



MAR - 1 1996

## Summary of Safety and Effectiveness

**Device Name:** Humidifier  
**Distributor:** Respironics Inc.  
1001 Murry Ridge Drive  
Murrysville, Pa. 15668  
Phone: 412 733-0200

### Statement of Intended Use:

The Respironics Humidifier is intended to add vapor phase moisture to the airstream provided to the patient by the Respironics BiPAP or CPAP systems. The Humidifier is a "passover" style which increases moisture content of the airstream by allowing the airstream to pass over a tray of water and absorb water by evaporation into the airstream.

### Technical Description and Construction Details:

The Respironics passover Humidifier is intended to be connected between the outlet port of the Bi-level or CPAP system and the tubing which goes to the patient. Small sections of patient tubing are included with the humidifier to allow the patient to connect the humidifier to the BiPAP.

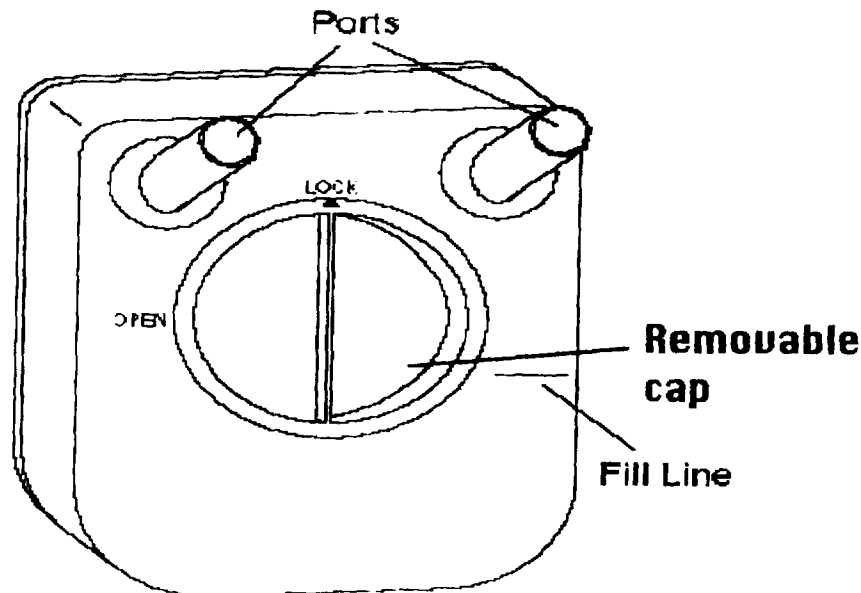


Figure 1 - Respironics Humidifier

The Humidifier consists of a transparent plastic storage tank with appropriate 22 mm OD connector ports to allow connection of the patient tubing and the BiPAP or CPAP connector tubing. The transparent structure allows the user to monitor the water level in the humidifier. The humidifier also has appropriate markings to allow the user to determine fill levels. A large opening in the center is designed to allow easy filling and cleaning of the humidifier.

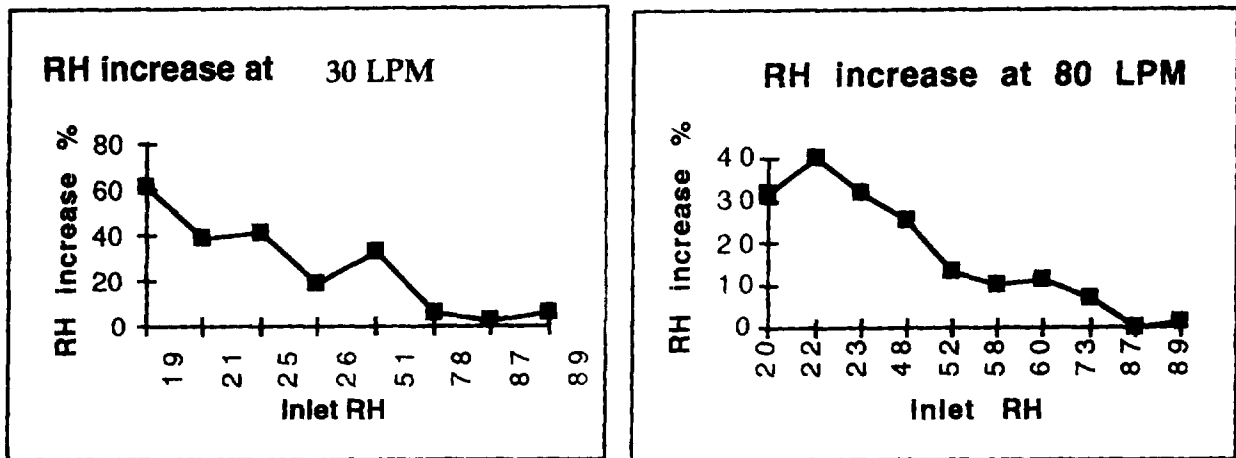
The Humidifier has been designed to increase the relative humidity of the airstream being supplied to the patient. The unit is designed to have a minimum 8 hours capacity of water when operated at 90°F and 25 % relative humidity, and a nominal patient air flow of 30 LPM. Humidifier has a capacity of approximately 425 ml. of water.

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An optional stand is available for the Humidifier which allows the Humidifier to be mounted beneath the BiPAP or CPAP systems.

### Safety and effectiveness data summary:



The above charts depict the results of Humidifier testing. Greater changes in the relative humidity were found at 30 LPM and flow rates of less than 50 LPM. This is within the expected operating ambient and flow demands of BiPAP and CPAP systems for normal breathing.

Impact testing was conducted on the Humidifier which indicates that the Humidifier can satisfactorily withstand a drop from 30" height onto concrete flooring without significantly affecting its performance.

Respironics recommends a low level decontamination process on a daily basis to reduce bacterial levels in the humidifier. Testing of the recommended decontamination procedure, soaking the unit in a 50% vinegar solution for 30 minutes, resulted in a bacterial reduction from  $1.7 \times 10^6$  / ml to 2.7 / ml. bacterial concentration.

An alternate method of low level decontamination can be achieved by using a quaternary ammonia compound as a decontamination agent. The levels of decontamination achievable are consistent with guidelines for low level decontamination as published in the American Journal of Infection Control.