

PHILIPS

RESPIRONICS

DreamStation

Heated Humidifier



User manual

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Intended Use

The DreamStation Heated Humidifier is an accessory for the Philips Respironics DreamStation therapy devices to provide moisture to the patient circuit. It is intended for use in spontaneously breathing patients who use mask-applied positive pressure ventilation therapy in the home or hospital/institutional environment.

The DreamStation Heated Humidifier is compatible with the following Philips Respironics ventilatory support systems:

- DreamStation BiPAP S/T
- DreamStation CPAP
- DreamStation BiPAP Pro
- DreamStation BiPAP AVAPS
- DreamStation CPAP Pro
- DreamStation Auto BiPAP
- DreamStation BiPAP autoSV
- DreamStation Auto CPAP



Warning: Use only the cleaning methods outlined in your user manual. Philips is unable to verify the safety or performance of any device if ozone or other unapproved cleaning and disinfection methods are used.

Warnings

A warning indicates the possibility of injury to the user or the operator.

- Use the humidifier only for its intended use as described in this manual. Use only with masks and connectors recommended by Philips Respironics.
- Periodically inspect the humidifier for signs of wear or damage. Never operate the humidifier if any parts are damaged, if it is not working properly, or if the humidifier has been dropped or mishandled. Do not use the humidifier if the water tank is leaking or damaged in any way. Have any damaged parts replaced before continuing use.
- Periodically inspect the therapy device power cord for signs of wear or damage. If it becomes worn or damaged, contact Philips Respironics or your home care provider for a replacement.
- The humidifier must always be positioned below the breathing circuit connection at the mask. The humidifier must be level for proper operation.
- Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient.
- Allow the humidifier heater plate and water to cool down for approximately 15 minutes before removing the water tank. A burn may result from: touching the heater plate, coming in contact with the heated water, or touching the tank pan.
- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- When installing the water tank, do not allow any water to spill into the humidifier or therapy device.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, or if the enclosure is broken, disconnect the power cord from the therapy device and discontinue use. Contact your home care provider.
- Before cleaning the humidifier, always remove from the therapy device.
- Empty and clean the water tank daily to prevent mold and bacteria growth.
- Repairs and adjustments must be performed by Philips Respironics-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- Do not use any accessories, detachable parts, and materials not recommended by Philips Respironics. Incompatible parts or accessories can result in degraded performance.
- To prevent disconnection of the tubing or tubing system during use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.
- Do not use the humidifier at an altitude above 2286 m (7500 ft) or outside a temperature of 5° C to 40° C (41° F to 104° F). Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient.

Note: Please see the “Limited Warranty” section of this manual for information on warranty coverage.

Cautions

A caution indicates the possibility of damage to the device.

- Do not place the humidifier directly onto carpet, fabric, or other flammable materials.
- Do not place the device in or on any container that can collect or hold water. Take precautions to protect furniture from water damage.
- Do not fill the water tank above the maximum fill line. If the water tank is overfilled, water may leak into the therapy device, humidifier, or onto your furniture. Damage to the humidifier or therapy device may occur.
- Use only room temperature distilled water in the tank. Do not put any chemicals or additives into the water. Possible airway irritation or damage to the water tank may result.
- Remove the tank, empty all water, and replace the empty tank before transporting the humidifier base.
- Do not attempt to fill the water tank while it is still inside the humidifier.
- To avoid spilling, do not disconnect the humidifier from the therapy device with water in the tank. Remove the water tank from the humidifier before disconnecting the therapy device.
- Do not turn the humidifier on without the water tank installed. The Humidifier setting must remain "off" if there is no water in the water tank.
- Do not move the humidifier while the water tank has water in it.
- Use a mild liquid dishwashing detergent only for either hand washing or when using a dishwasher.
- Only the hospital and institution cleaning procedures listed in this manual are recommended by Philips Respironics. Use of other cleaning and disinfecting processes, not specified by Philips Respironics, may affect the performance of the product.

Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of CPAP therapy for some patients:











- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Bypassed Upper Airway
- Pneumothorax
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus. (Chest 1989; 96:1425-1426)

The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of a sinus or middle ear infection. Not for use with patients whose upper airways are bypassed. Contact your health care professional if you have any questions concerning your therapy.

Refer to the instructions that accompanied your therapy device for any additional contraindications that may be specific to the use of that device.

Symbol Key

The following symbols may appear on the device:

| Symbol | Definition | Symbol | Definition |
|---|---|---|--|
|  | Maximum Fill Line |  | Type BF Applied Part |
|  | Hot Water, Hot Surface |  | Separate collection for electrical and electronic equipment per EC Directive 2012/19/EU. |
|  | Follow Instructions for Use |  | China RoHS - Environmentally Friendly |
| IP22 | Drip Proof Equipment |  | MR unsafe Do not use device in a Magnetic Resonance (MR) environment. |
|  | Medical Device Indicates that the item is a medical device. |  | Importer Indicates the entity importing the medical device into the EU. |
|  | Date of Manufacture: to indicate the date on which a product was manufactured Country of Manufacturer: to indicate the country of manufacture of the product Note: When applied to the label, "CC" is replaced by the two letter country code | | |

System Overview

The DreamStation Heated Humidifier attaches to the therapy device and provides an air outlet port to connect a breathing circuit. The breathing circuit is comprised of patient tubing, a mask, and in some instances a separate exhalation device. The patient tubing can be Respironics heated tubing, 22 mm (non-heated) performance tubing, 15 mm (non-heated) performance tubing, or optional 12 mm performance tubing. For information related to the mask to be used, including any need for a separate exhalation device, refer to the instructions that accompany both the mask and therapy device.

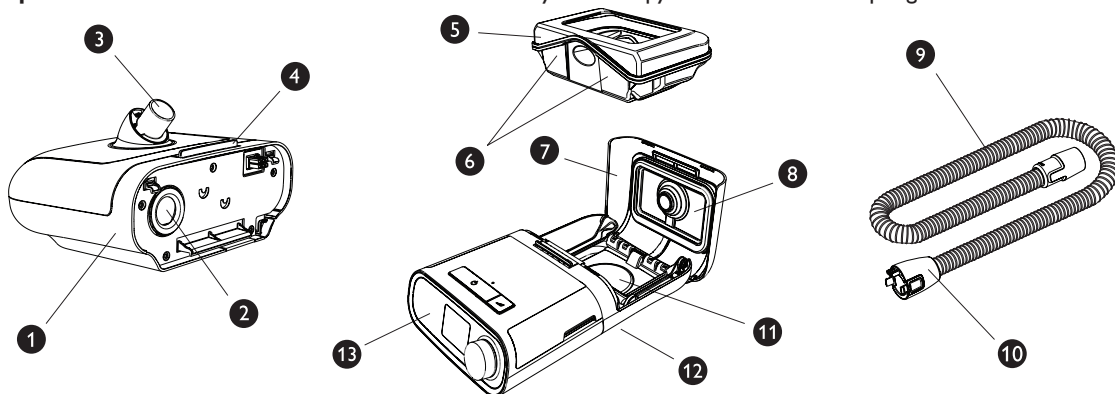
The DreamStation Heated Humidifier with Heated Tubing is designed to deliver humidification to provide added comfort during therapy. This humidification level is controlled through the output of the heated humidifier as well as the temperature of the optional heated tubing. Use of these two accessories allows for a comfortable level of humidity to be maintained at the mask.

The DreamStation Heated Humidifier is comprised of the following components:

- **Heated Humidifier** - The heated humidifier is the primary source of humidification. Humidification is controlled by adjusting the temperature of the heater plate. The heater plate is then used to heat water found in the water tank. This manual includes instructions that explain how to set up and take care of the heated humidifier. For instructions on how to adjust the heated humidifier settings, refer to the manual that accompanied the therapy device.
- **Water Tank** - The water tank stores the water that will be used by the heated humidifier. This manual includes instructions that explain how to use and take care of the water tank.
- **Heated Tubing** - The heated tubing is an optional accessory that is used, along with the heated humidifier, to control the provided humidification. This is accomplished by controlling the temperature of the air in order to ensure that it does not cool down prior to reaching the mask. This manual includes instructions that explain how to connect and take care of the heated tubing. For instructions on how to adjust the temperature of the heated tubing, refer to the manual that accompanied the therapy device.

System Features and Contents

Important: Read and understand the entire manual for your therapy device before attempting to use this humidifier.



This figure illustrates many of the device features and contents, described in the following table.

| # | Device Feature | Description |
|----|-----------------------------------|--|
| 1 | Humidifier | Connect your therapy device here. |
| 2 | Air Inlet Port | Connects to the outlet port on the therapy device. |
| 3 | Air Outlet Port | Connect the tubing here. |
| 4 | Humidifier Lid Release Latch | Slide this latch to open the humidifier lid. |
| 5 | Water Tank | This one piece removable water tank holds the water for humidification. |
| 6 | Maximum Fill Lines | The fill lines indicates the maximum water level for safe operation. |
| 7 | Humidifier Lid | Open the lid to access the water tank. |
| 8 | Humidifier Lid Seal | Seals the water tank to the humidifier lid. |
| 9 | Flexible Heated Tubing (optional) | The optional heated tube connects from the humidifier to the your mask. |
| 10 | Humidifier Connector End | Connect this end of the tubing to the humidifier. |
| 11 | Heater Plate | Warms the water in the water tank. |
| 12 | Humidifier Release Button | Press this button to remove the humidifier from the therapy device. Refer to the "Disconnecting the Therapy Device" section of this manual to see this button. |
| 13 | Therapy Device | The heated humidifier connects to the back of the therapy device. |

Note: This humidifier is specified for use with Philips Respironics DreamStation therapy devices only.

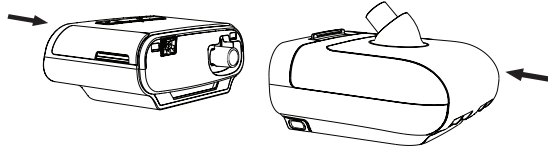
How to Contact Philips Respironics

Should you experience trouble with this equipment or require assistance setting up, using, or maintaining the device or accessories, please contact your home care provider. If you need to contact Philips Respironics directly, call the Philips Respironics Customer Service department at 1-724-387-4000. You can also use the following address:

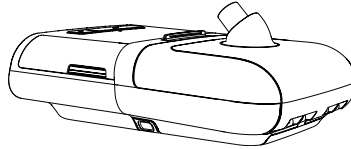
Respironics, Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

Connecting to the Therapy Device

1. Place the therapy device and heated humidifier (with an empty water tank) on a firm, flat surface.
Caution: Do not move the humidifier while the water tank has water in it.
2. Line up the back of the therapy device to the front (top lid release latch side) of the heated humidifier.
3. Make sure the air outlet port on the therapy device lines up with the air inlet port on the humidifier (not shown).
4. Slide the two units together until they snap into place.

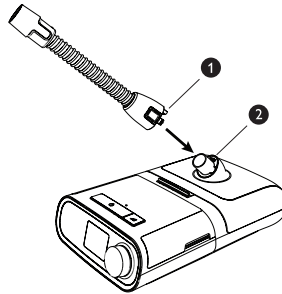


5. Make sure that the therapy device and the humidifier are completely seated against each other.

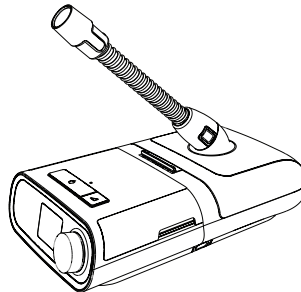


Connecting the Tubing

1. To attach the heated tube to the heated humidifier, line up the connector (1) at the top of the heated tube to the top of the air outlet port (2) on the humidifier.



2. Press the tubing into place over the air outlet port until the tabs on the side of the tube click into place in the slots on the sides of the outlet port.



Note: If you are using a standard tube (not shown) instead of a heated tube, simply slide the tubing over the air outlet port on the heated humidifier.

Note: If you are using the optional 12 mm tubing, an adaptor is required to connect to the therapy device.

Important: Before each use, examine the tubing for any kinks, damage, or debris. If necessary, clean the tubing to remove the debris. Replace any damaged tubing.

Daily Use

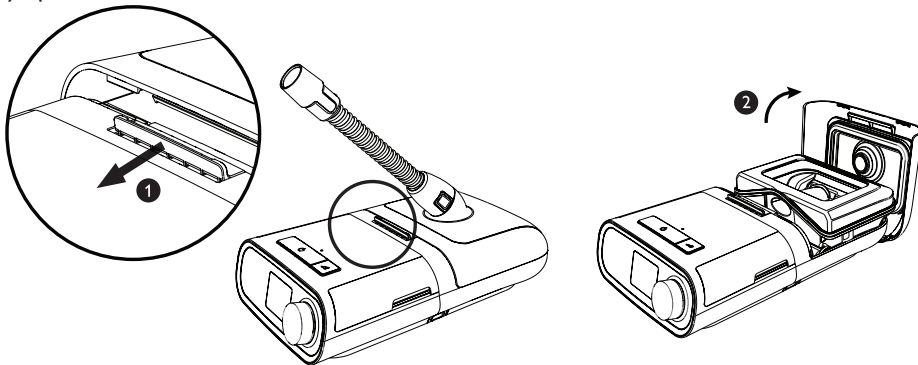
1. Place the connected therapy device with humidifier on a firm, flat surface lower than your sleeping position.

Warning: The humidifier must always be positioned below the breathing circuit connection at the mask. The humidifier must be level for proper operation.

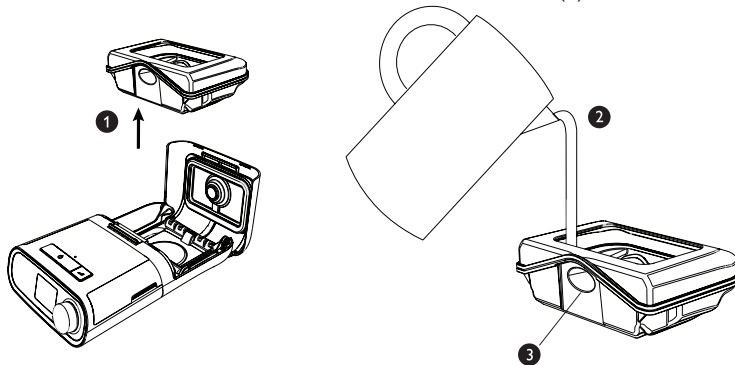
Caution: Do not place the humidifier directly onto carpet, fabric, or other flammable materials.

Caution: Do not place the device in or on any container that can collect or hold water. Take precautions to protect furniture from water damage.

2. Slide the humidifier lid release latch (1) toward the therapy device. Lift up on the humidifier lid (2) and swing completely open.



3. Remove the tank (1) by grabbing both sides of tank and lifting out of the humidifier base. Rinse the tank with water. Place the tank on a firm, flat surface. Fill the tank with water (2) no higher than the maximum fill line (MAX). To avoid spilling, the water level should not rise above the bottom of the tube (3) in the back of the water tank.



Note: Clean the water tank before first use. Refer to the “Home Cleaning Instructions: Water Tank” section in this manual.

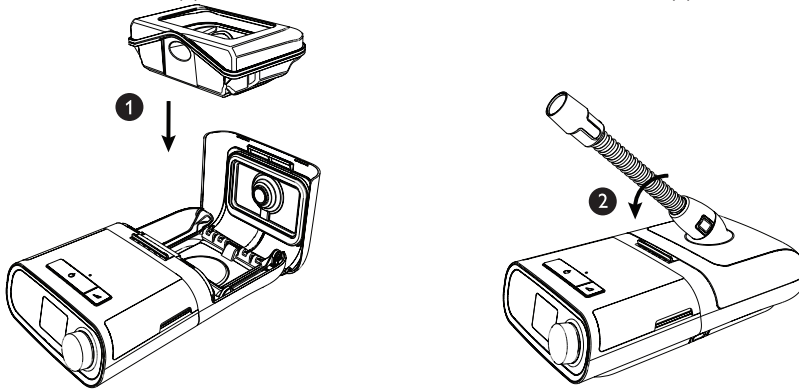
Caution: Do not attempt to fill the tank while it is still inside the humidifier.

Caution: Use only room temperature distilled water in the tank. Do not put any chemicals or additives into the water. Possible airway irritation or damage to the water tank may result.

Caution: Do not fill the water tank above the maximum fill line. If the water tank is overfilled, water may leak into the therapy device, humidifier, or onto your furniture. Damage to the humidifier or therapy device may occur.

Warning: Allow the humidifier heater plate and water to cool down for approximately 15 minutes before removing the water tank. A burn may result from: touching the heater plate, coming in contact with the heated water, or touching the tank pan.

4. Carefully replace the water tank (1) into the humidifier and close the humidifier lid (2) until it snaps shut.



Warning: When installing the tank, do not allow any water to spill into the humidifier or therapy device.

Caution: Do not move the humidifier while the water tank has water in it.

5. Supply power to your therapy device. Refer to the manual included with your therapy device.
6. Put on your mask assembly. Refer to the instructions supplied with the mask.
7. Turn on the airflow on your device and begin therapy. Refer to the manual included with your therapy device.

Note: If you are having trouble with your mask, refer to the instructions included with the mask.

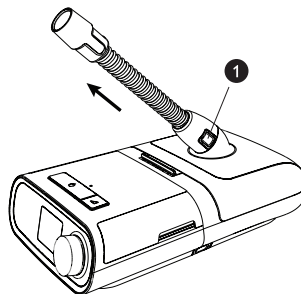
8. Refer to your therapy device manual for complete instructions on how to adjust both the Heated Humidifier and the optional Heated Tubing settings to achieve the desired humidity.

Caution: Do not turn the humidifier on without the water tank installed. The humidifier setting must remain “off” if there is no water in the water tank.

9. Refer to the manual included with your therapy device for instructions to turn off therapy.

Disconnecting the Tubing

To remove the heated tubing, press in the tabs (1) on the side of the tubing connector and pull the tubing away from the outlet port.

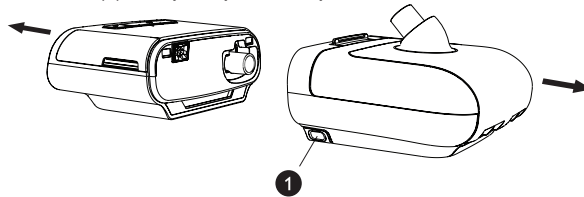


Note: If you are using a standard tube (not shown) instead of a heated tube, simply pull the tubing away from the outlet port.

Disconnecting the Therapy Device

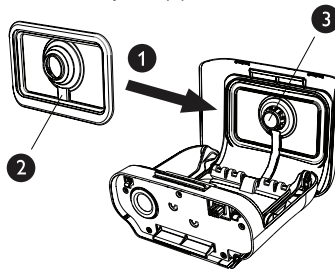
Caution: To avoid spilling, do not disconnect the humidifier from the therapy device with water in the tank. Remove the water tank from the humidifier before disconnecting the therapy device.

1. Disconnect power to the therapy device.
2. Pick up the system.
3. Place one hand on the therapy device and the other on the humidifier.
4. Press the humidifier release button (1) and pull apart to separate.



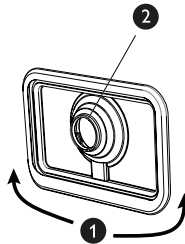
Checking the Humidifier Lid Seal

To install or reseal your humidifier lid seal, fully open the humidifier lid. Position the seal (1) against the inside of the lid so the seal's center hole aligns with the humidifier outlet port. Confirm that the seal is positioned so the wire channel (2) in the seal is below the humidifier outlet port (3).



Note: The seal only fits properly in one orientation.

With the seal loosely in place, start at the bottom (1) and gently press the edges of the seal into the channel in the lid of the humidifier. Continue sliding your fingers all around the rectangular perimeter of the seal until the outer edge is completely seated. Next, press the seal around the humidifier outlet port (2) until the center of the seal is fully seated. Finally, go back and run your fingers around the rectangular perimeter of the humidifier lid seal once more to confirm it has not become dislodged.



Home Cleaning Instructions: Water Tank and Seal

Clean the water tank and seal before first use. Hand wash the water tank and seal daily or wash it in a dishwasher, weekly.

1. Turn the humidifier setting to off. Turn the therapy device off. Allow the heater plate and water to cool.

Warnings: Allow the humidifier heater plate and water to cool down for approximately 15 minutes before removing the water tank. A burn may result from touching the heater plate, coming in contact with the heated water, or touching the tank pan.

Warning: Empty and clean the water tank to prevent mold and bacteria growth.

Warning: Before cleaning the humidifier, always remove the humidifier from the therapy device.

2. Open the humidifier lid with the release lever and remove the water tank from the humidifier. Empty any remaining water from the base of the tank. Carefully separate the seal from the tank.
3. Wash the water tank and seal in the dishwasher (top shelf only) or in a solution of warm water and a mild liquid dish washing detergent. Use 1 teaspoon (5 milliliters) of liquid dish washing detergent per gallon (3.8 liters) of water. Rinse with potable water for at least 1 minute.
4. Inspect the water tank and seal to ensure that it is visibly clean. Wipe it again completely with a cloth dampened with water if necessary.
5. Wipe completely on the top and bottom. Allow the water tank and seal to air dry completely.
Caution: Use a mild liquid dish washing detergent only for either hand washing or when using a dishwasher.
6. Inspect the water tank and seal for damage. If the water tank or seal show signs of wear or damage, contact your home care equipment provider for a replacement.
7. Before using the water tank, place the seal back into the tank (see Checking the Humidifier Lid Seal), and fill it with potable water no higher than the maximum fill line.

Home and Hospital Cleaning Instructions: Humidifier Base and Exterior

Warning: Allow the humidifier heater plate and water to cool down for approximately 15 minutes before removing the water tank. A burn may result from: touching the heater plate, coming in contact with the heated water, or touching the tank pan.

Warning: Before cleaning the humidifier, always remove from the therapy device.

1. Clean the humidifier base and heater plate by wiping it with a damp cloth solution of warm water and a mild liquid dish washing detergent to adequately remove adhering substances. Use 1 teaspoon (5 milliliters) of liquid dish washing detergent per gallon (3.8 liters) of water.
2. Wipe with a lint-free cloth dampened (not dripping) with potable water for at least one minute, turning the cloth frequently, to remove all detergent residue.
3. Allow to air dry completely before reconnecting to the therapy device.
4. Inspect the humidifier base for any damage and replace it if necessary.

Note: Refer to the Philips Respironics Disinfection Aid device instructions for information on cleaning the humidifier outlet port. The Philips Respironics Disinfection Aid is available for purchase separately.

Hospital and Institution Cleaning and Disinfection: Humidifier Base and Exterior

If using the humidifier on multiple users, complete the following steps to clean and disinfect the humidifier before each new user.

Warning: Allow the humidifier heater plate and water to cool down for approximately 15 minutes before removing the water tank. A burn may result from: touching the heater plate, coming in contact with the heated water, or touching the tank pan.

Warning: Before cleaning the humidifier, always remove from the therapy device.

Caution: Only the hospital and institution cleaning and disinfection procedures listed in this manual are recommended by Philips Respironics. Use of other cleaning and disinfection procedures, not specified by Philips Respironics, cannot be guaranteed to maintain the performance or durability of the product. Follow the manufacturer's instructions of the disinfection procedures.

Caution: Follow all instructions from the manufacturer of the disinfectant product. Any deviation from these instructions, the manufacturer's instructions, or agents not listed in this guide may impact the performance of the product. Review all applicable instructions for additional warnings and cautions.

Cleaning Prior to Disinfection

1. Clean the humidifier base and heater plate by wiping it with a damp cloth solution of warm water and a mild liquid dish washing detergent to adequately remove adhering substances. Use 1 teaspoon (5 milliliters) of liquid dish washing detergent per gallon (3.8 liters) of water.
2. Wipe with a lint-free cloth dampened (not dripping) with potable water for at least one minute, turning the cloth frequently, to remove all detergent residue.
3. Allow to air dry completely before reconnecting to the therapy device.
4. Inspect the humidifier base for any damage and replace it if necessary.

Note: Refer to the Philips Respironics Disinfection Aid device instructions for information on cleaning and disinfecting the humidifier outlet port.

Disinfection

Disinfect the humidifier exterior surface weekly or more often if necessary and between patients. If using the humidifier on multiple users, use one of the following methods to disinfect all exterior surfaces of the humidifier:

DisCide Ultra Towelettes

- Use towelettes to initially wipe the exterior of the enclosure to clear visible soil from the surfaces.
- Use the towelettes to thoroughly wet the exterior surfaces.

Chlorine Bleach (containing 6% sodium hypochlorite), 1 to 9 part reduction with water.

- Use a lint-free cloth to initially wipe the bleach solution onto the exterior of the enclosure to clear visible soil from the surfaces.
 - Use a lint-free cloth to thoroughly wet the exterior surfaces with the bleach solution.
5. Pay close attention to all corners and crevices of the humidifier exterior surfaces.
 6. Open the humidifier lid and disinfect the latch area with one of the disinfectants described above.
 7. Keep wet for 5 minutes.
 8. Wipe with a lint-free cloth dampened (but not dripping) with potable water for at least one minute, turning the cloth frequently, to remove all disinfectant residue.
 9. Allow the humidifier to air dry completely before plugging in the power cord.
 10. Inspect the humidifier for damage after disinfection. If any parts are damaged, contact Philips Respironics Customer Service. Replace any damaged parts.

Home Cleaning Instructions: Heated Tubing

Clean the heated tubing before first use and weekly. Replace the heated tubing every 6 months.

Important: For multi-patient use, complete the steps in the “Hospital and Institution Cleaning and Disinfection: Water Tank, Seal and Heated Tubing” section before each new user.

1. Disconnect the heated tubing from the heated humidifier.
2. Gently wash the heated tubing, including connectors, in a solution of warm water and a mild dish washing detergent to adequately remove adhering substances from the tubing and connectors. Use 1 teaspoon (5 milliliters) of liquid dish washing detergent per gallon (3.8 liters) of water.

Note: Be sure to clean the entire inner surface of the tubing by ensuring it is fully immersed in the detergent solution during gentle agitation by hand.

3. Rinse thoroughly with potable water for at least 1 minute to remove all soap residue from the tubing and connectors.
4. Visually inspect the tubing for cleanliness, including the connectors. Repeat the cleaning steps if not visually clean.
5. Allow to air dry completely out of direct sunlight. Make sure the tubing and connectors are dry before next use.
6. Inspect the heated tubing for damage or wear (cracking, crazing, tears, punctures, etc.). Discard and replace if necessary.

Home Disinfection Instructions: Water Tank, Seal, and Heated Tubing

Note: Be sure to follow the “Home Cleaning Instructions“ for the water tank, seal, heated tubing, and outlet port before disinfection.

The following process may be used for home disinfection of the water tank, seal, and heated tubing weekly.

- 70% Isopropyl Alcohol: Keep wet for 5 minutes

Note: When using Isopropyl Alcohol, thoroughly rinse the Humidifier Connector End with water and air dry completely before the next use.

Caution: Follow all instructions from the manufacturer of the disinfectant product. Any deviation from these instructions, the manufacturer’s instructions, or agents not listed in this guide may impact the performance of the product. Review all applicable instructions for additional warnings and cautions.

Caution: Rinse the tank, seal and heated tubing separately for at least one minute using potable water. Do not rinse the tank, seal and heated tubing using the same water.

1. Rinse thoroughly with potable water for at least 1 minute to remove all residue from the water tank, seal, tubing, and connectors.
2. Visually inspect for cleanliness, including the connectors.
3. Allow to air dry completely out of direct sunlight. Make sure the tubing and connectors are dry before next use.
4. Inspect the heated tubing for damage or wear (cracking, crazing, tears, punctures, etc.). Discard and replace if necessary.

Note: Refer to the Philips Respironics Disinfection Aid device instructions for information on disinfecting the humidifier outlet port. The Philips Respironics Disinfection Aid is available for purchase separately.

Hospital and Institution Cleaning and Disinfection: Water Tank, Seal, and Heated Tubing

If using the water tank, seal, and heated tubing on multiple users, complete the following steps to clean and disinfect the water tank, seal, heated tubing, and outlet port before each new user.

Caution: Only the hospital and institution cleaning and disinfection procedures listed in this manual are recommended by Philips Respironics. Use of other cleaning and disinfection procedures, not specified by Philips Respironics, cannot be guaranteed to maintain the performance or durability of the product. Follow the manufacturer's instructions of the cleaning and disinfection procedures.

Cleaning Prior to Disinfection

1. Gently wash using a commercially available anionic detergent (e.g. Medizime® LF, or equivalent enzymatic detergent) weekly and between patients. Use a soft bristle brush to adequately remove adhering substances.

Note: Pay close attention to all corners and crevices.

Note: A brush is not necessary for the inside of the tube of the heated tubing.

2. Rinse the items separately for at least one minute in potable water. Do not rinse all items together.

3. Drain the water from the water tank, seal, and heated tubing.

4. Allow to air dry completely out of direct sunlight.

5. Inspect for damage or wear (cracking, crazing, tears, punctures, etc). Discard and replace if necessary.

6. Visually inspect the tank, seal, and heated tubing for cleanliness. Repeat the cleaning if not visually clean.

Disinfection

The following processes may be used to disinfect the water tank, seal, and heated tubing weekly and between patients.

The recommended disinfection methods identified below may be used to disinfect the water tank, seal, and heated tubing for a maximum of 60 cycles. The water tank and seal should be replaced every year. The heated tubing should be replaced every 6 months.

- Thermal Disinfection: Immersion in a (potable) water bath at $75^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 30 minutes
- Cidex OPA

Note: When using Cidex OPA, thoroughly rinse the Humidifier Connector End with water and air dry completely before the next use.

Caution: Follow all instructions from the manufacturer of the disinfectant product. Any deviation from these instructions, the manufacturer's instructions, or agents not listed in this guide may impact the performance of the product. Review all applicable instructions for additional warnings and cautions.

Caution: Rinse the tank, seal, and heated tubing separately for at least one minute using potable water. Do not rinse the tank, seal and heated tubing using the same water.

After Disinfection

1. Inspect the tank, seal, and heated tubing for damage or wear (cracking, crazing, tears, or damage, etc.). Discard and replace if damaged.

2. After the final water rinse described in the chemical disinfection instructions, separately rinse the tank, seal, and heated tubing a minimum of 1 time each for at least 1 minute using potable water and air dry completely out of direct sunlight.

Note: Discoloration of the seal is normal after disinfection.

Service

The humidifier does not require routine servicing. If any part of the humidifier is worn or damaged, contact Philips Respironics or your home care provider. See the “Troubleshooting” section in this manual for additional information.

Traveling with the System

Packing the System

1. Remove the water tank, empty all water, and allow to air dry.
2. Put the empty water tank back into the device.
3. Pack your humidifier in your carry-on luggage.

Caution: Do not move the humidifier while the water tank has water in it.

When you are traveling, the optional carrying case for your therapy device can be used for carry-on luggage only. The carrying case will not protect the humidifier if it is put through checked baggage.

For your convenience at airport security stations, there is a note on the bottom of the humidifier stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the device.

If you are traveling to a country with a line voltage different than the one you are currently using with the therapy device, a different power cord or an international plug adapter may be required to make your power cord compatible with those where you visit. Contact your home care provider for additional information.

Disposal

Separate collection for electrical and electronic equipment per EC Directive 2012/19/EU. Dispose of this device in accordance with local regulations.

Troubleshooting

The table below lists some of the problems you may experience with your humidifier and possible solutions.

| Problem | Why it Happened | What to Do |
|---|---|---|
| Nothing happens when you apply power to the humidifier. | Loss of AC/DC power or the device is unplugged. | Verify that the humidifier and therapy device are properly plugged in. Make sure the AC power cord is connected correctly to the power supply, and the power supply cord is correctly plugged into the wall. If the problem continues to occur, contact your home care provider. Return the humidifier, therapy device, and power supply to your provider to determine if the problem is with the therapy device, humidifier, or power supply. |
| High Leak | The tubing is not connected correctly and doesn't seal properly. | Remove your mask and tubing, and check for kinks or tears. If it is torn or damaged, contact your home care provider or Philips Respironics for replacement tubing and/or mask. If the tubing is not damaged, reattach your tubing, turn on the airflow, and check to make sure you do not still feel air coming out of the port area. |
| | The therapy device is not seated correctly against the humidifier. | Remove the therapy device from the humidifier and reconnect. Make sure the air inlet port on the humidifier connects securely to the air outlet port on the device. If high leak persists, the issue may be caused by a missing, misaligned or damaged seal. Ensure that the dry box seal and humidifier lid seal are present, in their proper orientation and fully seated. If a seal has come loose, gently press around the edges of the seal to reseal it. |
| | The humidifier tank is not properly seated in the humidifier. | Remove the water tank from the humidifier base, and then place the tank back in the humidifier, making sure it is completely seated. If high leak persists, the issue may be caused by a misaligned or damaged seal. Ensure that the dry box seal and humidifier lid seal are present, in their proper orientation and fully seated. If a seal has come loose, gently press around the edges of the seal to reseal it. |
| The humidifier is cracked or damaged. | The humidifier was dropped or mishandled. | If the humidifier does not operate properly after being dropped or mishandled, contact your home care provider or Philips Respironics. |
| The therapy device is operating but the humidifier's airflow is low or stopped. | The humidifier has an airflow obstruction. | Contact your home care provider. Return the humidifier and power supply to your provider to determine the problem. |
| Excessive condensation in the tubing. | The humidity level setting is too high. | Reduce the humidity level setting. |
| | The humidifier is positioned incorrectly. | Verify that the humidifier and therapy device are away from air conditioning equipment. |
| Heated tube is not warming. | Heated Tubing setting is set to zero. | Make sure the heated tubing setting is not set to zero. Refer to your therapy device manual for complete instructions. |
| The humidifier has fallen off your table or night stand. | The humidifier may not have been properly positioned on the night stand, or the placement of the tubing may have caused the device to fall. | Always make sure your humidifier is placed on a hard, flat surface so the rubber feet on the bottom of the humidifier base can adhere to the surface (make sure there is no fabric under the base). The humidifier must be level for proper operation. Also, place the humidifier away from the edge of the night stand or table, so it doesn't accidentally get knocked off the table. If the humidifier falls and water gets into the therapy device, drain all water out of the therapy device. Allow it to air dry to make sure it is completely dry before reapplying power. If the placement of the tubing causes the humidifier to fall, make sure that you use proper hose management when setting up your device. Route the tubing behind the bed's headboard. If the humidifier does not operate correctly after falling, contact your home care provider or Philips Respironics. |

| Problem | Why it Happened | What to Do |
|--|--|--|
| I'm having difficulty adjusting the heated humidifier setting or the heated tube temperature setting. | The blower is not turned on, or the humidifier or heated tube is not fully connected. | The humidifier setting and tube temperature settings can only be adjusted from the Therapy ON screen on the therapy device. Confirm that the blower is turned on, and that the settings are visible on the right side of the screen, then adjust to desired comfort. If the blower is on but the humidifier settings are not displayed on the Therapy ON screen, then unplug the device. Confirm that the humidifier and/or heated tube electrical contacts are not obstructed or damaged. Then reconnect the humidifier and/or heated tube, and reconnect the device's power supply. Turn the blower on. If the settings are still not visible, contact your provider for assistance. |
| The water in the water chamber runs out before morning. | The water chamber was not full at the start of session, mask leak is excessively high, or the ambient conditions are very dry/cool. | Under most conditions, a full water chamber should last for a typical sleep session if the humidifier tank is filled to the maximum fill line at the beginning of the sleep session. However, many factors impact water consumption, including: the ambient temperature and humidity in your bedroom, your humidifier or heated tube settings, the level of mask leak, and the duration of your sleep session. First, make sure that the water chamber is filled to the maximum fill line at the start of your sleep session. Check that your mask is fitted properly, and adjust as needed to reduce mask leak to normal levels. You may use the Check Mask Fit feature to evaluate your mask fit. Also, confirm that the device, humidifier, humidifier seals and tube are connected properly and not leaking. You may also choose to lower your humidifier and/or heated tube settings or change the humidification mode from Fixed to Adaptive humidification mode to increase the time that your humidifier water will last. |
| I hear a leak or whistling sound coming from my therapy device or humidifier (not related to mask leak). | The therapy device air inlet may be obstructed. The humidifier or tube is not fully connected. The humidifier seals are not fully seated or are missing. | Check that the therapy device air inlet is not obstructed, and the filters are clean and properly inserted. Confirm that the device, humidifier, and tube are connected properly and not leaking. Confirm that the humidifier lid seal and dry box seal are present and properly seated. If needed, gently press around the perimeter of the seals to reseal them. |
| I accidentally spilled water into my humidifier basin. | The water chamber has been filled beyond the maximum fill line. | A small amount of water spilled in the basin of the humidifier will not harm your device. A small spill in the humidifier will evaporate under normal humidifier use. However, too much water in the humidifier basin could spill over the humidifier lid hinge and might damage your furniture. Disconnect power from the device. Remove the water chamber, pour out any excess water until the water level is at or below the maximum fill line and set the chamber aside. Separate the humidifier from the therapy device, and pour out the spilled water. Once the heater plate has cooled, wipe the inside of the humidifier with a paper towel or soft cloth. If needed, dry the underside of the humidifier and confirm that your table top is dry. Reconnect the humidifier and power supply, and reinstall the water chamber. |

Note: For information on troubleshooting your therapy device, see the manual included with your therapy device.

DreamStation Heated Humidifier Specifications

Environmental

Operating Temperature: 5° to 35° C (41° to 95° F)
Storage Temperature: -20° to 60° C (-4° to 140° F)
Relative Humidity (operating & storage): 15 to 95% (non-condensing)
Atmospheric Pressure: 77 to 101 kPa (0 - 2286 m / 0 - 7500 ft)

Physical

Dimensions (humidifier with therapy device): 29.7 x 19.3 x 8.4 cm (11.7" L x 7.6" W x 3.3" H)

Note: Height does not include humidifier air outlet port.

Weight (empty humidifier with therapy device and power supply): Approximately 1.98 kg (4.37 lbs.)

Service Life

The expected service life of the DreamStation Heated Humidifier is 5 years.

Maximum Recommended Pressure

25 cm H₂O

Water Capacity

325 ml (11 oz.) at recommended water level

Standards Compliance

This device is designed to conform to the following standards:

IEC 60601-1 General Requirements for Basic Safety and Essential Performance of Medical Electrical Equipment

ISO 80601-2-74 Particular Requirements for Basic Safety and Essential Performance of Respiratory Humidifying

Equipment

ISO 8185 General Requirements for Humidification Systems

Electrical

(When the heated humidifier is used with a Philips Respironics therapy device)

AC Power Consumption (with 80W power supply): 100 – 240 VAC, 50/60 Hz, 2.0-1.0 A

DC Power Consumption: 12 VDC, 6.67 A

Type of Protection Against Electric Shock: Class II Equipment

Degree of Protection Against Electric Shock: Type BF Applied Part

Degree of Protection against Ingress of Water: Drip Proof, IP22

Mode of Operation: Continuous

Electromagnetic Compatibility: The device meets the requirements of EN 60601-1-2.

Heater Plate

Max Temperature: 65° C (149° F)

Pressure Drop with Humidifier

Max: 0.6 cm H₂O at 60 LPM flow

Humidity

Humidity_{min} Output: ≥ 12 mg H₂O/L

Measured at expected leak across therapy pressures, 17° C to 35° C (63° F to 95° F), 15% RH for all compatible tubes

Heated Tubing Specifications

Maximum Recommended Pressure

25 cm H₂O

Inner Diameter

15 mm (0.6 in.)

Length

1.83 m (6 ft.)

Heated Tubing Temperature Range

16° to 30° C (60° to 86° F)

Heated Tubing Temperature Cut-out

≤ 41° C (≤ 106° F)

Material

Flexible plastic and electrical components

Electrical (Heated tubing is powered by the attached heated humidifier)

Refer to "Electrical" section of DreamStation Heated Humidifier Specifications

Environmental

Refer to "Environmental" section of DreamStation Heated Humidifier Specifications

15 mm Heated Tubing resistance

@15 l/min: 0,007 hPa/l/min (cmH₂O/l/min)

@30 l/min: 0,01 hPa/l/min (cmH₂O/l/min)

15 mm Heated Tubing compliance (@ 60hPa)

@ 60 hPa: 0,5 ml/hPa (ml/cmH₂O)

Limited Warranty

Respironics, Inc., a Philips company (“Philips Respironics”) provides this non-transferable, limited warranty for DreamStation Heated Humidifier (“Product”) to the customer who originally purchased the Product directly from Philips Respironics.

What this warranty covers: Philips Respironics warrants each new Product will be free from defects in materials and workmanship and will perform in accordance with the Product specifications under normal and proper use and maintenance in accordance with applicable instructions, subject to the exclusions below.

How long does this warranty last: two (2) years from the longer of the date of shipment to the purchaser or date of setup by purchaser for the end user, except:

- a. The warranty period for accessories, replacement parts, and disposables including, but not limited to, circuits, tubing, leak devices, exhaust valves, filters and fuses, is ninety (90) days from the date of shipment to the original purchaser.

What this warranty does not cover: This warranty does not apply to any software included with the Product as the software warranty is included in the software license. This warranty does not cover damage or injury whether to the Products, personal property, or persons caused by accident, misuse, abuse, Acts of God, water ingress, repair or alteration by anyone other than Philips Respironics or its authorized service center, failure to operate in accordance with the terms of the operating manual and instructions, lack of reasonable care, the discontinuance of a network (e.g. 2G, 3G, etc.) by a carrier (e.g. ATT, Verizon, etc.), or other defects not related to material or workmanship. This warranty is not transferable. If Philips Respironics finds that a Product returned for service or the issue raised is not covered under this limited warranty, Philips Respironics may charge an evaluation fee and return shipping.

What Philips Respironics will do: If a Product fails to conform to the warranties set forth above during the applicable warranty period, Philips Respironics will repair or replace the Product or refund the original purchase price, in Philips Respironics sole discretion. Philips Respironics may use new or remanufactured assemblies, components, and parts in repair and new or recertified refurbished devices for replacement. The balance of the original warranty period will apply to any Product or component of a Product repaired or replaced under this warranty.

Warranty Disclaimer; Limitation of Liability: EXCEPT AS SET FORTH IN THIS LIMITED WARRANTY, PHILIPS RESPIRONICS MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, STATUTORY OR OTHERWISE, REGARDING THE PRODUCT OR ITS QUALITY OR PERFORMANCE. PHILIPS RESPIRONICS SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL PHILIPS RESPIRONICS MAXIMUM LIABILITY UNDER THESE WARRANTIES EXCEED THE ORIGINAL PURCHASE PRICE OR WILL PHILIPS RESPIRONICS BE LIABLE FOR ANY ECONOMIC LOSS, LOSS OF PROFITS, OVERHEAD, OR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES. Repair, replacement, or return of purchase price by Philips Respironics is the original purchaser’s sole and exclusive remedy under this warranty.

This warranty gives you specific legal rights, and you may also have other rights that vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above exclusion and limitations may not apply to you.

How to get warranty support: Patients contact your local authorized Philips Respironics dealer and dealers contact Respironics, Inc. at:

1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550
+1-724-387-4000

Note: For Australian and New Zealand customers this warranty replaces the warranty contained above.

1. The following statement is provided to a customer who is a consumer under the Australian Consumer Law: Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the good repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.
2. The following statement is provided to a customer who is a consumer under the Consumer Guarantees Act 1993, New Zealand: Our goods come with guarantees that cannot be excluded under the Consumer Guarantees Act 1993. This guarantee applies in addition to the conditions and guarantees implied by that legislation.
3. Philips warrants that the products shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of five (5) years from the date of purchase from an authorised Philips Homecare Provider. This Warranty covers the replacement or repair at the option of Philips, of any product that has a manufacturing or material defect that is not the result of normal wear and tear, or a natural characteristic of the material used. This Warranty is not transferable and does not cover products used for commercial purposes, and it does not apply to any consumable items (including but not limited to filters, masks, tubes and humidifier chambers).
4. The customer is responsible for returning the product to an authorised Philips Homecare Provider, and collecting the product from the Homecare Provider after repair or replacement, at its own cost. Philips is responsible only for the freight cost of transporting the product between the Homecare Provider and Philips. Philips reserves the right to charge an evaluation and postage fee for any returned product where no problem is found following evaluation.
5. This Warranty does not cover:
 - products purchased outside of Australia and New Zealand
 - any damage caused as a result of misuse or abuse, modification, tampering with or alteration of the product, pest infestation, or liquid egress into the product
 - contamination due to cigarette, pipe, cigar or other smoke
 - failure to follow manufacturer's instruction for use as per user's manual
 - defects that are a consequence of repairs to a product made or attempted by a service provider other than one approved by Philips
 - products that have been subjected to incorrect electrical supply or inconsistent electrical supply or used with inappropriate accessories.
6. This Warranty is not transferrable in the event of any resale or transfer of products.
7. To the extent permitted by law, where the customer has the benefit of an implied guarantee under the Australian Consumer Law, but the product is not of a kind ordinarily acquired for personal, domestic or household use or consumption, Philips' liability shall be limited at the option of Philips to the replacement or repair of the product or the supply of an equivalent product.
8. To make a claim under this Warranty, contact your Homecare Provider. Alternatively, contact: Philips Electronics Australia Limited, 65 Epping Road, North Ryde NSW 2113 Australia. Tel: 1300 766 488, Email: repairs-src@philips-easyconnect.com


AUSTRALIAN SPONSOR DETAILS:

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