

# Performance of a Mask System Incorporating a Heat and Moisture Exchanger

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## Abstract

**Background:** Compliance with continuous positive airway pressure (CPAP) is a widespread issue. While heated humidification relieves the drying effect of CPAP and improves patient compliance, humidifiers require daily maintenance. Heat and moisture exchangers (HME) may provide humidification in a more compact and simple way. Concerns regarding cleanliness and acceptable humidification levels, and effects on airflow impedance and breathing comfort have limited HME use. A novel HME, the HumidX™ Mask System, may address these issues.

**Aim:** This study investigated the bioburden proliferation characteristics and impedance of the HumidX™ Integrated Mask System and assessed subjective humidification performance, breathing comfort and usability.

**Methods:** Subjects established on CPAP were randomly assigned to 6 groups and followed weekly for 6 weeks; visit order (face-to-face, SMS or phone call) was randomized. Subjective assessments of the HumidX™ performance were made at each visit. The HumidX™ component was replaced once for each group at the face-to-face visit. HumidX™ component samples were collected at the end of the study and underwent airflow impedance testing and bioburden enumeration within 24 hours.

**Results:** Forty-two subjects (29 male, mean age 61±9.5 years, mean time on CPAP 12± 10.3 years) were enrolled and 33 completed the study. Bioburden enumeration showed that the HumidX™ components maintained a safe, bacteriostatic state throughout the trial. Impedance in the system increased by 25% during use. Performance of the HumidX™ system did not change over the course of the study and the majority of subjects preferred the HumidX™ mask system over their current set-up (52.5%) or expressed no preference (12.5%).

**Conclusions:** The HumidX™ Mask System showed acceptable safety in terms of bioburden proliferation characteristics and impedance over 6 weeks of use, and humidification performance and breathing comfort were acceptable.

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## Introduction

Obstructive sleep apnoea (OSA) is a condition characterised by partial to complete collapse of the upper airway during sleep. Symptomatic OSA is highly prevalent in the general population, affecting 4% of males and 2% of females.<sup>1</sup> One of the main symptoms of OSA, excessive daytime sleepiness, results from arousals due to intermittent pauses in breathing and is a risk factor for motor vehicle accidents and poor work performance.<sup>2,3</sup> Symptomatic OSA can also have a marked negative impact on quality of life.<sup>4</sup> OSA, with or without daytime symptoms,<sup>5</sup> has also been associated with increased cardiovascular morbidity and mortality,<sup>6,7,8</sup> all-cause mortality, incident stroke, cancer,<sup>9</sup> type 2 diabetes,<sup>10</sup> renal disease,<sup>11</sup> and neurocognitive disease.<sup>12</sup>

Continuous positive airway pressure (CPAP) is the treatment of choice for OSA. Adherence to CPAP therapy (device usage for ≥4 hr/night) is associated with significantly improved quality of life, daytime sleepiness and other symptoms, with effects proportional to device usage.<sup>13</sup> However, despite its efficacy in clinical trials,

patient adherence to CPAP in routine clinical practice is often suboptimal, with non-adherence rates of 29-83%.<sup>14</sup>

Minor side effects are common with CPAP therapy and need to be managed to maintain patient adherence.<sup>15,16</sup> Oro-nasal dryness is common, potentially causing nasal congestion and epistaxis.<sup>17</sup> The nose is characterised by a rich vascular system responsible for warming and humidifying inspired air to maintain mucosal function of the upper and lower airways. In the presence of mouth leaks CPAP may overwhelm this system, causing airway drying and rebound congestion. Active humidification relieves nasal dryness by warming and humidifying inspired air using a heated water reservoir. The addition of heated humidification has been shown to improve adherence to CPAP.<sup>17</sup> Patients using active heated humidification feel more refreshed upon awakening and show a reduction in the side effects associated with upper airway dryness and congestion symptoms.<sup>17,18,19</sup> However, active humidification requires the addition of a heated water chamber to the CPAP system, necessitating regular cleaning and maintenance, including filling the chamber with distilled water each day, which some users find inconvenient.

Passive humidifiers, such as heat and moisture exchangers (HME) take advantage of the natural humidification processes within the nose. The natural heat and moisture from the respiratory tract that humidifies inhaled air is captured by the HME during exhalation and returned to the next inhaled breath.<sup>20</sup> HME technology provides a more compact solution for patients than active humidification through the addition of a small component into the inspiratory limb of the mask circuit in place of a heated water chamber. HME devices simplify therapy by eliminating the cleaning and maintenance tasks associated with active humidification. They also make it easier for patients to travel with their system.

In terms of effectiveness, active HME (with heated humidification) has been shown to be superior to passive HME for adding heat and moisture to inhaled air.<sup>21</sup> There are also a number of other concerns around the use of HME technology with positive airway pressure (PAP). Currently, HMEs are replaced frequently, detracting from the simplicity that the system can offer. Most commercially available HMEs have a 24-hour lifespan. This is largely based on the potential for bioburden proliferation (microbial growth) within the HME. In addition, questions have been raised about the effect on an HME on the ability of a PAP device to deliver appropriate air flow and adequate humidification performance.

This study investigated the bioburden proliferation and impedance of a proprietary heat and moisture exchanging component (HumidX™, ResMed) and assessed subjective humidification performance, breathing comfort and usability of the HumidX™ Integrated Mask System in patients with OSA established on CPAP therapy.

## Materials and methods

### Study design

This open-label study was conducted over a 6-week period. The study protocol was approved by the University of New South Wales Human Research Ethics Committee. All patients provided written informed consent before enrolment in the trial.

### Patients

Patients were recruited from ResMed Ltd's Sleep Trials Registry, a voluntary registry open to all current CPAP users in Australia. Inclusion criteria were age >18 years, established on CPAP therapy for OSA for ≥6 months, currently using any ResMed nasal pillows mask, and able and willing to provide written informed consent. Subjects were excluded if they were pregnant, could not participate for the duration of the trial or had a pre-existing lung condition (including chronic obstructive pulmonary disease, lung cancer, fibrosis of the lungs, recent pneumonia or lung injury) that would predispose them to a pneumothorax.

## Study objectives

The primary objectives of the study were to characterise the rate of bacterial accumulation and/or proliferation on the HumidX™ component, characterise the change in impedance of the HumidX™ component, and to establish the safe replacement interval (with respect to bioburden and impedance characteristics). A secondary objective was to assess subjective humidification performance, breathing comfort and usability of the HumidX™ Integrated Mask System.

## Intervention

The HumidX™ Integrated Mask System consists of a HumidX™ component and frame, and nasal pillows cushion assemblies (Figure 1). The corrugated HME paper and HumidX™ cartridge are detailed in Figure 2. The mask is fitted in the same manner as a ResMed nasal pillows mask system.

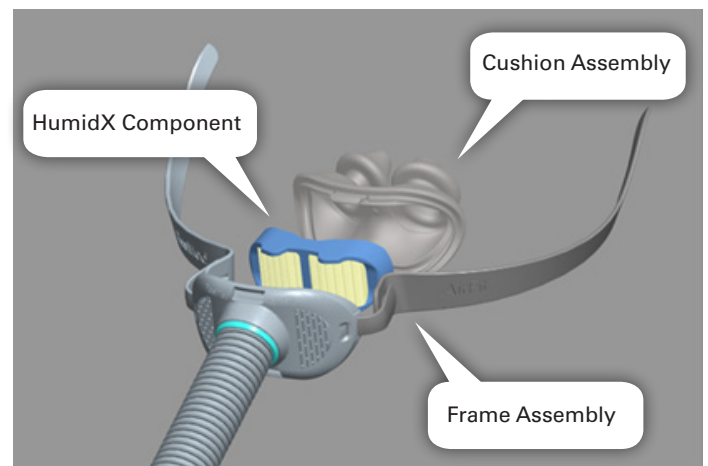


Figure 1. The HumidX™ Integrated Mask System

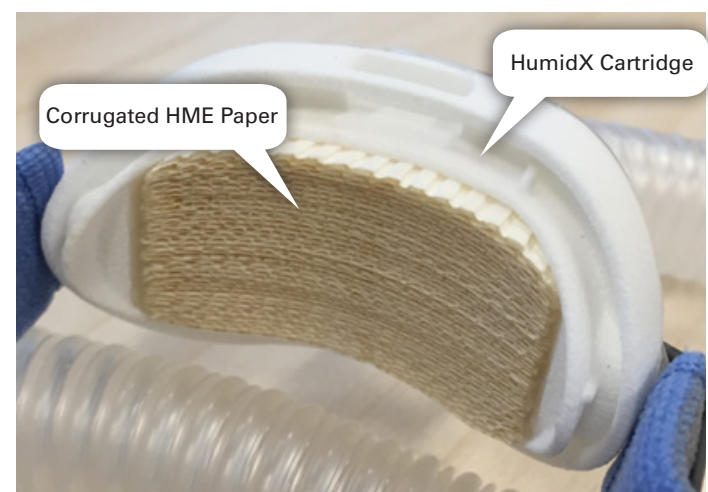


Figure 2. Corrugated HME paper and HumidX™ cartridge

## Assessment and follow-up

Each patient made an initial subjective assessment of the HumidX™ Integrated Mask System during the first consultation. At each weekly follow-up visit, patients were asked to rate humidification performance, dryness and

breathing comfort of the HumidX™ system on a 10-point Likert scale (0, very negative; 5, OK; 10, very positive). These weekly assessments were completed at a face-to-face visit, by telephone call, or with an SMS message reminding subjects to complete their weekly questionnaire. At the end of the study, patients were asked to indicate their overall preference for a mask system (HumidX™, current set-up, or no preference). Patients were randomised to one of six groups that differed in the order of how weekly follow-up visits were undertaken (Table 1).

At the face-to-face visits and at study completion, the HumidX™ Integrated Mask Systems were collected and HumidX™ components removed. The HumidX™ component was inspected for any degradation including damage, blockages or discolouration, and photographs of the HumidX™ components were taken for comparison with an unused control sample. Within 24 hours of collection, impedance testing was performed by ResMed Ltd and samples were sent to AMS Laboratories for bioburden enumeration and identification.

Impedance of the HumidX™ mask system was tested at 50 L/min and was recorded with and without the HumidX™ component as per the Resistance to Flow Procedure (Annex C) of ISO17510-2:2007 Sleep Apnoea Breathing Therapy – Part 2: Masks and application accessories with the deviation of blocking exhaust flow (vent holes) during testing.<sup>22</sup> The impedance attributed to the HumidX™ component was calculated by subtracting the pressure drop across the mask system without the HumidX™ component from the system with the HumidX™ component. Results were reported as percentage increase of the HumidX™ component impedance recorded during the mask system verification before use by the patient.

The bioburden present on each returned HumidX™ component was counted using ISO11737 Sterilisation of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products.<sup>23</sup> Colonies resulting from the bioburden measurement were gram stained and grouped by morphology.

**Table 1. Study visit schedule in randomisation groups.**

Week	Group					
	1	2	3	4	5	6
0	Face to face visit	Face to face visit	Face to face visit	Face to face visit	Face to face visit	Face to face visit
1	Face to face visit	Call	Call	Call	Call	Call
2	SMS	Face to face visit	SMS	SMS	SMS	SMS
3	SMS	SMS	Face to face visit	SMS	SMS	SMS
4	SMS	SMS	SMS	Face to face visit	SMS	SMS
5	SMS	SMS	SMS	SMS	Face to face visit	SMS
6	Face to face visit	Face to face visit	Face to face visit	Face to face visit	Face to face visit	Face to face visit

	Face to face visit
	Call
	SMS

## Sample size

A previous unpublished bioburden study<sup>24</sup> used a total of 20 subjects, with 5 subjects in each time period/subgroup. The results of the study showed that the bioburden count did not proliferate and remained stable within a 4-decade band over the life of the study (6 weeks). The spread of results observed indicated that a sample size of 5 subjects adequately represented the reality of measurable results to determine bioburden parameters. Therefore, it was determined that a sample size of 42 patients (7 per randomisation subgroup) would be appropriate, allowing for potential dropout.

## Statistical Analysis

Likert scale scores provided by subjects in the questionnaire were analysed using the Wilcoxon Signed Rank test with a score of 6 being regarded as good/acceptable. Scores obtained were compared with a score of 6 as a reference. Further analyses using the Mann-Whitney test were performed to compare the HumidX™ mask and the subject's current mask.

## Results

### Study sample

A total of 42 patients were enrolled in the study (7 in each of the 6 randomised groups); 9 withdrew early and 33 completed the trial. No subjects withdrew consent and all data available from the 42 subjects were included in the final analysis. All analysis for Groups 1, 2, 5 and 6 included 5 or more subjects for all 6 weeks of assessment; Group 3 included 5 or more subjects up until Week 4 onwards when only 4 subjects were assessed; Group 4 included 5 or more subjects up until Week 6 when only 4 subjects were assessed. Baseline characteristics of the study population are described in Table 2.

**Table 2. Patient demographic and clinical data at baseline.**

	Patients (n=42)
Age, years	61±9.5 (39–86)
Male, n (%)	29 (69)
Ethnicity, n (%)	
Caucasian	35 (83)
East Asian	7 (17)
Time on therapy, years	12±10.3 (1-30)
PAP device, n (%)	
S8	20 (48)
S9	20 (48)
Other	2 (4)
Therapy mode, n (%)	
APAP	28 (67)
CPAP	14 (95)
Currently using humidification, n (%)	40 (95)
Swift FX	21 (50)
Swift LT	11 (26)
Mirage Swift	3 (7)
AirFit P10	7 (17)
Dryness experienced at least once per week on current therapy, n (%)	23 (55)
Travel with device and humidifier, n (%)	29/38 (74)

Data are mean ± standard deviation (range), or number of patients (%).

APAP, automatically-adjusting positive airway pressure; CPAP, continuous positive airway pressure; PAP, positive airway pressure.

## Visual inspection

Visual inspection showed that there was no degradation of the paper structure of the 71 HumidX™ components. The HumidX™ corrugation structure was intact, no paper was dislodged and only minimal damage to the channels was observed. Paper tint colour variation occurred in 28% of samples, and was seen proximal to the HumidX™ paper. In 11% of samples there was accumulation of skin oils on the external surfaces of the Nylon 12 cartridge due to the cartridge resting on the subject's upper lip. However, there were no reports of skin issues at potential areas of contact between the HumidX™ cartridge and the patient's face.

## Bioburden

Bioburden enumeration of the 71 HumidX™ samples collected over the 6-week study period were found to be within a safe level. The bioburden colony forming unit (CFU) count remained stable in a 4-decade band ( $10^{3.1}$ – $10^{7.1}$ ) over the 42 nights of the study and showed no hyperbolic curving or points of positive or negative inflection (Figure 3). The vast majority of microbes identified were part of the normal human flora and/or ubiquitous to the environment. The microbial isolates and their pathogenicity and common source are shown in Table 3.

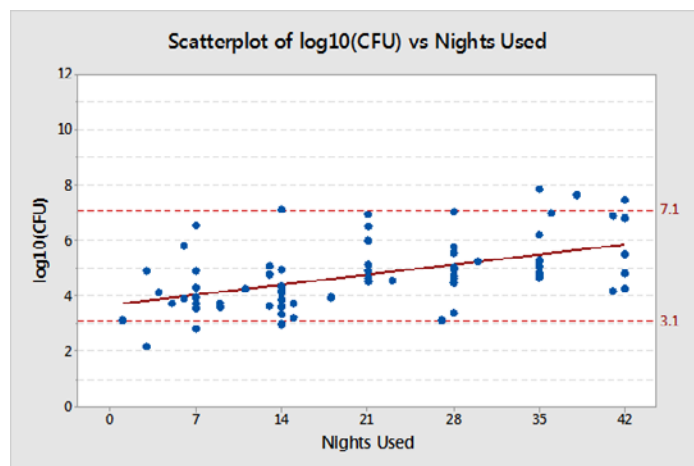


Figure 3. Bioburden results ( $\log_{10}$ CFU) from 71 samples, each used for up to 42 nights. Reference lines at 3.1 and 7.1 indicate a 4-decade band centred about the majority of samples. Line of best fit has a gradient of  $10^{0.052}$  CFU/night.

**Table 3. Pathogenicity summary of identified isolates**

<b>ID Result</b>	<b>Pathogenicity</b>	<b>Typical Sources for Microbes</b>
<i>Staphylococcus epidermidis</i>	Immunocompromised, Into the blood/ transcutaneous	Normal human flora
<i>Candida parapsilosis</i>	Immunocompromised, wounds	Human hands
<i>Rhodotorula mucilaginosa</i>	Not known to be pathogenic	Common environmental
<i>Micrococcus luteus</i> OR	A contaminant in sick patients	Normal human flora
<i>Micrococcus lylae</i>	Minimal	Normal human flora
<i>Pseudomonas oryzae</i>	Minor opportunistic pathogen	Environmental sources
<i>Prototheca zopfii</i>	Causes mastitis	Ubiquitous environmental
<i>Corynebacterium accolens</i>	Not known to be pathogenic	Ubiquitous environmental
<i>Staphylococcus saprophyticus</i>	Causes urinary tract infections	Human genital and gastrointestinal tracts
Yeast. Possibility of <i>Prototheca zopfii</i> OR	Causes mastitis	Ubiquitous environmental
<i>Cryptococcus terreus</i>	Not known to be pathogenic	Soils
Rhizopus spp	Unknown pathogenicity	Fruit & vegetables
Yeast- Trichosporon inkin	Possible opportunistic infections in immunocompromised	Normal human hair flora
Penicillium spp	Unknown pathogenicity	Soil
Aspergillus spp.	Unknown pathogenicity	Ubiquitous environmental
Alternaria spp.	Allergens & opportunistic infections in immunocompromised	Ubiquitous environmental
Possibility of <i>Bacillus atrophaeus</i> OR	Unknown pathogenicity	Unknown
<i>Bacillus subtilis</i> OR	Pathogenic in severely immunocompromised	Gastrointestinal tract
<i>Bacillus amyloliquefaciens</i>	Unknown pathogenicity	Possibly Soil
<i>Staphylococcus hominis</i> ssp <i>hominis</i>	Possible cause of opportunistic infections in immunocompromised	Normal human skin flora
<i>Staphylococcus aureus</i>	Common, not always pathogenic	Human respiratory tract and skin
Fusarium spp	Causes opportunistic infections	Cereal crops



## Impedance

Mean impedance of the HumidX™ prior to use was  $0.50 \pm 0.04$  cmH<sub>2</sub>O at 50 L/min; this increased by 25% (0.12 cmH<sub>2</sub>O) at the end of the study (mean HumidX™ impedance  $0.62 \pm 0.05$  cmH<sub>2</sub>O) (Figure 4).

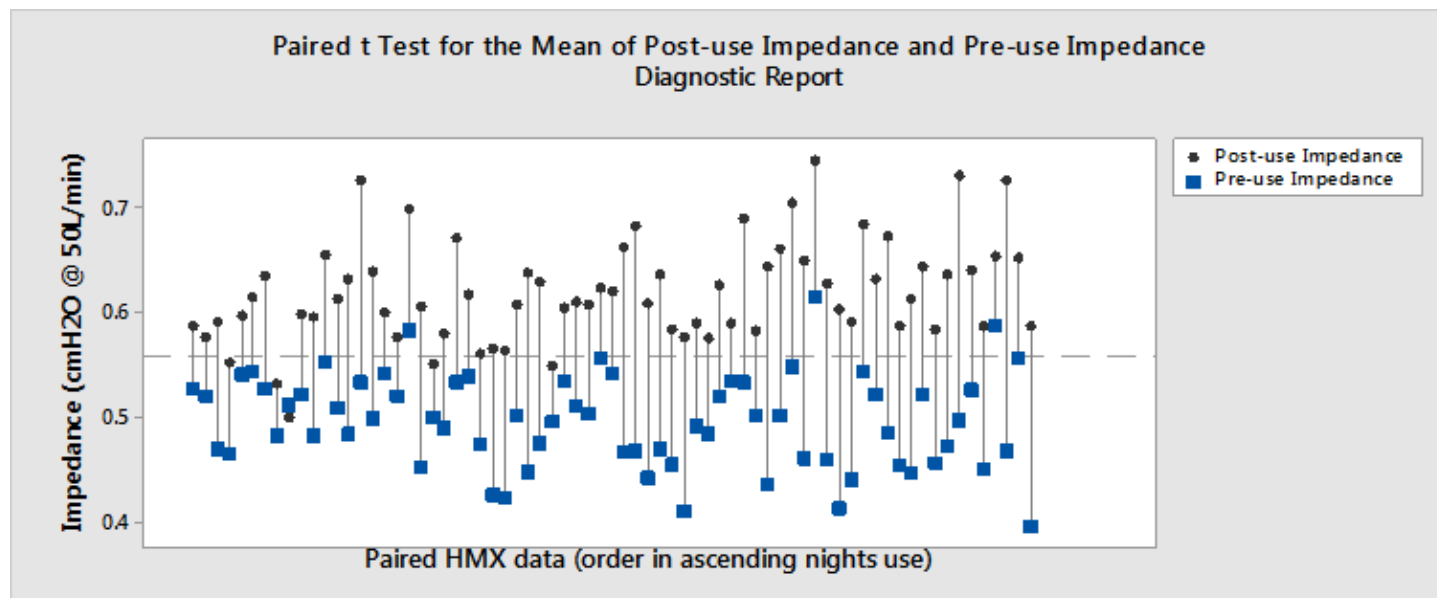


Figure 4. Paired data (pre- and post-use) for HumidX™ impedance (cmH<sub>2</sub>O) at 50 L/min based on number of nights used (7 nights at left to 42 nights on the right).

## Patient assessment

There were no significant differences between the patients' current mask system and the HumidX™ mask system with respect to initial ease of inhaling and exhaling, with or without pressure (Table 4).

A summary of Likert scale scores during the 6-week follow-up is provided in Table 5. Ease of inhaling, exhaling and overall breathing comfort on the HumidX mask system

was consistently scored at higher than 6 on the Likert scale. For breathing comfort, 45% of subjects preferred the HumidX Mask System, 30% preferred their current mask system and 25% stated no preference for either mask. The humidification performance of the HumidX mask system was scored at higher than 6 on the Likert scale at each week of the trial, and was not significantly different from the patients' current mask system.

**Table 4. Initial ease of use**

	Median score (interquartile range)		p-value
	Current mask system (n=42)	HumidX™ mask system (n=42)	
<b>Initial assessment</b>			
Ease of inhaling (without pressure)	8 (6.8–7)	8 (5.8–7)	0.14
Ease of exhaling (without pressure)	9 (7–10)	8 (7–9)	0.46
Ease of inhaling (with pressure)	9 (8–10)	8 (8–9)	0.56
Ease of exhaling (with pressure)	9 (8–9.3)	8 (7–9)	0.14

P-values were obtained from the Mann-Whitney test. Each variable rated on a Likert scale from 0 to 10, where lower scores indicate worse ease of use.

**Table 5. Summary of patient ratings, overall and by randomisation group.**

	Overall (n=42)	Group 1 (n=7)	Group 2 (n=7)	Group 3 (n=7)	Group 4 (n=7)	Group 5 (n=7)	Group 6 (n=7)
<b>Humidification performance<sup>a</sup></b>							
Week 1	8 (6–9)*	<u>8 (6–9)</u>	6 (5–9)	7 (4–9) <sup>1</sup>	10 (8–10) <sup>†</sup>	8 (5–8)	8 (7–9)*
Week 2	7 (6–9)**	8 (6–9)	<u>7 (6–8)</u>	7 (3–9) <sup>2</sup>	9 (7–10)	7 (6–8)	8 (7–9) <sup>2</sup>
Week 3	8 (7–8)*	8 (6–9)	8 (7–8) <sup>†</sup>	<u>8 (4–9)<sup>2</sup></u>	9 (6–10) <sup>1</sup>	7.5 (7–8) <sup>1</sup>	8 (6–8) <sup>2</sup>
Week 4	8 (7–8)*	8 (6–8)	8 (7–8) <sup>†</sup>	8 (8–10) <sup>2</sup>	<u>9 (5.3–10)<sup>1</sup></u>	8 (7–8) <sup>††</sup>	8 (6.5–8) <sup>2</sup>
Week 5	8 (8–9)*	8 (8–9) <sup>1</sup>	8 (8–8) <sup>†</sup>	8 (8–10) <sup>3</sup>	10 (6–10) <sup>2</sup>	<u>8 (7–8)</u>	8 (6–9) <sup>2</sup>
Week 6	8 (7–9)*	8 (7–8) <sup>1</sup>	7 (7–8) <sup>†</sup>	9 (8–10) <sup>3</sup>	10 (5–10) <sup>2</sup>	8 (8–8) <sup>††</sup>	8 (7–9) <sup>2</sup>
<b>Ease of inhaling<sup>b</sup></b>							
Week 1	9 (7–10)*	<u>7 (6–8)</u>	9 (7–10) <sup>†</sup>	10 (8–10) <sup>††</sup>	9 (9–10) <sup>††</sup>	8 (7–9)	8 (5–9)
Week 2	9 (7–10)*	7 (6–9)	<u>9 (7–10)<sup>†</sup></u>	10 (8–10) <sup>2</sup>	9 (8–10) <sup>1</sup>	8 (7–9)	9 (7–10) <sup>2</sup>
Week 3	8 (7–10)*	7 (7–9) <sup>†</sup>	9 (7–10) <sup>†</sup>	<u>9 (8–10)<sup>2</sup></u>	9 (7–10) <sup>2</sup>	8 (7–9) <sup>1</sup>	8 (8–10) <sup>2</sup>
Week 4	9 (7–9)*	7 (7–9) <sup>†</sup>	9 (7–10) <sup>†</sup>	10 (8–10) <sup>3</sup>	<u>9 (7–10)<sup>2</sup></u>	8 (7–8) <sup>1</sup>	8 (8–10) <sup>2</sup>
Week 5	9 (8–10)*	9 (8–9) <sup>††</sup>	8 (7–10) <sup>†</sup>	10 (8–10) <sup>3</sup>	9 (4–10) <sup>2</sup>	<u>8 (7–9)<sup>1</sup></u>	9 (8–10) <sup>2</sup>
Week 6	9 (8–10)*	9 (7–9) <sup>††</sup>	8 (7–10) <sup>†</sup>	10 (8–10) <sup>3</sup>	10 (9–10) <sup>3</sup>	8 (8–9) <sup>1</sup>	9 (8–10) <sup>2</sup>
<b>Ease of exhaling<sup>c</sup></b>							
Week 1	9 (8–10)*	<u>8 (6–9)</u>	9 (9–10) <sup>†</sup>	9 (8–10) <sup>††</sup>	9 (8–10) <sup>††</sup>	8 (8–10)	8 (6–9)
Week 2	9 (8–10)*	9 (6–9)	<u>9 (9–10)<sup>†</sup></u>	9 (8–10) <sup>2</sup>	9 (8–10) <sup>††</sup>	8 (7–10)	9 (7–10) <sup>2</sup>
Week 3	9 (8–10)*	9 (7–9) <sup>†</sup>	9 (9–10) <sup>†</sup>	<u>10 (8–10)<sup>2</sup></u>	9 (8–10) <sup>2</sup>	8 (7–10) <sup>1</sup>	8 (7–9) <sup>2</sup>
Week 4	9 (7–10)*	9 (7–9) <sup>†</sup>	9 (9–10) <sup>†</sup>	10 (8–10) <sup>3</sup>	<u>9 (7–10)<sup>2</sup></u>	8 (7–9) <sup>1</sup>	9 (7–9) <sup>2</sup>
Week 5	9 (8–10)*	9 (7–9) <sup>†</sup>	9 (9–10) <sup>†</sup>	10 (8–10) <sup>3</sup>	9 (5–10) <sup>2</sup>	<u>8 (6–10)<sup>1</sup></u>	9 (8–9) <sup>2</sup>
Week 6	9 (8–10)*	9 (7–9) <sup>†</sup>	9 (9–10) <sup>†</sup>	9.5 (8–10) <sup>3</sup>	10 (9–10) <sup>3</sup>	8 (8–10) <sup>††</sup>	9 (8–9) <sup>2</sup>
<b>Overall breathing comfort<sup>d</sup></b>							
Week 1	8 (7–9)*	<u>7 (6–8)</u>	8 (5–10)	10 (8–10) <sup>1</sup>	9 (7–9) <sup>1</sup>	8 (8–9) <sup>†</sup>	8 (7–9)
Week 2	8 (7–9)*	8 (7–8) <sup>†</sup>	<u>9 (6–10)</u>	10 (8–10) <sup>2</sup>	9 (7–9) <sup>1</sup>	8 (7–9) <sup>†</sup>	9 (8–9) <sup>2</sup>
Week 3	8 (7–9)*	8 (6–9)	9 (6–10)	<u>10 (9–10)<sup>2</sup></u>	9 (6–9) <sup>2</sup>	8 (6–9) <sup>1</sup>	8 (8–10) <sup>2</sup>
Week 4	8 (7–9)*	8 (6–9)	7 (6–10) <sup>†</sup>	10 (7–10) <sup>3</sup>	<u>9 (5–9)<sup>2</sup></u>	8 (5–9) <sup>1</sup>	8 (8–10) <sup>2</sup>
Week 5	8 (8–9)*	8 (6–9)	7 (6–10) <sup>†</sup>	10 (9–10) <sup>3</sup>	9 (4–9) <sup>2</sup>	<u>8 (5–9)<sup>1</sup></u>	8 (8–10) <sup>2</sup>
Week 6	8 (8–10)*	7 (6–9)	7 (6–10) <sup>†</sup>	10 (9–10) <sup>3</sup>	9 (8–9) <sup>3</sup>	8 (8–9) <sup>2</sup>	8 (8–10) <sup>2</sup>

Data are expressed as the median (interquartile range; IQR), rounded to the nearest whole number.

<sup>a</sup>How would you rate the humidification performance of the HumidX™ mask? <sup>b</sup>How would you rate the ease of inhaling with pressure while using the HumidX™ mask system, after each week? <sup>c</sup>How would you rate the ease of exhaling with pressure while using the HumidX™ mask system, after each week? <sup>d</sup>How would you rate the overall comfort of breathing while using the HumidX™ mask system, after each week? All answers were on a scale from 0 to 10 where lower scores represent better ratings.

<sup>1</sup>Statistical analysis based on n=6; <sup>2</sup>Statistical analysis based on n=5; <sup>3</sup>Statistical analysis based on n=4.

\*p<0.001, \*\*p<0.01 or <sup>†</sup>p<0.05 (Wilcoxon sign ranked method) for comparison with a Likert scale score of 6.

Underline represents the time of replacement/changeover from the first to the second HumidX™ component.

The proportion of subjects who reported feelings of dryness more than once per week was 54.8% at baseline on the current humidification system; values during the 6-week trial of the HumidX™ Mask System ranged from 39.4% to 52.9% of subjects per week.

At the end of the trial, 52.5% of patients stated that they preferred the HumidX™ system, 35% preferred their current set up and 12.5% had no preference. Specific comments about the HumidX™ system related to the convenience of the system, particularly for travel.

## Discussion

This study showed that a mask system utilising an HME component was able to be safely used for up to 6 weeks without marked increases in impedance and bacterial colonisation. Currently available HME components generally have a short lifespan, with safety recommendations for single use over a 24-hour period. The safety of HMEs was investigated by Hurni et al in 1997<sup>20</sup> who found no difference in the integrity of respiratory ciliated epithelium in patients using heated humidification versus those using an HME over a 5-day period.<sup>20</sup>

There are three possible outcomes for bioburden deposited onto the HumidX™ component. They might be prolific and colonize the HumidX™ component, enter a bacteriostatic state, or be reduced in a bactericidal manner. Microbes typically require the presence of water, nutrients, heat and optimal pH and oxygen concentrations in order to proliferate.<sup>25</sup> In this study, the HumidX™ component used showed no bioburden safety concerns over the six weeks. The bioburden measure remained stable, with no signs of hyperbolic curving over the 42 nights of the study, indicating a bacteriostatic state (i.e. no prolific bacterial growth).

Impedance of the HumidX™ was relatively stable, with only a small steady increase across the 6-week study period. This absolute increase in impedance is within the tolerance limits of ResMed PAP devices. Visual inspection showed no blocked or damaged channels, indicating that change in impedance was driven by normal use of the HumidX™ component. This use scenario results in natural geometry changes in the HumidX™ component as the heat and moisture exchanging paper swells and contracts relative to moisture content. Mask and accessory impedance is proportional to the breathing resistance experienced by the patient and the good rating for breathing comfort found in this study is indicative of impedance levels that were relatively similar over time. Subjectively, there was no difference in ratings for ease of inhaling and exhaling with the HumidX™ mask compared with the patients' current mask.

The number of subjects experiencing oro-nasal dryness each week during the study ranged from 39.4% to 52.9%, similar to the 54.8% of subjects who reported experiencing dryness with their current set-up. It is therefore likely that the humidification performance of the HumidX™ system was adequate, reflected in patient ratings of overall humidification performance, which were similar to those with the current mask system.

Overall, nearly two-thirds of patients (65%) either preferred the HumidX™ Integrated Mask System or found it to be similar to their current system. Positive subjective feedback was obtained about the compactness, simplicity and convenience of the HumidX™ system, and the ability

to achieve equivalent humidification performance without the need for continuous maintenance.

Due to inter-individual physiological variations it is hypothesized that different patients might require different levels of humidification to achieve the optimal level of comfort during CPAP therapy. Climate and ambient conditions might also impact on the level of humidification required to achieve patient comfort. This highlights a need for different grades of HumidX™ components allowing the humidity level to be customised, similar to the ability of patients to alter settings on active humidification systems to maximise their comfort during therapy. Further research to confirm the ability of varying grades of HumidX™ components to improve patient comfort and compliance across in a range of settings and climates is recommended.

## Conclusion

Advances in CPAP technology, particularly those aimed at improving patient comfort, may help to maximise patient compliance and adherence to therapy. Passive humidification technology such as HMEs can be used at home and while travelling and offer a compact and simple therapy solution. This study demonstrated acceptable safety in terms of the bioburden proliferation characteristics and impedance of the HumidX™ HME component for usage periods of up to 6 weeks. Humidification performance and breathing comfort were also found to be acceptable, and were rated by patients as equivalent to active humidification. Patient acceptability of the HumidX™ system was good, with more than half of the patients stating that they preferred this over their current humidification system.

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