

PURITAN
BENNETT *tyco*
Healthcare

GoodKnight[®] H₂O

Heated Humidifier



User's Manual

User's Manual Revisions: GoodKnight H₂O Heated Humidifier

The pages below are included in the American version of the user's manual
Ref. M-146DFU00-20 Revision D.

Current pages	Revision
Cover	D
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7	C
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CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

GoodKnight[®] is a registered trademark of Nellcor Puritan Bennett Inc.

BEFORE STARTING

Safety Instructions

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

WARNING

Warnings alert the user to potential serious outcomes (death, injury, or adverse events) to the patient or user.

CAUTION

Cautions alert the user to exercise care required for the safe and effective use of the *GoodKnight H₂O* Humidifier.

NOTE

Notes indicate information of particular interest for more efficient and convenient operation.

WARNINGS

1. Before initial use or with a new patient, disinfect and clean the *GoodKnight H₂O* heated humidifier as described in the section "Cleaning and Maintaining the Device" on page 8.
2. Before using, please inspect your *GoodKnight H₂O* heated humidifier, as described in the section "Checking the Components" on page 2.
3. The humidification chamber is intended for single patient use.
4. Follow the *GoodKnight H₂O* heated humidifier's installation instructions as described in the chapter titled "Installation" on page 4.
5. Do not use the *GoodKnight H₂O* heated humidifier in the presence of flammable anaesthetics products, independently or in mixture with other gases.
6. In the event of malfunction, contact Technical Support, the phone number for which is mentioned on the back cover of the manual. Maintenance should be performed only by trained and authorized personnel. Do not attempt to open the device.
7. Do not spill water on the *GoodKnight H₂O* heated humidifier.
8. Turn the *GoodKnight H₂O* heated humidifier off after use.
9. Pay special attention to the safety instructions in the *GoodKnight 420* or *GoodKnight 425* patient manual before using the *GoodKnight H₂O* heated humidifier with one of these devices.
10. To reduce the risk of personal injury, do not use the *GoodKnight H₂O* heated humidifier if the room temperature is warmer than 95° F (35 °C), because the temperature of the air flow may exceed 106 ° F (41 °C).

Indications for Use

The Puritan Bennett *GoodKnight H₂O* is an accessory intended to warm and add moisture to the inspiratory gas flow for administration to a patient undergoing CPAP or bi-level therapy.

This device is intended for use with adult patients receiving CPAP or bi-level therapy for the treatment of Obstructive Sleep Apnea in either the homecare or the hospital environment.

Precautions

The *GoodKnight H₂O* Heated Humidifier should not be used in patients with a deviation of the subglottic airways.

For precautions associated with the CPAP and bi-level devices, please refer to the section titled “Precautions for Use” in the Patient Manual of the relevant device.

The *GoodKnight H₂O* Heated Humidifier should be filled with water only.

Checking the Components

Please check that you have the following items:

- *GoodKnight H₂O* heated humidifier including water chamber
- Adapter for the connection to CPAP or bi-level pressure device
- *GoodKnight H₂O* heated humidifier power supply cord
- User's manual

In addition, you must have:

- Compatible *GoodKnight 420* or *GoodKnight 425* Series therapeutic device
- Corresponding power supply module
- Breathing circuit
- Non-invasive patient interface (mask)
- Device patient manual

CAUTION

Before each use, check the state of the water chamber. If it is damaged, contact the Service Provider.

In the event that an additional oxygen supply is needed, you must also have an oxygen adapter to connect between the patient circuit and the air outlet located on the water chamber.

DESCRIPTION OF THE HEATED HUMIDIFIER

The elements of the *GoodKnight H₂O* heated humidifier are described in Figures 1 and 2.

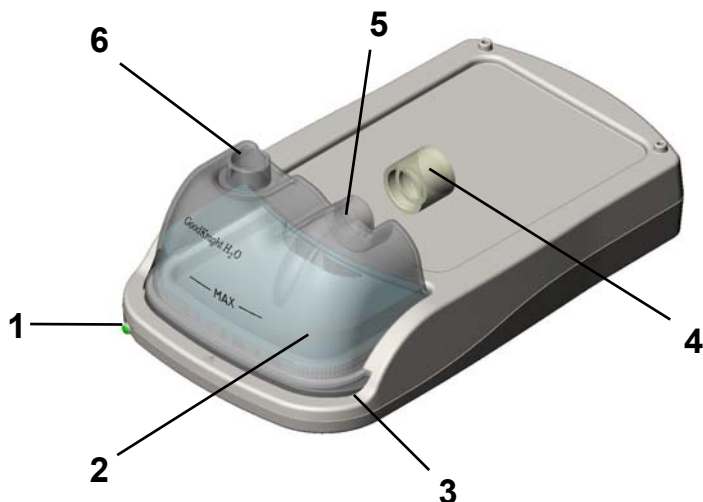


Figure 1 – General view

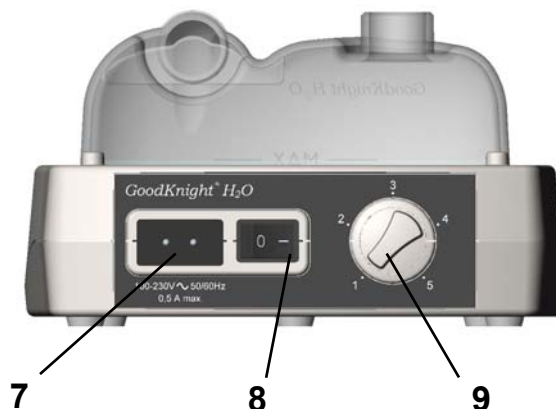


Figure 2 – Rear view

1. Operating indicator

A green indicator that illuminates when the device is connected to an AC power outlet and the ON/OFF switch is in the “1” (on) position (Figure 2).

2. Water chamber

Transparent plastic humidifier water container on which the maximum water fill level is indicated.

3. Heater

Located under the water chamber, heats the water contained in the chamber.

4. Connection adapter

Allows connection between the *GoodKnight H₂O* heated humidifier and the *GoodKnight 420* or *GoodKnight 425* device.

5. Inlet connector

Connector located on the water chamber into which the connection adapter is inserted

6. Outlet connector

Opening located on the water chamber to which the breathing circuit is connected and through which the water chamber is filled.

7. Supply connector

Connects the *GoodKnight H₂O* Heated Humidifier power supply cord to the power outlet.

8. ON/OFF switch

Used for switching the *GoodKnight H₂O* heated humidifier on or off.

9. Heater power adjustment dial

This rotary dial, graduated from 1 to 5, is used to adjust the heater’s power output. By default, this dial is set to the *minimum* power output (position 1). When it is set in position 5, the heater delivers maximum power.

INSTALLATION

The *GoodKnight H₂O* heated humidifier is designed to be used by a patient equipped with a *GoodKnight* CPAP device or with a *GoodKnight* bi-level pressure device.

WARNING

- **The water chamber is intended for single patient use.**
- **Always disconnect the *GoodKnight H₂O* Heated Humidifier prior to performing the following instructions:**

1. Remove the water chamber.

CAUTION

Before using the *GoodKnight H₂O*, always ensure that the water chamber is clean. Refer to the section "Cleaning and Maintaining the Device" on page 8.

2. Carefully fill the water chamber with water through the outlet connector opening (Figure 1, item 6, on page 3). Do not fill past the maximum water level mark.

CAUTION

- **It is advised to fill the chamber with distilled water or boiled and cooled tap water.**
 - **Do not add any products to the water in the chamber.**
 - **Use only room temperature water, do not fill the chamber with hot or chilled water.**
 - **Fill the water chamber away from the *GoodKnight H₂O* heated humidifier base to avoid spilling water onto it.**
3. Place the *GoodKnight H₂O* heated humidifier onto a flat, even surface.
 4. Equip the *GoodKnight 425* or *GoodKnight 420* device with the connection adapter provided with the *GoodKnight H₂O* heated humidifier (reference 4 of Figure 1 – General view on page 3).
 5. Position the *GoodKnight 425* or *GoodKnight 420* device onto the *GoodKnight H₂O* heated humidifier, as shown in Figure 3 on page 5.
 - The *front* of the *GoodKnight 425* or *GoodKnight 420* device must be turned *towards* the connections of the *GoodKnight H₂O* heated humidifier.
 - The *base* of the *GoodKnight 425* or *GoodKnight 420* device must be *inserted* into the *recessed* area of the humidifier.

CAUTION

- Install the humidifier and CPAP or bi-level device onto a flat, stable surface and keep them out of contact with flammable materials.
- Never place the *GoodKnight H₂O* on top of the CPAP or bi-level device. Doing so could allow water into the device, potentially causing damage.

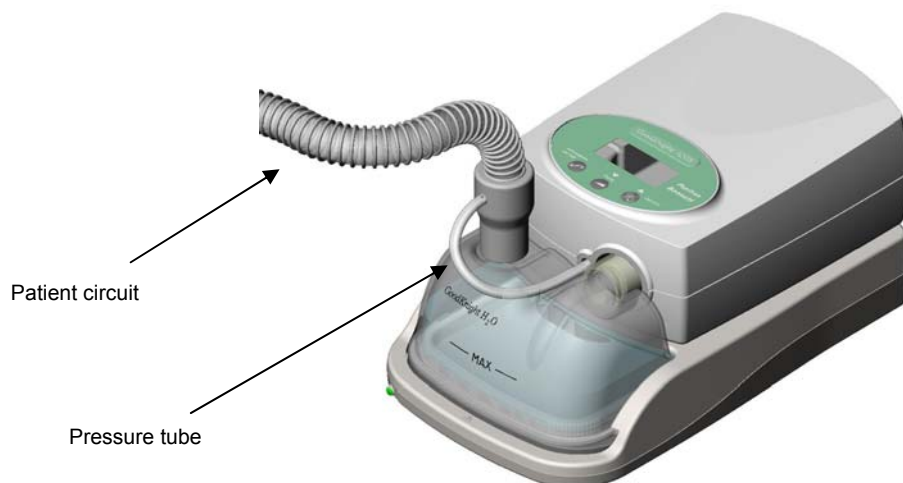


Figure 3 – Connection of the *GoodKnight 420* or *GoodKnight 425* to the *GoodKnight H₂O* heated humidifier

6. Replace the water chamber, being careful to avoid spillage, and ensure that the inlet connector of the humidifier (Figure 1, item 5 on page 3) reaches the thrust on the connection adapter (Figure 1, item 4 on page 3).
7. Connect the pressure tube from the breathing circuit to the *GoodKnight 425* or *GoodKnight 420* pressure port (this stage is not necessary with a *GoodKnight 420G*, because this device has no pressure port).
8. Connect the breathing circuit to the outlet connector of the humidifier (Figure 1, item 6 on page 3) located on the water chamber.
9. Follow the instructions contained in the chapter titled “Installation” in the patient manual for your *GoodKnight 420* or *GoodKnight 425* device to complete the set-up and to start therapy.

CAUTION

Disconnect the *GoodKnight 420* or *GoodKnight 425* device from the *GoodKnight H₂O* heated humidifier and empty the water chamber before carrying or moving the assembly. Failure to do so risks introducing water into the CPAP or bi-level device that can cause irreversible damage.

USING THE HUMIDIFIER

WARNING

- The water chamber is intended for single patient use.
- In the manual sections “Starting Treatment” and “Stopping Treatment” below, strictly follow the order of instructions to reduce the risk of accidents.

Adjusting the GoodKnight H₂O Heater

The heater power is adjusted using the rotary dial located at the rear of the humidifier. In position 1, the heater is set at its minimum. In position 5, the heater delivers its maximum power.

Starting Treatment

The *GoodKnight H₂O* heated humidifier must be filled with fresh water and connected to the *GoodKnight 420* or *GoodKnight 425* device as described in the “Installation” section on page 4.

1. Connect the power cord to the *GoodKnight H₂O* heated humidifier supply connector (Figure 2, item 7 on page 3) and to an AC power outlet.
2. Start the *GoodKnight 420* or the *GoodKnight 425* device by following the instructions contained in the patient manual.

WARNINGS

- Ensure that the water chamber is placed in the humidifier. If not, replace it; otherwise, contact with the heater could cause burns.
 - Check that the water chamber has been filled up to its maximum level to allow humidification.
 - When the *GoodKnight 420* or *GoodKnight 425* device is in operation mode, verify that air is flowing. If no air flow exists, stop the device immediately and contact Technical Support.
3. Start the *GoodKnight H₂O* heated humidifier by pressing the ON/OFF switch (Figure 2, item 8 on page 3). The green operating indicator illuminates.
 4. Adjust the humidification using the heater power adjustment dial (Figure 2, item 9 on page 3). Humidification is highest when the dial is set to 5.

CAUTION

- If condensation seems to be excessive in the chamber or in the patient tubing, or if water droplets appear on the interface, set the heater power to a lower value.
- If you experience dryness symptoms, increase humidity slowly to alleviate the symptoms.

NOTE

The *GoodKnight H₂O* heated humidifier is equipped with an automatic shut-off feature which automatically shuts off the heating element when the unit has been in use longer than ten hours. In this case, the operating indicator located on the front side of the device will remain green, although in fact the heating element will no longer provide heat to the base plate. To return the humidifier to normal operation, simply turn the unit off and on again and the humidifier will return to normal operation for another operating cycle of ten hours.

Stopping Treatment

To stop treatment, do the following:

1. Turn the *GoodKnight H₂O* heated humidifier off by pressing the **ON/OFF** switch (Figure 2, item 8 on page 3).
2. Always unplug the humidifier before turning off the *GoodKnight 420* or *GoodKnight 425*.

CAUTION

Always disconnect the *GoodKnight H₂O* humidifier from the *GoodKnight 420* or *GoodKnight 425* device after use to prevent humidity from entering the machine and degrading its performance.

3. Turn the CPAP or bi-level pressure device off; follow the instructions contained in the section titled “Stopping Treatment” in the corresponding patient manual.

CLEANING AND MAINTAINING THE DEVICE

WARNING

- Always unplug the *GoodKnight H₂O* heated humidifier from the AC power outlet before cleaning the humidifier. Let it cool.
- Between patients, clean the *GoodKnight H₂O* heated humidifier at any material recovery; refer to the corresponding section, below.

At home

1. Remove the breathing circuit from the *GoodKnight 425* or *GoodKnight 420* device and disconnect it from the *GoodKnight H₂O* Heated Humidifier by removing the connection adapter. Let the humidifier cool.
2. Remove the water chamber.
3. Empty the water chamber, then open it by separating the upper part from the base, as shown in Figure 4. To facilitate opening the chamber, use the following method :
 - Position the extraction tool (Ref. M-414600-12) as shown in Fig. 4.1.a.
 - Lift the chamber slightly by pulling on the chamber and pushing down on the plate with the tool (Fig.4.1b).
 - Slide the tool between the chamber and the plate (Fig. 4.2).
 - Push up and down to open (Fig. 4.3).

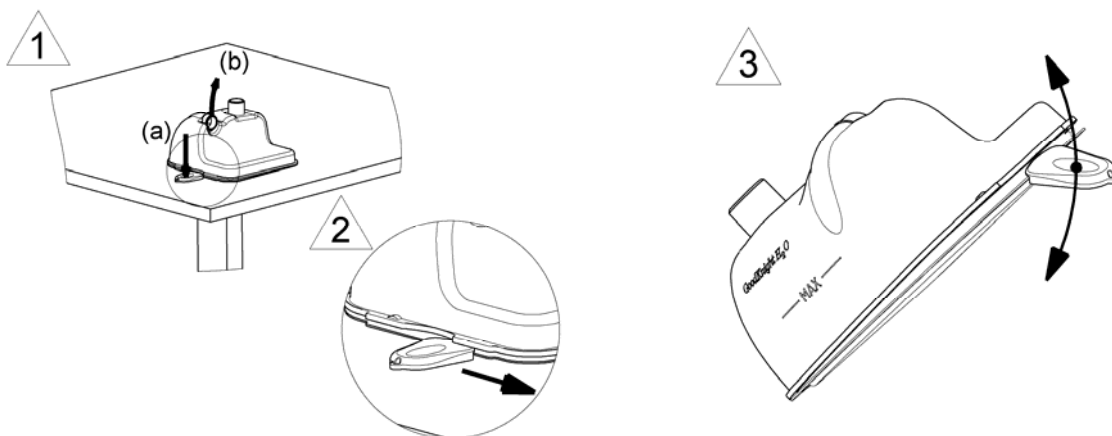


Figure 4 – View of the Water Chamber

4. Daily, clean the two parts of the chamber with warm soapy water and rinse thoroughly with tap water. Dry the external part using a clean cloth. Reassemble the upper part with the base of the chamber.
5. Once a week, soak the open chamber for 15 minutes in a solution of one part white vinegar to 9 parts water. Rinse with tap water and dry the external part using a clean cloth.
6. Clean the external part of the *GoodKnight H₂O* heated humidifier regularly using a cloth moistened with warm soapy water. Dry the humidifier thoroughly.

WARNING

Check that the *GoodKnight H₂O* heated humidifier is dry before reconnecting it to the mains (AC power).

Preparation for Use By a New Patient / After Technical Servicing

1. Dispose of the used chamber water.
2. Clean the external part of the *GoodKnight H₂O* heated humidifier using a detergent product. Dry the humidifier thoroughly.

CAUTION

The *GoodKnight H₂O* should be opened only by trained and authorized personnel.

If the *GoodKnight H₂O* has not been used for an extended period, empty the water from the chamber and follow the cleaning procedure before using it again.

LIST OF AUTHORIZED ACCESSORIES

GoodKnight H₂O Heated Humidifer:

P/N Y-GKH20-NA.

Water chamber assembly (upper chamber + base):

P/N M-314600-00.

Connection adapter water chamber/CPAP:

P/N M-414600-05.

Power cord US:

P/N M-660600-39.

22mm Ø 1.80 m long breathing circuit:

P/N M-261000-04 ; M-261000-27.

Extraction tool:

Ref. M-414600-12.

TROUBLESHOOTING

The *GoodKnight H₂O* heated humidifier does not require any servicing if you clean and maintain it in accordance with the instructions in this manual. If the device *does* malfunction, refer to the following table.

Problem	Probable Cause	Recommended Action
The <i>GoodKnight H₂O</i> humidifier is not working and the green operating indicator is not illuminated.	<ul style="list-style-type: none"> The <i>GoodKnight H₂O</i> is not properly connected. The heated humidifier is not switched on. No AC power. 	<ul style="list-style-type: none"> Check the connections between the <i>GoodKnight H₂O</i> and the AC power outlet. Press the ON/OFF switch located on the rear side of the device. Use another appliance (such as a lamp, radio etc.) to determine if AC power is present at the outlet.
The <i>GoodKnight H₂O</i> humidifier does not warm the water but the operating indicator is illuminated.	The heater is faulty.	Confirm that the heater is working: Turn the heater power adjustment dial up to a setting of 2, then hold your hand above the heater. If the heater does not warm, contact Technical Support.
Dry nose.	The level of humidification is too low.	Increase the level of humidification slowly by using the heater power adjustment dial (Figure 2, item 9 on page 3).
Water has spilled into the <i>GoodKnight H₂O</i> heated humidifier.	n/a	Unplug the heated humidifier from the AC power outlet and dry it thoroughly.
Water droplets appear in the breathing circuit.	<ul style="list-style-type: none"> The water level is too high in the chamber. The steam condensation is excessive. 	<ul style="list-style-type: none"> Check that the water level is not higher than the maximum water level mark in the chamber. Remove any excess water from the chamber. Turn the heater power adjustment dial down (Figure 2, item 9 on page 3) to set the humidification to a lower level.
White deposits appear in the water chamber.	Mineral deposits resulting from use of tap water with high mineral content.	Rub the traces with a sponge and a crockery (descaling) liquid. Rinse thoroughly with distilled water.
The <i>GoodKnight H₂O</i> is not running properly and seems subject to interference.	Excessive electromagnetic interference.	Move the device away from sources of interference, such as halogen lamps and cellular phones.
The <i>GK425</i> or <i>GK420</i> does not deliver air flow.	<ul style="list-style-type: none"> The connection between the heated humidifier and the <i>GK425</i> or <i>GK420</i> is incorrect. <i>GK425</i> or <i>GK420</i> operation is incorrect. 	<ul style="list-style-type: none"> Check that the connection between the <i>GK425</i> or <i>GK420</i> device and the heated humidifier, via the connection adapter, is correct. Contact Technical Support.
The <i>GK420</i> or <i>GK425</i> is not delivering the correct pressure(s), per the display.	The pressure tube is not connected (not true for the <i>GK420G</i>).	Check that the pressure tube is properly connected to the device.

TECHNICAL SPECIFICATIONS

Performance

Pressure fall according to flow:	0.2 cmH ₂ O
Service maximum pressure:	25 cmH ₂ O
Maximum gas temperature at the breathing circuit outlet:	106° F (41°C)
Humidification rate:	12 mg H ₂ O/L at 60 L/min and at the maximum setting
Heating time:	≤ 45 minutes

Physical Characteristics

Dimensions (W x H x L):	6.7 in x 3.7 in x 11 in (including the water chamber)
Weight (when empty):	1.76 lb (including the water chamber)
Operational volume: (minimum gas volume in chamber)	213 cm ³
Volume (usable) of water chamber:	350 mL
Maximum liquid level:	Indicated on the chamber

Transport and Storage Conditions

Temperature:	-20°C to +60°C (-4 °F to +140 °F)
Relative humidity:	up to 95 % without condensation
Relative pressure range:	500 hPa to 1060 hPa (1 hecto-Pascal \simeq 1 cmH ₂ O)

Operating Conditions

Maximum temperature:	+5°C to +35° C (+41 °F to +95 °F)
Relative humidity:	between 15 % and 95 % without condensation
Relative pressure range:	700 hPa to 1060 hPa (1 hecto-Pascal \simeq 1 cmH ₂ O)

Disposal

In order to protect the environment, various parts of the equipment and its accessories must be disposed of in conformity with the local regulations.

Electrical characteristics

Input voltage: 100 VAC ($\pm 15\%$), 120 VAC (+ 10 % / - 20 %), 230 VAC ($\pm 10\%$), 50 / 60 Hz
(power supply cord adaptable in accordance with the country).

Maximum power consumed: 40 W



Class II (double insulation)

Symbols

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 to sale by or on the order of a physician.

WARRANTY

Puritan Bennett warrants the **GoodKnight H₂O** heated humidifiers devices to be free from defects in material and workmanship for two (2) years following the delivery of the device to the original purchaser.

Puritan Bennett shall repair or replace any part or parts of the device that Puritan Bennett's examination shall disclose to have become defective within the warranty period. At Puritan Bennett's discretion, it may elect to supply a similar, new, or equivalent replacement, or refund the purchase price (as of the date of Puritan Bennett's sale of the device). To qualify for such repair, replacement, or refund, the defective device must be returned within thirty (30) days after discovery of the defect. Such repair, replacement, or refund obligation does not apply to any device which has been repaired or altered outside Puritan Bennett's facility or which has been—in Puritan Bennett's judgement—subjected to misuse, negligence, or accident.

APPENDIX A

Test Standards

Standard Type	Standard Number	Description
SAFETY USA	UL 60601-1	Medical Electrical Equipment, General Requirements for Safety, (2 nd Edition)
SAFETY Canada	CAN/CSA C22.2 No. 601.1-M90	Safety of Medical Electrical Equipment, General Requirements (Supplement 1:1994), (A2:1998)
SAFETY Europe & International	EN 60601-1 (Compliant with all applicable collateral standards and particular requirements)	Medical Electrical Equipment, Part 1: General Requirements for Safety, 1st Edition, 1988. (A1:1993), (A2:1995)
Other Standards	EN 60601-1-2 (Compliant with all applicable tests)	Medical Electrical Equipment, Collateral Standard: EMC - Requirements and Test, 2nd Edition, 2001
	CISPR 11	EMC Disturbance Characteristics - Limits and Methods of Measurement, Industrial Scientific and Medical (ISM) RF Equipment, Edition 3.1, 1999-08

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