

# An Evaluation of 2 New Devices for Nasal High-Flow Gas Therapy

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**BACKGROUND:** The traditional nasal cannula with bubble humidifier is limited to a maximum flow of 6 L/min to minimize the risk of complications. We conducted a bench study of 2 new Food and Drug Administration-approved nasal cannula/humidifier products designed to deliver at flows > 6 L/min. **METHODS:** Using a digital psychrometer we measured the relative humidity and temperature of delivered gas from each device, at 5 L/min increments over the specified functional high-flow range. **RESULTS:** The Salter Labs unit achieved 72.5–78.7% relative humidity (5–15 L/min range) at ambient temperature (21–23°C). The Vapotherm device achieved 99.9% relative humidity at a temperature setting of 37°C (5–40 L/min). **CONCLUSIONS:** Both devices meet minimum humidification standards and offer practical new treatment options. The patient-selection criteria are primarily the severity of the patient's condition and cost. *Key words:* cannula, oxygen, humidification, oxygen therapy, oxygenation. [Respir Care 2004;49(8):902–906. © 2004 Daedalus Enterprises]

## Introduction

The nasal cannula is a staple of oxygen therapy and continues to be refined for improved patient comfort and compliance. It is classified as a low-flow oxygen device,<sup>1</sup> which means that the fraction of inspired oxygen ( $F_{I_{O_2}}$ ) varies with the patient's inspiratory flow.<sup>2</sup> Humidification of oxygen delivered via nasal cannula at flows  $\leq 4$  L/min is generally thought to be unnecessary.<sup>3–4</sup> The recently updated American Association for Respiratory Care clinical practice guideline for oxygen therapy in the acute care setting recommends that nasal cannula not be used at flows higher than 6 L/min.<sup>3</sup>

Adequate humidification is required to maintain ciliary activity, prevent squamous epithelial changes, prevent dehydration and thickening of secretions, minimize atelecta-

sis and tracheitis, and decrease heat loss. When gas reaches body temperature and pressure saturated (BTPS) (37°C and 100% relative humidity), it has an absolute humidity of 43.9 mg H<sub>2</sub>O/L of gas. Medical gases are essentially anhydrous (without water) and require artificial humidification, depending on the flow used and the patient's condition. The American Society for Testing and Materials (ASTM) specifies that humidification systems must produce an output of at least 10 mg H<sub>2</sub>O/L (equivalent to approximately 60% relative humidity at 22°C ambient conditions), and if the upper airways are bypassed, the output must be at least 33 mg H<sub>2</sub>O/L.<sup>5</sup> An unheated bubble humidifier yielding a water vapor content of 13.5 mg H<sub>2</sub>O/L would result in a deficit of 30.4 mg H<sub>2</sub>O/L for the body to hydrate.

As delivered gas flow increases, however, the humidifier efficiency becomes more important for at least 2 reasons. One concern is the potential drying of the upper airways from "excess" gas (that which is not inspired into the lower airways during the respiratory cycle) that is below BTPS. Most patients tolerate flows up to 6 L/min at less than BTPS ( $\leq 4$  L/min without humidification and 4–6 L/min with humidification), but the airway moisture loss from higher flows becomes problematic and a source of physiologic stress.<sup>6</sup> Second, the energy loss from raising the temperature of inspired gas from ambient to body temperature is a minor concern under normal conditions but increases as delivered flow exceeds demand.

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Vapotherm Inc (1) loaned their product and provided disposables for testing, (2) paid for the Salter Labs disposable product units tested, and (3) partly funded the testing (less than half of the testing costs).

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The utility of high-flow BTPS gas has been documented, and high-flow, warm, humidified gas is beneficial independent of an elevated  $F_{IO_2}$ ; however, it is not clear whether that is due to the warmth and humidity, the velocity, or both. Chen and Chai<sup>7</sup> found that spontaneously breathing BTPS gas at an  $F_{IO_2}$  of 0.21 during sleep significantly reduced or eliminated nocturnal asthma episodes during sleep testing. Another group found that the expired air of asthmatics measured in the emergency department was drier than that of nonasthmatic controls and that the  $FEV_1$  decrease associated with a dry-air tachypneic challenge could be prevented by fully humidifying the inspired air.<sup>8</sup>

Two new respiratory devices may change how the nasal cannula is used and categorized. Salter Labs Inc (Arvin, California) offers a nonheated nasal cannula and bubble humidifier combination capable of flows up to 15 L/min (models 1600HF and 7900, respectively). The manufacturer states that these devices deliver a relative humidity range of 72–78% at flows between 6 and 14 L/min. The Vapotherm 2000i (Vapotherm, Annapolis, Maryland) is a high-flow gas delivery device that heats and humidifies gas for delivery through a nasal cannula, face mask, tracheostomy mask, or other common respiratory appliances. The high flow cartridge is rated for 5–40 L/min at > 95% relative humidity (33–43°C); the low flow cartridge has a range of 1–8 L/min. In the present study we measured the humidity output of these devices, compared our measurements to the manufacturers' humidity claims, and determined whether the devices meet the minimum humidification standards promulgated by the ASTM.

### Methods

Humidity measurement of moving gases near 100% relative humidity requires special measurement considerations, such as matching sampling equipment temperature to gas temperature and avoiding condensation on the hygrometer probe. Our measurements were performed using a new digital psychrometer/thermohygrometer (Mannix, Lynbrook, New York) that has a specified accuracy of  $\pm 1^\circ\text{C}$  and  $\pm 4\%$  relative humidity when humidity is > 90%. Factory calibration was confirmed in the laboratory, using a calibration salt. Humidity and temperature measurements were made at 5, 10, and 15 L/min, with 60 min between each measurement run. Four new Salter Labs cannula humidifier units (Fig. 1) and 4 new Vapotherm humidifier cartridges (Fig. 2) were each measured once to generate a mean value and a standard deviation for each device. Measurements were recorded when a stable reading was obtained per the manufacturer's instructions to wait until the measurement reading remained stable for 5 s. Between each measurement the hygrometer probe was exposed to dry oxygen gas flow until a zero percent humidity reading was observed, to ensure that the probe was dry before the



Fig. 1. The Salter Labs high-flow cannula and humidifier combination (Courtesy Salter Labs, Arvin, California).



Fig. 2. Left: Cross section of Vapotherm humidifier cartridge. Right: Frontal view of the Vapotherm 2000i (Courtesy Vapotherm, Annapolis, Maryland).

next measurement. A short, U-shaped silicone tube of approximately 2.5 cm inner diameter served as the sampling chamber and to slow the gas, to stabilize readings (Fig. 3).

The Salter Labs high-flow device is not heated and its output gas is therefore near room temperature, so humidity measurements were made with the sampling chamber at room temperature (21–23°C). Serial gas output humidity and temperature measurements were made with the nasal prongs attached to the sampling chamber.

The Vapotherm device output is above room temperature (set to 37°C), so the U-shaped sampling chamber was

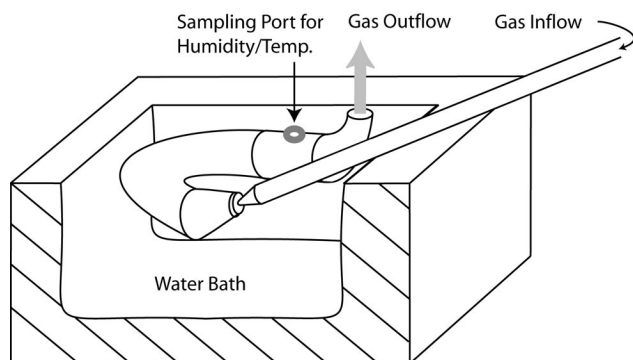


Fig. 3. Water bath setup for humidity measurements.

immersed in a temperature-controlled water bath set to 38°C (see Fig. 3), which ensured that the gas flow from the VapoTherm did not cool upon exiting the outflow tubing connector, which would increase the humidity measurement. Output gas humidity and temperature measurements were made at flows of 5, 10, 20, 30, and 40 L/min. To ensure that the gas temperature did not decrease in the nonheated cannula and increase the humidity value, the connection port of the 213-cm delivery tube was attached to the sampling chamber, rather than measuring from the nasal prongs. We allowed at least 3 h between each test run (5–40 L/min) of the VapoTherm, because of its higher humidity range.

Connecting the VapoTherm delivery tube directly to the heated sampling chamber rather than the nasal prongs is the clearest test of its function. The VapoTherm delivery tube is a triple-lumen system that contains a warm-water bath to maintain the set gas temperature (Fig. 4). The temperature de-

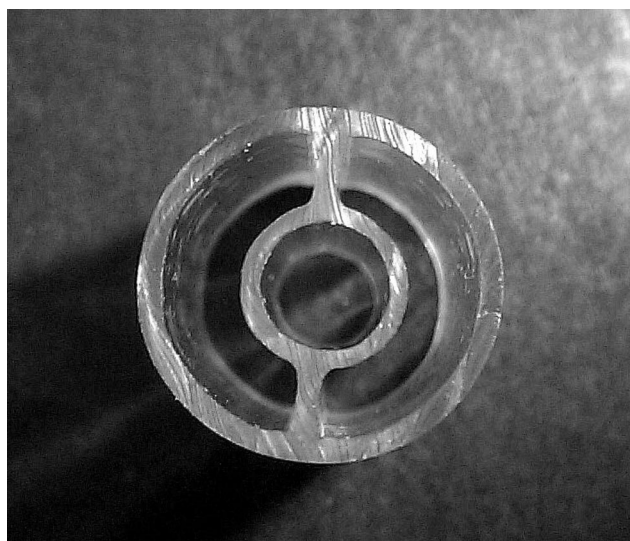


Fig. 4. Cross section of the VapoTherm triple-lumen system. The gas delivery (center) lumen is surrounded by 2 heated-water chambers (Courtesy VapoTherm, Annapolis, Maryland).

creases as the gas passes from the heated delivery tube through the unheated cannula tubing, so the relative humidity increases. Therefore, eliminating unheated tubing from the circuit connecting the unit under test to the sampling chamber should yield the lowest relative humidity reading. The VapoTherm cannula is designed to allow a high gas flow with little resistance and absorb body warmth from the patient's face to nearly eliminate condensation in the tubing.

## Results

Table 1 compares our measurements to the manufacturers' claimed (unpublished) humidity values. The Salter Labs combination produced 72.5–78.7% relative humidity during flows of 5–15 L/min at ambient temperature (21–23°C). The VapoTherm produced the maximum humidity reading (99.9%) in all our measurements, throughout its 5–40 L/min flow range. Intermeasurement variability is indicated by the percent coefficient of variation. The VapoTherm had essentially no water vapor deficit ( $\leq 1.3$  mg H<sub>2</sub>O/L) compared to BTPS, at all flow settings. At typical ambient temperatures (21–23°C) the Salter Labs combination delivered an average of 15.8 mg H<sub>2</sub>O/L and the VapoTherm produced an average of 43.3 mg H<sub>2</sub>O/L for the measured flow ranges. There were statistically significant differences between the humidity values we obtained and the manufacturers' claimed humidity values with 5 of the 6 flows analyzed, although those differences may not be clinically important.

## Discussion

Both devices met minimum standards for humidification at their highest flows (well in excess of the conventional 6 L/min). With the Salter device the measured humidity values were significantly lower than the manufacturer's stated humidity values at flows of 5 and 10 L/min but the measured value was not significantly lower than the manufacturer's stated humidity value at 15 L/min. With the VapoTherm device the measured humidity values were significantly higher than the manufacturer's stated humidity values at 5, 10, and 20 L/min (but the 30 and 40 L/min values were not provided by the manufacturer). At their highest settings both devices yielded a water vapor content that exceeded the minimum recommended by the ASTM humidification guidelines. The Salter Labs disposables are less expensive, but the VapoTherm delivers flows up to 40 L/min at or greater than BTPS.

Inhaled gases that are at BTPS may provide greater patient comfort.<sup>9–12</sup> Airway cooling, whether caused by inspiring cold air or by a drop in body temperature, can trigger asthma. A study of patients with nocturnal asthma showed that breathing BTPS air improved morning spirometry, compared to breathing ambient air, and unlike ambient air, it eliminated nocturnal asthma occurrences

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Table 1. Humidity and Temperature Data Compared to Manufacturers' Claimed Relative Humidities

Device	Flow (L/min)	Temperature (°C) [CV%] Mean ± SD	Water Content (mg H <sub>2</sub> O/L)	Water Content Difference From BTPS (mg H <sub>2</sub> O/L)	Measured Relative Humidity (%) [CV%] Mean ± SD	Manufacturers' Claimed Relative Humidity (%)	p*
Salter Labs	5	23.1 ± 0.2 [0.9]	17.3	26.6	78.7 ± 4.6 [1.5]	85.7 ± 0.3	0.0031
	10	23.2 ± 0.2 [1.1]	16.0	27.9	76.9 ± 5.8 [1.6]	79.1 ± 0.3	0.0002
	15	23.3 ± 0.2 [0.9]	14.2	29.7	72.5 ± 0.9 [4.3]	70.4 ± 0.3	0.0809
Vapotherm	5	36.5 ± 0.1 [0.2]	42.6	1.3	99.9 ± 0 [0.0] <sup>‡</sup>	94.8 ± 0.5	<0.0001
	10	36.6 ± 0.1 [0.3]	42.9	1.0	99.9 ± 0 [0.0] <sup>‡</sup>	95.7 ± 0.4	<0.0001
	20	36.7 ± 0.2 [0.5]	43.1	0.8	99.9 ± 0 [0.0] <sup>‡</sup>	94.8 ± 0.8	<0.0001
	30	37.0 ± 0.2 [0.5]	43.7	0.2	99.9 ± 0 [0.0] <sup>‡</sup>	‡	‡
	40	37.1 ± 0.3 [0.8]	44.0	No deficit	99.9 ± 0 [0.0] <sup>‡</sup>	‡	‡

BTPS = body temperature and pressure saturated.

CV% = percent coefficient of variation.

\*p value of single-sample *t* test for study data versus manufacturers' claimed relative humidities.

<sup>‡</sup>Maximum value obtained on all measurements (accuracy of hygrometer ± 4% at > 90% humidity).

<sup>‡</sup>Manufacturer did not include data for flow rates > 20 L/min.

when used in conjunction with evening medication.<sup>7</sup> Moloney et al observed that asthmatics in the emergency department had dryer exhaled gas than nonasthmatic controls, and more than half of the asthmatics developed a > 10% FEV<sub>1</sub> reduction after a laboratory dry-air tachypnea challenge,<sup>8</sup> but fully humidifying the air at 37°C prevented the bronchoconstriction during tachypneic challenge. That finding has implications for patients limited by severe exercise-induced asthma. A severely asthma-limited patient who is waiting for lung transplant and needs to exercise in preparation for surgery and to avoid going on mechanical ventilation (to remain a transplant candidate) might benefit from a BTPS high-flow cannula.

Nugent et al found that 50% of sample chronic obstructive pulmonary disease patients required an F<sub>IO<sub>2</sub></sub> increase during exercise to maintain a saturation of 88% when using conventional oxygen delivery, whereas none of the patients using BTPS gas at 20 L/min via nasal cannula required increased F<sub>IO<sub>2</sub></sub>.<sup>13</sup>

The results of the present study are uncomplicated other than the lack of variation seen in the Vapotherm humidity measurements. That device was designed to operate at the extreme end of the humidity range, and the psychrometer consistently gave its maximum humidity reading with the Vapotherm, which resulted in a zero coefficient of variation for the humidity measurements with the Vapotherm.

Both manufacturers supply a particular nasal cannula that they recommend be used with their respective devices. It is possible to use other cannula brands with these devices, but there are 2 concerns: (1) the gas flow resistance imposed by the cannula tubing, and (2) the volume of unheated tubing, particularly with the Vapotherm. With either device, if cannula resistance is too high, a pressure-

relief valve activates to limit peak pressure and therefore the associated peak flow.

The present experiment's verification of the humidification abilities of these devices entreats clinical research be done on the benefits of nasal high-flow BTPS gas. For instance, what other disease conditions and patient groups (besides nocturnal asthmatics) would benefit from breathing nasal high-flow gas at BTPS room-air F<sub>IO<sub>2</sub></sub>? In a bench study using an anatomically correct model of the upper airways, Tiep and Barnett<sup>14</sup> found that the Vapotherm achieved a higher F<sub>IO<sub>2</sub></sub> than a nonbreather mask at similar flows (range 10–30 L/min), which suggests the possibility of substituting the cannula for the mask. If high-flow nasal cannula therapy proves to be effective, research is needed to determine how it would be incorporated into clinical practice guidelines. An extension of existing clinical practice guidelines to incorporate high-flow nasal cannula devices might start with recommending the use of a nonheated device capable of a minimum delivered relative humidity of X% at flows above 6 L/min.

### Conclusion

The Salter Labs and Vapotherm devices exceed minimum humidification standards at higher-than-traditional flow and meet ASTM standards. The ability of a nasal cannula to exceed the average adult spontaneous peak inspiratory flow (30 L/min) may allow it to function as either a low-flow or high-flow device, depending on patient factors.

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