

Patient Manual

EcoStar Info



EcoStar Auto



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Before starting

Please read this manual carefully before using your device so that you fully understand the limitations of this device.

Safety instructions

WARNING

In this manual, this signals a risk of injury or accident to vou or to others.

- Only use the EcoStar Info or EcoStar Auto device for its intended purpose indicated in this manual. The advices given in this manual do not replace the instructions of your home care provider.
- The device is not intended to provide assistance for vital functions.
- The device must only be used with the circuits, masks, fittings and accessories recommended by a physician or supplied by your home care provider. Confirm the Instructions for Use for each accessory are in the package and read them carefully.
- When a facial mask is necessary, always use one which is equipped with an anti-asphyxia valve.
- If you suspect that the device or one of the accessories is defective, damaged or not working properly, please contact your home care provider.
- Use only with the power supply module provided with the device.
- Do not try to open, disassemble or modify the device. Maintenance of this equipment is to be performed by skilled personnel only. Contact your home care provider.
- If the device is connected to a base of multiple sockets, then an additional base of multiple sockets or an extension wire should not be connected to the system.
- During treatment, only one of the accessories provided by your home care provider must be connected to the device USB connector.
- If necessary, the device can be detached from the electrical network by unplugging the power cord. Make sure that the power cord is accessible.
- Place the device on a stable horizontal surface in a clean, dry environment. Keep the device away from sources of water.
- Keep the device away from children and pets or pests.
- In the event of additional oxygen supply, scrupulously observe the safety instructions for using oxygen.
- Once the mask is in place, make sure that the device produces airflow. If not, remove the mask immediately and contact your home care provider.

- Be careful not to obstruct the air outlet, or any other opening of the device or respiratory circuit, either accidentally or intentionally. Avoid covering the device or placing it too close to a wall. Do not introduce liquids or objects into the air outlet.
- Never block the mask exhalation vent, which allows air to be expelled continually and reduces to a minimum the reinhalation of carbon dioxide. When the CPAP device is turned on and is functioning properly, fresh air from the CPAP device flushes the exhaled air out through the interface vent hole. However, when the device is not operating, insufficient fresh air is produced in the mask presenting a risk of re-inhaling exhaled air, which under certain circumstances could lead to a risk of suffocation within several minutes.
- At lower CPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the hose. There may also be a risk of re-inhalation.
- Do not leave long pieces of unused tubing on the bed, to prevent them from wrapping around your head or neck while you sleep.
- If the device experiences a loss of power or a malfunction, remove the mask.

CAUTION

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

- The EcoStar Info or EcoStar Auto device cannot be used without a medical prescription. Under no circumstances should you attempt to adjust these prescribed settings without the agreement of your medical team.
- Since this is a medical electrical device, please follow the installation instructions regarding electromagnetic compatibility indicated by your home care provider.
- Like all medical electrical devices, the device is vulnerable to interference from mobile and portable radiofrequency communication equipment (cordless phones, WiFi) which could be placed nearby, except authorised accessories.

EcoStar Info, EcoStar Auto Before starting ◆ 3

If the device is used with the GoodKnight H₂O heating humidifier:

- Refer to the safety instructions in the user manual for your humidifier.
- Adding a humidifier may affect the device performance.

Intended use

The EcoStar Info and EcoStar Auto devices are Positive Pressure devices indicated for the mask treatment of Obstructive Sleep Apnea and Hypopnea Syndrome (OSAHS) in patients weighing more than 30 kg (66 lbs). They can be used at home or in a sleep center.

The device can be used with the GoodKnight H_2O humidifier if a prescription for heated humidification has been added to the patient's treatment. The heating humidifier is designed to heat and raise the humidity of the air delivered to the patient through the Continuous Positive Airway Pressure device.

Contraindications

Studies have shown that the use of positive airway pressure is contraindicated for certain patients with one of the following pre-existing conditions:

- Severe bullous emphysema or emphysema previously complicated by pneumothorax.
- 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, hemophilia.
- Acute sinusitis, otitis media, or perforated tympanic membrane.
- Tracheotomy.

Adverse effects

Please contact your health care professional if you develop the follow symptoms when using the device: unusual thoracic pains, severe headache, dyspnea increase, airway or nasal passage dryness, skin sensitivity, runny or bleeding nose, discomfort or pain in ear or sinus, bloating, daytime drowsiness, mood changes, disorientation, irritability or memory loss.

Checking the components

The device is delivered with the following components:

- Specific power supply module
- Air intake filter
- Carrying Case
- Flexible tubing
- Patient Manual

It can also be used with the following optional accessories. For more information about available accessories, contact your home care provider. When using the accessories, follow the instructions provided.

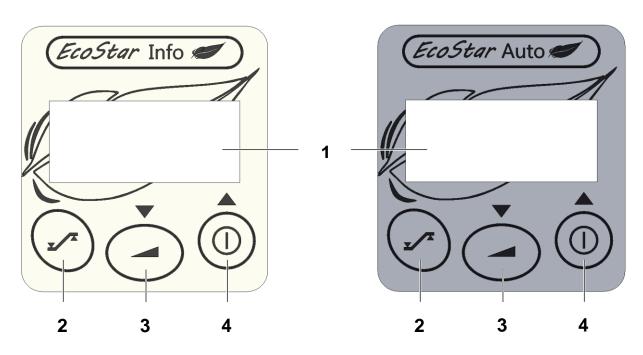
- GoodKnight H₂O heating humidifier
- Cigarette-lighter Cable
- Fine filter

Description of the device

The EcoStar Info or EcoStar Auto device is powered by an external electrical power supply module and comes with specific accessories

Views of the Device

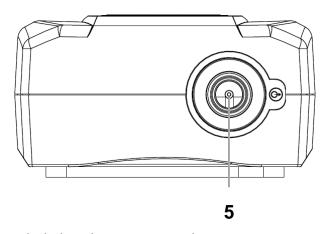
Figure 1 View of the user interface



1 Display

- this allows information such as the pressure delivered and the device settings or the clock to be viewed.
- 2 Information access button
- this allows access to various information about the device.
- 3 Ramp button
- this allows the pressure ramp to be disabled. It is also used to decrease The value of the parameters during the device settings.
- 4 On/Off button
- this allows the device to be turned on or off. It is also used to increase the value of the parameters during the device settings.

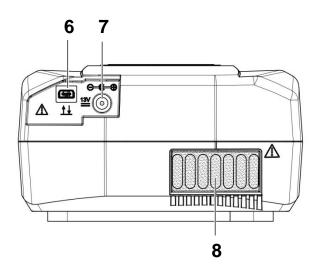
Figure 2 View of the front side



5 Outlet connector

air outlet to which the tubing is connected.

Figure 3 View of the rear side



6 Serial cable / mini USB it is connector

it is used by your physician or home care provider.

7 Supply connector

this allows the device to be powered by the power supply module or by

an external battery.

8 Air intake filter prevents dust from entering the device and the airflow.

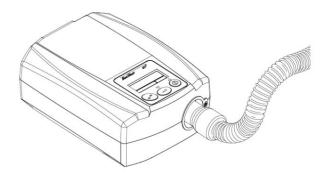
Symbols on the device

Symbol	Description	Symbol	Description
	On/off button symbol.		Ramp button symbol.
\triangle	Symbol for raising the value of the parameter displayed on the screen.	∇	Symbol for lowering the value of the parameter displayed on the screen.
型	Information access button symbol.	\rightarrow	Outlet symbol.
IP21	Device is protected against the penetration of solid objects larger than 12 mm and against falling drops of water.	A	Device at the end of its life, separate from household waste for disposal. For further information, refer to "Disposing of the device at the end of its life" page 22.
	Class II device.	☀	BF-type device.
⊖ <u></u> <u>©</u> ⊕	Direct current power supply 13 V.		Direct current.
C C 0459	Device complies with the requirements of European Directive 93/42/EC on medical devices.	Ţ	Specific warning (see "Safety instructions" page 3).
	Refer to the user manual.	<u>↑↓</u>	Recording and play back.
** *	Keep dry.		

Installation

Standard installation of the device

Connect the end of the tubing to the outlet connector of the device (Item 5 of Figure 2 page 6).



- 1. Prepare the mask as described in the operating instructions included with the mask.
- 2. Connect the mask to the free end of the patient circuit.
- Connect the power supply module cord into the supply connector on the rear side of the device (Item 7 of Figure 3 page 6) and the power supply module plug into the power outlet.
- 4. "SEFAM" is displayed, followed by the standby screen showing the time. The device is ready to operate.



Installing the GoodKnight H₂O humidifier

Refer to your GoodKnight H₂O's humidifier user manual to prepare it and proceed with installation with your device.

Then continue with steps 2 through 5 of the standard installation procedure.

Installation for use with cigarette-lighter cable

The EcoStar Info or EcoStar Auto device can be powered from a cigarette-lighter socket using the optional cable specially designed for this purpose.

To do this, connect one end of the cigarette-lighter cable to the supply connector on the rear side of the device (Item 7 of Figure 3 page 6) and the other end directly to the cigarette-lighter socket.

CAUTION

- Do not use a cigarette-lighter cable other than the one intended with the device.
- Use only a 13-volt DC power source and observe the correct connection polarity (+ and -).

EcoStar Info, EcoStar Auto Installation ● 7

Use

Starting Treatment

 Put the mask in place according to the instructions included with the mask.
 If a mask with exhalation vent is used, it includes a hole by which the exhaled gases will be flushed and could not be rebreathed.

If the mask does not have an exhalation vent, your physician must provide you with an attachment for expelling air as closely as possible to the nose.

 If the Auto ON feature has been enabled by your home care provider, the device will automatically start during your first breathings in the mask.

Otherwise, press the button to start treatment.

The pressure delivered is displayed on the screen



Indicates that the device is operating

Note:

The symbol displays only when the ramp function is enabled.

- 3. If you use a heating humidifier, turn it on according to the instructions included with the humidifier.
- 4. The symbols which may be displayed on the screen are summarized in the table entitled "Description of symbols displayed on the screen" page 9.

WARNING

Following a power supply interruption, the device will resume the same mode (on/off) which it was in before the disconnection.

Stopping treatment

- If you use a heating humidifier, turn it off according to the instructions included with the humidifier. Always unplug the humidifier before turning off the device.
- 2. Remove the mask.
- 3. Press the on/off button to turn off the device. The device will go into standby mode and display the clock. You can then unplug the power supply module cord from the power outlet.

Transporting the device

Unplug the power supply module and disconnect all the device's accessories. Place them with the device in the carrying case.

CAUTION

Disconnect the device from the GoodKnight H_2O heating humidifier and empty the water chamber before moving or transporting the assembly, to eliminate any risk of introducing water into the device and thereby causing irreversible damage.

Available features

The EcoStar Info device operates in continuous mode, whereas the EcoStar Auto operates either in constant mode (CPAP) or in automatic mode (Auto-CPAP). Both machines record the compliance data.

Mask disconnected feature

If you remove your mask, the device automatically switches to low power. The machine will restore normal power when you reconnect you mask or if you press one of the three buttons. Otherwise, it will stop after 30 minutes.

This feature can be used at night if you need to get out of bed.

Comfort Calibration feature

The Comfort Calibration feature available on the device aims to increase the treatment pressure during inspiration and to decrease it during expiration to make the breathing more comfortable during the treatment. It can be enabled during the ramp or continuously by the physician or home care provider.

Ramp function

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

The Indexed Ramp feature allows you also to start your treatment at the comfort pressure, then to have a rise in pressure in CPAP mode or the activation of the Auto-CPAP as soon as the device starts to detect respiratory events indicating that you are asleep.

Press the on/off button to start the ramp;
 the ramp indicator displays.

Note:

If the ramp time or the latency time is set at zero, the ramp function is disabled.

2. Press the ramp button to turn off the ramp function. You can reactivate it by stopping and restarting the device using the on/off button.

Accessing information on the device

The three buttons shown in the user interface allow access information on the device and are used to change the value of the parameters for certain settings.



provides access to information



lowers the value of the parameter displayed



raises the value of the parameter displayed

The parameters accessible on the screen when the machine is in standby or operating mode are:

- device parameters relating to your treatment
- general settings, such as time
- compliance counter data.

Description of a screen page

Each screen of the patient settings menu includes:

- an upper section indicating the value of the parameter displayed
- a lower section which includes various symbols indicating whether the machine is on or off, as well as the nature of the parameter displayed (see table entitled "Description of symbols displayed on the screen" page 10).

EcoStar Info, EcoStar Auto

Use ● 9

Access to parameters

The display allows information of the device's settings to be viewed. The information is available whether the device is in standby or in operation.

To access the device settings: press the information access button for one second.

On the screen which appears:

• the \circ symbol or the \circ symbol shows if the device is in standby or in operation.

■ the symbol indicates that the parameter displayed can be modified. Raise the value of the parameter by pressing the on/off button or lower it using the ramp button.

To access the next data: press the information access button

To exit the parameter settings menu: press the information access button again.

The display will indicate the time (in standby mode) or the prescribed pressure (in operating mode).

Note:

Exiting the parameter setting menus happens automatically if you do not press any buttons for 30 seconds.

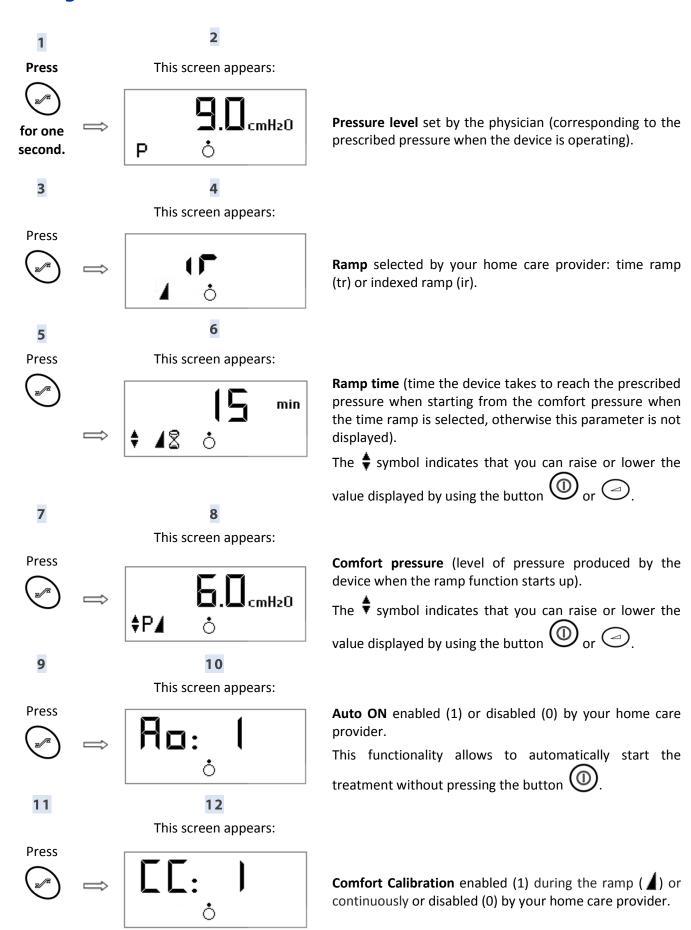
Description of symbols displayed on the screen

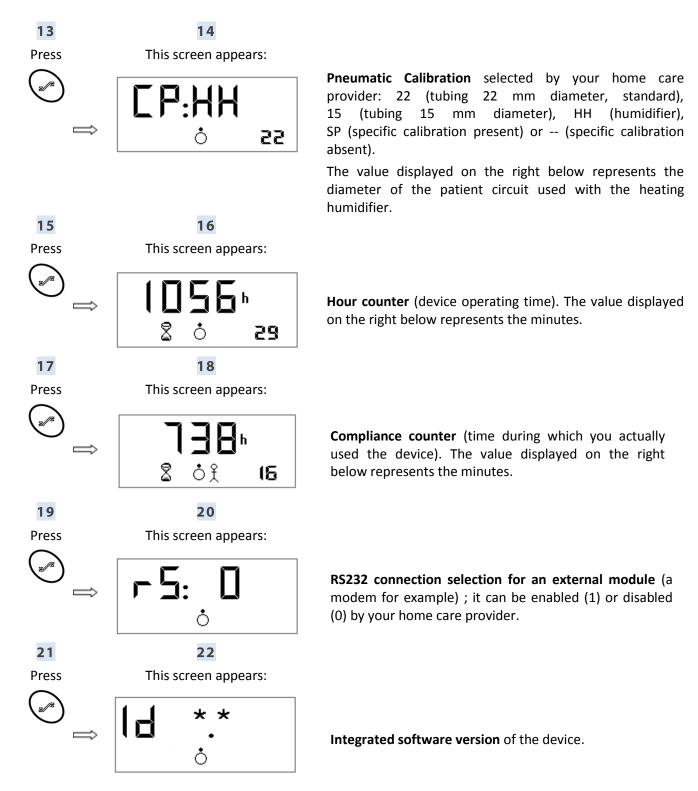
Symbol	Description	Symbol	Description
ċ	Standby mode	•	Operating mode
1	Ramp function	Р	Pressure symbol
	Time symbol	Ĵ	Compliance symbol
‡	Adjustable parameter	Id *.*	Software version
In	Information message	Er	Error message

Note:

The EcoStar Info or EcoStar Auto device is shown in standby mode in the setting access sequence below and all the values displayed are given by way of example.

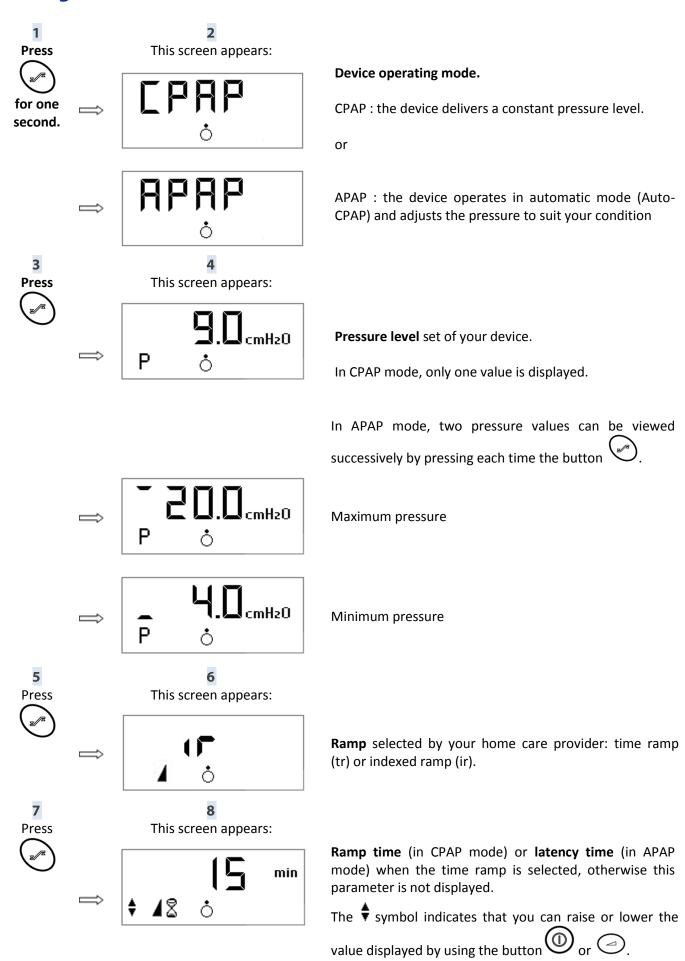
Setting EcoStar Info device

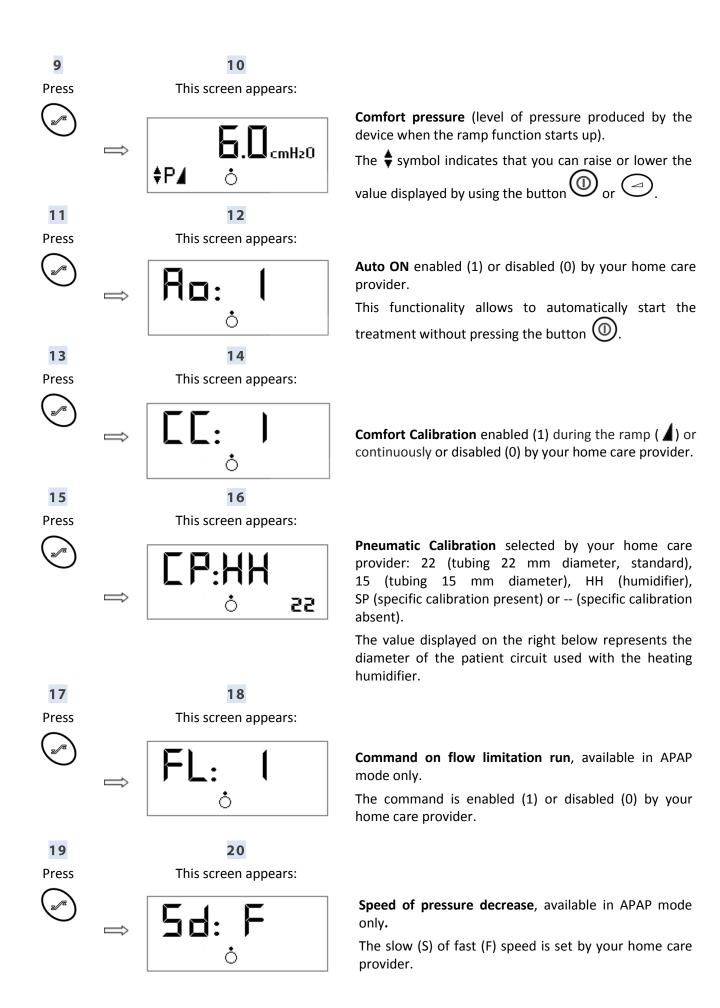


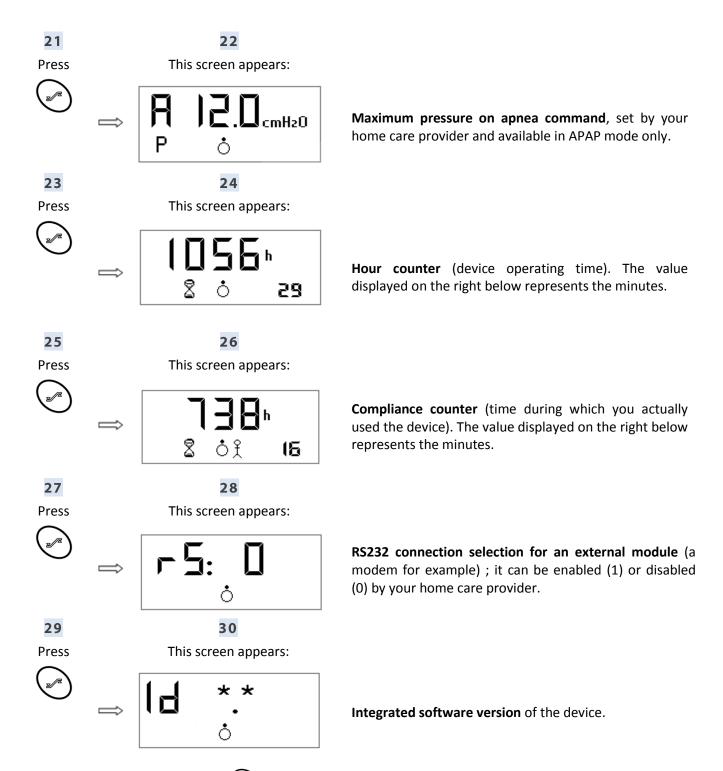


Press the information access button again to exit the parameter settings menu.

Setting EcoStar Auto device







Press the information access button again to exit the parameter settings menu.

When you exit the settings menu, the display returns to one of both following screens showing the status of your device:

The device is in standby.

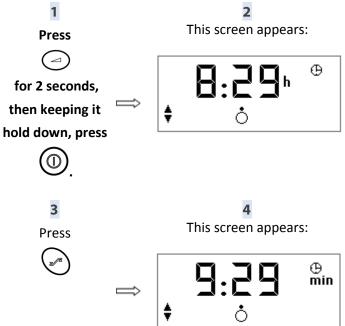


The device is in operation.



Setting the clock

You can set the time only when the device is in standby.



Once the buttons are released, the symbol of adjustment \displayed appears under the hour and the letter \displayed by using the button or or .

The symbol of minute **min** blinks in turn. You can set the minutes by following the same procedure as for the hour.

Press the information access button to exit the men

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Use with added oxygen (optional)

WARNINGS

- When using oxygen, always follow the instructions of the medical team or home care provider. The source of oxygen should be placed at over one meter of the device.
- Do not smoke in the presence of oxygen.
- Do not inject oxygen into the device's air intake.
- Carefully follow the instructions of "Starting and stopping treatment".
- when using an additional oxygen supply, stop the flow of oxygen when the device is not operating. If the added oxygen remains on when the device is turned off, the oxygen delivered into the patient circuit could accumulate inside the device, creating a fire hazard.
- The maximum flow of oxygen used must not exceed 12 l/min.

CAUTION

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

Installation with an oxygen adapter (optional)

In case of additional oxygen supply, you must use a valve designed to prevent the accumulation of oxygen in the device.

This valve must be installed between the device and the patient circuit.

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

Starting and stopping treatment

- It is essential that the EcoStar Info or EcoStar Auto device is turned on and generating air flow before the oxygen flow is started so that oxygen does not accumulate in the device.
- Likewise, you must stop the oxygen flow before turning off the EcoStar Info or EcoStar Auto device so that oxygen does not accumulate in the device.

Cleaning and Maintenance

Please follow the instructions for cleaning and maintenance below and refer to the user procedures of your mask, heating humidifier and respiratory circuit for the care and maintenance of these accessories.

WARNING

Always unplug the device from the electrical source and disconnect the respiratory circuit from the device before cleaning.

CAUTION

- Use appropriate material for cleaning: do not use harsh detergent, abrasive sponges or brushes with hard bristles.
- Do not let water come into contact with the device.

Weekly

Air intake filter

- Remove the filter from the rear of the device.
- Wash the filter with warm water and mild detergent (for example one drop of dishwashing liquid on the filter).
- Rinse well to eliminate any trace of detergent.
- Dry the filter:
 - Dry the filter by pressing in a clean, absorbent cloth
 - Allow it to dry completely away from sunlight
- Once dry, reinstall the filter at the rear of the device. Do not use a filter which is not completely dry.

Monthly

Device

- Clean the device exterior regularly by using a damp cloth or paper towel moistened with a little water and a drop of gentle detergent.
- Remove detergent residue by repeating this step with a clean cloth or paper towel, slightly moistened with water only.
- Wipe the entire device with a dry cloth or paper towel.

Air intake filter and fine filter

Change the air intake filter whenever it is damaged or soiled.

The fine filter, which is optional, cannot be washed; it must be changed once a month at least, or more often if it is visibly clogged.

WARNINGS

- Do not use detergent spray. Chemical product residue could enter the air outlet, the filter's foam or the device interior, causing airway irritation.
- Never use the device without making sure that an air intake filter is installed.

Trouble-shooting

Helpful hints

Problem	Possible cause	Solution
Your nose is cold.	The room temperature is too low.	Raise the room temperature.
	The air delivered is too cold.	Place the patient tubing under a blanket to reduce heat loss.
Running nose.	Reaction to the airflow and pressure.	Contact your medical technical team or your attending physician.
Nose or throat is dry or irritated.	The air is too dry.	Humidify the air in the room using a humidifier. Contact the medical technical team to obtain a heating humidifier.
Nose, sinus or ear pain.	Sinus infection or nasal congestion.	Contact the attending physician immediately.
Redness of skin in contact with the mask.	The headgear is too tight or the size is too small.	Adjust the headgear. Contact your attending physician or home care provider to try another size of mask.
	Allergic reaction to mask components.	Stop using the mask. Contact your attending physician or home care provider.
Dry or irritated eyes.	Air leakage around the mask.	Reposition the mask. Ask your attending physician or home care provider to try another size of mask.
The device is delivering too hot air.	The air intake filter may be dirty. The air inlet is clogged. Room temperature is too	Clean or replace the filter as necessary (see "Cleaning and Maintenance" page 18). Move the device away from all linens and clothing. Lower the room temperature. Make sure that
	high.	the device is well away from any source of heat. Remove the patient tubing from underneath the blanket.
Discomfort from feeling that the pressure is too high.	Device pressure.	Getting used to the nasal pressure takes some time. Use the pressure ramp when you go to sleep (see "Ramp function" page 9). The pressure level will gradually increase before reaching the prescribed value and the ramp indicator will be displayed. Relax and breathe slowly through the nose.
	The EcoStar Auto is set in Auto-CPAP mode.	The pressure level has been prescribed by your physician; it can be changed only by medical prescription. If the pressure delivered by the device seems to have changed, contact your home care provider to have the device pressure checked.

EcoStar Info, EcoStar Auto Trouble-shooting • 19

Problem	Possible cause	Solution
The device does not display the correct pressure.	The ramp is enabled.	Check that the ramp indicator is displayed. Disable the ramp function by pressing the ramp button.
The device does not light up (no display).	The power supply module is not properly connected. No mains power. The device's internal fuse is defective.	Check the connections between the device, the power supply and the power source. Plug another device (e.g. lamp, radio, etc.) into the power source to confirm that current is available at the source. Contact your home care provider.
The device seems to be experiencing interference and is not operating properly.	Excessive electromagnetic interference.	Move the device away from sources of interference, such as halogen lamps, cordless phones, etc.

CAUTION

If other problems occur, contact your home care provider.

Device messages

Message displayed	Description	Solution
In 1	The mask is disconnected.	Check the connections between the mask, the tubing, and the device. This message disappears when you breathe in your mask well reconnected or when one of the three buttons of the device is pressed. Otherwise, the device will stop after 30 minutes.
Er XX (XX = 2 digits).	The device has detected an operating fault.	Contact your home care provider.

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Technical characteristics

Device performance

Device pressure range:	$4~\text{cmH}_2\text{O}$ to $20~\text{cmH}_2\text{O}\pm0.5~\text{cmH}_2\text{O}$ device adjustable in increments of $0.5~\text{cmH}_2\text{O}$
Maximum pressure at the patient-side connection port under single fault condition:	30 cmH₂O
Ramp duration :	0 to 45 minutes ±1 minute device adjustable in increments of 5 minutes
Patient-side connection aperture:	Conical connector of 22 mm diameter
Sound pressure level measured in accordance with NF EN ISO 17510-1:2009 and ISO 80601-2-70:2014 §201.9.6.2.1.101 standards:	27,5 dB(A) without humidifier 29,5 dB(A) with GoodKnight H₂O humidifier
Lifetime planned for the device:	5 years (8 hours per day)

Conditions of use

Absolute pressure range:	700 hPa to 1060 hPa	Maximum power consumption:	25 W
	+5°C to +40°C (+41 °F to +104 °F)	Input voltage:	13 V
Temperature :	+5°C to +35°C with GKH₂O humidifier (+41 °F to 95°F)	Current consumption at 20 cmH ₂ O with a 4 mm leak:	0.750 A
Relative humidity:	between 10 % and 95 % without condensation		
Altitude range:	0 – 2.400 m approx.		

Transport and storage conditions

Physical characteristics

Electrical characteristics

Relative pressure range:	500 hPa to 1060 hPa	Dimensions (D x W x H):	202 x 145 x 79 mm approx. without power supply module (7.9 x 5.7 x 3.1 ins approx.)
Temperature :	-20°C à +60°C (-4 °F to +140 °F)	Weight:	0.750 kg without power supply module (1.65 lbs approx.)
Relative humidity:	up to 95% without condensation		

Electrical characteristics of the power supply module

Class II power supply:

Input voltage: 100 – 240 VAC (-15%, +10%), 50 - 60 Hz

Power supply module provided	Input current	Output voltage
TPI GTSA-130180WV2 (EU plug)	1 000mA	13 V – 1,80 A
PW-M024A-1Y120K (non EU plug)	600 mA	12 V – 2 A

WARNINGS

- Use only one of the above-mentioned specific power supplies provided with the device.
- The above-mentioned power supply module is not intended to be repaired. If it stops working, please contact your home care provider for a replacement.

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 EcoStar Info and EcoStar Auto devices comply with the following directives and standards:

- IEC 60601-1:2005 + Amd1:2012: Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2007: 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.
- EN ISO 5356-1:2005: Anaesthetic and respiratory equipment. Conical connectors.
- Council Directive 93/42/EC concerning medical devices.
- European Parliament and Council Directive 2011/65/EU on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment.
- European Parliament and Council Directive 2012/19/EU on waste electrical and electronic equipment (WEEE).

Disposing of the device at the end of its life

In European Union this device has to be considered as an electrical and electronic piece of equipment as defined in Directive 2012/19/EU, and must be collected and processed separately from household waste for disposal as indicated by the symbol of the crossed out garbage bin (see "Symbols on the device" page 6)

In other countries, this device must be processed following local regulation.

Unsuitable disposal of the device at the end of its life could harm the environment.

Contact your home care provider.

CE marking

EcoStar Info: 2015 EcoStar Auto: 2015

Home care Provider Information



	ϵ	0459
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Manufacturing plant:
SEFAM
10 ALLEE PELLETIER DOISY
54600 VILLERS-LES-NANCY
FRANCE