Abstract

This work investigates the restoration of the lost functions of the upper airway in patients who have undergone total laryngectomy surgery. The primary airway functions were defined as ventilation and patency, heating and humidification of air, filtration of air, coughing, swallowing, speech, olfaction, gustation and chemo sensitisation and air resistance.

Through a review of the literature, the performance of the airway functions was compared pre and post laryngectomy. It was found that all of the aforementioned functions were negatively affected by total laryngectomy which led to lower quality of life and increased risk of harm or disease compared to healthy individuals of the same age groups.

There are medical devices described in the literature used for the restoration of upper airway function. For most identified functions there was a medical device and or therapeutic solution to restore them partially or fully. Research found no evidence that existing medical devices had the level of filtration they provided verified. Many devices in the literature restored one function, requiring patients to use a combination of devices, this has benefits and disbenefits, mostly relating to in use life. This work aimed to restore as many functions as possible within a singular device.

A singular device was designed to restore the upper airway functions. The variability of the difference in resistance of the larynx to inhalation and exhalation identified in the literature was incorporated into the device, the phenomenon was approximately matched by employing fluid structure interaction within the device. The design featured a novel bistable diaphragm that the patient can close hands free when they want to redirect air through a speech device. This had the benefit of remaining closed during pauses in speech.

Different functions of the candidate device were evaluated through a combination of tests, including tests following established methodologies and new tests and test apparatus developed as part of this work. Pneumatic test apparatus was built to produce outputs that matched laryngectomy patient spirometry data found in the literature.

The first iteration of the design was tested in vitro. The design was translated into FEA, validated with the lab results and optimised. Heat and moisture exchange and filtration were fully restored. Cough, breathing resistance and speech were partially restored. It was concluded that a singular device can restore most of the upper airway functions to a level closely resembling pre-laryngectomy. Additionally, it was concluded that a device must be used in conjunction with other restorative medical devices to effectively restore all lost functions to pre-laryngectomy upper airway performance.

The Design & Verification of an Automatic Occlusion Speech Valve for Voice Rehabilitation

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List of Abbreviations

TL – Total Laryngectomy
TEP – Tracheo-oesophageal puncture
HME – Heat Moisture Exchange(r)
HMEF – Heat Moisture Exchange Filter
FEA – Finite Element Analysis
FMEA - Design Failure Mode (&) Effects Analysis
CAD – Computer Aided Design
MEP – Maximal Expiratory Pressure
FSI – Fluid Structure Interaction
CFD – Computational Fluid Dynamics
PEF – Peak Expiratory Flow
MVC – Maximal Voluntary Cough
TLC – Total Lung Capacity
VC – Vital Capacity
FEVt Forced expiratory volume (total time)
FEV1 - Forced expiratory volume (1 Second)
OD – Outer Diameter
RCST - Reflex cough efforts at suprathreshold stimulus intensity
NAIM - nasal airflow-inducing manoeuvre
PEEP - Positive end-expiratory pressure
Fractional Efficiency – The efficiency of a filter at a variety of particle sizes.

Statement of Copyright & Declaration

 The work in this thesis is based on research carried out while a MSc Student in the Department of Engineering at the University of Durham. Research was undertaken while employed at Kapitex Healthcare Limited and is relevant to them, all work presented is the work of the author. No part of this thesis has been submitted elsewhere for any other degree or qualification and it is all my own work unless referenced to the contrary in the text.

1. Introduction

1.1. Motivation

In Europe over 39 thousand people are diagnosed laryngeal cancer annually [1]. There are many factors which are known to increase the likelihood of contracting laryngeal cancer including age, frequency of smoking, drinking alcohol and poor diet, however anyone can be affected. The larynx can be involved in oral, pharyngeal, or laryngeal carcinomas. These are usually squamous carcinomas and are treated with radio therapy and surgery, depending on the site and condition of the patient [2]. Once carcinomas are detected in the patient's larynx and surrounding areas, often the most effective way of removing the cancer and stopping its spread is surgery. Laryngeal cancers can be dealt with utilising a range of surgical procedures, endoscopic surgery, cordectomy, partial laryngectomy, or full laryngectomy. There may also additionally be pharyngectomy, thyroidectomy and lymph node removal surgeries dependant on the spread and stage of the cancer. Most of these procedures are partial in nature, they attempt to preserve as much of the patient's anatomy as possible [3]. Research has demonstrated that most patients receiving partial laryngectomy have significantly worse survival rates versus those with total laryngectomy [4]. This fact is the reason total laryngectomy is still so frequently utilised. It is estimated that over one hundred thousand patients worldwide are living with a total laryngectomy [5]. Total laryngectomy involves complete surgical removal of the larynx which disconnects the upper airway from the lungs. The trachea is transected and then the open end is stitched to the front of the neck. This is a permeant and irreversible procedure and once this has been performed the patient can no longer breathe or be oxygenated or ventilated via the upper airway. See figure 1 showing the anatomy of a laryngectomy [6].

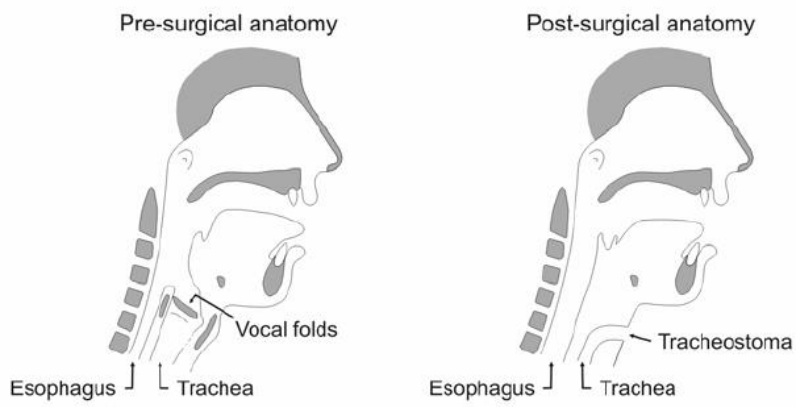

Figure 1 – Diaghragm of the anatomical differences between pre and post laryngectomy (from [6])

Most laryngectomy patients tend to have other conditions hindering effective oesophageal communication resulting from life choices and/or patient age. Head and neck cancers more often affect patients aged between 70-74 with a history of smoking and drinking alcohol. Meetings with laryngectomised individuals as part of this work highlighted that many did not smoke or drink but were affected by a broad range of environmental or industrial factors, which influenced their larynx or lungs.

Although total laryngectomy is an effective procedure for removing carcinomas and improving the survival rate of the patient, the result is a loss of all upper airways and larynx functions. About 20% of patients do not acquire any useful verbal communication following laryngectomy [7]. The main

aim of this research is to discover if utilising and integrating an elastically bi-stable component into the design of a hands-free speech valve will allow for better overall speech. Research will also be conducted to ascertain how many additional functions can be restored within the singular device.

1.2. Literature review

Total laryngectomy results in lost airway functions. To find a solution that can restore upper airway functions, critical discrimination and evaluation must be carried out to ascertain information regarding the functions and the potential restoration. This can be achieved by focusing on three questions.

- What are the functions of the Upper Airway?
- What remains of the primary functions post laryngectomy?
- What are the existing restorative devices (and what, where appropriate are their performance)?

Before a solution can devised that can restore upper airway function, the functions of the upper airway must be understood. It will be the aim of any proposed solution to regain the performance of a non-laryngectomised patient in each upper airway function. This literature review will aim to provide quantifiable pre and post laryngectomy performances for all upper airway functions which will act as maximum and minimum targets of restoration by a solution proposed in this thesis. Additionally, the literature review will highlight the current state of the art devices and quantify how successfully they are restoring the lost functions of the upper airway, this will allow for a direct comparison. The methods, mechanisms, or technologies which can fulfil a function will be recorded.
A review on which functions are affected and what the remaining performance is will act as a minimum threshold on which any solution will aim to improve upon. Where practical, the post laryngectomy performance will be considered 0% and pre-laryngectomy 100% in the assessment of effectiveness of a solution. The review will also be used to gain an understanding the current laryngectomy medical device landscape and how effective each device is at restoring the lost upper airway functions.
When possible, literature using similar subject demographics will be used when comparing pre and post laryngectomy. This will reduce the potential that differences between pre and post laryngectomy results are a factor of subject differences such as age.

1.2.1. Functions of the Upper Airway

Ward et al [8] describes the upper airway as the respiratory system above the cricoid cartilage. This includes the nasal cavity, pharynx, epiglottis and larynx. The upper airway not only provides a passage for air to be breathed in and out of the lungs, but it also heats, humidifies and filters the air and is involved in cough, swallowing and speech [9]. Figure 2 shows the anatomy post laryngectomy with the upper airway disconnected from the lower airway or removed completely.

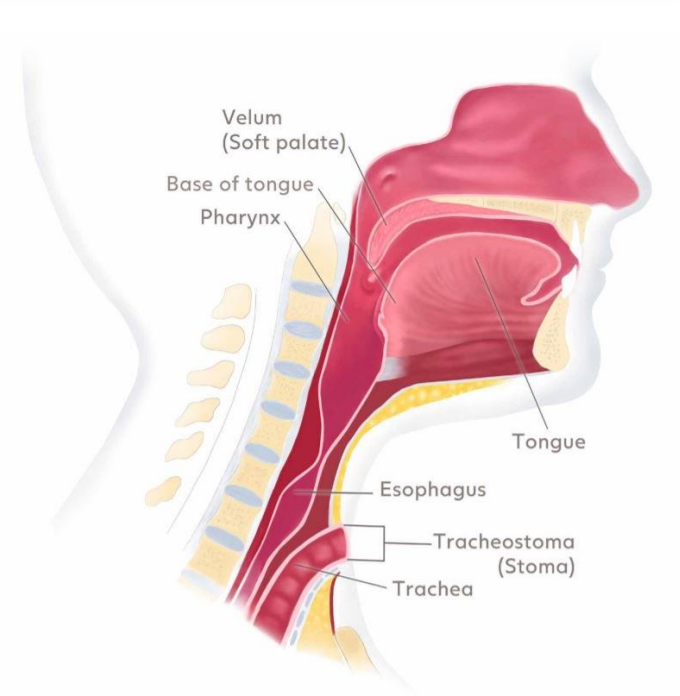

Figure 2 - Illustration of anatomy post laryngectomy [8]

Function 1, Ventilation & Patency

The upper airway provides a passage for air to be breathed in and out of the lungs [9]. It is presumed that in a healthy person the airway is consistently allowing air to enter and exit the lungs. A primary function of the respiratory system and therefore the upper airway is to take in oxygen and expel carbon dioxide [10]. The upper airways contribution to the primary function of ventilation is to remain patent. Airway patency allows a person to breathe, with airflow passing to and from the respiratory system through the oral and nasal passages. Airway patency may be impacted by anatomical or physiologic changes that impede airflow, total laryngectomy being an example of major change [11]. The cricoid cartilage where the upper airway ends is the only complete ring of cartilage around the trachea. The cricoid cartilage serves to maintain airway patency, forms part of the larynx, and provides an attachment point for key muscles, ligaments, and cartilage, which function in the opening and closing the vocal cords for sound production [12]. Randestadt et al [13] measured the size and shape of the trachea and surrounding cartilage in men and women. The mean inner diameter of the cricoid cartilage with mucous membrane in situ was in women 11.6mm (range, 8.9–17.0 mm) and in men 15.0 mm (range, 11.0–21.5 mm). The mean area of the trachea at the cricoid cartilage with mucous membrane in situ is 280mm². The distal opening of the upper airway is the anterior nares, a study found that the mean area of the total nostril opening was 357 mm² (SD=108 mm²) [14].

The volume of breath through the upper airway is about 500mL at rest. Resting respiratory frequency is about 15 breaths/min so the volume entering the lungs each minute is about 7500mL/min at rest. The upper airways make up part of the body's anatomical dead space which reduces gas exchange. Normal anatomical dead space is around 150ml. Alveolar ventilation is the volume taking part in gas exchange each minute. At rest alveolar ventilation is about 5250mL/min [8].

Minute ventilation, a product of volume inhaled per breath and respiratory rate over one minute, is identical in younger and older individuals. There is no change in tidal volume with age, and older

individuals maintain the required minute ventilation by increasing the respiratory rate [15]. the mean respiratory rate of male and female individuals between 65 and 80 is 19.3BPM [16]. It is noted that there is some variation between sources on exact breathes per minute. This seems to be explained by the latter source's specificity of the age group. As 65-80 closely matches the age range of laryngectomy patients, it can be considered more useful to this research.

Spirometry is the measurement of breathing and is used as a measurement of lung and airway health. A study [17] conducted to find the spirometry values in the elderly (aged 65-95 years) found that the mean absolute values across men and women for FVC_1 (Forced vital capacity) and FEV (Forced Expiratory Volume) was 1.9L and 1.4L respectively and FEV_1/FVC was 70.9%. FEV_1/FVC is the ratio of FEV_1 to FVC and can be an indication of lung restrictive disease. In healthy adults this should be approximately 70–80% (declining with age). When assessing upper airway obstruction $FEV_1/PEFR$ is used as an indicator, in healthy patients, this index is less than 10 (mean 7.3). In non-laryngectomised patients, if the index of $FEV_1/PEFR$ is higher than 10, an airway obstruction is suspected [18].

A study [19] conducted on pre-op patients recorded the Spirometry values shown in Table 1.

Spirometry value	Mean Value	Standard Deviation
Vital capacity	4.5 L	0.86 L
Forced Expiratory Volume 1 sec	2.9 L	0.82 L
Peak Expiratory Flow	7.5 L/s	2.0 L/s
Maximal Expiratory Flow @ 50% VC	2.2 L/s	1.3 L/s
Forced Inspiratory Volume 1 sec	3.1 L	0.87 L
Peak Inspiratory Flow	4.2 L/s	1.1 L/s
Maximal Inspiratory Flow	3.4 L/s	1.2 L/s
Total Lung Capacity	7.1 L	0.96 L

Table 1 – Pre & Post Laryngectomy Spirometry Data (Based on [19])

Function 2, Heating and Humidification of Air

The non-laryngectomised upper airway is responsible for humidifying and heating inspired air, a process defined as conditioning of inhaled gas. This process is critical for optimally conditioning the gas and avoiding potential damage to the structure and function of the respiratory epithelium [21].

During normal nasal inspiration of a healthy individual, air inspired at typical temperatures and humidity's are conditioned for optimal gas exchange. For example, air at 22°C and 40% Relative Humidity (RH) is conditioned to 29°C and 20 mg H_2O/L (70% (RH)) in the nose and is further heated to 32° C and 36 mg H_2O/L (100% RH) at the subglottic level [22] [23] [24]. As the inspired air passes further through the respiratory tract it reaches the isothermal saturation boundary (ISB) at body temperature (44 mg H_2O/L (100% RH) at 37°C) in the small peripheral airways [25].

Function 3, Filtration of Air

During normal breathing in healthy individuals, the upper airway filters inhaled air. There are many things which can be suspended in inhaled air which require filtration such as viruses, bacteria and airborne pollutants. Many of these particles are filtered by the nose [26]. Effective filtration of viruses and infectious diseases from the airway is important as the area where the particle is deposited and the number of particles, or the dose, increases the likelihood of infection [27] [28]. In

addition to viruses there are other particles such as allergens, pollen, dust and particulate matter [26].

Relating the areas of the airway to particle size and deposition, one study [29] found that above 1µm to 2µm penetration to and deposition in the lung lobules decreases with increasing size simply because fewer particles escape upper respiratory trapping. Above 10µm, the probability for penetration to the lobules is essentially zero. During mouth breathing 20% of 5µm and 70% of 10µm particles deposit before air reaches the larynx. In contrast during nose breathing at light exercise respiration, 80% and 95% particles deposit in the head region [29]. Another study on aerosol deposition found that particles over 6µm are deposited in the upper airway and particles smaller than 2µm can be deposited in the alveolar region [30]. A study on inhalers found that particles 3.30-4.70µm penetrate as far as the trachea and primary bronchi. There seems to be an agreement that particles 0µm-3.3µm are not completely filtered by the upper airway and are either stopped by the trachea mucosal cilia or are deposited in the lung.

When a healthy upper airway's filtration fails to stop small particulate matter, it is deposited in the lung. These particles are either retained by the body or are broken down by macrophages. Depending on the type of particle, this could cause different types of harm [26]. There appears to be an agreement [29] [30] that particles 0-10µm enter the airway, the smaller the particle the further it can be deposited. The upper airway filters the majority of particles >5µm approximately with the tracheal mucociliary clearance removing the majority of particles less than approximately 2µm or equal to 5µm. nasal and oral breathing plays a factor, with nasal breathing being more effective at filtration. Higher breathing flow and volume rates also reduces the effectiveness of filtration.

Function 4, Coughing

Coughing is a critical human reflex that prevents aspiration of foreign materials into the airway, responds to aerodigestive irritants, and expectorates mucus and foreign materials from the tracheobronchial airway and lungs [31]. A study on the frequency of cough in healthy and diseased patients found that healthy individuals aged 20-80 years old coughed on average 18.6 times in a 24-hour period [32]. A second source [33] states that in 12 normal subjects between 0 and 16 times daily. The second study uses a slightly lower age range of 21-62 for their normal subjects which may be a factor [33]. It is possible the grouping of coughs was defined differently in each study also.

Information gathered on the aerodynamic measures of normal adult cough stratified by age found the peak flow was 604.5 L/min among subjects in the older age group (50-80). In the same group, the peak pressure was 1.30Pa and the expiatory rise time was 65.1ms [31]. It is mentioned in this article that pressure measures may have been more precise if different techniques had been used. It is presumed that this frequency and peak flow rate of cough is effective in healthy 50–80-year-olds in removal of foreign materials, irritants and mucus from the upper airway.

A relevant study [34] comparing the cough of healthy and laryngectomised patients with a mean age of 67.3 years (46-76) provided quantifiable data of the cough itself. In healthy individuals, the maximal voluntary cough flow rate was 5.31 L/s and reflex cough flow rate at threshold level was 5.25L/s. Time to reach the peak flow was recorded as 29.5ms in both voluntary and reflex cough. Volume acceleration in MVC (maximal voluntary cough) and RCst (reflex cough efforts at suprathreshold stimulus intensity) was 199.25 L/s^2 and 196.75 L/s^2 respectively. The study also recorded maximal static expiratory pressure (PE(max)) in healthy subjects at 119.10 cmH_2O [35].

Function 5, Swallowing

The process of deglutition involves the movement of substances from the oral cavity to the stomach via the pharynx and oesophagus. This pathway shares anatomy with the airway; the swallowing mechanism serves as a vital protector of the airway. The reflexive and voluntary actions of over 30 nerves and muscles produce this coordinated movement [37]. There are three major phases in the swallowing mechanism: Oral, Pharyngeal and Oesophageal Phase. The area of greatest concern for this literature review is the pharyngeal phase. During this phase there are five defined steps. The nasopharynx closes which prevents pressure escaping into the nasal cavity. Second is the airway protection. The pharyngeal phase serves to protect the airway via swallowing apnoea, a well-coordinated physiologic response where respiration ceases during swallowing. This apnoeic period tends to interrupt the expiratory phase of breathing, lasting approximately 0.5 to 1.5 seconds, serving to prevent aspiration during inspiration. The primary mechanism of airway protection is the closure of the vocal folds. The pharynx becomes elevated and pulled anteriorly by contraction of the suprahyoid muscles, which helps to open the pharyngeal-oesophageal transition. The substance or bolus is moved in a peristaltic fashion down towards the Upper oesophageal sphincter. The end of the pharyngeal phase involves the food bolus descending through a patent upper oesophageal sphincter into the oesophagus [38].

Bolus volume affects Velopharyngeal duration, maximum tongue base pressure, tongue base pressure rise rate, UES opening duration, and total swallow duration varied significantly across bolus volume [39]. It is presumed that in healthy adults that swallowing can be achieved without incident and the ingested substance and subsequent bolus volume can be controlled effectively by the user to prevent risk of choking or aspiration into the airway.

Function 6, Speech

Speech is produced in the upper airway, specifically the larynx, a tubular structure connected to the top of the trachea. Air passes through the larynx on its way to the lungs. The larynx also produces vocal sounds and prevents the passage of food and other foreign particles into the lower respiratory tracts. The centre portion of the larynx is reduced to slit like openings in two sites. Both sites represent large folds in the mucous membrane lining the larynx. The first pair is known as the false vocal cords, while the second is the true vocal cords (glottis). Muscles attached directly and indirectly to the vocal cords permit the opening and closing of the folds. Speech is normally produced when air expelled from the lungs moves up the trachea and strikes the underside of the vocal cords, setting up vibrations as it passes through them; raw sound emerges from the larynx and passes to the upper cavities, which act as resonating chambers (or in some languages, such as Arabic, as shapers of sound), and then passes through the mouth for articulation by the tongue, teeth, hard and soft palates, and lips [40].

In terms of measuring speech, there are multiple potential variables that may be useful. The first is volume. In one study [41] 80 healthy untrained participants (40 females, 40 males) were investigated to assess the softest possible sustained phonation volume level. these levels were in the range of 48-61 dB(C)/41-53 dB(A) for females and 49 - 64 dB(C)/35-53 dB(A) for males (5% to 95% quantile range). A second study which included maximum phonation volume stratified by age found that healthy adults aged 70-80 could produce a maximum phonation of 98dB [42]. Typical speech pressures are 600-1200 pascals below the glottis [43].

The second quantifiable metric of speech is Phonation time, a study on older adults (65-93) found the mean maximal phonation time to be 18.0 seconds in one breath for both males and females [44].

The third quantifiable value of speech is Phonation frequency. when a single 'a' sound was produced, the same subjects produced a frequency range of 28.39hz [44].

Overall speech is measured in some combination of the above variables. Literature concerning hands free speech valve performance provides data in the form of dynamic volume range, maximum phonation time, number of breaths taken to read standard text, syllables per minute and breaths per minute. A notable addition to testing of laryngectomised speech is the time needed to produce speech, this will be discussed in detail later in the literature review.

Speech intelligibility is the most important aspect of effective vocal speech and is the key indicator of speaking effectiveness. Although the easily definable and quantifiable metrics above are important, they are irrelevant if the speaker is unintelligible. Clarity and intelligibility of speech is complex and has multiple variables including number of pauses, speaking rate, annunciation, and frequency modulation.

Function 7, Olfaction, Gustation & Chemosensation

One of the most critical functions of the nasal airway is Chemosensation. The detection of hazards in the environment is mediated by the olfactory and trigeminal systems that act as surveillance systems over the air as it traverses the upper airway. A second critical function is the role that the sense of smell plays in pleasure, including nutrition. In healthy persons, inspired air passes into the nose above the inferior turbinate and is carried upward toward the olfactory neuroepithelium by turbulent airflow. Normal airflow travels above the inferior turbinate toward the nasopharynx, this process is known as olfaction [45].

Within the nasal cavity is a portion of the trigeminal system's nerve endings. Nociceptive neurons of the trigeminal nerve are activated by chemicals classified as irritants, including air pollutants, ammonia, ethanol and other alcohols, acetic acid, carbon dioxide, menthol, capsaicin, and others [45].In terms of upper airway function, this activation of irritants highlights that olfaction plays a role in keeping a subject safe from harm as well as quality of life aspects.

As a person ages, their taste and odour discrimination reduces. A study [46] conducted on 20 subjects, 10 female, 10 male, aged between 59 & 75 found that in a taste and odour discrimination tests, the elderly group were giving correct answers approximately 20% and 40% less respectively than subjects aged 21-40. In total, across a variety of taste and odour discriminating tests, those in the older age subject group were correct in identifying mixed substances approximately 50% and 30% of the time respectively. [46] the same study reveals a strong correlation between olfaction effectiveness and gustation effectiveness.

Function 8, Resistance

Resistance to breathing or work of breathing is not referred to as a primary function in literature describing normal healthy airways. The upper airway offers lesser resistance to airflow during inspiration than expiration [47]. Oommen [48] describes details of the respiratory function of the upper airway, the anterior nose is a major but variable site of this resistance, and this is controlled by the alae nasi muscles, the larynx provides 25–30% of total airway resistance. A study on the laryngeal resistance to respiratory airflow in humans quantifies the resistance to breathing of 1.245 $cmH_2O/L/s$ in expiration and 0.354cm $H_2O/L/s$ per second during inspiration.

Whether a primary function of the upper airway or not. It is clear that the upper airway provides airway resistance, and that the amount of resistance is dependent on oral or nasal breathing, the type of activity being done by a subject and that there is a major difference between inspiration and

expiration. In an ideal scenario, the level of resistance would be matched post laryngectomy. it could be that anatomical dead space and breathing resistance is a by-product of all of the true airway functions and that the subject compromises on some functions such as filtration by breathing orally during exercise when lower resistance is more important. While upper airway resistance as a function pre-laryngectomy is not clearly defined, it is important to know the level of resistance caused by the upper airways so as not to exceed it with any introduced medical devices.

1.2.2 Airway Functions Post Laryngectomy

After a total laryngectomy or tracheotomy, the patient breathes in and out through the tracheostoma in the neck, instead of through the nose and mouth. Therefore, the functions of the upper airways of warming, humidifying and filtering of the inhaled air are lost, as is upper airway resistance.

Function 1 Ventilation & Patency

After laryngectomy, the nares are replaced as the opening to the respiratory system during rest by the surgically created tracheostoma. Two studies [49] [50] found the mean tracheostoma is 17mm high, 13mm wide and roughly oval in shape. The area of a simple oval of those dimensions is approximately 173mm². In most patients the cricoid cartilage is spared. When comparing the Tracheo stoma to the nares, there is a reduction in mean cross-sectional area of 184mm² (approximately 48%). The tracheostoma is made from the trachea just above the cricoid cartilage, so this cross-sectional area is to be expected. The narrowest point in the upper airway has an oval shaped cross-sectional area of 146.9mm² [51] meaning the stoma itself not a restriction.

Some patients experience permanent problems with stoma patency, requiring permanent use of a laryngectomy tube [49].

Spirometry studies [52] conducted to find the spirometry values in laryngectomised patients (aged 41-87 years) found that the mean absolute values across men and women for FVC (Forced vital capacity) and FEV (Forced expiratory volume) was 3.3L and 2.4L respectively for FEV_1/FVC was 71.4%. FEV_1/FVC is the ratio of FEV_1 to FVC. FEV_1 is Forced expiratory volume in one second. This is still within the range of what is considered healthy for adults. A physiologic study [53] on Respiratory Handicap shows the difference in key spirometry data of a male individual aged 74, pre and post laryngectomy. Figure 2 shows the total lung capacity of this individual increases by 1.55L, vital capacity reduces by 5%, FEV_1 reduces by 27%. These values would represent a reducing in FEV_1/FVC from 73% (which is considered normal) to 58%. It is fair to state that some reduction in FEV_1, FVC & FEV_1/FVC is likely in laryngectomised patients. The results will not be considered definitive due to the sample size of one, but the comparison pre and post laryngectomy of the same patient is interesting. This data is illustrated in figure 3.

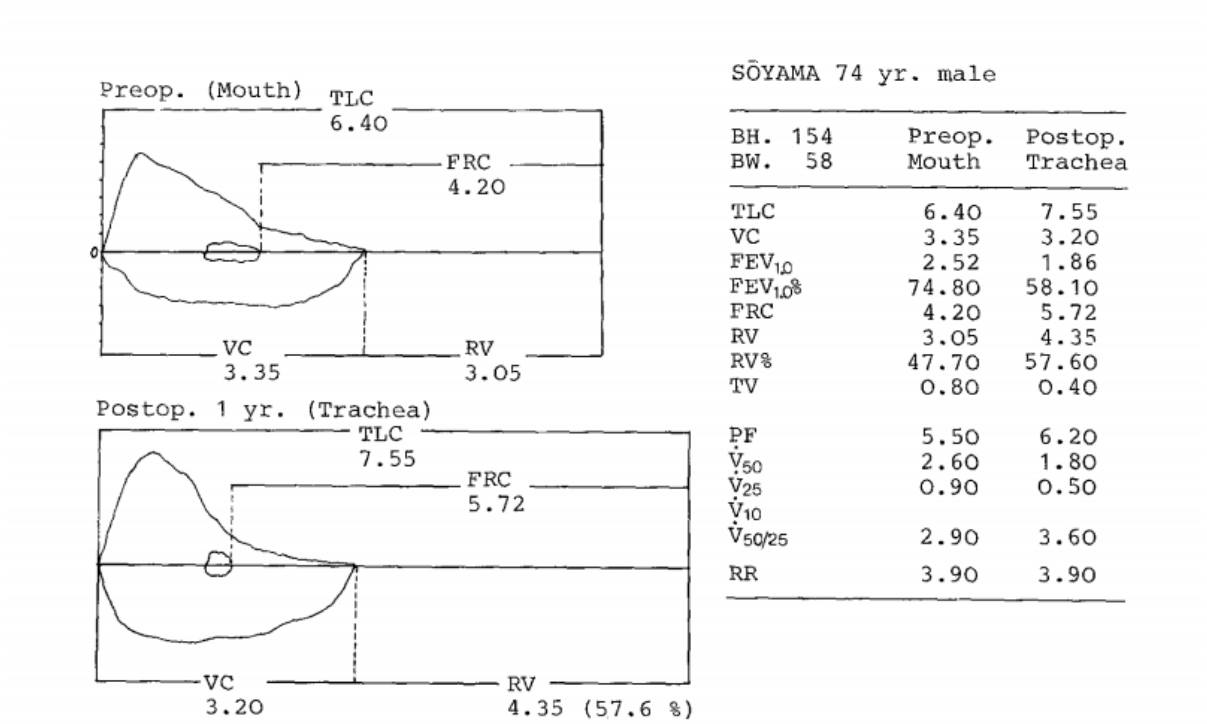

Figure 3 - Comparison of respiratory function measured before and after laryngectomy [53]

The study referenced in the previous section of the literature review tested the same subjects at 9 days and 6 months post operatively and collected the following results shown in table 2 [19].

Spirometry value	Value (9 days)	Sd	Value (6months)	Sd
Vital capacity	4.2 L	0.93 L	4.2 L	0.86 L
Forced Expiratory Volume 1 sec	2.8 L	0.80 L	2.7 L	0.82 L
Peak Expiratory Flow	7.8 L/s	2.0 L/s	8.0 L/s	2.0 L/s
Maximal Expiratory Flow @ 50% VC	2.3 L/s	1.4 L/s	2.1 L/s	1.3 L/s
Forced Inspiratory Volume 1 sec	3.6 L	0.94 L	3.9 L	0.87 L
Peak Inspiratory Flow	5.8 L/s	1.6 L/s	6.2 L/s	1.1 L/s
Maximal Inspiratory Flow	5.0 L/s	0.86 L/s	5.3 L/s	1.2 L/s
Total Lung Capacity	6.8 L	0.86 L	7.2 L	0.96 L

Table 2 – Post laryngectomy day nine and six month spirometry data. (Based on [19])

The study concluded that in conclusion the removal of the larynx short circuiting the upper airways result in significant changes in some pulmonary function values i.e., a decrease in maximum vital capacity and in an increase in inspiratory flow-volume values, while other values remain unchanged e.g., TLC and FEV_1.

Function 2 Heating and humidification of air

Inspiration through a tracheostoma leads to a shift in the ISB (isothermal boundary) towards more peripherally located airways, leaving a large part of the airways at suboptimal humidification levels [54]. Ambient air of, for example, 22°C and 40% RH is only conditioned to 27-28°C and 50% RH at the level of the upper trachea. Both temperature and humidity have a significant impact on the ciliary

activity in the trachea. Studies in a rabbit model have shown that at body temperature (37°C) the cilia stop beating when the RH drops below 50%. If RH is less than 60% there is a reduction in mucociliary frequency of 30% [55] [56]. Although laryngectomy causes this suboptimal humidity condition for filtration, evidence suggests that in normal environmental conditions with the subject at rest, the isothermal boundary layer is higher than the lungs meaning normal gas exchange can occur. It seems possible however that in low humidity and temperature environments and/or with the patient increasing their breathing rate due to exercise, that the isothermal boundary may drop even further into the lower airway and could result in sub-optimal gas exchange and lower blood oxygenation.

Function 3 Filtration of air

After total laryngectomy with the upper airway removed or disconnected from the lower airway, the patient's ability to filter air before it enters the lower airway is impossible. Instead, aerosol particles and debris smaller than the tracheostoma and are potentially able to be deposited in the lower airway. The only remaining normal filtration method is mucociliary clearance in the trachea and lower tracts leading to the lungs. Unfortunately, due to reduced relative humidity and temperature conditioning of the air into the trachea, the mucociliary activity is reduced as mentioned above. This means that in the worst case, it would be possible that any aerosol particulate matter suspended near the stoma could be aspirated and deposited in the lungs. It can be presumed that particles from 0-10µm could be aspirated and may not be effectively cleared [29] [30] [27] [26]. This could explain why laryngectomy patients complain of spontaneous coughing [34], it is the only remaining method of removing foreign objects from the lower airway.

Function 4 Coughing

Directly comparable frequencies of non-laryngectomised cough were discovered in this literature review. A study [57] on laryngectomized patients with a median follow up period of 2.9 years found 55% were bothered by a spontaneous cough. Another study [58] found that of 37 non-HME wearing laryngectomy patients, 21 had incidences of coughing 5 or more days a week, on those days the mean number of coughs was 9.5. This is within the normal healthy ranges established in multiple studies [31] [33] on healthy adults in similar age groups. It is possible that as the healthy subject tests were closely monitored and the laryngectomised subjects self-reported their number of daily coughs, that they did not record their less significant coughs.

A review [34] of the laryngectomised patients with a mean age of 67.3 years (46-76) provided quantifiable data of the cough itself. In laryngectomised subjects, the maximal voluntary cough flow rate was 4.76 L/s and reflex cough flow rate at threshold, level was 4.55 L/s. Time to reach the peak flow was recorded as ~47.5ms in both voluntary and reflex cough. Volume acceleration in MVC and RCst was 92.32 L/s^2 and 91.79 L/s^2 respectively. The study also recorded maximal static expiratory pressure (PE(max)) in laryngectomy subjects at 122.04 cmH_2O [34]. In every metric, the laryngectomy patients cough was lower than non-laryngectomy cough and therefore likely to be less effective.

Function 5 Swallowing

One study [59] found 98% of laryngectomy patients experience dysphagia at discharge. After 3 years, 58% of laryngectomy patients have normal diets. Patients experience long term dysphagia identified significantly increased levels of disability and distress. This is due to the significant anatomical changes that result from total laryngectomy. In a study [60] on 89 patients with total laryngectomy, swallowing ability (6 to 12 months after surgery) as determined by the capacity to

swallow different consistencies of food was as follows: 58 (48%) could swallow solids, 23 (19%) could swallow soft food, and 40 (33%) had serious difficulties with 25 (21%) able to take only fluids and 17 (14%) who required a PEG (percutaneous endoscopic gastrostomy) as supplementary (to the fluids) or as primary means of feeding.

Function 6, Speech

After total laryngectomy with the larynx removed patients have limited options to communicate. Patients may utilise other forms of communication such as writing on a board or sign language. The only form of speech rehabilitation that does not require a medical device is oesophageal speech. Oesophageal speech is a technique in which air is swallowed and then allowed to escape through the pharynx. Appropriate tensing of the pharyngeal walls during exhalation results in pharyngeal wall vibration which creates a sound. Speech is often lower pitch than normal. Very few patients can use oesophageal speech as a sole method of speech [61].

Function 7, Olfaction, Gustation & Chemosensation

One study [62] found that after total laryngectomy, olfaction was impaired in 51.4%, and was even not possible in 30.5% of patients. Decreased gustation abilities were reported in 26.7%, and dysgeusia in 11.4% of patients. Almost 21% of patients were bothered by an impaired gustatory ability and 50.5% of patients were affected by their loss of olfaction. Various nasal and gustatory problems were reported in more than 80% of laryngectomized patients. The olfaction and gustation abilities are connected and have a substantial impact on the quality of life.

A study concerning rehabilitation of olfaction after laryngectomy found that using Nasal Airflow-Inducing Manoeuvre (NAIM) in a single training session resulted in 46% of 'non-smellers' tested being able to smell again. [63]

Another study [64] found that using the Nasal Airflow-Inducing Manoeuvre (NAIM) technique to draw air through the nose can allow patients to regain some of their olfactory ability. In this three-year study 78% of the laryngectomies reported being able to smell in a questionnaire.

While NAIM appears to greatly improve the olfaction of non-smelling laryngectomy patients, and 18.1% of laryngectomy patients do not suffer a loss in olfaction, a significant percentage of the laryngectomy population is unable to smell due to their inability to pass air through their nose. It seems likely that with the strong link between olfaction and gustation that improving olfaction would result in improved gustation also.

Function 8, Resistance

While resistance to breathing or work of breathing is not considered a primary function it is affected by laryngectomy and may have effects on patients. After laryngectomy, the anatomical dead space is disconnected from the airway, there is a reduction in resistance to breathing. The loss in resistance may the reason for the reduced Vital Capacities recorded in laryngectomy patients. Reduced Vital Capacity is also evidence of diaphragm weakening and lowering of lung tissue elasticity. The result of these changes is weak cough which leads to accumulation of secretions in the lower airway. Diaphragm weakening and lowering of lung elasticity may also explain the lower tidal volumes and faster breathing rate. Although sources specific to this subject are limited, a broader review of the information available suggests a relationship between the reduction in breathing resistance of laryngectomies and many of the diseases they can develop.

1.2.3 Existing devices and their performance

There are a range of medical devices available to laryngectomy patients. The intended use of these devices is to restore the lost functions of the upper airway. Generally, the range of devices can be categorised into distinct groups, which are used in combination to restore multiple functions simultaneously. This section of the literature review will attempt to quantify the performance of each device, based upon the pre and post laryngectomy upper airway function data gathered.

Heat Moisture Exchangers

Heat moisture exchange (HME) devices, shown in figure 4, are small cassettes worn over a tracheostoma, via an interface with a stoma patency device or baseplate. The devices retain heat and moisture from exhaled air and re-saturate and heat inhaled air. The body of the HME contains a hydroscopic, air permeable material which captures exhaled moisture within it. The overall effectiveness of a device to retain heat and moisture is dictated by the HME medium and its overall volume. A common component in all HME's is a heat moisture exchange medium. This works as a condensation and absorption surface; the most popular materials are reticulated foams. Papers and other mediums can be used in assisted respiration circuits, because they generate high resistance that a patient could not tolerate unassisted. In order to enhance the water-retaining capacity, the foam is often impregnated with hygroscopic substances like Calcium Chloride [65] An HME has three physical properties [66]:

Heating and Humidification of air. Multiple studies concerning the effects of heat moisture exchangers in laryngectomy patients in comparison to nasal breathing confirm a person breathing through a tracheostoma loses about 500 ml of water daily. By using an HME it is possible to retain 250 to 300 ml of this water loss in the respiratory system [67] [68] this would indicate an 80-100% restoration, with water loss matching pre laryngectomy levels. There are many environmental and activity related factors that affect water loss. A study [69] demonstrated that the use of an HME increased the temperature from 27-28°C to 29-30°C and increased the RH from 50% to 70%. In healthy adults the normal tracheal temperature is 31-33°C and RH is 98% [70], meaning the HME restores temperatures to within 92% of pre laryngectomy levels. The exact position where RH is taken does affect the result.

Primiano et al. [71] reported a HME conditioned the air in the trachea of a ventilated tracheotomized patient better than mouth breathing would have done, but not as well as nose breathing would have done.

Resistance. HMEs add a flow rate dependent resistance to the airway resistance. One study suggests airflow resistance of an HME is lower than the airflow resistance of the nasal airway. The effect of the increased resistance (compared to stoma breathing without HME) in laryngectomees is still poorly understood, the HME's resistance may reduce dynamic airway compression, thereby improving ventilation [66]. McRae [72] reported that the use of an HME with increased breathing resistance, approximating the normal upper airway resistance, has a positive influence on tissue oxygenation. Lorenz and Maier [73] conducted a review that assessed the effects of HME cassettes on the conditioning of respiratory air, lung function and psychosocial problems. The conclusion added the possibility that breathing resistance may further benefit the respiratory system.

Filtration. HME's due to their position in front of the airway, their porous construction and HME medium also act as an airway filter. The pore size of the foam style HME housing can prevent coarse particles and debris from entering the airway. There are no sources available which describe in detail the performance of HME's to filter particles [66]. The reticulated foam components of HME's can utilise multiple effective filtration mechanisms, including sieving, inertial collision, direct interception, or even Brownian motion depending on the size of the particle. There is no evidence

available to confirm what type of filtration performance a HME offers. There is evidence that users are experiencing the benefits of filtration, a study showed that the HME user group showed significant reductions in the incidence of coughing [57].

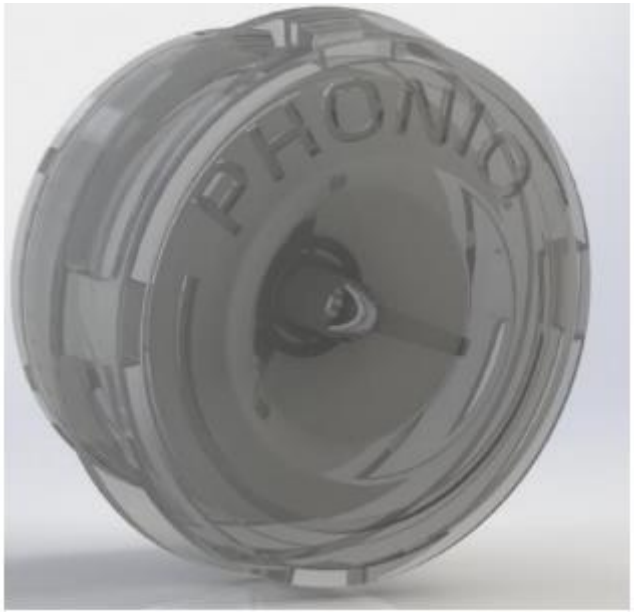

Figure 4 - An example of an HME with button occlusion [74]

There are many studies conducted that indicate that patients who chronically wear a HME of the type described above have improved health overall. In regard to heat moisture exchange, using the indicators of RH, Temperature and water loss, these devices are highly effective as restoring this function. With regards to resistance, the function is not completely restored, with many patients unable to tolerate pre laryngectomy breathing resistance. There is no data to compare HME's to pre laryngectomy filtration, but it is understood that HME's offer some filtration.

A product of HME use is a reduction in the incidence of coughing and lower mucus production which helps restore one aspect of coughing to pre laryngectomy levels.

Speech Prosthesis & HFSV

Voice prostheses, show in figure 5, have been commercially available since 1980 [75]. A voice prosthesis has retaining flanges at each end, the 'tracheal flange' and 'oesophageal flange'. All voice prostheses have a safety strap, which is cut off in indwelling devices after the prosthesis is put in place. A voice prosthesis has a one-way valve near the oesophageal flange that enables pulmonary air to pass into the oesophagus and pharynx for sound production and prevents content from the food pipe, such as liquids or saliva, from entering the trachea [76]. The voice quality when speaking with a voice prosthesis is influenced by pulmonary support, airflow resistance of the voice prosthesis, and airflow resistance of the new voice source [77]. Although the voice prosthesis is only responsible for part of the total resistance – the neoglottis is responsible for the other part – favourable airflow characteristics are expected to enable the laryngectomized patient to speak with less effort [78]. One study comparing state of the art speech prostheses found that the pressure to open, and therefore use, the prosthesis ranges between 67 and 1187 Pa [79]. This is within the range of normal speech pressures below the glottis.

Speech. A prospective nonrandomized cross-sectional study by Dabholkar et al [80] evaluated voice quality in thirty patients with a prosthesis. Voice quality measures were taken immediately

postoperatively and at 6-month and 1-year intervals using the parameters of functional outcomes GRBAS (grade, roughness, breathiness, asthenia, strain) scale, maximal phonatory duration (MPD), and words per breath (WPB). All patients had good voice results at the end of 1 year after prosthesis insertion with voice quality results improving with time.

This form of voice prosthesis can only operate when the stoma is occluded, usually by covering the stoma with the hand or occluding inlet of the HME, if installed. Some users utilise a hands-free speech valve attachment which clips into a HME and can be closed without use of the hands. Natural non-laryngectomised speech is very complex. HFSV's struggle to replicate some of the features involved in speech such as pauses to take breath, glottal stops and voiceless stops, this is due to the fact that HFSV's return to an open position at low or zero pressure scenarios [81].

Literature concerning the testing of hands-free speech valve performance provides data in the form of dynamic volume range, maximum phonation time, number of breaths taken to read standard text, syllables per minute and breaths per minute. Results are shown in table 3. A notable addition to testing of laryngectomised speech is the time needed to produce speech.

Parameter	Provox (manual)	Blom Singer (Hands free)	Provox (hands free)
Maximum phonation time (s)	17.9	11.6	15.2
Dynamic Loudness dB range	28.2	24.8	33
Number of breathes to read standard text	16.4	18.3	19.9
Number of patients with time lag of 1-2s	0	3	0-2

Table 3 – Speaking Data of Patients using hands free devices

The results of the testing illustrated in this table show that users of hands-free speech valves cannot phonate for as long as patients who occlude their stoma or HME manually. 13%-25% of HFSV users also experience a delay at the onset of voicing.

Because of the rapid pressure drop during speech, patients with a hypotonic neoglottis have more difficulty keeping the valve closed and ensuring a sufficiently long phonation time. In addition, there are pulmonary/respiratory and physical/psychosocial factors which also contribute to the limited use of the hands-free tracheostoma valve in laryngectomized individuals [61] [81] [80].

Figure 5 - An example of a speech prosthesis [77]

<u>Laryngectomy Tube, Stoma Buttons, Baseplates & Ingress protectors.</u>

Some patients experience permanent problems with stoma patency, requiring permanent use of a laryngectomy tube [49]. Laryngectomy Tubes are flanged, cuffless, curved silicone tubes intended to

be placed within the tracheostoma (see figure 6). They maintain stoma and tracheal patency and a clear airway. Usually, SOA Laryngectomy Tubes have a connection interface to a Heat Moisture Exchanger. Laryngectomy Tubes also have eyelets or slots allowing them to be held securely in position by a tube holder, a device which passes around the neck. Laryngectomy Tubes are generally reusable for up to 28 days.

A Stoma Stud is a short length tracheal cannula, designed specifically to sit within a surgically created tracheostoma, in order to maintain stoma patency (see figure 6). The device is designed to be maintained in position within the tracheostoma by interference fit, which is achieved through a combination of a protruding retaining lip around the innermost opening of the cannula seating against the anterior wall of the trachea. A conical flange around the external opening of the cannula seating against the exterior surface of the skin around the tracheostoma; and the exterior surface of the tube section of the cannula opposing the wall of the surgically created tracheostoma [82].

Base Plates / Adhesive Carriers (see figure 6) – Baseplates are designed to ensure an airtight interface between the patient and the heat and moisture exchange (HME) filter attachments. The baseplates have an adhesive layer, which affixes to the patient (which, depending on the material used, may have a film layer added to provide a non-tacky outer surface) and is a flexible base to which a rigid interfacing ring is welded. Baseplates come in two main adhesive material types. Hydrocolloid materials are recommended for use on sensitive skin, e.g. following a surgical procedure or on completion of radiotherapy. Adhesive baseplates are made from a clear, usually breathable, flexible materials with higher levels of skin adhesion and are recommended for a secure application necessary for longer term in-use life and better sealing for users during higher levels of activity. [82]

A shower shield device (see figure 6) is used by laryngectomy patients to shield their HME Filter device and or Stoma from the downward flow of water. Shower shields come in two forms. The first is HME attachments or accessories, which allow the user to continue to use their HME while showering/washing. The second form is usually a flexible impermeable material, which attaches around the circumference of the neck above the stoma, directing water away from the Stoma. Users can choose whether they wear an HME under the latter Shower Protector device. Due to their intended use. Water ingress protectors are considered optional or occasional devices and are not always referred to as part of the larger restorative system which is primarily made up of devices which need to be used chronically [82].

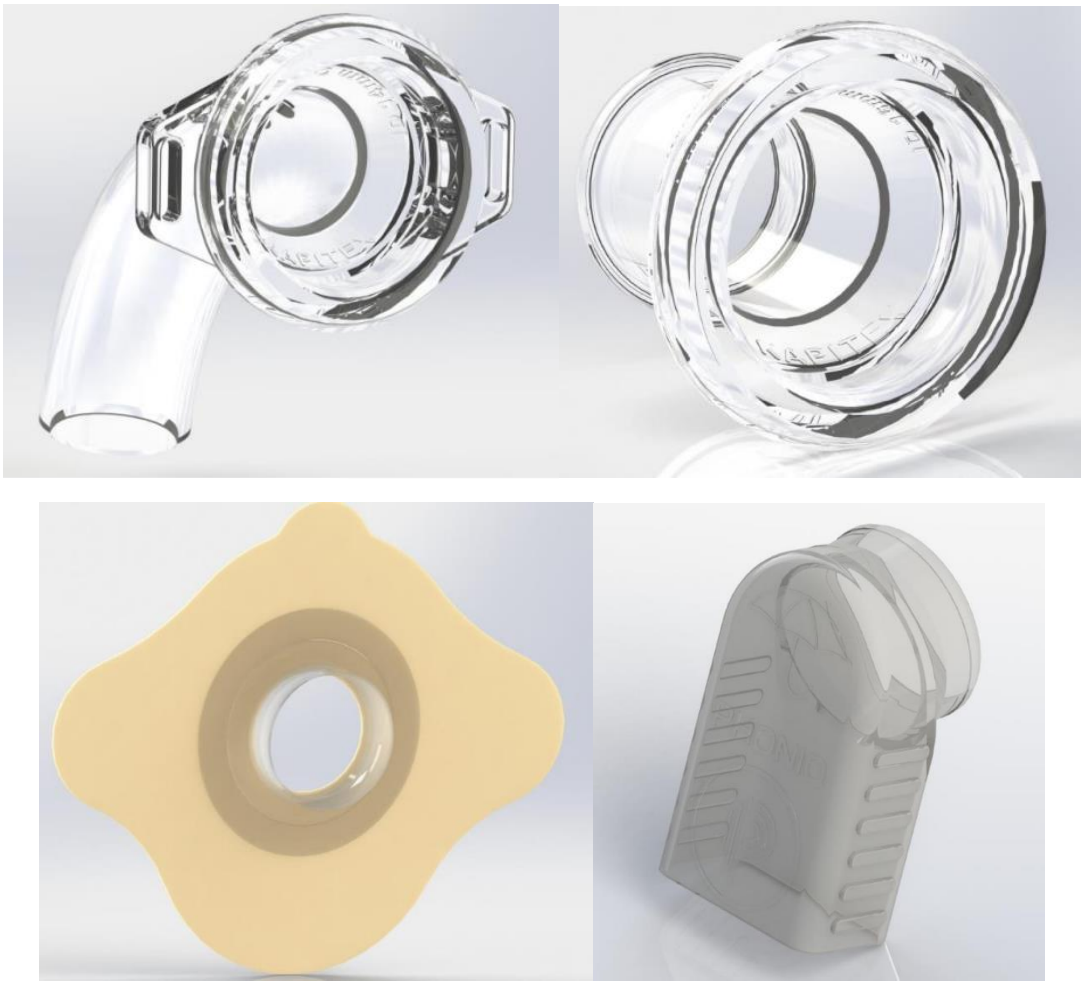

Figure 6 - laryngectomy tube (TL), Stoma Button (TR), Base Plate (BL) & Ingress Protector (BR) [83]

Electro Larynx

As many as one-third of laryngectomized patients find tracheoesophageal speech unsuitable for anatomical considerations [84]. Electrolarynx phonation is the most used form of phonation. An electrolarynx is a battery-powered device, shown in figure 7, which incorporates the internal pre-set pitch that can be adjusted to meet with individual preference for male and female speakers. During phonation, the hand-held device is held against the neck approximately at the level of the former glottis to put the sound into the oral and pharyngeal cavities by an electromechanical vibrator. The vibrated electronic sound source is transmitted through the neck tissues, where the user modulates it to create speech by movements of articulators such as the lips, teeth, tongue, jaw and velum [85]. Work has been conducted to improve the electrolarynx phonation, adding tone and pitch modulation and volume adjustment. Monotonic or robotic speech quality is produced when certain acoustic deficits are present including a flattened fundamental frequency, radiating noise, and an improper source spectrum [86]. Radiating noise represents the mechanical hum from the electrolarynx that is not filtered by the vocal tract and instead is perceived directly by the listener [87].

This difference between healthy speech and electrolarynx speech, coupled with the requirement to use one hand while speaking is the main drawback of the electrolarynx. Due to anatomical considerations, many patients must use the electrolarynx.

Figure 7 - Photograph of an Electrolarynx [83]

Dysphagia Devices

There is a broad range of medical devices to treat dysphagia. Some are therapeutic and can improve or restore the function of swallowing, some utilise neuromuscular electrical stimulation to strengthen the remaining muscles and encourage better swallowing. Swallowing quality is measured in multiple ways but is often measured by one of, or a combination of either PAS (Penetration–Aspiration Scale), Swal-Qol (Swallow-Related Quality of Life) or FOIS (Functional oral intake scale) [88].

Many more devices and products are focused on patients who cannot restore their swallowing to a safe level and assist with the delivery of food or drinks. These can be drinking vessels that deliver a measured dose, utensils that deliver a measured dose and food that has been produced to a consistency that makes swallowing easier. Often, the solution for treating dysphagia and improving the lost function of swallowing is purely therapeutic, where patients are trained to swallow more effectively by a speech and language therapist.

1.3. Literature Review Summary

Total laryngectomy has a negative effect on pulmonary health by preventing the functions of the upper airway. These primarily are the conditioning of air entering the lungs, including heating, humidification to the isothermal boundary, filtration and speech. swallow, gustation, olfaction and cough are also reduced or completely prevented. There are devices and therapeutic techniques that restore all these functions to a satisfactory level in some patients.

Part of the upper airway is the larynx which is completely removed and therefore speech without devices is extremely difficult. Speech prosthesis devices coupled with finger occlusion or hands-free occlusion of Heat Moisture Exchangers, or the patient stoma restore speech to some extent. Speech is restored to level which patients are intelligible and can speak at comparable volumes and durations to pre-laryngectomy. Some nuance of speech such as stops and pauses are affected by the design of hands-free speech valves, this is an area where improvements could be made. Additionally, hands free speech valves are an extra device in the sequence of required devices for laryngectomies. From the literature review, it seems a combined HME & HFSV may be possible and preferable to patients.

Spirometry values are a test of pulmonary health that can provide insights into the condition of the airways. Changes in spirometry values in laryngectomy patients seem to suggest reduced pulmonary health. There is some evidence in the literature to suggest that changes in breathing resistance may also play a factor in the reduced pulmonary function of laryngectomies, furthermore reduced resistance may explain laryngectomy patients lower cough effectiveness. Functions of the gustatory and olfactory systems are also affected, olfaction and gustation abilities in most laryngectomy patients are significantly reduced.

Heat moisture exchange medical devices restore the lost functions of heating, humification and filtration. Although most HME factors are restored adequately, there is little evidence in the literature to demonstrate the effectiveness of filtration in HMEs. HMEs aiming to restore upper airway functions should be tested for filtration effectiveness of particles 2.5µm - 10µm as these are effectively filtered in healthy individuals. This is an area that requires further investigation. Although HME's offer some resistance as a by-product of obstructing airflow, they do not create varying resistance during inhalation and exhalation. Having low resistance to inhalation and higher resistance during exhalation would mimic pre-laryngectomised airways which may be beneficial.

Standard HME's have fixed openings and components that do not consider coughing or sneezing. Coughing in HME and HFSV (Hands Free Speech Valve) can result in higher airway pressures which cause discomfort, remove baseplates or HMEs from the patient, or prevent proper movement of mucus and secretions. Incorporation of a pressure release for involuntary coughing or sneezing may be beneficial to patients.

Laryngectomy tubes, stoma buttons and baseplates act as patient-HME interfaces, with the former having the additional function of improving tracheal and stomal patency in patients that require it. Ingress protection devices prevent rain or shower water from entering the stoma. Use of a water ingress protector can prevent occlusion of HME's which prevents speech in patients, this could be an area of improvement.

Any device that is designed should either incorporate or be compatible with laryngectomy tubes and ingress protectors as an efficient way of restoring airway functions. Ingress protectors in particular should be removable from the device as their function is not permanently required.

Regarding speech, there are hands free speech devices available. When tested, hands free speech valves consistently underperformed when compared to manual occlusion and digital speech devices such as the electrolarynx. The requirement for the user to close the HFSV with an increased air flow and pressure, expels a volume that would otherwise be usable capacity for speech. Additionally, a consistent air pressure is required to maintain closure of the HFSV, which limits the dynamic volume range as attempts to speak quietly would result in inadvertent leaks and opening of the HFSV. These factors of the design of the HFSV also result in a higher number of breaths needed to read a standardised text, between breathes some users experience lag before valve closure, resulting in unnatural speech patterns. A design which can remain closed with no pressure would allow a patient to have natural pauses when required, not waste breath repeatedly closing the HFSV and speak as quietly as the prosthesis would permit without leaking due to lack of pressure on the HFSV. The theorised HFSV may benefit an increased number of patients, as currently a low percentage of laryngectomy patients are able to use existing HFSV [81].

At the time of this literature review there is no device which helps restore olfaction or gustation. The inability for laryngectomy patients to create airflow through the nose significantly reduces olfaction. Therapeutic techniques such as NAIM (nasal airflow-inducing manoeuvre) can help with a significant percentage of patients. A device-based solution which created an air flow though the nasal cavities may increase the olfaction ability of patients, and this may also improve gustation to some extent as the two functions are linked.

The thesis will focus on a device with combined HME & filtration that also allows for speech, quietly and with pauses. This appears to be where there are notable knowledge gaps and where a resolution is not available to patients.

1.4. Objectives, Justifications & Considerations

Objective 1: Create an initial design of a medical device that restores lost airway functions in CAD software. Produce representative prototypes of the initial device.

Objective 2: Test device for retainment of moisture. Healthy adults lose 1.9 x 10(-3) g/L min nasally compared to 2.7 x 10(-3) g/L min orally of water; 2.14 x 10(-3) g/L min is lost with current devices. The aim is to achieve a moisture loss, approaching or achieving (1.9 x 10(-3) g/L min.

Objective 3: Test device airflow resistance. A healthy larynx provide resistance to both inspiratory and expiratory stages of the respiratory cycle. The aim is to achieve 1.245 cmH_2O/L per second in expiration and 0.354 cm H_2O/L per second during inspiration.

Objective 4: Test device for ability to filter particles. Healthy upper airways filter particles 2.5µm and above. Current devices particle filtration properties are not verified. The aim is to verify the devices filtration performance in the 2.5µm-10µm range.

Objective 5: Test for cough compliance. Laryngectomized patients cough more frequently and with lower flow rates than healthy individuals. The aim is to test the device with a representative number of ramping pressure cycles to verify that pressure build up does not exceed 122.04 cmH_2O & that the device is not damaged or effected by coughing. Device manually reset after each cough.

Objective 6: Test for closure, sealing and opening. The aim is to verify that the device closes at when a flow rate of >4.76l/s is applied, a max flow rate achievable by patients. Opening pressure <75 ± 27 cmH_2O in line with average adult MIP

Objective 7: Redesign the device based on these findings, aiming to add features to increase effectiveness of device to achieve objectives 1-6.

Objective 8: Repeat simulation of mk2 to verify new design as achieving objectives 1-6 effectively.

1.4.1. Justifications

1. **Initial design**

Laryngectomised patients have lost upper airway functions. Medical devices must be utilised to restore these lost functions to pre-laryngectomy levels. The primary objective is to create a single device which restores as many upper airway functions as possible, as closely to pre-laryngectomy levels as possible. All other objectives are to verify this primary objective.

2. **HME Test**

A device which restores HME (heat and moisture exchange) must be able to effectively retain moisture within lower airway. A test must be conducted to compare the effectiveness of device HME element to retain water to the effectiveness of the normal healthy respiratory system to retain water. Water and heat retention are essential to airway health primarily as drying of mucous and cilia reduces the airways' ability to trap and to remove foreign particles from the remainder of the airway.

A HME test can ascertain what level of moisture is lost from the airway when different HME mediums are introduced to the airway. A HME test can also compare the moisture loss with HME, without HME (representing laryngectomy without HFSV) and due to nasal or mouth breathing. To confirm which one of the HME mediums selected closely matches the moisture loss of a healthy upper airway and that it can be incorporated into the device achieving the primary objective.

3. **Resistance Test**

A device which restores upper airway functions must be able to generate a resistance to breathing. The resistance generated is important to maintain lung recruitment, capacity and overall lung health.

To ensure that the air flow resistance generated by the hands-free speech valve, when in an open position, are comparable to breathing resistance created by the normal healthy adult respiratory tracts. To compare the breathing resistance test results of the HFSV to the breathing resistance provided by healthy respiratory tracts at normal flow rates. To achieve the aims and Objective 3 that a medical device can provide resistance to breathing similar to the larynx in a healthy individual.

4. **Filtration Test**

A device which restores upper airway functions must be able to filter particles. The aim of this study was to measure the filtration performance of filter media samples. Basic validation tests will be performed on the proposed test rig to ensure that meaningful measurements of fractional efficiency can be made. Once validated, repeatable filtration fractional efficiency data on media samples will be obtained and compared to the filtration performance achieved by a healthy non-laryngectomised respiratory tract to achieve Objective 4. These results and comparisons will verify whether the proposed material and volume of filter medium restores the function to an appropriate level or

whether a different solution can be found. The aim of the tests is to demonstrate the fractional efficiency that the selected filter materials are able to achieve with particles within the 2.5-10+ μm micron range.

5. **Pressure Release Mechanism Test (Cough Test)**

Laryngectomised individuals wear heat and moisture exchangers (HMEs) chronically and hands-free speech valves (HFSVs) occasionally. These are attached to patients near their tracheostoma by a patient interfacing device. The patient interfacing device is affixed to the user by insertion into the stoma or adhesive. When a user coughs or sneezes the air pressure behind the HME or HFSV increases significantly, occasionally this results in either the HME/HFSV disconnecting from the interface device, the interface device disconnecting from the patient or the patient experiencing discomfort or some harm as a result of excessive pressure. This is particularly concerning when the user has just undergone their total laryngectomy and has wounds and stitches around the stoma site. It is necessary to include a method of reducing pressure built up in a HFSV to prevent damage to the devices or the user. This test aims to restore the function of pressure release, normally achieved consciously through the opening of the mouth and nose and involuntarily, through relaxing and contracting of various portions of the respiratory tract, that are no longer achievable or no longer connected to the new airway.

The objective of this test is to ensure that the static pressure required to activate the cough pressure valve falls within the physiological range of laryngectomised patients. The desired result was an activation pressure above the activation pressure of the speech valve but below the MEP of laryngectomised patients. The FEA results will be compared the results of the physical testing, the aim of comparison being to prove the accuracy of the simulation and therefore validate that it can be used for further optimisation of the pressure release mechanism.

The static pressure required to activate the speech valve must be higher than the static pressures used during speech. Research suggests the highest static pressures seen during speech are 70 cmH_2O [89]. The pressure at the CSA between the trachea and larynx during a sneeze with a closed mouth is 428 cmH_2O and with occluded nose is 228 cmH_2O. The cough feature should activate at a static pressure less than this and the pressure with the pressure release activated should be comparable to sneezing with mouth and nose open which is 70 cmH_2O, which coincides with the highest level used in speech. The valve should be tested when completely shut simulating a sneeze or cough during speech. The valve should be tested when open simulating a sneeze or cough during normal quiet breathing.

6. **Closing, Opening and Sealing tests**

To function correctly, a speech valve must open and close when a pressure is applied to it via expiratory pressure, this allows for air to pass through a speech prosthesis during expiration for speech. To allow to patient to breathe normally, the device must close at a pressure higher than normal breathing at rest. To allow the user to speak as normally as possible, the device must remain sealed closed with minimal or no pressure. Additionally, the device must open during inspiration with minimal or no pressure applied to it.

As part of Objective 6, it is important understand the force, pressure and distance at which the diaphragm changes state. When assembled into the device, it is the pressure threshold on the diaphragm which causes the device to close. Understanding when the diaphragm changes state in terms of pressure and distance will help simulate the device, and therefore to optimise the device.

Tests must be conducted to find a value of force and of pressure at which the device closes, seals and opens. The device must be able to repeatably open close and seal to allow for safe and consistent use over the devices in use life. The valve must activate above the pressure and flow rate generated during normal quiet breathing. 0.134l/s minute ventilation, max flow rate at normal tidal breathing 1l/s during expiration, max pressure 2.4 cmH_2O. The valve must close at a pressure and

flow rate below the maximum values achievable my laryngectomy patients, flow rate 4.76l/s, pressure 122cmH_2O.
The valve must deactivate at a lower vacuum pressure than it is activated. The closer to ≥0 cmH_2O the better the performance of the Diaphragm. The valve must be cycled 700 times with no significant change in the values of the other acceptance criteria. This problem will be simulated and physically tested to allow for more efficient optimisation if required.

7. **FEA, CFD & FSI Testing**

FEA simulations will be created where applicable and necessary of the device, eliminating the requirement for trail and error improvement and minimal physical iterations of the device.
Models and simulations will be created using Mk1 device data, validated by the physical testing. Simulations will be used in the verification of the Mk2 device. CFD simulations will be utilised to ascertain the total airway resistance created by the device during exhalation.

1.4.2. Design Considerations

The literature review demonstrates that multiple medical devices must be used to restore the functions of the upper airway, it also highlighted that some functions remain completely unrestored, unsatisfactorily restored, or restored but not verified, such as particle filtration. Furthermore, use of devices can create new problems such as how to manage high airway pressures due to coughing or sneezing.

Therefore, the overarching design requirement is to create a device which restores as many airway functions as is practicable so that they can be later verified. The outcome will be a device which provides the potential for improved speech and restoration of other airway functions to pre-laryngectomy performance. The potential to restore the most functions in a singular device appears to be in the HFSV, where Speech, filtration, resistance and cough can all be addressed, therefore this is the device this work will focus on.

HFSV stay open during normal calm breathing but can be closed by an increase in air pressure in order to produce speech. There are some problems in existing HFSV that prevent restoration of upper airway functions. The mode of operation of the Free Hands ASV is such that a constant pressure is required to keep it shut during speech. Towards the end of the user's lung capacity the pressure drops, and the valve can be partially open leading to gradually poorer speech quality over the length of a sentence or breath. This issue is noted in intellectual property regarding this type of ASV [8]. The pressure must be maintained at the closing pressure, which varies depending on the hardness of the silicone in the ASV, of which there are three grades.
By changing the mode of operation to one in which the ASV or HFSV is closed by a high exhalation pressure, but remains closed with no pressure, the user could utilise a lower air pressure to speak. This is theorised to lead to longer, more legible speech, with breaks in speech between breaths without the need to increase exhalation pressure again.

A set of design inputs has been created to expand upon the key aspects of upper airway function restoration in a practical way. The inputs are based upon the assumption of the device being a disposable HFSV with a 24 hour in-use life. The assumption is also made that the device is to be used in conjunction with other laryngectomy medical devices such as laryngectomy tubes, therefore allowing the HFSV to be utilised while the patient also uses effective devices which restore functions such as airway patency.

A series of specification points to be integrated into the design of a device focusing on restoring upper airway function. this includes some practical requirements regarding in use life and integration with other devices, which will influence the designs features including overall size and volume.

1. Device must aid in the retention of heat and moisture in the lungs and lower airway. The device must be as effective at heat and moisture exchange to a comparable level to water loss found in normal breathing of healthy non-laryngectomised patients. Water loss in nasal and oral breathing is 28.5 mg/l @ 15 minutes and 40.5 mg/l @ 15 minutes respectively presuming a tidal volume of 0.5l and a respiratory rate of 0.3 l/s which is common in healthy adults [91]. The solution to this input will be verified with a HME test.
2. Device must create breathing resistance to a level comparable to the resistance created by the upper airways.
3. Device must filter particles. Materials or methods should be utilised to filter particles previously filtered by the upper airway. Particles ranging from 5-20+µm would be filtered by the upper respiratory system of a non-laryngectomised individual. The device must be an effective filter at this particle range [92] [93]. The proposed solution will be verified with a filtration test.
4. Device must allow the user to speak hands free. Device must contain feature that allows the user to stop airflow through the device, thereby redirecting it through a speech prosthesis.
5. Device must not leak while activated, pressures vary but stomal pressures could reach 70 cmH_2O during speech [94]. Device must be capable of remaining closed with the air pressure of speech applied to it. Device must remain closed for duration of phonation until user inhales.
6. Device must be capable of a number of cycles equivalent to the number of times a user would phonate during the use life of the device, assuming a conversational rate of around 150 words per minute, approximately 7000 words per day and 10 words per speaking turn, the valve must be able to change state 700 times per day without damage or leak [95]. Activation level must be in a range that is higher than normal breathing values. Activation level must be lower than maximum exhalation levels capable of the user. The values for speech are defined as max phonation time and dynamic loudness.
7. Device must allow user to cough. Device must contain feature that allows the user to cough without the requirement to remove the device. To achieve this, the cough feature must reduce pressure once activated. Feature must be able to be reset multiple times; the number of cycles must exceed the potential number of times a user could cough in the devices 1-day usable lifespan. Research suggests that a normal healthy adult sneezes on average 4 times per day and coughs approximately 18 times daily. Assuming all of these coughs and sneezes are significant enough to cause discomfort to the user or cause a leak path between the user and the interface device or the interface device and the HFSV, the feature must be able to activate and reset 22 times [32] [96]. Feature must activate at a flow rate and pressure that exceeds normal breathing to avoid accidental activation of feature/mechanism. When activated, feature must significantly reduce pressure in the user's airway, thereby preventing the potential hazards of coughing through the HME and the lungs being subjected to higher-than-normal pressures.
8. Device must be able to mount into existing patient interfacing devices. The HFSV must be capable of being combined, mounted, attached or otherwise joined to a patient interfacing device. The connection between the HFSV and interfacing device must be simple enough to be achieved by any potential user without the user being able to see either device (as the

connection may be made *in situ* at the stoma site). The forces required to connect the devices must be low enough that any user can do so. The force required to remove the HFSV from the interface device must be lower than the force to remove the interfacing device from the patient, an important point as the interface device may have to remain *in situ* for up 24 hours. This interface must not leak during speaking when the HFSV is closed, therefore must not leak at pressures of up to 70 cmH_2O [94]. Most patient-device interfacing devices such as laryngectomy tubes feature a 22mm connector.

1.5. Thesis Outline

In chapter 2, the outcomes from the literature review are used to direct the design of a hands-free speaking valve. This includes the overall design of the device, its method of operation, key dimensions, materials, and how features will restore upper airway functions.

Chapter 3 documents the evaluation of the mk1 hands free speech valve. The device, either as a whole or its individual elements are subjected to a battery of tests which provide data to compare the devices performance of an upper airway function, such as filtration, to the performance of a healthy non-laryngectomised upper airway. Also in chapter three will be a discussion of how the mk1 device compares overall to the healthy upper airway.

Chapter 4 describes a second iteration mk2 design of the device. The changes to the device between mk1 and mk2 will be driven by the results gathered in the previous chapter. Changes will be made to the device to improve the performance, allowing it to restore upper airway functions more effectively.

Chapter 5 documents the evaluation of the mk2 hands free speech valve. As in chapter three the devices' elements are subjected to tests which provide data to compare the devices performance of an upper airway function and the mk1 design. The testing will verify that the HFSV restores upper airway functions for patients.

Chapter 6 contains an overall discussion aiming to illustrate that the device has been verified to restore lost upper airway functions identified in the literature review. The discussion will compare the level of restoration to the healthy upper airway functions and laryngectomised patient without the device to demonstrate the degree of benefit or disbenefit.

Chapter 7 has concluding remarks on the research conducted, suggestions for further testing of the mk2 device outside of the scope of this thesis. It also includes information regarding how to restore other airway functions not achieved in this thesis, that still effect laryngectomy patients.

2. The Design of the Mk1 Device

2.1 Design Overview

Taking the findings from the literature review, a device was designed which has the potential to restore the lost upper airway functions identified. The Mark I concept shown in figure 8 and figure 9 below, was produced based on the design requirements outlined in section 1.3.1. Figure 15 illustrates the various features of the design with alphabetical labelling.

Concept Refinement & Development

There were various iterations of the selected concept. an iteration was selected which could best achieve the requirements and objectives specified.

Device Component Modelling

With a single concept selected, CAD models were produced of the individual components using Solidworks 2018.

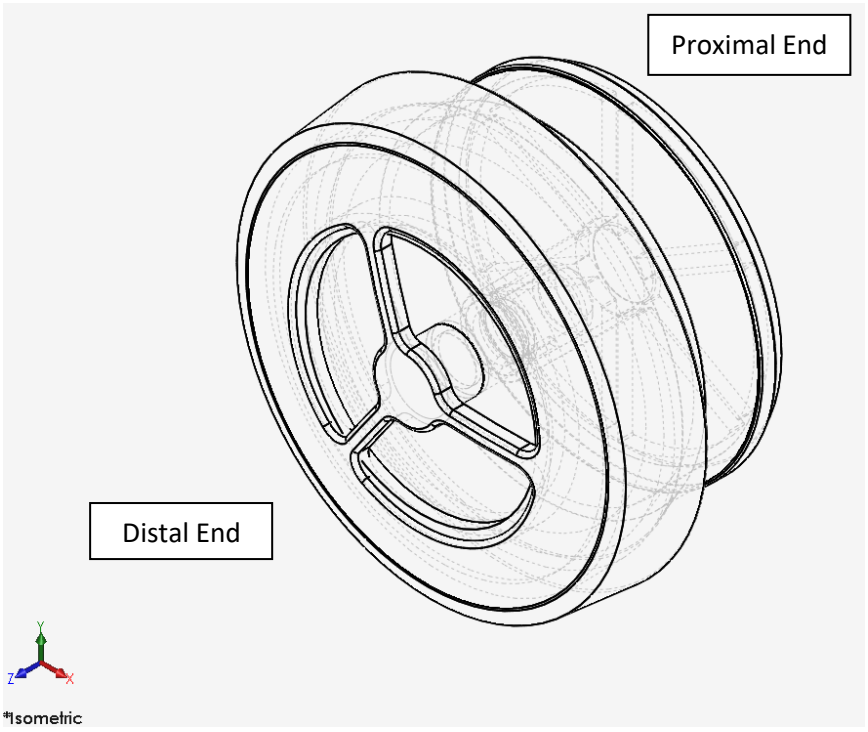

Figure 8 - Isometric line drawing of the Mk1 concept

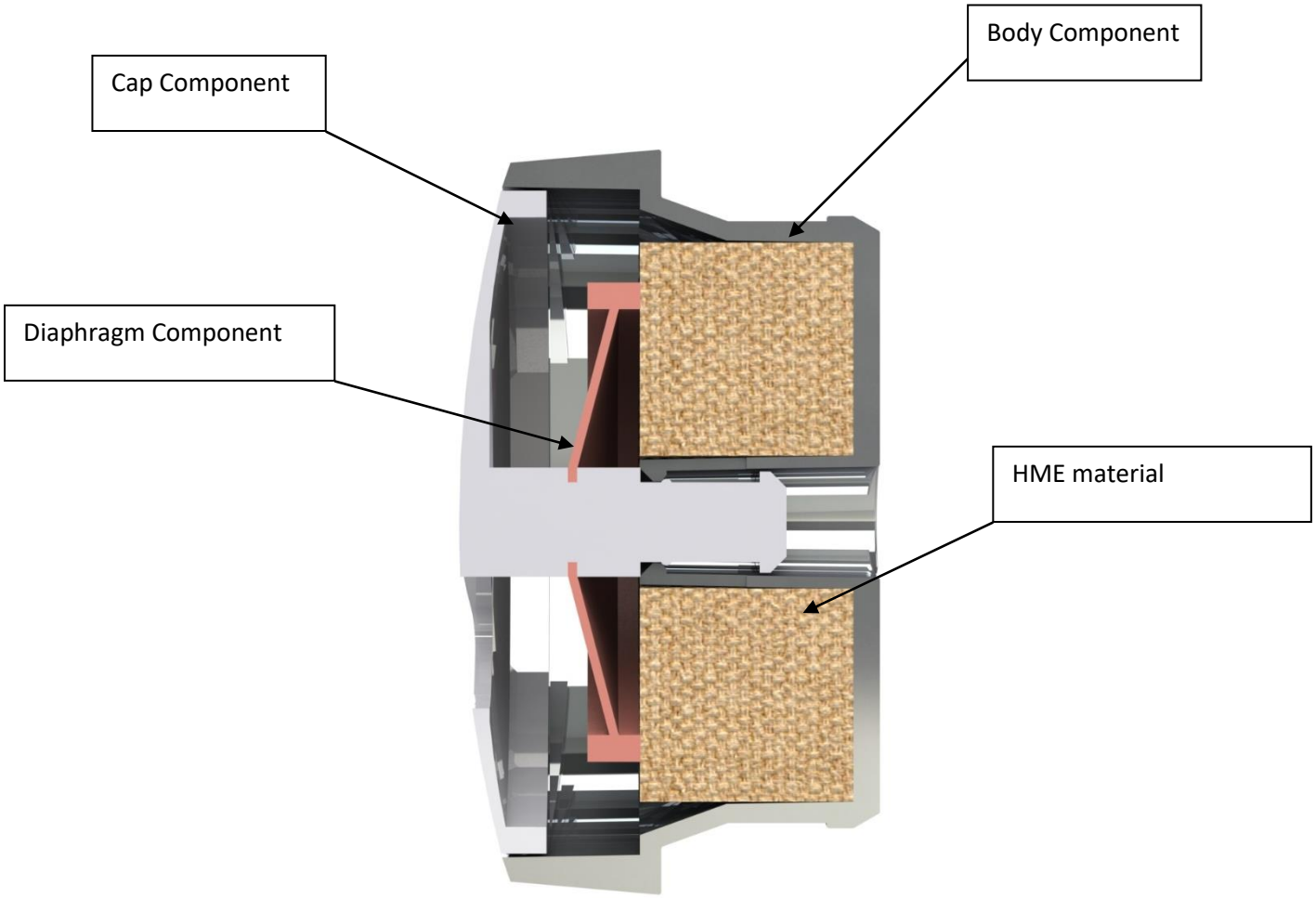

Figure 9 – Sectional View Showing Layout of Concept.

2.2 Method of operation

- The user breathes at a normal ventilation up to rate. The user breathes normally through the HME portion and open HFSV portion, the diaphragm open remains in open position and state.
- When the user wishes to speak, the user takes a full inhalation of breath and at the start of exhalation increases their exhalation breathing rate to exceed 8-litres per minute.
- The diaphragm surfaces in the path of the exhaled air experience an increase in pressure across them, sufficient to change its state from open to closed. The movement of the diaphragm is interrupted by the sealing surface of the HFSV, the diaphragm is now applying a constant light pressure against the sealing surface allowing the user to redirect the remainder of their usable lung capacity to speak through their prosthesis.
- The HFSV remains closed while the user speaks via their prosthesis, experiencing pressure changes between 0 cmH_2O and 70 cmH_2O. No leaks form between any device allowing 100% of the capacity and pressure to be utilised.
- After a sentence the user inhales, overcoming the diaphragm and returning it to the first, fully open state.

- If the user coughs or sneezes while the valve is open the diaphragm will change states, closing the HFSV.
- The pressure of the cough or sneeze will increase, activating the pressure release mechanism.
- The HFSV opens, a large CSA (cross sectional area) is created for the pressurised air to escape.
- The open cough mechanism is closed manually.

The refined concept includes a pressure relief, as illustrated in Figure 18. This feature allows for cap and body to separate and remains open during and after coughing. The device is reset by the user manually. This allows the users breathing to normalise before resetting the valves cough feature. To achieve this, the cap and body components are connected via a rod and tube, the tube is slotted to allow its tip to be deformed. The rod on the cap has a torus around it along its length, slightly oversized compared to the opening at the end of the tube. When pressure builds within the HFSV, the pressure forces the cap away from the body, the torus splays the tip of the cylinder allowing the cap to be displaced forward, opening a cross sectional area from which air can escape.

For clarity figure 10 shows the HFSV in the open, closed and pressure release states.

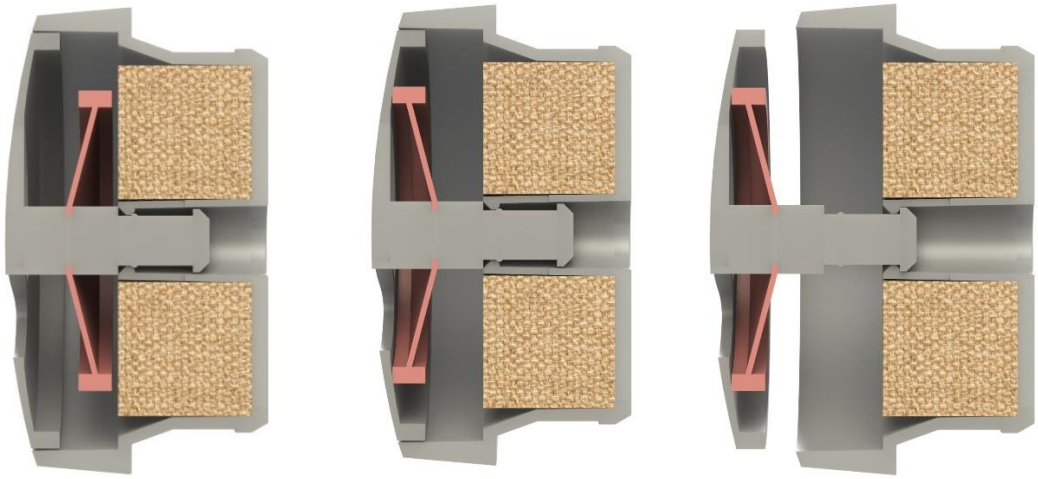

Figure 10 - Rendered image of HFSV in open, closed & pressure released states (left to right)

2.3 Component Design

The concept comprises of four main elements:

1. A housing or body component that acts as the interface between the device and other components in the assembly. This includes a diameter with barbed tip will hold the device within the interface device and create a seal between them. The back face of the component will be open to allow air to pass freely through, the centre of would comprise of a cylinder which will connect it to a cap component. Towards the back of the device will be room for HME material. Towards the front will be a large tapering frontal annulus which will seat the cap.
2. The cap component will sit on the front of the device, contacting the housing in two places, along the central shaft previously described, and around the larger open annulus. The cap will contain a slot or feature in which the diaphragm component will sit.

3. The diaphragm sits on the cap component and is deformed into its bi-stable state by it. When shown in the Figure 6 the valve is open, when a higher air pressure acts upon the diaphragm it changes state, touching the inner surface of the cap and creating an airtight seal.
4. HME material shown in Figure 6 will act to retain heat and moisture, sitting behind the diaphragm and in the housing.

The first component is the housing/body, shown in Figure 11. It is the component which contains and connects the other three components. Figure 15 illustrated where the alphabetical features are found on the assembly. The housing has a 22mm cylindrical feature (a) which acts as the interfacing surface when connecting it to mounting devices such as baseplates. The end of the cylindrical surface is a barb which secures the housing component into the interfacing device. Following the outer profile from feature (a) is a step, from 22mm to 28mm in diameter (b). Feature (b) acts as a positive stop, preventing over insertion of the device into the interfacing device, thereby preventing accidental aspiration. Feature (c) is a cylindrical taper, which decreases in diameter along its length in the direction of the distal end of the component. Feature (c) sits outside of the interfacing device and is designed to contain the diaphragm component. The size of feature (c) is driven by the operating area of the diaphragm component. The proportions of feature (c) are optimised to take up as little volume as possible to reduce snagging risks and maximise comfort and neck mobility of the user. Feature (d) is a 26mm diameter opening at the distal end of the housing. This opening is where the cap is seated. Taking a sectional view of the housing component, feature (e) is a series of 6 spokes. These spokes have three functions. The first function is to provide enough rigidity to allow feature (a) not to deform when being inserted into an interfacing device. The second is to prevent components held within the housing, the diaphragm, cap and HME material, from escaping the housing if they become dislodged, which could lead to aspiration. The third function is to connect central feature (f) in place, connecting it to the rest of the housing. The cross section of the spokes that make up feature (e) are optimised to ensure the maximum possible cross-sectional area exists for breathing through. Feature (f) is a small diameter tube, open at the proximal end and slotted at the distal end. At the distal end, there is a step down on the internal diameter. Then the cap component is combined with the body by forcing its central shafts proximal barb spreading the slot of feature (f), locking the two together once the cap component is fully inserted. Feature (f) has a second function, which is as the female half of the cough feature. When the user coughs strongly a torus on the cap is forced against the slotted distal end of feature (f). If the force is sufficient the slot spreads, allowing the cap torus to pass through the slotted end which in turn allows the cap to slide forward. The free volume whose boundaries are defined by feature (a)(e)(f) is where the HME component is held. Feature (g) is a stepped area around the distal opening of the housing component where the cap component seats, and the tapered design ensures concentricity between the housing and cap components. The small sectional area of this feature is where the seal between the housing and cap components is made, ensuring no leaks occur during speech.

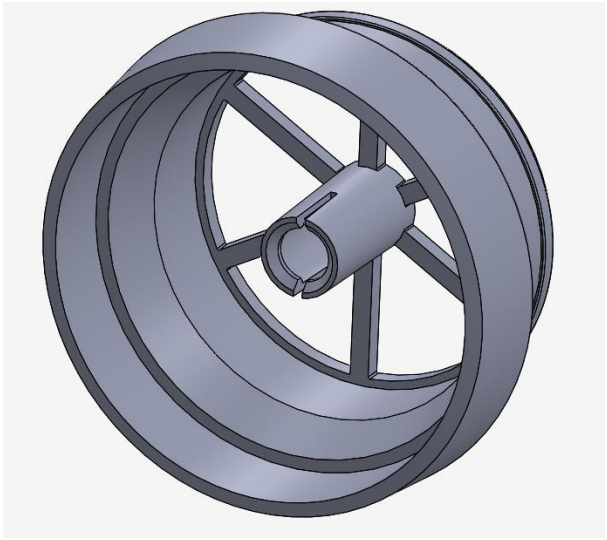

Figure 11 – Body with slotted cap retaining feature which splays, releasing the cap.

The second component is the Cap, as shown in Figure 12. The Cap connects to the Diaphragm and Housing components. Feature (2a) is the shaft of the Cap, which is comprised of multiple areas: the first is a barbed tip which enters feature (f), tapered to allow it to enter, which a straight step down to prevent it from being removed. The size of feature (2a) dictates the level of locking between the Cap and Housing. If feature (2a) is too large the components do not assemble, too small and the Cap and Housing may accidentally separate during cough. Further along the shaft is feature (2b), which is the male element of the cough feature. Feature (2b) is a plain shaft with a torus protruding radially. The centre point of the torus circumference is within the diameter of the plain shaft resulting in a slightly raised curve which interacts with feature (f). The max OD of the torus revolution on feature (2b) controls the level of interference between the Cap and Housing Component. The larger the torus, the higher the pressure the user would have to generate with a cough to activate the cough feature, allowing the torus to spread the slot and partially separate the Cap from the Housing. The length between feature (2a) and (2b) dictates how far the Cap and Housing Separate and therefore how much larger the open cross-sectional area will become during a cough. The larger this area is, the lower the back pressure in the lower airway. This effect diminishes beyond a certain point, where the cross section that is opening is no longer the smallest restriction to the airway. Feature (2c) is a portion of the shaft where the diaphragm is seated. This is an important part of the design of the HFSV. The diameter of this plain shaft stretches the diaphragm causing it to become bi-stable. The larger this diameter, the more displaced the diaphragm will be, and the more deformation will result in a larger linear distance between states and a higher pressure on the diaphragm to cause it to switch states. Feature (2d) is the proximal opening on the front of the Cap component. The opening is where air enters and exits the device. The opening is a 15mm diameter with three spokes extending from its centre. The purpose of the spokes is to connect the front of the cap to features 2(a) 2(b) and 2(c). When the Diaphragm component is closed, feature (2d) becomes occluded, thereby preventing airflow through it. Feature (2e) is the domed surface area of the cap. The interior of this area is where the Diaphragm component seals when activated. The outer area is where the user can press the Cap and Housing component together after the cough feature has been activated. Feature (2f) is the radial edge of the domed front of the Cap. It is where the Cap and Housing seal. A slight ridge ensures a high-pressure contact surface which aids in sealing. The three spokes of feature 2(d) deform slightly to ensure constant tension between the cap and the body, further increasing the effectiveness of the seal between them.

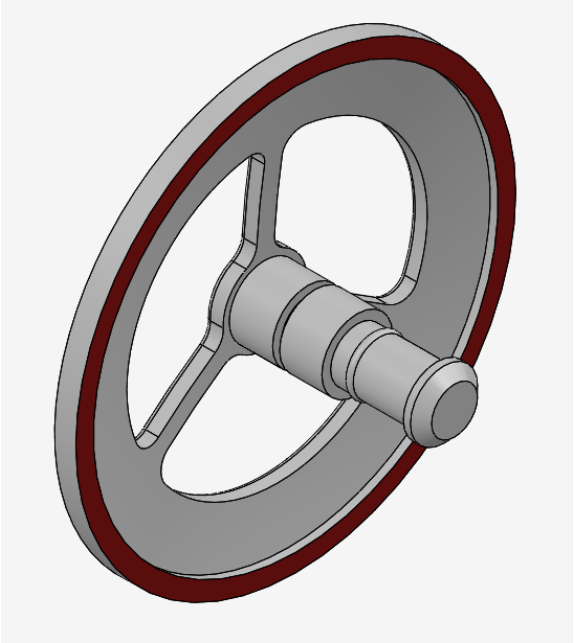

Figure 12 – illustration of the Cap component of HFSV

The third component is the HME medium (3a), shown in Figure 13. The Heat Moisture exchange is a 21mm diameter by 8mm deep piece of material with a hole in the centre to allow for feature (f) of the housing component to pass through it. By having the central shaft of the housing pass through the HME component the HME cannot disconnect from the assembly and potentially become aspirated. The diameters and depths are maximised to ensure all inhaled and exhaled air must pass through the component and be conditioned by it. The volume of the HME material must be sufficient to provide HME performance comparable to the current state of the art. The HME component must fit within the Housing component. There are some additional practical considerations that can be stated in relation to the HME medium. The selected HME material must not retain too much moisture so that it increases breathing resistance or blocks the passage of air completely. As the HME material also acts as the filter medium, the component could become clogged and increase resistance or block the passage of air. The envisioned in-use life of the device is 24 hours, at which point the patient or user will replace the device thereby circumventing the potential for the material to become excessively clogged. In the event the user was exposed to an unusually high level of particulate matter, the frequency of the change would increase to less than 24 hours. The trigger for the changing of the device would be 24 hours maximum, or if the user experiences clogging or perceivable discomfort from increased airway resistance. The housing the device sits in is a simple push fit into a laryngectomy tube or stoma button, meaning changing of this device would take a few seconds and minimal effort or training. A material will be selected which achieves a similar amount of moisture retention to the upper airway, more moisture retention than pre-laryngectomy levels is unlikely to provide any patient benefit. When testing the material for filtration performance the component will be completely dry therefore providing the maximum challenge to the device and representing the first inhalation by the user after installing the device. It is assumed that as the filter medium becomes moist, this will increase the filtration performance further.

Figure 13 – Simple representation of HME material which is incorporated into the HFSV concept.

The final component in the assembly is the Diaphragm component, shown in Figure 14. This elastomeric component comprises of 4 main features. Feature (4a) is an annulus in the centre of the component. The surface of (4a) interfaces with the shaft of the cap component (2c). The diameter of (4a) is smaller than (2c). When assembled this stretches (4a) increasing its diameter to that of (2c), the pressure and surface roughness between the two materials is sufficient to ensure they remain connected. Feature (4b) is the end faces of (4a). These act as a positive stop between the cap component and the housing component. (4c) is the disc of material radiating from the centre of (4b). This is where most of the exhaled and inhaled air will interact with the diaphragm component. The final feature of the component is (4d). This is the thicker and deeper cylindrical area around the outside diameter of the component.

The ratio of the ID of the Diaphragm and the Cap components plain shaft diameter dictates the offset distance of the diaphragms OD. The distance between the bi-stable states must be sufficient to ensure that breathing resistance is not too high. The material hardness, the level of offset, the thickness of (4c) and the overall diameter of the component dictate how much air pressure is required to change the state of the diaphragm.

The thickness of (4b) and (4d) must be sufficient to ensure that the diaphragm does not tear during installation or use. (4d) must be sufficient in cross section to ensure the OD of the diaphragm does not increase, thereby ensuring bi-stability.

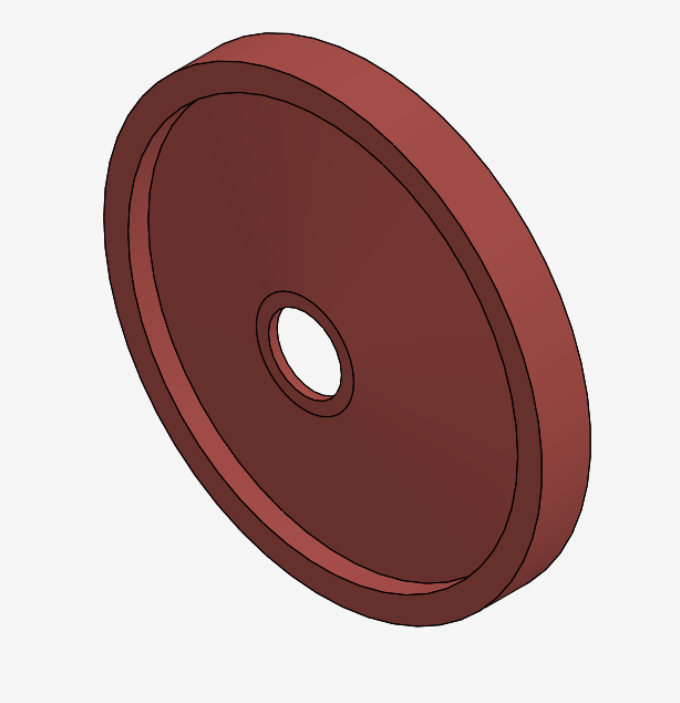

Figure 14 - HFSV Silicone Diaphragm in Neutral as Moulded Condition

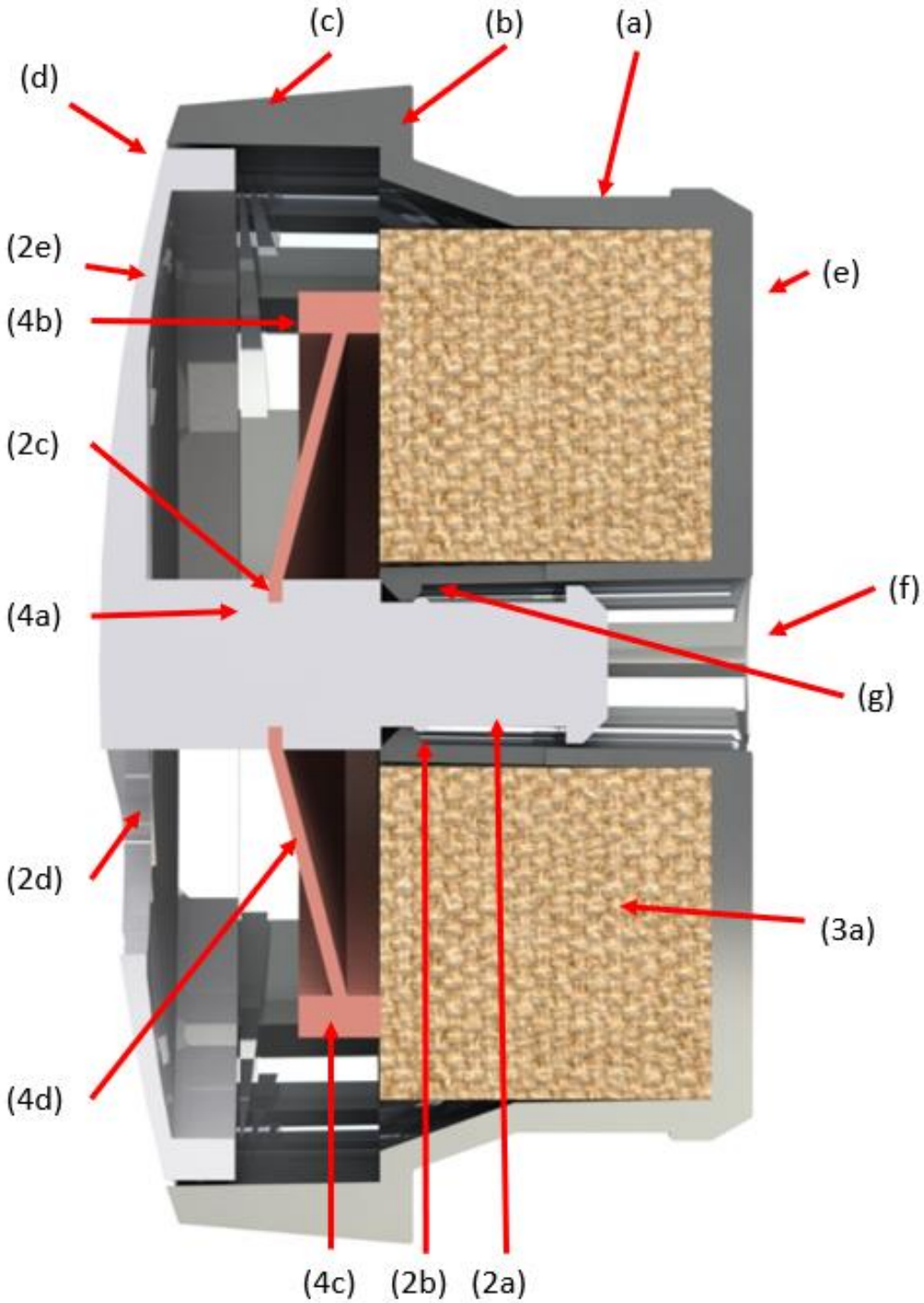

Figure 15 - Sectional view of device, with details numbered

Figures 16-19 have been included to illustrate the components and highlight the critical and overall dimensions of the components.

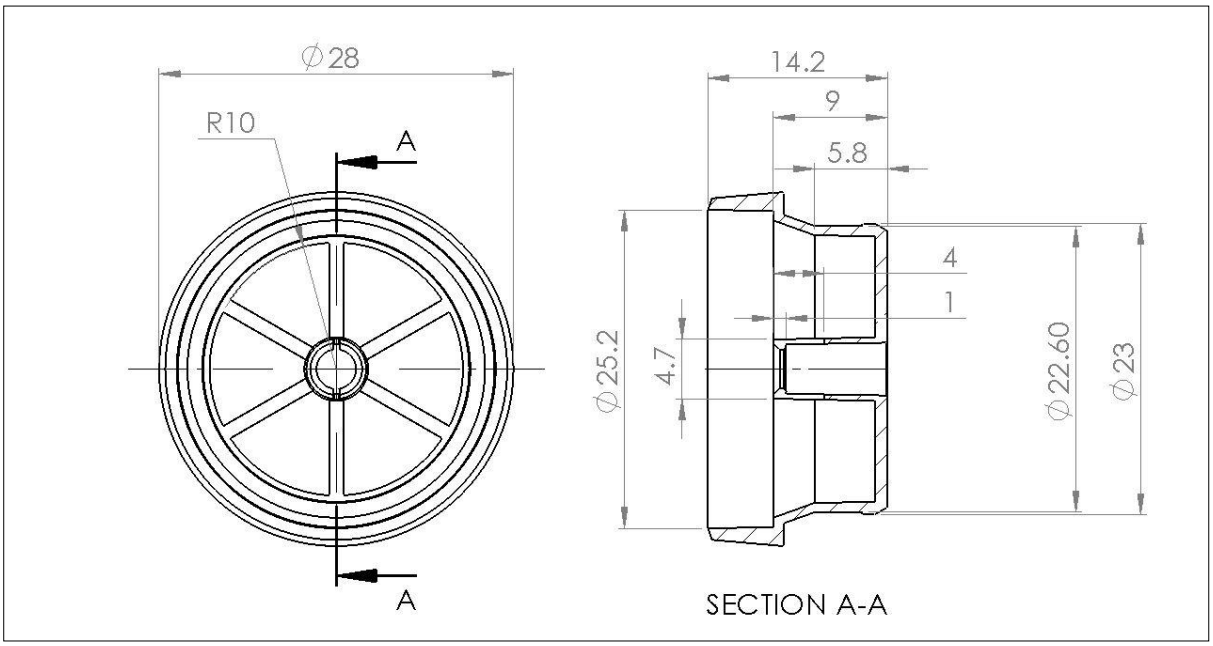

Figure 16 - Drawing of Housing Component

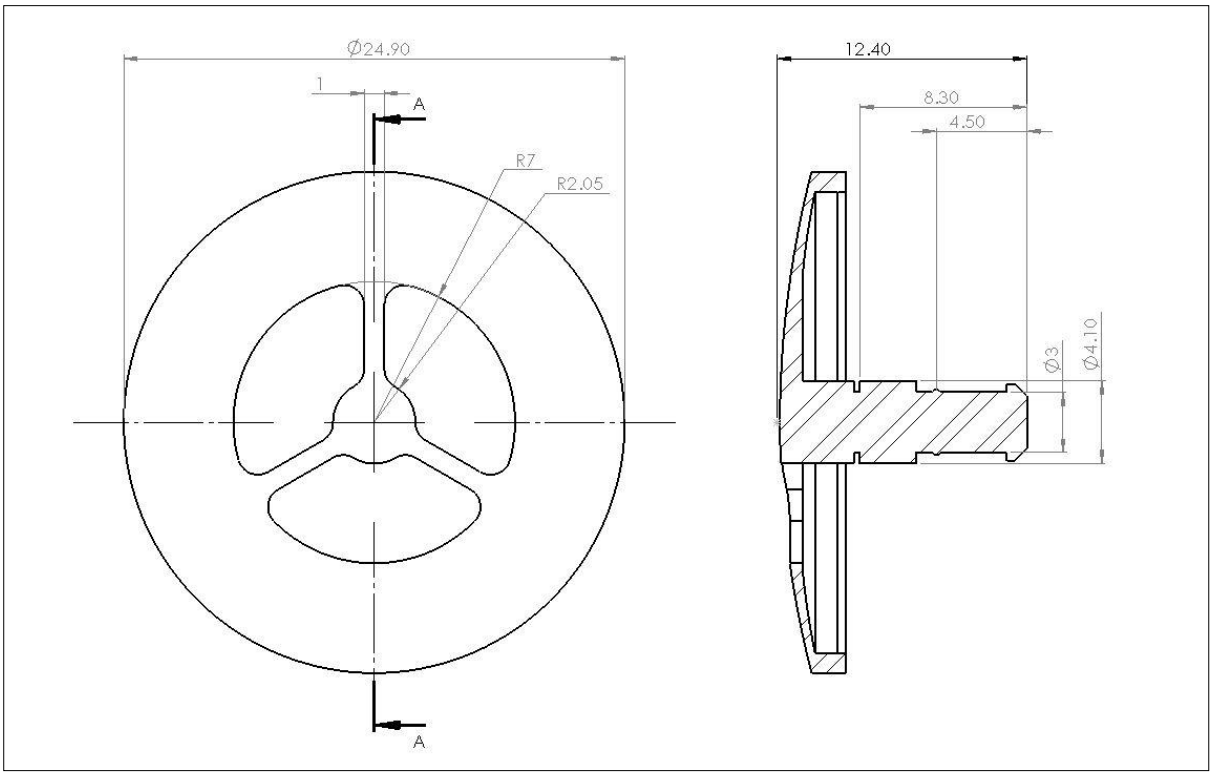

Figure 17 - Drawing of Cap Component

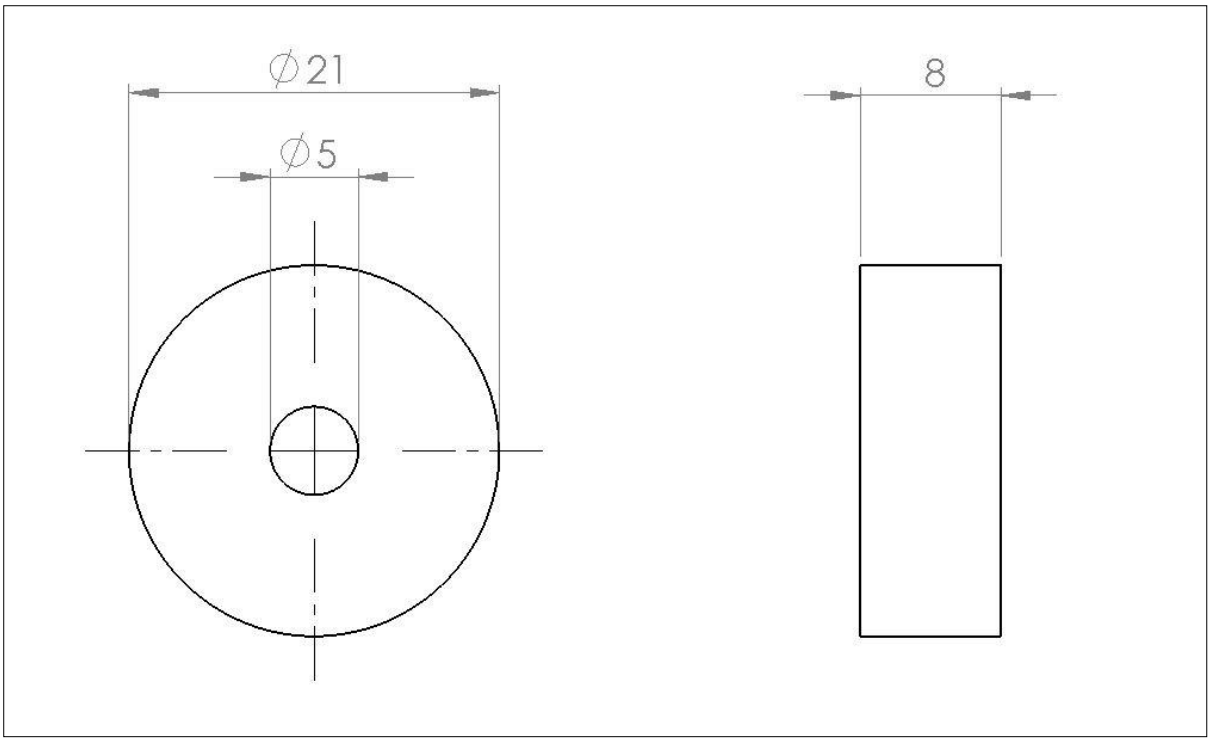

Figure 18 - Drawing of HME component

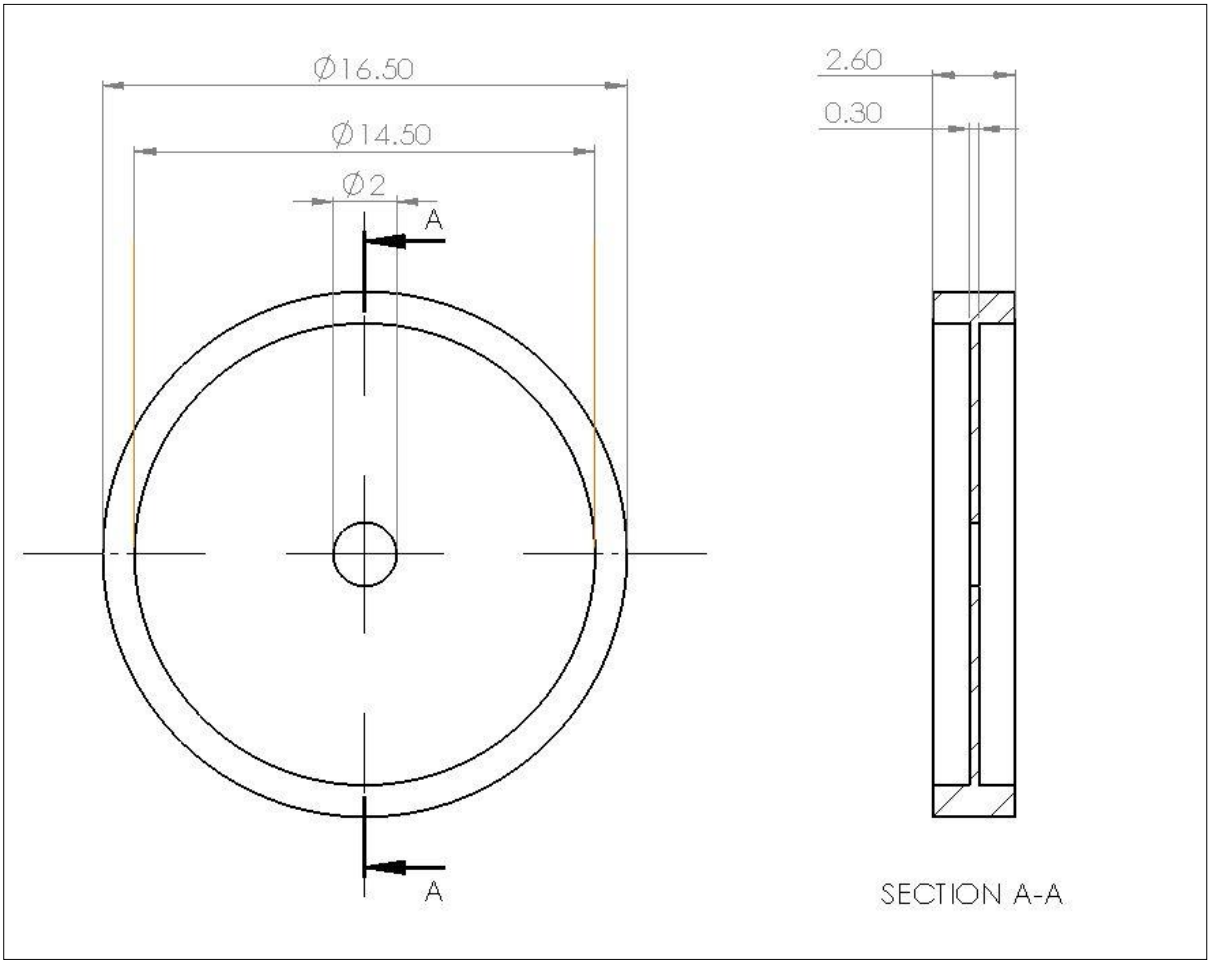

Figure 19 - Drawing of Diaphragm Component

2.4 Material selection

The HME material selected is open cell reticulated polyester based polyurethane foam impregnated with calcium chloride through a dipping process. Reticulated foams have a large surface area with a low porosity to ensure filtration performance for larger particles over 300µm through physical barrier sieving filtration, inertial impaction for particles around 5-10µm, interception filtration for particles around 1-5µm and finally, diffusion because of Brownian motion [98]. It is noted that the upper airway would not filter all particles under 2.5µm and so these are therefore not required to be filtered by the HME. Calcium Chloride is hydroscopic allowing it to retain moisture normally expelled through the stoma. the combination of foam, calcium and absorbed water absorbs and retains heat from the airway.

It is believed that the combination of reticulated foams with calcium chloride will produce the best heat moisture exchange properties. There is a balance that must be found between the HME performance, filtration performance and breathing resistance. High levels of HME performance and Filtration performance will increase resistance to an intolerable level. To account for this compromise in the volume available, different densities along with calcium chloride and non-calcium chloride samples will be verified in the HME testing.

The diaphragm material selected was NUSIL 49(40-70). The material is readily available in four hardness's. The different hardness's can be utilised to allow for different activation pressures without the need for geometric changes. This will broaden the range of potential users.
The silicone diaphragms are produced using small batch injection moulding with an aluminium injection mould tool. The flash and runner are removed manually. Colourant was added to the prototypes to highlight the shore hardness of the component, shown in Figure 20.

Figure 20 - Injection Moulded Silicone Diaphragms Shore A hardness's, 40, 50, 60 & 70.

The reticulated foam is manufactured using conventional chemical mixing techniques, the expanded foam then has the faces of the cells removed by bursting with hydrogen ignition. Once reticulated, the foam is dipped in a solution of calcium chloride at a density of 4.6-7.0kg/m³. The sheets are cut into sheets of the desired part thickness and die cut to produce the final component shape.

The Body and Cap components were 3D printed with a Form2 3D printer. The prints were produced at a layer height of 0.025mm, creating the resolution and most accurate parts possible. The resin used for all Cap and Body components was Grey (V4FLGPGR04). The printed components were removed from their support material and cleaned of excess resin in a 90% isopropyl bath for ten minutes, then transferred to a second 90% isopropyl bath for a further 10 minutes to ensure all excess resin had been removed. It is important to note the differences in material properties between the prototypes used and the selected material. Table 4 gives the properties of the selected prototype materials. Once prototypes were produced, they were assembled by hand.

Parameter	FLGPGR04		Test Method
	Cured	Post Cured	
Ultimate Tensile Strength	38 MPa	65 MPa	ASTM D 638-10
Tensile Modulus	1.6 GPa	2.8 GPa	ASTM D 638-10
Elongation at Break	12%	6.20%	ASTM D 638-10
Flexural Modulus	1.25 GPa	2.2 GPa	ASTM C 790-10
Notched IZOD	16 J/m	25 J/m	ASTM D 256-10
Heat Deflection Temp. @ 0.45 MPa	49.7	73.1	ASTM D 648-07

Table 4 - Table showing specification of resin used for 3D printed Prototypes.

3. Evaluation of Mk 1 Design

This study performed functional verification to test whether the design requirements were achieved by the proposed design. The tests are as follows:

1) Heat Moisture Exchange Performance Testing
2) Breathing Resistance Testing
3) Filtration Testing
4) Cough Feature Activation Testing
5) Diaphragm Activation Testing
6) Diaphragm Deactivation Testing
7) Diaphragm Cycling Testing

3.1 Test 1 – HME Testing

The purpose of this test is to ascertain the level of moisture loss through the device. This is important to allow for comparison between the device pre-laryngectomy moisture loss and therefore whether the device restores this function.

3.1.1 Materials

The samples selected comprised of:

- 3x 45ppi reticulated PU foam
- 3x 60ppi reticulated PU foam
- 3x 100ppi reticulated PU foam
- 3x 5ppi reticulated PU foam dipped in Calcium Chloride at a density of 6 kg/m^3
- 3x 60ppi reticulated PU foam dipped in Calcium Chloride at a density of 6 kg/m^3

The sample size used for the Heat Moisture exchange testing was 3 per each variant of HME material. Though three samples of the selected materials under test are not statistically significant it should be sufficient to highlight any anomalous results and to identify if sample variability were important. Maximum, Minimum and mean results will be shown on results graphs. A range of reticulated foam densities were selected between 45ppi & 100ppi with the aim of finding a pore size or range of pore sizes which provided a balance of HME, filtration & resistance similar to the normal healthy upper airway. By having calcium chloride and non-calcium chloride versions of some of the foam varieties, the effectiveness of the CaCl2 can be observed and compared to non-impregnated foam, and non-impregnated foam of higher densities to see if it is necessary.

Note: A material with a higher pores per square inch value have a denser structure than a material with lower ppi, i.e., 100ppi is twice as dense with holes half the size of a 50ppi sample. It is therefore expected that a higher the pore value will have a higher resistance to air flow and improved HME properties.

3.1.2 Testing Equipment and Measurement Devices

The HME is installed into the outlet of a testing rig specified by the author. The approach was selected to match design specified in international standard ISO 9360-1 "*Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans"* comprising the following components. [99]

- Bidirectional flow generator. - This is a mechanically driven piston used to produce a flow having sinusoidal waveform.
- Humidity generator - Consisting of
    - a heated water bath through which air is bubbled in both directions.
    - A rigid cylindrical reservoir with a maximum volume of 7L and a diameter of approximately 150mm, containing a 2L reservoir bag.
    - A thermally insulated chamber which contains the water bath, the reservoir and a heat source.
- Air delivery system consisting of a T-piece with an internal diameter greater than 15mm, and an exhaust tube at least 200 mm in length.
- Weighing equipment, with an accuracy of ±0.1 g or better in the range of the mass to be measured.
- Flowrate measuring equipment, with an accuracy >5 % of the reading.
- Calibration HME consisting of a housing containing 81 polyvinyl chloride (PVC) tubes arranged in a 9x9 array, each with an internal diameter of 2mm, an external diameter of 4 mm, and a length of 50mm.

The apparatus was constructed and operated as specified then calibrated using the method stated in the standard. The accuracy of water loss results from this equipment are ±0.1g

3.1.3 Methods

The HME properties of the samples were measured using a protocol based on ISO 9360-1:2000 “Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml”. The moisture output was measured using ISO 9360-1:2000 section 6.2 “Measurement of Moisture Loss” and the pressure drop was measured using ISO 9360-1:2000 section 6.3 “Measurement of Pressure Drop”.

Clean, dry air is directed through the sample HME filter into the testing rig using an internal pump within an air-tight chamber. The pump uses a 0.5L tidal volume (V_T) at 15 “breathes” per minute (n) and an inhalation: exhalation ratio of 1:1 is used. A one-way valve controls the direction of this air during inhalation or exhalation. During inhalation, the valve is open and the air passing through the HME filter is directly drawn into the air-tight chamber. During exhalation, the one-way valve closes and redirects air through a water bath heated to 34°C. A visual representation of the HME testing set up can be found in figure 21.

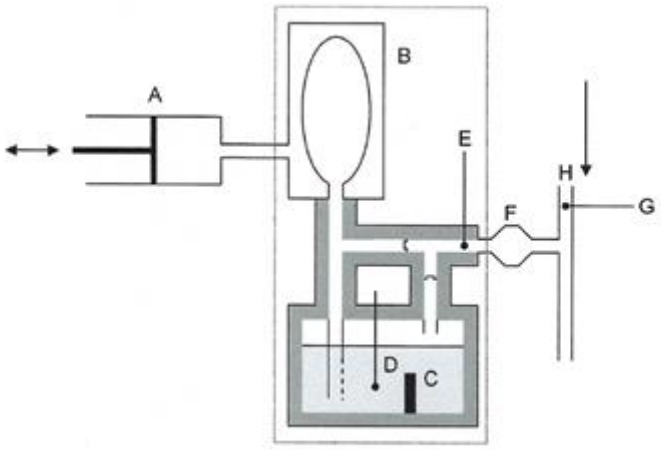

Figure 21 – Picture of HME testing rig 1. A) Internal Pump. B) Air-tight chamber. C) Water bath heater. D/E/G) Thermocouples. F) HME sample chamber. H) Dry air delivery [99]

The exhaled air is saturated with water vapour by the water bath. An efficient HME filter will remove the moisture from this air during exhalation, retain it and then re-humidify the air during inhalation. The moisture output of an HME device can be calculated by weighing the water bath and identifying the amount of water lost during testing. The water bath weight is recorded at 1 hour (m_0), which allows the test rig/sample to stabilise, and at 7 hours (m_1). The moisture loss and moisture output are measured using

$$\text{Moisture loss (g m}^{-3}) = \frac{m_0 - m_1}{n - V_T}$$

and

$$\text{Moisture output (g m}^{-3}) = 37.6 \times \left(1 - \frac{\text{Moisture loss with HME}}{\text{Moisture loss without HME}}\right)$$

37.6 is the moisture content of fully saturated air at 34°C The absence of the cassette represents a worst-case scenario for the HFSV as the foam is further exposed to releasing moisture than it would be as a complete device.

3.1.4 Results

The components were subjected to heat moisture exchange efficiency tests. Figure 22 illustrates the performance of the HME mediums tested. Error bars represent the maximum and minimum values recorded. The results showed that when compared to non-calcium chloride equivalent of the same material and porosity that the HFSV 45ppi and 60ppi samples lost 17% and 29% less water respectively. Verifying that Calcium Chloride significantly improves the efficiency of the HME without increases in size or porosity.

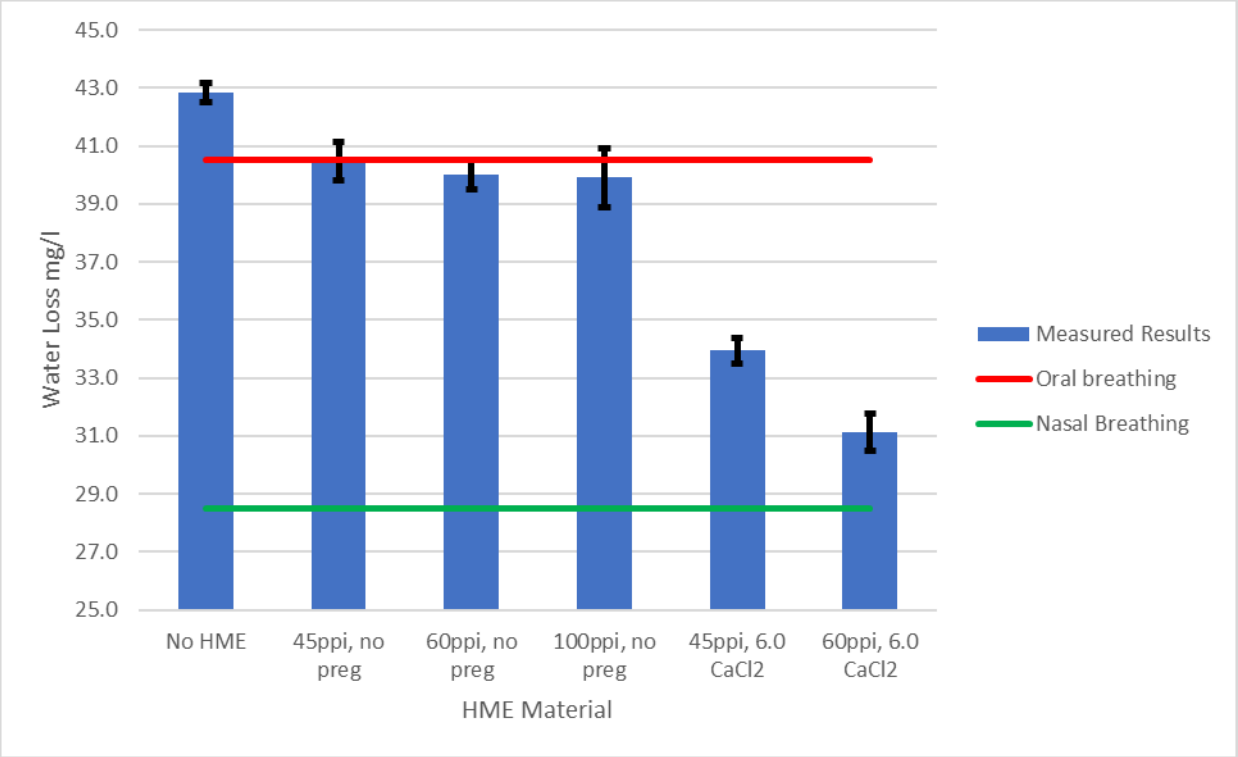

Figure 22 – Chart Showing Water Loss in mg/l of Each HME Medium

When comparing the HME materials tested for HFSV to normal water loss of healthy individuals, both 45ppi and 60ppi densities impregnated with CaCl2 lost water at rates between nasal and oral breathing. As anticipated, all samples reduced water loss when compared to the control of no HME material present.

3.2 Test 2 – Breathing Resistance Test

The purpose of this test is to ascertain the level of breathing resistance or pressure drop created when breathing through the device. This is important to allow for comparison between the device pre-laryngectomy resistance and therefore whether the device restores this function.

3.2.1 Materials

Figure 23 shows an example of the foams that were tested, and Table 4 contains the foams pore size, cell count, density, and calcium chloride density. All filter samples were hand cut using a 21 mm OD, 5mm ID template and they were tested using the same filter media 3D printed housing. The samples were cut from the same sheets as the samples used in HME & Filtration testing for consistency. Table 5 gives a description of the samples.

The sample size used for the breathing resistance testing was 3 per each variant of HME material. Variability between samples was not expected to be significant and three samples per variant was used in order to highlight any potential anomalous results. Maximum, minimum, and mean results will be shown on results graphs.

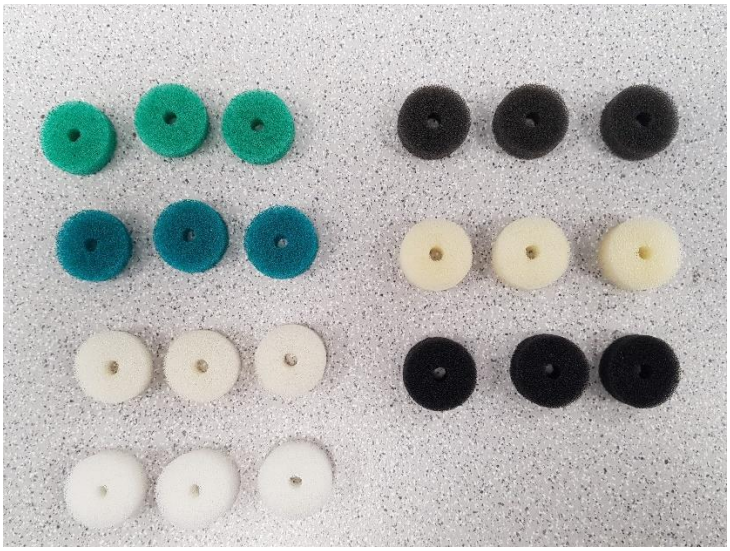

Figure 23 - green 45ppi CaCl2, Blue 60ppi CaCl2, cream 45ppi, white 60ppi, dark grey 80ppi (not used), black 100ppi.

	Sample Density	Impregnated with CaCl2?	Number of Samples Tested	Identifying Colour
1	45ppi	Yes	3	Green
2	45 ppi	no	3	Cream
3	60 ppi	no	3	White
4	60 ppi	Yes	3	Blue
6	100 ppi	No	3	Black

Table 5 - Table illustrating foam density, colour and if impregnated with CaCl2

Methods

A Pneumatic test rig was developed for this project, shown in Figure 24. The set up was in series comprising of a manual adjustment pressure regulator, flow meter, 15mm copper piping, 3D Printed 15mm to 22mm foam adaptor, a manometer was installed with points either side of the foam.

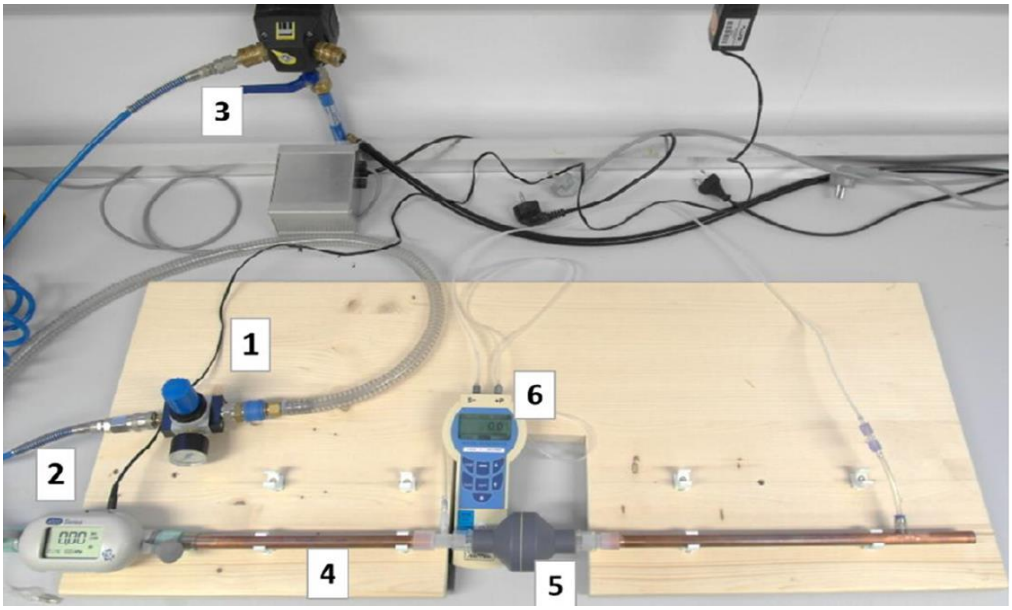

Figure 24 – photo illustrating test set up to measure pressure build up behind HME material

Table 6 shows the calibrated measurements devices used for the breathing resistance test. The test system was laid out in series in the order shown in figure 23.

1	Festo LR-1/4-D-MINI Pressure regulator
2	4000 SERIES ANALOG DIGITAL FLOW METER 0-300l/min
3	Compressed air inlet
4	15mm diameter copper piping
5	3D Printed 15mm to 22mm HME holder & Adaptor (Printed at Kapitex Healthcare)
6	Digital Handheld Pressure Gauge HM35

Table 6 - Table contains a list of the calibrated measurement devices used during test.

Based upon calibrated equipment used, flow rates accurate to ±2% of F.S. The pressure readings which are the primary result are accurate to ±0.2% of F.S.

The compressed air pressure at the inlet was controlled using the regulator to get a reading on the flow meter of 8L/min, 30l/min, 60l/min or 90l/min. These flow rate values are in accordance with ISO 9360 except for 8l/min which is the average minute ventilation rate of a healthy adult and so beneficial to include for comparison purposes. The HME material was installed into the housing and sealed, the manometer was switched on and measurements taken of pressure drop. The values were recoded for three samples of both HME foam types and averages taken. A foam sample was added to the 3D printed housing (5). All measuring equipment was turned on and zeroed, the system was pressurised using valve (3), manually adjusting the pressure regulator (1) until the desired flow reading was achieved on the flow meter (2). Once flow had been shown to be stable for one minute, the pressure loss was monitored for 1 minute on the pressure gauge (6)

3.2.3 Results

The pressure drop measures the difference in air pressure as the air passes through the HME sample. The value is calculated by subtracting the difference between the pressure drop with and without an HME sample in place. The pressure drop value can be used to represent the breathing resistance presented by an HME filter. It can also be used to indicate the contact time between the air and the HME material. For example, an increased pressure drop would suggest a higher contact time and improved heat and moisture exchange. Ultimately the importance of these results and their relevance to the research is in the comparison between the pressure build up in the normal healthy airway and the pressure build up generated by breathing through the HFSV. Breathing resistance occurs normally as a person inhales and exhales through the length of their airways, the restrictions throughout the airway particularly in the vocal folds of the larynx and the narrow cross sections of the nasal openings cause this. This breathing resistance is an intrinsic PEEP, Positive end-expiratory pressure, which assists in the maintenance of end expiratory pressure. Loss of breathing resistance reduces total usable lung capacity, reduces maximal expiratory pressure achievable and alveolar collapse lowering total recruitment [72]. Lower maximum expiratory pressures all translate to lower cough pressure making the removal of secretions less effective. By using a HME, which provides a resistance to breathing comparable to the resistance generated by a normal upper airway, the health issues discussed in the literature review could be mitigated.

The results presented in Figures 25 & 26 compare a range of reticulated foams to the inspiratory and expiratory resistance of the larynx. The porosity of the foam has the anticipated effect on resistance. A higher number per square inch means an increase in the total number of pores and a smaller individual pore size. A higher PPI number represents a tighter, denser pore structure which offers

more resistance to air flow than a lower PPI foam does. The level of resistance increases as the PPI value increases. The inclusion of CaCl2 results in a small increase in resistance. At normal minute ventilation flow rates, the 60ppi foam variants provide the similar levels of breathing resistance as the larynx, around 0.15 cmH_2O lower resistance. The variation of pressure drop with volumetric flow rate follows a squared relationship as expected.

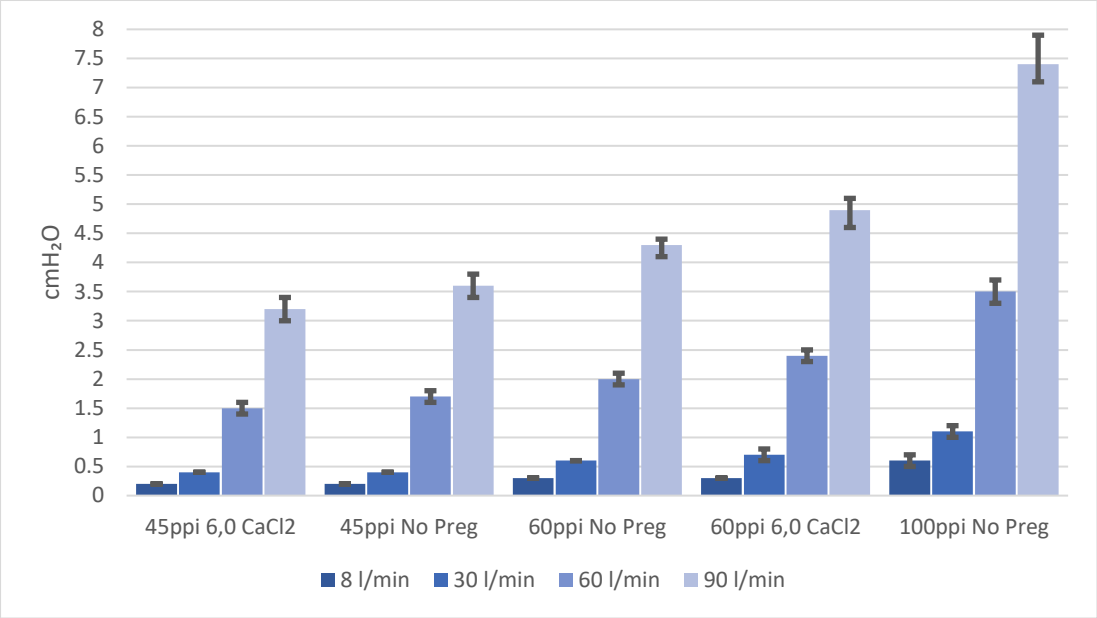

Figure 25 - Chart showing Pressure loss of HME medium at different flow rates

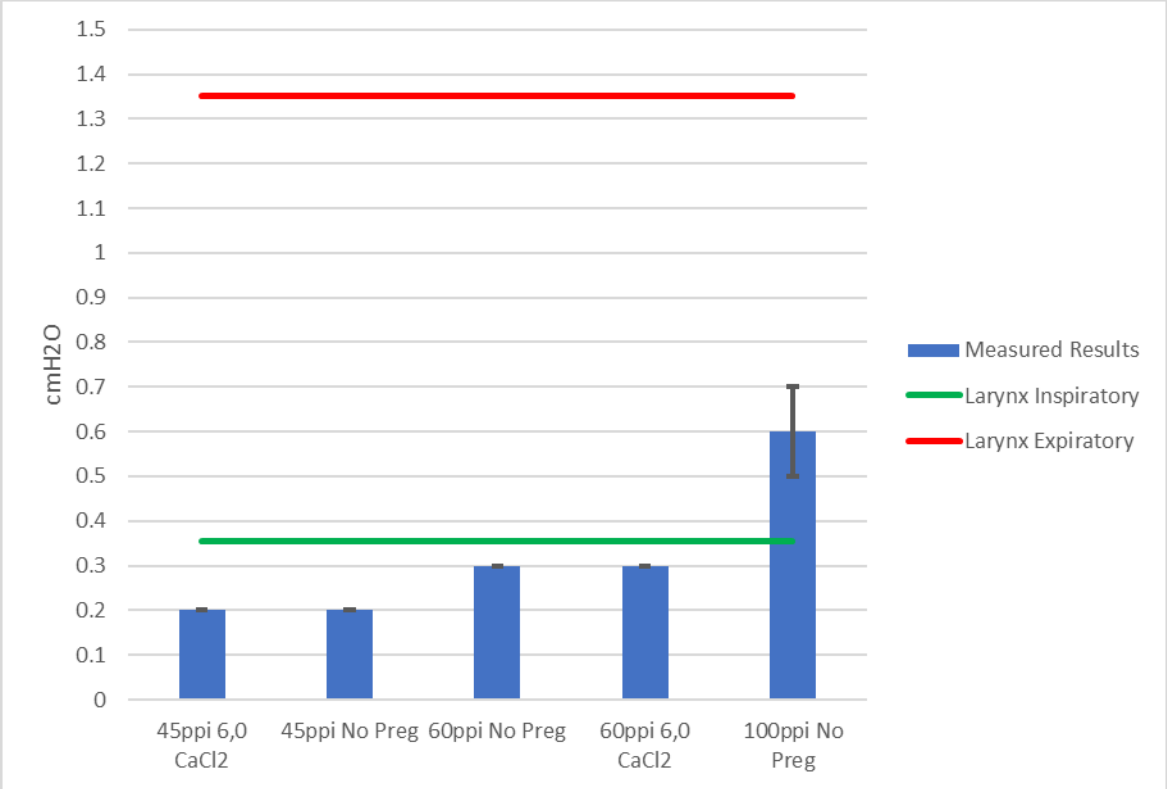

Figure 26 – Graph comparing pressure loss at 8l/min of each HME medium to larynx [48]

3.3 Test 3 – Device Filtration Testing

3.3. 1 Materials

The samples used for filtration testing was reticulated polyurethane (PU) foams with porosities of 45ppi and 60ppi, impregnated with CaCl2, 8mm depth. The other densities of foam material have been eliminated from testing at this stage as they fall outside of the acceptance criteria of either the heat moisture exchange and or breathing resistance tests.

3.3.2 Testing Equipment and Measurement Devices

The main test duct was originally built to test the performance of HVAC filters in accordance with international standards EN 779:2012 and ISO 16890:2016. In this study, the main test duct was used to generate a stable particulate aerosol, operating at a test air flow rate of 3400 m³/hr under vacuum conditions. The air flow inside the main duct was automatically controlled using a PID control loop, orifice plate and air flow meter. A bank of H13 grade HEPA filters cleaned the incoming air before it reached the entrance to the test duct. A series of M6 and E10 high efficiency filters cleaned the air before it returned back into the test lab environment. The temperature and relative humidity of the test air at the inlet of the main duct were recorded during the test, along with the atmospheric pressure. Temperature control of the test air was achieved using a water-cooled heat exchanger on the inlet side of the test duct. The layout of the system can be seen in Figure 27.

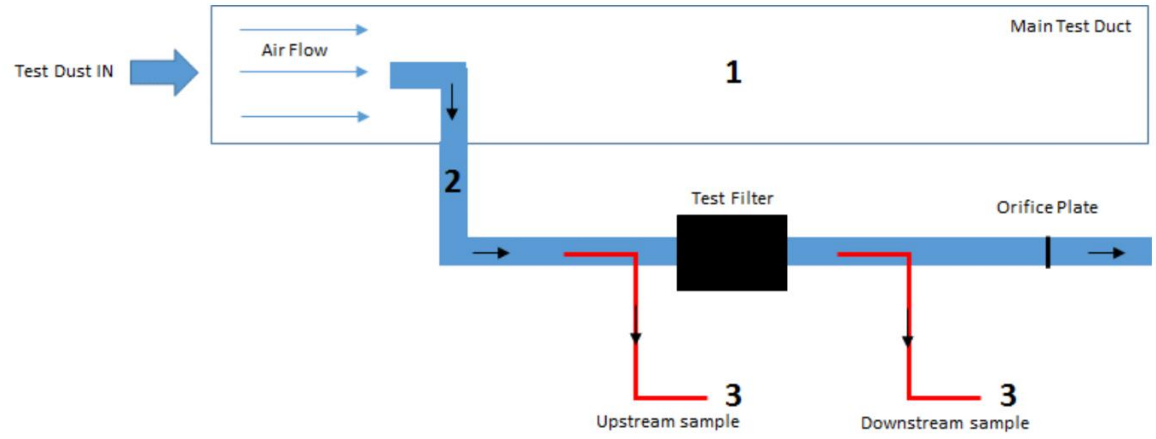

Figure 27 - Schematic of testing duct used for filter media testing

A nominal 25.4mm circular diameter pipe in a horizontal configuration was used to sample the dust aerosol air from the main duct at a rate of 5.4 m³/hr using a fan which was located downstream of the flow measurement orifice plate. The test air was therefore drawn into the system under vacuum. A HEPA filter was used downstream of the Test Filter to remove any residual test dust from the air before it was returned to the test lab environment.

A linear belt aerosol generator was used to introduce the 'B8 Oversize' dust into the main duct (TOPAS SAG 440). For a test air flow rate of 3400 m3/hr and dust concentration of 100 mg/m3, a fully loaded belt could last for approximately 30-40 minutes. The nominal dust concentration was achieved by altering the linear speed of the belt. A mixing orifice was installed at the front of the main test duct to achieve a uniform aerosol concentration.

The particle counting was performed using a Welas 3000H optical particle counter (OPC) with a 2300 windowless sensor. The OPC measured the size and concentration of the particles upstream (dirty air side) and downstream (clean air side) of the Test Filter, which enabled the fractional efficiency values to be calculated and plotted as a function of particle size. The same sensor was used at both

the upstream and downstream sample points. Details of the volumetric flow rates and air velocities used in this study are contained in Table 7.

Location in Test System	Parameter	Value
Main Test Duct	Volumetric Flow Rate	3400 m^3/hr
	Velocity	2.6 m/s
25.4mm Nominal Pipe	Volumetric Flow Rate	5.4 m^3/hr
	Velocity	4.1 m/s
Particle Counter Sample Pipes	Volumetric Flow Rate	0.3 m^3/hr
	Velocity	2.7 m/s

Table 7 – Table detailing the flow rates and air velocities used during testing.

The filter media samples were installed into a housing, along with a metal filter media support and a rubber O-ring, shown in Figure 28. The filter media support sits on the clean air side of the filter. It is a metal disc containing a number of larger diameter holes, which keeps the filter media rigid and in position during the test.

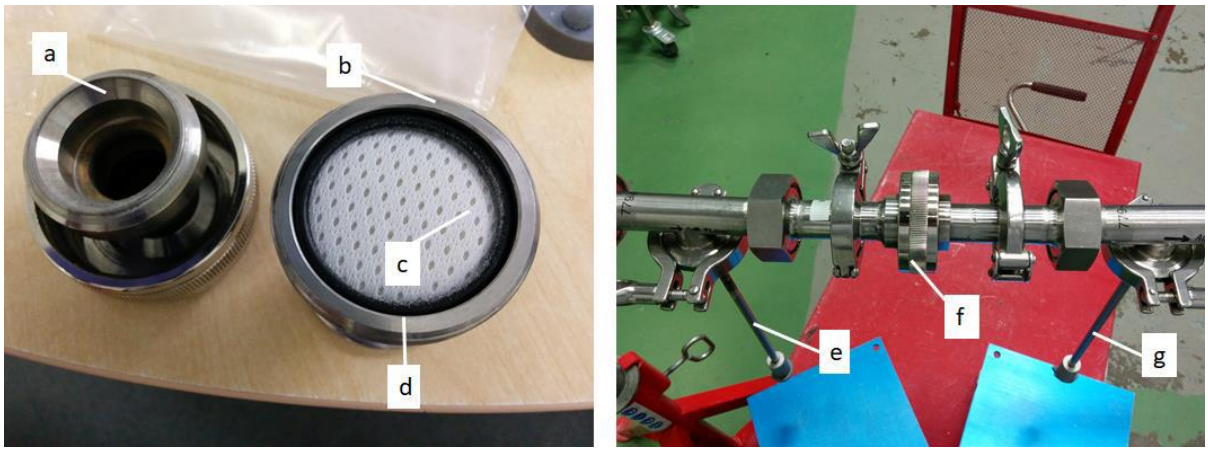

Figure 28 – Photo of test samples installed into the test system for fractional efficiency. (a) 47 mm holder top section (b) 47 mm holder bottom section (c) filter media sample (d) rubber O-ring (e) upstream OPC sample point (f) filter holder for Test Filter

For air flow measurement, an orifice plate was used with a calibrated flow range of 1 to 35 m3/hr. The differential pressure and static pressure measurements were made using calibrated manometers, and the air flow rate was adjusted using a variable speed drive on the fan. The reported air flow values were corrected to standard conditions of temperature and atmospheric pressure (20°C and 1013.25 cmH_20).

The absence of the cassette represents a worst-case scenario for the HFSV as the Cap and Diaphragm would typically reduce the number of particles that would reach the foam. The foam samples tested were completely dry. Though there was the option to use samples that had absorbed water, it was decided that a dry foam would represent the worst possible case for filtration. A dry foam sample used for this test would be representative of the first inhalation of a patient user with the HFSV before any moisture has been absorbed into the device. The foam will be tested as a

47mm diameter disc in order to meet the ISO 16890:2016 standard. While this is significantly larger than the component used in a HFSV, the results are recorded as a percentage of particles removed and would therefore be representative of a component of any size. Table 8 shows a summary of the calibrated equipment used to carry out measurements.

Device	Details
Welas OPC	Digital 3000 H
Welas Sensor	2300 (SN 7511)
Stop-Clock	RS, 440-9805
Air Flow Meter	Schneider Electric, IMV30
Orifice Plate	EMCO, 2012055-1
4-wire RTD	CDL
Orifice Plate	beta = 0.38
Digital Manometer (DP/TF)	Digitron, 2080P, 0-25 mbar
Digital Manometer (DP/OP)	Digitron, 2082P, 0-2 bar
Hygrometer/Thermometer	Vaisala PTU 300

Table 8 - list of measurement devices used during filtration testing

A validation test was carried out to measure the natural loss of test dust within the measurement section of the duct under normal test conditions. This test was performed without a Test Filter and media support plate installed.

3.3.3 Methods

A Welas Optical Particle Counter (OPC) was checked at the start of the test date according to the 'day-of-use' calibration check procedure for the instrument. Size channel number eight (0.6 – 40.0 microns) was selected and the 2300 sensor head.

The test dust was dried, weighed and then loaded onto the dust feeder. The linear belt speed of the feeder was calculated to provide a dust concentration of 100 mg/m³ for an air flow rate of 3400 m³/hr inside the main duct.

A disc of filter media fitted into the filter holder along with a filter media support and rubber O-ring. The filter holder was then installed in the small duct and all clamps checked for tightness.

The main duct fan and cooling water were switched on. Ten minutes were allowed for the air conditions to stabilise. The small duct fan was then switched on and the flow valves were adjusted until a flow rate of 90 litres/minute was achieved. The OPC was then used to measure the background particle counts at the upstream and downstream locations. The air flow inside the small duct was then stopped and the duct was isolated. The dust feeder was switched on and five minutes were allowed for stabilisation inside the main duct. The small duct was then restarted with a further five minutes for stabilisation. Measurements of the upstream and downstream particle counts then commenced in an alternating pattern. The exposure time of the filter media samples to the aerosol was approximately 40 minutes, including stabilisation and particle counting time.

A set of 0% efficiency tests were also performed whereby the efficiency is measured without a filter media sample and filter media support in place. The aim of the test is to determine the particle losses inside the pipes of the measurement section.

A total of six filter media samples were tested at a dust concentration of 100 mg/m³. Table 9 lists the test parameters.

Parameter	Value	Unit
Nominal dust concentration	100	mg/m3
Exposure time to dust (approx.)	40	mins
Test air flow rate (small duct)	5.4 90	m3/hr l/min
Test air temperature	23.0 (+/- 5)	°C
Test air relative humidity	50.0 (+/- 15)	%

Table 9 – Conditions of filtration test.

Particle counting was performed using the Welas 3000 H Optical Particle Counter, which included five upstream and four downstream measurements. Each measurement lasted two minutes. The number distribution data were saved to Excel files and then used to calculate the fractional efficiency values for grouped channel ranges.

Once the final particle count had been completed, the dust feeder was switched off and a purge time of 10 minutes was used to sweep the duct before the air flow was stopped and the filter media sample removed.

The fractional efficiency values were obtained by performing a series of two-minute particle counts at the upstream and downstream locations under stable test conditions. This pattern of alternating upstream and downstream samples was repeated until a total of four pairs of upstream and downstream measurements had been obtained. The data set was concluded by a fifth upstream measurement.

Results

Figure 29 shows the mean fractional efficiency curves for the media samples tested in this study at particle sizes between 1-10 microns.

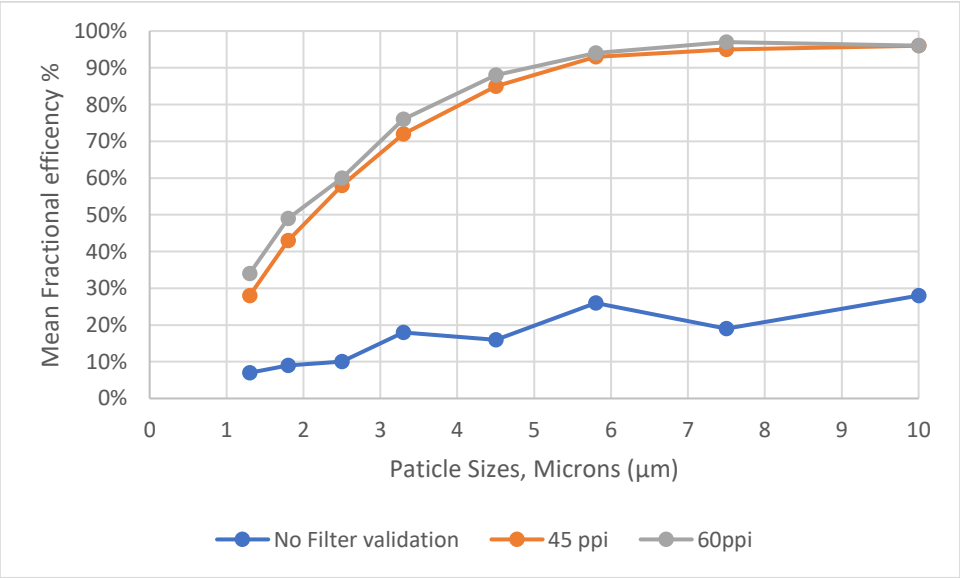

Figure 29 – Mean Fractional Efficiency data for the HME Media Samples at 0-10 microns

The data in Figure 28 shows the level of particulate losses within the test rig based on the size and size distribution of the test dust. Data above 10 microns is not considered in the analysis due to the low number of particles counted above 10 microns and the effect that has on the measured result.

Earlier research into particle deposition and clearance from the respiratory tract suggests that the respiratory tract from larynx to nasal cavity are where particles of 5µm and above are deposited and cleared in normal healthy adults without laryngectomy [100] [101]. Particles of a smaller size may be deposited lower in the airway or into the lungs and some but not all may be cleared or removed. To clear or remove any particles it is important not only that coarse particles are filtered, but that the condition of the air and the airway below the tracheostoma is kept moistened. The results presented above strongly suggest that incorporating either 45ppi or 60ppi reticulated foam with 8mm of material depth into the path of inspired air is sufficient to restore the coarse filtration expected from a healthy airway. It can also be stated that the filter mediums do filter particles in the 2.5-5.0µm range with an effectiveness of 58-88% depending on exact particle size. Chronic use of a HFSV device which includes the filter mediums tested will likely result in considerably improved overall lung and respiratory tract health if compared to breathing through a tracheostoma without filtering device. It is possible that increasing the volume or density of the filter medium or using a medium such as folded paper would achieve higher filtration performance however the increased resistance to breathing and increased resistance over time due to blockage would likely be intolerable to the user, exceeding the normal levels of resistance produced by the respiratory tract of healthy individuals.

3.4 Test 4 – Manual State Change force & Distance Test

As part of Objective 6, it is important understand the force, pressure and distance at which the diaphragm changes state. When assembled into the device, it is the pressure threshold on the diaphragm which causes the device to close. Understanding when the diaphragm changes state in terms of pressure and distance will help simulate the device, and therefore to optimise the device.

3.4.1 Materials

Five bi-stable diaphragm MK1 prototypes with shore A hardness 40 and OD of 15mm were used in this testing.

The sample size used for the manual force to change state testing was 5. 5 samples are not statistically significant it should be sufficient to rule out highlight anomalous results. Maximum, Minimum and mean results will be shown on results graphs.

3.4.2 Testing Equipment and Measurement Devices

Figure 30 shows the test set up.

- FL20 Force Gauge (Accuracy: ± 0.2 % @ full load) using flat attachment
- 3D printed stomal interface with pneumatic connection option (ADAPTOR_003),
- CD-AX/APX 500-151-30 Mitutoyo 150mm Digital Caliper accuracy ±0.02mm, repeatability ±0.01mm connected to laptop via USB-ITN-C to record position and distance to state change.
- Laptop (not shown) connected to force gauge with AFH software to record force versus time graph.
- Sauter FL-20 Force Gauge, serial number 1732899. Calibrated 17/5/19 – 17/5/20.

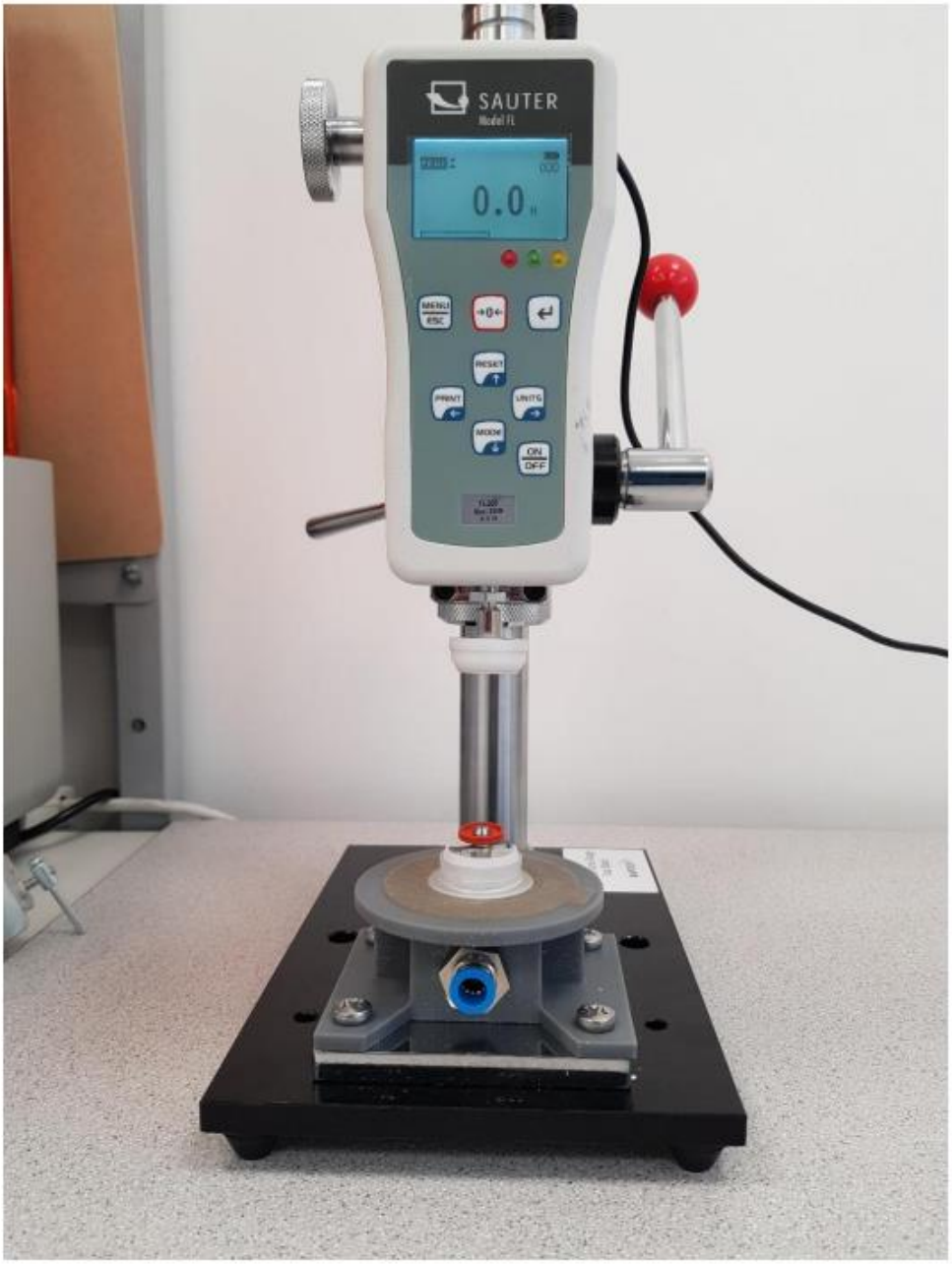

Figure 30 - Test Stand set up for manual state change

3.4.3 Method

A diaphragm sample was installed onto a pin shaft as per its intended design. The pin was assembled into a housing which was in turn mounted into a baseplate interfacing device. The interfacing device was mounted securely via adaptor onto the test stand and aligned with the FL20 force gauge which is secured to the moving half of the stand. The gauge was fitted with a ring fitting which would interface with the sealing ring of the diaphragm to apply pressure to a specific 54mm² surface area. Each of the five samples were tested for thirty cycles by applying pressure to the sealing ring until the state is changed, the force and distance travelled before state change was recorded.

Results

The results of the force and distance testing found that the mean force applied to the Diaphragm sealing ring required to change the state was 0.15N, which equated to 2778 Pa. The distance

required to move the sealing ring before state change was 1.68mm. Full results tables for manual force and distance travelled by diaphragm rim before state change are figure 31 and figure 32.

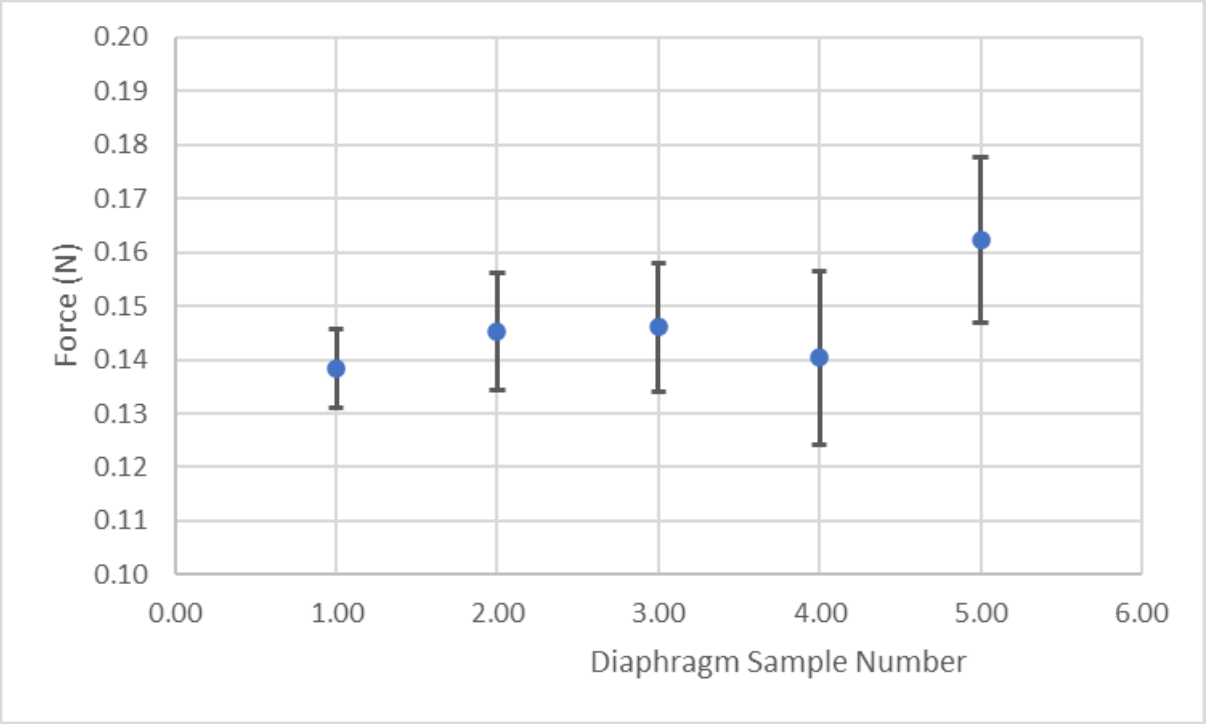

Figure 31 - Graph of Force (N) to change Diaphragm State

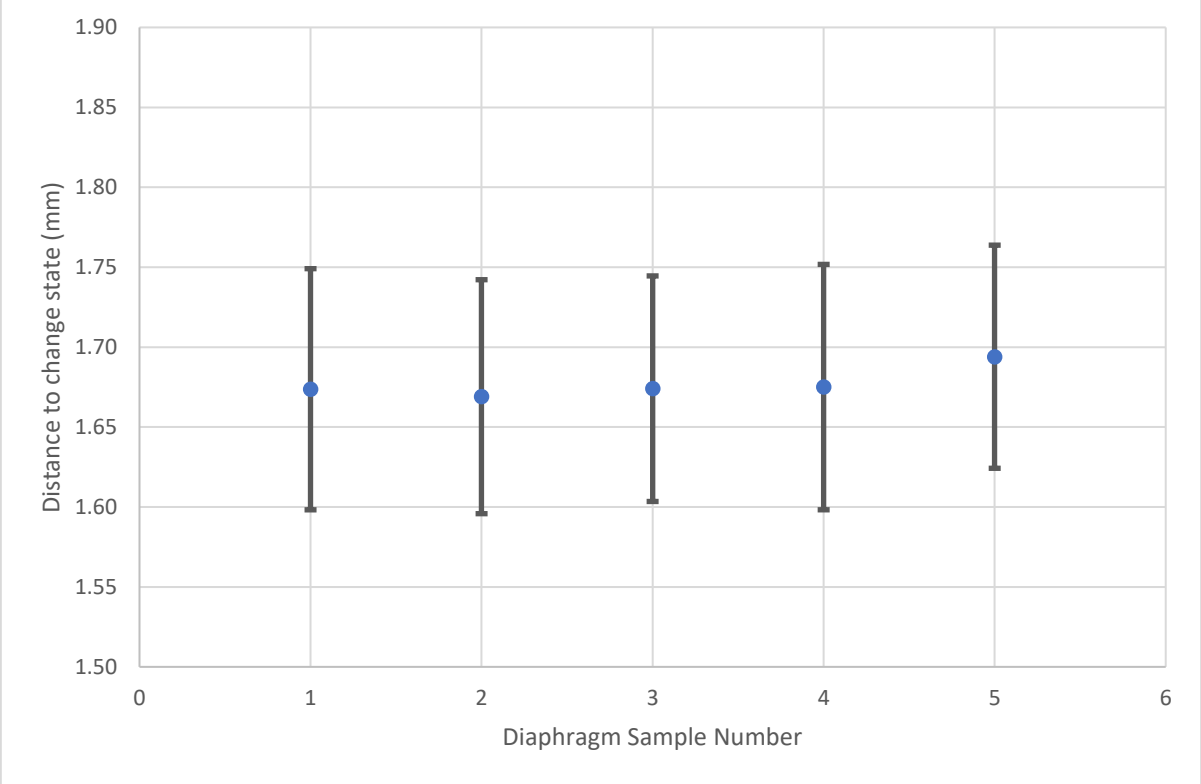

Figure 32 – Distance at which the Diaphragm changed state.

The material of the diaphragm was measured using a calibrated durometer and it was found that the shore A hardness ranged between 39 Shore A and 40.5 Shore A, a variation of -2.5% and +1.25. These values may not be accurate as the surface area tested is smaller than the suggested area to be used in a test of this type. It is however an indication that the diaphragms are approximately 40 Shore A as expected.

3.5

3.5 Test 5 – Pressure Release Mechanism Test

As part of Objective 5, it is important understand the pressure at which the pressure release mechanism activates. This test is to verify the pressure that the mk1 device triggers. When the user attempts to cough, the pressure in the lower airway and device will increase, potentially to levels which may harm the patient. The pressure threshold which causes the device to open must be lower than the MEP of laryngectomised patients to avoid harm and ensure activation. The pressure must also be higher than the pressures encountered during speech to avoid unnecessary activation. Understanding what pressure the mechanism triggers will help simulate the device, and therefore to optimise the device between these values.

3.5.1 Materials

5 x 3D printed HFSV prototype.
The sample size used for the pressure release mechanism test was 5 devices. 5 samples are not statistically significant it should be sufficient to rule out highlight anomalous results. Maximum, minimum and mean results will be shown on results graphs.

3.5.2 Testing Equipment and Measurement Devices

FERM 1036 Compressor, 6L Capacity, 8 Bar Outlet Pressure.
Pneumatic test system (See figure 33)

The origins of the apparatus formed from the requirements of the test and the variables which needed to be monitored and recorded. Each element of the system was chosen based on its ability to replicate the values of a patient or user. The five litre tank represents the vital capacity of patients, which is the total volume of air that can be displaced from the lungs by maximal expiratory effort. The proportional valves when opened using PLC can provide a rate of acceleration from closed to fully open similar to the rate of acceleration to peak flow rates found when patients cough and sneeze. Pressure and flow rate sensors were required to record data on pressure and flow, and the sensors chosen had appropriate ratings in accuracy, precision and range. Pressure reducing valves were added to restrict pressure entering the pneumatic test rig from the compressor.

Figure 33 illustrates the test system used for all pneumatic testing related to pressure release and diaphragm activation/deactivation. Pressurised air enters the system filling the VBAT 05, 5L tank. The VEF2131 and PVQ33 proportional valves are controlled by the VEA250, PLC (programmable logic controller) and HMI (human machine interface (screen)). These valves can be controlled to open or close at a rate set by via the PLC representing patient cough, or patient exhalation. The ISE30A, PFMB750 record flow and pressure. The PLC is loaded differently depending on the test. For diaphragm activation, for example, it can measure the highest flow, and pressure before the diaphragm changes state, the time at which flow stops is also recorded.

The pneumatic test system underwent performance qualification and validation, the system was operated with a range of inputs for pressure, flow rate & ramping up time, the resulting outputs were measured using external calibrated measuring equipment to ensure the displayed results were accurate. The external pressure & flow gauges measuring from the system exhaust, validated that

the displayed peak values of flow pressure and time were accurate within the ranges of interest. Table 13 below shows the values.

Parameter	Mean percentage of full-scale result
Pressure accuracy	±2.1%
Pressure repeatability	±0.3%
Flow Rate accuracy	±3%
Flow Rate Repeatability	±1%
Time accuracy	±5%
Time Repeatability	±3%

Table 10 - Accuracy and repeatability of test system regarding pressure, flow rate and time.

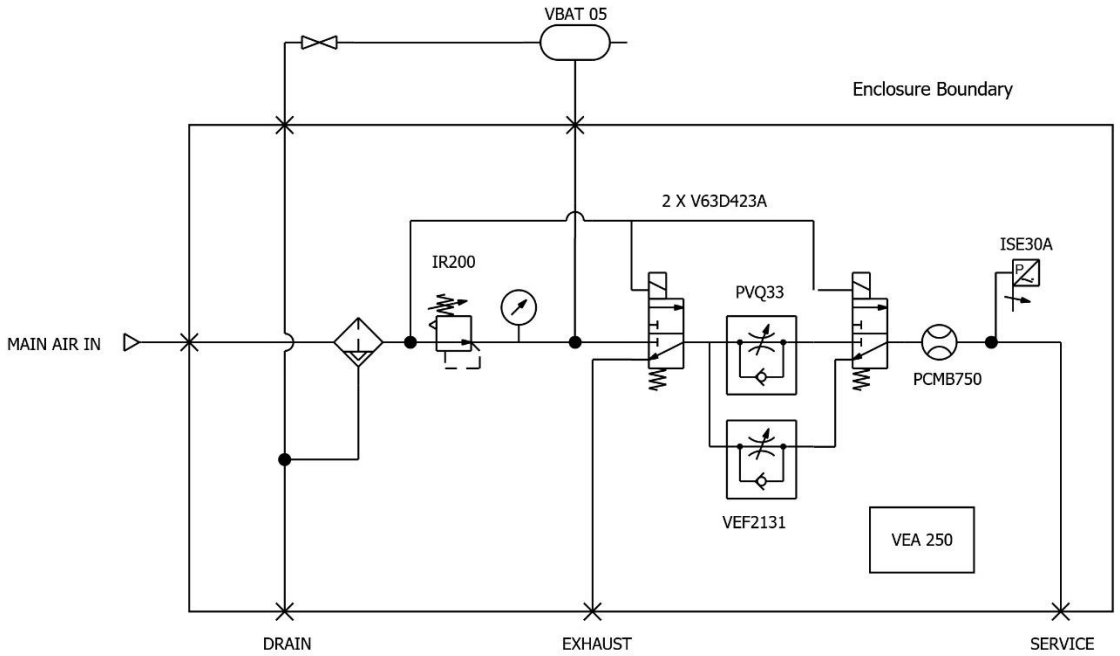

Figure 33 - Schematic of Pneumatic Test System used Diaphragm & Pressure Release test.

3.5.3 Methods

The pressure was set to 428 cmH_2O using the pressure reducer within the enclosure of the pneumatic test system. The HFSV was installed into adaptor three which was connected via 8mm pneumatic tubing to the output of the pneumatic system. The HFSV prototype was set to the closed (speaking) position.

The ramp rate of the system was set to 100m/s (as quickly as the system could reliably open the valve to 100%). The valve position was set to 100%. The test system would record maximum value registered in the system; the pressure release would be able to be visually inspected for signs that it had activated.

To assess the robustness of the design, the devices under test were subjected to 20 cycles of pressure load. This is equivalent to the number of coughs and sneezes experienced by a normal health adult in one day [32] [96]. The difference between the 20 cycles will be assessed to ensure the mechanism is not worn or damaged which may lead to lower activation pressure, which may prevent speaking.

To assess the pressure release effectiveness once activated the test would be repeated with the pressure release already in the fully open position and all pressures and ramp settings as above. This would mean the maximum pressure registered would be the pressure of the user's trachea.

3.5.4 Results

Figure 34 illustrates the peak pressure registered by the pneumatic system before the pressure release mechanism was activated. The plot shows maximum and minimum values, lower, median and upper quartiles. Across the devices under test there is a high degree of consistency in pressure at which the device activated. This is a positive result indicating the tolerance of the 3D printed parts is producing reliable results. The total range of results is 15 cmH_2O for a single device which is not ideal. It is unclear how this range can be reduced without higher tolerances between components which cannot be achieved using printed parts.

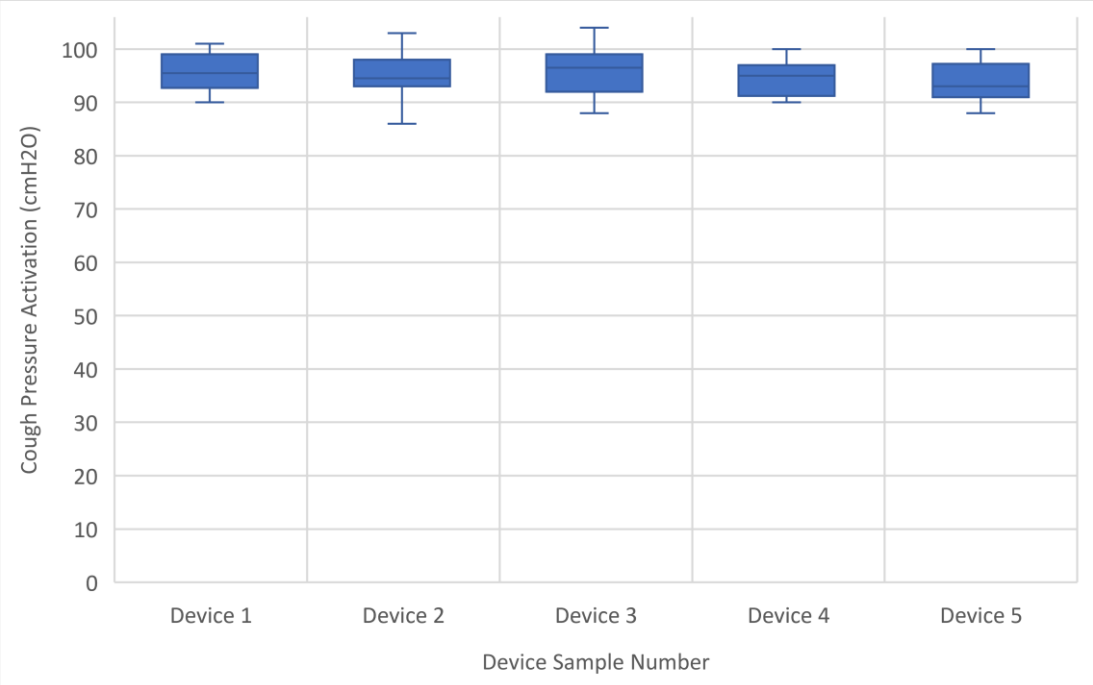

Figure 34 - Graph of Mean Pressure Release Opening Pressure, 20 cycles per sample device

It was found that out of the five samples, all of them activated between 86 cmH_2O Pressure and 101 cmH_2O Pressure with the mean pressure being 96 cmH_2O.

There were signs that once activated the pressure release was easier to activate subsequently with the first activation pressure being 4% higher on average than the second, with the remaining activation pressures being more consistent.

The overall cough feature activation pressures were within acceptable limits. During the ramp up to 428 cmH_2O the device would trigger as high as 104cmH_2O. This is within the limits of acceptability as it is lower than the pressures reached during a cough or sneeze and higher than during speech, it is

only considerably higher than the upper limit of speaking pressures researched [104] [89]. Ideally, the trigger threshold could be reduced, bringing it closer to the upper limit of stomal pressures during speech with a prosthesis.

The pressure within the system peaked at 96 cmH_2O and once opened immediately released the static pressure as intended. The result is positive as it demonstrates that the cross-sectional area which opens to allow air to escape reduces the pressure during the rest of the cough or sneeze, eliminating of risk or discomfort to the patient, no higher than during speech.

3.6 Test 6 – Diaphragm Activation and Deactivation Test

3.6.1 Materials

The sample size used for the pressure release mechanism test was 5 3D printed HFSV prototype devices. 5 samples are not statistically significant it should be sufficient to rule out highlight anomalous results. Mean results with confidence interval error bars will be shown on results graphs.

3.6.2 Testing Equipment and Method

FERM 1036 Compressor, 6L Capacity, 8 Bar Outlet Pressure.
Pneumatic test system (the test system illustrated in figure 33.)

- The pressure was set to 120 cmH_2O using the pressure reducer within the enclose of the pneumatic test system. The HFSV was installed into adaptor three which was connected via 8mm pneumatic tubing to the output of the Pneumatic system. The HFSV prototype was set to the open (breathing) position.
- The HFSV prototype was set to the closed (Speaking) position. The speech valve is placed in the opposite orientation to the activation test. The results from the test are therefore positive pressure to activate/deactivate the valve.
- The ramp rate of the system was set to 100m/s. The valve position was set to 100%. The test system would read the pressure at the point airflow stopped, which should be the closing pressure valve activation would be able to be visually inspected for signs that it had activated.
- To assess the robustness of the design, the devices under test were subjected to 700 cycles of activation, only the first and last 30 pressures were extracted for analysis. This is equivalent to the number individual phonation events a user was likely to have in a 24-hour period. [95]. The difference between the first and last 30 cycles was assessed to ensure the diaphragm was not worn and was providing consistent results throughout its intended in use life cycle.

3.6.2 Activation Results

Figure 35 shows the closing pressure of the 5 sample devices. The plots show maximum and minimum values represented by error bars, lower, median and upper quartiles are represented by the solid bars. It was found that out of the five samples all of them activated between 98 cmH_2O Pressure and 120 cmH_2O Pressure with the mean pressure being 108 cmH_2O, the activation flowrate was found to be between 1.76l/s flow rate and 1.96 l/s flowrate with the mean flowrate being 1.86l/s and the time to close the diaphragms was between 65ms and 73ms with the mean closing time being 69ms. The chart shows that there is no perceivable trend, either increase or decrease, in closing pressure after the number of diaphragm cycles representative of one day of speech.

Figures 36 and 37 show the maximum measured flow rate before the diaphragm closes and the time at which no flow was recorded indicating closure. No discernible change in either flow rate or closing time can be noticed between the first 30 cycles and the last 30 cycles of a 700 cycle test indicating that the devices work consistently over their 1 day 700 cycle use life.

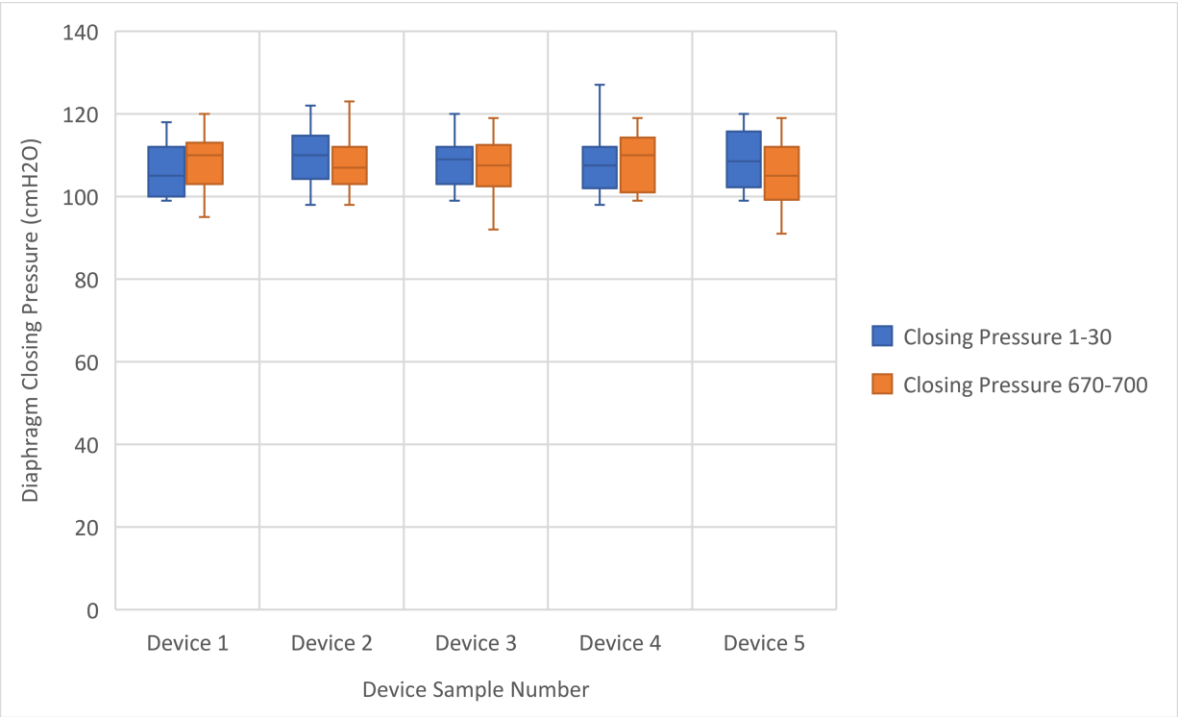

Figure 35 - Graph of Pressure to Close Diaphragm

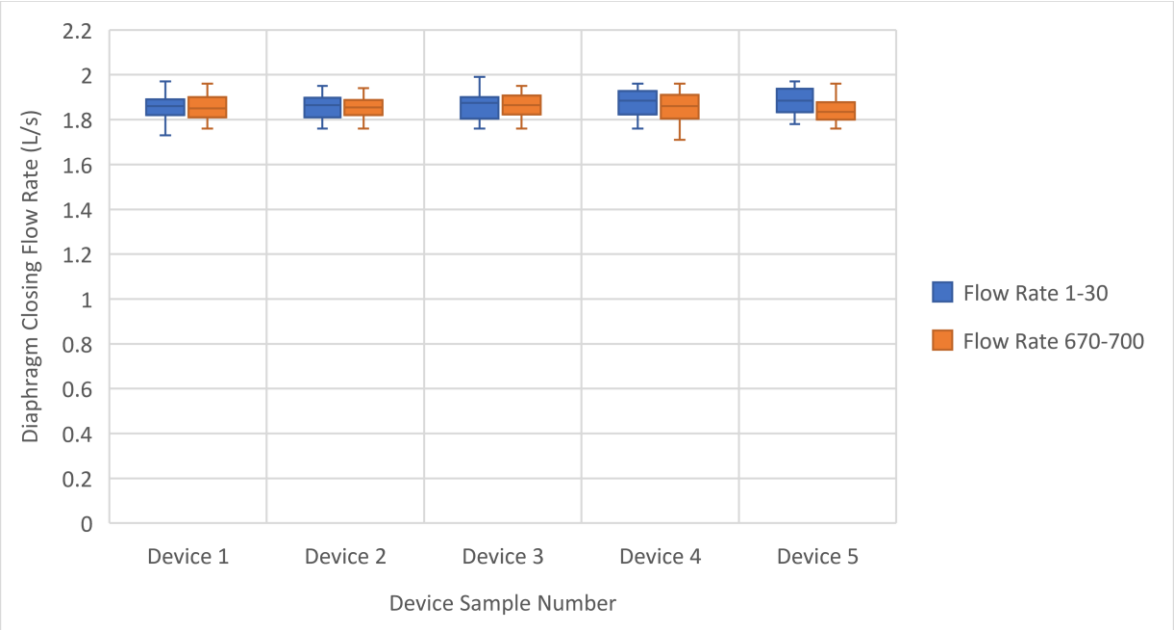

Figure 36 – Graph of Flow Rate to Close Diaphragm

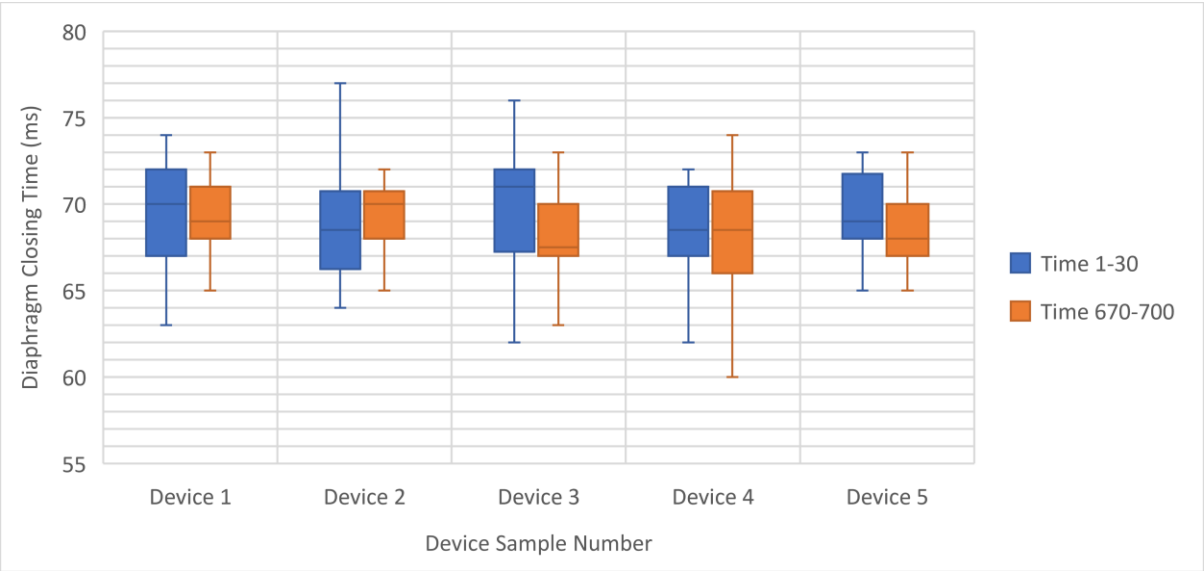

Figure 37 - Graph of Time to Close Diaphragm

3.6.4 Deactivation Results

Figure 38 and 39 show the closing pressure and closing time of the diaphragms at cycles 1-30 and 670-700.

It was found that out of the five samples the deactivation range pressure was between 1 cmH_2O and 2 cmH_2O with the mean pressure being 1.5 cmH_2O.

It was found that out of the five samples all of them deactivated between 13ms and 14.7ms with the mean opening time being 13.5ms. The mean value for the diaphragm state change pressure is 1.75 cmH_2O.

There was no deactivation flow rate to record as the HFSV is shut and flow is 0 l/s, pressure builds until the diaphragm changes state, opening the valve, at which point the time is recorded.
It was assumed that the pressure to change the state of the diaphragm was the same in both directions. By setting the sealing surface of the HFSV as close to the distance at which the diaphragm reliably changed state, the pressure to deactivate the HFSV will be as close to zero as possible. From the manual state change test, we know the diaphragm changes reliably at 1.8mm distance travelled.
Overall, the prototype demonstrates that the HFSV can open at a pressure and a flow rate achievable by the typical user. During optimisation, to be consistent and minimise the inspiratory pressure required, the distance from diaphragm to sealing surface should have a high tolerance to reduce variation from valve to valve.

These results show variation between the first and last cycles which correlates to consistent performance throughout the diaphragms intended use lifecycle. There is similarly no discernible change in performance between device samples demonstrating consistent closing pressure and closing time between devices.

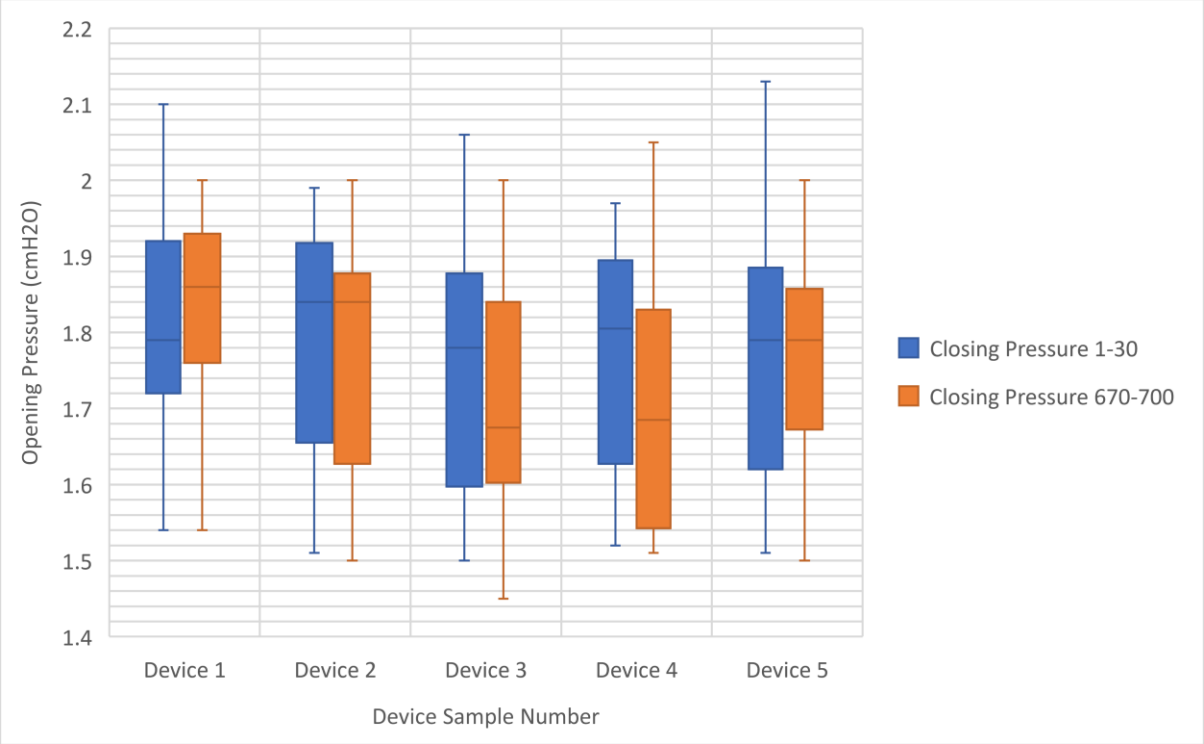

Figure 38 - Graph of Deactivation Pressure

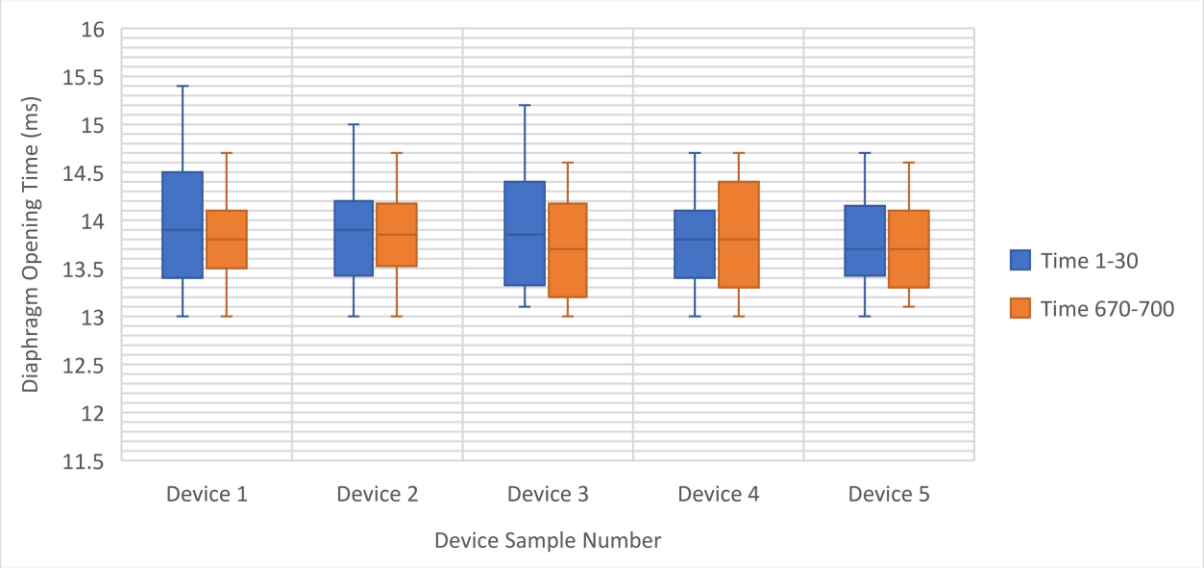

Figure 39 - Graph Showing Deactivation Time (ms)

3.7 Discussion of Mk1 Design

The discussion of the Mk1 Device Design has been organised by airway function; the device testing provides information on how effective the design has been at restoring each function.

HME

The results demonstrate that the combination of reticulated foam in densities of 45 and 60 pores per square inch and calcium chloride impregnation at 6kg/m³ results in a HME that has comparable performance to the levels of moisture loss expected from normal healthy individuals breathing nasally or orally. When the volume of foam used in these tests is incorporated into the HFSV and forms the path through which air is breathed, the HME exchange levels are restored to pre-laryngectomy levels. 100ppi non calcium chloride impregnated foam also falls within the oral and nasal breathing water loss levels. Ideally, at the lowest recorded flow rates, the HME levels should be as close to nasal breathing as possible, as generally, individuals' breath nasally at rest. Objective 2 is considered achieved by the Mk2 device.

Resistance

At first assessment, the results of the breathing resistance suggest that the 100ppi foam should be used in the device to restore the breathing resistance provided by the respiratory tract as it falls within the range inspiratory and expiratory resistance to breathing caused by the larynx. It is clear from the literature review that breathing resistance is completely different when comparing inspiratory to expiratory flow and pressure build up is very different depending on flow rates. Utilisation of a 60ppi foam with a volume of 2.5cm³ would adequately restore the inspiratory resistance to breathing but not the expiratory, where in healthy subjects, the larynx changes profile changes restricting air flow. There is also resistance caused by the other components of the HFSV not included in the first verification tests. The results show partial achievement of the requirements of Objective three, by offering resistance to a similar level to the removed larynx, but not to the level of the entire upper airway. Objective 3 is not achieved by the Mk1 device. Changes are required to design a device which could provide bi-resistance to a user. Additionally, testing should be carried out on the Mk2 device which includes the whole assembly now data has been collected on the HME medium.

Filtration

Calcium Chloride impregnated PU foam with 45ppi and 60ppi porosity were tested at to assess the materials filtration effectiveness between 2.5-10 microns. The other samples, 80ppi, 100ppi were not included in the filtration test as they did not pass tests for resistance when compared to healthy individual data.

The results demonstrate that at 5 microns the 45ppi and 60ppi materials are both approximately 94% effective at filtering these particles. The results demonstrate that at 10 microns that the 45ppi and 60ppi materials are both approximately 95% effective at filtering these particles. It can be assumed based on the data that at higher particle sizes both material densities would provide 95%+ filter effectiveness thereby proving that chronic use of an HME containing these materials would consistently filter materials within the 5-20 micron range. This result demonstrates that a HFSV is capable of also providing a level of particle filtration comparable to a healthy non-laryngectomised airway, achieving Objective 4.

Cough

It was found that the mean value for pressure release activation is 96 cmH_2O, which is too low and may result in accidental activation during speech. This is a performance issue and not a safety concern. To ensure that the user can normally speak the activation pressure should be 120 cmH_2O which is approximately the MEP (maximal expiratory pressure) of laryngectomy patients meaning the change of accidental activation is highly unlikely and that activation would ensure the patient would not be harmed by an involuntary cough or sneeze.

A simulation methodology could facilitate the design of this feature. When this is created it can be used to ascertain what shape and size of torus on the cap pin will result in the ideal 120 cmH_2O to overcome the mechanism. This could also be achieved with a material change.

Speech

It was found that the mean value for the diaphragm state change pressure is 108 cmH_2O, which is too high and may result in many users not being able to operate the HFSV. This is a performance issue and not a safety concern. To ensure that the user can normally speak the activation pressure should be closer to 60 cmH_2O which is approximately the half the MEP of laryngectomy patients meaning the users should be easily capable of achieving this. It also is high enough that accidental activation during normal quiet breathing is unlikely. There was no significant change in activation pressure, activation flow rate or activation time between the first and last cycles suggesting the design would be highly reliable over its use life. There is the possibly that the introduction of moisture, particulate matter or secretions may change these results, however, it is not likely within a 24 hour use cycle.

To bring the pressure of activation down, the diaphragm material could be made from a lower shore hardness. The OD of the diaphragm could be increased to increase the contact surface with the accelerating air.

The mean value for the diaphragm state change pressure is 1.75 cmH_2O, which is higher than what is acceptable and will result in an uncomfortable experience for users. To ensure that the user can deactivate the diaphragm without discomfort the inspiratory pressure required should be 0.36 cmH_2O, like the resistance provided by the larynx during inspiration during normal quiet breathing. This issue can be resolved with high tolerances and precision in the sealing distance from the diaphragm at 1.8mm.

To meet the criteria set out in Objective 6, a diaphragm must close, redirecting the air through the speech prosthesis as many times a user wished to speak. The test proves that the diaphragm has been designed to achieve this.

To achieve Objective 6; a bi-stable diaphragm was designed and incorporated into the device. The diaphragm operated on a principal of bi-stability and changed states from open to closed when the user exhales.

To be successful the diaphragm must change state when an air pressure is applied, the pressure level is in the range from exhalated breath at a higher flow rate than normally produced during quiet breathing but lower than the maximal expiratory pressure achievable. To design a diaphragm capable of doing this an FEA simulation of the diaphragm was created to allow for optimisation.

A set of objectives were created that a medical device concept must achieve. The objectives represented lost upper airway functions in laryngectomised patients. From the reviewed literature the upper airway functions lost because of total laryngectomy are:

1. Ventilation & patency
2. Heating and humidification of air
3. Filtration of air
4. Coughing
5. Swallowing
6. Speech
7. Olfaction, Gustation & Chemosensation
8. Resistance

The chosen design solution can work in conjunction with another device. Ventilation and patency is maintained by ensuring that the HFSV can connect to an existing patient interfacing device such as a Tracheo-Stoma Button or Laryngectomy Tube. These devices maintain tracheal and stomal patency, the HFSV housing has a conical barbed 22mm connection surface which allows interfacing with the tubes and buttons, the combination of devices successfully restores these functions. These functions are considered restored by the initial solution and do not require further optimisation.

To achieve speech, the chosen solution incorporates a bi-stable diaphragm. The diaphragm was designed to remain open during normal breathing and close when a higher than normal expiratory breathing rate passes over it. Once closed the diaphragm would remain shut, sealing to a surface within the HFSV, thereby redirecting air through an indwelling tracheoesophageal speech prosthesis implant. The main benefit of the design is that it can be used handsfree, thereby more accurately restoring normal speech when compared to manually occluded versions. It is not possible to directly compare the upper airway performance to the HFSV performance in this regard as upper airway does not need a closing pressure before phonation occurs. Instead, the closing pressure should be as close to equal to, or greater than normal peak expiratory pressures when users are breathing normally. It was found that the mean value for the diaphragm state change pressure is 105 cmH_2O, which is too high and would result in many users not being able to operate the HFSV. The mean value for the diaphragm state change pressure is 1.5 cmH_2O, which is higher than what is acceptable and will result in an uncomfortable experience for users. The design of the diaphragm must be altered to lower the pressure required to change its state. The design of the diaphragm must also be altered to lower the pressure required to re-open the HFSV.

To achieve the functions of Resistance, Filtration of air and Heating and humidification of air the design incorporates a volume of reticulated foam. Reticulated foams have a large surface area with a low porosity to ensure filtration performance for larger particles over 300µm through physical barrier sieving filtration, inertial impaction for particles around 5-10µm, interception filtration for particles around 1-5µm and diffusion as a result of Brownian motion. The results demonstrate that at 5 microns that the 45ppi and 60ppi materials are both approximately 94% effective at filtering these particles. The results demonstrate that at 10 microns that the 45ppi and 60ppi materials are both approximately 95% effective at filtering these particles. It is fair to assume that at 20 microns both material densities would provide 95%+ filter effectiveness thereby proving that chronic use of an HME containing these materials would consistently filter materials within the 5-20 micron range. This result proves that a HFSV is capable of also providing a level of particle filtration comparable to a healthy non-laryngectomised airway. Overall, Objective 4 is considered achieved, the airway function is considered restored by the initial solution and does not require further optimisation or testing.

The results of both 45ppi calcium chloride impregnated foam and 60ppi calcium chloride foam selected for the device provide similar levels of water retention as a healthy upper airway during normal oral and nasal breathing. This function is considered restored by the initial solution and does not require further optimisation or testing.

Utilisation of a 60ppi foam with a volume of 2.5cm³ will replace the inspiratory resistance to breathing but not the expiratory, where the larynx changes profile changes restricting air flow. This result partially achieves Objective 3. Further research would be required, and a solution proposed that could be incorporated into the design of a device which could provide bi-resistance to a user. The design of the HFSV device should be altered to produce bi-resistance to restore the functions of the upper airway more accurately.
Upper airway functions olfaction, gustation and chemosensation have not been incorporated into the chosen solution. The design methodologies utilised to create the selection solution did not yield any method of incorporating these functions into a single device. It is likely one or more additional devices would have the be combined with the HFSV to successfully restore full olfaction and taste, which are themselves intrinsically linked.

The cough feature is not a function of the airway but a solution to the newly added risk of closing the Tracheo-stoma during speech. This function is considered restored by the initial solution and but will require further optimisation to adjust the trigger threshold, inadvertent activation while initiating speech is likely and would prevent speech at higher volumes.

4. The Design of the Mk2 Device

The design of the Mk2 device is driven by the results of the Mk1 testing. The areas which required some changes were

- Lowering the activation pressure of the bi-stable diaphragm
- Increasing the activation pressure of the Pressure release mechanism
- Adding bi-resistance to the device.

The first two changes require only minimal iterative adjustments to the design features incorporated into the Mk1 device.

To lower the activation pressure of the bi-stable diaphragm, there are three parameters which can be adjusted. The diaphragm can be made larger in diameter, therefore increasing the level of interfacing volume with the passage of air. The diaphragm can be made softer, therefore allowing it to deform easier when subjected to an air pressure. The diaphragm can be made with a thinner cross section in the deformation area, thereby requiring less pressure to buckle and change state.
There are drawbacks to some of these possible solutions. A larger diaphragm will increase the breathing resistance through the device, this potentially adds risk to patients as increased exhalation resistance will likely exceed normal healthy breathing resistance during exhalation. Changing the thickness or other geometric features of the diaphragm carries less risk, however it may require changes to the other components of the device such as the cap component. Optimisation will instead focus on selecting an appropriate hardness of material for the diaphragm, this is the more simplistic method of reducing pressure without requiring further redesign.

To increase the activation pressure of the pressure release mechanism there are two identified methods. Firstly, the hardness of the splaying feature, (g) from figure 15, of the body could be increased. This is not ideal as control of materials in practice is not as accurate as when simulated and could lead to some devices having higher thresholds of pressure release than others. The profile of the interface between cap and body which makes up the cough feature could be modified to make it more aggressive in some way, the most efficient way to do this is to increase the torus on the cap. The torus on the cap is what interfaces with the splaying of the body. Increasing the diameter of the torus will increase the pressure required by a patient to release the cap from the body. Optimisation will focus on the overall size of the torus.

A solution that provided varying resistance depending on flow direction would better achieve Objective 3, device airflow resistance. It was theorised that the addition of another component that would behave differently depending on the direction of the flow of air over it could be incorporated. This would restore the bi-resistant nature of the upper airway, giving patients a natural resistance to breathing. If breathing resistance is fulfilled by an additional component then the HME foam no longer needs to provide this function and could therefore be a different reticulation density and a different overall volume, to maximise its use as a heat and moisture exchange and filtration component.

A major failing of the test for breathing resistance was the lack of any control over the rate of inhalation and exhalation flow rates or velocities. during physical testing of breathing resistance, air through the HME medium in one direction at a constant rate. Patients breathing cycles are completely different to this with a cycle which differs greatly from inhalation to exhalation and will affect resistance results greatly. It would be far more useful to create the breathing resistance problem with a full device in an FSI simulation. This would provide not only total resistance of the

device, but additionally it will allow for efficient and accurate replication of the spirometry flow volume loop. This could in turn allow for a much more realistic, accurate comparison between healthy upper airway and HFSV device.

Addition of Bi-Resistance

One function of the upper airway only partially restored by the original solution is resistance to breathing. The addition of reticulated foam provided resistance to breathing by introducing a restricted area and convoluted pathway through which breathed air could travel. While this provided adequate breathing resistance equivalent to the removed larynx during inspiration, the resistance was the same during expiration. This is not representative of normal breathing, where the larynx provides higher resistance to exhaled air than inhaled air. The proposed solution was the addition of a flat silicone disc which would be introduced into the assembly between the reticulated foam and the patient. The silicone disc would be deformable toward the direction of the patient but could not deform away from the patient due to contact with the foam material, highlighted in figure 40. During inhalation the disc would deform, not significantly restricting the passage of air through the device and causing a minimal change to resistance. During exhalation, the disc will maintain its flat original position, creating a larger restriction and therefore increasing resistance to breathing. A CAD model was created of the assembled solution with silicone disc within the HFSV housing, shown in detail in Figure 40 and 41.

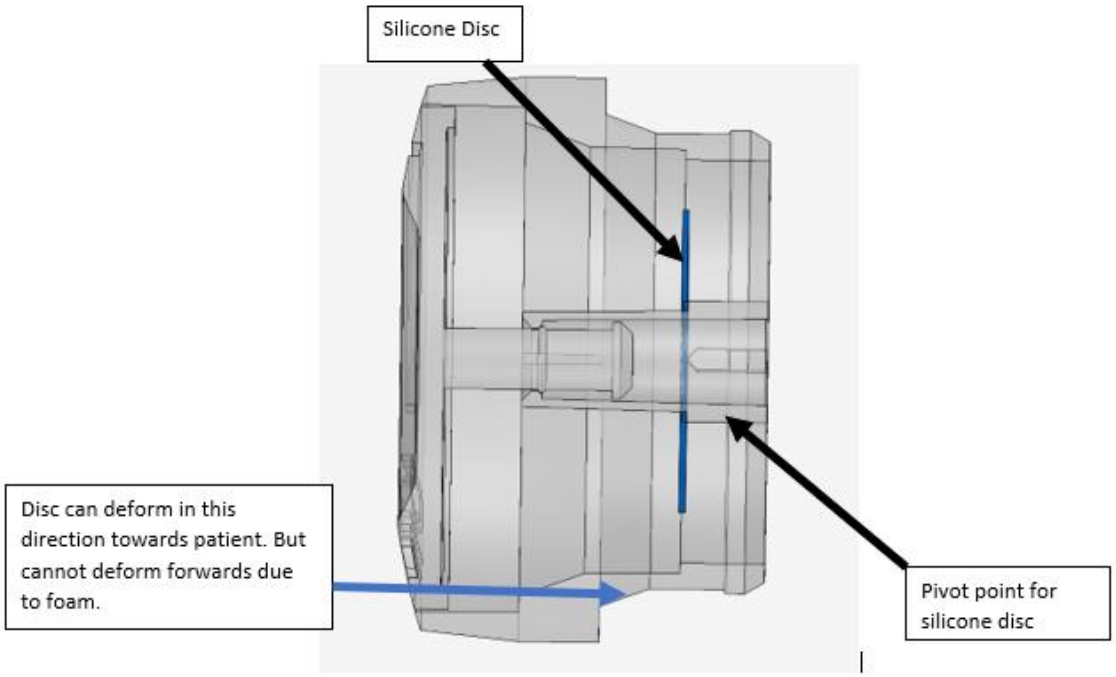

Figure 40 - introduced silicone disc (blue) for bi-resistance

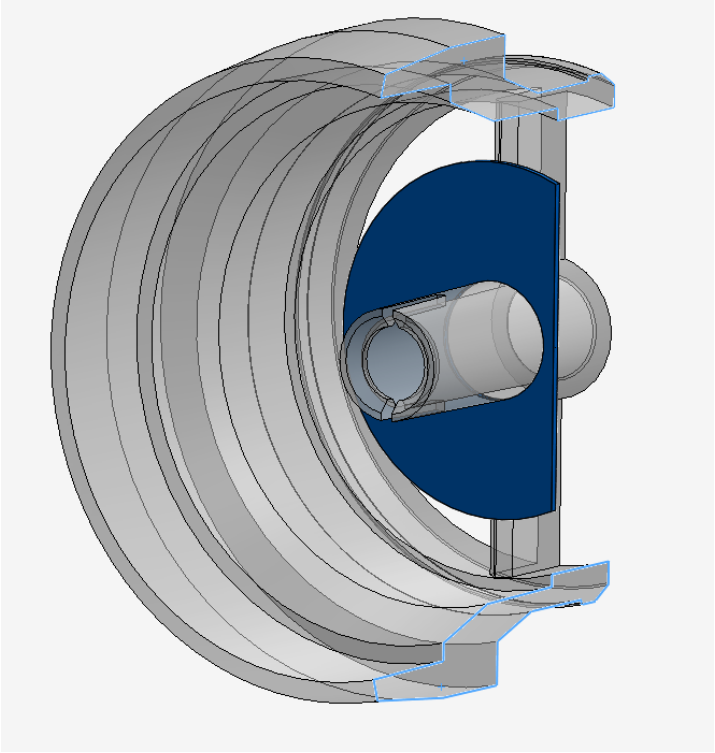

Figure 41 - Partially sectioned view showing silicone bi-resistant disc

5. Evaluation of MK2 Design

5.1 Methodology

Evaluation of the MK2 device's rigid and elastomeric materials was conducted using FEBio. FEBio is a software tool for nonlinear finite element analysis in biomechanics and biophysics and is specifically focused on solving nonlinear large deformation problems in biomechanics and biophysics. Aside from structural mechanics, it can also solve problems in mixture mechanics (i.e., biphasic, or multiphasic materials), fluid mechanics, reaction-diffusion, and heat transfer. As a true multiphysics code, it can also solve coupled physics problems, including fluid-solid interactions [105]. There are three identified design features that could be evaluated and analysed using FEA (Finite Element Analysis).

Problem 1 - Elastic instability of the hands-free speech valve diaphragm.
To ensure the component achieves its function by closing when the user exhales, the pressure at which the diaphragm changes state must be determined. Knowing this pressure allows the design to be optimised. Optimisation of this component is to change its hardness and dimensions to tune the activation pressure, thereby preventing accidental closing of the speech valve during normal breathing, and to ensure the pressure is within the pressures achievable by the user. Determining the activation pressure of the first iteration design and validating a model simulation with the physical testing results would allow the design to be optimised using FEA.

Problem 2 - Resistance to breathing for inhalation and exhalation.
The bi-resistant feature of the device must be tested to ensure the exhalation resistance is higher than the inhalation resistance. Ideally the device can be tuned by adjusting the properties of the silicone disc to achieve resistance equivalent to the larynx.

The data gathered on the first physical iteration of the design helps validate the simulations and allows the design to be optimised with using FEA.

It is assumed that:

- Neo Hookean materials are suitable for use in the analysis of rubber & Polymers. A Neo-Hookean model is a hyperelastic material model that can be used for predicting the stress-strain behaviour of materials and therefore used for all elastomeric objects. Although Mooney-Rivlin and Ogden models could be used, it is unlikely that any large strains will occur during the simulations that would require a model other than Neo Hookean [106] [107].
- Fully rigid materials can be used for polymers where they interact with rubber materials as the effect the rubber has on the polymer components is negligible.
- Simplified components can be modelled that only contain the relevant geometric features required for each simulation.
- Where FSI (Fluid Solid Interaction) simulations are concerned, axisymmetric models will be used to reduce computational demand.
- Regarding FSI & CFD (Computational Fluid Dynamics), extensions to inlet and outlet ports will be added to devices to ensure normalisation of fluids before reaching end faces where measurements for pressure drop is taken.
- Rigid fixing surfaces of components will be applied on surfaces where components would be held or assembled in the physical tests where possible. It is assumed that this sufficiently

represents real world conditions without adding addition components and interactions, frictional forces etc to simulations.

- Regarding mesh creation, Delaunay 3D algorithms shall be used for all meshes in all simulations. Based on the complexity of the components use of this algorithm is most appropriate [106] [108] [109].
- 10 node tetrahedrons will be suitable for all mesh types and densities, for polymeric and elastic objects.
- Material data for density, Young's modulus and Poisson's ratio will be taken from materials data sheets collected during the design of the device. These data sheets originate from the material suppliers. It is assumed that the quality of the material data from the suppliers is acceptable for this application.
- Where applicable, a temperature of 20°C will be used in all simulations.
- In all simulations, models are created with nominal dimensions as designed. The physical devices under test have dimensional and material property tolerances which will not be modelled for the simulations.
- For CFD and FSI simulations, inlet and outlet ports will have backflow and stabilisation constraints so that fluids (air) enter the device in a consistent way along the axis of the device. This would not be the completely representative of air entering the device from the lower airway

5.2 Optimised Bi Stable Diaphragm Simulation

Air Activated Elastic Instability.

To achieve Objective 6, a diaphragm must be designed and optimised to change state when a pressure is applied to it. The activation pressure must be higher than the pressure generated when a flow rate is applied to its surface, simulating normal breathing rates. The activation pressure must be lower than the pressure generated when the flow rate applied to the activating surface is 4.76L/s, simulating peak expiratory flow values of users.

Set Up

A CAD model of the device was created in Solidworks 2018 as shown in Figure 42. The geometry of the components was converted to Standard Triangle Language (.STL) and imported into FEBio.

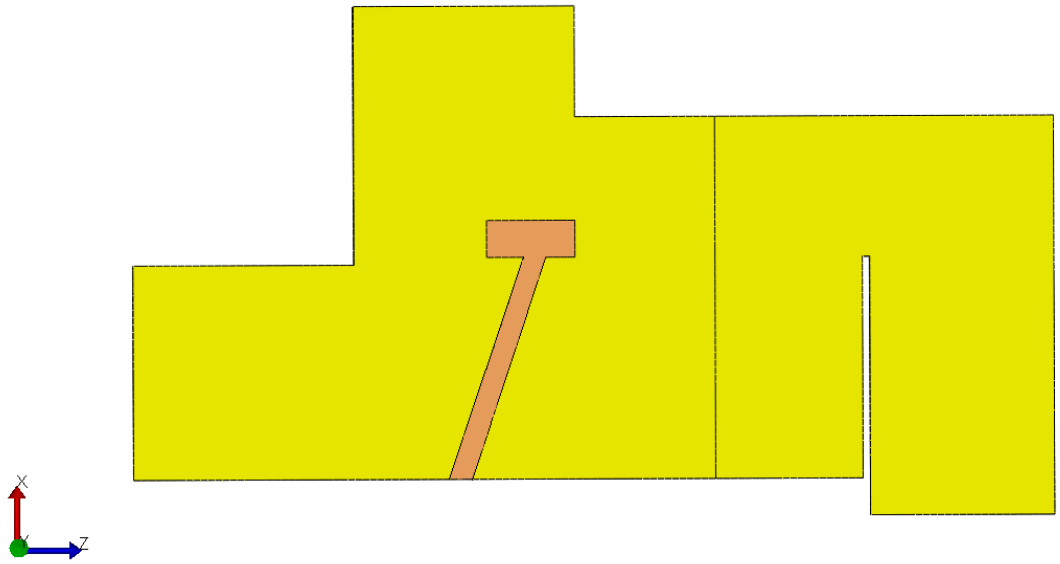

Figure 42 – CAD file including geometry or representation of all components in device.

The model is a 3 degree axisymmetric version of the device, yellow representing the inner volume of the device, plus 5mm past the inlet and outlet. The orange component represents the silicone diaphragm used for speech, modelled in the deformed, open state. The white line on the right hand side of the model represents the silicone diaphragm which is fully rigid as it does not deform during exhalation. The line in the centre is a surface partition from which the flow resistance can be applied, this will represent the foam.

Next an editable mesh was applied. In FEBio, all CFD and FSI simulations require biased mesh near boundaries where the (relative) fluid velocity is set to zero. This includes fixed boundaries as well as interfaces between fluid and structural domains. That is because the fluid velocity profile forms a boundary layer near a no-slip boundary. A mesh bias of 2, with 5 additional segments was applied to every surface in the model. The remainder of the mesh had a Tet10 0.05mm element applied throughout for all components.

Neo-Hookean was selected as the elastic material type for the diaphragm. The density of 1.2 kg/m3, Young's modulus of 1 MPa and Poisson's ratio of 0.47 were applied to the diaphragm as per the manufacturers data. The shaft, bi-resistance disc and housing were deleted.

Fluid (FSI) material type was selected from the FEBio material types for the air surrounding the diaphragm. Density 1.168 kg/m^3, bulk modulus 101 kPa.

Boundary conditions of fixed displacement and zero fluid velocity were applied to all surfaces of the air, zero fluid boundary conditions were applied to the diaphragm surfaces.

Loads were applied to the model next. Fluid Flow resistances of 0 were applied to the inlet and outlet ports. Fluid backflow and fluid tangential stabilisation loads were applied to the inlet and outlet ports also. To the inlet port, a normal fluid pressure load of 142cmH_2O was applied. Peak pressure was programmed to be reached at 55ms in line with MVC (Maximal Voluntary Cough) data found during the literature review [35].

A normal fluid flow constraint was applied to the inlet port to ensure air entered the inlet normally to it surface with a penalty factor of 1000, augmented Lagrangian off.

Mesh Convergence Study

The model was validated against the physical test, presented in section 3.4. This was achieved by matching the simulation pressure values to change the state of the diaphragm to the physical result in a convergence test. Using industry standard methodology [110] [111], a mesh convergence study was undertaken to ensure the mesh was appropriate. The maximum element size was controlled and reduced to create meshes with increasing numbers of elements with size factors. It was noted that the pressure and time that the diaphragm changed state did not vary significantly at meshes with the total number of elements exceeding 20,000. Aiming to achieve a digression error <2.5%, the same simulation was run 6 times with the mesh being refined each time. The physical testing showed that the diaphragm changed state when a force of 0.15N was applied. With each degree of mesh refinement, the degree of freedom value become closer to our desired true value. By the 4^{th} and 5^{th} refinement, the results became an ~95% & ~99% accuracy respectively. Figure 43 shows the relationship between the number of elements and the error compared to the value found in the physical test.

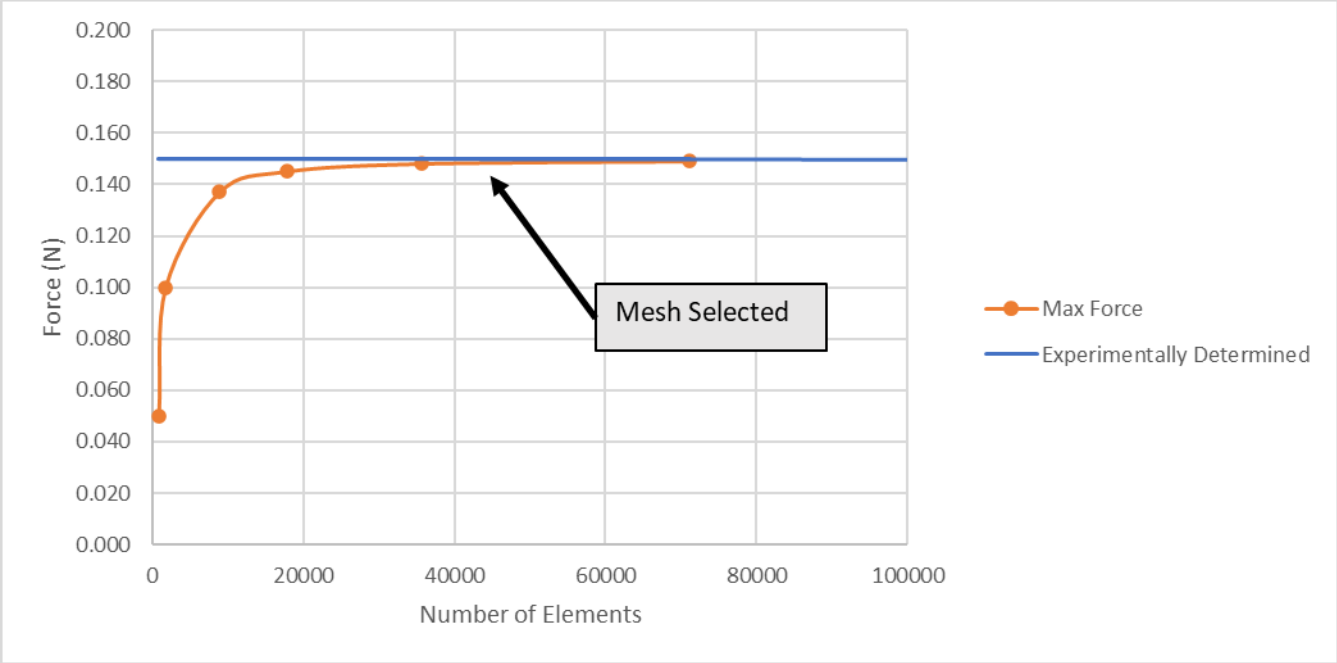

Figure 43 – Convergence test graph force over number of elements. (Elastic Mesh)

With the elastic model and mesh model validated, can be used to fully analyse the diaphragm design with an acceptable level of confidence.

Methods

Axisymmetric FSI simulations were performed to evaluate the movement characteristics of the diaphragm as it transitions from one state to the other. The simulation provides a value of pressure and time at which the diaphragm transitions from state to state.

The FSI simulation was arranged as a single dynamic step. The simulation consists of a ramping pressure, the acceleration and peak of which is derived from exhalation and cough data found in the literature review. The step has 1000 time steps at 0.002 intervals. Auto time stepper on, non-symmetric matrix symmetry, residual tolerance 0.001, max reformations 5, max retries 50. All other properties were left unchanged.

Results

It was found that out of the five physical samples all of them activated between 98 cmH_2O and 120 cmH_2O inlet Pressure with the mean pressure being 108 cmH_2O, the activation pressure was found to be between 1.76l/s flow rate and 1.96 l/s flowrate with the mean flowrate being 1.86l/s and the time to close the diaphragms was between 65ms and 73ms with the mean closing time being 69ms.

Analysis of the post simulation results found that the last time step before termination, where the diaphragm contacts the sealing surface on the cap component, occurs at 66ms. The last time step can be seen in figure 45 below. The displacement of the silicone diaphragm and the pattern of the flow through the HFSV model behave as predicted through observation of the physical prototype, as can be seen in figure 45 and 46.

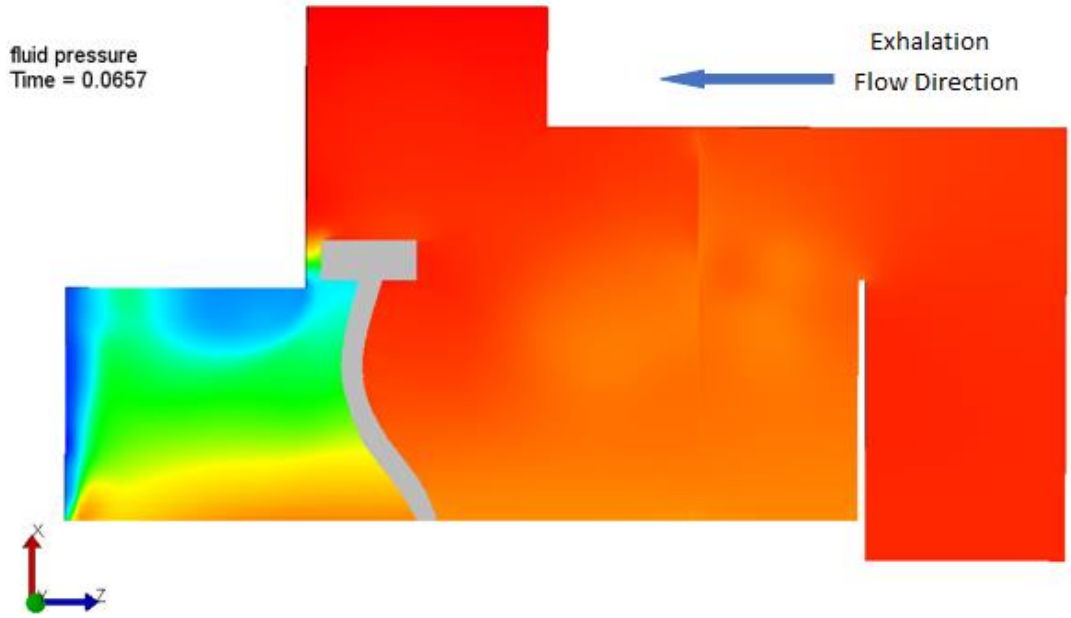

Figure 44 - Last Time Step before termination. (65.7 milliseconds)

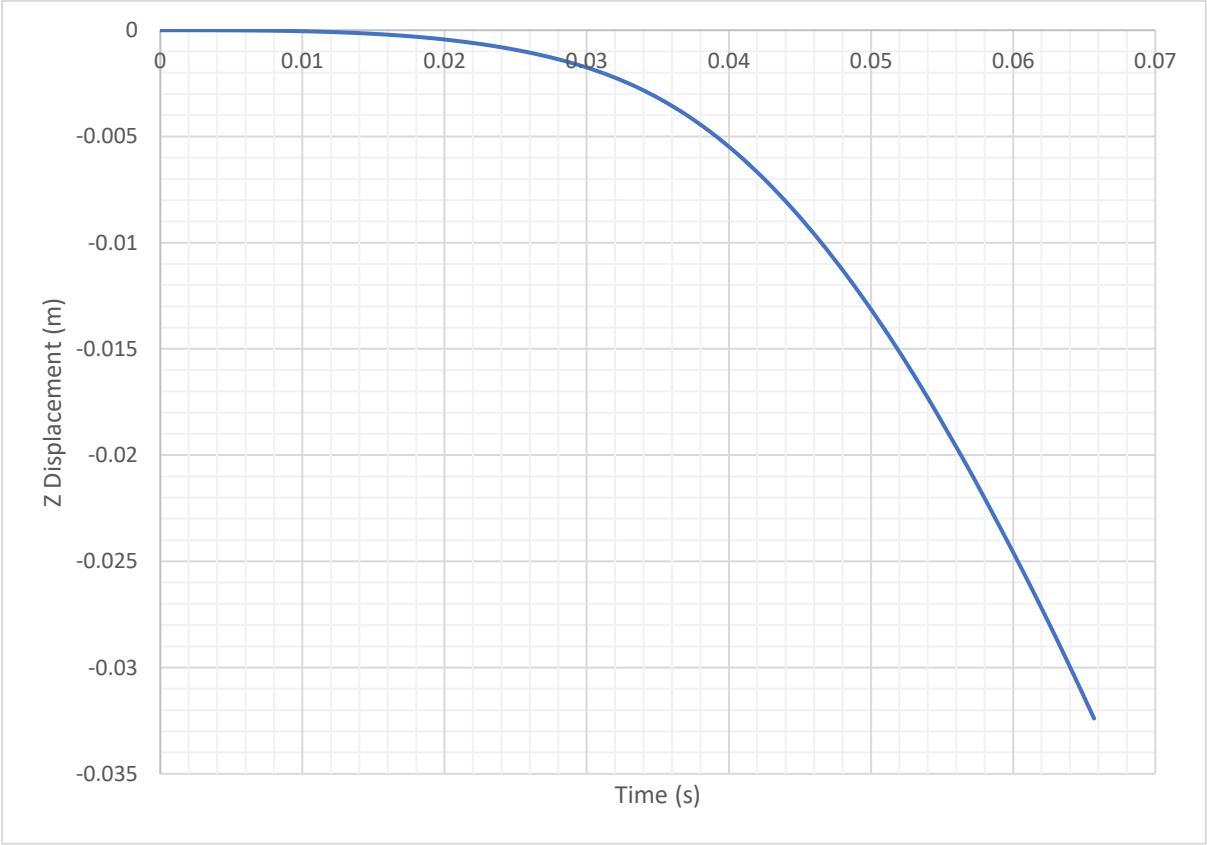

Figure 45 - Z displacement of Diaphragm rim over time

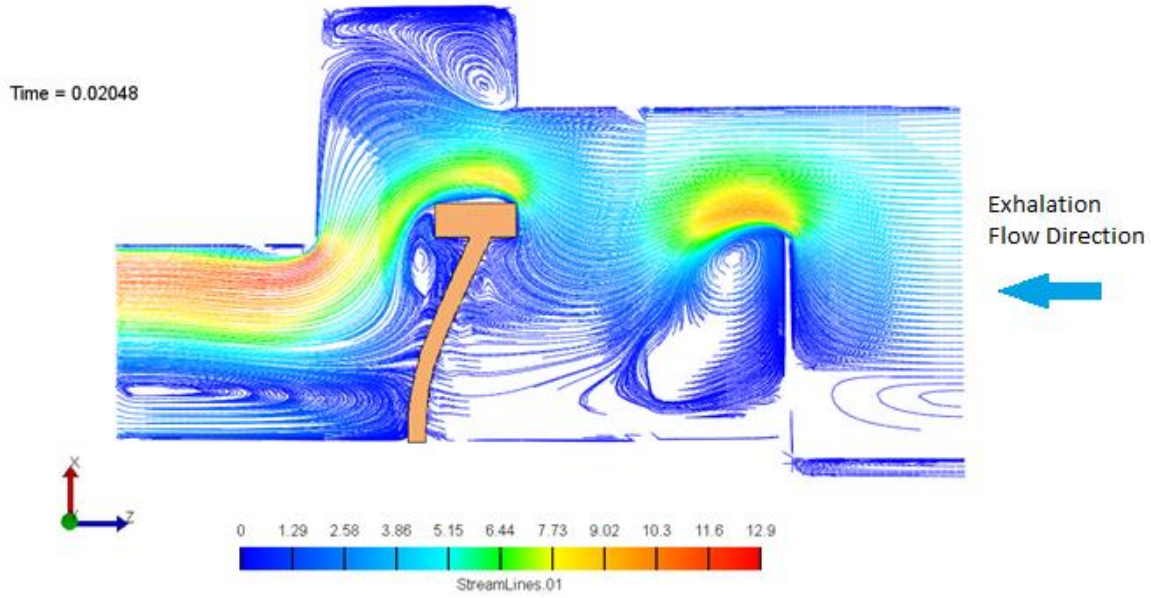

Figure 46 - Velocity of air through HFSV at peak load

It was expected that the diaphragm would close when a pressure of 142cmH_2O was applied. Data had already been collected on the physical samples showing that they can close as low as 98cmH_2O. optimisation of the diaphragm could occur by adjusting the material of the diaphragm to reduce the pressure required to change its state.

Through iterative adjustment of the material properties of the diaphragm in the simulation to soften it. With a density of 1.0 kg/m³, Youngs modulus of 0.5 MPa and Poisson's ratio of 0.29, the closure pressure was reduced to 30cmH_2O with closure time 74ms. This is arguably the best practical closure threshold for the HFSV as it is the upper limit of stomal pressure during speech with a speech prosthesis.

5.3 Optimised Breathing Resistance Simulation

To achieve Objective 3 more effectively, restoring the function of breathing resistance, the HFSV was redesigned to include a bi-resistance feature in the form of a silicone disc added to the proximal end of the device. This would deform towards the patient during inhalation providing low resistance to air flow. During exhalation the disc would maintain its position, offering high resistance to airflow, thereby mimicking the larynx.

Set up

A CAD model of the device was created in Solidworks 2018 as shown in Figure 40. The geometry of the components was converted to Standard Triangle Language (.STL) and imported into FEBio. The model is a 3 degree axis symmetric version of the device, yellow representing the inner volume of the device, plus 5mm past the inlet and outlet. The orange component represents the bi resistance silicone disc used to create the bi-resistance desired, modelled in the neutral as moulded position. The white line on the left hand side of the model represents the silicone diaphragm which is fully rigid as it does not deform during inhalation. The line in the centre is a surface partition from which the flow resistance can be applied, this will represent the foam. (See figure 41).

Next an editable mesh was applied. In FEBio, all CFD and FSI simulations require biased mesh near boundaries where the (relative) fluid velocity is set to zero. This includes fixed boundaries as well as interfaces between fluid and structural domains. That's because the fluid velocity profile forms a boundary layer near a no-slip boundary. A mesh bias of 2, with 5 additional segments was applied to every surface in the model. The remainder of the mesh had a Tet10 0.05mm element applied throughout for all components.

Neo-Hookean was selected as the elastic material type for the silicone disc. The density of 1.2 kg/m3, Youngs modulus of 1 MPa and Poisson's ratio of 0.47 were applied to the diaphragm as per the manufacturers data. The shaft, bi-stable diaphragm and housing were deleted.

Fluid (FSI) material type was selected from the FEBio material types for the air surrounding the silicone disc. Density 1.168 kg/m^3, bulk modulus 101 kPa.

Boundary conditions of fixed displacement and zero fluid velocity were applied to all surfaces of the air, zero fluid boundary conditions were applied to the silicone disc surfaces.

Fluid Flow resistances of 0 were applied to the inlet and outlet ports. Fluid backflow and fluid tangential stabilisation loads were applied to the inlet and outlet ports also. To the inlet port, a normal fluid flow was applied. The acceleration curve and velocities matched the spirometry data of laryngectomy patients during the literature review [53]. For the foam representative surface, a fluid flow resistance of 0.3 cmH_2O was applied at full flow, equivalent to the data gathered on the 60ppi foam in physical testing.

Mesh Convergence Study

As most of the parameters and components are similar to those found in the air activated instability simulation, the same overall meshing configuration and density were used. See 5.2 for details.

Methods

Axisymmetric FSI simulations were performed to evaluate the pressure drop variation from inhalation to exhalation with the silicone disc deforming during inhalation. The simulation provides a value of pressure at the inlet and outlet, the difference is the pressure drop.

The FSI simulation was arranged into two dynamic steps representing inhalation and exhalation. 1000 time steps at 0.002 intervals. Auto time stepper on, non-symmetric matrix symmetry, residual tolerance 0.001, max reformations 5, max retries 50. All other properties were left unchanged.

A second step with the same parameters was performed, however this time the fluid flow direction was reversed, and the acceleration curve and velocities matched the spirometry data of laryngectomy patients in exhalation.

The pressure values at each time step were taken from all elements that make up the inlet of the device, the average value of pressure from all the inlet elements was taken for each time step providing one curve of inlet pressure over time. The same process was carried out using all elements from the outlet. The average inlet values at each time step were subtracted from the average outlet values at each time step to provide an average pressure drop through the HFSV over time.

Visualisations of the simulation can be seen below. Figure 47 shows inhalation fluid velocity. It also shows the predicted deformation of the bi-stable disc (grey).

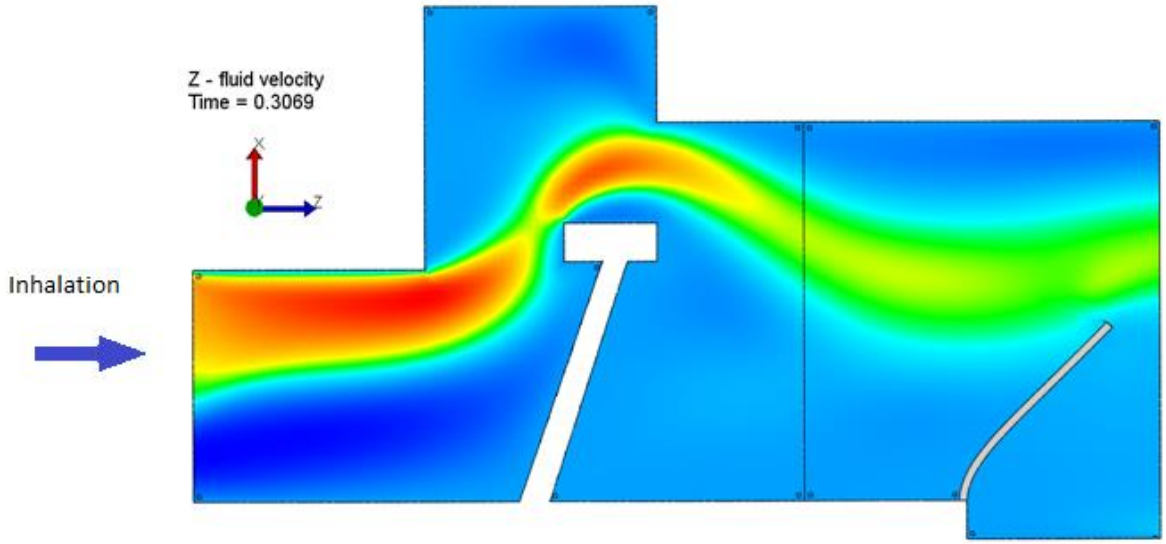

Figure 47 - The silicone Disc deforming during inhalation.

Results

Analysis of the inhalation simulation found that during inhalation the maximum pressure drop was 5.0 cmH_2O at 0.95 seconds at a flow rate 6l/s.

Analysis of the exhalation simulation found that during inhalation the maximum pressure drop was 10.4 cmH_2O at 0.22 seconds at a flow rate 8.4l/s. The pressure drop curves for inhalation and exhalation can be seen in figure 48. Values of resistance at expiratory and inspiratory peak flow of 1.3 $cmH_2O/L/s$ and 0.80 $cmH_2O/L/s$ respectively.

The profile of the bi-stable diaphragm allows air to pass over its diameter smoothly. The profile has the opposite effect during exhalation where the profile is concave in relation to the incoming flow of air rather than convex. This is mitigated by the flow path of the incoming air was it is directed towards the outer diameter of the housing during exhalation by the flat silicone disc.

The simulated device provides resistance to inhalation that matches the larynx in a healthy airway, 1.3 cmH2O/L/s, but is lower than the total extra thoracic airway resistance of 2.65 to 5.3 cmH2O/L/s. The Mk2 design achieves an appropriate level of resistance during inhalation, 0.80 cmH2O/L/s, which is within the estimated limits of the extra thoracic airway resistance of 0.71 to 1.41 cmH2O/L/s.

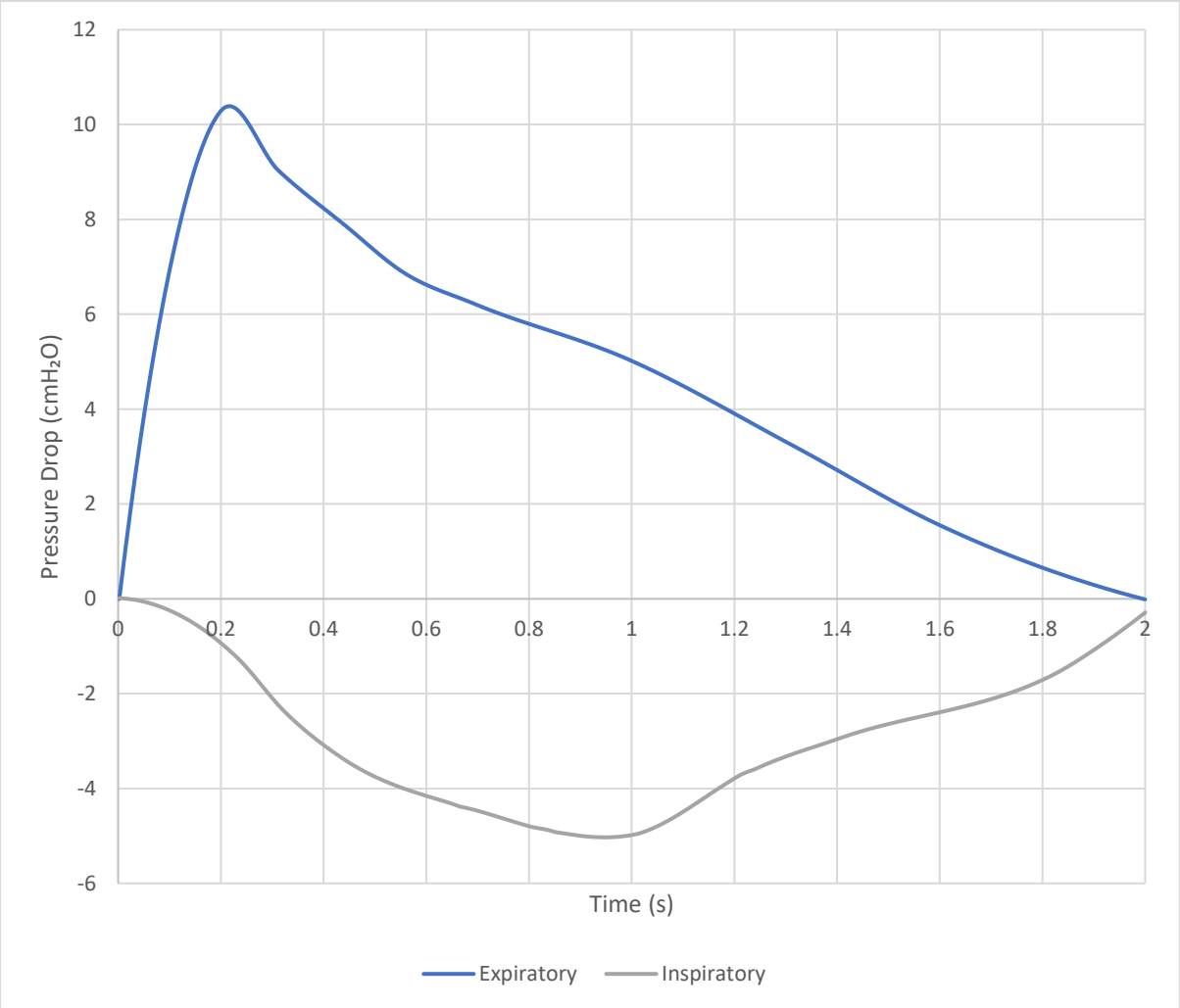

Figure 48 - Pressure drop through HFSV during expiration and inhalation.

Discussion of Mk2 Design

Optimised Diaphragm Activation

Simulations of the HFSV bi-stable diaphragm found that it was possible to tune the activation pressure to 30cmH_2O with closure time 74ms if required. This is arguably an optimal activation pressure as it is matched to the pressures required to produce intelligible speech from popular speech prosthesis, which this HFSV would be used in conjunction with. Matching the pressures may result in minimal excess strain on patients. A closure time of 74ms is as fast as was possible with the input of maximal acceleration to peak flow data obtaining during the literature review. This rapid closure time reduces the amount of air wasted on closing of the valve and maximises the volume of air available for speech.

Breathing Resistance

Results gathered from the simulation of the inhalation resistance of the HFSV indicate that in the current configuration, the Mk2 device provides resistance to inhalation that matches the larynx in a healthy airway, 1.3 cmH_2O/L/s, but is lower than the total extra thoracic airway resistance of 2.65 to 5.3 cmH_2O/L/s. The Mk2 design achieves an appropriate level of resistance during inhalation, 0.80 cmH_2O/L/s, which is within the estimated limits of the extra thoracic airway resistance of 0.71 to 1.41 cmH_2O/L/s. Having a range of hardness options for the silicone disc that provide lower or harder than normal resistance may allow for more rehabilitation potential. The patient could start with a lower than normal breathing resistance and once comfortable, increase the hardness or thickness of the disc and continue to move closer to normal levels of inspiratory resistance. In conclusion, utilisation of a silicone disc, which can deform during inspiration but not during expiration due to a physical barrier, does provide a pattern of inspiratory resistance like that of a normal healthy airway. This result has partially achieved Objective 3. pre-laryngectomy levels of breathing resistance due to the upper airway would differ from patient to patient, using the simulation, different variants of the bi-resistance feature could be simulated and tailored to individual patients' requirements.

6. Discussion

When beginning this research, the primary objective was to design a device which restores lost airway functions in laryngectomy patients. this objective was divided into the multiple objectives related to the different unrestored functions, with each requiring its own solution to restore.
From the literature review the upper airway functions lost as a result of laryngectomy are:

1. Ventilation & patency
2. Heating and humidification of air
3. Filtration of air
4. Coughing
5. Swallowing
6. Speech
7. Olfaction, Gustation & Chemo sensation
8. Resistance

Where possible, solutions were combined into components of the HFSV assembly to maximise the number of functions restored in a single device. Some of the lost functions regarding stomal and tracheal patency could be integrated into a single device, but practicalities of device use duration and cleaning made combining two devices make this non-beneficial. Instead, the HFSV can be used in conjunction with a patient interface device such as a laryngectomy tube. For the lost function of speech, no clear single device solution could be found, and it was decided to focus attention on improving the hands free functionality of a speech valve, devising a new mode of operation which could offer patients longer, louder and more clear speech when used in combination with existing speech prosthesis devices.

Objective 1 was achieved, an initial design of a medical device that restores lost airway functions was designed in CAD and protypes were created for physical testing.

Objective 2 was achieved, the device was tested for water loss performance, the aim was to achieve a level of water loss equivalent to nasal and oral breathing of healthy individuals at rest. Testing found that the incorporation of reticulated foams impregnated with Calcium Chloride reduced water loss compared to controls with no HME medium. Foam with density of 60 pores per square inch produced water loss of 31.1mg/l over 15 minutes. This is 9% higher than nasal breathing and 23% lower than oral breathing, within the threshold of suitability.

Objective 3 was partially achieved, results gathered from the simulation of the inhalation resistance of the optimised HFSV indicate that the device provides bi-resistance to breathing. The resistance to inhalation matches the larynx in a healthy airway, 1.3 $cmH_2O/L/s$, but is lower than the total extra thoracic airway resistance of 2.65 to 5.3 $cmH_2O/L/s$. The device achieves an appropriate level of resistance during inhalation, 0.80 $cmH_2O/L/s$, which is within the estimated limits of the extra thoracic airway resistance of 0.71 to 1.41 $cmH_2O/L/s$.

Objective 4 was achieved; the aim was to verify the devices filtration performance in the 2.5µm-10µm range. The device filter medium was tested and found to be 60% efficient at filtering particles 2.5µm and 96% efficient at filtering particles 10µm. Though not 100% efficient, neither is the healthy individual's upper airway, with mucociliary clearance removing any particles that make it to the lower airway.

Objective 5 was achieved. The aim was to test the device with a representative number of ramping pressure cycles to verify that pressure build up does not exceed 122.04 cmH_2O & that the device is not damaged or effected by coughing. Device manually reset after each cough. 5 sample devices were pressurised rapidly for 20 cycles. It was found that the pressure release mechanisms activated at a mean pressure of 96 cmH_2O. This objective and device could be further refined or optimised to achieve the desired results of 70 cmH_2O in line with the pressure healthy individuals experience in the mouth and nose during sneezes.

Objective 6 was achieved. The HFSV silicone diaphragm was tested for closure, sealing and opening, ensuring that it would close with the user exhalated at a higher than resting expiratory flow rate, allowing for redirection of air through the prosthesis. The final device was found to have a closure pressure of 30cmH_2O with closure time 74ms the mean flowrate being 1.86l/s. This is within the achievable limits derived from the spirometry data of laryngectomy patients. The data cannot be compared to healthy individuals easily as healthy individuals do not need to close their airway or redirect air in the same was as laryngectomy patients.

Objectives 7 and 8 were achieved. The device was redesigned based on findings of the physical test findings and simulations were utilised to optimise the Mk2 design.

It would be beneficial to test the device in vivo to verify if the device achieved some of the objectives. Objective 6 relates to speech but is limited to verifying that the closing and opening pressures are achievable by patients. Utilising patients for a speech study with the device would have allowed for objective 6 to be expanded to include measurement of speech itself. Within the scope of this research and the with the current global pandemic, there is insufficient time and the risk to patients too high.

7. Conclusion

Many patients diagnosed with laryngeal cancer undergo full laryngectomy. Over one hundred thousand patients worldwide are living with a total laryngectomy. These patients lose all upper airway function including speech. The motivation of the thesis was to ascertain how many functions could be restored with a singular medical device.

A literature review was conducted which found that total laryngectomy has a negative effect on patient health by preventing the functions of the upper airway. These primarily are the conditioning of air entering the lungs, including heating, humidification to the isothermal boundary, filtration and speech. Swallow, gustation, olfaction, cough, breathing resistance and speech are also reduced or completely prevented. Airway patency issues also occurred with patient anatomy being surgically modified. There are devices and therapeutic techniques that restore all these functions to a satisfactory level in some patients. The literature review found that filtration was restored using medical devices, but the exact performance of those devices had not been verified.

A device has been designed and refined; physical tests were carried out to validate the main functions of the device. Physical tests found the device would restore HME performance in patients with a water loss of 31.1mg/l at normal respiratory rates, within the HME performance ranges of nasal and oral breathing.

Filtration testing found that the device could filter particles normally filtered by the upper airway (2.5µm - 10µm), with the device filtering 10µm particles with 95% efficiency. Patency, swallow and olfaction functions were not integrated or into the device.

A series of FSI and CFD simulations were used to refine the design to restore the functions of breathing resistance and speech.

The device's cough feature, a pressure release mechanism which allows the user to cough normally with the device in situ, activated within the threshold of patient maximal expiratory pressure.

The device was proven to create a bi-resistance to breathing which mimics the larynx and upper airway. It was found that the device creates expiratory and inspiratory resistance of 1.3 cmH2O/L/s and 0.80 cmH2O/L/s respectively. This is comparable to the laryngeal resistance to breathing of 1.245 cmH2O/L/s in expiration and 0.354cm H2O/L/s per second during inspiration.

The device's hands free speech function was tested. The diaphragm was designed so that the patient would be able to close it by applying a high exhalation pressure, redirecting air through an implanted speech prosthesis. It was confirmed that the diaphragm could be closed with appropriate pressure. The closure pressure was 30cmH2O with closure time 74ms. This is within the capability of patients and the short time to closure ensured minimal volume wasted when initiating speech. The bi-stable nature of the valve allows for pauses during speech without reclosure of the device, again extending the duration of phonation between breaths.

Physical testing confirmed that heat and moisture exchange and filtration are fully restored by the device. Coughing, Speech and resistance are partially restored by the device. Patency can be restored when the device is used in conjunction with other medical devices. Swallowing, olfaction and gustation are not restored by the device but are partially restored by therapeutic techniques which can be utilised while using the device.

8. Further Work

Further optimisation activities utilising the simulations

With regards to inspiratory resistance, it is clear that small refinements to the materials or thickness of the silicone disc would achieve a match to normal healthy upper airways. Physical testing of a refined Mk2 device or a Mk3 iteration would be beneficial.

Clinical Trials/Evaluation of Speech Valve (In Vivo)

The most complex function the HFSV is trying to restore is speech. Although the testing carried out in this thesis verifies the mode of operation could theoretically open and close at pressures achievable by the patient only clinical trials would demonstrate the effectiveness of speech. A study beyond the scope of this thesis that would assess HFSV speech in vivo.

The one aim of the study would be ascertaining speech performance utilising tests for maximum phonation time, speech legibility and maximum phonation loudness. The study could also assess the patient's ability to pause during speech. A second aim of the study could be a long term use study to assess benefits to patients, such as reduced coughing and improved spirometry results.
Tests would demonstrate a speaking volume range, phonation time, ability to pause speech, ease of speech initiation and overall speech quality. This would be able to be compared to healthy non-laryngectomised speech to gain a more definitive answer to whether Objective 6 were achieved in practice.

A proposal for unrestored functions

The functions not restored by the device proposed in this thesis are olfaction and gustation. The literature review highlighted that there is no device-based solution to this problem. Over the course of this thesis, it was concluded that another separate device would be required to restore olfaction and gustation. The reason olfaction and gustation is reduced in laryngectomised patients is due to no air flowing through the nasal cavity. This has a limiting effect on gustation also as the senses are demonstrably linked. The solution appears to be to create an air flow through the nasal passages. This could be achieved with a device that generates an airflow that connects to the nasal cavity, pushing or drawing air.

The proposed Olfactor device comprises of a mouthpiece which is placed into the oral cavity and forms a seal. The housing of the device contains a motorised fan which can generate flowrates required for olfaction. Air is drawn through the nasal opening, though the mouth and out through the open outlet of the device. This device would be used at the patient's discretion when olfaction was required. This device may be particularly useful for improving patient safety by aiding in the detection of hazards such as smoke, solvents or food.

With more time and broader scope including more than a single device, this may have been the solution required fully restore olfaction and partially or fully restore gustation. This device could be tested with an FEA simulation of the device attached to a model of the oral and nasal cavities, an airflow initiating in the device could be simulated and the resultant air flow in the nasal cavity could be observed. The airflow rate could then be optimised for ideal airflow in the nasal cavity, matching that of a healthy individual inhaling nasally. A physical prototype could then be produced and used with patients to gain in vivo data comparing healthy, laryngectomised and laryngectomised plus device users. the test would take the form of odour and taste discrimination.

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