

# Laryngectomy Clinical Summaries

## AT A GLANCE

### Post-laryngectomy pulmonary and related symptom changes following adoption of an optimal Day-and-Night Heat and Moisture Exchanger (HME) regimen

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#### Background

- Total laryngectomy (TL) has negative consequences for pulmonary health. Post-surgery, the lower respiratory tract is exposed to unfiltered, colder and drier air. This leads to an increase of mucus production that causes involuntary coughing and forced mucus expectorations.
- The use of HMEs can partially compensate for the humidification deficit, and therefore, contributes to improving pulmonary health post-surgery.
- Benefits on pulmonary health can be observed by consistently using HMEs throughout the day and night; however, patients can be sensitive to breathing resistance when using HMEs and this hinders the adherence.
- A new generation range of HMEs (Provox® Life™) has been developed to offer optimized humidification and different devices with distinct levels of breathing resistance to facilitate device use throughout the day and night.
- The different breathability levels offered by the new generation HME range facilitate device adherence 24/7, since it addresses participants' specific needs and individual breathing requirements.<sup>1</sup>

#### Objective

To evaluate the effect of the use of new generation devices (Provox Life) and the establishment of an "optimal Day & Night regimen" on pulmonary health, HME adherence and use, sleep, skin irritation, quality of life and participants' overall satisfaction.

#### Patient Experience with Provox Life HMEs

- More than 70% of the participants reported positive advantages including reduced pulmonary complaints, improved breathability, improved voice, better adhesive seal (Phase 1) and improved sleep (Phase 1 and 2).
- 79% of the patients got used to the new range in less than 1 week.
- 90% found it easy or very easy to choose among the different new generation HMEs.
- 95% would like to continue using Provox Life range in the future.
- At the end of Phase 2, 95% of the participants stated that they would continue using the Day & Night range if reimbursement would allow it.
- 41% would pay out-of-pocket to continue using the Day & Night range.

#### Study Design and Methods

- Multi-center, prospective, two-phase study conducted in 3 different centers in Australia, between August 2021 and April 2022.
- 48 laryngectomized participants initially recruited, 42 of them included in the study (6 withdrew for varied reasons).
- Participants were total laryngectomized patients who routinely used HMEs and attachments prior to the study.
- **Phase 1** ("Like-for-like" transition to Provox Life): Participants were provided with a set and number of Provox Life HMEs comparable to their Provox usual care; either Go HME (if they used XtraFlow HME) or Home HME (if they used XtraMoist HME). This phase explored the benefits participants achieved from the optimized humidification properties of the new generation devices.
- **Phase 2** (Optimal Day & Night regimen with Provox Life): Participants were asked to use the full range of Provox Life products including HMEs and attachments. They were encouraged to achieve an optimal Day & Night regimen to reach the highest humidification levels possible. An optimal Day & Night regimen implied use of Home HME during the day and Night HME when sleeping. Go HME, Energy HME and Protect HME were to be used dependent on the situation or activity level.
- Data were collected at baseline and at the end of Phase 1 and 2 using the Cough and Sputum Assessment Questionnaire<sup>2</sup> (CASA-Q); the Jenkins Sleep Evaluation Questionnaire<sup>3</sup> (JSEQ); the EQ-5D-5L<sup>4</sup> to evaluate quality of life; questions about skin integrity; a tally sheet on coughing; a diary on HME hours of use; and study specific questions around use of HMEs, shortness of breath and reimbursement options.

#### Key Points

- Transition from the participants' usual care (Provox® HMEs) to the new, optimized performance devices (Provox Life HMEs) improves pulmonary health.
- Implementing an optimal Day & Night regimen further improves pulmonary health.
- Adopting an optimal Day & Night regimen improves sleep.
- The new generation range of HMEs facilitates adherence to an optimal Day & Night regimen, offering options for specific needs. This leads to an increase in duration and types of HMEs used across the study phases.

#### Full Article

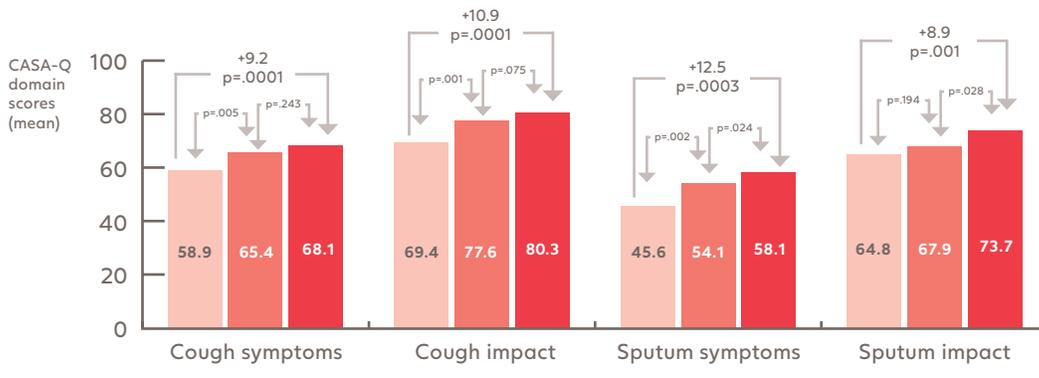
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<https://doi.org/10.1002/hed.27323>



## Results

### Pulmonary Health

Analysis from CASA-Q showed a significant improvement for all 4 domains between baseline and Phase 2. Significant improvements were also observed for all domains except Sputum impact between baseline and Phase 1 (Figure 1).

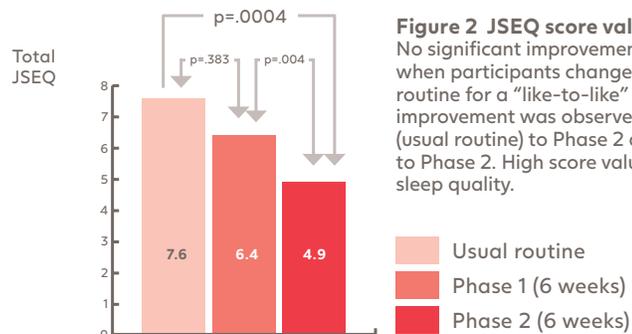


**Figure 1 CASA-Q domain scores**  
The graph shows CASA-Q domain scores (from left to right: Cough symptoms, Cough impact, Sputum symptoms, Sputum impact) as reported by participants for usual routine, Phase 1 and Phase 2. Lower score values indicate higher pulmonary symptoms/impact level. A significant improvement was observed for all domains between baseline and Phase 2, and for all domains except Sputum impact between baseline and Phase 1.

- An additional analysis was performed across all CASA-Q domains for the subgroup of 26 participants that were already 24/7 HME adherent at baseline. Cough symptoms, cough impact and sputum symptoms showed significant improvements across all the phases. No significant changes were observed for sputum impact.
- Shortness of breath significantly improved when walking. No changes were reported when resting or climbing stairs.

### Sleep

- Significant improvements were observed in total sleep score between baseline and Phase 2. The Jenkins sleep questionnaire also showed significant improvements from Phase 1 to Phase 2 (Figure 2).
- The greatest improvements were in waking up several times at night, having trouble staying asleep, tired, and worn out.



**Figure 2 JSEQ score values**  
No significant improvement was observed when participants changed their usual routine for a "like-to-like" routine. Significant improvement was observed from baseline (usual routine) to Phase 2 and from Phase 1 to Phase 2. High score values indicate lower sleep quality.

### Quality of life, attachments and skin irritation

- No significant changes in the EQ-5D-5L index score or VAS scale were observed.
- Mean duration of adhesive life (hours) did not change across the phases.
- Skin status, skin irritation, and impact on skin irritation was unchanged.

### HME adherence and use

- A significant increase in hours of HME use was observed across the phases. Participants went from using HMEs an average of 21.6 hours at baseline to 23.1 hours at the end of Phase 2.
- The number of participants that reported achieving an optimal Day & Night HME routine increased from 62% at baseline to 76% in Phase 1 and 90% by the end of Phase 2.
- The number of HMEs used per day went from 1.5 in baseline to 2.4 in Phase 2. This was primarily driven by the fact that the participants used different types of HMEs.

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<sup>1</sup>Longobardi Y, Galli J, Di Cesare T, D'Alatri L, Settini S, Mele D, et al. Optimizing Pulmonary Outcomes After Total Laryngectomy: Crossover Study on New Heat and Moisture Exchangers. *Otolaryngol Head Neck Surg.* 2022.

<sup>2</sup>Cough and Sputum Assessment Questionnaire. A 20-item questionnaire, used to assess the frequency and severity of cough and sputum and their impact on daily activity (validated for Chronic Obstructive Pulmonary Disease-COPD).

<sup>3</sup>Jenkins Sleep Evaluation Questionnaire, used to assess sleep by recording scores on 4 different sleep items

<sup>4</sup>European Quality of Life 5 Dimensions, used to self-assess QoL by recording scores on five health care dimensions (mobility, self-care, daily activities, pain/discomfort, and anguish/depression).

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