

tyco / Healthcare / **Puritan
Bennett**

GoodKnight[®] 420S



Patient Manual

Ref. : M-139DFU00-50 Revision D

List of patient manual revisions GoodKnight® 420S

The pages below are included in the *GoodKnight*® 420S patient manual
Ref. M-139DFU00-50 revision D.

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Reference or revision	Description	Date
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The Puritan Bennett **GoodKnight 420S** device (GK420S) is intended for the treatment of patients suffering from Obstructive Sleep Apnoea Syndrome (OSAS). The main characteristic of this pathology is the occurrence of multiple respiratory events caused by closure of the upper airways, which disturb sleep. The *GoodKnight* 420S delivers a Continuous Positive Airway Pressure (CPAP) which prevents the upper airways from becoming obstructed and thus eliminates respiratory events.

It is essential for you to understand the limitations on the use of this device. Therefore, please read this manual carefully before using the *GoodKnight* 420S.

The information contained here is intended to help you to use this device under optimum conditions of safety and operation. For any questions relative to the equipment and its use, contact your medical team or your home service provider.

It is your doctor who has decided on the treatment of your illness. He/she has prescribed the different parameters that the hospital or your home service provider will programme completely. You must not therefore make any adjustment, except under special circumstances.

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BEFORE STARTING

Safety instructions

In order to ensure that you use your device safely and efficiently, please read all the information contained in this operating manual. Please pay special attention to the passages preceded by the following terms:

WARNING

Means that there is a danger of death or accident to you or others.

CAUTION

Means that there is a possibility of material damage to this or another device.

NOTE

Indicates special points aimed at more efficient and practical operation.

WARNINGS

1. Before any use, please check your **GoodKnight 420S**, as specified in the chapter “Checking the components” on page 3.
2. In the event of additional oxygen supply, scrupulously observe the safety instructions for using oxygen given in the chapter “Starting treatment” on page 11.
3. Only use the accessories that have been given to you by your service provider. Check that you do have the instructions for using each of these accessories and read through them.
4. Use only the specific power supply module provided with the device.
5. Do not use the device in the presence of inflammable fumes.
6. Follow the device’s installation instructions as specified in this manual in the chapter “Installation” on page 7. In particular, keep the machine away from any sources of water.
7. Do not accidentally or intentionally obstruct the air outlet or any other opening in the device or the respiratory circuit.
8. Do not introduce liquids or objects into the air outlet.
9. You must contact the medical team if, when using the *GoodKnight 420S*, the following symptoms appear: dryness in your airways or nose, skin sensitivity, running nose, earache, sinus trouble, daytime drowsiness, mood changes, disorientation, irritability or memory loss.
10. Contact your home service provider in the event of any malfunction, whatever it may be. Maintaining this equipment is solely the responsibility of the competent personnel. Do not attempt to open the device.

Indications for use

The *GoodKnight 420S* device is indicated for the treatment of obstructive respiratory sleep disorders, particularly Obstructive Sleep Apnoea Syndrome (OSAS) in patients weighing 30 kg or more.

Precautions for use

The *GoodKnight 420S* device must be used with caution in patients with the following conditions. If you are affected by one of these, contact your doctor at the beginning of your treatment.

- Pneumothorax or pneumomediastinum
- Severe bullous emphysema or previously complicated by pneumothorax
- Massive epistaxis or previous massive epistaxis
- Decompensated cardiac insufficiency or hypotension, especially in case of depletion in blood volume or in case of cardiac rhythm disorder
- Pneumoencephalus, traumatism or recent surgery with the after-effect of a cranio-nasopharyngeal fistula
- Acute sinusitis, otitis media or perforation of the tympanic membrane
- Severe claustrophobia.

Checking the components

In order to be able to use the *GoodKnight 420S* with its specific electrical power supply, you must have at least the following items:

- A spiral hose enclosing a second small transparent hose
- A nose-mask with all its fastening accessories as specified in the instructions for using this mask.

In addition to these accessories, your doctor could have prescribed the use of a humidifier. In this case, check that you have all the accessories for this humidifier specified in its operating instructions.

In the case of an additional oxygen supply, you must also have an adaptor (only in the case where the oxygen supply is not fitted directly onto the mask). See the chapter “Fitting an oxygen adaptor” on page 8 of this manual.

Carefully check the device and each accessory. Check especially that the hoses are not damaged and that the mask does not have any cracks or distortion in the cup and bellows (part of the mask coming in contact with the face).

Carefully check the device and the specific power supply module and verify that there is no obvious fault. Plug the device to the mains using the power supply module, referring to steps 4 and 5 of the chapter “Standard installation” on page 7.

The type of the device is displayed for a few seconds then the following standby screen showing the hour (the value displayed is given as example):

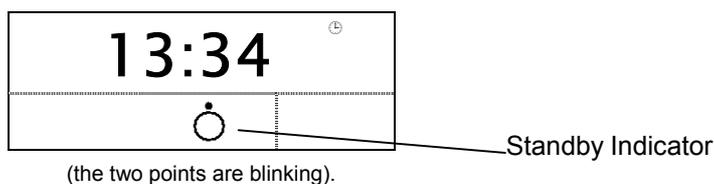


Figure 1 – View of the display when the device is in standby mode

If the device was disconnected while it was running, the screen displays the pressure. The device shows the same mode as at the time of the power supply cord disconnection and is set on the pressure used at the time of disconnection.

Start the device by pressing the on/off button (Reference 4 in Figure 2 – Top view on page 5). The turbine should start up and the noise should be regular.

Stop the device by pressing the on/off button and unplugging the power supply lead from the mains.

WARNING

In the event of problems or if you discover any anomaly, do not start the treatment and contact your home service provider.

DESCRIPTION OF THE DEVICE

The **GoodKnight 420S** is powered from an external power supply and equipped with specific accessories. The device is described below.

See figures 2, 3 and 4 on page 5.

1. Display

Allows you to visualise different information such as the delivered pressure, the settings of the device or the hour. For further information, refer to the chapter “Accessing information on the device” on page 14.

2. Information access button

Allows you to access the different information concerning the device. For further details, refer to the chapter “Accessing information on the device” on page 14.

3. Ramp button

Used for starting or stopping the pressure increase ramp (for further information, refer to the chapter “Using the ramp” on page 12). It is also used to decrease the value of the parameters during the device settings.

4. On/Off button

Used for switching the device on or off. It is also used to increase the value of the parameters during the device settings.

5. Pressure point

This is the connector onto which the small hose is connected. For further information, refer to the chapter “Installation” on page 6.

6. Outlet connector

This is the air outlet onto which the spiral hose is connected. For further information, refer to the chapter “Installation” on page 7.

7. Serial link connector

This connector is intended to be used solely by your doctor or your home service provider. Do not connect it to anything.

8. Supply connector

Used for powering the device from the specific power supply module or from an external battery. For further information, refer to the chapter “Installing for powering by battery” on page 9.

9. Air inlet filters

These filters prevent dust from entering the device and the air flow. Please refer to the chapter on “Maintenance” on page 17 for further information on the maintenance instructions for these filters.

The items in the Figures below are described on page 4.

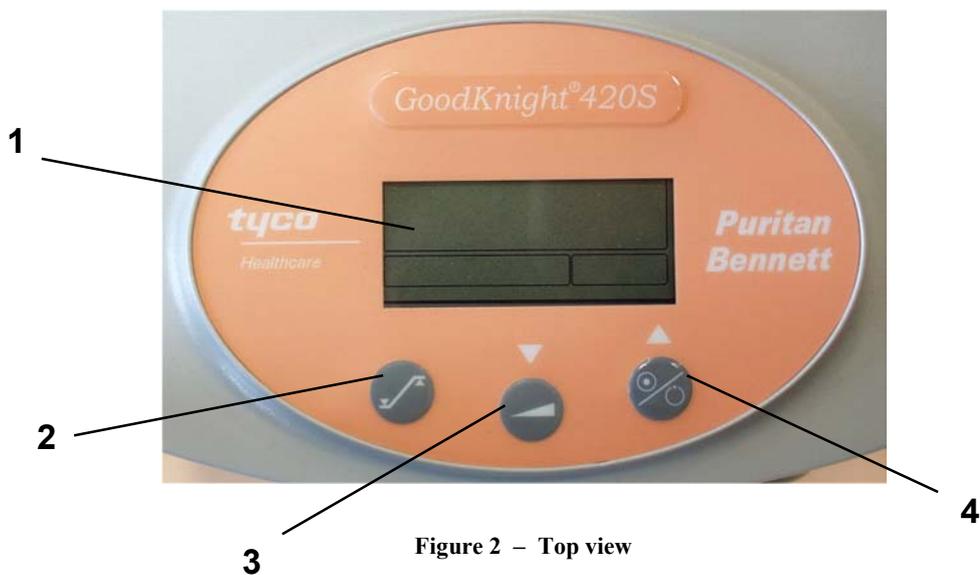


Figure 2 – Top view



Figure 3 – General view

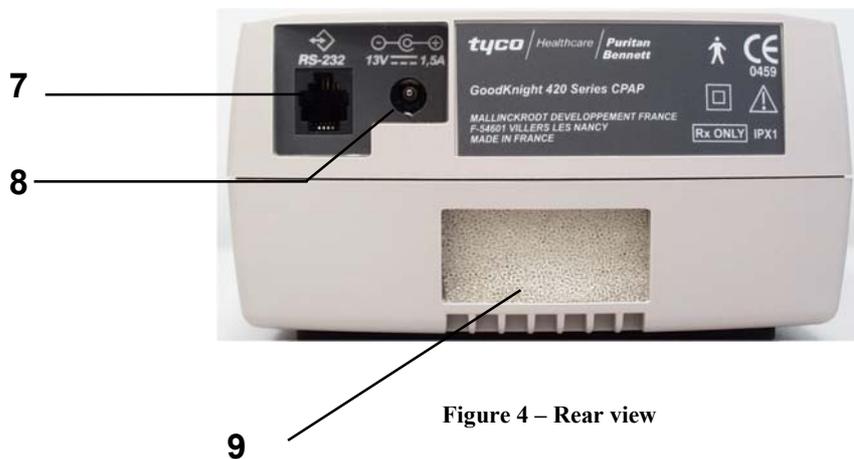


Figure 4 – Rear view

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INSTALLATION

This chapter shows you how to connect the different accessories and cables to your device. Before starting the installation, please check your device and its accessories, by referring to the chapter on “Checking the components” on page 3.

CAUTION

In general, place the device on a stable surface. Avoid placing it too near a wall or any other obstacle which could hamper the intake of air into the machine.

Standard installation

1. Connect the spiral hose to the device. To do this, connect the small hose that emerges through one of the large nozzles of the spiral hose, to the pressure point (Reference 5 in Figure 3 – General view on page 5). Connect the large nozzle of the spiral hose onto the outlet connector of the machine (Reference 6 in Figure 3 – General view on page 5).

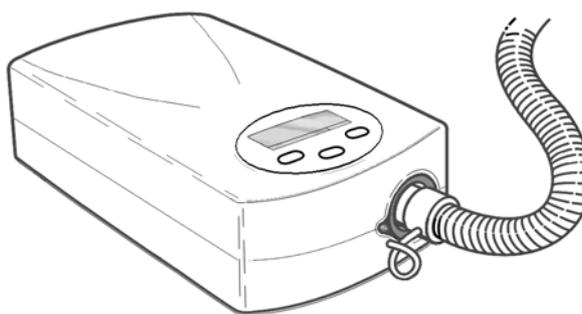


Figure 5 – Connection of the spiral hose to the device

WARNING

Take care that the small hose is not twisted or bent.

2. Prepare the mask as described in its instructions for use.
3. Connect the mask to the spiral hose’s free nozzle.
4. Connect the cable of the power supply module to the supply connector located on the back of the device (Reference 8 in Figure 4 – Rear view on page 5).

CAUTION

Use only the specific power supply module provided with the device.

5. Connect the plug of the power supply module to the mains. The type of the device is displayed for a few seconds then the following standby screen showing the hours and the minutes:



The two points are blinking.

6. The device is ready to operate. Please refer now to the chapter on “Use” on page 11.

Fitting an oxygen adaptor

Replace step 1 of the standard installation with the following step:

- Connect the oxygen adapter onto the device's outlet connector and connect the other end of the adapter onto the large nozzle of the spiral hose. Connect the small hose that emerges through one of the spiral hose's large nozzles to the pressure point (Reference 5 in Figure 3 – General view on page 5).

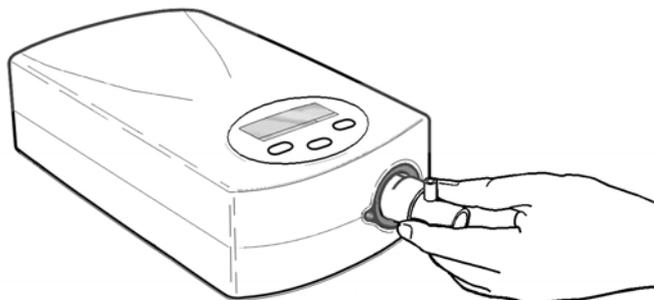


Figure 6 – Connecting the oxygen adaptor to the device

You can then repeat steps 2 to 6 of the standard installation to continue installing the equipment.

WARNINGS

- Always follow the instructions of the medical team or home service provider in the event of using oxygen.
- Do not smoke in the presence of oxygen.
- Do not inject oxygen through the air inlet of the device.
- Carefully follow the start-of-treatment and end-of-treatment steps described in the chapter on “Use” on page 11.

CAUTION

If the supplemental oxygen flow rate is fixed, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, interface selection, and the leak rate.

Installing a humidifier

Please refer to the instructions for using your humidifier for further information on preparing it and on the safety precautions.

WARNING

The humidifier must be filled before being connected to the device.

Replace step 1 of the standard installation with the steps below:

1. Connect one of the nozzles of the small spiral hose onto the outlet connector of the device (Reference 6 in Figure 3 – General view on page 5).
2. Connect the other nozzle of the small spiral hose onto one of the humidifier's connectors.

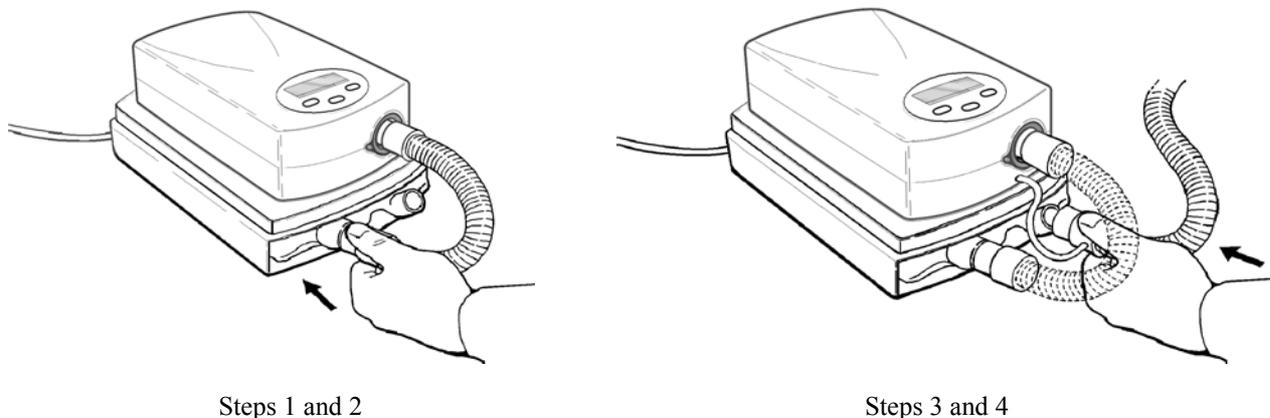


Figure 7 – Connecting the humidifier to the device

3. Connect the small hose that emerges through one of large spiral hose's nozzles to the pressure point (Reference 5 in Figure 3 – General view on page 5).
4. Connect this same nozzle of the large spiral hose onto the humidifier's second connector.

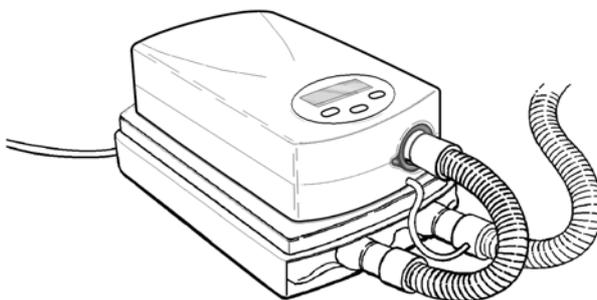


Figure 8 – View of the humidifier connected to the device

You can then resume with steps 2 to 6 of the standard installation to continue installing the equipment.

Installing for powering by battery

The *GoodKnight 420S* can be powered by a 12-Volt battery by using a special cable provided for this purpose.

CAUTION

- Do not use any battery power cable other than that supplied with the *GoodKnight 420S*. There would be a risk of damaging the device and your battery.
- Only use 12-Volt DC sources and make the proper polarity connections (+ and -).

For fitting the battery cable, replace steps 4 and 5 of the standard installation by the following steps:

1. Connect the battery power cable onto the supply connector at the back of the device (Reference 8 in Figure 4 – Rear view on page 5).
2. Connect the other end of the cable directly onto the battery.

NOTE

The *GoodKnight 420S* can use a lot of power. We advise you to use a fully charged battery.

USE

This chapter shows you how to use the device after installing it as described in the previous chapter. It also shows you how to use the pressure increase (ramp) function and how to access information on settings (you will not be able to alter these settings, but only view them).

WARNING

In the sections “Starting treatment” and “Stopping treatment” below, please follow the order given scrupulously. If this order is not followed, it can cause an accident, especially where the use of oxygen is concerned.

Starting treatment

Once the device has been installed in accordance with the directions given in the previous chapter, please follow the instructions below to start treatment:

- Put the nasal mask in place according to the instructions for its use. 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 a mask without exhalation vent is used, your doctor must provide you with a *Pirouette*[™] silent leak or equivalent allowing gases flushing as close as possible to the nose.

WARNING

The vent hole associated with the interface should never be blocked. This CPAP device is intended to be used with interfaces (or connectors) that have vent holes to allow a continuous flow of air out of the interface. 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 CPAP device is not operating, adequate fresh air will not be provided through the interface, and exhaled air may be rebreathed. Rebreathing exhaled air for longer than several minutes could, in some circumstances, lead to suffocation.

- Start the device by pressing the on/off button .

Breathe normally. The display shows the pressure available in the mask as well as the operation indicator (see Figure 9 – View of the display when the device is running).

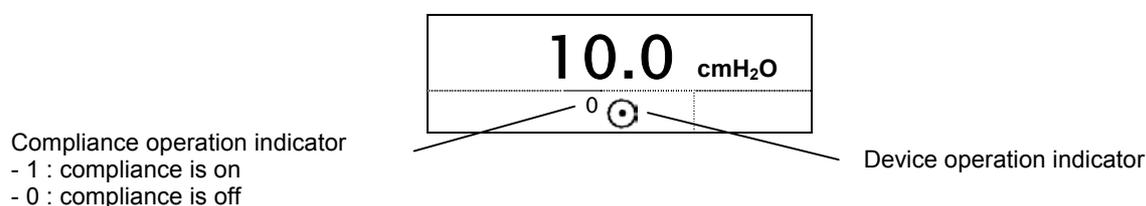


Figure 9 – View of the display when the device is running

NOTES

- The pressure unit displayed (hPa or cmH₂O) can be modified by the Practitioner.
 - The compliance operation indicator is only displayed after 15 minutes operation of the device.
- If you are using a heated humidifier, turn it on according to the instructions for its use.
 - If you are using oxygen, open the flow now.

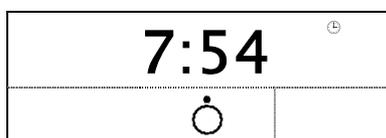
WARNINGS

- When the device is in operation mode, check that it delivers an air flow. In the opposite, stop it immediately and contact the service provider.
- At lower CPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the hose. Some rebreathing may occur.

Stopping treatment

When the device is in operation, please follow the instructions below to stop the treatment:

1. If you are using oxygen, stop the flow now.
2. If you are using a heated humidifier, turn it off as described in the instructions for its use.
3. Stop the device by pressing the on/off button . The machine returns to standby and displays the following standby screen showing the hour:



4. Remove the nasal mask.

Using the ramp

First of all adjust the starting ramp pressure of your **GoodKnight 420S** device by observing the following instructions:

NOTE

If the Ramp time is set to zero, this adjustment is not accessible.

The initial ramp pressure can be set to a value between 4 cmH₂O and the pressure level prescribed by your doctor. This function allows you to set the appropriate pressure level to enable you to fall asleep.

To access the parameter setting menu, just press for a second the information access button shown in the Figure 10 – View of the control buttons, whether the device is on standby or in operation.

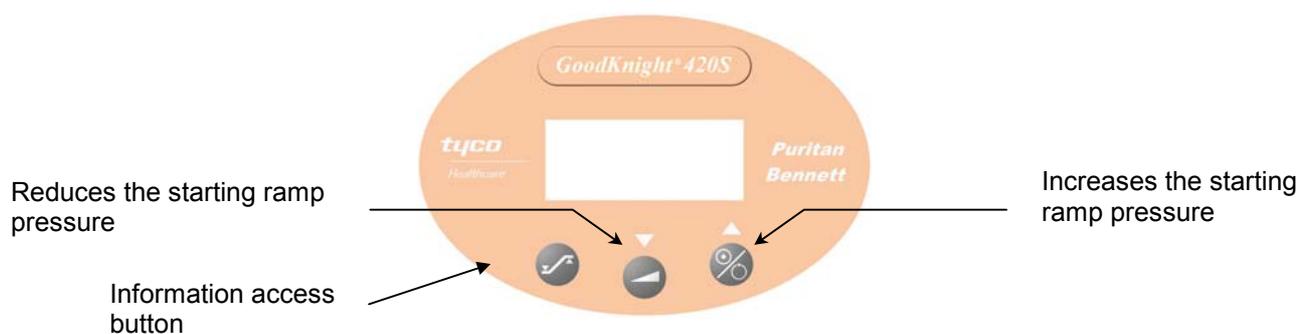
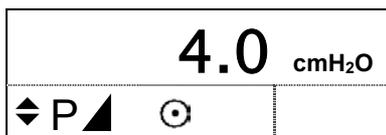


Figure 10 – View of the control buttons

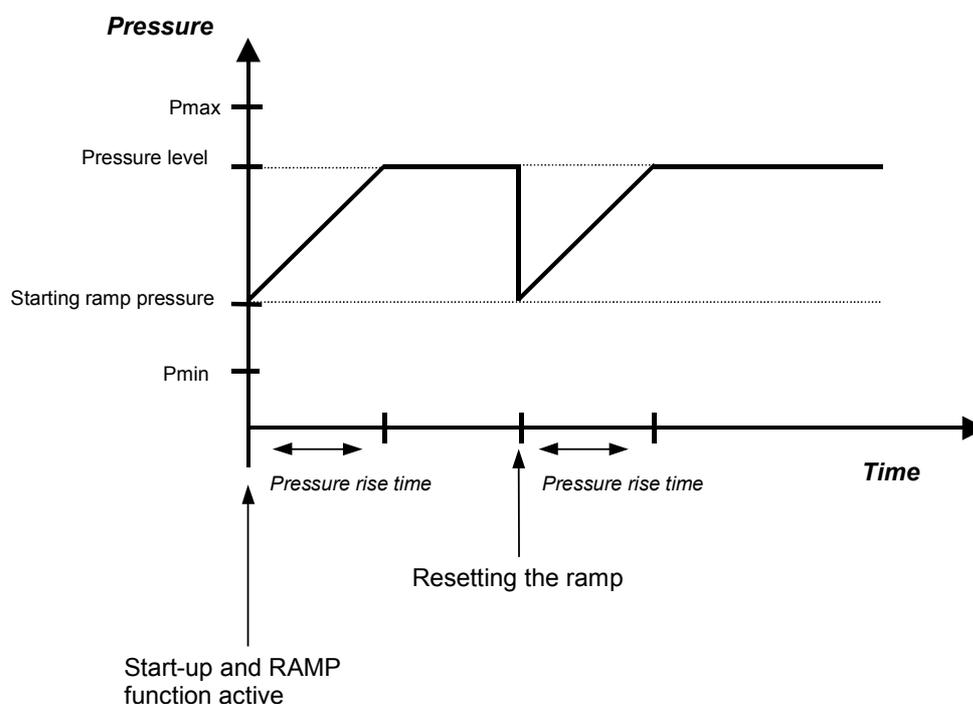
You have to press this button the number of times required for displaying the screen below:



The pressure value can then be changed by using the on/off  and ramp  keys.

The ramp function enables you to make the rise in pressure progressive. Thus, the pressure level is low at the start of the night to help you to fall asleep. You can also use this function if you have to get up during the night and have difficulty going back to sleep. The pressure rise time up to the final pressure is prescribed by your medical team and the setting carried out by your service provider is between 0 (no progressive rise) and 30 minutes in 5-minute increments. The ramp may have been preset to 0 according to the prescription provided by your medical team. In this case, the ramp function is disabled and pressing the ramp button on the front panel of the machine has no effect (refer to Reference 3 in Figure 2 – Top view on page 5).

1. To start the ramp, just press the ramp button when the device is on. The pressure will fall to a low value, then increase progressively up to the prescribed pressure level, so as not to wake you. The device will run normally, delivering a treatment pressure throughout the night unless you press the ramp button again, in which case the pressure will drop down again to the ramp level that you have selected.
2. To end the ramp, press the ramp button again and the function will be disabled. It is possible to reset the ramp time by reactivating the ramp function (the ramp indicator lights up when this is activated).



**Figure 11 – Changes in pressure over time
when activating the ramp function**

Accessing information on the device

The display enables you to view the different information on the settings of the **GoodKnight 420S** (refer to Reference 1 in Figure 2 – Top view on page 5).

The setting information is accessible whether the device is on standby or in operation. For this, just press the information access button for one second (Reference 2 in Figure 2 – Top view on page 5). With each additional key press, you access further data.

NOTE

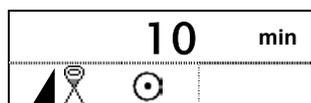
In the following screens, the device is shown in operation mode and all the values are given as examples.

Press for one second on



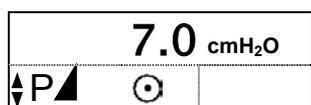
- **The pressure level** set by the doctor (equivalent to the prescribed pressure when the device is running).

Press



- **The ramp time** set by the doctor (period of time over which the pressure gradually increases from the starting ramp pressure to the pressure level).

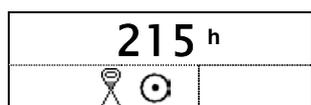
Press



- **The starting ramp pressure** (pressure level at the beginning of ramp); this parameter is adjustable and visible only if the ramp time is other than 0.

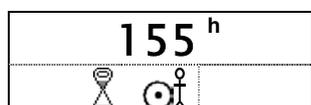
The symbol \updownarrow used shows that the parameter is adjustable. You can increase or reduce the value displayed by using the on/off or ramp keys. For further details, refer to the chapter “Using the ramp” on page 12.

Press



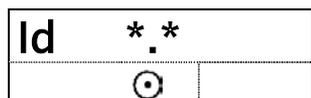
- **Hour meter value** (device operating time).

Press



- **Compliance meter value** (time during which the patient has breathed with the device).

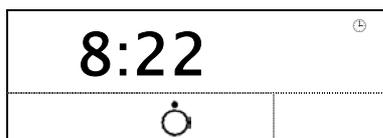
Press



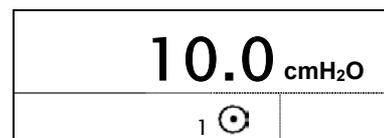
- **The GoodKnight 420S on-board software version.**

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

In this case, the display again shows one of the following two screens indicating the status of your device (the values are given as examples).



The device is on standby.



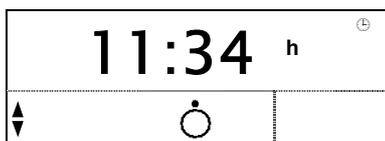
The device is running.

NOTE

Exit from the parameter setting menu takes place automatically when you do not press any key for 30 seconds.

Setting the time

You can set the time only when the device is on standby. To do so, just press the ramp button for one second (see Reference 3 in Figure 2 – Top view on page 5), then press the on/off button at the same time (see Reference 4 in Figure 2 – Top view on page 5). If you release the pressure on the buttons, the symbol of adjustment \updownarrow appears under the hour, as shown on the screen hereafter:



The letter h indicating the hour blinks, you can then set it using the ramp and on/off keys.

To set the minutes, just press the information access button, the symbol of minutes blinks in its turn and you can set them by following the same procedure as for the hour.

Press the information access button again to exit the menu.

NOTE

Exit from the parameter setting menu takes place automatically when you do not press any key for 30 seconds.

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MAINTENANCE

In order to ensure that you use your *GoodKnight 420S* safely and efficiently, please observe the maintenance instructions specified below.

GoodKnight 420S

The rigid plastic case protecting the internal components of the device does not require any special maintenance. When it proves necessary, clean the device using a rag moistened with warm soapy water. Dry the machine thoroughly.

WARNINGS

- Always unplug the device before cleaning it.
- Do not use a spray; because residues may lodge in the air outlet, the foam filter or inside the device. This could cause irritation of the airways due to chemical residues.

Air inlet filters

Change the filters as soon as they are torn or dirty (refer to Reference 9 in Figure 4 – Rear view on page 5).

Clean the outer foam filter at least once a week, or more often if necessary, in the following way:

1. Wash the filter with warm soapy water.
2. Rinse thoroughly so as to remove all traces of soap.
3. Dry it by pressing it sandwiched in a terry towel.
4. Leave it to dry completely before replacing it.
5. Replace the filter at the back of the device.

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

Hose

Please refer to the instructions for use which were sent to you with the hose.

Nasal mask

Please refer to the instructions for use which were sent to you with your nasal mask.

Humidifier

Please refer to the instructions for use which were sent to you with your humidifier.

Oxygen adaptor

Please refer to the instructions for use which were sent to you with the oxygen adaptor.

TROUBLE-SHOOTING

PROBLEM	PROBABLE CAUSE	SUGGESTION
Discomfort due to a feeling of the pressure being too high.	Pressure of the <i>GoodKnight</i> 420S.	Adapting to the nasal pressure takes a while. Try to use the pressure increase ramp when you go to sleep (see the chapter "Using the ramp" page 12). Relax and breathe slowly through your nose. If you feel that the pressure has changed, contact your service provider to have the equipment checked.
The device is not delivering the correct pressure (display).	The pressure port tube is not connected. Moisture is getting into the pressure port tube. The ramp is activated.	Check that the small pressure port tube is properly connected to the device. Dry the small tube. To do this, connect the spiral hose onto the <i>GoodKnight</i> 420S, leaving the small tube disconnected, block up the large hose with your hand, turn the device on. It stops at the end of 30 seconds. Repeat if necessary. Check whether the ramp indicator is displayed. Press the ramp button to cancel the function (see Reference 3 in Figure 3 – General view page 5).
Dry or irritated nose or throat.	The air is too dry.	Humidify the air in the room using a humidifier. Ask the medical-technical team to obtain a humidifier.
Cold nose.	The room temperature is too low.	Raise the temperature of the room or place the hose under the blankets to reduce heat loss.
Running nose.	Reaction to the air flow and pressure.	Break off the treatment. Contact the attending physician.
The device is delivering air that is too hot.	The air inlet filters may be dirty. The air inlet is clogged. The room temperature is too high.	Clean or replace the filters as the case may be (refer to the chapter on "Maintenance" on page 17). Move any linen, bedding or clothing away from the <i>GK420S</i> . Lower the thermostat for the room. Make sure that the <i>GK420S</i> is away from any heat source. Remove the hose from under the blankets.
Pains in your nose, sinuses or ears.	Sinus infection or nasal congestion.	Contact the attending physician immediately.
Dryness or irritation of the eyes.	Air leak around the mask.	Reposition the mask. Ask the attending doctor or the service provider to try different sizes of mask.

PROBLEM	PROBABLE CAUSE	SUGGESTION
Redness of the skin area in contact with the mask.	<p>The harness is too tight or too small.</p> <p>Allergic reaction to the components of the mask.</p>	<p>Adjust the harness. Contact the attending physician or the service provider to try on masks of different sizes.</p> <p>Stop using the mask. Contact the attending physician or the service provider.</p>
Recurrence of the first symptoms of sleep apnoea syndrome.	<p>The <i>GoodKnight</i> 420S is not set to the correct pressure or is not operating correctly.</p> <p>Your physical condition or your pressure needs have changed.</p>	<p>Ask the service provider to check the operation of the <i>GK420S</i>.</p> <p>Contact the attending physician.</p>
The <i>GoodKnight</i> 420S does not come on (no display).	<p>The power supply module is not properly connected.</p> <p>No mains power.</p> <p>The fuse of the device has blown.</p>	<p>Check the connections between the power supply module, the <i>GK420S</i> and the mains socket.</p> <p>Use another appliance (e.g.: lamp, radio etc.) to check that the a.c. power supply is present at the socket.</p> <p>Contact the service provider.</p>
The <i>GoodKnight</i> 420S is not running properly and seems to be subject to interference.	Excessive electro-magnetic interference.	Move the device away from sources of interference such as halogen lamps, portable telephones, etc.
In 01 is displayed.	A major leak (disconnection) has been detected in the patient circuit for more than 30 seconds.	This message disappears as soon as the mask is connected and you have breathed 3 or 4 times, or if you press the on/off button twice. Otherwise, check the patient circuit connection.
In 02 is displayed.	Excess pressure has been detected by the device for more than 10 seconds.	Check the connection of the small pressure point hose. Check that it is not trapped and that it is properly clean and dry (see the instructions for use of the patient circuit).
In 03 is displayed.	Reduction of the power supply voltage.	<p>Check the connections between the power supply module, the device and the mains socket. Unplug the supply module, then connect it again to the mains. If the problem remains, contact the service provider.</p> <p>Check the battery and replace it, if necessary. If the problem remains, contact the service provider.</p>
Er XX appears on the display. (XX = 2 digits).	The device has detected an operating fault.	Contact the service provider.

TECHNICAL CHARACTERISTICS

Device performances

Pressure range of the <i>GoodKnight</i> 420S:	4 cmH ₂ O to 20 cmH ₂ O ± 1 cmH ₂ O adjustable by increments of 0,5 cmH ₂ O
Maximum pressure at the connection opening: patient side in condition of first defect	24 cmH ₂ O
Ramp time:	0 to 30 minutes ± 1 minute device adjustable by increments of 5 minutes
Sound level measured in accordance with: PrEN ISO 17510-1 :2001	25,1 dBA
Maximum sound level:	31 dBA at 10 cmH ₂ O
Lifetime of the battery soldered onto the board:	> 5 years

Physical characteristics

Dimensions (W x H x L):	142 x 77 x 194 mm (without power supply)
Weight:	0,760 kg (without power supply module)

Transport and storage conditions

Temperature:	-20°C to +60°C
Relative humidity:	up to 95 % without condensation
Relative pressure range:	500 hPa to 1060 hPa

Conditions of use

Temperature:	+5°C to +40°C
Relative humidity:	between 10 % and 95 % without condensation
Relative pressure range:	700 hPa to 1060 hPa

Electrical characteristics of the power supply module

Class II power supply: Input voltage: 100 – 240 VAC (-15%, +10%), 50 / 60 Hz (± 1 Hz)



Output voltage: 13 V – 1,85 A.

CAUTION

- Use only the specific power supply Egston N2GFMW 24 W 13 V provided with the device.
- The power supply module Egston N2GFMW 24 W 13 V is not intended to be repaired. In case of failure, please contact your service provider to have the module replaced.

Electrical characteristics of the device

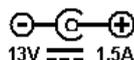
Input voltage: 13 V – 1,85 A.

Maximum power consumed : 20 W (without humidifier)

Current consumed at 20 cmH₂O with a 4 mm leak: 0,750 A.



Direct current



13 V battery connector

Symbols



On/off



Information access



Ramp



PC connection



Increases setting values



Reduces setting values



Output connector

IPX1

Device protected against the vertical falls of water drops.



Type B device



Consult the instructions for use before using this device.



Device complies with the requirements of the directive 93/42/CEE relating to medical appliances.



For USA only:

Federal law restricts this device for sale by or on the order of a physician.

Details of your Service Provider

