K964653



# SECTION 12

# SUMMARY OF SAFETY AND EFFECTIVENESS

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RESPIRONICS INC.

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| **Classification Name** | 21 CFR 868.5450 73BTT |
| **Common/Usual Name** | Respiratory Gas Humidifier |
| **Proprietary Name** | Oasis Humidifier |
| **Predicate Device** | RI Humidifier (K945782) |

## Reason for Submission

The Oasis Humidifier is a new device.

## Substantial Equivalence

The Oasis Humidifier is substantially equivalent to the RI Humidifier (K945782). Both devices provide moisture to the patient circuit when used as an accessory to CPAP and BiPAP devices.

Testing was performed to demonstrate that the performance of the Oasis Humidifier in its intended environment is as safe and effective as that of the legally marketed predicate device. The safety and effectiveness of the Oasis Humidifier was verified through performance related Environmental Testing. The Oasis Humidifier was found compliant and has been certified to the standards referenced in the "FDA Reviewer Guidance for Premarket Notifications."

## General Technical Description

### Intended Use

The Oasis Humidifier is an accessory for Respironics CPAP and BiPAP systems to provide moisture to the patient circuit. The Oasis is the only humidifier with the acoustical design that enables effective operation of Respironics' Auto-CPAP mode. As such, it is the only humidifier that can be used with Respironics' Auto-CPAP products (i.e., Virtuoso Smart CPAP System (K953930) and Quartet Clinical System (K963761, currently under review)). The Oasis can also be used with standard CPAP devices from other manufacturers which have maximum operating pressures of 20 cm $H_2O$, and do not have bi-level or automatic pressure titration capabilities. Performance of non-Respironics CPAP systems with the Oasis humidifier should be verified before use.

### Device Description

The Oasis Humidifier (Figure 12-1) consists of a top ("lid"), bottom ("reservoir"), gasket, and a 24" reusable flexible tube that connects the Oasis to the pressure-generating unit (Respironics CPAP or BiPAP unit). The lid and reservoir are held together by four release latches. The latches are connected to the reservoir.

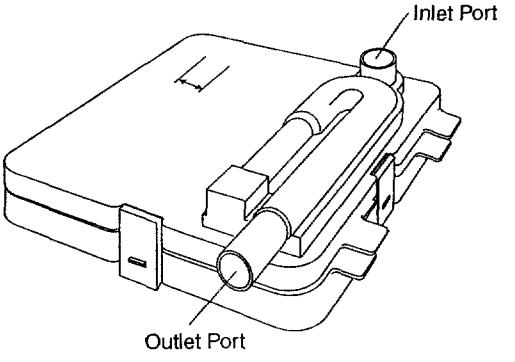


**Figure 12-1.** The Oasis Humidifier

The Oasis has an inlet port and an outlet port on its lid. The inlet port is on the *top* of the lid. The inlet port is where water is poured into the reservoir and where flexible tube connects the Oasis to the pressure-generating unit. The outlet port is on the *front* of the lid. (The six-foot patient circuit tubing is attached to the Oasis outlet port.) A J-shaped tube molded in the top of this lid is an acoustically-tuned passage. This passage gives the Oasis the acoustical characteristics that enable effective operation of Respironics' Auto-CPAP mode. As such, it allows the Oasis to be used as an accessory for Respironics' Auto-CPAP devices.

The inlet port's 26 mm outside diameter corresponds with the larger end of the 24" flexible tubing (26 mm inside diameter). The smaller end of the tubing -- 22 mm inside diameter -- connects to the outlet port of the pressure-generating unit. Refer to K945782 for complete information on the 24" flexible tubing.

The Oasis (excluding the gasket) is made of dishwasher-safe plastic.

**Specifications:**

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| Ambient Operating Temperature | 5° to 40° C |
| Storage Temperature: | -20° to +60° C |
| Ambient Operating Relative Humidity Range | 5% to 95% non-condensing |
| Reservoir Capacity | 440 ml |
| Relative Humidity Output | >25% |
| Pressure Drop (humidifier and 24" tubing) | .17 cm $H_2O$ at flow of 30 L/min;<br>.5 cm $H_2O$ at flow of 60 L/min. |

## Principles of Operation

Air passes through a container partially filled with water and absorbs vapor by evaporation. No heating is used to vaporize the water. The humidified air is conveyed to the patient through the patient circuit.

The unit conditions dry (5% RH at 40° C) inspiratory air at 85 L/min to a minimum of 25%RH, using distilled water, when subjected to pressure range of 3 to 20 cm $H_2O$. A full reservoir (2 cups, or 440 ml) will give approximately ten hours of humidification at those environmental conditions.

The Oasis is to be filled only when it is disconnected from the pressure-generating unit. It is filled by pouring 2 cups (440 ml) distilled or sterile water into the inlet port. To verify the correct amount of water has been added, the humidifier is tilted up vertically, so that the water line can be seen against the fill line. By design, bulk liquid in the reservoir will not enter any other part of the patient circuit when the device is tilted up to 20°.

The Oasis is positioned below the circuit connection at the mask and the air outlet on the CPAP or BiPAP unit.

The Oasis can support a CPAP or BiPAP unit placed directly on top of it. An optional shelf placed around the Oasis is recommended if the user chooses to place a BiPAP Ventilatory Support System or the Great Performers' BiPAP Duet System or Quartet Clinical System on top of the Oasis.

The humidifier has the same acoustical impedance as the RI Virtuoso CPAP unit so that it can be used as an accessory for Respironics' Auto-CPAP devices (i.e., Virtuoso and Quartet).

The Oasis can be used with standard CPAP devices from other manufacturers which have maximum operating pressures of 20 cm $H_2O$, and do not have bi-level or automatic pressure titration capabilities. The Oasis was tested, in part, with the Respironics REMstar CPAP System, which is representative of most currently marketed standard CPAP devices. The pressure drop performance characteristic, resulting from additional flow resistance through the humidifier, is the only humidifier performance characteristic that would affect the performance of a standard CPAP device. The Oasis humidifier pressure drop is

approximately 0.5 cmH2O @ 60 LPM, which is negligible relative to the performance of any currently marketed standard CPAP device.

### Cleaning/Disinfection/Sterilization

The performance of the Oasis has been validated for the following methods:

**Cleaning**

- Hand washing in a solution of warm water and mild dish washing liquid.
- Dishwasher cleaning (The gasket and tubing are not dishwasher safe and must be removed when dishwasher cleaning).

**Disinfection**

- Pasteurization.

**Sterilization**

- Ethylene Oxide (EtO) Sterilization.