

Fact sheet performance PURINOX HME

Performance indicators

The PURINOX HME aims to approach normal breathing for laryngectomized patients. Key performance indicators for heat and moisture exchangers (HMEs) are the humidification and breathing resistance.

The higher the humidification, the better the heat and moisture exchanging capacity. The heat and moisture exchanging capacity improves the tracheal conditioning of inspired air within the upper tracheal segment [1]. Use of HMEs is reported to significantly reduce pulmonary symptoms in laryngectomized individuals [2] [3] [4] [5] [6].

The HME's resistance may reduce dynamic airway compression, thereby improving ventilation; however, there is no evidence for increased transcutaneous oxygenation by high-resistance HMEs. Since high-resistance HMEs negatively affect user comfort, HMEs with a convenient breathing resistance have the first choice. [7]

Scientific evidence

The PURINOX HME is made from stainless steel. An important factor determining humidification performance is the material's total heat capacity, presenting the ability to store and release heat for the evaporation and condensation of water. Stainless steel has a high heat capacity per volume, which is the product of the specific heat capacity per mass (0.5 J/g·K) and density (8.00 g/cm³). Leemans et al. showed that 3D-printed stainless steel HME prototypes had a higher humidification performance at a similar acceptable low breathing resistance compared to a commercially available disposable HME of a similar size [8]. Humidification performance is also influenced by the contact surface and geometry of the HME. A core design with small parallel cylindrical flow channels presented optimal performance.

Test results

According to the ISO 9360-2:2002 guideline, the humidifying performance of an HME shall be measured by recording the moisture loss, which is the mass of water lost from the specified test apparatus. The lower the moisture loss, the better the humidification. Resistance of an HME shall be measured by the pressure drop at flow rates of 30, 60 and 90 L/min. [9] These tests were independently performed in a qualified laboratory.¹

Moisture loss and pressure drop at different flow rates of the PURINOX HME are presented in Figures 1-3. Results are showed in comparison to the other commercially available HMEs. The PURINOX HME has a lower moisture loss, meaning a better humidification, while the breathing resistance is still low. The PURINOX HME is therefore suitable for the various levels of activity.

¹ Tests were performed at a temperature between 22.7 and 23.8 °C and an atmospheric pressure of 1005 to 1011 hPa. The ISO rig maintained water at 37 °C, so the 'alveolar' humidity was 44 mg/L. The ambient absolute humidity was 0 mg/L. Tests were performed with a tidal volume of 1000 ml and a sinusoidal waveform flow with a frequency of 10 breaths per minute.

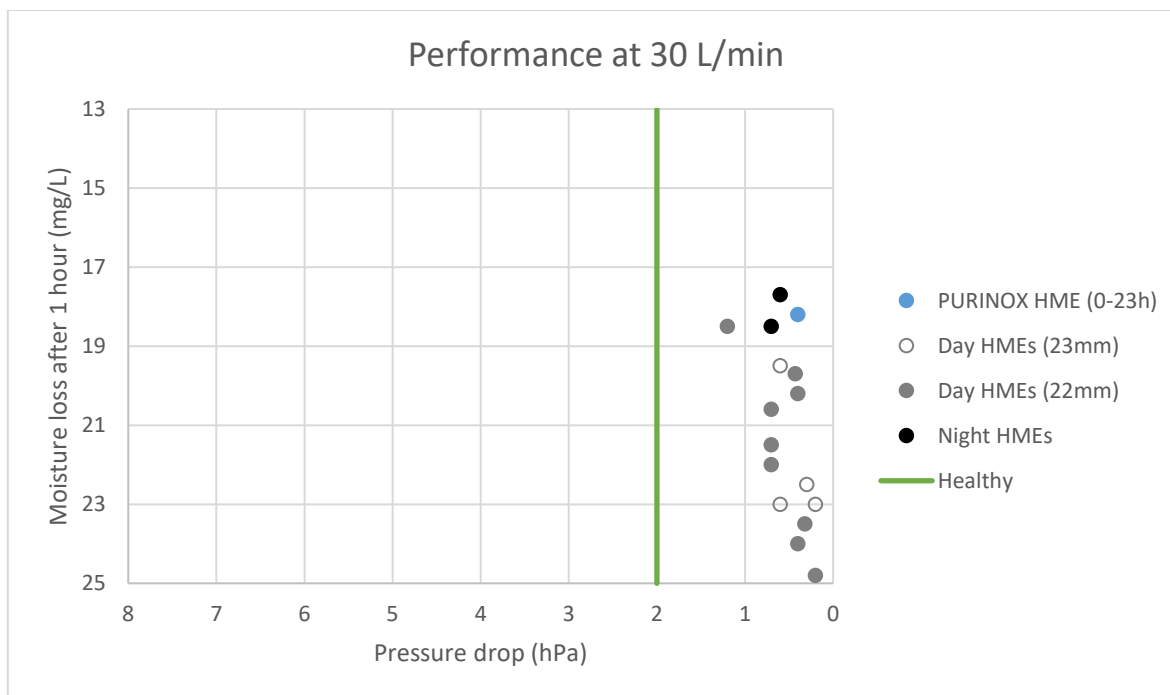


Figure 1. Moisture loss and pressure drop (at 30L/min) of the PURINOX HME compared to other commercially available HMEs.²

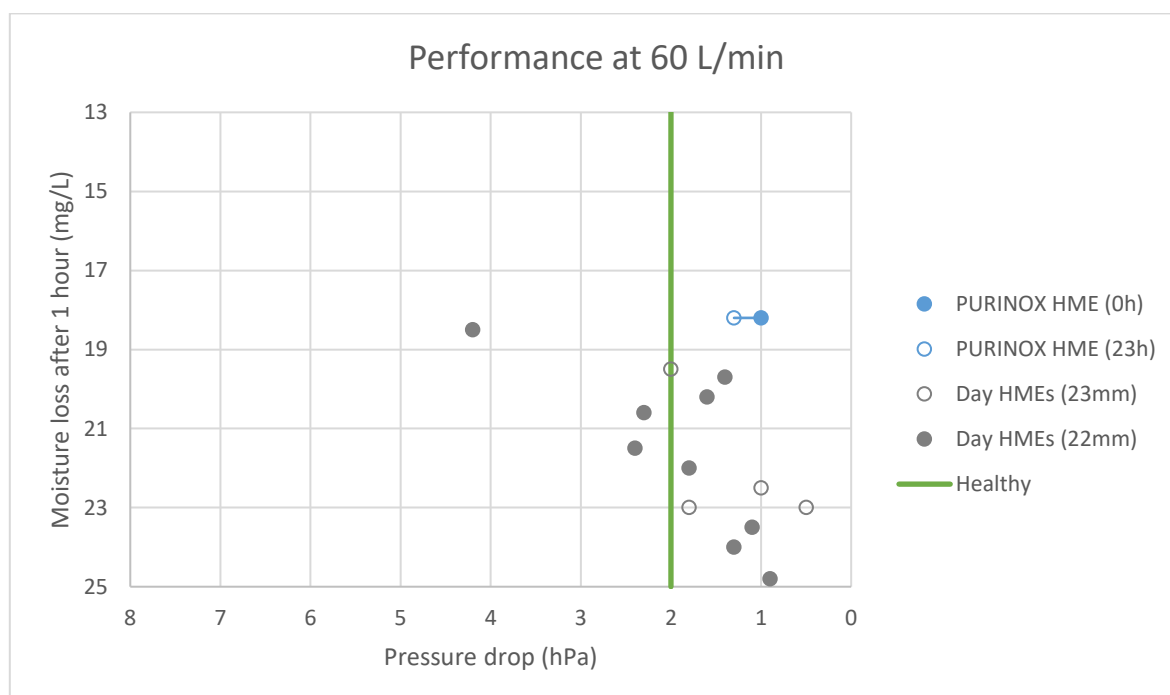


Figure 2. Moisture loss and pressure drop (at 60L/min) of the PURINOX HME compared to other commercially available HMEs.³

² The upper airway (larynx, pharynx and nose) expiratory resistance at rest is 4.2 cm H₂O/L/s in healthy individuals, meaning a pressure drop of 2.05 cmH₂O at a flow rate of 30 L/min, which is 2.0 hPa. [11]

³ The expiratory nose resistance during exercise is 2.0 cm H₂O/L/s in healthy individuals. This means a pressure drop of 2.0 cmH₂O at a flow rate of 60 L/min and 3.0 cmH₂O at 90 L/min. [12]

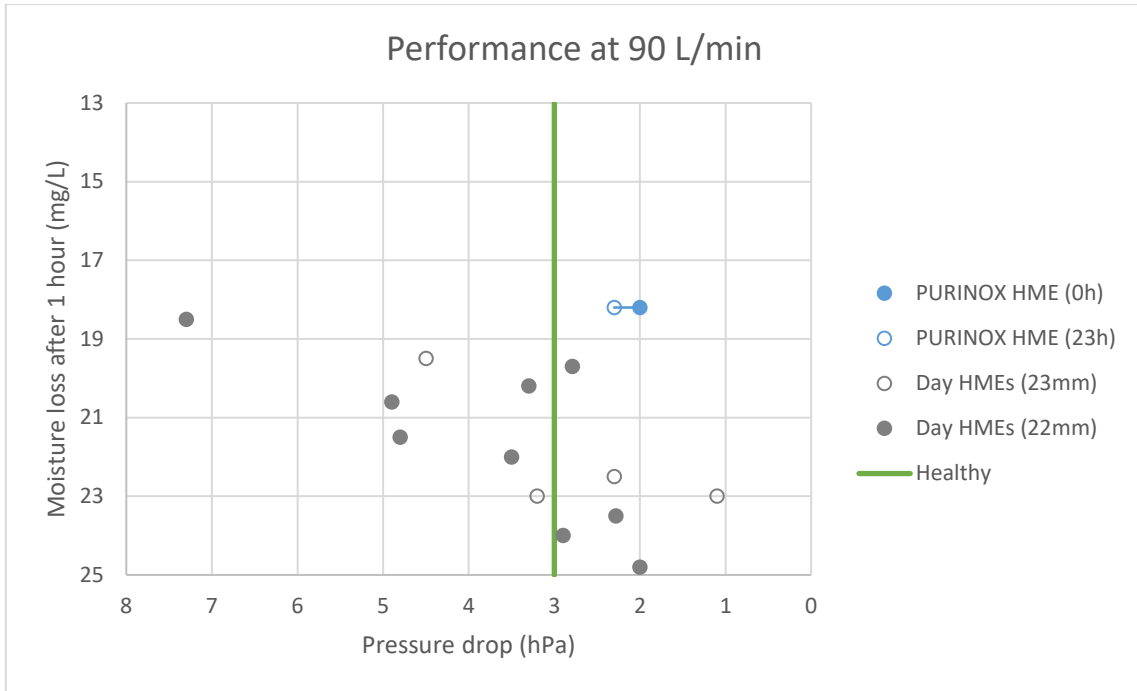


Figure 3. Moisture loss and pressure drop (at 90L/min) of the PURINOX HME compared to other commercially available HMEs.³

Reusable

The PURINOX HME can be cleaned and reused. Cleaning is independently tested and validated according to the AAMI TIR 30 acceptance criteria for reusable medical devices for 30 cleaning cycles [10]. Reusing the PURINOX HME instead of single-use disposables HMEs reduce the waste stream.

References

- [1] T. Keck, J. Dürr, R. Leiacker, G. Rettinger and A. Rozsasi, "Tracheal Climate in Laryngectomees after Use of a Heat and Moisture Exchanger," *The Laryngoscope*, no. 115(3), pp. 534-537, 2005.
- [2] A. Jones, P. Young, Z. Hanafi and Z. Makura, "A study of the effect of a resistive heat moisture exchanger (Trachinaze) on pulmonary function and blood gas tensions in patients who have undergone a laryngectomy: A randomized control trial of 50 patients studied over a 6-month period.," *Head Neck*, no. 25(5), pp. 361-367, 2003.
- [3] A. Ackerstaff, D. Fuller, M. Irvin, E. Maccracken, J. Gaziano and L. Stachowiak, "Multicenter study assessing effects of heat and moisture exchanger use on respiratory symptoms and voice quality in laryngectomized individuals.," *Otolaryngol Head Neck Surg.*, no. 129(6), pp. 705-712, 2003.
- [4] F. Hilgers, N. Aaronson, A. Ackerstaff, P. Schouwenburg and v. Z. N., "The influence of a heat and moisture exchanger (HME) on the respiratory symptoms after total laryngectomy," *Clin Otolaryngol*, no. 16(2), pp. 152-156, 1991.
- [5] A. Ackerstaff, F. Hilgers, A. Balm and I. Tan, "Long-term compliance of laryngectomized patients with a specialized pulmonary rehabilitation device: Provox stomafilter.," *Laryngoscope*, no. 108(2), pp. 257-260, 1998.
- [6] J. Herranz gonzález-botas, T. Suárez, B. García carreira and A. Martínez morán, "Experiencia con el uso del hme-provox® stomafilter en pacientes laringuectomizados," *Acta Otorrinolaringológica Española*, no. 52(3), p. 221-225.
- [7] J. Zuur, S. Muller, M. Sinaasappel, G. Hart, N. van Zandwijk and F. Hilgers, "Influence of heat and moisture exchanger respiratory load on transcutaneous oxygenation in laryngectomized individuals: a randomized crossover study.," *Head & Neck*, no. 29(12), pp. 1102-1110, 2007.
- [8] M. Leemans, M. van Alphen, S. Muller, B. van Putten, B. Koper, R. Dirven and M. van den Brekel, "Development of a reusable metal 3D-printed heat and moisture exchanger," *Respiratory Care*, pp. 1119-22, Aug 2023.
- [9] "ISO 9360-1:2001 - Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - part 2: HMEs for use with tracheostomized patientts having minimum tidal volumes of 250 ml ISO 9360-2".
- [10] A. f. t. A. o. M. Instrumentation, "AAMI TIR 30: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.," 2011.
- [11] P. Cole, P. Savard, H. Miljeteig and J. Haight, "Resistance to Respiratory Airflow of the extrapulmonary Airways," *Laryngoscope*, pp. 447-450, April 1993.
- [12] J. Wheatley, T. Amis and L. Engel, "Nasal and oral airway pressure-flow relationships," *The American Physiological Society*, no. 71(6), pp. 2317-2324, 1991.