humidification feature.



 $^{\circ}$ Press $\overset{\frown}{2}$ at the bottom of the page or $\overset{\frown}{2}$ to return to the page header.

 \odot Press \smile to move to the next page.

Note: When the device is battery-powered, the heated humidification feature cannot be used (see paragraph "Installation for use with battery power or (optional) cigarette-lighter cable page 9).

2) Settings

In CPAP mode

This page displays only if the ramp feature and (or) the Pressure Alter feature and (or) the Comfort Calibration + feature were activated by the home care provider.

U	Ø	3	(4)
The page displays:	Press	The page changes:	If the Comfort Calibration (C.C.+) is
SETTINGS CPAP		SETTINGS CPAP	disabled (OFF), you can enable it
C.C+ OFF		C.C+ OFF	(ON).by pressing the left or right
COMFORT PRESSURE 6.0 cmH2O	as many times	COMFORT PRESSURE 6.0 cmH2O	parameter settings button.
ROMPTIME 15 min	as necessary to	RAMPTIME 15 min	
PRESSURE 8.0 cmH2O	access the	PRESSURE 8.0 cmH2O	Press 🖾 to access the next
	desired	i≁ C>	menu parameter.
	parameter		Increase the or decrease the
	setting.		nerezeter velve with the right or
			parameter value with the right or
			left parameter settings button.

 \bigcirc Press at the bottom of the page or \bigcirc to return to the page header.

[®] Press by to move to the next page.

C.C. +: Comfort Calibration +.

Comfort pressure: Level of pressure produced by the device when the ramp feature starts up. **Ramp time:** Time the device takes to reach the prescribed pressure when starting from the comfort pressure.

Pressure: set pressure, level of pressure prescribed, which may be altered by $\pm 1 \text{ cmH}_2\text{O}$.

Note: Adjusting the ramp time is also accessible by pressing the ramp button when the device is in standby only.

In Auto-CPAP mode

This page displays only if the ramp feature and (or) the calibration feature were activated by the home care provider.

\bigcirc	2	3	4
The page displays:	Press as many times as necessary to access the desired parameter setting.	The page changes:	If the Comfort Calibration (C.C.+) is disabled (OFF), you can enable it (ON).by pressing the left or right parameter settings button. Press to access the next menu parameter. Increase ••• or decrease ••• the parameter value with the right or left parameter settings button.

 \odot Press at the bottom of the page or 0 to return to the page header.

[©] Press by to move to the next page.

C.C. +: Comfort Calibration +.

Comfort pressure: Level of pressure produced by the device when the ramp feature starts up or when the device detects that there has been no respiratory cycle for more than 2 minutes.

Latency time: Time the device takes to reach the comfort pressure upon which Auto-CPAP mode is activated.

Note: Adjusting the latency time is also accessible by pressing the ramp button when the device is in standby only.

3) Set Parameters Display

In CPAP mode

The page displays:		Prescribed P.: Level of pressure prescribed by your physician.
SETTINGS PRESCRIBED P	CPAP 8.0 cmH2O	Pressure Alter: The Symbol shows that the feature has been
PRESSURE ALTER	v	enabled by the nome care provider.
C.C+	V	C.C. +: Comfort Calibration +. The V symbol shows that the feature
MAXRAMPTIME	45 min	has been enabled by the home care provider.
14 B		Max ramp time: Maximum ramp time set by the home care provider.

^② Press **D** to move to the next page.

In Auto-CPAP mode

0		
The page displays:		\mathbf{C} \mathbf{C} \mathbf{C} and \mathbf{C} with the factor \mathbf{C} and \mathbf{V} and \mathbf{C} and \mathbf{C}
SETTINGS AUTO		C.C. +: Confort Calibration +. The symbol snows that the feature
C.C+		has been enabled by the nome care provider.
MAX LATENCY TIME	45 min	Max latency time: Maximum latency time set by the home care
MIN. PRESSURE	4.0cmH2O	provider.
MAX PRESSURE 20.0 cmH2O		Min. Pressure: minimum pressure level.
I+ 8		Max. Pressure: maximum pressure level.



Command on IFL: this command raises the pressure if the flow is restricted. The \checkmark symbol shows that the the feature has been enabled by the home care provider.

Max. P on apnea: maximum pressure on apnea command.

Pres. decrease: decrease in pressure, either Fast or Slow, set by the home care provider.

Press
 to move to the next page.

4) Set Patient Reminders display

This page displays only if the home care provider has activated a reminder to remind you for example to replace the filter or the mask.

The reminder activation date is shown opposite the corresponding
reminder.

② Press to move to the next page.

5) Setting the clock

The time can be set when the device is in standby only.



S Press at the bottom of the page or <i>The page header.
Press <i>The page header.
The page header.

6) Setting the date

The date can be set when the device is in standby only.



⑤ Press 🖾 at the bottom of the page or 🙆 to return to the page header.

Fress
 to move to the next page.

7) Miscellaneous Settings

D	2	3	4
The page displays: MISCELLANEOUS LANGUAGE ENGLISH UK CONTRAST 5 	Press as many times as necessary to access the desired parameter setting.	The page changes: MISCELLANEOUS LANGUAGE ENGLISH UK CONTRAST 5 	The language can be selected by successive presses on the left or right parameters settings button. Then press to access the contrast. Increase or decrease the contrast with the right or left parameter settings button.

S Press at the bottom of the page or to return to the page header.

©Press (1) to exit the menu.

General Information

On the DreamStar[™] Intro or DreamStar[™] Intro Evolve device

When the device is in standby, press the left variable parameters settings button to select the symbol on the screen: the General Information menu appears.

① The page displays: GLOBAL INFO. HOUR COUNTER HOUR COUNTER 106 h 15 TOTAL USE 67 h 32 TOT.SESSION NBR 11 Tot. Session Nbr.: Number of on/off sessions in the device memory.
--

② Press by to move to the next page.

3		
The last session is		
displayed:		
SESSION		
DATE		4.07.2011
TOTAL DURATIC	N	8h 15
USAGE DURATI	0 N	6h37
AVERAGE PRES	SURE	9.2 cmH20
-	8	****

Date: Date of the last on/off session.

Total duration: Total duration of the last session.

Usage duration: duration during which the patient was actually breathing in the mask during the last session.

Average pressure: Average pressure delivered during the last session.

Press the on/off button to exit the menu.

Note: The Session page is only available if the device is in standby and if at least one session was recorded.

On the DreamStar[™] Info, DreamStar[™] Auto, DreamStar[™] Info Evolve and DreamStar[™] Auto Evolve devices

Press the left yarameters settings button to select the symbol on the screen: the General Information menu appears.

0		
The page dis	splays:	
GLOBAL INFO.		Hour counter: Device operating time.
HOUR COUNTER	94 h 15	Total user Total duration during which the national was actually
TOTAL USE	48 h 32	Total use. Total duration during which the patient was actually
TOT.SESSION NBR.	10	breathing in the mask.
	•	Tot. Session Nbr.: Number of on/off sessions in the device memory.
≺ A	>	
		1

^② Press by to move to the next page.

(3)	
The last session is		
displ	aye	d:
SESSION	11/0	18/11-11h25
USAGE DURATIK	NC	6 h 27
AVERAGE PRES	SURE	6.1 cmH2O
AVERAGE LEAK		ОК
A.H. INDEX		10.0
diam'r a san a	8	

Date: Date and start hour of the last on/off session.

Usage duration: duration during which the patient was actually breathing in the mask.

Average pressure: Average pressure delivered during the session.

Average leak: Indicates the average leak, displaying OK, +, ++, +++, or ++++.

A.H. index: Index of obstructive apneas and hypopnoeas.

The session date and time are displayed in the upper right of the screen.

The pages for the last 5 sessions can be displayed, from the most current to the oldest.

It o access the next page.

 $\$ 9 Press the on/off button (0) to exit the menu.

Note: The Session page is only available if at least one session was recorded.

Reminders about to expire

This functionality is identical on all devices in the DreamStar™ product range.

When one or several reminders are about to expire, the information access symbol in the lower left of the screen changes to the blinking envelope symbol

Pressing the button located opposite the symbol brings up a window with a list of the reminders involved, as the following example shows.



© Press at the bottom of the page or 0 to return to the page header.
© Press 0 to exit the menu.

WARNINGS

- When using oxygen, always follow the instructions of the medical team or home care provider.
- Do not smoke in the presence of oxygen.
- Do not inject oxygen into the device's air intake.
- Carefully follow the instructions for starting and stopping treatment.
- If you use an oxygen concentrator or liquid oxygen unit, stop the flow of oxygen when the device is not
 operating. If the oxygen concentrator remains on when the device is turned off, the oxygen delivered into
 the patient circuit could accumulate inside the device, creating a fire hazard.

CAUTION

For a given oxygen flow, the concentration of oxygen inhaled varies as a feature of the pressure settings, your breathing, the type of mask used and the leak rate. This precaution applies to most Continuous Positive Airway Pressure devices.

Installing an oxygen adapter (optional)

When using an additional oxygen supply, you must use an oxygen adapter equipped with a specific valve designed to prevent the accumulation of oxygen in the device.

Refer to manufacturer's instructions for installation, cleaning and maintenance of the specific valve.

To install the oxygen adapter, replace Step 3 of the standard installation procedure with the following step:

• Connect one end of the oxygen adapter to the free end of the patient circuit and the other end to the mask.

Continue with steps 4 through 6 of the standard installation procedure.

Starting and stopping the treatment

- 1. It is essential that the DreamStar[™] device be turned on and generate air flow before the oxygen flow is started so that oxygen does not accumulate in the device.
- 2. Likewise, you must stop the oxygen flow before turning off the device so that oxygen does not accumulate in the device.

Please refer to the user instructions for your mask and tubing for details on their maintenance.

Daily

WARNING

Unplug the device from the power source and always detach the breathing circuit and the water chamber from the device before cleaning them.

CAUTION

- Use for the cleaning material intended for this purpose.
- Do not use strong detergent, abrasive sponge or stiff brush.

Water chamber (if included)

- Disassemble the water chamber.
 - Remove the water chamber from the device.
 - \circ Unlock the cover by pressing the center tab and rotating it backwards $\mathbb{O}.$
 - Empty any water remaining in the chamber.
 - Separate the cover from the base of the water chamber.
 - o To remove the inner tubing @:
 - 1: Gently press the clip (A) to release it from the locking system (B).
 - 2: Then pull carefully the tubing to extract it from the cover.
 - Next remove the cover gasket.



- Clean the various parts of the water chamber ③ with warm water and mild detergent (for example 3 drops of dishwashing liquid diluted in water).
- Rinse well with water to eliminate any trace of detergent.
- Allow to dry naturally.
- Once dry, reassemble the water chamber.
 - First, attach the gasket to the groove of the cover and ensure that it is well seated.
 - \circ $% \left(1\right) =0$. Insert the inner tubing into the hole of the gasket and ensure it is clipped.
 - Place the cover on the water chamber base ④ and tilt it forward to lock the chamber with the center tab.
 - Fill the water chamber before replacing it into the device.



Notes:

- The different parts of the water chamber may also be washed in a dishwasher (at 60°C maximum during 2 hours).
- To prevent micro-organisms growth, do not allow water in the chamber to stagnate.

Weekly

- Unplug the device from the power source.
- Disconnect the breathing circuit and remove the cover or water chamber (if included).
- Washable filter:
 - Pull the filter holder ① towards you to remove it ②.
 - Remove the filter from the filter holder **③**.
 - Wash the filter and the filter holder with warm water and mild detergent (for example one drop of dishwashing liquid on the filter and the filter holder, then rub...)
 - Rinse well to eliminate any trace of detergent.
 - Allow to dry :
 - Pad the filter dry using a clean absorbent towel, then allow it to dry thoroughly naturally.
 - Allow the filter holder to dry naturally.
 - Once dry, place the filter into the filter holder, then the assembly at the back of the device. Do not use a filter which is not completely dry.



• Reinstall the cover or the water chamber.

Monthly

- Device
 - Clean the outside of the unit using a damp tissue (cloth, paper towel) with a little water and one drop of mild detergent.
 - Eliminate any trace of detergent in repeating this operation with a new tissue (cloth, paper towel) moistened with water only.
 - Wipe the device thoroughly using a dry tissue (cloth, paper towel).
- Air intake filters:
 - The high-efficiency filter, which is offered as an option, cannot be washed. It must be changed once a month or more frequently if visibly dirty.
 - Change the filters systematically, as soon as they are torn or soiled or when the device displays a reminder to do so.
- Water chamber (if included):
 - After the water chamber has been disassembled and cleaned, you can let it soak for 15 minutes in a solution of 1 part white vinegar to 9 parts water.
 - Rinse well with water to eliminate any trace of vinegar.
 - Allow to dry naturally.

WARNINGS

- Do not use spray detergent. Harmful product residue could enter the air outlet, the air intake filter, or the device interior, causing airway irritation.
- Never use bleach at a concentration higher than 0.1%. For example: pour 200 ml of 2,6 % bleach into 5 liters of cold water.
- Never use the device without making sure that an air intake filter is installed.
- Check that the heating element is completely dry before reconnecting the device to the power supply.

TROUBLESHOOTING

Helpful hints

Problem	Possible cause	Suggestion
Your nose is cold.	The room temperature is too low.	Raise the room temperature.
	cold.	Place patient circuit under a cover and run next to your body to reduce heat loss.
Runny nose.	Reaction to air flow and to pressure levels.	Contact your medical technical team or your attending physician.
Nose or throat is dry or irritated.	The air is too dry.	Use the humidification feature if your device is equipped with a water chamber. Increase the heat level by following the instructions in the parameter settings procedure of the corresponding device.
	There is no water in the water chamber (if included).	Check the water level in the water chamber. If necessary, raise the water level following the instructions under "Filling the water chamber (if included)", on page 10.
Nose, sinus or ear pain.	Sinus infection or nasal congestion.	Contact the attending physician immediately.
Redness of skin in contact with the mask.	Possible pressure sores indicating the headgear is too tight or the size is too small.	Adjust the headgear. Contact the attending physician or home care provider to try another size mask.
	Allergic reaction to mask components.	Stop using the mask. Contact the attending physician or home care provider.
Dry or irritated eyes.	Air leakage around the mask.	Reposition the mask. Ask the attending physician or home care provider to try another size mask.
The air delivered by the device is too hot.	Air intake filters may be dirty. Air intake is clogged.	Clean or replace filters as necessary (see "Cleaning and Maintenance", on page 29). Move away from all bedclothes and clothing.
	Room temperature is too high.	Lower the room temperature. Make sure that the DreamStar product range device is well away from any source of heat. Remove patient circuit from under the cover.
Discomfort from feeling that the pressure is too high.	Device pressure.	Getting use to the nasal pressure takes some time. Use the pressure ramp when you go to sleep (see "Ramp feature", on page 10). Relax and breathe slowly through the nose.
		If the pressure delivered by the device seems to have changed, contact the home care provider to have the device pressure checked.
	The DreamStar™ Auto or DreamStar™ Auto Evolve device is set to Auto- CPAP mode.	The pressure may vary during use. If you are dissatisfied with the pressure, ask your home care provider to check the device.
The device does not display the correct pressure.	The ramp is enabled.	Confirm that the ramp indicator is displayed. Disable the ramp feature referring to the setting procedure for the device concerned.
	The Pressure Alter feature is enabled in CPAP mode.	Disable the Pressure Alter feature referring to the setting procedure for the device concerned.

Problem	Possible cause	Suggestion
Symptoms of sleep apnea syndrome recur.	The device is not set to the correct pressure or is not operating properly. Your physical condition	Ask your home care provider to check the device operation.
	or pressure needs may have changed.	
The DreamStar™ product range device does not turn on (no	The power supply cord is not correctly plugged into the power port.	Check the connections between the device, the power cord, and the power source.
display).	No power.	Plug another device (e.g., lamp, radio, etc.) into the power source to confirm that current is available at the source.
	The device's internal fuse is defective.	Contact your home care provider.
The DreamStar™ product range device appears to be experiencing interference and does not work correctly.	Very high electromagnetic interference.	Move the device away from sources of interference, such as halogen lamps, cordless phones, etc.
Humidifier does not seem to heat water.	The heat level is set at 0. The heating element is defective.	When the device is battery-powered, the heated humidification feature cannot be used. Set the heat level between 1 and 10, by following the instructions in the parameter settings procedure of the corresponding device. Confirm that the heated humidifier indicator is displayed on the screen and is not blinking. If the indicator is blinking or is not present, contact your home care provider.
Water spilled into the device.		Unplug the device and allow it to dry at least 24 hours. Re-apply power and then check for proper operation.
Excessive droplets of water appear in the patient circuit or in the mask.	The water level in the water chamber (if included) is too high. A small amount of water droplets are normal, especially during winter months. Excessive condensation of water vapor.	Check that the water level is not above the water chamber maximum fill level; if it is, pour out the excess water. Adjust the heating power to a lower level by following the instructions of the procedure for setting the corresponding device. Route the patient circuit under your blanket.
White, powdery deposits appear in the water chamber.	Traces of scale from the tap water.	Rub the traces with a sponge and mild detergent. Soak the water chamber in a solution of 1 part white vinegar to 9 parts water as described under "Cleaning and Maintenance", on page 29. Rinse well with tap water. Dry the exterior with a clean cloth.

Device messages

Code	Description	Corrective action
MASK UNPLUGGED is displayed on the screen.	The mask is disconnected.	Check the connections between the mask, the patient circuit, and the device. This message disappears when any of the four buttons on the front of the device is pressed or when you breathe in your mask well reconnected. Otherwise, the device will stop after 30 minutes.
The SERVICE symbol blinks alternately with the error code at the center of the display.	The device has detected an operating error.	Unplug the device from all sources of electrical power. Plug it in again and turn on. If the error persists, contact your home care provider.
The SERVICE symbol blinks alternately with the error code at the center of the humidifier heat level page.	The device has detected a humidifier operating error.	Unplug the device from all sources of electrical power. Plug it in again and turn on. If the error persists, contact your home care provider.

Performance of the device

Device pressure range:	$4 \text{ cmH}_2\text{O}$ to $20 \text{ cmH}_2\text{O}$
	Device adjustable in increments of 0.5 cmH ₂ O
Maximum steady limiting pressure at the patient	
connection port under single fault condition:	30 cmH₂O
Maximum pressure that can be set:	20 cmH ₂ O
Ramp duration:	0 to 45 minutes \pm 1 minute
	Device adjustable in increments of 5 minutes.
Sound pressure level measured in accordance with	
NF EN ISO 17510-1 : 2002:	< 30 dBA without humidifier
Sound pressure level measured in accordance	
with NF EN ISO 17510-1:2007:	33 dBA without humidifier
	34 dBA with humidifier
Patient-side connection aperture:	Tubing with diameter of 22 mm.
Air intake filter efficiency:	Optional high-efficiency filter.
	Disposable fabric HEPA paper, which is 90% effective
	for particles > 3 microns.
	High Density Foam (reusable) and is 90%
	effective with particles > 20 microns.

Integrated Humidifier performance

Humidification rate:	> 10 mg H_2O/I at the maximum setting for a leak flow
	< 60 l/min
Heating time:	45 minutes
Pressure loss as a function of flow:	0,59 cmH ₂ O at 1 l/sec
Compliance of the water chamber :	14,2 ml/kPa (chamber empty)
	12,2 ml/kPa (chamber full)
Maximum service pressure:	20 cmH ₂ O
Maximum gas temperature delivered from patient	
tubing:	43°C (109.4°F)

Device electrical characteristics

Universal internal electrical power with the detachable electrical power cord (which varies by country).

Input voltage (auto-ranging):	100, 115, 120, 230 and 240 VAC (-15%, +10%),
	at 50 or 60Hz
Maximum power consumption:	90VA at maximum setting.*
Current consumed at 20cmH ₂ O with a 4mm leak:	130 mA eff. at 230 VAC
DC power supply (13 V)	Voltage range allowed: 13V (-15%, +25%).

*Power consumption is based on the type of model. The DreamStar[™] Auto[™] Evolve with heated humidification enabled is the highest-consumption device.

Transportation and storage conditions

Pressure range:	500 hPa to 1060 hPa
Temperature:	-20°C to +60°C (-4 °F to +140 °F)
Relative humidity:	Up to 95% without condensation

Operating conditions for the device and humidifier

Pressure range:	730 hPa to 1060 hPa
Temperature:	+5 °C to + 40 °C (41 ºF to 104 ºF) without humidifier
	+5° C to + 35 °C (41 ºF to 95 ºF) with humidifier
Relative humidity:	between 10% and 95% without condensation
Altitude range:	0 – 2 700 m (0–9,000 ft) approximately

Physical characteristics

	-
Dimensions (D x W x H):	200 x 230 x 120 mm (7.8 x 9.0 x 4.7 in) approximately
	with water chamber
Carrying case Dimensions (D x W x H):	260 x 350 x 150 mm (10.2 x 13.7 x 5.9 in)
	approximately
Weight:	1,5 kg (3.3 lbs) approximately with water chamber
	1,4 kg (3.1 lbs) approximately with cover
Operational volume (minimal gas volume in water	
chamber):	811 ml
Useful volume of water chamber:	300 ml
Maximum liquid fill level:	Indicated on water chamber

Standards compliance

Risks pertaining to this medical equipment were assessed in accordance with the ISO 14971:2007 standard, specifically with reference to global residual risk.

The DreamStar[™] product range device complies with the following standards.

- IEC 60 601-1:1988 + A1:1991 + A2:1995 + US/CAN deviations: Medical electrical equipment. Part 1: General requirements for safety.
- IEC 60 601-1-2:2007: Medical electrical equipment. Part 1: General requirements for safety. Collateral standard: Electromagnetic compatibility Requirements and tests.
- EN ISO 17510-1:2009: Sleep Apnea Breathing Therapy Devices.
- EN ISO 8185:2009: Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems.
- Directive 93/42/EEC of the Council concerning medical devices.
- Directive 2002/95/EC of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
- Directive 2002/96/EC of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE).

End-of-Life disposal of device

According to the European directive 2002/96/EC, this device represents an electrical and electronic equipment which should be collected and treated separately from the household waste. The crossed-out wheeled bin symbol (see paragraph "Symbols on the device" page 7) informs you that you have to use a separate disposal, which should be adapted for the collect and the treatment of this equipment. Inappropriate disposal of the waste could have negative consequences on the environment. Please contact your homecare provider.

Homecare Provider Information

Manufacturer:

C € 0459

HEALTHC'AIR 144 AV CHARLES DE GAULLE 92200 NEUILLY SUR SEINE FRANCE

Manufacturing plant:

HEALTHC'AIR 10 ALLÉE PELLETIER DOISY 54600 VILLERS-LES-NANCY FRANCE

REF : M-155DFU00-20 Revision A 2011-09