

# Climate Control: Humidification with heated tube

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## Abstract

Nasal congestion, dry nose and throat, epistaxis and discomfort associated with the cold air of positive airway pressure (PAP) therapy occurs in up to 70% of patients. Humidification is a means to counteract these symptoms and has been shown to increase compliance. There are issues associated with humidification, namely tube condensation or rainout which may adversely impact therapy and compliance. Current humidifiers do not properly address this issue and may deliver lower levels of absolute humidity than patients require to treat nasal symptoms. This paper describes the development of a Climate Control algorithm where both temperature and humidity remain constant using the H5i™ humidifier and ClimateLine™ heated tube. Extensive bench testing conducted over varying ambient conditions showed the S9™ humidification system was able to maintain a constant temperature at the mask and absolute humidity without tube condensation. After the development and bench testing of this new system it was tested in a validation trial where it was shown to address the issues of rainout whilst maintaining therapeutically appropriate humidification. There was an increase in average daily usage with the S9 humidification system and it was preferred compared to the traditional humidification systems of a standard humidifier with standard tube.

## Introduction

The normal function of the upper airway is to heat, humidify and filter inspired air. When a patient uses positive airway pressure (PAP) therapy, there is the possibility of high unidirectional nasal airflow due to mouth leak or unintentional mask leak [1]. This causes progressive drying of the upper airway mucosa, release of inflammatory mediators, increased nasal mucosal blood flow, increased nasal resistance and daytime upper airway symptoms [2,3]. A majority of patients (up to 70%) using PAP report these symptoms of nasal congestion, dry nose and throat, sore throat, epistaxis and discomfort associated with cold air [4-7], which can lead to a reduction in compliance and efficacy of treatment [8,9].

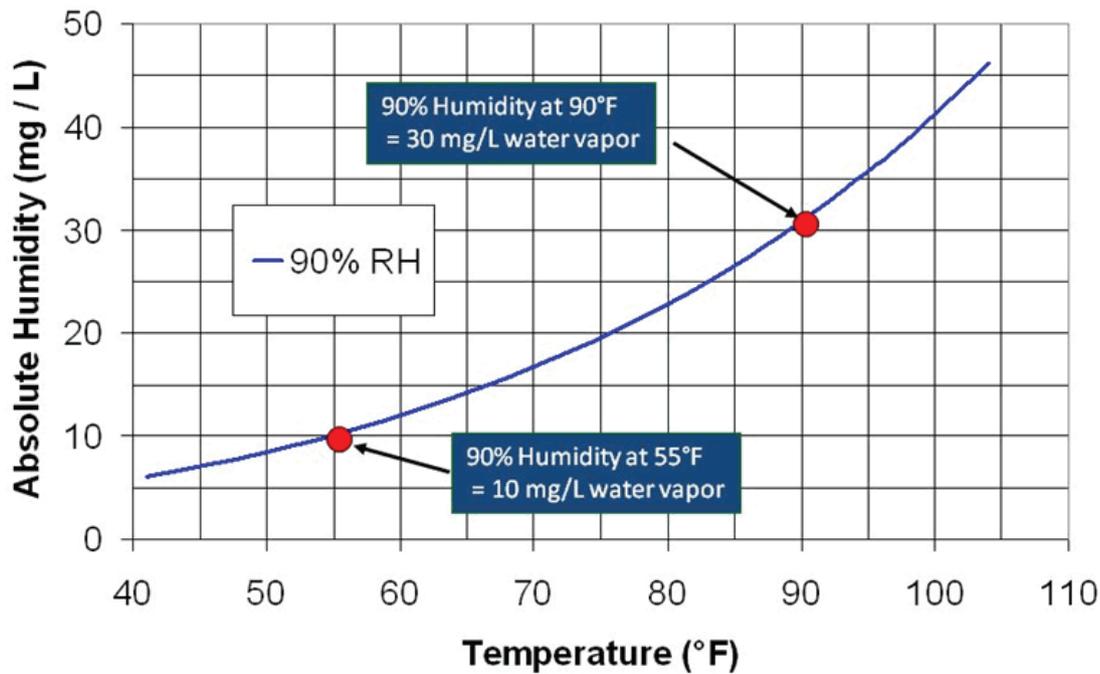
A heated humidifier placed between the PAP system and the patient can prevent the upper airway drying and mucosal inflammation associated with mouth leaks [1,2]. Use of heated humidification early in PAP therapy has been shown to reduce symptoms and increase compliance [8, 9]. Use of heated humidification has rapidly increased over the last 10 years and more than 50% of new PAP users have heated humidification.

The output of a heated humidifier is principally limited by the issue of tube condensation, or rainout. This occurs because air rapidly cools between the humidifier and mask, reducing its ability to transport water, and the excess water forms droplets on the inside surface of the tube. Excessive condensation is a nuisance to patients and has been

shown to adversely impact therapy and compliance [10]. It increases in conditions that promote heat loss from the tube such as cold ambient conditions or drafts and can be reduced by insulating the tube with a wrap, by running it under the bed clothes or by directly heating the tube. It can also be reduced by decreasing the humidifier temperature but this also reduces the humidity delivered to the user. In some ambient conditions it may be difficult to deliver sufficient levels of humidity to prevent symptoms while avoiding excessive condensation.

The majority of current humidification systems for PAP therapy have a single patient adjustable control which alters the temperature of the water heater. Patients set the humidifier at the beginning of each night of therapy and it remains unchanged through the night. Condensation can be reduced if the humidifier automatically responds to changes in ambient conditions (temperature and humidity) or increases in total flow due to mask leak.

Relative humidity (RH) is the amount of water vapor in the air as a percentage of the maximum amount it can hold (saturation point, 100%) at a specific temperature. Absolute humidity (AH) is the total amount of water vapor (mg/L) in the air and is independent of temperature. The relationship between RH, temperature and AH is shown in Figure 1. For a RH of 90%, if the ambient air temperature is 55°F (13°C) the AH is 10 mg/L but at 90°F (32°C) the AH is 30 mg/L with RH still 90%. To maintain a consistent level of humidification during therapy the AH, not the RH, needs to be constant.



**Figure 1. The relationship between relative humidity (RH), temperature and absolute humidity (AH).**

For a constant RH as the temperature changes so does the AH which represents the amount of water vapor to treat nasal symptoms caused by PAP therapy.

This paper describes the development and validation of a humidification system designed to automatically provide constant high levels of humidity without tube condensation over a wide range of ambient conditions. This system is part of the S9 series and uses a control algorithm (Climate Control), with a heated tube (ClimateLine) and integrated heated humidifier (H5i).

## Development trial

The aim of the development trial was to determine the effect of the inclusion of heated tubing to a PAP humidification system on patient comfort and rainout. The secondary aim was to derive the relationship between patient reported outcomes with temperature and humidity.

## Methods

This was a multi-center, prospective study of 33 subjects enrolled at five sites in the USA (Table 1). The subjects were compliant with PAP therapy (> 4 hours/night for at least five nights/week) for at least three months prior to the study. The study was approved by each sites' Independent Review Board and all subjects gave informed consent.

All subjects used an S8 device with H3i humidifier prior to the study and were given a heated tubing unit to replace the standard tube for the two week study period. The heated tube contained a temperature sensor at the mask end and manual controllers to allow the subject to change temperature and humidity levels.

During the study subjects recorded diary information on ambient temperature, device settings and the presence of rainout or cold humidification while using the heated tubing. The subjects were encouraged to adjust the settings on the heated tube and H3i as needed during the course of the evaluation. The heated tube had temperature and humidity digital loggers (DS1923 Hygrochron, Maxim Integrated Products, CA) incorporated into the circuit for the purposes of this study.

**Table 1. Site table for the development trial.**

Site #	Site	Location	Enrolment
1	Avastra Clinical Trials/ Sleepwell Partners	Midvale, Utah	5
2	Pro2 Respiratory Services	Lexington, Kentucky	7
3	TriState Sleep Disorders Center	Cincinnati, Ohio	3
4	Arete Sleep Health	Vancouver, Washington	3
5	Avastra Clinical Trials/ South Towns Sleep Medicine	West Seneca, New York	15
			33

Subjective responses were rated using an 11-point Likert scale to capture and analyze comparative data between the heated tubing and the subject's current tubing system. A score of 10 represents a rating of significantly better compared to the standard tube, 5 is the same and a rating

of 0 is significantly worse. Wilcoxon Signed Rank test with a criterion value of 6 was used to statistically analyze the Likert scale scores.

## Results

Demographics of the subjects are shown in Table 2. All subjects had experienced rainout or discomfort due to the cold air in the past year. 39% (13/33) reported experiencing rainout and discomfort due to cold air, 49% (16/33) experiencing rainout and 12% (4/33) experiencing discomfort due to the cold air. These issues were principally experienced in winter (79%) but occurred throughout the entire year (spring 33%, summer 30% and fall 27%).

**Table 2. Patient demographics for the development trial**

Number of subjects	33
Age (years)	49 ± 11
Gender	25 Male / 8 Female
Current mask:	
Pillows / Nasal / Full face	36% / 49% / 15%
PAP mode:	
AutoSet / CPAP	12% / 88%
Chin strap	9%
Tube wrap	36%

Five patient reported outcomes were significantly improved with the heated tube compared to the current tube system (Table 3).

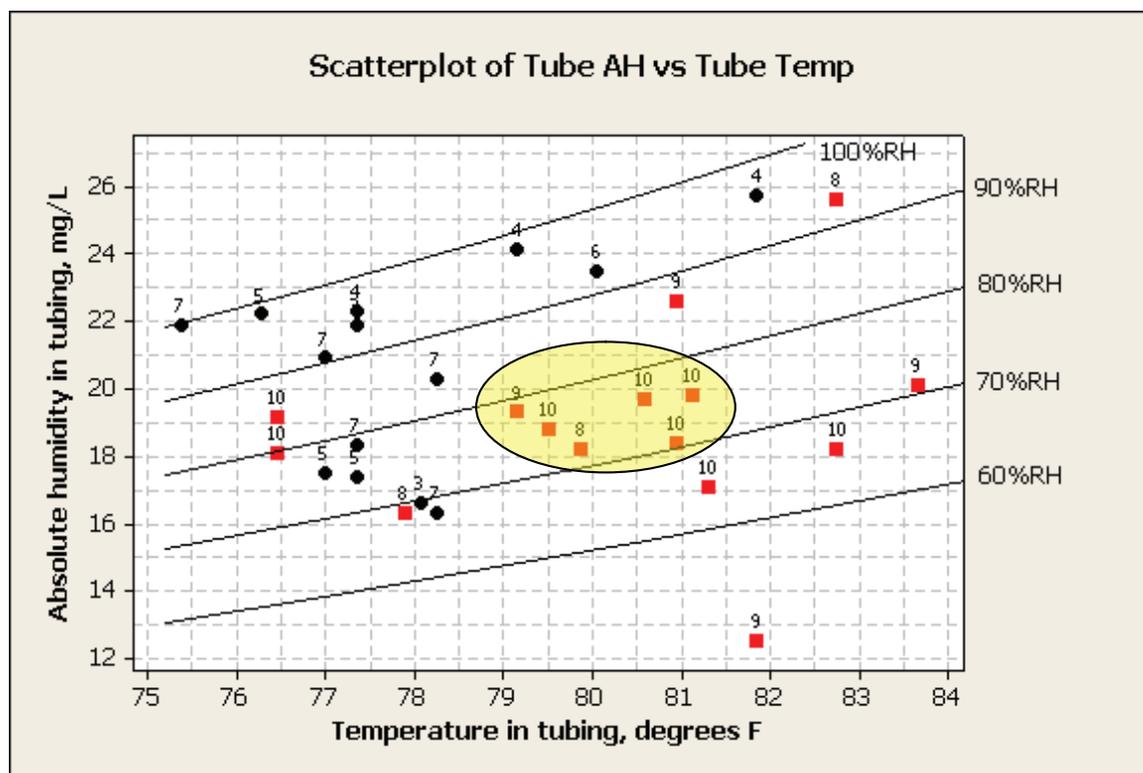
**Table 3. Features reported to be significantly improved with the heated tube compared with subject's current tube system.**

Measurement at mask	Mean	Median	Min	Max	WSR, C = 6
Temperature	7.1 ± 2	7	3	10	p = 0.004
Achievement of optimal temperature	7.3 ± 2.3	8	4	10	p = 0.003
Humidity level	7.2 ± 2.4	7	3	10	p = 0.01
Achievement of optimal humidity	7.3 ± 2.3	8	3	10	p = 0.003
Amount of rainout	8.2 ± 1.9	9	5	10	p < 0.0001

WSR, C=6: Wilcoxon Signed Rank, Criterion = 6.

The main positive features reported on the heated tubing system were directly related to the increased levels of humidity delivered by the heated tube:

- comfort of temperature at the mask
- less rainout



**Figure 2. AH and RH (y-axis) versus temperature (x-axis) of the heated tubing system in relation to subjective ratings of comfort.**

Values above each point represent the actual rating value. The shaded area represents a zone of highest subjective ratings of comfort.

- comfort of humidity at the mask
- less cold air
- reduction of mouth/nose dryness.

The relationship between AH, temperature and RH at the mask, based on subjective ratings of comfort were plotted (Figure 2). This showed a clustering (shaded area) of highest subjective ratings with an AH of 17-20 mg/L, RH of 80%  $\pm$  10% and a tube temperature mean of 80°F (27°C).

## Outcomes

Despite being long term users of humidification a number of subjects had residual upper airway symptoms and all had ongoing issues with rainout and discomfort due to the cold air.

The study results demonstrated that a heated tube was perceived as being more comfortable than standard tubing indicating that improved comfort may be achieved with set table mask air temperatures and higher levels of humidity than available from current humidifier systems. The study also showed that maximum comfort was achieved with humidification and temperature settings in the region of 80°F (27°C) and 80% RH which is approximately 21 mg/L AH. This AH corresponds with findings of Richards et al. [1] for maximal improvement of nasal resistance.

A new heated tube, ClimateLine, was developed based on the study's results. It has a smaller internal diameter of 15 mm, is more flexible than standard tubing, has a temperature sensor at the mask end of the tube and the controls fully integrated into the system. A control algorithm, Climate Control, was also developed.

## Description of Climate Control

Climate Control is a control algorithm that automatically adjusts the humidity delivered by the S9 system in response to ambient conditions of temperature and humidity. It also adjusts for changes in pressure and flow rate. This is to maintain a target AH at the mask equivalent to a RH of 80% at the user set temperature. The control algorithm utilizes five sensors:

- ambient temperature sensor in the H5i
- ambient humidity sensor in the H5i
- flow sensor in the S9 PAP device
- heater plate temperature sensor in the H5i humidifier
- mask temperature sensor in the ClimateLine tube.

The ambient condition sensors in the H5i and the heater plate sensor allow the adjustment of the humidity output of the H5i in response to changes in ambient temperature

and humidity. The flow sensor in the S9 PAP device allows compensation for increases in flow rate which occur when there is unintentional leak or changes in pressure with an auto-adjusting PAP device. The temperature sensor at the mask end of the ClimateLine tube allows the output from the system to be monitored. The information from these five sensors combine to allow Climate Control to deliver constant AH, RH and temperature, to protect against rain-out whilst providing suitable levels of humidification.

## Bench testing

The use of bench testing permitted the humidification system of S9 to be tested in various temperature and humidity conditions. The testing was performed in an environmentally controlled chamber where both the ambient temperature and humidity could be changed to the desired test conditions. The temperature and humidity outputs of the S9 humidification system were independently measured using a calibrated electronic hygrometer (DS-U-2 Hygroclip S1, Rotronic, Switzerland).

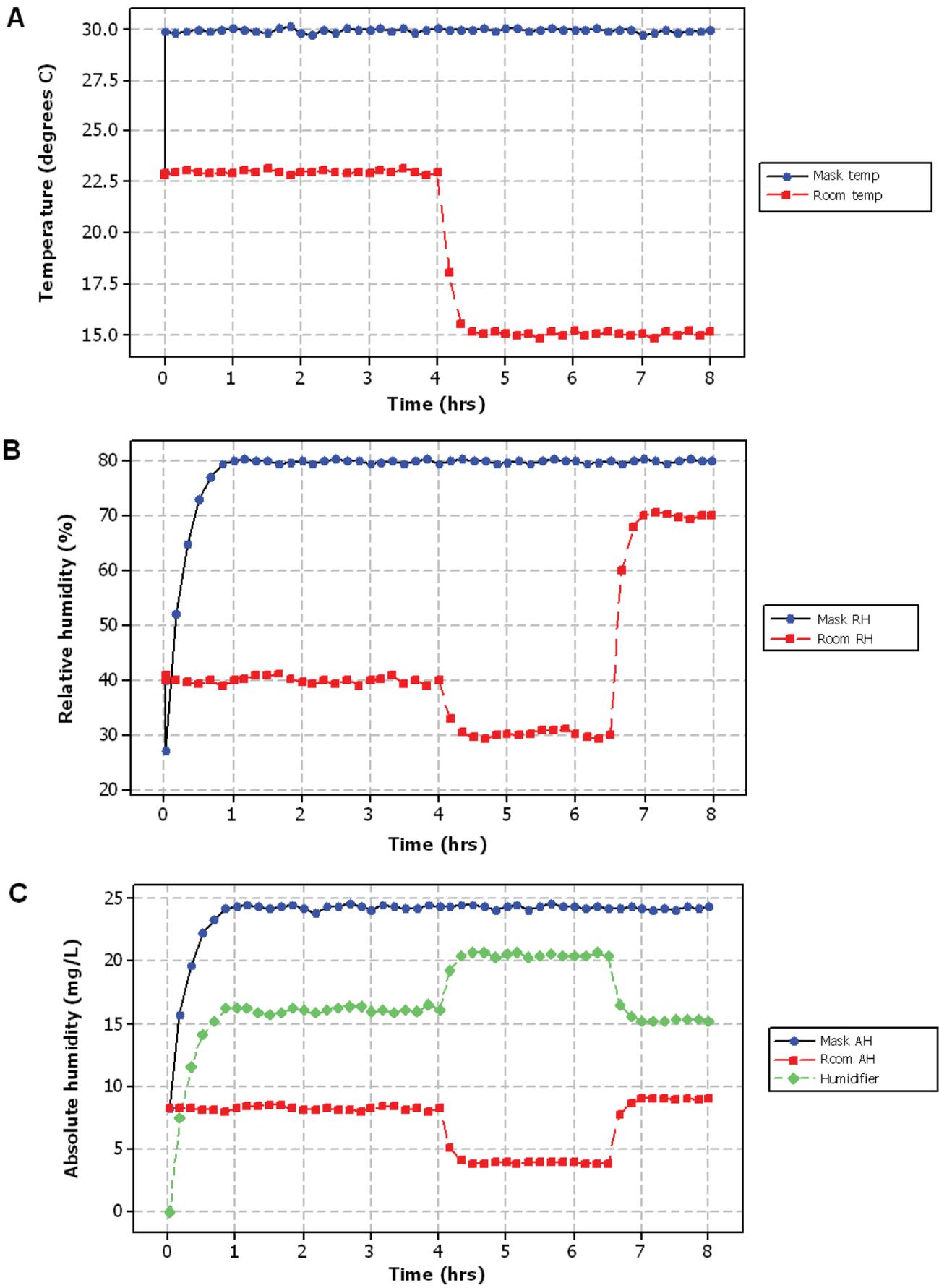
The behavior of the Climate Control system to varying temperature and humidity changes is shown in Figure 3. The Climate Control system was set to 86°F (30°C) Auto with a PAP setting of 10 cm H<sub>2</sub>O and a mask flow of 35 L/min giving it the target of 24 mg/L AH (at 80% RH). The data was collected simultaneously from one recording sequence.

At time zero the device was started, with the H5i filled with water at ambient temperature, in a room stable at 73°F (23°C), 40% RH, AH 8 mg/L. Within two minutes the mask air temperature reached the set point of 86°F (30°C). After 30 mins the water warmed sufficiently to add 15 mg/L to the air and within one hour from start the H5i was adding a stable 17 mg/L, to provide 24 mg/L to the patient at 80% RH.

At 4 hours the room was cooled, over 30 mins, to 59°F (15°C) and 30% RH. The Climate Control system responded by increasing the evaporation rate from the humidifier to 20 mg/L, maintaining constant temperature and humidity at the mask.

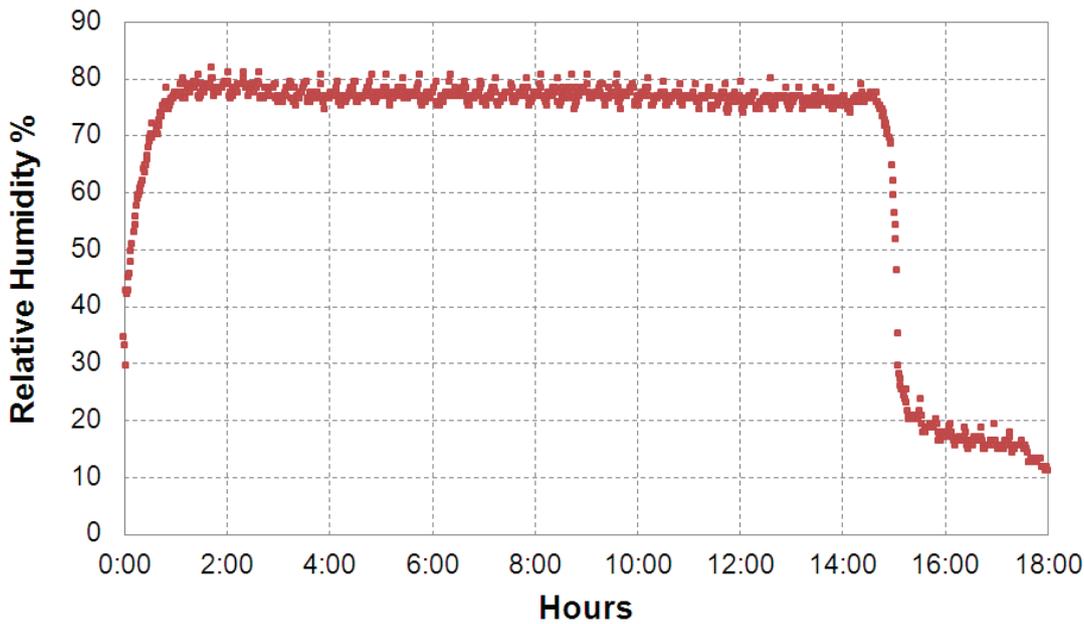
At 6 hours 30 mins the room humidity was raised to 70% RH. The Climate Control system responded by decreasing the evaporation rate from the humidifier to 15 mg/L, and maintained constant temperature and humidity at the mask.

The duration that the H5i with a full water tub and ClimateLine could deliver an absolute humidity of 21 mg/L (temperature = 80°F (27°C), RH = 80%) with a PAP setting of 10 cm H<sub>2</sub>O and a mask flow of 35 L/min was 14 hours



**Figure 3. Performance of the Climate Control system to varying temperature and humidity changes.**

Graph A shows the mask and room temperatures. Graph B shows the mask and room RH. Graph C shows the mask and room AH as well as the AH output of the H5i. All three graphs were collected simultaneously from the one recording sequence. The Climate Control system was set to maintain a temperature of 86°F (30°C) with 80% RH and 24 mg/L AH. At 4 hours the room temperature was dropped to 59°F (15°C) and 30% RH. At 6 hours 30 mins the room humidity was raised to 70% RH.



**Figure 4. Plot of humidity output from the H5i with ClimateLine over time.**

The test was performed at a PAP = 10 cm H<sub>2</sub>O, mask flow = 35 L/min and the humidifier water tub filled to the maximum fill line. Output decreased after 14 hours 36 min when the water tub was empty.

36 min (Figure 4). Humidity levels dropped after this as the water tub was empty.

## Validation trial

The aim of the validation clinical trial was to evaluate the efficacy of treatment and the subjective comfort and usability of the S9 system with Climate Control (S9 PAP device, H5i humidifier and ClimateLine heated tube) in its final production implementation.

## Methods

A prospective study of 20 subjects was conducted at the ResMed Sleep Research Centre, Sydney Australia. Subjects all had OSA (AHI>15) and were compliant with PAP therapy (>4 hours/night for at least five nights/week) for at least six months prior to the study. Their current PAP devices were the ResMed S8 Series II (nine subjects), S8 (ten subjects) and S7 (one subject) with humidifiers. The study was approved by the Ethics Committee of the University of New South Wales and all subjects gave informed consent.

Subjects used the S9 system with Climate Control for seven nights in their home. Objective data was downloaded from the S9 device and compared with seven nights downloaded from the subject's current device. Subjective data related to the comfort, humidification and heated tube of the S9 system compared to the participant's current system was collected using questionnaires and 11-point Likert scales. Objective data was analyzed using the Paired t-test and subjective data with the Wilcoxon Signed Rank

test. Objective data is presented as mean ± standard deviation.

## Results

Demographics of the subjects are shown in Table 4. There was no clinical difference in the downloaded apnea hypopnea index (AHI) of the S9 system compared to the current devices (AHI < 5 on both systems). The S9 system uses a revised AHI scoring algorithm meaning that a statistical comparison is not meaningful.

**Table 4. Patient demographics for the validation trial**

Number of subjects	20
Gender	18 Male / 2 Female
Current mask:	
Pillows / Nasal / Full face	30% / 45% / 25%
PAP device:	
S7 / S8 / S8 Series II	5% / 50% / 45%
PAP mode:	
AutoSet / CPAP	65% / 35%
Humidifier:	
H2i / H3i / H4i	5% / 90% / 5%
Chin strap	15%

There was an increase of 30.6 mins in average daily usage from the subject's current device with the S9 system (6.63 hours ± 1.2 versus 7.14 ± 1.4, respectively p = 0.06). Though this increase was clinically significant it did not reach statistical significance as the study was underpowered (39% power) to show statistical significance. To detect a significant change of 30 mins with 80% power, 48

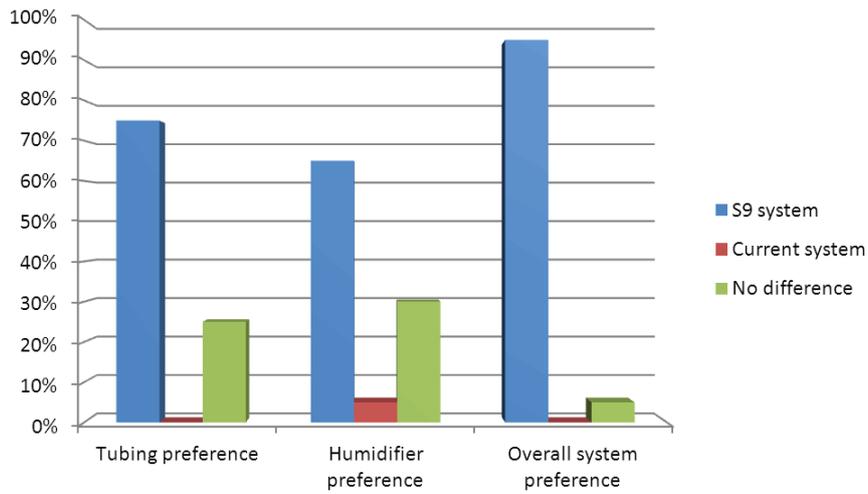


Figure 5. Participant preferences for tubing, humidifier and overall system

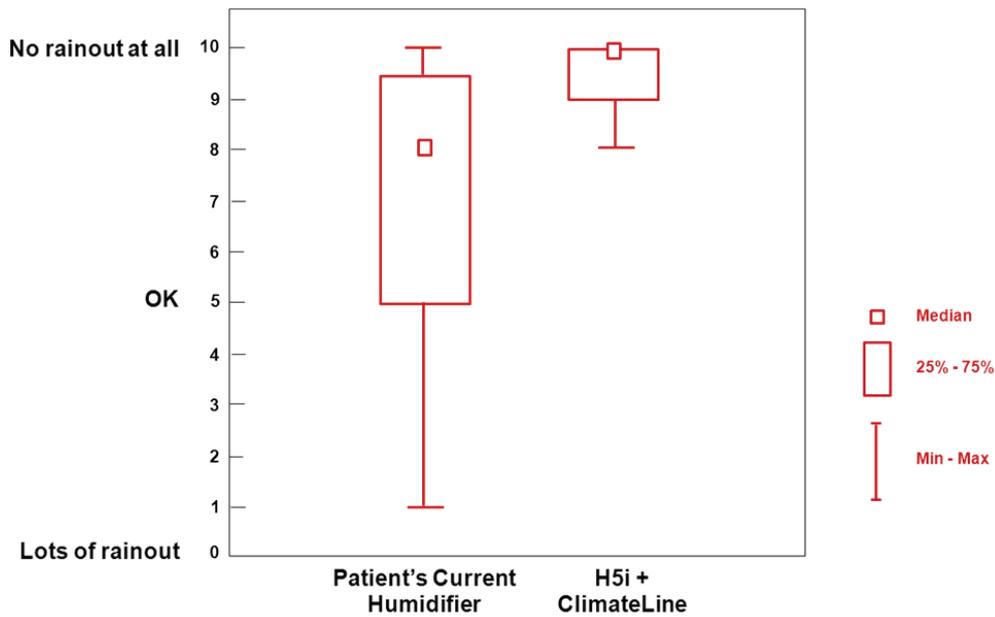


Figure 6. Box and whisker plots for subjective ratings of the amount of rainout each morning in the tube and mask. Climate Control with the H5i and ClimateLine was significantly better ( $p=0.008$ ).

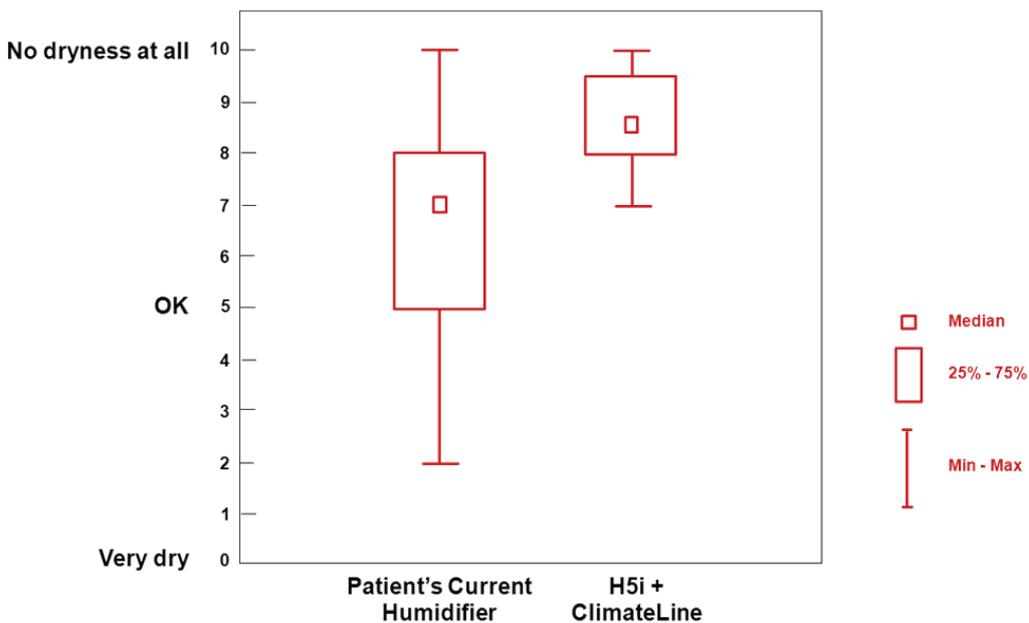


Figure 7. Box and whisker plots for subjective ratings of the dryness of the nose and mouth each morning. Climate Control with the H5i and ClimateLine was significantly better ( $p=0.003$ ).

subjects would have been required. This is the subject of a future trial.

The humidifier and ClimateLine tubing were found to be easy to set up and convenient to use. Subjective preferences are shown in Figure 5. 75% (15/20) preferred the ClimateLine tubing over standard tubing, 65% (13/20) preferred the H5i humidifier over their current humidifier and 95% (19/20) preferred the overall S9 system over their current therapy system.

The increased humidity output of the S9 system led to a significant ( $p = 0.003$ ) decrease in the subjects symptoms of upper airway (Figure 6). This was achieved with significantly less ( $p = 0.008$ ) rainout than with their current device (Figure 7).

## Conclusion

Heated humidification has become an important component of PAP therapy, but current humidification systems are limited in their output by the occurrence of tube condensation. The new Climate Control system on the S9 series was developed to address the findings of a trial where PAP users indicated they were most comfortable at humidity and temperature levels unachievable by conventional humidifiers, and to minimize tube condensation. To achieve its goals the system utilizes feedback from 5 different sensors and includes a new 15 mm heated tube. The user selects a temperature that they feel is most comfortable and the system is automatically controlled to provide a constant AH. Extensive bench testing demonstrated consistent high humidity and temperature output over a wide range of ambient conditions without the development of tube condensation. The final design was tested in a validation clinical trial which demonstrated an increase in average daily usage and a very strong preference for the new system compared to current humidification systems.

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