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CAUTION: U. S. federal law restricts this device to sale by or on the order of a physician.

Intended Use

The System One Heated Humidifier is an accessory for the Philips Respironics REMstar and BiPAP therapy devices to provide moisture to the patient circuit. It is intended for use in spontaneously breathing patients weighing over 30 kg (66 lbs), in the home or hospital/institutional environment, who use mask-applied positive pressure ventilation therapy.

Warnings

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

- Use the humidifier only for its intended use as described in this manual. Use only with Philips Respironics full-face masks, nasal masks and connectors.
- 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 humidifier 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 and the air outlet on the device. The humidifier must be level for proper operation.
- 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, if water is spilled into the enclosure, 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. Wipe the seal completely.
 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. Damage to the humidifier or therapy device may occur. If the water tank is overfilled, water may leak out of the tank inlet (located on the back of the tank) when installing the tank lid.
- 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.
- The humidifier door must be set in the open position before removing the water tank. Do not remove the water tank without making sure that the humidifier door locks into the open position.
- · 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 for use 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 |
|---------|-----------------------------|--------|----------------------|
| w▼ MAX | Maximum Fill Line | IP22 | Drip Proof Equipment |
| <u></u> | Hot Water, Hot Surface | · · | Type BF Applied Part |
| Ţi | Follow Instructions for Use | | |

System Overview

The System One 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 or 15 mm (non-heated) performance tubing. For information related to the mask to be used, including any need for a separate exhalation device, consult the instructions for use that accompany both the mask and therapy device.

The System One 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 System One 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 of the heated humidifier. For instructions on how to adjust the output of the
 heated humidifier, refer to the instructions for use 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 cover how to fill up 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 cover 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 instructions for use that accompanied the
 therapy device.

Available System One Heated Humidifiers

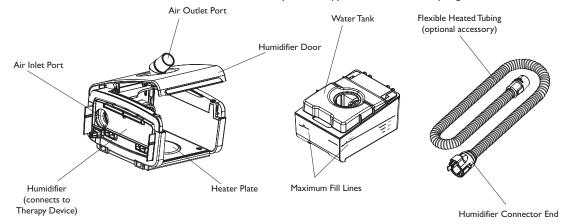
The System One Heated Humidifier is available in the following configurations:

Heated Humidifier - This humidifier provides moisture to the patient circuit. It has a standard air outlet port for use with Philips Respironics 15 and 22mm tubing.

Heated Humidifier with Heated Tubing - This humidifier provides moisture to the patient circuit but also allows for the option of heated tubing. In order to function with the heated tubing, it has a modified air outlet port that includes both a 3-pin connector and a heated tubing locking mechanism. The heated tubing compatible System One Heated Humidifier can be seen in the "Connecting the Optional Heated Tubing" section of this manual.

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 table below.

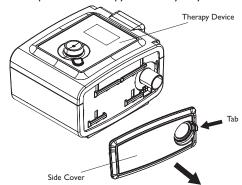
| Ітем | Description | |
|---|--|--|
| Humidifier | Connect your therapy device here. | |
| Air Inlet Port | Connects to the outlet port on the therapy device. | |
| Air Outlet Port (conical, 22 mm) (Standard Port shown here) | Connect the patient circuit here. (If you are using the optional heated tubing, this outlet port will look slightly different. Refer to "Connecting the Optional Heated Tubing" section of this manual.) | |
| Heater Plate | Warms the water in the water tank. | |
| Humidifier Door | Open the door to access the water tank. | |
| Humidifier Door Lever | Lift up on the lever to open the humidifier door. | |
| Water Tank | The removable water tank holds the water for humidification. | |
| Maximum Fill Lines | The fill lines indicates the maximum water level for safe operation. (Found on front and both sides of tank.) | |
| Flexible Heated Tubing (optional) | The optional heated tube connects from the humidifier to the patient's mask. | |
| Humidifier Connector End | Connect this end of the tubing to the humidifier. | |

Note: This humidifier is specified for use with Philips Respironics REMstar and BiPAP therapy devices only.

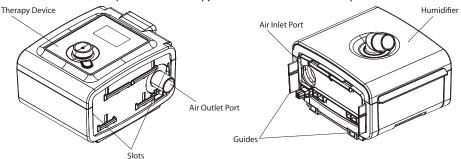
Connecting the Therapy Device

- 1. When using a humidifier, the patient circuit attaches to the air outlet port on the humidifier.
- 2. To connect the therapy device to the humidifier, first you must remove the side cover on the therapy device. Press in the tab on the side cover and pull the cover away from the unit.

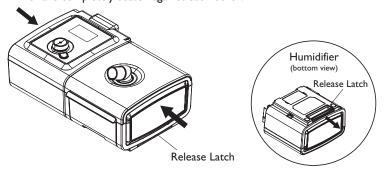
Note: Therapy device shown is an example. Actual therapy device may vary.



3. Next, line up the components side by side. Make sure that the guides on the humidifier fit into the slots on the therapy device and the air outlet port on the therapy device fits into the air inlet port on the humidifier.

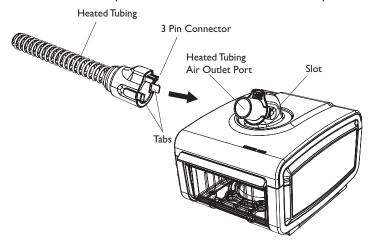


4. While holding both the therapy device and the humidifier, pull the release latch (on the bottom of the humidifier) and press the two units together until they snap into place. Let go of the release latch. Make sure that the therapy device and the humidifier are completely seated against each other.



Connecting the Optional Heated Tubing

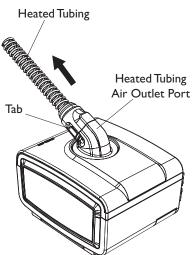
1. To attach the optional heated tubing to the humidifier, line up the humidifier connector end of the tubing with the Heated Tubing compatible air outlet port on the humidifier. Make sure the 3-pin connector at the top of the tube lines up with the opening at the top of the air outlet port. Press the 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 side of the outlet port.



Note: Non-heated Philips Respironics tubing (15 or 22 mm) can still be used with this humidifier with the heated tubing air outlet port. Simply connect the tubing to the air outlet port. Refer to the therapy device manual for setup instructions.

Disconnecting the Optional Heated Tubing

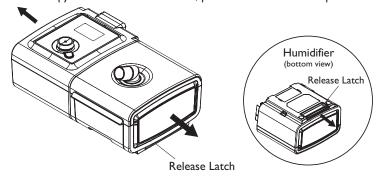
1. To remove the heated tubing, press in the tabs on the side of the tubing connector and pull the tubing away from the outlet port.



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. Grasp the release latch on the bottom of the humidifier.
- 2. While holding both the therapy device and the humidifier, pull the release latch and pull the two units apart.



3. If you will be using the therapy device without the humidifier, reattach the side cover to the therapy device.

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 and the air outlet on the device. 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.

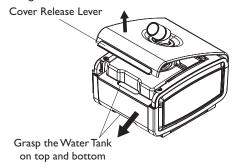
CAUTION: Do not turn the humidifier on without the water tank installed. The Humidifier setting must remain "off" if there is no water in the water tank.

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

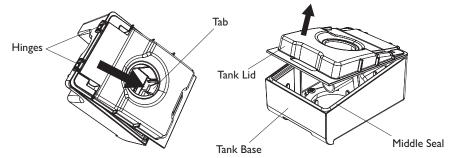
WARNING: Allow the humidifier heater plate and water to cool down for approximately 15 minutes before removing the water tank. A burn may result from: touching the heater plate, coming in contact with the heated water, or touching the tank pan.

2. Lift up on the release lever to open the humidifier door until it locks in an open position. You will hear a "click" once the door is opened far enough to remain in an open position. Remove the water tank by grasping the front of the tank and sliding it out of the humidifier base.

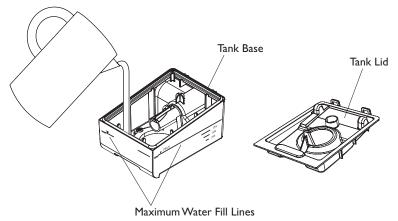
CAUTION: The humidifier door must be set in the open position before removing the water tank. Do not remove the water tank without making sure that the humidifier door locks into the open position.



3. Press the tab in the hole on top of the tank in toward the front of the tank. Gently remove the tank lid from the tank base and set aside. Empty any remaining water from the base of the tank.



4. Rinse the tank with water. With the water tank sitting on a flat surface, fill it with distilled water (approximately 325 ml) no higher than the maximum fill line located on the front and both sides of the tank.

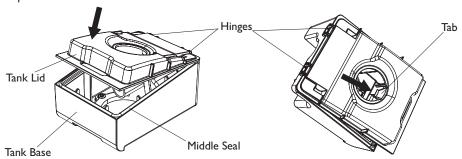


Note: Clean the water tank before first use. Refer to the "Home Cleaning" section in this manual.

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. Damage to the humidifier or therapy device may occur. If the water tank is overfilled, water may leak out of the tank inlet (located on the back of the tank) when installing the tank lid.

5. Reassemble the tank by placing the hinges on the tank lid over the 2 tabs on the back of the tank base. Close the lid until the tab on the lid snaps back under the lip in the tank base. Inspect the tank. When it is closed correctly, the lid should be seated completely on the middle seal and it should sit snugly on the tank base so the tab can easily snap back in place.



Note: If the lid does not close easily onto the base, separate the two parts, reassemble the tank, and inspect it again. **CAUTION:** Do not fill the water tank above the maximum fill line. Damage to the humidifier or therapy device may occur. If the water tank is overfilled, water may leak out of the tank inlet (located on the back of the tank) when installing the tank lid.

6. Slide the water tank back into the humidifier.

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.

- 7. Plug the power supply cord into the back of the therapy device.
- 8. Plug the AC power cord into the power supply provided with your therapy device, and then plug the AC power cord into an electrical outlet that is not controlled by a wall switch.

IMPORTANT: You must use the 80W power supply when using the heated tube humidifier with your therapy device. The appropriate power supply can be identified by the www symbol.

9. Attach the flexible tubing from the patient circuit to the humidifier's air outlet port. (If using the optional heated tubing, Refer to "Connecting the Optional Heated Tubing" section of this manual.)

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

10. Turn on the airflow on your device and begin therapy.

Note: For complete instructions on how to turn on the airflow, refer to the manual included with your therapy device.

11. Put on your mask assembly when the air starts to flow.

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

12. 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.

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

Using the Heated Tubing

Refer to the instructions for use that accompanied the therapy device for adjusting the warming and/or humidification level of the tubing. The heated tubing can be used with the following Philips Respironics families of devices: System One sleep therapy devices, C-Series ventilatory support systems, and A-Series ventilatory support systems.

Home Cleaning Instructions: Water Tank

Hand washing can be performed daily. Dishwashing can be performed once a week.

- 1. Turn the humidifier setting off, turn the therapy device off, and allow the heater plate and water to cool.
 - **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.
- 2. Open the humidifier door with the release lever, and then slide the water tank out of the humidifier base.
- 3. Press the tab in the hole on top of the tank in toward the front of the tank. Gently remove the tank lid from the tank base. Empty any remaining water from the base of the tank.
- 4. Wash the parts of the tank in the dishwasher (top shelf only) or in a solution of warm water and a mild liquid dishwashing detergent. Gently wash the middle seal. Rinse the parts with clean water. Wipe the parts completely on the top and bottom. Allow them to air dry.

CAUTION: Use a mild liquid dishwashing detergent only for either hand washing or when using a dishwasher.

WARNING: Empty and clean the water tank daily to prevent mold and bacteria growth. Wipe the seal completely.

5. Inspect the tank and seal for damage.

Note: Never use the water tank if the tank lid does not fit comfortably on the tank base.

- 6. Before using the tank, fill it with distilled water (per the directions in the "Daily Use" section) no higher than the maximum fill line located on the front and sides of the tank.
- 7. Reassemble the tank by placing the hinges on the tank lid over the 2 tabs on the back of the tank base. Close the lid until the tab on the lid snaps back under the lip in the tank base. Inspect the tank. When it is closed correctly, the lid should be seated completely on the middle seal and it should sit snugly on the tank base so the tab can easily snap back in place. Inspect the water tank for any leaks or damage. If the water tank shows signs of wear or damage, contact your home care provider for a replacement.

Note: If the lid does not close easily onto the base, separate the two parts, reassemble the tank, and inspect it again.

Home Cleaning Instructions: Humidifier Base

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. Allow the platform to air dry before reconnecting to the therapy device.
- 2. Inspect the humidifier base for any damage and replace it if necessary.
- 3. Clean the humidifier outlet port by using a damp bottle brush or a damp cloth. Insert the brush or cloth approximately 7 cm (2.75 inches) into the outlet opening while cleaning.

Home Cleaning Instructions: Heated Tubing

Clean the heated tubing before first use and weekly. For multi-patient use, complete the steps in the "Hospital and Institution Disinfection" section before each new user.

- 1. Disconnect the heated tubing from the heated humidifier. Refer to the "Disconnecting the Optional Heated Tubing" section earlier in this manual.
- Gently wash the heated tubing, including the connectors, using a commercially available anionic detergent (e.g. Medizyme) to adequately remove adhering substances from the tubing.

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

Note: Be sure to thoroughly rinse all soap residue from the connectors and tube, and air dry before the next use.

- 3. Rinse with 3 gallons (11.4 liters) of water, and allow to air dry out of direct sunlight.
- 4. Visually inspect the tubing, including hte connectors, for cleanliness. Repeat the cleaning steps if not visually clean.
- 5. Inspect the heated tubing for damage or wear (cracking, crazing, tears, punctures, etc.). Discard and replace if necessary.

Hospital and Institution Disinfection: Water Tank and Heated Tubing

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

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

Cleaning Prior to Disinfection

Clean the water tank and heated tubing before disinfection. Refer to the "Home Cleaning Instructions: Water Tank" and "Home Cleaning Instructions: Heated Tubing" sections.

Disinfection

The following processes can be used to disinfect the water tank and heated tubing for a maximum of 60 cycles:

- Thermal Disinfection: Immersion in a (tap) water bath at 75° C ± 2° C for 30 minutes
- Cidex

Note: Thoroughly rinse the Humidifier Connector End with water and air dry before the next use.

Cidex OPA

Note: Thoroughly rinse the Humidifier Connector End with water and air dry before the next use.

CAUTION: Treat the water tank and heated tubing as different medical devices when rinsing them with water. For example, the water tank and heated tubing cannot be rinsed in the same volume of water.

CAUTION: Use 3 gallons (11.4) liters as the rinse volume when following the instructions.

After Disinfection

- 1. Inspect the water tank and heated tubing for damage or wear (cracking, crazing, tears, punctures, etc). Discard and replace if necessary.
- 2. After the final water rinse described in the chemical disinfection instructions, separately rinse the water tank and heated tubing a minimum of 1 time each in at least 3 gallons (11.4 liters) of water and air dry out of direct sunlight.

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 and empty all water.
- 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

Dispose of this device in accordance with local regulations.

How to Contact Philips Respironics

To have your device serviced, contact your home care provider. If you need to contact Philips Respironics directly, call the Philips Respironics Customer Service department at 1-800-345-6443 or 1-724-387-4000. You can also use the following address:

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

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, issue may be caused by a misaligned or damaged seal. Seals are not user-serviceable components. Please contact your home care provider or Philips Respironics. |
| | The humidifier tank is not properly seated in the humidifier. | Remove the water tank from the humidifier base, and then slide the tank back in the humidifier, making sure it is pushed back as far as it can go. If high leak persists, issue may be caused by a misaligned or damaged seal. Seals are not user-serviceable components. Please contact your home care provider or Philips Respironics. |
| The humidifier LED icon on the therapy device is flashing. | There is no communication between the therapy device and the humidifier. | Following the "Daily Use" section earlier in this manual, check the outlet power and verify that the humidifier and therapy device are properly plugged in. Make sure the AC power cord is connected correctly to the therapy device's power supply. Make sure the AC power 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. |
| | The therapy device is not seated properly against the humidifier. | Remove the therapy device from the humidifier and reconnect it. Make sure the air inlet port on the side of the humidifier connects securely to the air outlet port on the side of the device. |
| | Using the wrong power supply. | If you are using the optional heated tubing, make sure you use the correct 80W power supply. |
| | Heated tubing is not connected properly or is damaged. | Remove the heated tubing and check for damage. If it is not damaged, reconnect the heated tubing. If the problem continues, contact your home care provider. |
| | The heater plate is not heating. | Check the power connections to the humidifier. If the problem continues, contact your home care provider or Philips Respironics. Note: If the water is not heating, you can temporarily use the humidifier as an unheated pass-over humidifier. |
| 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. |

| Problem | Why it Happened | What to Do |
|--|---|---|
| The water tank's middle seal is damaged. | The seal may become damaged during use. | Check the seal for any tears or other damage. If it is damaged, contact your home care provider. |
| 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. | Using the wrong power supply. | Make sure you use the correct 80W power supply. The correct power supply should have the www symbol. |
| | Heated Tubing setting is set to zero. | Make sure the Heated Tubing setting is not set to zero. Refer to your therapy device's user manual for instructions. |
| The humidifier door has | Humidifier door was lifted past the locked open position. | The humidifier door can be easily reattached. |
| been accidentally removed from the humidifier. | | With the water tank removed, align the hinge side of the door with the back of the humidifier in a fully open position (see figure below). Make sure the hinges are aligned with the grooves of the humidifier. Rotate the door closed. You will need to apply pressure until the door snaps past the locked open position. Verify that the door is working properly. |
| | | |
| | | If further assistance is needed, contact your home care provider. |
| your table or night stand. have been on the right placement. | The humidifier may not have been properly seated 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. |

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

System One 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: $18 \times 14 \times 10 \text{ cm} (7" \text{ L} \times 5.5" \text{ W} \times 4" \text{ H})$

Weight: Approximately 0.89 kg (1.95 lbs.)

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 Safety of Medical Electrical Equipment

EN ISO 8185 General Requirements for Humidification Systems

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

AC Power Consumption (with 60W power supply): 100 – 240 VAC, 50/60 Hz, 2.1 A

AC Power Consumption (with 80W power supply): 100 - 240 VAC, 50/60 Hz, 2.0 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, 2nd edition.

Heater Plate

Max Temperature: 75° C (167° F)

Pressure Drop with Humidifier

Max.: 0.3 cm H₂O at 60 LPM flow

Humidity

Humidity_{min} Output: 10 mg H₂O/L Measured @ max flow, 35° C, 15% RH.

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 32° C (60° to 89° 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 System One Heated Humidifier Specifications

Environmental

Refer to "Environmental" section of System One Heated Humidifier Specifications

Limited Warranty

Respironics, Inc. warrants that the system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace – at its option – the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, water ingress, and other defects not related to material or workmanship. The Respironics, Inc. Service department shall examine any devices returned for service, and Respironics, Inc. reserves the right to charge an evaluation fee for any returned device as to which no problem is found after investigation by Respironics, Inc. Service.

This warranty is non-transferable by unauthorized distributors of Respironics, Inc. products and reserves the right to charge dealers for warranty service of failed product not purchased directly from Respironics, Inc. or authorized distributors.

Respironics, Inc. disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

This warranty is given in lieu of all other express warranties. In addition, any implied warranties – including any warranty of merchantability or fitness for the particular purpose – are limited to two years. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To exercise your rights under this warranty, contact your local authorized Respironics, Inc. dealer or contact Respironics, Inc. at:

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



REF 1095653

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

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