SpiroTect™ HME System

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Breathing is a physiological function essential for sustained life that occurs largely unconsciously. During inspiration, air flows through the upper airway into the lungs where respiration (exchange of gases) occurs. In a non-laryngectomized individual, the inspired air is conditioned (warmed, humidified and cleaned) as it passes through the upper respiratory tract. The conditioning that occurs in the upper airways is lost when an individual undergoes a total laryngectomy. Breathing occurs through the tracheostoma and this has significant consequences for the respiratory physiology of laryngectomized individuals.

The relationship between the heat and moisture content of inspired air and pulmonary function is well established, and there is a large body of literature documenting the adverse effects of inadequate humidification on the respiratory tract. In a laryngectomized individual the conditioning of the inspired air during its passage through the airways is precluded, and results in chronic pulmonary complaints such as frequent involuntary coughing, increased sputum production, crusting, forced expectoration and dyspnoea. Clinical research has clearly demonstrated that the pulmonary function of laryngectomized individuals is significantly compromised by the division of the upper and lower airways. Studies suggest that these pulmonary complaints develop and gradually increase during the six to twelve months post-laryngectomy and then tend to stabilise. Seasonal variations in symptoms have also been observed, with an increase in pulmonary complaints during the winter months.

The loss of the filtration function of the upper respiratory tract results in an increased susceptibility to lower respiratory tract infection, as airborne particulates which would normally be filtered by the upper airways enter the respiratory system via the tracheostoma. Mucociliary clearance is impeded by a lack of sufficient heat and moisture in the lower respiratory tract.

These pulmonary complaints negatively impact the quality of life of the laryngectomized individual; psychological distress, increased fatigue, sleeping problems and social disruption have all been cited as psychosocial consequences of a total laryngectomy. It is of particular note that in a study into the negative side effects of total laryngectomy, laryngectomized individuals indicated that the creation of a permanent tracheostoma and the associated Clinical research has clearly demonstrated that the pulmonary function of laryngectomized individuals is significantly compromised by the division of the upper and lower airways. Studies suggest that these pulmonary complaints develop and gradually increase during the six to twelve months post-laryngectomy and then tend to stabilise. Seasonal variations in symptoms have also been observed, with an increase in pulmonary complaints during the winter months.

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pulmonary complaints ranked higher in significance than loss of voice. Healthcare professionals who undertook the same survey believed that loss of voice was the main concern.

Heat and Moisture Exchangers (HMEs) were developed to address the loss of pulmonary function experienced by laryngectomized individuals. It is now well established in the literature that HMEs play an important role in pulmonary rehabilitation following total laryngectomy. Consistent daily use of an HME has been shown in studies to significantly reduce the severity of post-laryngectomy pulmonary disorders.

**How HMEs work**

Heat and moisture exchangers designed to address the loss of pulmonary function following a total laryngectomy have been in clinical use for over 30 years. It has been noted that these medical devices are currently the only effective, non-pharmaceutical treatment for the pulmonary symptoms experienced by laryngectomized individuals.

The upper airway moistens, warms and filters inspired air. Mucosal functions are optimised when inspired gases arrive at the carina at a core temperature of 37°C and are fully saturated with moisture (100 relative humidity (RH) = 44mg/L). The natural humidification process which occurs in the upper airway is bypassed in laryngectomized individuals. Artificial airway humidification is therefore required to optimise the function of the mucociliary escalator and enable mucosal clearance.

The HME is designed to sit above the tracheostoma and provides a passive humidification system that captures warm and humidified air as it is exhaled from the body. Inspired air, which is cool and dry, is then warmed and moistened as it passes through the filter into the trachea.

HMEs are composed of paper, foam or other material and may be impregnated with hygroscopic salts such as Calcium Chloride (CaCl2), exchangers as a treatment option in the post-operative rehabilitation of laryngectomized patients. Clin Otolaryngol Allied Sci. 1995 Dec;20(6):504-9.


Aluminium Chloride (AlCl\(_2\)), Magnesium Chloride (MgCl\(_2\)) or Lithium Chloride (LiCl) to increase moisture retention\(^\text{12}\). Antibactericidal solutions such as chlorhexidine may also be impregnated into the device to inhibit bacterial colonization\(^\text{13}\). Some HMEs also contain an electrostatic filter material which further inhibits the ingress of particulates into the trachea.

Alongside the heat and moisture exchange function, HMEs also provide airway resistance and particulate filtering and are designed to be used daily to maximise post-laryngectomy pulmonary function.

**Heat and Moisture Exchange**

Heat and moisture exchange is one of the most important functions of the respiratory system. During normal breathing, the airways function as a heat and moisture exchanger.

Inspired air is conditioned by the upper airways in a non-laryngectomized individual and reaches a temperature of up to 32°C and relative humidity (RH) of up to 99% at the level of the trachea\(^\text{14}\). Air inhaled via a tracheostoma reaches a temperature of 27-28°C and relative humidity (RH) of only 50% at the level of the trachea.

The effect of moisture loss during expiration on a laryngectomized individual is significant, with daily moisture loss of approximately 500ml. During normal nasal breathing approximately 250ml of water is lost from the lungs each day. Daily use of an HME facilitates the conservation of moisture within the respiratory system, and can reduce moisture loss due to tracheostoma breathing to approximately 250-300ml per day\(^\text{16}\).

It has been recognized that normative data may not be fully representative for laryngectomized individuals, who generally are older and often have been smokers and/or were treated with radiotherapy\(^\text{11}\). Atrophy of the nasal mucosa may lead to lower intra-nasal temperature and humidity values in the aging population\(^\text{17}\).

Studies have confirmed that use of an HME increases both intratracheal temperature and humidity values\(^\text{18}\). A


\(^{18}\) Keck T, Dürr J, Leitacker R, Rettinger G, Rozsasi A. Tracheal climate in laryngectomies after use of a
A recent review noted that in laryngectomized individuals, typically air of 22°C/40% RH (8 mg/L, 8 g/kg) is conditioned to 27–28°C/50% RH (13 mg/L, 14 g/kg) at the level of the upper trachea without an HME, and to 29–30°C/70% RH (21 mg/L, 22 g/kg) with an HME. Without artificial airway humidification, the air entering the lower respiratory tract will lack sufficient heat and moisture, the function of the mucociliary escalator will be compromised, and damage may occur to the respiratory cilia and epithelium leading to an increase in pulmonary complaints.

The validation of the water exchange performance of HMEs has been the subject of a number of recent studies. Performance is determined by assessment of the weight change of the HME between the end of inhalation and end of exhalation. It has been found that wet core weight is a predictor of HME water exchange performance. HMEs containing a hygroscopic salt, which increases the weight of the core material, demonstrate enhanced HME performance.

Whilst it is recognized that an HME cannot completely restore the physiological functions of the upper respiratory tract, daily use of an HME ensures that a better quality of air is delivered to the lower airways which has a positive effect on tracheal mucosa.

To ensure optimal performance the HME should be changed daily. More frequent changes may be required if the HME becomes obstructed with mucus. Studies have confirmed that from a functional point of view the recommendation for daily device replacement is justified.

The positive impact of HMEs on post-laryngectomy respiratory function is now well established. Regular use of an HME, which increases


intra-tracheal humidity, has been shown to lead to significant improvement of both pulmonary complaints and the associated psychosocial problems of laryngectomized individuals. This in turn has a significant impact on quality of life post-laryngectomy\(^8,10\). It has also been recognized that regular use of an HME appears to have a positive influence on voice quality\(^11\).

A recent study into the long-term use of heat and moisture exchangers concluded that compliant HME users tend to make less use of external humidifiers and vaporisers, have better pulmonary status and lower health-care costs\(^28\).

### Airway Resistance

Airway Resistance is a concept in respiratory physiology that describes the resistance of the respiratory tract to airflow during inspiration and expiration. In non-laryngectomized individuals 75% of total airway resistance takes place in the upper respiratory tract.

In laryngectomized individuals, where air bypasses the upper airways and enters the body through the tracheostoma, airway resistance is compromised.

Whilst it is recognized that an HME cannot completely replicate the airway resistance of the upper respiratory tract, daily use of an HME has been shown to help restore lost airway resistance\(^29\) and it has been argued may also play a role in improving arterial oxygenation although this influence has been challenged\(^30,31\).

HMEs are available which offer differing levels of resistance to suit individual requirements. HME devices which deliver normal airway resistance are most suited for everyday use. Low-resistance devices are suitable for periods of increased activity\(^32\). As HMEs have been shown to have a positive impact on post-laryngectomy pulmonary function it is essential that compliance is optimised, and the level of breathing resistance provided by the device should be as comfortable as possible.

It has been noted that the clinical advantage of high-breathing resistance HME devices, if any, is expected to be limited. Patients may perceive breathing through a high-resistance HME to be uncomfortable, particularly

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during exercise as the HME resistance is fixed and thus does not adapt to different levels of physical exertion\textsuperscript{11}. It has been shown that greater compliance is achieved by the use of a lower breathing-resistance HME\textsuperscript{30}.

Reducing the risk of infection

An adult inspires up to an estimated 10,000 litres of air per day and the nasal cavity forms the first line of defence against airborne environmental particles such as pollen and dust as well as microorganisms such as bacteria, fungi and viruses.

In non-laryngectomized individuals the inhaled air is filtered as it passes through the upper airways. Bacteria and viruses have to run the gauntlet of the respiratory epithelium of the upper airways in order to enter the trachea.

Laryngectomized individuals are statistically more prone to chest infections, including pneumonia. Pneumonia has been found to be the most frequent medical complication after total laryngectomy\textsuperscript{33}.

An increase in prevalence of lower respiratory tract infections (LRTIs) in patients in British hospitals has been demonstrated in patients with a tracheostomy\textsuperscript{34}. Prevalence was found to be greater in smokers, in males, and in those aged over 75 years. This is of particular relevance as 70% of those undergoing a total laryngectomy procedure in England and Wales between 2003-04 and 2013-14 were aged 60 and above. 85% of those undergoing total laryngectomy were male\textsuperscript{35}. A recent study has shown that the incidence of LRTIs and community acquired pneumonia increases markedly with age which has significant implications for the laryngectomized population\textsuperscript{36}.

It is recognized that effective mucus clearance is a critical innate airway defence mechanism\textsuperscript{37}. It is thus to be anticipated that laryngectomized individuals, whose upper airway function has been lost, will be more susceptible to LRTIs. Unless the airway is kept sufficiently humidified, mucus will become thicker and harder to expel, providing an ideal breeding climate for bacteria and viruses.

HME compliance significantly reduces pulmonary complaints and pulmonary infection rates


Regular daily use of an HME will encourage mucociliary clearance and thus help reduce the risk of airway infection.

It has been shown that long-term HME compliance significantly reduces pulmonary complaints and pulmonary infection rates. In a randomized control trial comparing pulmonary complaints between HME users and a placebo group, subjective lower airway parameters, including cough, number of chest infections, mucus production, and shortness of breath at rest, were significantly improved in the active group compared with the placebo group.

The HME device itself provides a moist environment that is potentially an ideal breeding ground for pathogens. A recent study has concluded however that the use of HMEs does not endanger tracheostomy patients in terms of additional exposure to pathogenic microorganisms. Indeed use of an HME is associated with a decrease in incidence of tracheobronchitis and/or pneumonia in laryngectomized individuals. A recent survey found that a lower incidence of severe tracheobronchitis and/or pneumonia was found in HME users compared to non-HME users.

LRTIs impact severely on the quality of life of laryngectomized individuals. It is unsurprising that “fear” of pneumonia has been found to have a severe impact on quality of life post total laryngectomy.

Conferring further clinical benefits, HMEs are now available with antibacterial properties that help prevent bacteria and viruses entering the airway. A filtration layer is added to the traditional HME to provide antimicrobial filtering. Whilst further studies are required to validate the antibacterial function of these devices within the laryngectomy population, HMEs with filters have long been used in ventilated patients. In a randomized study to compare the degree of bacterial circuit colonization in patients undergoing mechanical ventilation, circuits with a bacterial-viral filtering HME were found to be less readily colonized by bacteria. There is evidence from a comparative study suggesting that HMEs with filters significantly decrease the rate of ventilator-associated pneumonia in comparison with heated humidifiers.

As noted above to ensure optimal performance and maximise the protective effect the HME should be changed daily.

Whilst there is debate in the literature as to whether the reduction in airway infection should be attributed more to pathogen filtration or the improved

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humidity values which may stimulate cilia activity\textsuperscript{7}, studies have convincingly shown that a decrease in the frequency of airway infections may be attributable to the consistent use of an HME\textsuperscript{32,39}.

**Reducing the cost of infection**

LRTIs including pneumonia represent a significant burden of illness for both the patient and the NHS\textsuperscript{43}.

Treatment may include antibiotics (oral and intravenous), and involve routine diagnostics such as X-rays, CT scans and cultures all of which have a significant cost.

It is estimated that 22-42\% of people with community-acquired pneumonia are admitted to hospital. Based on HES (Hospital Episode Statistics) data, approximately 175,000 people were admitted to hospital in 2013/14 with community-acquired pneumonia. The mean length of stay was 12.32 days\textsuperscript{44}.

The mortality rate in hospital is between 5\% and 14\%. Between 1.2\% and 10\% of adults admitted to hospital with community-acquired pneumonia are managed in an intensive care unit, and for these patients the risk of dying is more than 30\%.

As noted above, due to underlying health issues and the average age of laryngectomized individuals, there is an increased likelihood that hospitalisation will be required in the event of acquiring a respiratory infection.

Reducing emergency hospital admissions for ambulatory care-sensitive conditions (ACSCs) is listed as a key indicator for transforming care for people with long-term conditions in The Operating Framework for the NHS in England 2012/13 (Department of Health 2011b). ACSCs are defined as conditions for which hospital admissions could be avoided by interventions in preventive and primary care. A 2012 Data Briefing from the King’s Fund estimated that influenza and pneumonia account for the largest proportion of hospital admissions (13 per cent) and expenditure (£286 million)\textsuperscript{45}.

The NHS Reference Costs for 2013/14 indicate that treatment for respiratory tract infections with complications and comorbidities can cause a significant financial burden to the NHS. The cost of treating a single episode of an acute lower respiratory tract infection can cost the NHS in excess of £7,000\textsuperscript{46}.

HME systems are available on NHS prescription and help protect laryngectomized individuals from LRTIs from £5.27 per day, at a cost to the NHS per annum of £1923.55 (based on the daily use of a

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\textsuperscript{43} NICE Costing statement: Pneumonia – diagnosis and management of community- and hospital acquired pneumonia in adults: Implementing the NICE guideline on pneumonia (CG191), December 2014.

\textsuperscript{44} Office for National Statistics (ONS), Admitted Patient Care: England 2013-14, Diagnosis.

\textsuperscript{45} The King’s Fund Data Briefing (2012. Emergency hospital admissions for ambulatory care-sensitive conditions: identifying the potential for reduction

\textsuperscript{46} NHS Reference Costs 2013-14 - Unspecified Acute Lower Respiratory Infection with CC Score 14+; Elective Stay £8851.05, Non-Elective Stay £7077.07.
SpiroTect™ antibacterial HME cassette and baseplate).

A recent study in Poland investigated the cost-effectiveness of HMEs versus usual care and concluded that HMEs were both less costly and more effective than traditional rehabilitation techniques\textsuperscript{47}.

**Conclusion**

Pulmonary function is compromised following total laryngectomy. Without humidification the air entering the lower respiratory tract will lack sufficient heat and moisture. Use of an HME increases intratracheal temperature and humidity values.

Consistent daily use of an HME aids pulmonary rehabilitation and significantly reduces the severity of post-laryngectomy pulmonary disorders and associated psychosocial problems.

Laryngectomized individuals are statistically more prone to lower respiratory tract infections including pneumonia. Lower respiratory tract infections represent a significant burden of illness for both the patient and the healthcare system. A decrease in the frequency of airway infections is associated with consistent use of an HME and may thus be expected to ease the financial burden on the NHS.

**SpiroTect™ HME System**

The SpiroTect™ Cassette, Antibacterial has an antibacterial coating, which previously published literature has determined that it can help reduce the potential of infection at the laryngectomy stoma site. The SpiroTect™ Cassette, Antibacterial is suitable for day or night use and allows the laryngectomee to easily obtain airflow closure and speech by using only a light finger touch.

- Antibacterial coated foam as seen from previously published literature has determined that it can help reduce the potential of respiratory lung infection
- High porous foam increases airflow and reduces breathing resistance, helping to restore normal airway resistance
- Excellent filtration, moistening and warming of air to protect the trachea
- Suitable for both day and night use
- To speak, closure can be obtained by a light finger touch

### SPIROTECT™ HME FILTERS

<table>
<thead>
<tr>
<th>PTC1004*</th>
<th>SpiroTect™ Cassette, antibacterial</th>
<th>To speak, closure can be obtained by a light finger touch</th>
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<tbody>
<tr>
<td>PTC1006*</td>
<td>SpiroTect™ Cassette Night, antibacterial</td>
<td>Speech cannot be obtained by finger, making this product ideal for night use when speech isn’t required</td>
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<tr>
<td>PTC1007**</td>
<td>SpiroTect™ Duo Cassette, antibacterial</td>
<td>Airflow is controlled in the same way as a standard HME but without the bulky casing and with a lower profile baseplate for added discretion</td>
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<tr>
<td>PTC1003*</td>
<td>SpiroTect™ Hands Free Cassette, antibacterial</td>
<td>The Hands Free System enables a laryngectomee to breathe through the valve and to speak freely without using a finger to control the airflow, clothing will not block airflow</td>
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* Use in conjunction with SpiroTect™ Fabric, Hydrocolloid or Clear and Strong baseplates  
** Use in conjunction with SpiroTect™ Duo baseplate

The SpiroTect™ Hands Free System enables the laryngectomee to speak freely without having to use a finger to control airflow.

- ✔️ Airflow is controlled by the laryngectomee’s breathing
- ✔️ Can be used on varying breathing patterns and strengths, sensitivity is controlled by rotating the front plate
- ✔️ Cough release function, meaning the diaphragm within the valve will pop out when there is increased pressure and can easily be put back in after cleaning

### SPIROTECT™ HANDS FREE SYSTEM

| PTC1001 | Hands Free Valve  
PTC1002 | Hands Free Valve, Low Resistance  
For use with SpiroTect™ Fabric, Hydrocolloid or Clear & Strong baseplates and the SpiroTect™ Hands Free Cassette, antibacterial |
**SpiroTect™ Baseplates**

The SpiroTect™ HME cassettes are specially designed to be used in conjunction with a SpiroTect™ baseplate. Baseplates are available in a choice of shape and material to suit different preferences, and are designed to secure HME cassettes and Valves at the stoma opening and make speech easier.

SpiroTect™ baseplates are skin friendly and are designed to prevent air leakage and provide security.

- Round and oval shapes for patient preference and stoma size
- Large surface area for better adhesion, helping to prevent air leakage
- Lightweight design
- Available on prescription

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<th>SPIROTECT™ BASEPLATES</th>
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<tr>
<td><strong>PTW100</strong>* Fabric, oval</td>
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<tr>
<td><strong>PTW101</strong>* Fabric, round</td>
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<tr>
<td><strong>PTW200</strong>* Hydrocolloid, oval</td>
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<tr>
<td><strong>PTW201</strong>* Hydrocolloid, round</td>
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<tr>
<td><strong>PTW300</strong>* Clear &amp; Strong, oval</td>
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<tr>
<td><strong>PTW301</strong>* Clear &amp; Strong, round</td>
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<tr>
<td><strong>PTW600</strong>* Fabric, oval</td>
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<tr>
<td><strong>PTW601</strong>* Fabric, round</td>
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* Use in conjunction with SpiroTect™ HME cassettes
** Use in conjunction with SpiroTect™ HME cassettes and SpiroTect™ Laryngectomy Tubes
*** Use in conjunction with SpiroTect™ Duo cassette

For more information on the SpiroTect™ Antibacterial HME System and other products within the SpiroTect range, please contact your local SpiroTect™ representative.