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Design of a Novel Video-Assisted Tube Over Tube Rigid Bronchoscope for the Removal of Foreign Bodies from the Bronchi Following Aspiration

Minor Dissertation

In partial fulfilment of the academic requirements for MSc degree in Biomedical Engineering by coursework and dissertation

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Declaration

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Abstract

Foreign body aspiration (FBA) is a prevalent occurrence in the paediatric population. FBA is when a foreign body (FB) is inhaled accidentally into the airways. The location of the FB may differ according to each patient, but in most cases, the FB is found in the right bronchial tree. FBA symptoms are often misdiagnosed, resulting in late discovery of the obstruction. There is an increase in difficulty to remove a FB, dependent on how long it remains within the airway. This poses a greater risk to the patient, fatality or other serious long-term complications.

Currently, FBs are removed using a bronchoscope in conjunction with a pair of forceps. The two types of bronchoscopes used currently are the flexible and rigid bronchoscopes. The rigid scope is preferred for FB removal due to better control and clear visuals of the airwayand an array of forceps ends. The costly flexible scope is more difficult to use and is used in cases where radiological findings of a FB are inconclusive. During insertion ofthe scope, no ventilation is supplied to the patient, posing a high risk of hypoxia. Bothinstruments require considerable skill and extensive training, limiting the procedure applicability.

The difficulty experienced when handling the current instruments and the high risk of hypoxia are motivations for a product redesign. Therefore, this study aims to design and develop a novel video-assisted tube-over-tube rigid bronchoscope to remove foreign bodies from the airways following aspiration, whilst providing constant ventilation and visualisation of the airway.

The redesign compromises of several subsystems: the rigid bronchoscope (and attached camera), ventilation connector tube and an uncuffed endotracheal tube (ETT). These subsystems were designed to ensure constant ventilation throughout the insertion of the bronchoscope, whilst providing real-time imaging of the airways. The design incorporated a guiding mechanism to increase the usability further.

A testing protocol was performed on a Laerdal airway management trainer using the designed device, named the ‘Re-Aspire’ device and its competitor, the Karl Storz rigid bronchoscope. The testing participants were a group of anaesthesiologists who have had prior training in bronchoscopy, but do not practise the procedure. A common FB was placed inside the airway of the trainer, and both scopes were used to retrieve it. The facilitator timed the procedure and observed the participants. Post testing, each participant was interviewed about the functionality of each device and completed a system usability scale.

A total of 34 attempts of FB removal was recorded for the rigid bronchoscope compared to 14 attempts for the Re-Aspire device. As hypothesised, the estimated average hypoxic time was more than double for the rigid bronchoscope compared to that of the Re-Aspire device. According to the system usability scale, the Re-Aspire device resulted in a higher average system usability score. These results demonstrated that the Re-Aspire device has a higher perceived ease of use and system satisfaction according to the user’s perspective. Therefore, achieving all the stated testing hypotheses. However, the design of the device can be improved to increase the usability and efficacy further.

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List of Acronyms and Symbols

ATS	American Thoracic Society
BS	Bronchoscope Subsystem
CAD	Computer-Aided Design
CCD	Charge Coupled Device
CMOS	Complementary Metal Oxide Semiconductor
ETT	Endotracheal Tube
FB	Foreign Body
FBA	Foreign Body Aspiration
FBES	Foreign Body Extraction Subsystem
FOV	Field Of View
FRC	Functional Residual Capacity
HREC	Human Research Ethics Committee
LED	Light Emitting Diode
PPS	Perceived Procedure Success
SUS	System Usability Scale
TIVA	Total Intravenous Anaesthesia
TV	Tidal Volume
UCT	University of Cape Town
VCS	Ventilation Connector Subsystem
VS	Visualisation Subsystem

1 Introduction

Within this chapter, an introduction to the clinical problem will be discussed, highlighting the significance thereof. After that, the research proposal will be reviewed, specifically looking at the research question, hypothesis, aims and objectives.

1.1 Background and Problem Identification

Foreign body aspiration (FBA) is prevalent in the paediatric population. The age range affected varies from 6 months to 14 years old. Foreign body aspiration (FBA) occurs in 70% of children younger than 3 years old (Figueiredo et al., 2012; Lowe, Vasquez, & Maniaci, 2015). If the foreign body (FB) is not removed within a suitable timeframe; the obstruction could lead to fatality or other serious long-term complications. These prolonged medical conditions include reoccurring pneumonia, bleeding, hypoxia or a collapsed lung (Nicolai, 2001). FBA is the "sixth most common cause of accidental death in children" (Sahin, Meteroglu, Eren, & Celik, 2013-02).

Discovery of a FB can occur within a few hours or several years after initial aspiration. Currently, FBs are removed with a bronchoscope in conjunction with a pair of forceps (Rodríguez et al., 2016). A bronchoscope is a device used to view the airway and provide a working channel for the forceps to pass through (Cutrone et al., 2011).

The two bronchoscope types used currently are the rigid and the flexible bronchoscopes. The rigid bronchoscope is the preferred approach for FB removal due to better control and clearer visuals of the airway, in conjunction with the wide availability of various forceps ends (Singh & Parakh, 2014). A flexible bronchoscope is used if there is suspected FBA and if the radiological findings of a FB are inconclusive (Hitter, Hullo, Durand, & Righini,2011). The introduction of the current scopes into a patient's airway puts the patient athigh risk of becoming hypoxic, due to the lack of oxygen being supplied to the patientduring insertion of the scope (Sharma, 2014).

Both instruments require extensive training, limiting the procedure to specialised clinicians, such as thoracic surgeons and pulmonologists. Presently in South Africa, paediatric bronchoscopies are only performed in tertiary and central hospitals and taught in academic institutions where cardiac and thoracic surgeries occur. Consequently, there is restricted access to paediatric bronchoscopy procedures in developing countries due to the lack of specialists and socio-economic status (Boufersaoui et al., 2013).

The difficulty experienced when handling the current instrument and the high risk of hypoxia serve as motivations for a product redesign. This research aims to make this life-saving procedure more accessible, by redesigning the paediatric bronchoscope. The project will prioritise the need for a bronchoscope that does not require a specialised surgeon to operate whilst remaining affordable for hospitals and clinics across Africa.

1.2 Overview of the Clinical Problem

Due to a child's inquisitiveness, the types of FBs aspirated vary significantly. FBs can be categorised into organic or inorganic FBs. Organic FBs constitute of animals, plants, or minerals; whilst inorganic FBs include all artificial products such as pen lids, Lego pieces and toys (Lowe et al., 2015).

According to Kim, Shapiro, and Bhattacharyya (2015), there is a strong correlation between the geographical location of the patients and the type of FBs aspirated. Patients from remote, developing areas commonly aspirate organic FBs, whilst patients from developed countries, such as the United States, aspirate 66% more inorganic FBs than organic FBs (Lowe et al., 2015). Currently, only toys have been regulated and packaged as high-risk chocking items, yet there is a clear need for regulation of the packaging of high-risk foods (Green, 2015). The type of FBs aspirated also differs according to the patients' ages, with small food items commonly aspirated by newborns and babies, whilst inorganic FBs are more apparent in elder children (Sultan& van As, 2016).

Radiographs are captured if a patient is suspected of FBA. However, more often than not, the radiograph will only reveal the FB if it is made of a radiopaque material. As seen in Figure 1.1, Image A, a 13-month-old aspirated a wooden bead which is not displayed on the radiograph. Yet, the radiograph demonstrated hyperinflation of the left lung.

The right main bronchus is situated vertically compared to the left main bronchus. Consequently, the right bronchial tree, specifically the right main lobe, of the lung is where aspirated FBs are most commonly found. In Figure 1.1, Image B, a plastic FB was discovered in the right main bronchus. The second most common location is the left bronchial tree. The common FB, and the corresponding probabilities are listed in Table 1.1.

Initially, aspirated FBs may be expelled by coughing. However, if the FB moves down the airway, it can be retrieved using a pair of forceps placed within the lumen of a bronchoscope. FBA symptoms are dependent on the type of FB aspirated, the anatomical location of the FB, the FB length of stay within the airways and the extent of airway obstruction (Lowe et al., 2015).

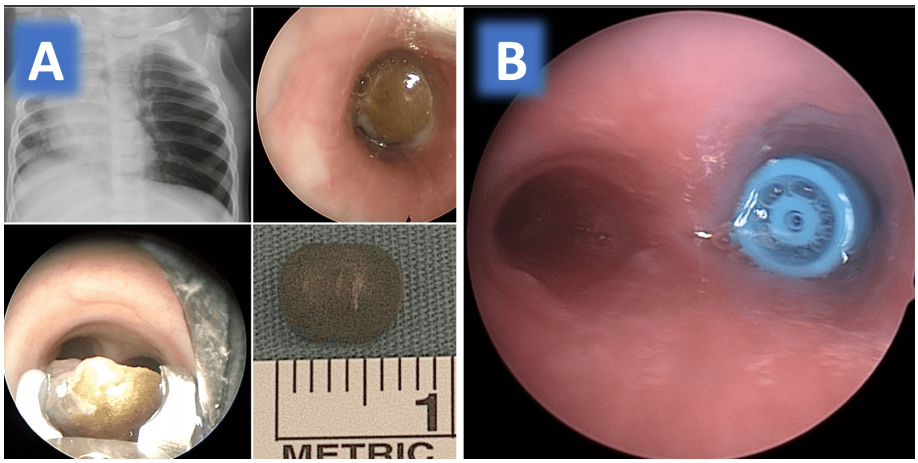

Figure 1.1: A) A 13-month-old patient aspirated a wooden bead found in the left mainstem, B) a 12-month-old patient aspirated a plastic FB found in the right main bronchus of the airway, obtained from (Chaffin et al., 2015)

Table 1.1
Likelihood of locating FBs within a patient's airway, obtained from (Eren S; Balci AE; Dikici B; Doblan M; Eren MN, 2003)

Area of the airway	% of Foreign bodies found
Right main bronchus	52 %
Left main bronchus	18 %
Trachea	13 %
Right lower lobe bronchus	6 %
Left lower lobe bronchus	5 %
Larynx	3 %
Bilateral	2 %
Right middle lobe bronchus	1 %

1.3 Significance of the Clinical Problem

If a FB remains within an airway for an extended period, there is a greater risk of the patient developing long term medical complications. These medical conditions include airway bleeding, fever, hypoxia and pneumothorax (collapsed lung) (Nicolai, 2001).

Clinical development of FBA symptoms can occur within a few hours to as long as several years after aspiration, where a long-term patient may suffer from reoccurring pneumonia. A study in Toronto describes a 54-year-old woman who was clinically assessed for episodic chest tightening, only to find a bone fragment stuck within her left mainstem bronchus aftera chest CT scan (Bain, Barthos, Hoffstein, & Batt, 2013). The FB had remained withinher airway for 22 years and demonstrated "near-total obliteration of the airway" (Bainet al., 2013).

The most frequently affected patients are between 6 months to 4 years old (Figueiredo et al., 2012). Children learn how to use both their upper and lower limbs at these early ages whilst developing their mouthing behaviour. These behavioural characteristics further increase the risk of FBA. Other factors that make this a high incidence age group include anatomical features such as a higher epiglottis position, in conjunction with behavioural characteristics such as crying during eating (Lowe et al., 2015). There are 60% more male patients than females, assumedly due to their more mobile and curious behaviour (Grover, Bansal, & Singhi, 2011; Sultan & van As, 2016; Lowe et al., 2015). Although ingestion is more common than aspiration, there have been accidental aspiration cases of endodontic instruments during routine endodontic procedures. (Venkataraghavan, Anantharaj, Praveen, Rani & Krishnan, 2011)

As bronchoscopy procedures are typically carried out where cardiothoracic surgeries take place, these procedures are restricted to tertiary and central hospitals in South Africa. South Africa's central or tertiary hospitals make up 7.72% ofall the hospitals in South Africa (Department of Health, 2012). The locations of these central and tertiary hospitals are localised, as illustrated in Figure 1.2. Families from the Northern Cape Province and surrounding areas must travel great distances to access these hospitals. This limited access to bronchoscopy procedures is a worldwide issue, especially in developing countries, due to the lack of thoracic departments offering training in this specialised field (Schuhmann, 2017).

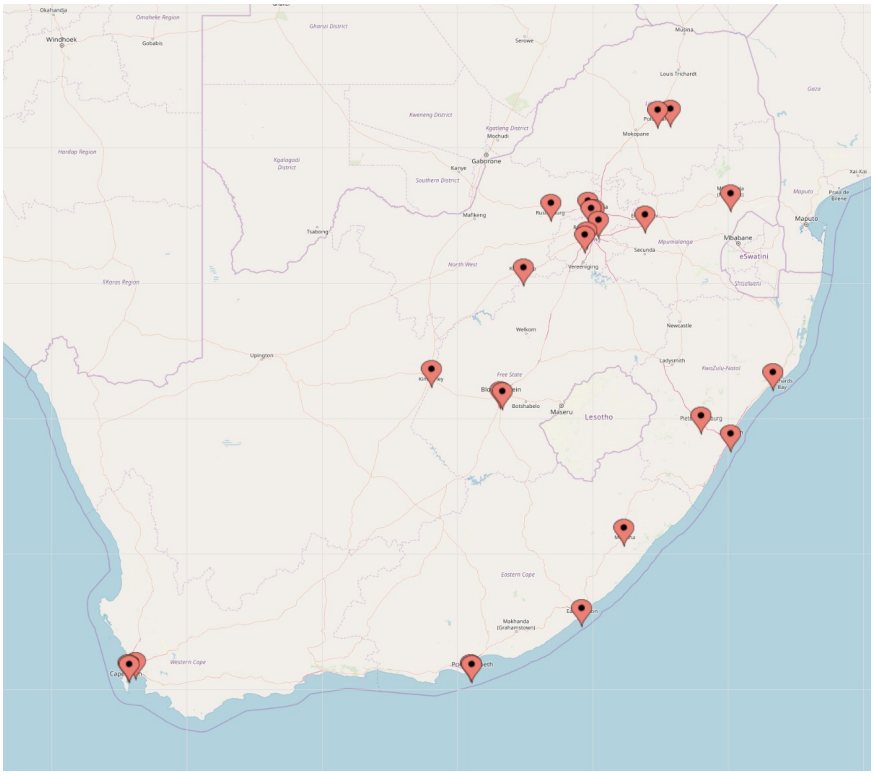

Figure 1.2: Central and provincial tertiary hospitals (represented by red pins) in South Africa

Paediatric bronchoscopy is only performed in three Western Cape hospitals, namely, Groote Schuur Hospital, Tygerberg Hospital and Red Cross War Memorial Children's Hospital. At Tygerberg Hospital, 60 to 70 bronchoscopies are performed each year (Myburgh & Tumbo, 2018). Red Cross War Memorial Children's had 407 cases of paediatric FBA from 2010 to 2015 (Myburgh & Tumbo, 2018).

More than 6000 bronchoscopies were performed to treat FBA in children at Bologhine Ibn Ziri Hospital, in Algeria, from 1989 to 2012 (Boufersaoui et al., 2013). In the United States, more than 1000 FBA emergency visits were reported over three years from 2009 to 2011 (Kim et al., 2015).

1.4 Research Question

The research question for this study is:

Whether aspirated foreign body retrieval procedures could be successfully performed whilst offering increased patient safety without compromising the efficacy of existing bronchoscopy methods?

1.5 Hypothesis

The hypothesis is that a novel video-assisted tube-over-tube rigid bronchoscope and a means of constant ventilation will improve the procedure's overall efficacy and patient safety.

1.6 Study Aim

The project aims to design and develop a novel video-assisted tube-over-tube rigid bronchoscope to remove foreign bodies from the bronchi following aspiration whilst providing constant ventilation and visualisation of the airway.

1.7 Research Objectives

The study's objectives can be classified into three primary objectives: design, assembly and testing. Each of these primary objectives has a set of secondary objectives.

- Design and integrate the novel video-assisted tube-over-tube rigid bronchoscope and its subsystems by designing and implementing:
    1. A ventilation connector subsystem that will provide constant ventilation to the patient.
    2. A visualisation subsystem that can integrate with a smart device and provide real-time visuals of the airways.

3. A bronchoscope subsystem can be used in conjunction with an uncuffed endotracheal tube to guide the bronchoscope to the distal portion of the airways and provide a working channel for the existing forceps to pass through.

- Validate the design of the novel video-assisted tube-over-tube rigid bronchoscope through testing the subsystems to determine:
  1. The usability of the system for medical professionals untrained in bronchoscopy.
  2. The adaptability of the system for both the adult and paediatric population.
- Perform pre-clinical bench testing (on a respiratory mannequin) and cadaver testing to determine:
  1. The system's usability compared to the existing devices, by completing a system usability scale (SUS) (Brooke, 1986) following pre-clinical testing.
  2. The system's perceived procedure success compared to the existing devices, following pre-clinical testing.

1.8 Scope of the Study

The primary focus for this study is the design, development and assembly of a working prototype of a novel video-assisted tube-over-tube rigid bronchoscope. A pilot study consisting of cadaver and respiratory mannequin testing will prove the manufactured device's concept. This is done to ensure that the functionality and usability of the designed device was achieved to an appropriate standard without compromising its efficacy. As this is the initial stage of the frugal biodesign process, it is not necessary to manufacture all of the device's components according to strict medical-grade standards. This study is also limited because the dissertation component makes up 90 credits of the MSc compared to 180 credits for a full dissertation.

1.9 Dissertation Overview

An overview of the dissertation is shown in Figure 1.3, which details the design and experimental methodologies and outcomes of the discussed study. An in-depth literature review (Chapter 2) is first done, highlighting the relevant anatomy, clinical problem and analysis of the existing devices. After that, design requirements and specifications are determined, and a design methodology (Chapter 3) is described for each subsystem of the device. The outcomes of the design for each subsystem are analysed in Chapter 4.

The device is then tested following the experimental methodology (Chapter 5). An analysis and discussion of the testing results are discussed in Chapter 6. The dissertation is then concluded with Chapter 7.

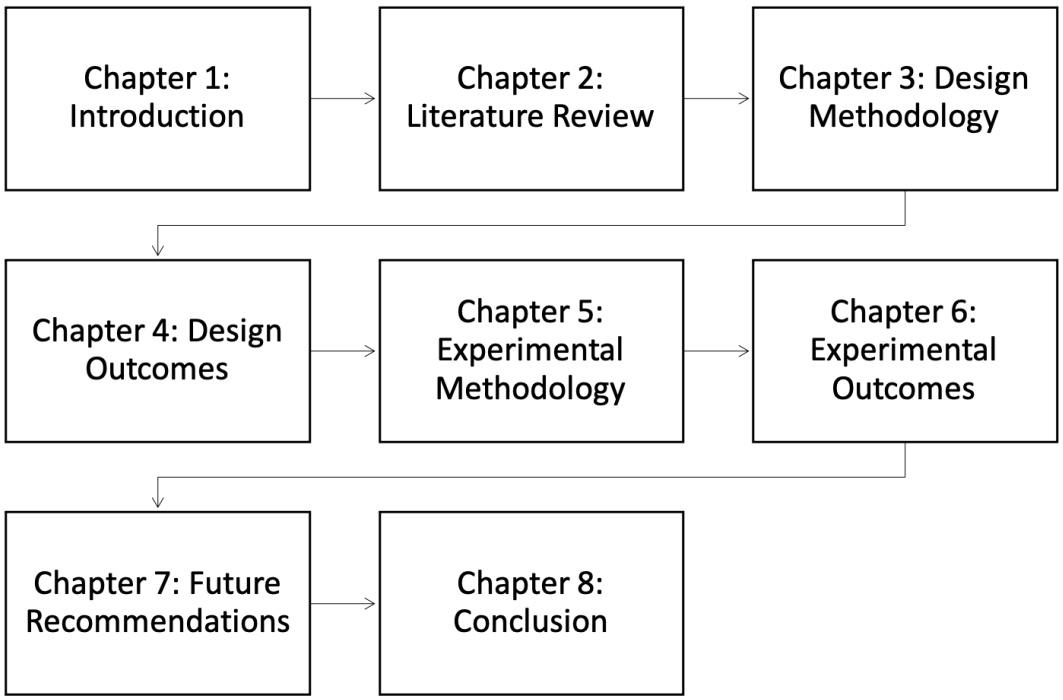

Figure 1.3: Dissertation overview

2 Literature Review

The relevant anatomy of FBA is discussed in this chapter, highlighting the differences between the paediatric and adult populations. The pathology, epidemiology and clinical protocols for treatment of FBA and its complications are also analysed in detail. The chapter is concluded with a discussion of several design and manufacturing considerations for the subsequent design phase.

2.1 Anatomical Overview

2.1.1 Relevant Anatomy of the Respiratory System

The respiratory system is grouped into two zones according to its function: the respiratory and conducting zone. The respiratory zone is the portion of the airway directly involved in gas exchange, whilst the conducting zone consists of passages for incoming and outgoing air passages (Hickin, 2013). The path of the incoming air is identical for both adults and children; the air is inhaled through the nostrils or mouth, passes through the pharynx, and enters the tracheobronchial tree through the larynx.

The pharynx is a cavity surrounded by skeletal muscles superior to the larynx. The larynx is formed from various cartilaginous structures, which regulate the volume of air permitted to pass between the pharynx and lungs (McFarland, 2009). The primary structure of the larynx is formed from three unpaired cartilages, namely the cricoid cartilage, thyroid cartilage and epiglottis, as seen in Figure 2.1. The cricoid diameter, formed by the ring of the cricoid cartilage, is the narrowest section of the airway (Calais-Germain, 2006). This dimension is dependent on the age of an individual (Sharma, 2014).

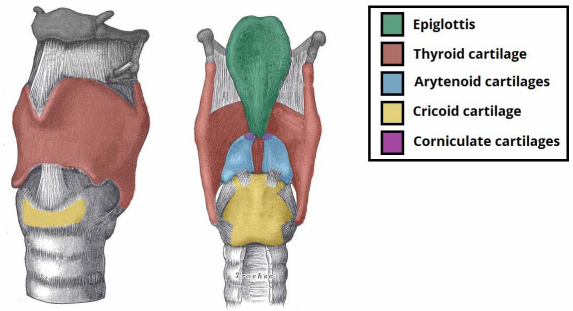

Figure 2.1: Major structural cartilages of the larynx, obtained from (Jones & Barnes, 2018)

The epiglottis is connected to the thyroid cartilage and controls the opening of the trachea (Calais-Germain, 2006). When in the "closed" position, the unattached end of the epiglottis rests on the glottis. When swallowing, the pharynx and larynx lift upward.

This causes the pharynx to expand whilst the epiglottis moves downward, covering the entrance to the trachea (McFarland, 2009). However, the epiglottis does not close when a FB is aspirated, allowing for the FB to enter the airways.

2.1.2 Anatomy and Physiology of the Paediatric Respiratory System

The anatomical features of an adult's lung are substantially equivalent to that of a child. Yet, there are significant differences that affect the approach in which FBs should be removed from the airway. The differences of the respiratory system, anatomicallyand physiologically, are detailed in Table 2.1 and annotated in Figure 2.2 for both the paediatric and adult populations. These differences must be considered for the redesign to fit both the adult and paediatric populations.

Table 2.1
Anatomical and physiological differences between the respiratory systems of adult and child subjects

Anatomy	**Physical difference**
Tongue	An adult's tongue occupies less space in the mouth compared to that of a childt.
Larynx	An adult's larynx is located more posteriorly and inferiorly than that of a child's larynx.
Epiglottis	An adult's epiglottis is more rigid and U-shaped, whilst a child's epiglottis is concave anteriorly, long, flexible and narrow.
Vocal cords	A child's vocal cords are concave anteriorly, whilst lie at 90°to the trachea (horizontal) in an adult's airway. (Harless, Ramaiah, & Bhananker, 2014).
Trachea	An adult's trachea is longer compared to that of a child's trachea. The trachea increases in diameter and length with age.(Wheeler, Wong, & Zingarelli, 2011).
Cricoid cartilage	The narrowest section of a child's airway is the cricoid cartilage ring. Whilst, for adults, the narrowest section is the vocal cords.
Oxygen consumption	Oxygen consumption at rest of an infant is 6mL/kg/min compared to 3mL/kg/min for an adult (Mortensen, Lenz, Abildstrøm, & Lauritsen, 2011).
Carbon dioxide production	Carbon Dioxide production is 100-150mL/kg/min for a child, compared to 60mL/kg/min for an adult (Brambrink & Braun, 2005).
Functional residual capacity	A child's functional residual capacity is 1.8 L compared to 2.9 L in adults (Helliesen, Cook, Friedlander, & Agathon, 1958), this is due to compliance of a child's chest wall and the reduced recoil pressure in the alveoli (Wheeler et al., 2011).
Surface area for gas exchange	An infant has 20 million alveoli individually sized at 150-180 µm m diameter compared to a 8 year old child who has 300 million alveoli individually sized at 250-300 µm diameter (Wheeler et al., 2011).

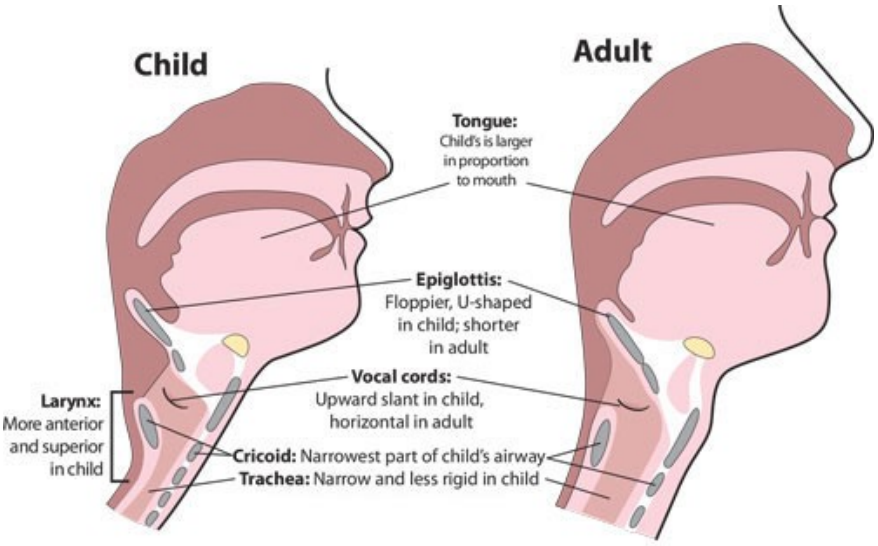

Figure 2.2: Anatomical differences between an adult and child's airway, obtained from (Shocket & Braude, 2017)

Understanding the ventilation requirements of a patient is crucial when designing an airway device. The significant lung volumes and capacities for a human's lung are shown in Figure 2.3. Tidal volume (TV) is the amount of air displaced during passive inspiration and expiration; for infants, the tidal volume is fixed (Roberts & Thornington, 2005). However, a child has a low functional residual capacity (FRC) (Wheeler et al., 2011), defined as the volume of air remaining in the lungs after normal expiration. Therefore, for a child to maintain a fixed TV, it requires more breathing work than an adult. Hence, when ventilating a child, the minute ventilation must be increased, which can be done by increasing the ventilator's frequency (Roberts & Thornington, 2005).

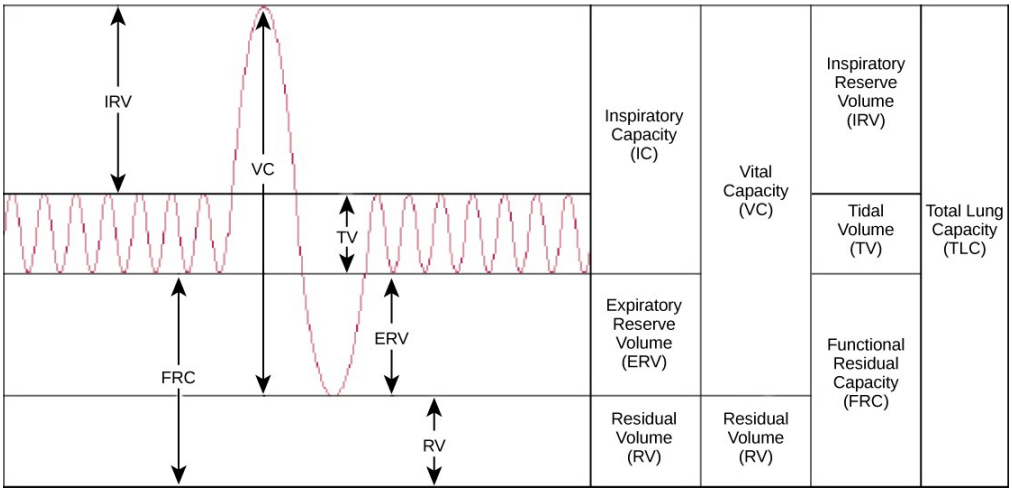

Figure 2.3: Lung volumes and capacity of a human, obtained from (*Breathing Capacity — Biology for Majors II*, 2019)

2.2 Clinical Presentation and Symptoms

Initially, aspirated FBs may be expelled by coughing. However, if the FB continues to move down the airway, it must be retrieved using a bronchoscope and a pair of forceps. FBA symptoms are dependent on the type of FB aspirated, the anatomical location of the FB, the duration of the FB within the airways and the extent of airway obstruction (Lowe et al., 2015). Swelling, bronchial mucosa and obstructive granuloma are apparent for organic FB (Boufersaoui et al., 2013) and FBs that are not removed within 8 days (Grover et al., 2011). To date, there is no formal consensus for a suitable clinical predication model for suspected FBA (Lee, Philteos, Levin, Namavarian, Propst & Wolter, 2021). However, FBA can be categorised into three phases.

Phase 1 involves a choking or coughing episode. After that, for the following 24 hours, the patient will display symptoms of "a cough, noisy breathing, voice change and drooling" (Lowe et al., 2015). If a choking episode is witnessed, there is a greater chance of a quicker and easier diagnosis of FBA (Kim et al., 2015). Phase 1 symptoms are often misdiagnosed, leading to Phase 2 FBA.

Phase 2, also known as the asymptomatic period, is when all phase 1 symptoms are resolved. Patients are often asymptomatic when an FB is stuck in the lower portion of the airways (Sultan & van As, 2016).

Phase 3 involves the development of respiratory complications such as fever, hypoxia and pneumothorax if the FB is not removed. These symptoms are hard to differentiate with pneumonia and bronchial asthma (Grover et al., 2011), causing delayed diagnosis.

2.3 Current Methods of Foreign Body Removal and Limitations Thereof

A bronchoscope is an instrument used to visualise the airway for various medical purposes. It is explicitly used to remove aspirated FBs, observe pulmonary complications within the distal airways, and biopsy removal from a patient's airways. The two types of bronchoscopy instrumentations used currently are the rigid and flexible bronchoscope.

An average of 41 million dollars is spent on inpatient healthcare for FBA (Kim et al., 2015). There is a significant difference between the charges and the actual cost of FBA treatment and management exists. The actual costs are $6720 compared to the charges costing $20820 (Kim et al., 2015). The cost of bronchoscopes, operating theatres and specialised staff account for the charges and cost differences. The rigid bronchoscope is the low-cost alternative (Patel, 2013) compared to the flexible bronchoscope, which hasa high initial purchase cost and repair cost (Fagan & De Groot, 2017).

A bronchoscopy procedure may be emergent or elective, dependent on the specific patient's case. The procedure is performed by a medical specialist, such as a thoracic surgeon or pulmonologist. To confirm FBA, posteroanterior and lateral inspiratory and expiratory chest graphs are captured (Sultan & van As, 2016). Expiratory radiographs are essential because these graphs display air underneath a radio-translucent FB (Sultan & van As, 2016). If the radiograph appears normal, but FBA is suspected, a CT scanis then captured. After that, a patient-specific surgery protocol is developed if deemed positive FBA.

A rigid bronchoscope is used if an FB is confirmed within the airways. Otherwise, a flexible bronchoscope is first deployed within the airways (Grover et al., 2011). The rigid bronchoscope is the preferred method of FB removal; as there is better control of the airway, clear visuals are provided, an array of forceps are available, and larger instruments can pass through the working channel of the rigid scope (Schuhmann, 2017). According to the American Thoracic Society (ATS), the rigid bronchoscope is referred to as the gold standard for bronchoscopy(Sultan & van As, 2016).

During a bronchoscopy procedure, anaesthetic is required to relax the patient's muscles. Therefore, the anaesthesiologist and medical specialist must share the airway. Consequently, the time allocated for the procedure must be kept to a minimum as there is a high risk of hypoxia (S.-J. Chen & Tang, 2012; Chumpathong, Tscheikuna, Boonsombat, Muangman, & Luansritisakul, 2017). Depending on the specific clinical practice, general anaesthesia is essential for both rigid and flexible bronchoscopy (Lowe et al., 2015).

2.3.1 Rigid Bronchoscope

During a rigid bronchoscopy procedure, the patient's neck must be positioned in an anterior flexion position whilst extending of the atlanto-occipital joint (Sharma, 2014), as illustrated in Figure 2.4. The rigid bronchoscope can reach the left or right main bronchi and associated bronchioles by moving the patient's neck accordingly.

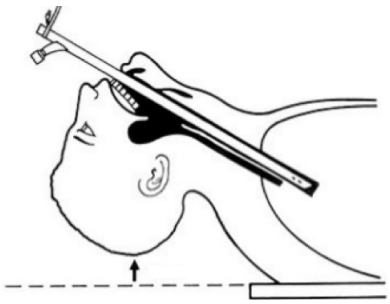

Figure 2.4: Patient's position during a rigid bronchoscopy, obtained from (Preethie Charles, 2015)

Rigid bronchoscopes can be grouped into either a ventilating or venturi rigid bronchoscope. A ventilating rigid bronchoscope attaches to an anaesthetic breathing system, whilst trans-tracheal jet ventilation is used for a venturi rigid bronchoscope (Brownlee & Crabbe, 1997). The venturi rigid bronchoscope is known for complications with carbon dioxide retention and pressure differences.

Rigid bronchoscopes are available in an array of various lengths and diameters. The rigid bronchoscope has attachment ports for auxiliary equipment such as suctioning cannula, forceps, telescope and ventilation, as shown in Figure 2.5. Light is supplied to its distal end to visualise the airway through the telescope placed inside the bronchoscope.

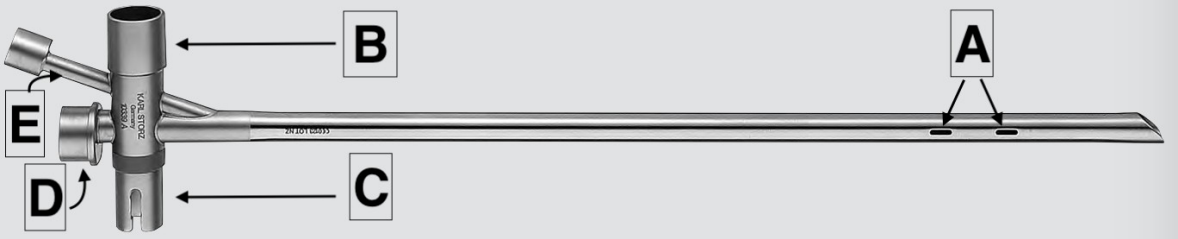

Figure 2.5: Labelled parts of the rigid bronchoscope, A) ventilation vents, B) ventilation port, C) light source port, D) telescope guide, E) suction port, adapted from (*Thorax 3rd EDITION 2 /2011 US*, 2011)

To determine whether the correct bronchoscope size has been chosen for the patient, there must be an audible leak of 20 *cm* H_2O (Sharma, 2014). Forceps pass through the lumen of the bronchoscope to retrieve the FB from the airway. Various forceps distal attachments exist and are chosen to suit the type of FB aspirated and its location (Figueiredo et al., 2012). There is a high risk of the foreign body dislodging and disintegrating into smaller pieces, if the suitable distal forceps ending is not used or the surgeon is untrained for the procedure. This further increases the difficulty in removing the FB.

The rigid bronchoscope is the preferable scope because a surgeon has complete control of the airway when in use. This control is achieved because the rigid bronchoscope functions as an endotracheal tube when placed within the distal portion of the airway (Brownlee & Crabbe, 1997). However, owing to the physical characteristics of the bronchoscope, it cannot navigate inside the upper lobes of the lung.

FB removal and the introduction of the rigid scope may cause notable damage to a patient's airway. If there is significant bleeding, suction catheters are placed through the bronchoscope. Rigid bronchoscopy procedures pose several risks, the most pertinent being hypoxia (Chumpathong et al., 2017-10). Due to the neck position of the patient, as seen in Figure 2.4, ankylosis (immobility) of the jaw or neck can occur post bronchoscopy (Brownlee & Crabbe, 1997).

2.3.2 Flexible Bronchoscope

A flexible bronchoscope is used at first if there is suspected FBA or to evaluate inflammation and bronchial mucosa present within the airways. Flexible bronchoscopes use either fiber optic bundles or a camera to visualise the airways. In the rare case of FBA in adults, flexible bronchoscopes have proven to be more appropriate in cases with less granulation (Sehgal, Dhooria, Ram, Singh, Aggarwal, Gupta, Behera & Agarwal, 2011). A flexible bronchoscope being deployed in a patient is shown in Figure 2.6. The distal end of the device has a flexion range of 210 °(Hsia et al., 2013) in a single plane (Fagan & De Groot, 2017). Thus, when rotated, it can navigate the entire airway without causing significant damage to the patient. A detailed flexible bronchoscope is displayed in

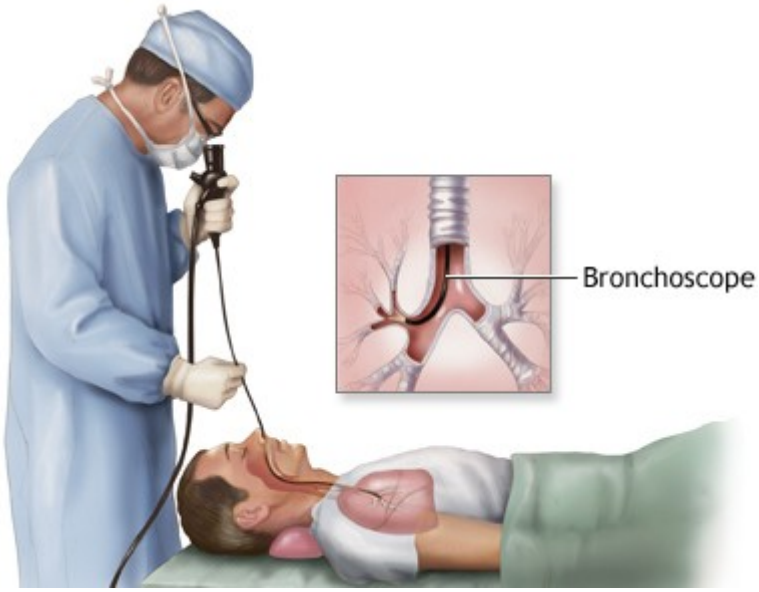

Figure 2.6: A flexible bronchoscope within the patient's airways, obtained from: (*Bronchoscopy: MedlinePlus Medical Encyclopedia*, 2020)

Figure 2.7. If the FB is located within the upper airways, topical anaesthesia may be used during spontaneous breathing of the patient, despite any discomfort experienced (Nicolai, 2001). However, if the FB is located within the lower portion of the airway, deep sedation or general anaesthetic is essential to ensure optimal removal conditions and patient comfort for FB removal.

Flexible bronchoscopes are available in a finite range of diameters with limited forceps ending types, resulting in difficulty retrieving the FB. Due to its small diameter and lack of ventilation supply, occlusion occurs easily, primarily in cases where granulation and other obstructions are present (Fagan & De Groot, 2017). The flexible scope is more expensive, costing £16000 for an entire unit (including the portable monitor) and requires a more skilled clinician than the rigid scope. There is also a high risk of FB dislodgement further within the airways when a flexible bronchoscope is used (Kim et al., 2015).

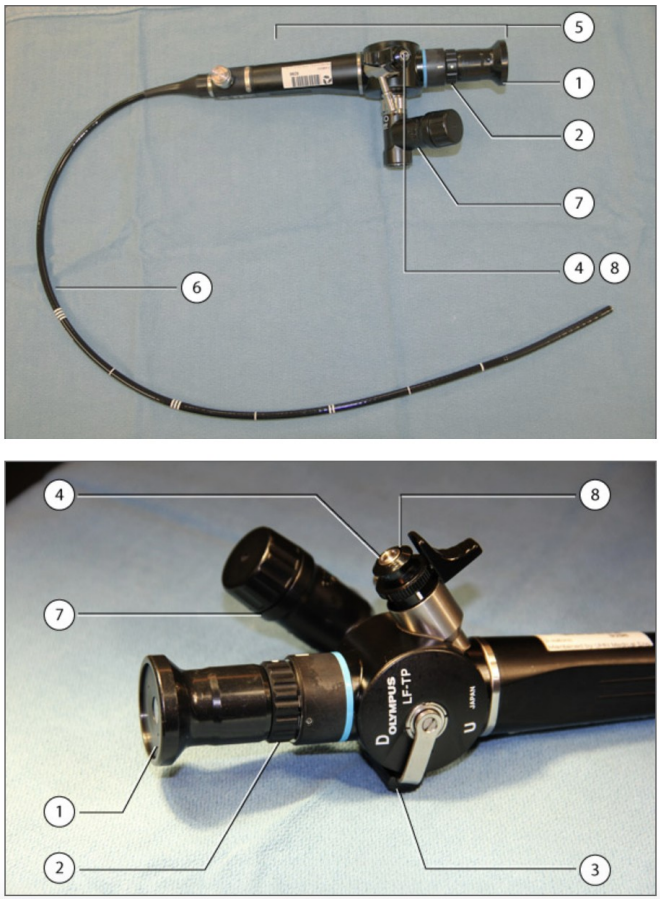

Figure 2.7: Flexible bronchoscope and its labelled parts: 1) eyepiece, 2) focus ring, 3) control lever for the distal end, 4) working channel, 5) body including the previous four parts, 6) insertion cord, 7) light source, 8) suction valve and port, obtained from: (Cooper & Ellard, 2012)

2.4 Design Considerations

A set of design considerations was determined before manufacturing an initial video-assisted tube-over-tube rigid bronchoscope. A set of design requirements was determined through an analysis of the current bronchoscopes and limitations thereof. Financialfactors were taken into consideration when looking at the materials, manufacturing and the various methods of ventilation and imaging. Each design decision and requirement determined was aligned with the aim and objectives of this research.

2.4.1 Sizes and Dimensions

Bronchoscopes are designed to accommodate the anatomical features of a patient's airways. The narrowest section of the airway limits the external diameter of the bronchoscope. This dimension is different for both the paediatric and adult populations. The narrowest section of a child's airway is the cricoid airway diameter, tabulated in Table 2.2 for various age groups.

Table 2.2
Cricoid airway diameters for various paediatric age groups, obtained from (Sharma, 2014)

Age	Cricoid airway diameter (mm)
Premature	4.0
Term new-born	4.5
6 months	5.0
1 year	5.5
2 years	6.0
3 years	7.0
5 years	8.0
10 years	9.0
14 years	11.0

In line with the scope of this research, a tube-over-tube rigid bronchoscope is required to be designed and tested. Therefore, an analysis of the rigid bronchoscopes available was done. Dimensions of the standard rigid bronchoscopes for each age group is shownin Table 2.3. The lengths of these scopes are between 16 - 30 cm long, with the internal diameter ranging from 3.2 - 7 mm (Sharma, 2014). The left-facing bevel at the distal end of the bronchoscope is essential during insertion, as it aids in lifting the epiglottis, which allows the bronchoscope to pass through the vocal cords (Fagan & De Groot, 2017).

Table 2.3
Bronchoscope's dimensions used according to the patient's age, obtained from (Fagan & De Groot, 2017) and (Patel, 2013)

Age	Internal diameter (mm)	External diameter (mm)
1 - 6 months	3.0	5.0
6 - 18 months	3.5	5.7
18 months - 3 years	4.0	7
3 - 6 years	4.5	7.7
6 - 9 years	5.0	7.8
9 - 14 years	6.0	8.2

There are four leading manufacturers of the current bronchoscopes, namely, Karl Storz (Germany), Richard Wolf (Germany), EFER Endoscopy (France) and Novatech (France). Since the initial introduction of rigid bronchoscopy, there have not been any significant design changes (Diaz-Mendoza, 2018). However, there have been minor improvements, such as universal ports for the EFER Endoscopy bronchoscope (Dutau, Vandemoortele, & Breen, 2013). Another modification has been a way to measure the oxygen and carbon dioxide levels in conjunction with the expiratory and inspiratory pressures of the patient for the Richard Wolf bronchoscope (Schuhmann, 2017).

2.4.2 Material Specifications, Repair and Maintenance

Single-use devices cannot be reused and discarded after initial use, whilst reusable products can be used multiple times and have a finite, moderate lifespan.

The rigid bronchoscope is currently reusable and requires sterilisation after each use. The rigid bronchoscope is made of medical-grade stainless steel, demonstrating high durability. However, the device can easily damage the patient's airway because of the sharp bevelled end and the material's rigidity. Therefore, care must be taken when using the device to avoid trauma to the patient's teeth, lips, tongue and airway(Alraiyes & Machuzak, 2014). Because of its durability, the scope can be sterilised using autoclave methods where cross-contamination is non-existent (Mehta et al., 2005). There are few hidden costs, due to a simple, convenient maintenance plan. The rare incidence of the rigid bronchoscope being damaged or defected can be easily replaced owing to its affordability.

The flexible bronchoscope is a delicate device that can navigate the entire airway but can be easily damaged in the preparation, handling, cleaning, or storing of the device (Rozman, Duh, Petrinec-Primozic, & Triller, 2009). The costly flexible bronchoscopeis either reusable or single-use. The single-use flexible bronchoscope (retails for £220)is more cost-effective compared to the latest reusable flexible bronchoscope (retails for £249) (Mankikian et al., 2014). The reusable bronchoscope has multiple hidden costs including complex, time-consuming, delicate disinfection methods (Mehta et al., 2005), frequent repair costs due to inexperienced usage and routine wear and damage (Rozman et al., 2009) as well as the treatment of cross-contamination. The actual cost of the reusable flexible bronchoscope is approximately £511 (Mankikian et al., 2014).

Reviewing the preceding literature, the novel bronchoscope and its accessory instruments must be made of a biocompatible material, demonstrate high durabilityand either be single-use or have a user-friendly sterilisation protocol in place. The Ciaglia Blue Rhino ® G2, a percutaneous tracheostomy introducer, is made of rigid, durable blue opaque polyurethane (Spence, 2014) and demonstrates little to no resistance during insertion. This characteristic is achieved through its hydrophilic coating (Byhahn, Lischke, Halbig, Scheifler, & Westphal, 2000) and distal longitudinal grooves (*Ciaglia Blue Rhino G2* , 2020). The material demonstrates high durability whilst remaining slightly flexible. These features and material composition will be trialled in the prototype and testing phase to see if similar properties can be achieved with the designed device.

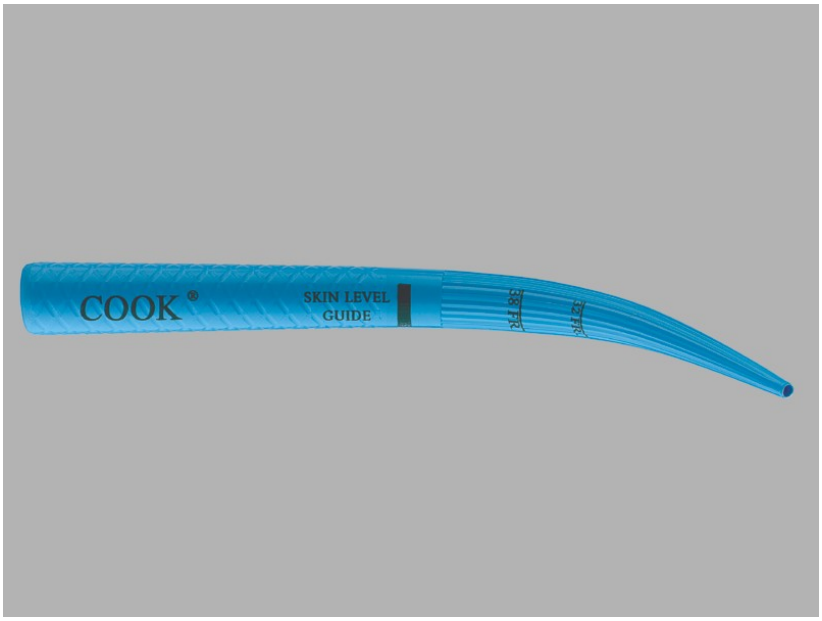

Figure 2.8: Ciaglia Blue Rhino ® G2, a percutaneous tracheostomy introducer, obtained from (*Ciaglia Blue Rhino® Advanced Percutaneous Tracheostomy Introducer Sets and Trays — Cook Medical*, 2020)

2.4.3 Anaesthesia Methods

The majority of the hospitals worldwide are performing bronchoscopy procedures, both flexible and rigid, under general anaesthesia instead of sedation. Not only does general anaesthesia provide additional comfort to the patient, but it is also more safe for the patient whose airway is already compromised with the FB obstruction and its associated symptoms, as well as the inserted bronchoscopy instrumentation (Balfour-Lynn & Spencer, 2002). Preoperative planning and effective communication between the anaesthetist and bronchoscopist are essential to ensure a safe and successful procedure (Alraiyes & Machuzak, 2014).

The choice of delivery for general anaesthesia is either between inhalational anaesthesia or total intravenous anaesthesia (TIVA). There are high risks associated with inhalational anaesthesia due to leakage and exposure to personnel. Therefore, TIVA is recommended (Diaz-Mendoza, 2018). Nevertheless, the choice of anaesthetic will be a patient-specific decision, considering the patient's medical history, symptoms, and procedure-related factors.

2.4.4 Ventilation Methods

Various ventilation modes can be used for bronchoscopy, with none of them more superior than the other (Diaz-Mendoza, 2018). The choice of ventilation is based on the preference of the surgeons and anaesthesiologists. The three types of ventilation used in bronchoscopy procedures are controlled ventilation, spontaneous-assisted ventilation and jet ventilation, which are detailed and compared in Table 2.4.

Table 2.4
Comparison of different ventilation methods, information adapted from (Diaz-Mendoza, 2018) and (Alraiyes & Machuzak, 2014)

Type of ventilation	Description	Typically associated with	Requirements
Spontaneous -assisted ventilation	Pressure controlled, work is shared between the muscles of the patient and ventilator	TIVA	-Dependent on patient's breathing capability -Assistance required from medical personnel
Controlled ventilation	Pressure or volume control ventilation	Neuromuscular blockade	-Semi-closed circuit desirable to minimise leakage -Manual assistance sometimes necessary
Jet ventilation	-Jet ventilation: 10-14 breathes/minute with 50 psi -High-frequency jet ventilation: 60-300 breathes/minute with 12-18 psi	Paralysis of patient	-An open circuit

Ventilation is crucial during bronchoscopy; one in four patients experience hypercarbia and/or hypoxemia during a bronchoscopy procedure (L. H. Chen et al., 2009). Spontaneous-assisted ventilation will be the chosen ventilation method for the designed bronchoscope, as it is associated with TIVA, the safest method of anaesthesia. However, the ability to switch over to another mode of ventilation will be considered in the design for increased usability for a range of patients.

There are several delivery methods for ventilation either through a mask, nasally, an endotracheal tube and a bronchoscope (proximally through the inlet and distally through the ventilation slots). An endotracheal tube is an easy and effective means of ventilation, and most general medical professionals can implement this technique.

Barneck, Webb, Robinson, & Grimmer (2016) conducted a study analysing the flow dynamics in paediatric bronchoscopes compared to equivalent diameter endotracheal tubes, using computer-aided design (CAD) modelling software. Pressure and volume-controlled ventilation were implemented in a flow simulation.

The flow resistance was determined using the Navier Stokes Equation for the endotracheal tube and bronchoscope. Turbulent airflow consists of chaotic eddies and vortices, increasing airflow resistance. An increase in pressure is required to counteract this resistance and produce an equivalent volume flow rate.

The simulated flow produced in the endotracheal tube was steady and laminar with negligible turbulence. However, the flow in the rigid bronchoscope was only laminar near the inlet but rapidly changed to a turbulent flow throughout the length of the bronchoscope (Barneck et al., 2016). When the telescope was inserted, the turbulence of the flow was further increased, thus decreasing the volume flow rate through the bronchoscope. Interestingly, the airflow resistance was greater for volume-controlled ventilation than pressure-controlled ventilation.

From this study, it is clear that the anatomical curve and the length of the endotracheal tube contribute to efficient oxygen delivery. There are two types of endotracheal tubes: cuffed and uncuffed endotracheal tubes. Cuffed endotracheal tubes have a balloon at its distal end to form an airtight seal within the airway, whereas an uncuffed endotracheal tube has no balloon. An uncuffed endotracheal tube is recommended for the paediatric population due to the low risk of airway damage from high pressure. The design features of an uncuffed endotracheal tube are shown in Figure 2.9 .

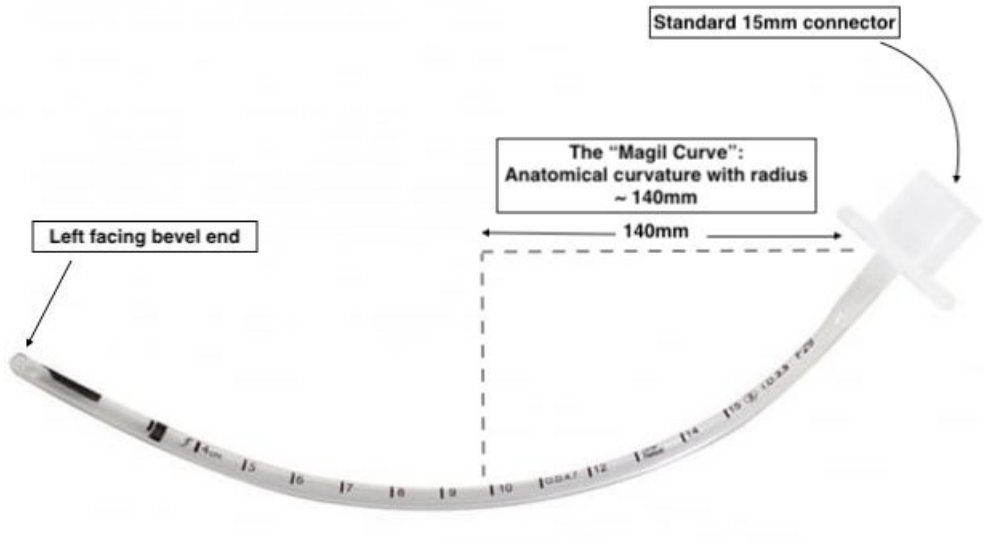

Figure 2.9: Features of a standard uncuffed endotracheal tube, original image obtained from (*Uncuffed Endotracheal Tubes — ET Tubes — DS Medical*, 2018)

Endotracheal tubes come in an array of sizes to fit the airways of neonates to the adult population. The size and length guide for the correct endotracheal tube for a particular age group is shown in Table 2.5.

Table 2.5
*Endotracheal tube size and length guide, obtained from (*Tracheal Tubes - A Guide To Size and Length*, 2009)*

Demographic	Size/Age	ID (mm)	OD (mm)	Length (cm)
Neonates	0.7 - 1.0 kg	2.5	3.4	7.5
	1.6 - 2.0 kg	3.0	4.2	10.5
	3.1 kg +	3.0	4.2	10.5
Paediatrics	2- 3 years	5.0	6.8	13.0 - 13.5
	4 - 5 years	5.5	7.4	14.0 - 14.5
	6 - 7 years	6.0	8.2	15.0 - 15.5
	8 - 9 years	6.5	8.8	16.0 - 16.5
	10 - 11 years	7.0	9.6	17.0 - 17.5
	12 - 13 years	7.5	10.2	18.0 - 18.5
	14 - 15 years	8.0	11.0	21.0
Adults	Adult Female	7.5 - 8.0	10.2 - 11.0	21.0
	Adult Male	8.5 - 9.5	11.6 - 13.0	22.0 - 23.0

The design will include the standard uncuffed endotracheal tube's characteristics to ensure adequate oxygen delivery to patients through a bronchoscope. Not only will this significantly reduce the airflow resistance, but it will also increase the usability of the device as there would be no need for extensive training to use the medical device.

2.4.5 Imaging Methods

Clear visualisation of a patient's airway throughout bronchoscopy is critical for surgeons to perform a safe and successful procedure. Traditionally, flexible bronchoscopes are madeup of a' delicate bundle of optical fibers that produce visuals of the distal airways through delivering light'. However, the imaging produced by the flexible fiberoptic bronchoscope is inferior compared to the imaging obtained from the fiberoptic Hopkins rod used in rigid bronchoscopy (Balfour-Lynn & Spencer, 2002). Although some bronchoscopes still utilise this form of image capturing, modern bronchoscopes use image sensors that convert light waves into digital signals to produce an image.

Due to the camera technology advancements used in cellphones, digital endoscope cameras have benefited in their small size and increasing capabilities, in parallel to being cost-effective for uses across multiple industries (Leiner, 2015). Digital cameras have exceeded the capabilities of basic analogue cameras by providing a higher image resolution and quality whilst being smaller in size. Lightning is provided by a set of Light Emitting Diodes (LEDs), where their brightness can be adjusted accordingly to a user's preference.

Two image sensors are used in digital cameras, namely a complementary metal-oxide-semiconductor (CMOS) and a charge-coupled device (CCD). Both sensors consist of pixels made up of three photosites that convert light into a charge. Both sensors implement the same basic principles, as illustrated in Figure 2.10, to produce an image/video. CMOS sensors provide a low-cost alternative solution compared to CCDs without compromising the image quality (Golden & Ligler, 2002).

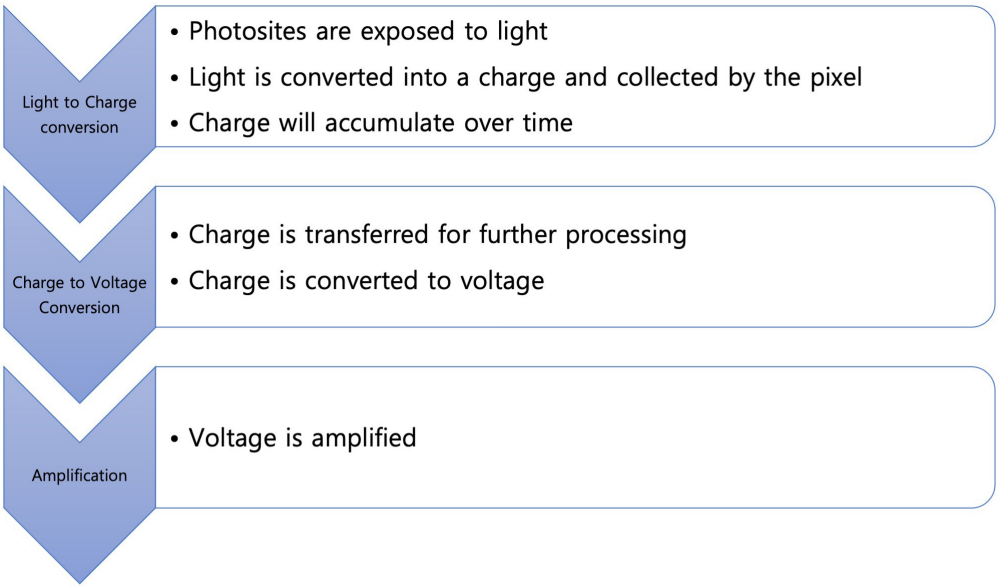

Figure 2.10: The conversion process of basic imaging sensors

Accessibility to CMOS endoscope cameras with LEDs has improved drastically over the past few years. Image transmission is either through wires or a wireless connection via WIFI or Bluetooth. Real-time imaging is displayed on either monitors, tablets or cellphones. These cameras come in various sizes, with some as small as 1.18mm. The smaller the camera, the higher the price of the endoscope. Endoscope suppliers differ drastically in cost, with private medical manufacturing companies costing at the higher end of $9700, compared to online commerce stores such as Alibaba.com retailing at $680for the smallest in diameter endoscopes range. The cheapest endoscope, with an LED setup and connection to a phone and/or tablet screen, will be considered for this study's requirements.

2.5 Manufacturing Considerations

To ensure rapid and cost-effective prototyping, 3D printers provided by UCT's Medical Device Lab were utilised. Once the design and concept of each subsystem of the device were finalised, the material and the manufacturing process was determined. Throughout this process, clinical interaction was maintained to ensure a successful device.

Subsystems that required machining were sent to UCT's workshop, whilst the subsystems which required moulding was completed in the Medical Device Lab. Each design decision considered the usability and limited budget without compromising the quality and efficacy of the designed device.

3 Design Methodology

Within this chapter, the design of the FB retrieval system is detailed. However, before designing the FB retrieval system, system parameters were identified and defined for a successful design process. After that, the design of each subsystem was considered and detailed. The initial system parameters were determined through the literature review and analysis of the existing technologies. The parameters that would determine the success of the FB retrieval system are shown in Table 3.1.

Table 3.1
System parameters and specifications

Parameter	**Specification**
External diameter	The external diameter of the system is restricted by the cricoid cartilage. Premature babies have a cricoid airway diameter of 4.0 mm (Sharma, 2014). Therefore, the system must account for this dimension depending on the patient's age.
Working length	The system must be of an appropriate length, between 16 - 30 cm (Sharma, 2014), to navigate the entire airway.
Safety of the patient	The system must provide constant ventilation and ensure that the oxygen saturation levels never drop below 92 % to a point of hypoxia (Majumdar, Eurich, Gamble, Senthilselvan, & Marrie, 2011).
Working channel	The working channel (lumen of the scope) provided by the device must allow for the existing forceps to pass through.
Image transmission	A light source is essential at the end of the scope for clear viewing of the patient's airway. A suitable CMOS endoscope camera must be used and transmit real-time imaging of high quality and displayed on the screen of a smart device.

3.1 Design of Subsystems

The FB retrieval system was broken down into several subsystems, namely the Visualisation Subsystem (VS), Ventilation Connector Subsystem (VCS), Bronchoscope Subsystem (BS) and Foreign Body Extraction Subsystem (FBES), as shown in Figure 3.1. Each subsystem influences the overall functioning of the entire device and, in turn, its efficacy. The design process was iterative to allow for rapid prototyping and correctany design and functional errors within each subsystem.

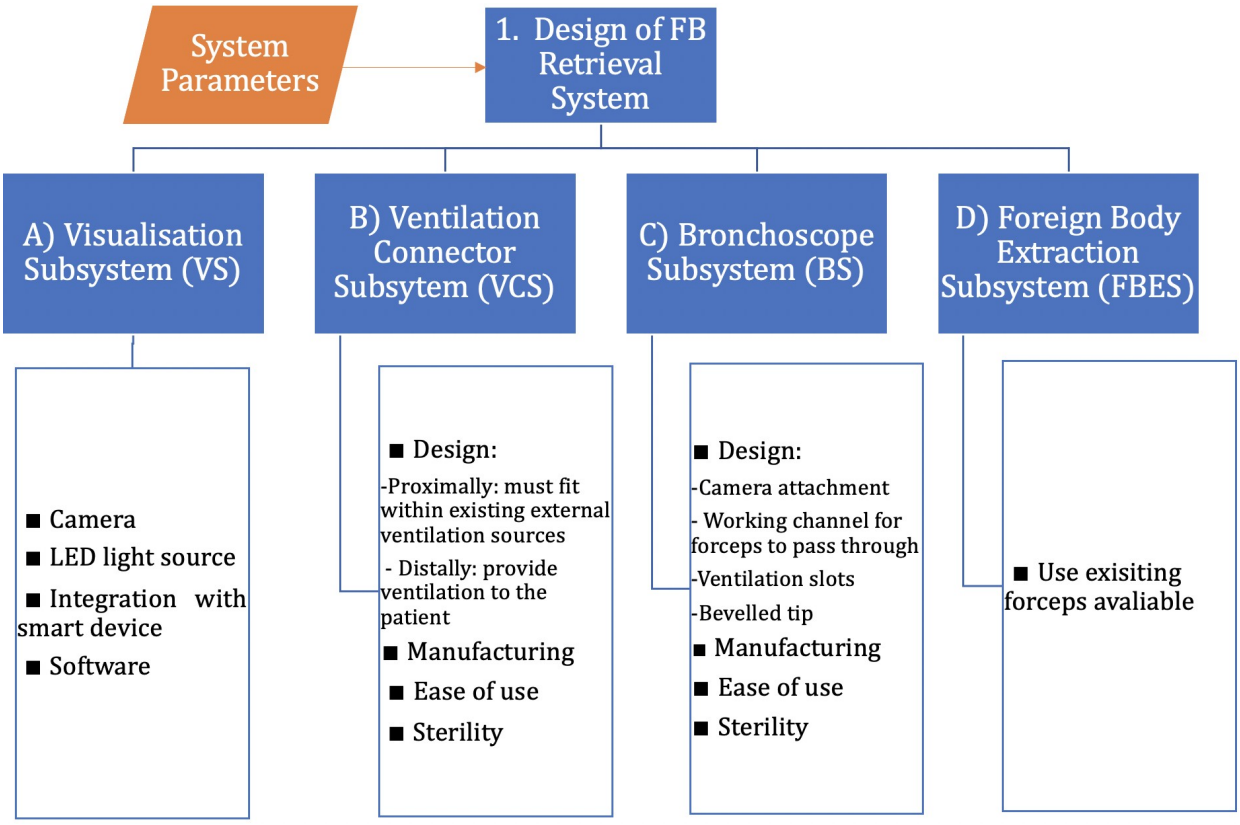

Figure 3.1: Design methodology of the FB retrieval system

3.1.1 Visualisation Subsystem (VS) Design

Real-time imaging of the workspace, being the patient's airways, will be provided by the Visualisation Subsystem (VS), situated at the distal end of the bronchoscope subsystem (BS). The visuals produced from the camera would be displayed on a screen of a smart device, allowing for recording and capturing images of the entire bronchoscopy procedure. Design considerations of the VS, based on the overall system's requirements, are listed below:

- Image quality: Clear and precise real-time imaging of the airway is required throughout the procedure.
- Image transmission: Reliable transmission of the captured video must be seamless, without any lagging, whilst being displayed on the screen of a smart device.
- Camera connection accessibility: The ability of the camera to easily connect to a range of smart devices, ranging from IOS to Android operating systems, is essential to ensure the usability of the device.
- Camera dimensions: The external diameter of the camera must be as small as possible without causing a significant increase in the overall price of the device.

- Camera availability: The camera must be readily available on a mass-production scale.
- Attachment to BS: The camera system must be fitted securely to the distal end of the BS.
- Light source: Light must be provided distally to ensure that the camera can function under low light conditions within the airway.
- Sterility: The entire VS should be reusable and have the ability to be sterilised using the current sterilisation methods available at hospitals.
- Camera field of view (FOV): A sufficient FOV of the airway and aspirated FB is essential to ensure a successful procedure.

3.1.2 Ventilation Connector Subsystem (VCS) Design

The current bronchoscopy instrumentation poses a high risk of hypoxia to the patient, which makes the procedure unsafe for the patient and results in increased difficultly for surgeons to perform. A means to provide constant ventilation is required. Therefore, the design considerations for the Ventilation Connector Subsystem (VCS) includes:

- Proximal connection to existing ventilation sources: Ventilation should be easily integrated with current ventilation methods available across all hospital levels.
- Ventilation pathway: Adequate ventilation (spontaneous-assisted ventilation) must reach the distal portion of the airways during TIVA.
- Sterility: If the subsystem is reusable, easy sterilisation methods are required; else, the subsystem must be discarded after each use.
- Integration with the BS and VS: Ventilation must be supplied to the patient throughout the Bronchoscope Subsystem (BS) (and attached VS) deployment. Seamless integration between these subsystems is essential.
- Material consideration: The material chosen must display suitable durability and biocompatibility whilst being readily available, easy to manufacture and affordable.
- Ease of use: The addition of this subsystem should be user friendly and not cause additional complications to the procedure.

3.1.3 Bronchoscope Subsystem (BS) Design

The Bronchoscope Subsystem (BS) will incorporate the critical design features of the current bronchoscopes. However, the BS will differ in its increased usability and availability compared to existing scopes. This will be achieved through completing the following requirements in the design of the BS:

- Proximal connection to existing ventilation sources: The BS must easily integrate with ventilation methods currently available across all hospital levels.
- Ventilation pathway: Adequate ventilation must reach the entire length of the airway through the BS during TIVA.
- Working channel for FBES (Foreign Body Extraction Subsystem): The design of the BS must include an appropriately sized working channel for the FBES to pass through.
- Attachment of VS (Visualisation Subsystem): The design of the BS must provide a means of secure attachment of the VS to its distal end.
- Material considerations: The material chosen must display suitable durability and biocompatibility whilst being readily available, easy to manufacture and affordable.
- Ease of use: The BS must allow for any general medical professional, with basic knowledge of endotracheal tube intubation, to perform a bronchoscopy.
- Dimensions: The diameter and length of the BS must consider the anatomical dimensions of the airway.
- Sterility: If the subsystem is reusable, easy sterilisation methods are required; else, the subsystem must be discarded after each use.

3.1.4 Foreign Body Extraction Subsystem (FBES) Design

The current forceps used in conjunction with the rigid bronchoscope will be incorporated as its own subsystem. No redesign of the current rigid forceps was necessary, as there are various distal end attachments of the forceps which can retrieve a range of aspirated FBs with ease, as shown in Figure 3.2. However, an essential requirement of this Foreign Body Extraction Subsystem (FBES) is:

- Integration with the BS (Bronchoscope Subsystem) and VS (Visualisation Subsystem): The FBES must successfully work in conjunction with the BS (and attached VS).

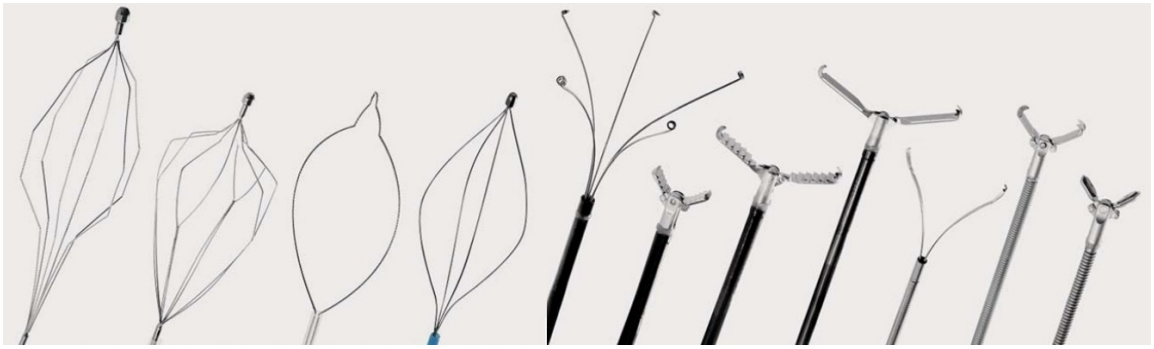

Figure 3.2: Various distal endings for rigid bronchoscope, obtained from (Birk et al., 2016)

4 Design Outcomes

This chapter details the outcomes based on the requirements and specifications highlighted in Section 2.4 and Chapter 3. Before analysing each subsystem, a summary of how the entire FB retrieval system is detailed. Each subsystem went through several design iterations until a final working prototype was developed; this is briefly described in the subsequent sections.

4.1 Design Overview

The system would be classified as a medium risk device. The device would require two clinicians to operate. One clinician would navigate the device through the patient's airway and remove the FB using a pair of forceps, whilst the other clinician would assist. The procedure will require general anaesthetic and a source of ventilation. The ideal position of the patient is anterior flexion of the neck region and extension of the atlanto-occipital joint, whilst the patient lies horizontally on a hospital bed.

The FB retrieval system is broken down into its subsystems and associated components in Figure 4.1 and annotated accordingly in Figure 4.2. The system will incorporate an uncuffed endotracheal tube (B.1) as part of the Ventilation Connector Subsystem (B). This is done to increase the bronchoscope's usability and safety, detailed further in the following section.

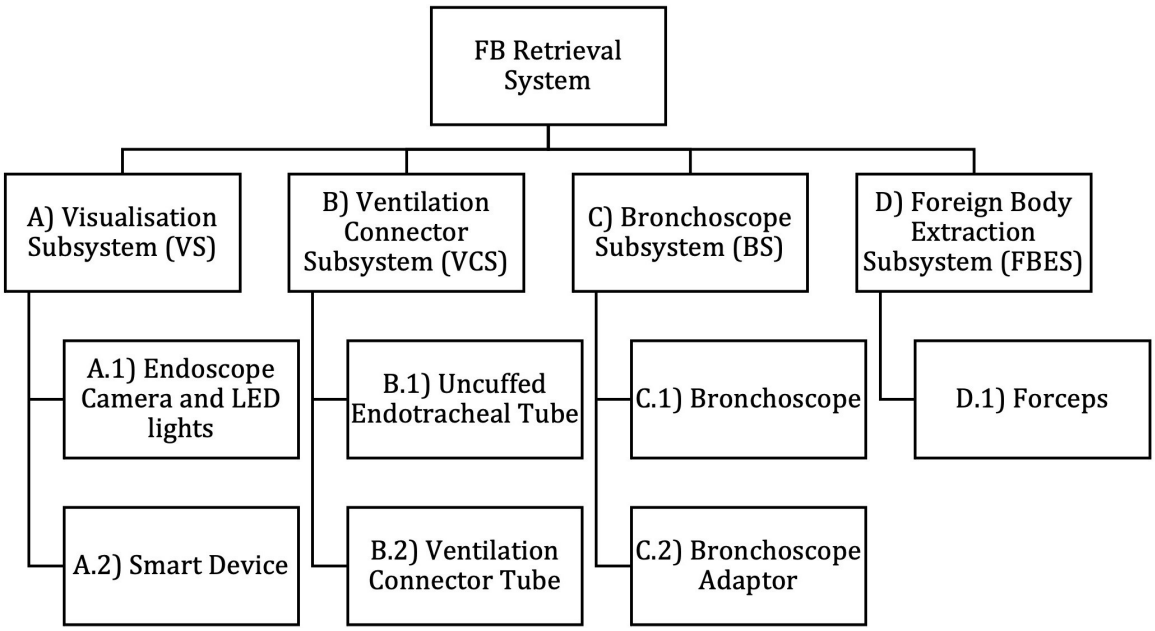

Figure 4.1: The FB retrieval system and its subsystems

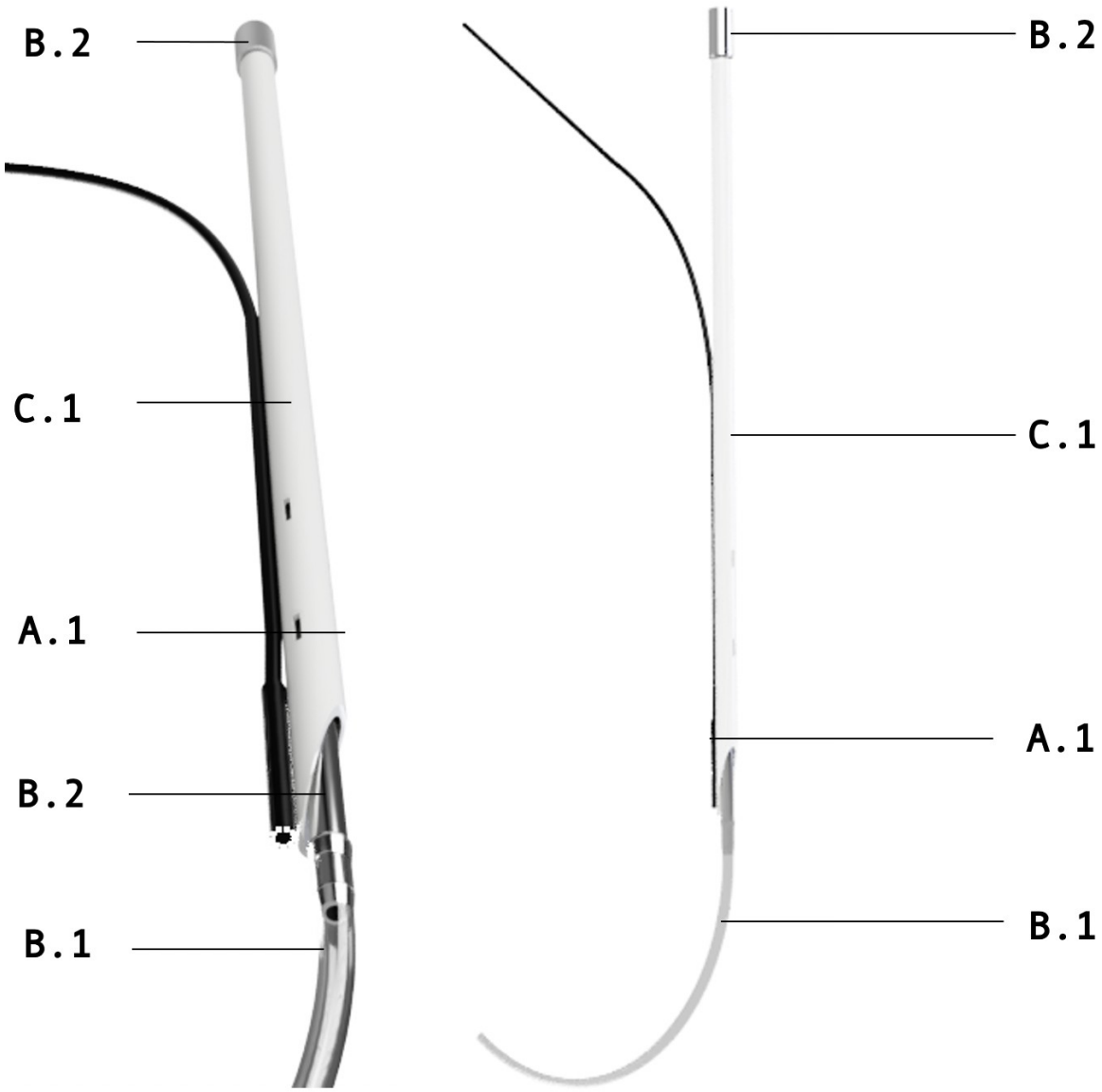

Figure 4.2: The labelled FB retrieval system and its subsystems (The smart device (A.2) and forceps (D.1) are not displayed in this Figure)

The device's working and how each subsystem works in conjunction with one another is shown in a process flow diagram in Figure 4.3, where the red dotted line depicts the patient's airway and how far the device is within the airway. (Note, anything above this line is outside the patient's airway, whilst anything below this line means that the device is within the patient's airway)

The working of the device, as shown in Figure 4.3, is detailed on the following page:

(i) The ventilation connector tube (B.2) will first be connected to a ventilation source at its proximal port. The bronchoscope (C.1) will then be placed over the ventilation connector tube (B.2). During this time, the patient will be anaesthetised, and the patient will be ventilated using a mask.

(ii) The uncuffed endotracheal tube (B.1) will be inserted into the patient's airways. A laryngoscope may be necessary for ease of insertion of the uncuffed endotracheal tube (B.1).

(iii) The distal end of the ventilation connector tube (B.2) will be securely placed within the proximal opening of the uncuffed endotracheal tube (B.1). This connection will be secured with medical tape. The ventilation flow through the endotracheal tube end (B.1) should be confirmed before moving to the subsequent step.

(iv) The ventilation connector tube (B.2) must be held stationary above the patient, whilst the bronchoscope (C.1) slides over the ventilation connector tube (B.2) and endotracheal tube (B.1), until reaching the carina of the trachea. Visualisation will be provided using a camera and LED light source (A1) attached to the distal endof the bronchoscope (C.1). This will allow for real-time imaging of the workspace during insertion and be displayed on the screen of a smart device (A.2).

(v) The entire VCS (B.1 & B.2) may then be removed from the patient's airways. The bronchoscope (C.1) and attached camera and LED setup (A.1) will remain within the patient's airways.

(vi) A bronchoscope adaptor (C.2) will be connected to the ventilation source and securely placed into the proximal opening of the bronchoscope (C.1). The forceps (D.1) may then be placed inside the bronchoscope's working channel, through the port of the bronchoscope adaptor (C.2). Finally, the FB can be retrieved using the forceps (D.1). Once the FB is held by the forceps' teeth, the BS and forceps (and FB) can be removed from the patient in unison. The FB is often more prominent than the lumen of the BS. Therefore, the forceps and FB should never pass through the lumen and always be in front of the bronchoscope tip during removal.

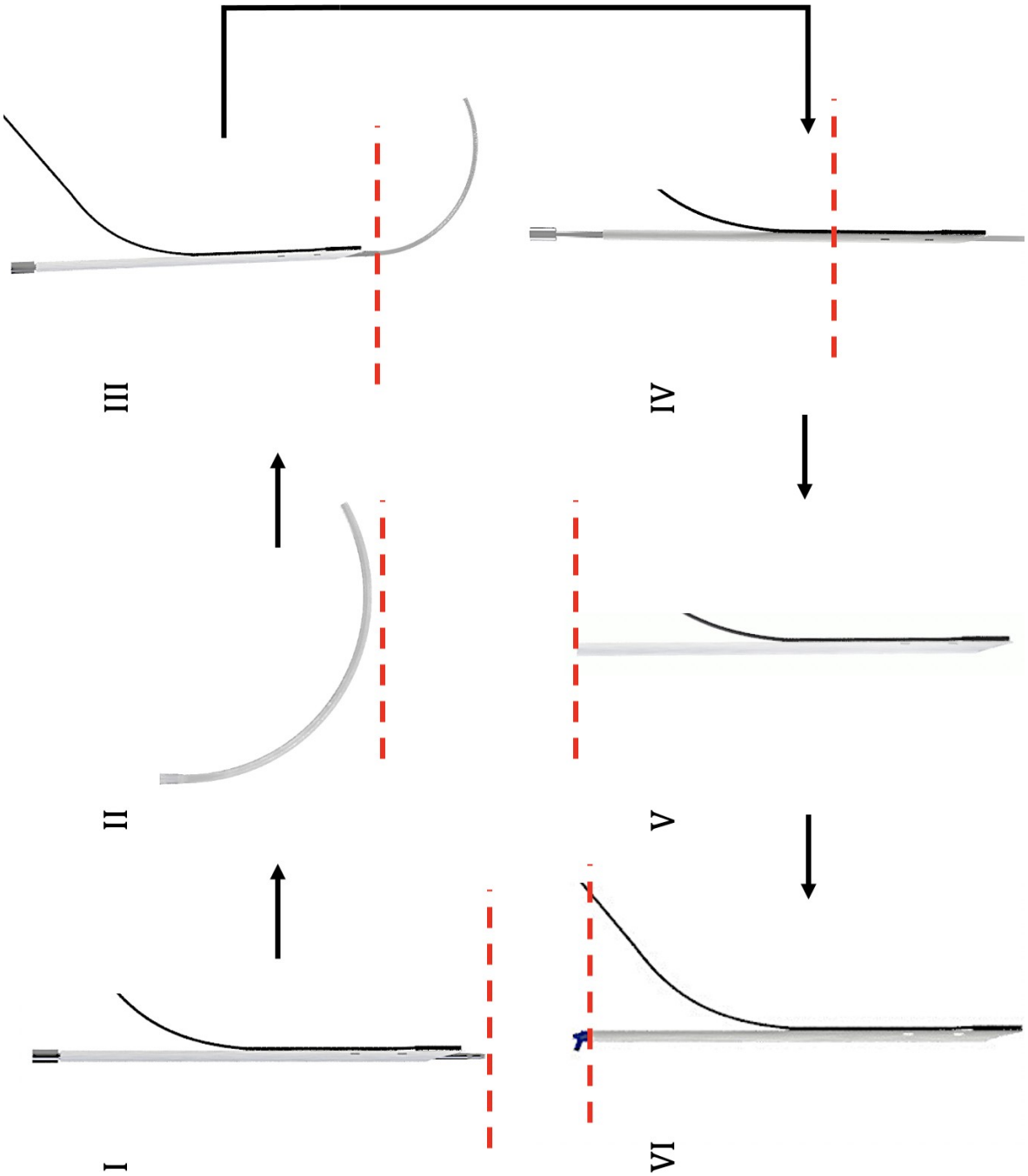

Figure 4.3: Flow process of the working of the device and its subsystems

4.2 Visualisation Subsystem (VS)

The Visualisation Subsystem (VS) and its components, camera with a LED light source (A.1) and smart device (A.2), are annotated in Figure 4.4. The camera and LED light source (A.2) must be user friendly and provide reliable, real-time imaging of the airways displayed on the screen of a smart device (A.1). This requirement is essential for successful bronchoscopy procedures, as this is the only means to view the airway and aspirated FB. The entire VS is proposed to be reusable and will be sterilised using existing methods available at all hospital levels.

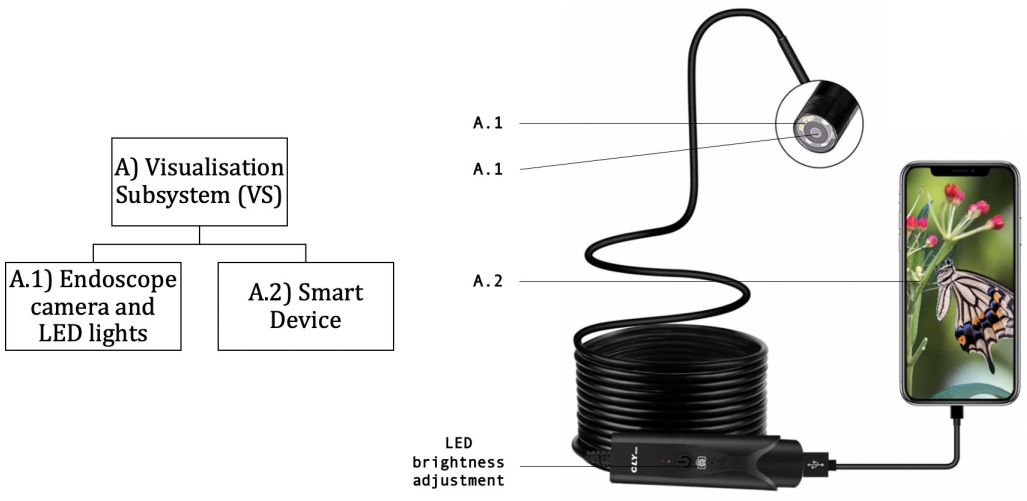

Figure 4.4: Visualisation subsystem and its components: A.1) LED light source, camera and LED brightness adjustment dial A.2) connected smart device

4.2.1 Camera and LED Light Source (A.2)

An IP67 waterproof, off-the-shelf, endoscope camera was attached to the distal end of the Bronchoscope Subsystem (BS). The visuals produced were transmitted to a smart device's screen via a USB C, USB A or micro-USB connection, allowing it to connect to both IOS and/or Android operating systems. The LED light brightness could be adjusted using the dial situated on the proximal end of the camera's wires.

A 5.5mm external diameter endoscope camera with 6 LED lights was deemed the most cost-effective for this study. It was initially used in preliminary testing to determine the correct camera placement. Therefore, the working prototype was initially designed for the adult female/teenage population. This was the most frugal, time-saving and easily manufacturable solution for the initial design phase of the device, given the resources available at UCT and allocated budget and time. However, the anatomical requirements and limitations of the paediatric population were considered in each design decision.

The best camera placement was on the bevelled end side, which was determined through preliminary testing on cadavers, with the user being an experienced anaesthesiologist. A 1.65mm external diameter endoscope camera surrounded by LED lights was sourced for the experimental testing to decrease the overall outer diameter of the device to fit within the airway of the respiratory mannequin.

4.3 Ventilation Connector Subsystem (VCS)

The Ventilation Connector Subsystem's (VCS) main requirement is to provide a means of constant ventilation through connecting to existing ventilation sources. The system's design must also allow for any trained surgeon to operate regardless of prior bronchoscopy experience. The VCS and its two components (B.1 & B.2) work as a complete unit. Figure 4.5 shows the ventilation connector tube's distal ending inside the proximal port of the uncuffed endotracheal tube, which will be secured with medical tape.

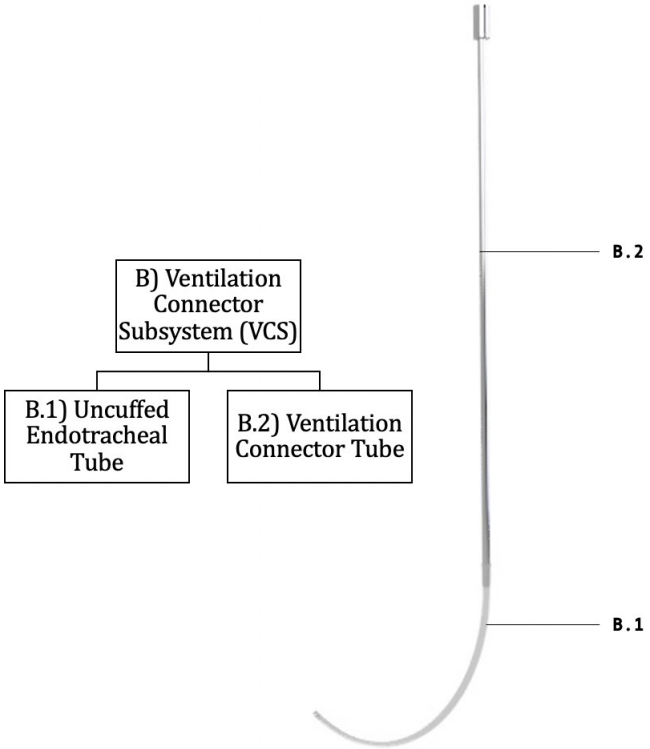

Figure 4.5: The ventilation connector subsystem (VCS) and its components: B.1) uncuffed endotracheal tube and B.2) ventilation connector tube

4.3.1 Uncuffed Endotracheal Tube (B.1)

Due to its anatomical curvature, every general medical professional has the basic ability to intubate a patient using an endotracheal tube (ETT). Thus, there would be no need for extensive training to use the designed bronchoscope if it were to be incorporated into the functioning of the device.

Additionally, an ETT provides sufficient ventilation to a patient instead of the rigid bronchoscope, as highlighted in Barneck, Webb, Robinson, & Grimmer (2016)'s study. Thus, to increase the usability and safety of the device, an uncuffed endotracheal tube will be used as a guiding mechanism for the BS (and attached VS) to enter into the patient's airways, as shown in Figure 4.6.

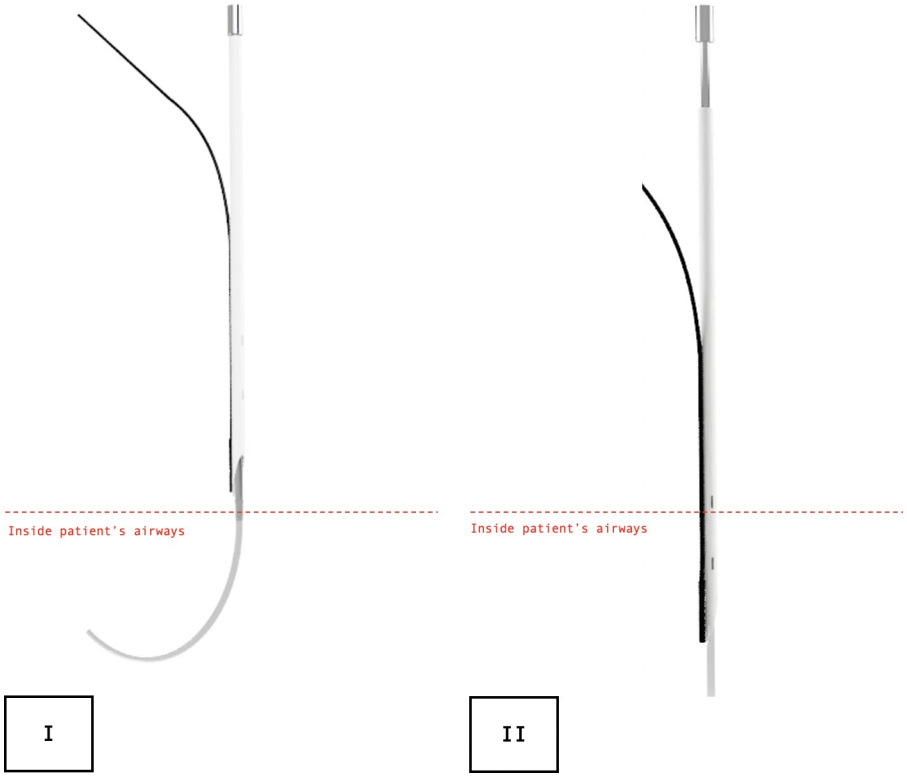

Figure 4.6: The uncuffed endotracheal tube guiding the bronchoscope into the airways: I) the ETT within the airways and the BS above the patient, II) the BS entering the airways of the patient by sliding over the endotracheal tube into the distal portion of the airways

The uncuffed endotracheal tube will first be inserted into the patient's airways. Thereafter, the BS will slide over the endotracheal tube to enter the distal airways of the patient with ease. During insertion, constant ventilation will be supplied through the endotracheal tube to the distal airways via the ventilation connector tube.

4.3.2 Ventilation Connector Tube (B.2)

The ventilation connector tube was manufactured out of stainless steel by UCT's Department of Human Biology's as shown in Figure 4.7. This was done using the mechanical manufacturer's drawings shown in Figure A.1 in Appendix A. The ventilation connector tube will be securely placed within the proximal opening of the endotracheal tube, as shown in Figure 4.9. Medical tape will surround this connection to secure placement and prevent the endotracheal tube from displacing when the BS slides over it.

The proximal port of the ventilation connector tube is 15mm in diameter to ensure a universal connection to external ventilation sources. The ventilation pathway will start from the opening of the ventilation connector tube (B.2) to the outlet of the endotracheal tube (B.1) and finally reach the distal portion of the patient's airways.

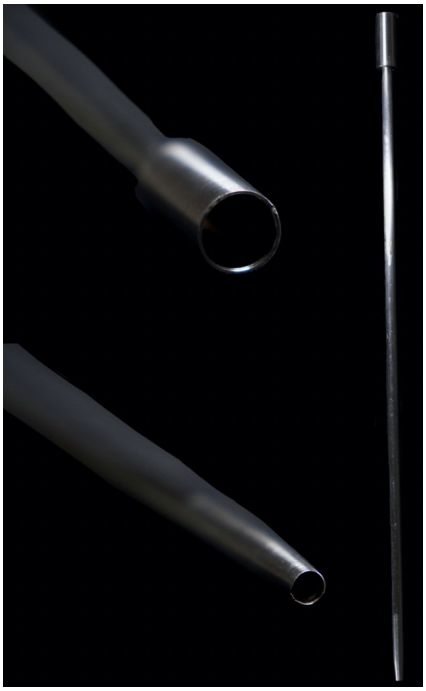

Figure 4.7: Ventilator connector tube (B.2)

Figure 4.8: Ventilator connector tube (B.2) and the endotracheal tube (B.1)

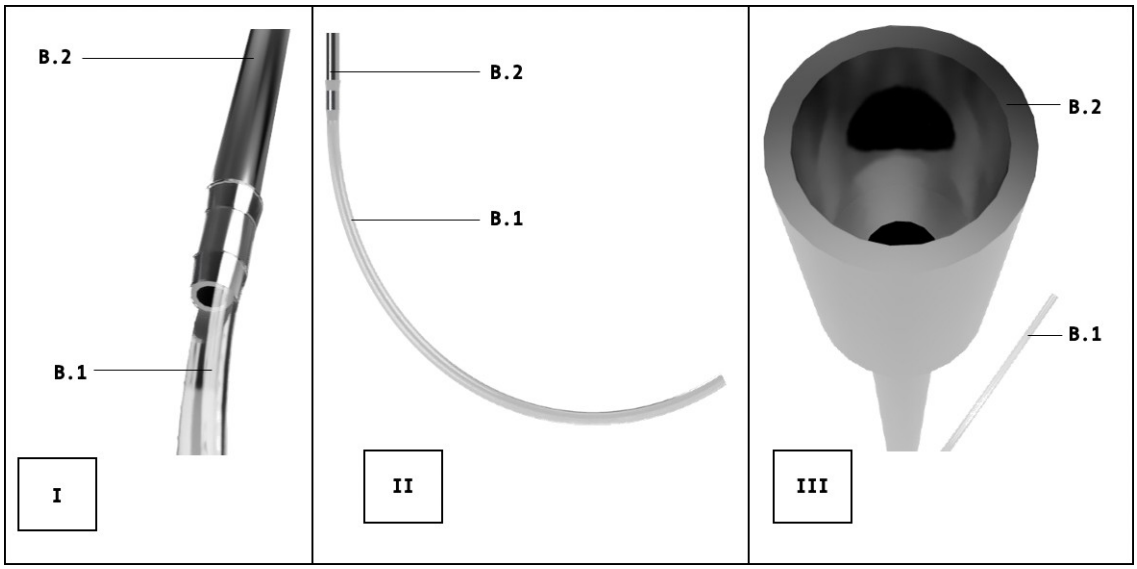

Figure 4.9: Ventilation connector tube: I) distal end of the ventilation connector tube within the proximal opening of the endotracheal tube, II) path of ventilation from the ventilation connector tube through the endotracheal tube, III) proximal opening of the ventilation connector tube which will be connected to existing ventilation sources

4.4 Bronchoscope Subsystem (BS)

The BS's primary role is to provide a working channel for the forceps to pass through, whilst providing a pathway for ventilation to reach the patient's lungs. The VS will permanently be attached to the distal end of the BS; however, their main user requirement differs. The BS (without the attached VS) and its components are highlighted in Figure 4.10.

4.4.1 Bronchoscope (C.1)

The bronchoscope has several design features that allow for quick and easy removal of aspirated foreign bodies whilst providing constant ventilation. The camera and LED light source (A.1) of the VS is placed at the distal end of the bronchoscope on the bevelled end, as shown in Figure 4.11. The bronchoscope (C.1) was cast out of semi-rigid plastic. Hence, it will be a single-use device.

The ventilation slots are on either side of the distal end of the bronchoscope. This is done to ensure that both lungs are ventilated whilst the bronchoscope is inside either of the lungs. The bevelled distal end allows the device to pass through the vocal cords easily. The bronchoscope's working channel slides over the endotracheal tube during insertion and provides a pathway for ventilation. Once the bronchoscope is within the patient's airways, the forceps (D.1) can be inserted through the working channel, via the bronchoscope adaptor, to remove the aspirated FB whilst ventilating the patient.

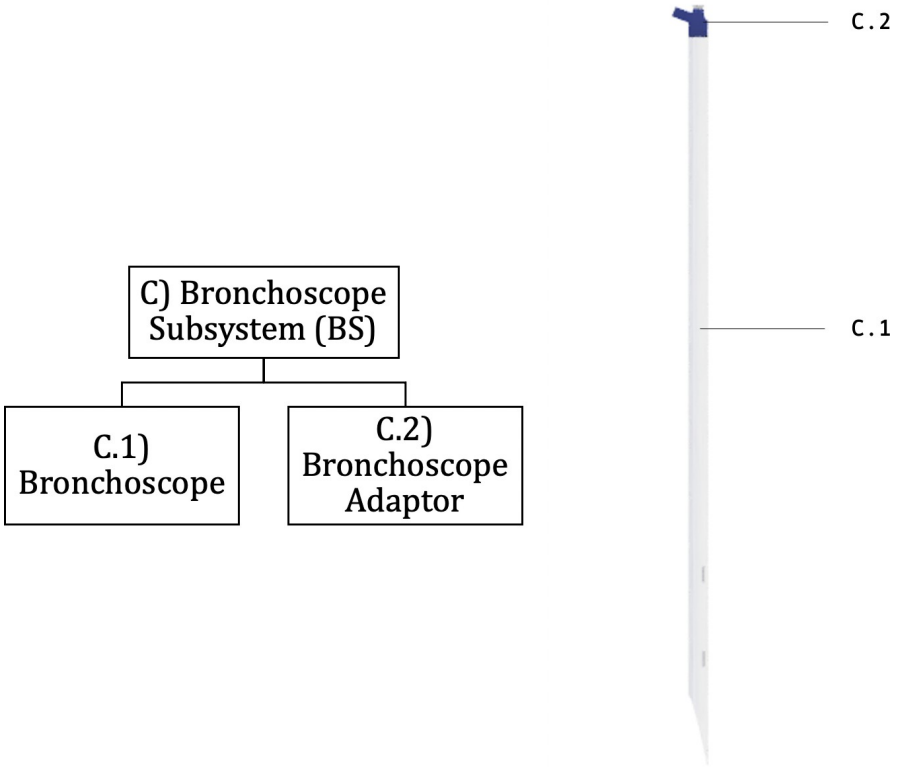

Figure 4.10: Bronchoscope subsystem (BS) and its components: C.1) bronchoscope and C.2) bronchoscope adaptor

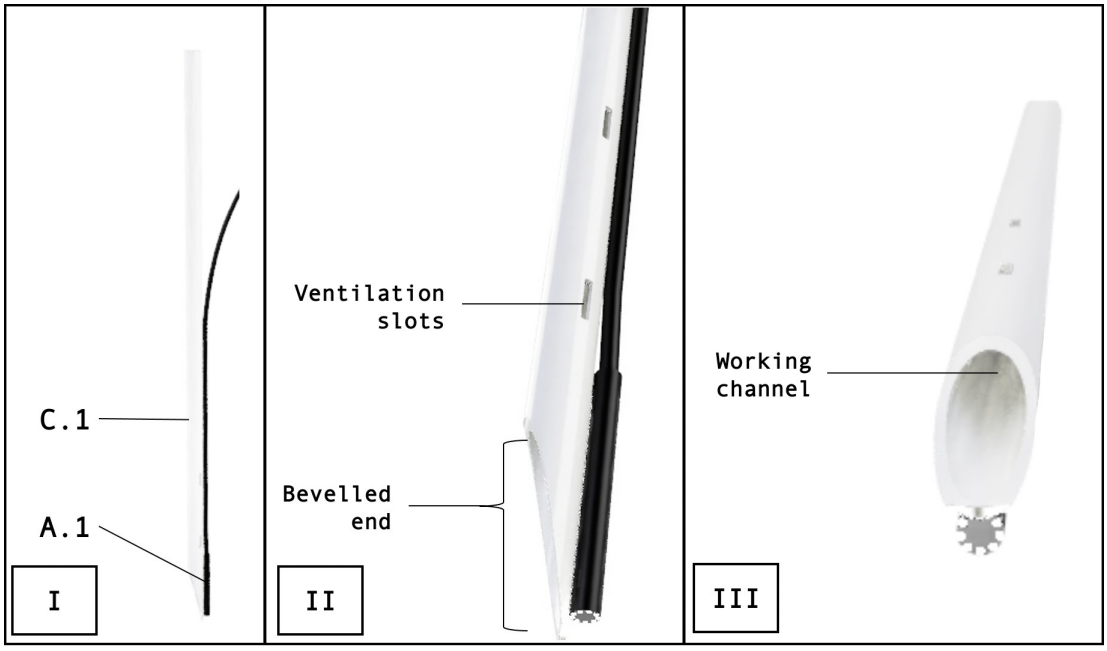

Figure 4.11: Bronchoscope (C.1) : I) bronchoscope and attached VS (A.1) II) distal end features of the bronchoscope, ventilation slots & bevelled end III) working channel of the bronchoscope

4.4.2 Casting of Bronchoscope

The hollow bronchoscope was manufactured using a rotational casting method. This method was chosen as it proved to be the most cost-effective when incorporating specific design features, whilst allowing to test different materials for the device quickly. Another benefit of rotational casting was that uniform thickness could be easily achieved.

The casting process started with creating a flexible negative hollow mould which was used to rotational cast the final product. The negative mould was made of a flexible silicone compound, Smooth Cast ™Dragon Skin, mixed in a 1A:1B ratio by volume. The negative mould was chosen to be flexible for ease when casting and removal of the produced solid, hollow bronchoscope from the mould. The casting process of the flexible, negative mould is shown in Figure 4.12 and described below:

(i) An insert in the shape and size of the desired bronchoscope was designed in CAD and 3D-printed in three separate parts due to the restricted 3D printer bed size.

(ii) The inserts were glued together to form one continuous insert that would produce the flexible negative mould cavity. The insert incorporated a hollow, centralised, circular channel and distal longitudinal grooves.

(iii) A rod was glued inside the insert for easy removal of the insert when casting the negative mould.

(iv) The insert and connected rod were placed inside a hollow plastic cylinder. The inner wall of the plastic cylinder would cast the outer surface of the flexible negative mould. The insert, rod, and inner walls of the plastic cylinder were coated with a mould release agent to easily remove the insert and cylinder from the produced mould.

(v) The casting material, a silicone compound, was mixed in the appropriate ratio and poured inside the cylinder. Pouring was done in one place to prevent bubbles from forming within the mould. A lid was then placed on top of the cylinder, and the rod was secured to the lid to keep the insert stationary and centralised throughout curing.

(vi) For optimal curing results, the mould was left overnight. Once cured, the lid was then carefully removed.

(vii) The insert and rod were removed slowly from the cured mould, leaving the produced mould and cavity.

(viii) Finally, the entire negative mould was removed from the plastic cylinder.

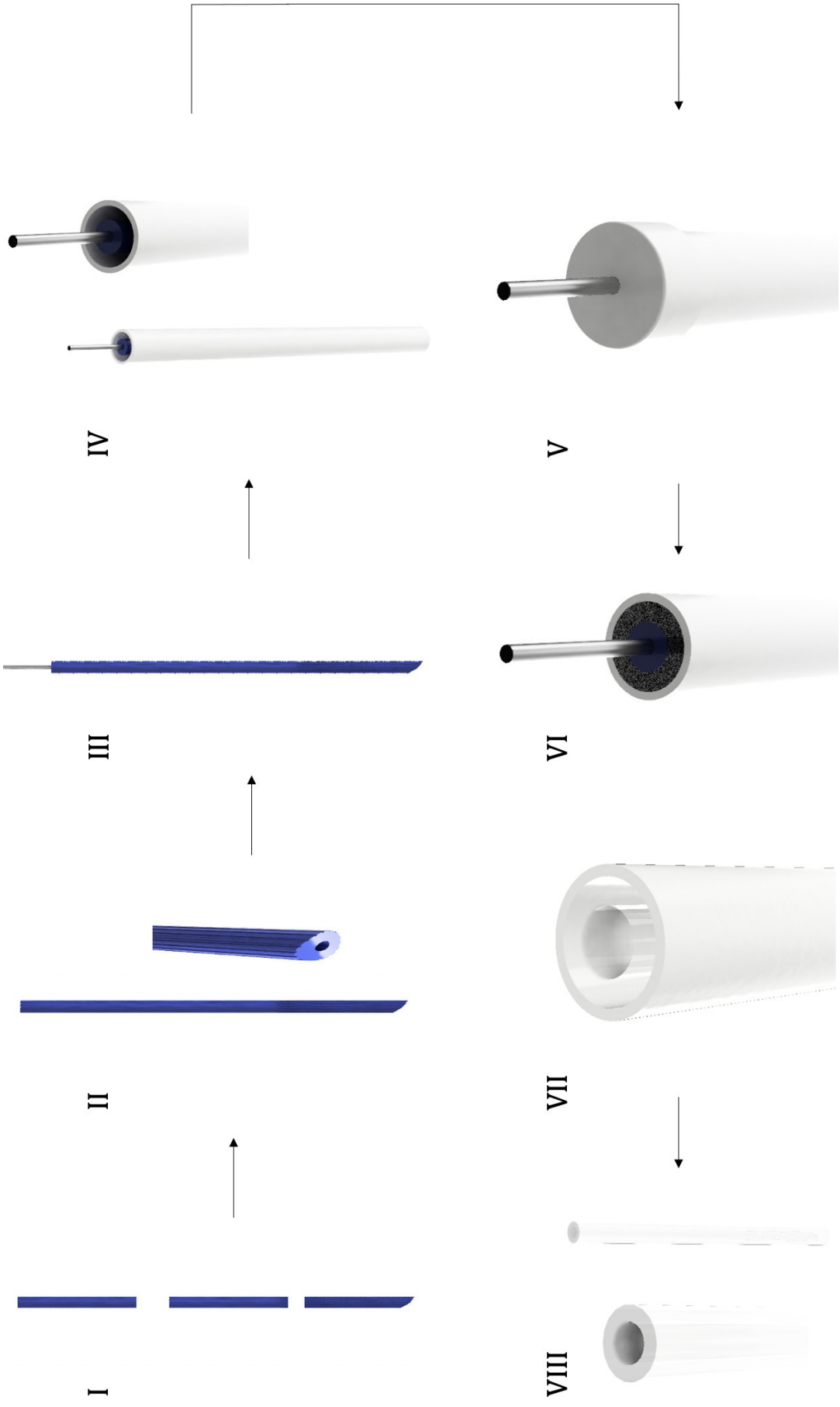

Figure 4.12: Process of casting the negative mould

The bronchoscope was rotational cast using the flexible, negative mould. The flexible, negative mould was placed within the plastic cylinder during casting to form a continuous straight cast. An annotated technical drawing of the flexible, negative mould within the plastic cylinder is shown in Figure 4.13.

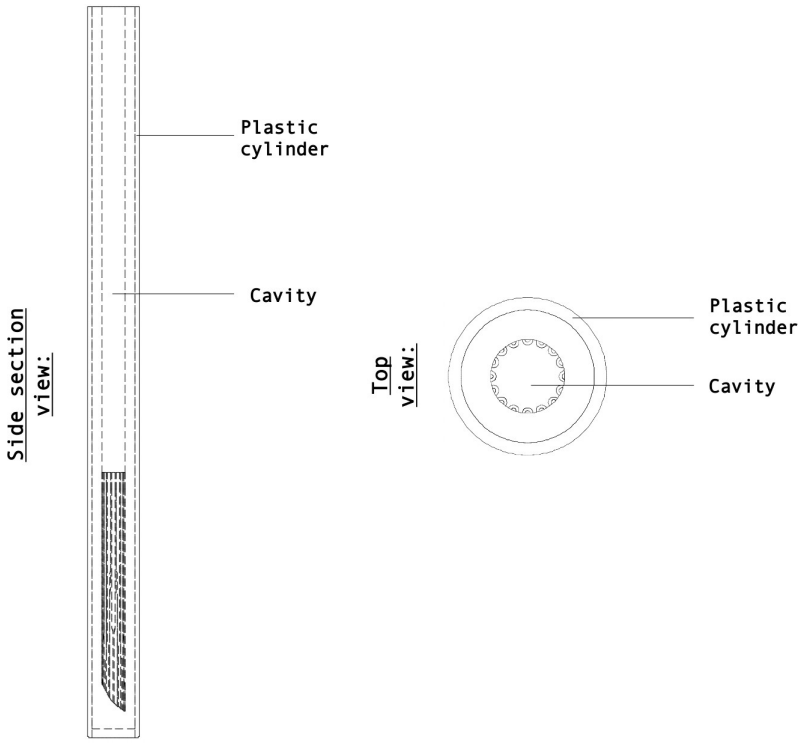

Figure 4.13: Side section and top view of the negative mould within the plastic cylinder

The bronchoscope was cast from a semi-rigid urethane resin. Smooth Cast ™65D was chosen as its low viscosity and quick curing times make it ideal for rotational casting whilst offering high impact resistance and strength. These cured castings can easily be post-processed through machining. Plastic gloves were worn throughout the casting process.

The casting process of the bronchoscope is described below:

(i) A liberal coat of mould release agent was sprayed inside the flexible, negative mould cavity.

(ii) Equal parts of Smooth Cast ™65D Parts A and B were dispensed in a cup and mixed. The mixture was then poured inside the cavity of the negative mould.

(iii) Once the mixture was poured inside the mould's cavity, the mould's opening was covered with the gloved hand.

(iv) The negative mould (placed inside the plastic cylinder) was then slowly rotated around the two perpendicular axes of the mould to ensure that the uncured resin coated the entire mould cavity. This motion was repeated for 3 minutes until the resin layer was cured.

(v) The next layer of resin could then be poured into the cavity. The rotational casting process (from the previous steps) was repeated until a desired thickness of the bronchoscope was achieved.

(vi) The mould was then left overnight to ensure optimal curing results of the bronchoscope.

(vii) The flexible, negative mould was then removed from the plastic cylinder. The flexible mould could then be pulled apart to remove the cured, hollow bronchoscope.

The rotational casting process underwent several trials to determine the number of resin layers, the appropriate rotational casting motion and duration thereof to ensure uniform thickness of the bronchoscope. Two thicker layers of resin yielded the best results instead of multiple thin layers.

Air bubbles were trapped within the inner walls of the cavity of the flexible,negative mould during the casting process of the mould. Therefore, the cured bronchoscope required significant amounts of post-processing. The residual mould release agent was first removed from the bronchoscope's surface using rubbing alcohol.

After that, the outer surface of the bronchoscope was smoothed using sandpaper. Sandpapering first started with a coarse grit (40 grit), then a medium grit (80 grit) and finally, a fine grit (120 grit) was used. Because of the mould's quality, the bronchoscope's longitudinal distal grooves were not achieved to the desired standard. These were sanded down as a less prominent design feature for this initial prototype design.

Once all flaws had been smoothed out sufficiently, the surface was cleaned and covered with two coats of prime and paint spray-paint to achieve a glossy, satin finish. Finally, the ventilation slots could be machined into the distal portion of the painted bronchoscope. Two complete bronchoscopes were cast using this rotational casting process for experimental testing.

Figure 4.14: Bronchoscope subsystem and attached visualisation subsystem

4.4.3 Bronchoscope Adaptor (C.2)

An off the shelf bronchoscope adaptor (C.2), as shown in Figure 4.15, will be secured into the proximal port of the bronchoscope when the bronchoscope is within the distal airways of the patient, as shown in Figure 4.16.

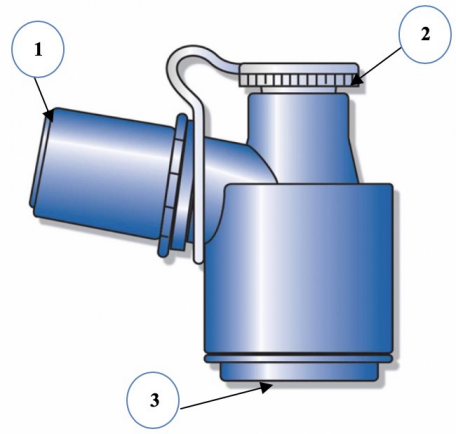

Figure 4.15: Bronchoscope adaptor and its labelled parts: 1) ventilation side port, 2) sealed port with a small hole for the entrance of forceps, 3) exit port, to be securely placed within the opening port of the bronchoscope

The bronchoscope adaptor allows the patient to be ventilated throughout the insertion of the forceps and retrieval of a FB. An external source of ventilation will be supplied through the bronchoscope adaptor via its ventilation side port. Whilst ventilation is being supplied; the forceps can pass through the alternate sealed port into the bronchoscope's working channel to retrieve the FB.

Figure 4.16: Bronchoscope (C1) and the bronchoscope adaptor (C2)

4.5 Summary of the Final Design of the FB Retrieval System

The FB Retrieval System, named the 'Re-Aspire' device, was successfully designed, as shown in Figure 4.17. Although there is limited literature, Anton-Martin, Bhattarai, Rycus, Raman & Potera (2019) have demonstrated that extracorporeal membrane oxygenation during bronchoscopy has proven to be useful in life-threatening FBA cases. However, this technique would not be necessary as the Re-Aspire device allows for the patient to be continuously ventilated throughout the procedure.

Due to the restricted budget, limited time andmanufacturing considerations, the current device was designed for the female adult and/or teenage populations. However, the design methodology was carefully developedto ensure simple downscaling, should the resources become available, to a final design iteration that would fit the paediatric population.

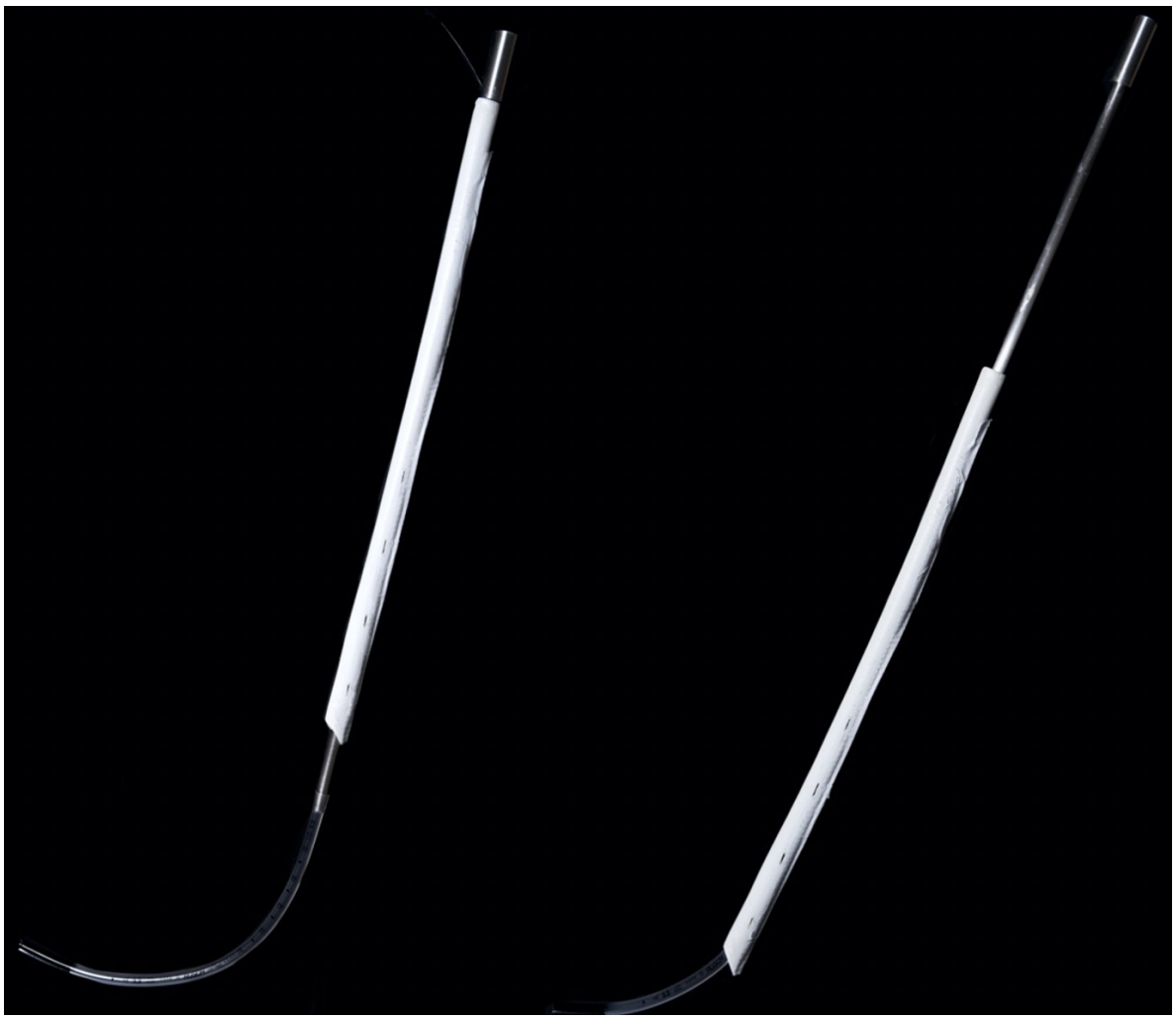

Figure 4.17: The Re-Aspire device and its subsystems

5 Experimental Methodology

This chapter documents the testing protocol that will determine the user evaluation of the designed medical device. Through performing specific task-based scenarios in the testing, design recommendations and conclusions can be determined.

The purpose of testing the device is to determine all usability risks associated with the system. The testing results will be analysed and used to determine future recommendations for modifying the device to a final working prototype used to perform successful bronchoscopy procedures for the paediatric and adult population. The implementation of these recommendations is out of the scope of this study. The summative usability evaluation will highlight any design shortcomings and usability risks.

5.1 Overview

The experimental methodology flow chart followed is shown in Figure 5.1. The experimental methodology is broken down into three separate phases, namely:

(i) Phase 1: Perform the experimental testing method on a respiratory airway demonstration model for the testing participants to be familiar with both devices.

(ii) Phase 2: Perform the same experimental testing method (as mentioned in Phase 1) on the Laerdal ® Airway Management Trainer.

(iii) Phase 3: This involves analysing results from Phase 2. A system usability score will be determined for the designed device and design flaws will be identified. Phase 3 will conclude with design recommendations for future iterations for the subsequent design phase of the device.

Phase 1 and Phase 2 testing will be performed with the designed device, the 'Re-Aspire' device and the Karl Storz rigid bronchoscope. The Karl Storz rigid bronchoscope is the current standard device used in hospitals across Africa. Hence, the Karl Storz rigid bronchoscope provides an effective benchmark for comparison of the resulting usability scores. The following sections detail the experimental methodology performed in both Phase 1 and Phase 2 and how the results from Phase 2 testing will be retrieved and analysed.

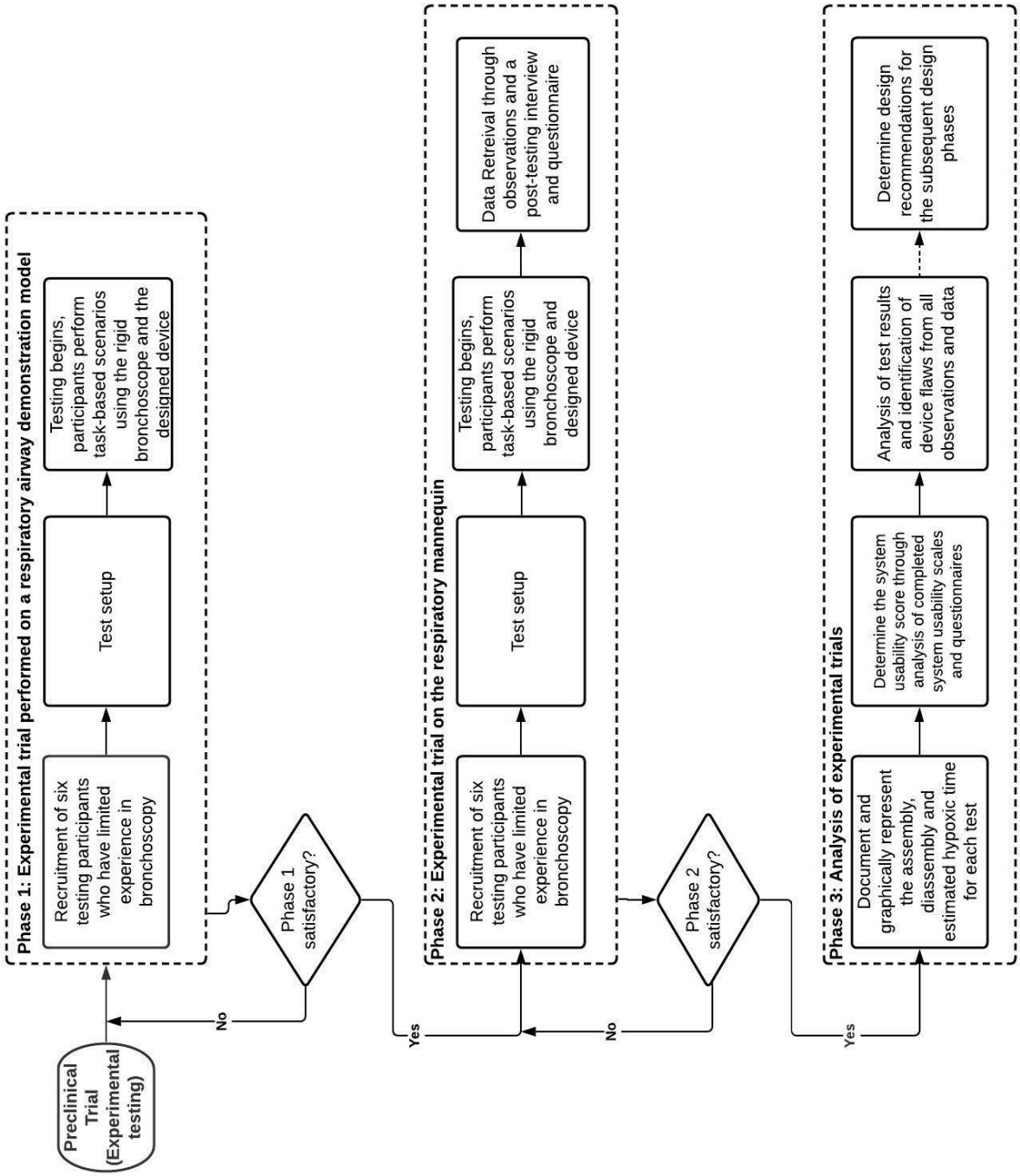

Figure 5.1: Overview of the experimental methodology

5.2 Hypothesis

The hypothesis for this experimental testing is that:

1. The designed 'Re-Aspire' device (FB retrieval system) will have improved efficacy and usability compared to the rigid bronchoscope.
2. The 'Re-Aspire' device will result in little to no hypoxic time during the procedure.
3. The 'Re-Aspire' device will have improved patient safety as constant ventilation will be provided throughout the use of the device.

5.3 Overview of Experimental Procedure

A common FB (a green lid pen), as shown in Figure 5.2, will be placed in the right main bronchus of the respiratory airway demonstration model for Phase 1 testing. For Phase 2 testing, the same FB will be placed in the right main bronchus of the Laerdal ® Airway Management trainer. The FB, the respiratory airway demonstration model and the Laerdal ® Airway Management trainer are shown in Figure 5.2, Figure 5.3, and Figure 5.4, respectively.

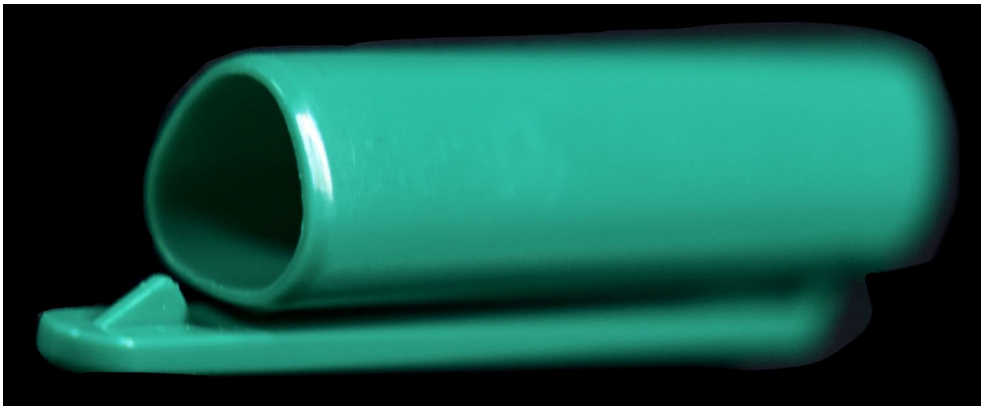

Figure 5.2: Green FB to be retrieved from the airway models

Phase 1 and 2 testing will be performed on the respiratory airway demonstration model and respiratory airway Laerdal ® Airway Management trainer, respectively. These models are available at the Airway Management Skills Lab located in the Department of Anaesthesiology at Groote Schuur Hospital. These models are currently used as the method of teaching and training surgeons in bronchoscopy. These models are more challenging to intubate than that of a cadaver or a human patient, due to the rigidity of the airway of these models.

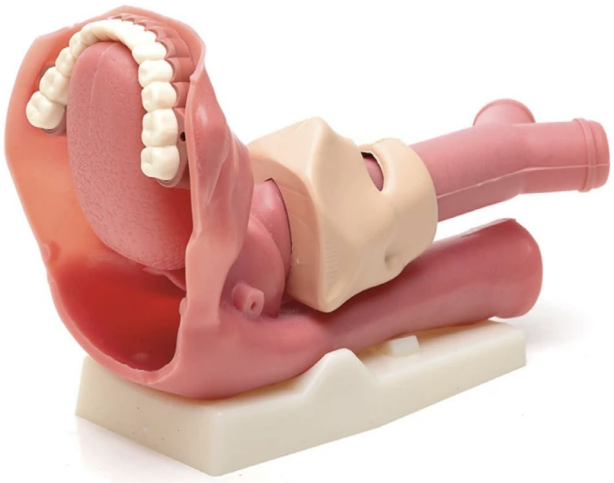

Figure 5.3: Laerdal ® airway demonstration model used for phase 1 testing, obtained from (*Survival Technology - Adult Airway Management Trainer - Laerdal*, 2019)

Figure 5.4: Laerdal ® airway management trainer used for phase 2 testing, obtained from (*Survival Technology - Adult Airway Management Trainer - Laerdal*, 2019)

The testing participant will perform several task-based scenarios on the 'patient' (demonstration model/respiratory mannequin). Each task scenario will be detailed and explained to the participant before testing commences. Overall, the task scenarios will demonstrate the device's ability to remove aspirated foreign bodies from the airway.

The total procedure time and the estimated hypoxic time will be recorded for each device. After that, the testing participant will complete a usability questionnaire, which includes a system usability scale. The testing procedure and task scenarios will be repeated for both Phase 1 and Phase 2 testing, using the rigid bronchoscope and Re-Aspire device to compare the designed device's usability.

5.4 Participant Recruitment

The investigators will do the device's development and design whilst considering clinical design recommendations made by the clinical partner, a specialised anaesthesiologist from Groote Schuur Hospital trained in bronchoscopy.

The testing participants are a group of anaesthesiologists who have had prior training in bronchoscopy during their previous studies but do not practise the procedure. This will be done to determine the device's usability for a general medical professional. The primary purpose of this pilot study is to test the ability of the Re-Aspire device to safely remove a commonly aspirated FB from the airway of a patient compared to that of the rigid bronchoscope.

5.5 Test Personnel

Due to the COVID-19 pandemic, the number of testing personnel will be limited to the investigator (a biomedical engineering postgraduate student). The investigator will be responsible for informing the study participants and what is required of them for each task-based scenario. This role will involve two distinct tasks for usability testing. The two tasks required for the usability test is as follows:

- Facilitating- Inform the participants of what is expected of them through reading the testing protocol. The investigator will guide and observe the participant through each task-based scenario. Additionally, a post-testing interview will be conducted and documented, which will involve the participant completing a questionnaire.

- Observing – The observing role will be for the collection of data. This will be in the form of both ordered qualitative data and continuous quantitative data. The qualitative data will consist of observational data through observing the participants performing each task-based scenario. The quantitative data will record the total testing time and the estimated hypoxic time. To ensure that all data collected is accurate, the testing participants will be filmed, with consent given a priori. These recordings can be analysed post-testing to ensure all data is correctly documented.

5.6 Experimental Testing Materials and Setup

The testing will be performed with the rigid bronchoscope and the tube-over-tube rigid bronchoscope (FB Retrieval System), named the 'Re-Aspire' device. The testing will first be done on the respiratory airway demonstration model and then on Laerdal® Airway Management Trainers (mannequins), respectively, in Phase 1 and Phase 2. Nevertheless, the same test materials will be required for both testing phases.

The list of test materials required for the Re-Aspire device (tube-over-tube rigid bronchoscope) consists of a:

1. Foreign body to place within the airway,
2. laryngoscope for ease of insertion of the endotracheal tube,
3. camera and LED light source,
4. Micro-USB/USB C connection cable,
5. smart device,
6. ventilation connector tube (can connect proximally: with existing external ventilation sources and distally: within an uncuffed endotracheal tube),
7. bronchoscope (provides working channel for forceps to pass through, the camera is attached to this component),
8. bronchoscope adaptor,
9. pair of forceps (use existing rigid forceps),
10. and an uncuffed endotracheal tube (use existing endotracheal tube).

The Re-Aspire device is currently designed for the female adult and teenage populations. The final iteration of the device will be downscaled to fit the paediatric population. The configuration of the video-assisted tube-over-tube rigid bronchoscope (the Re-Aspire device) and its components will be explained to the user before testing.

The list of test materials required for the rigid bronchoscope consists of a:

1. Foreign body to place within the airway,
2. laryngoscope for ease of insertion of the bronchoscope,
3. bronchoscope (provides working channel for forceps to pass through, the camera is attached to this component),
4. and a pair of forceps.

A similar-sized Karl Storz rigid bronchoscope, currently being used in practice, will be chosen to ensure appropriate comparison when testing and to analyse the post-testing results. The configuration of the rigid bronchoscope and its components will be explained to the user before testing.

In alignment with the current global pandemic, cleaning the testing environment with 70% alcohol-based sanitisers will be done between each testing participant, before and after testing. Before entering the testing environment, the participants will be requiredto wash their hands with soap and water for at least 20 seconds, followed by donning of masks.

5.7 Ethical Considerations

Approval (HREC REF: 836/2020) was obtained by the UCT's Human Research Ethics Committee (HREC) before testing commenced, as shown in Appendix B. The experimental method conformed to all ethical standards and requirements to ensure ethical responsibility for this study.

Preliminary testing was performed on full-bodied, non-embalmed, fresh cadavers to ensure that the device was anatomically correct for each design iteration. The identity and personal information of the cadaver were concealed, and subject numbers were allocated for each cadaver. This testing determined the best camera placement on the distal end of the Re-Aspire bronchoscope. The determined placement was on the tip of the bronchoscope of the Re-Aspire device. This testing also determined the material used for the ventilator connector tube. Originally the component was 3D printed. However, the component broke due to the force exerted on the tube during the insertion of the bronchoscope into the airway. Therefore, the tube was manufactured out of stainless steel for improved rigidity.

Phase 1 and Phase 2 testing was conducted on a demonstration model and a respiratory mannequin, respectively. Before the participant tested the devices, an informed consent document was signed by each participant along with a Non-Disclosure Agreement (NDA) form as seen in Appendix C and Appendix D respectively.

5.8 Testing Protocol Task-Based Scenarios

The following tasks were identified through analysing the working of the existing bronchoscopes. Given the simplicity and short duration of the procedure, every task associated with the device was included in the testing protocol. The user-related tasks included in the protocol will identify all specific hazard-related for each use scenario. Once all tasks for the Re-Aspire device are completed, similar tasks will be repeated using the rigid bronchoscope for comparison. The task-based scenarios are summarised in Table 5.1.

Table 5.1
Task-based scenarios for the Re-Aspire device and Karl Storz rigid bronchoscope

Re-Aspire device	Karl Storz rigid bronchoscope
Task 1: Assembly of the Re-Aspire device	Task 1: Assembly of the rigid bronchoscope
Task 2: Preparation of the patient	Task 2: Preparation of the patient
Task 3: Insertion of the endotracheal tube	Task 3: Insertion of the rigid bronchoscope
Task 4: Insertion of the ventilation connector tube into the proximal opening of the endotracheal tube	Task 4: Identification of the FB
Task 5: Insertion of the bronchoscope into the airway	Task 5: Insertion of the forceps
Task 6: Removal of the ventilation connector and endotracheal tube	Task 6: Removal of the FB and rigid bronchoscope from the airway
Task 7: Identification of the FB	
Task 8: Insertion of the forceps	
Task 9: Removal of the FB and Re-Aspire device from the airway	

5.8.1 Task-Based Scenarios for the Designed 'Re-Aspire' Device

Task 1: Assembly of the Re-Aspire device

The user must:

1. Listen to the explanation of the working of the device by the facilitator.
2. Ensure that all device components are available; if a component is missing, the user must inform the facilitator.
3. Ensure that the laptop has a minimum battery level of 50% and storage of 1 Gig.
4. Connect the camera and LED light setup to the smart device.
5. Ensure that the LED lighting of the camera is on and turned to its maximum brightness.
6. Ensure that the visuals produced from the camera are displayed on the screen of the laptop.
7. Start recording on the imaging system.
8. (If there were a ventilation outlet, the patient would be ventilated using an oxygen mask.)
9. Place the bronchoscope over the ventilation connector tube.
10. Spray anti-fog spray on the lens of the camera.

Task 2: Preparation of the patient

The user must:

1. Position the patient with anterior flexion of the neck region and extension of the atlanto-occipital joint.
2. Stand directly behind the head of the patient.

Task 3: Insertion of the endotracheal tube

The user must:

1. Insert an uncuffed endotracheal tube into the patient's airways using a laryngoscope. (The facilitator should note the time, this is the beginning of the hypoxic time and total procedure time)
2. The facilitator will confirm the correct placement of the endotracheal tube.

Task 4: Insertion of the ventilation connector tube into the proximal opening of the endotracheal tube

The user must:

1. Ensure that the bronchoscope is placed over the ventilation connector tube.
2. Insert the ventilation connector tube into the proximal port of the endotracheal tube.
3. (If there were a ventilation outlet, the proximal port of the ventilation connector tube would be connected to the ventilation source.) The facilitator will note the time as the end of the hypoxic time

Task 5: Insertion of the bronchoscope into the airway

The user must:

1. Ensure that the visuals produced by the camera are shown clearly on the screen of the laptop.
2. Hold the ventilation connector tube stationary above the patient whilst guiding the bronchoscope into the airways. (The bronchoscope will first pass over the ventilation connector tube and then the endotracheal tube. Finally, the bronchoscope will pass the vocal cords and enter the distal portions of the airway.)

Task 6: Removal of the ventilation connector tube and endotracheal tube

The user must:

1. Once the bronchoscope has passed the vocal cords, slowly remove the ventilation connector tube and endotracheal tube in unison from the patient's airways.
2. Insert the bronchoscope adaptor into the proximal port of the bronchoscope.
3. (If there were a ventilation outlet, the side port of the bronchoscope adaptor would be connected to the ventilation source.)

Task 7: Identification of the FB

The user must:

1. Identify the location and type of the FB within the airway, using the visuals displayed on the laptop's screen.

Task 8: Insertion of the forceps

The user must:

1. Insert the forceps within the top port of the bronchoscope adaptor.

Task 9: Removal of the FB and Re-Aspire device from the airway

The user must:

1. Capture the FB using the teeth of the forceps.
2. Remove the entire device, forceps and the FB in unison from the patient's airways. The FB is often larger than the diameter of the bronchoscope. Therefore, the FB cannot pass through the lumen of the bronchoscope. Thus, the forceps and attached FB must always be ahead of the distal end of the bronchoscope when removing the components from the patient's airway. (The observer will note the time, this is the end of the total procedure time)

5.8.2 Task-Based Scenarios for the Rigid Bronchoscope

Task 1: Assembly of the rigid bronchoscope

The user must:

1. Listen to the explanation of the working of the device by the facilitator.
2. Ensure that all device components are available; if a component is missing, the user must inform the facilitator.
3. Connect the external light source to the side port of the rigid bronchoscope.

Task 2: Preparation of the patient

The user must:

1. Position the patient with anterior flexion of the neck region and extension of the atlanto-occipital joint.
2. Stand directly behind the head of the patient.

Task 3: Insertion of the rigid bronchoscope

The user must:

1. Hold the rigid bronchoscope in the dominant hand. (The observer should note the time, this is the beginning of the hypoxic and total procedure time)
2. Use the middle finger of the non-dominant hand to protect the gums and upper teeth and restrict head movement.
3. Insert the rigid bronchoscope with the tip facing forward into the lateral aspect of the patient's mouth.
4. Pass the bronchoscope through the vocal cords into the distal airways of the patient.
5. The facilitator will note the time as the end of the hypoxic time. (If there were a ventilation outlet, the side port of the rigid bronchoscope would be connected to the ventilation source.)

(If the patient is in danger of becoming hypoxic during task 3, the patient would be ventilated immediately until the patient's oxygen levels have stabilised. Task 3 would then be repeated until the bronchoscope is safely inserted into the airway.)

Task 4: Identification of the FB

The user must:

1. Identify the location of the foreign body within the airways through the proximal port of the rigid bronchoscope.

Task 5: Insertion of the forceps

The user must:

1. Insert the forceps within the proximal port of the bronchoscope (Note that this is the same port used to view the distal airways).

Task 6: Removal of the FB and rigid bronchoscope

The user must:

1. Capture the FB using the teeth of the forceps.
2. Remove the entire device, forceps and the FB in unison from the patient's airways. The FB is often larger than the diameter of the bronchoscope. Therefore, the FB cannot pass through the lumen of the bronchoscope. Thus, the forceps and attached FB must always be ahead of the distal end of the bronchoscope when removing the components from the patient's airway. (The observer will note the time, this is the end of the total procedure time)

5.9 Data Retrieval

The usability test data that will be collected include:

1. task-based scenarios success for each test,
2. descriptions of observed errors or difficulties relating to the use of each device,
3. feedback from the participants about the functionality of the devices,
4. description of the causes of the errors or difficulties on the functioning of the device from the participant's perspective,
5. participants ratings on each device's capability of removing a FB from the airway
6. The total testing, bronchoscope insertion, FB retrieval time and estimated hypoxic time was recorded.

The data will be collected using two methods: from the observations of the test personnel (objective data) and the participants' debriefing interviews (subjective data). Details on these two methods are as follows:

Objective data – While participants perform each task-based scenario, the investigator will observe and record their performance of each task and subtasks as one of the following: correct use, use error, close call or not applicable. A task is deemed successful (S) when the user had no difficulty performing the task, whilst a task in which the user was ableto perform successfully with observed difficulty will be marked as SOD. A close call (CC) task is when an error occurred, but it was recovered. Lastly, a Not Applicable (NA) rated task is a task that is blocked by a previous task and cannot be performed. This objective data key is shown in Table E.1. It will be used to complete the following Table E.2, and E.3 in Appendix E. Additionally, all spontaneous comments made by participants during testing will be noted. The total testing time from assembly to the removal of the FB will be recorded and completed in Table E.4 in Appendix E. The estimated hypoxic time will also be recorded; this is when the patient is not ventilated.

Subjective data – Upon completion of each test, participants will participate in a short debriefing interview to clarify the root cause of potential use errors, close calls or use difficulties that were observed or unobserved. Participants will be asked questions by the investigator relating to each task and sub-task, which will be recorded on the form shown in Table F.1 and F.2 in Appendix F.

Additionally, each participant will complete a system usability scale (SUS) to indicate their impression of the device, as shown in Appendix G. From this scale, a fair system usability score can be determined by:

- Subtracting 1 from the score for every odd-numbered question
- Subtracting 5 from the score for every even-numbered question
- Sum the above responses and multiply it by 2.5 to obtain a score out of 100

Even though the score is out of 100, it is not a percentage (Laubheimer, 2018). The average system usability score is 68; if the final usability score is anything under this number, then the device and its functioning must be reconsidered for a redesign. The Re-Aspire device and rigid bronchoscope will be evaluated using this system, as shownin Figure 5.5.

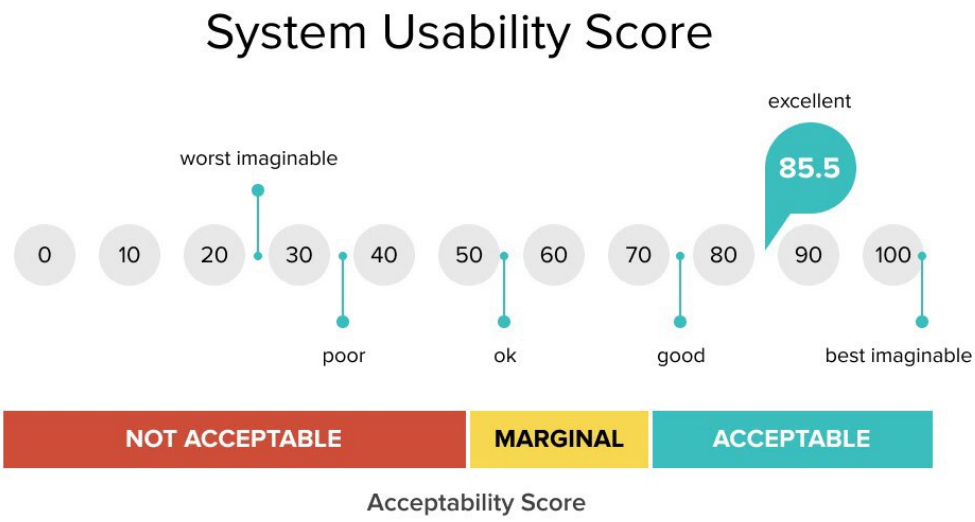

Figure 5.5: System usability score scale, obtained from (Smyk, 2020)

6 Experimental Outcomes

Over three days, the experimental methodology was performed on the Laerdal Airway Management Trainer at the Department of Anaesthesiology in Groote Schuur Hospital. Before testing on the mannequins, the testing participants practised both devices on the airway demonstration model. This section details the results from the testing protocol performed on the respiratory mannequin by the six testing participants. The collected data was categorised into objective and subjective data.

6.1 Testing Participants

All testing participants were experienced anaesthesiologists who have been trained in rigid bronchoscopy during their studies. However, they do not perform bronchoscopies in their current field of work. Therefore, the obtained system usability scores of the Re-Aspire device and the rigid bronchoscope are comparable with limited user bias. The details of the testing participants are tabulated in Table 6.1. It was noted whether the participant is a glass wearer, as this may affect the results from the testing.

Table 6.1
Testing participants details

Participant number	Glass wearer	Experience in anaesthesiology [years]	Gender
1	Yes	4	Female
2	No	4	Male
3	Yes	20	Female
4	Yes	3.5	Male
5	No	10	Male
6	No	10	Male

6.2 Objective Results

Each testing participant performed the task-based scenarios described in the testing protocol on the respiratory mannequin. With consent from each participant, testing was recorded to ensure that all observations were noted and to determine the accurately recorded times for each device.

6.2.1 Task-Based Scenario Observations

Each task-based scenario was observed and scored according to the following key:

- S: Success (correct use)
- SOD: Success with Observed Difficulty
- CC: Closed Call (an error occurred but was corrected)
- UE: User Error (user does not complete task, i.e. fail)
- NA: Not Applicable (blocked by a previous task)

The results were tabulated in Table 6.2 and Table 6.3, for the Re-Aspire device and rigid bronchoscope, respectively. The testing protocol was repeated with both devices until the foreign body was removed from the right main bronchus of the respiratory mannequin. Therefore, there were no user errors observed for both devices. However, most participants took several attempts to remove the FB for both devices, as indicated below.

Table 6.2
Task-based scenario success for the Re-Aspire device

Tasks	**Testing participant**					
	1	**2**	**3**	**4**	**5**	**6**
Task 1 - Assembly	S	S	S	S	S	S
Task 2 - Preparation	S	S	S	S	S	S
Task 3 - Insert ETT	S	S	S	S	S	S
Task 4 - Insert VCT	S	S	S	S	S	S
Task 5 - Insert bronchoscope	S	SOD	S	S	S	SOD
Task 6 - Removal of VCT	S	S	S	S	S	S
Task 7 - Identify the FB	S	S	S	S	S	S
Task 8- Insert forceps	CC	CC	CC	S	S	CC
Task 9 - Removal of the FB	S	S	S	SOD	S	CC
Task 9 - No. of attempts	3	2	4	1	1	3

Table 6.3
Task-based scenario success for the rigid bronchoscope

Task	**Testing participant**					
	1	**2**	**3**	**4**	**5**	**6**
Task 1 - Assembly	S	S	S	S	S	S
Task 2 - Preparation	S	S	S	S	S	S
Task 3 - Insert bronchoscope	SOD	S	SOD	S	S	S
Task 4 - Identify the FB	SOD	S	SOD	S	S	S
Task 5 - Insert forceps	SOD	S	CC	S	S	CC
Task 6 - Removal of the FB	CC	CC	CC	S	S	CC
Task 6 - No. of attempts	7	3	17	3	1	3

The additional tasks for the Re-Aspire device were all completed with success. The testing participants did not find the additional subsystems and associated tasks more cumbersome than the standard rigid bronchoscopy procedure. As a result, the additional tasks of the Re-Aspire, Task 3 (ETT) and Task 4 (VCT), was scored with success. Both devices' assembly and preparation tasks (Task 1 and Task 2) were achieved with success. As the Re-Aspire device was slightly larger in diameter than the rigid bronchoscope, it was a tighter fit to get the Re-Aspire device to pass the vocal cords. Nevertheless, all participants could insert both bronchoscopes into the patient's airways. Each participant had their preference of device, which will be discussed further according to the system usability scores.

Task 4, the identification of the FB, proved to be problematic in the rigid bronchoscope compared to that of the Re-Aspire device (Task 7). Participants who wear glasses struggled to retrieve the FB with the rigid bronchoscope, due to the physical barrier of the glasses and the lack of depth perception when identifying the FB through the lumen of the scope. Furthermore, it was more challenging for the users to determine whether the teeth of the forceps were open or closed when the forceps were placed within the port of the rigid bronchoscope. These difficulties experienced resulted in a higher number of attempts to retrieve the FB for the rigid bronchoscope than thatof the Re-Aspire Device. A total of 34 attempts for FB removal was recorded for the rigid bronchoscope as opposed to 14 attempts for the Re-Aspire device.

6.2.2 Time Measurement

Different time measurements were recorded for both devices, as tabulated in Table 6.4 and Table 6.5. It must be noted that these measurements were determined from a single complete successful FB retrieval and did not consider the multiple attempts of FB retrieval.

The insertion time represents how long it took for the participant to insert the bronchoscope into the airway of the respiratory mannequin. The estimated hypoxic time is the amount of time that the respiratory mannequin would not be ventilated. For the rigid bronchoscope, the hypoxic time is the same as the insertion time, as the mannequin would not be ventilated during the insertion of the rigid bronchoscope. The hypoxic time for the Re-Aspire device is when the ETT is being inserted into the airway and the VCT is placed into the distal port of the ETT. The retrieval time is how long the participant took for the FB to be removed from the right main bronchus of the mannequin. The total time starts from insertion of the bronchoscope until the FB is removed.

An average of these specific time measurements was graphed for each device, as shown in Figure 6.1. On average, the hypoxic time was more than double for the rigid bronchoscope than the Re-Aspire device, measuring at 18.87s and 7.7s respectively. However, the bronchoscope insertion time took longer for the Re-Aspire device (44.33s) compared to that of the rigid bronchoscope (18.87s). This resulted in a longer overall procedure time (100.55s) for the Re-Aspire device than the rigid bronchoscope (68.08s).

The crucial time for any bronchoscopy procedure is the hypoxic time. Patients who have a FB lodged within their airway are already compromised in terms of breathing. Asa result, the patient will only breathe through a single lung.

Table 6.4
Re-Aspire device testing times

Re-Aspire device testing times				
Test participant	**Estimated hypoxic time [s]**	**Insertion time [s]**	**Retrieval time [s]**	**Total time [s]**
1	10.6	8.7	26.3	45.6
2	5	84	96	185
3	6.7	32.3	31.5	70.5
4	6.6	12.7	33.7	53
5	9.4	38.3	43.6	91.3
6	7.9	90	60	157.9
Average times [s]	7.7	44.33	48.52	100.55
Standard Deviation	2.04	34.96	26.13	57.78

Table 6.5
Rigid bronchoscope testing times

Rigid bronchoscope testing times				
Test participant	**Estimated hypoxic time [s]**	**Insertion time [s]**	**Retrieval time [s]**	**Total time [s]**
1	19.4	19.4	126	145.4
2	38.4	38.4	15.9	54.3
3	5.7	5.7	34.4	40.1
4	11.4	11.4	16.4	27.8
5	15	15	42.6	57.6
6	23.3	23.3	60	83.3
Average time [s]	18.87	18.87	49.22	68.08
Standard Deviation	11.36	11.36	41.14	42.23

If the patient is becoming hypoxic during insertion of a rigid bronchoscope, the surgeon must immediately remove the device and ventilate the patient. If the surgeon does not ventilate the patient within an appropriate time frame, it can prove to be fatal.

The estimated hypoxic time for the rigid bronchoscope and the Re-Aspire device for each participant is graphed in Figure 6.2. For the majority of the participants, except for one, the hypoxic time for the rigid scope was longer. The mannequin would have been ventilated throughout the insertion of the Re-Aspire bronchoscope. However, the model would not be ventilated during insertion of the rigid scope which resulted in these findings. Therefore, when tested on the mannequin, the Re-Aspire device displayed an increased patient safety compared to the rigid scope.

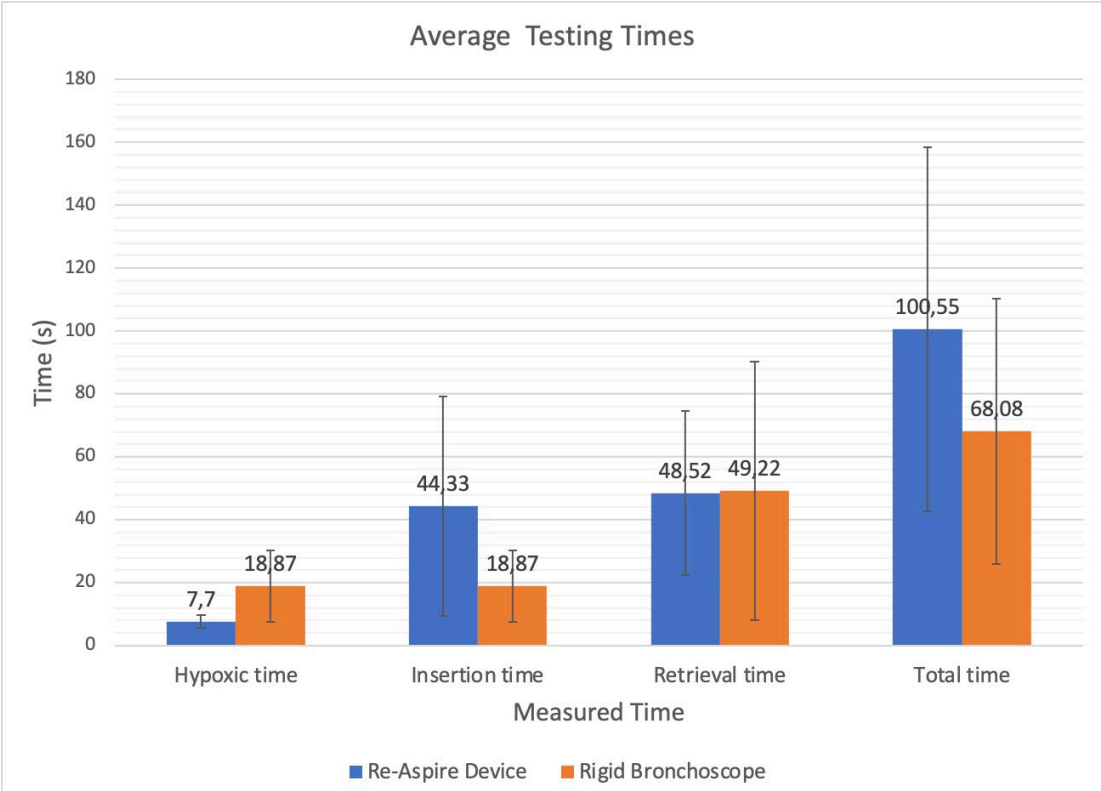

Figure 6.1: Average testing times for each testing participant

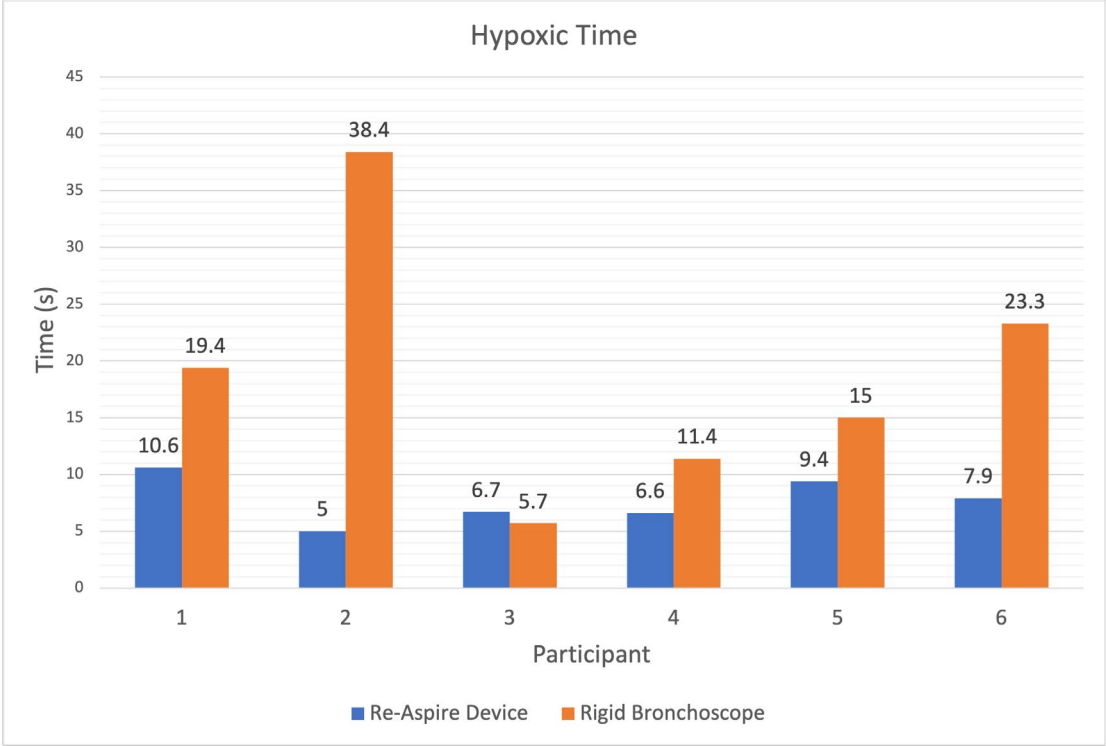

Figure 6.2: Estimated hypoxic times for each testing participant

The FB retrieval time for each testing participant for both the rigid bronchoscope and the Re-Aspire device is shown in Figure 6.3. The same set of forceps were used for both devices as a constant variable for testing to ensure appropriate comparison. The FB retrieval time was similar for both devices given the multiple attempts that the participants took to remove the FB.

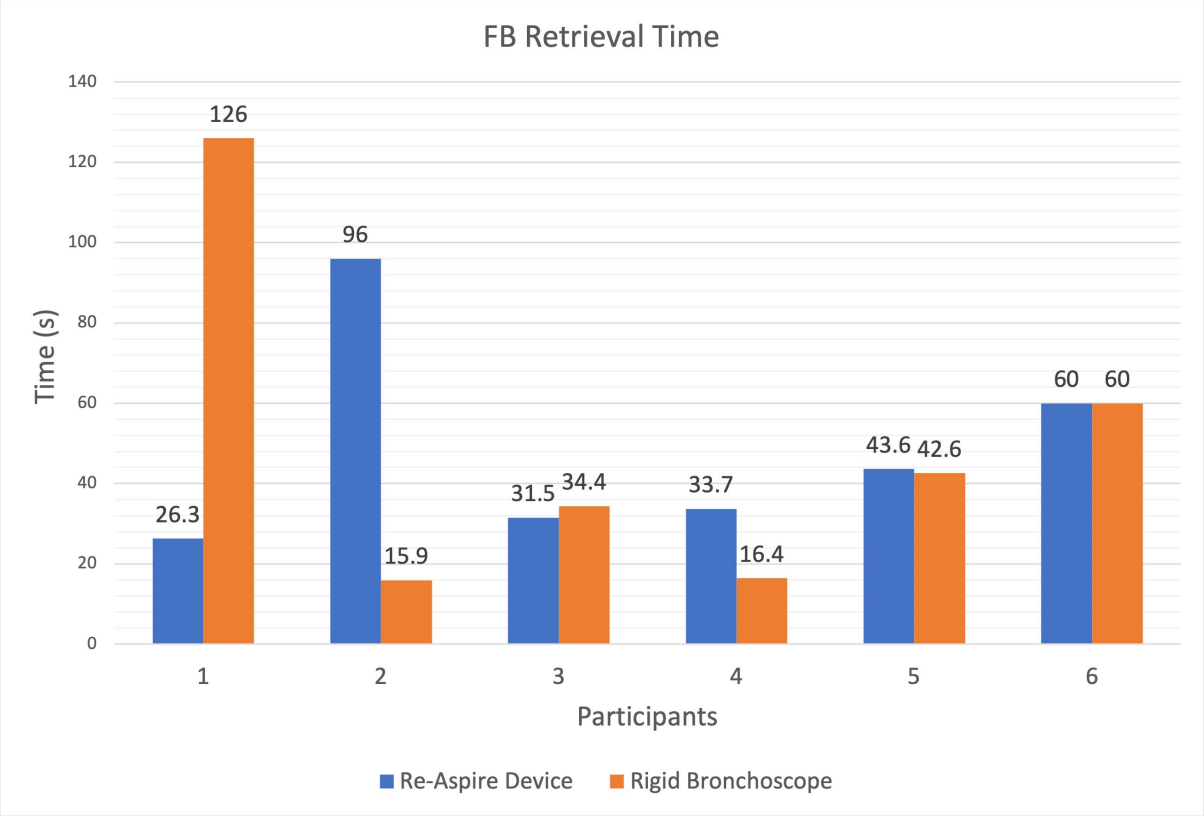

Figure 6.3: FB retrieval times for each testing participant

6.3 Subjective Results

The subjective results were collected from the completed post-testing questionnaire and system usability scale. A comparison of the usability and functionality of each device from the user's perspective was determined.

6.3.1 Post-testing Questionnaire

The post-testing questionnaire, shown in Table F.1 and Table F.2 in Appendix F, was completed by each participant after completing the testing protocol for each device on the respiratory mannequin. Questions were grouped into several categories according to the subsystems, the device's general usability, and difficulties experienced during use.

Each question was scored out of 5. Thereafter, each category was totalled, and a percentage was determined per a category as shown in Table 6.6 and Table 6.7. An average score was calculated by averaging all scores, excluding the difficulty score. The average design score was determined by calculating the mean of the score given for each subsystem, excluding the forceps score as this was a constant subsystem for both devices. However, the average functionality score of the device took into account the working of the forceps.

Table 6.6
Post-testing questionnaire for the Re-Aspire device

Post-testing questionnaire (Re-Aspire device)								
Category	**Test participant**						**Average score**	**Standard Deviation**
	1	**2**	**3**	**4**	**5**	**6**		
General usability	75	90	100	85	100	50	83.33	18.89
Endotracheal tube	100	100	80	100	100	100	96.67	8.16
Ventilation connector tube	70	80	85	80	100	65	80.00	12.25
Video	80	66.67	93.33	86.67	100	60	81.11	15.44
Bronchoscope	80	80	40	80	100	60	73.33	20.66
Forceps	90	70	90	100	100	30	80.00	26.93
General difficulties	40	60	20	-	20	80	44.00	26.08
Overall average score	82.41							
Average design score	82.78							
Average functionality score	82.22							

Table 6.7
Post-testing questionnaire for the rigid bronchoscope

Post-testing questionnaire (Rigid bronchoscope)								
Category	**Test participant**						**Average score**	**Standard Deviation**
	1	**2**	**3**	**4**	**5**	**6**		
General usability	75	100	100	85	100	90	91.67	10.33
Telescope	80	60	60	60	60	80	66.67	10.33
Bronchoscope	80	20	80	80	100	80	73.33	27.33
Forceps	80	60	50	80	100	70	73.33	17.51
General difficulties	60	20	20		20	40	32.00	17.89
Overall average score	76.25							
Average design score	70							
Average functionality score	71.11							

The data from the post-testing questionnaire tabulated in Table 6.6 and Table 6.7 is graphed in Figure 6.4. The Re-Aspire's average overall score, design and functionality scores were higher than the rigid bronchoscope. However, the general usability score of the rigid bronchoscope scored higher than the Re-Aspire device. The topic of usability is further discussed, clarifying the system usability of each device.

The resulting average score of the bronchoscope subsystem and general difficulties were identical for both devices. However, when looking at the individual bronchoscope scores, not all users had the same opinion about the bronchoscope, as shown in Figure 6.5. According to these scores, half of the participants had their preference in choice of the bronchoscope, compared to the rest who scored the two devices equally.

The visualisation scores for each participant are shown in Figure 6.6. How the user views a patient's airway using the Re-Aspire device and rigid bronchoscope is shown in Figure 6.7. The participant had to look through the proximal port of the rigid bronchoscope, with the forceps within that same port, to identify and retrieve the FB. Whilst for the Re-Aspire device, the participant was able to identify the FB using the imaging displayed on the laptop, provided by the camera placed situated on the distal end of the bronchoscope. Overall, the resulting average for the visualisation score of the Re-Aspire device and rigid bronchoscope was 81.11% and 66.67% respectively. When analysing the participant's individual scores, the majority of the users preferred the Re-Aspire device over that of the rigid bronchoscope.

The Re-Aspire device captured images from the videos, as shown in Figure 6.8. The camera displayed clear, real-time imaging of the bronchoscope throughout insertion into the airway of the respiratory mannequin. The participants could navigate the airway, passing the vocal cords (Image II), until reaching the FB lodged within the right main bronchus (Image III). In contrast to the rigid bronchoscope, the participants were able to see the teeth of the forceps (when inserted) and determine whether they were open or closed (Image IV). The brightness from the set of LEDs of the camera was sufficient for the participant to direct the bronchoscope through the airway safely.

Participants who are glass wearers found that the visualisation provided by the Re-Aspire device was far superior compared to that of the rigid bronchoscope. The glasses provided an increased difficulty when identifying the FB using the rigid bronchoscope. The glasses were an additional barrier that the user had to navigate around while identifying the FB through the lumen of the rigid bronchoscope. When the forceps were inserted within the lumen of the rigid bronchoscope, in conjunctionwith wearing glasses, it proved problematic when identifying and retrieving the FB. This resulted in a lower scoring for the forceps for the rigid bronchoscope.

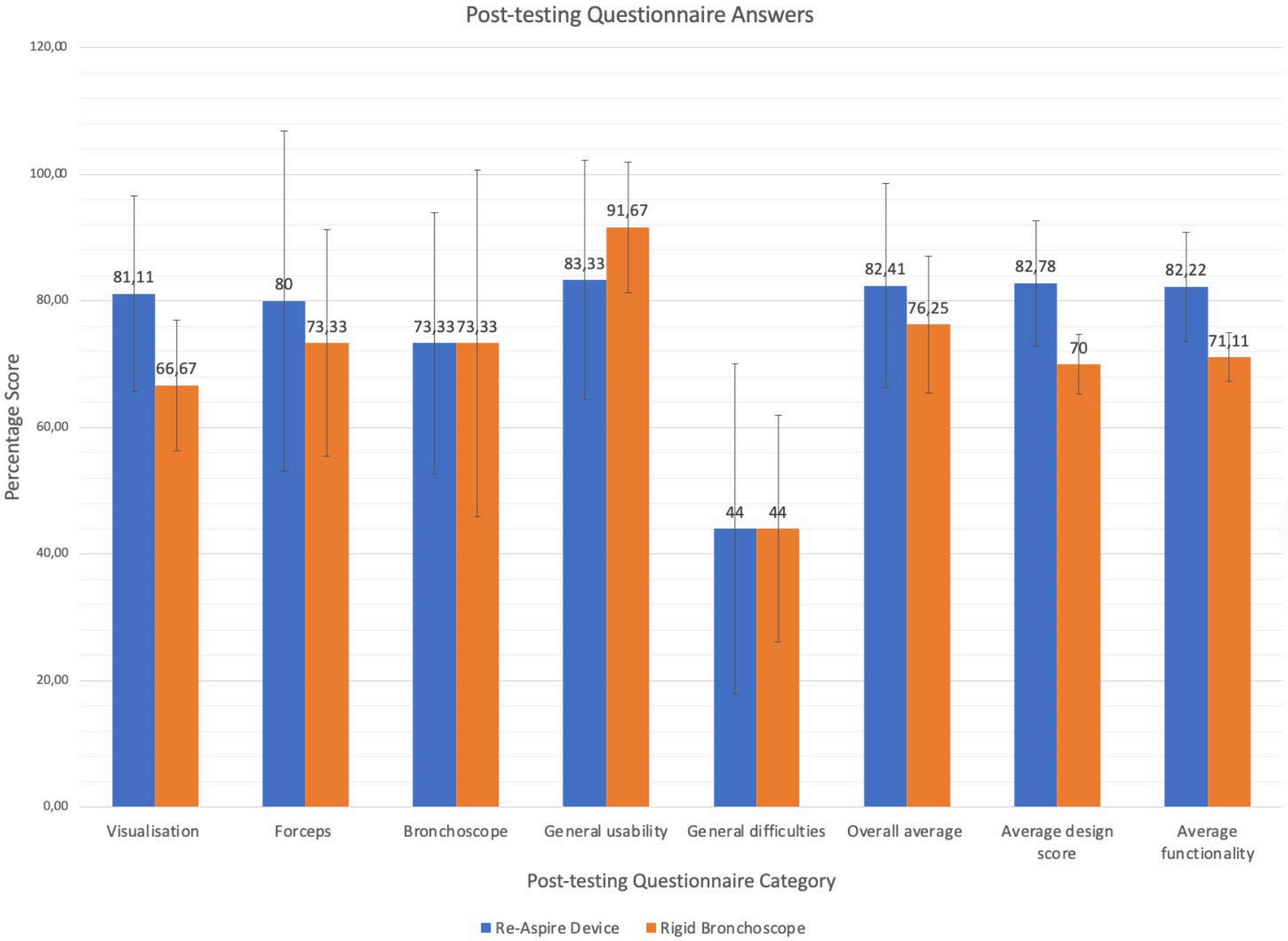

Figure 6.4: Average score for each post-testing questionnaire category

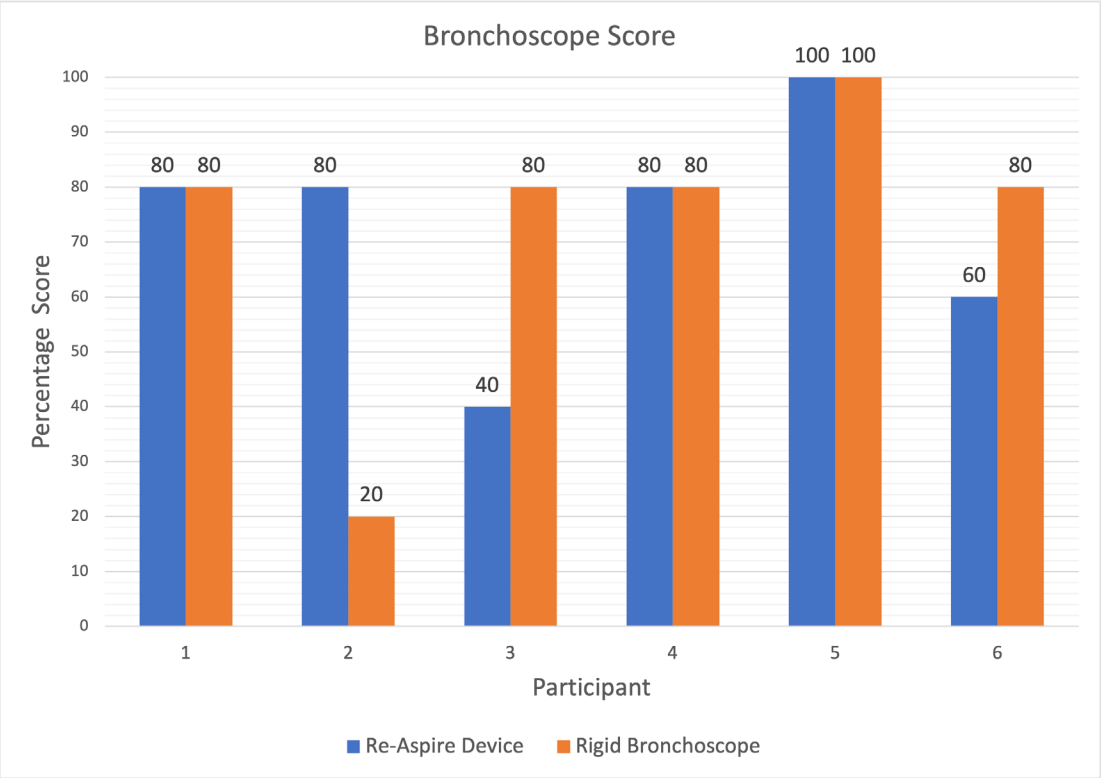

Figure 6.5: Average bronchoscope rating score for each testing participant

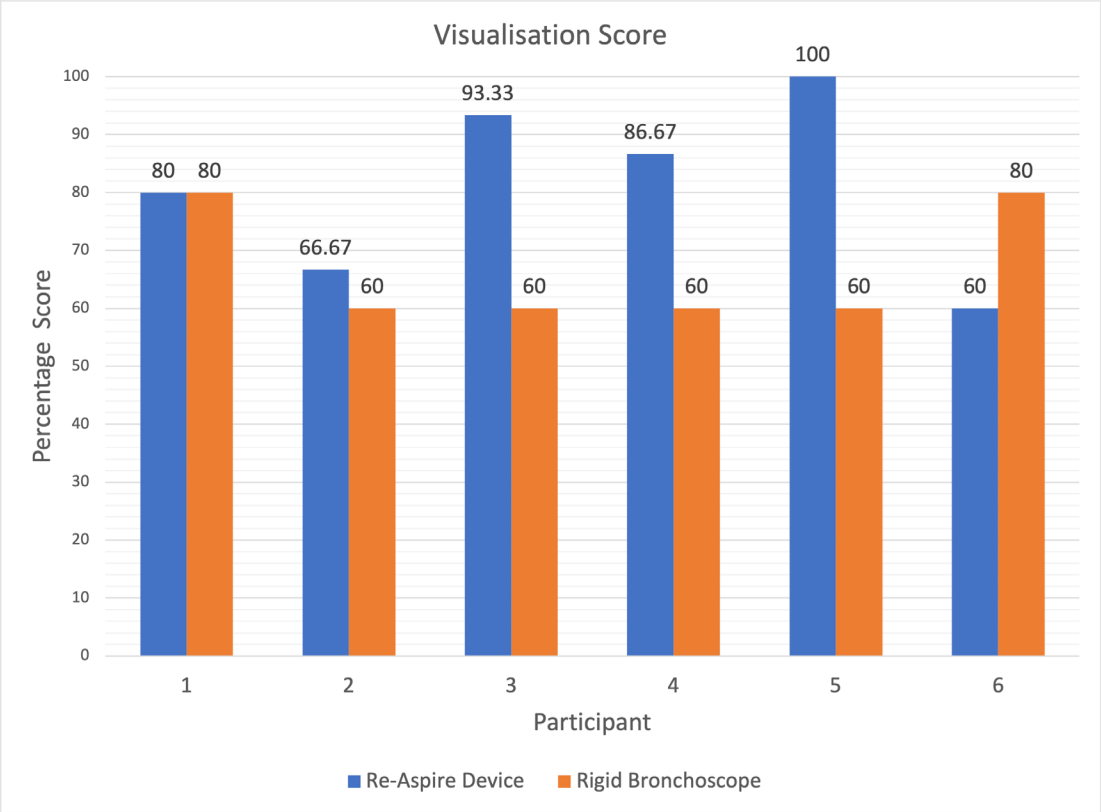

Figure 6.6: Average visualisation rating score for each testing participant

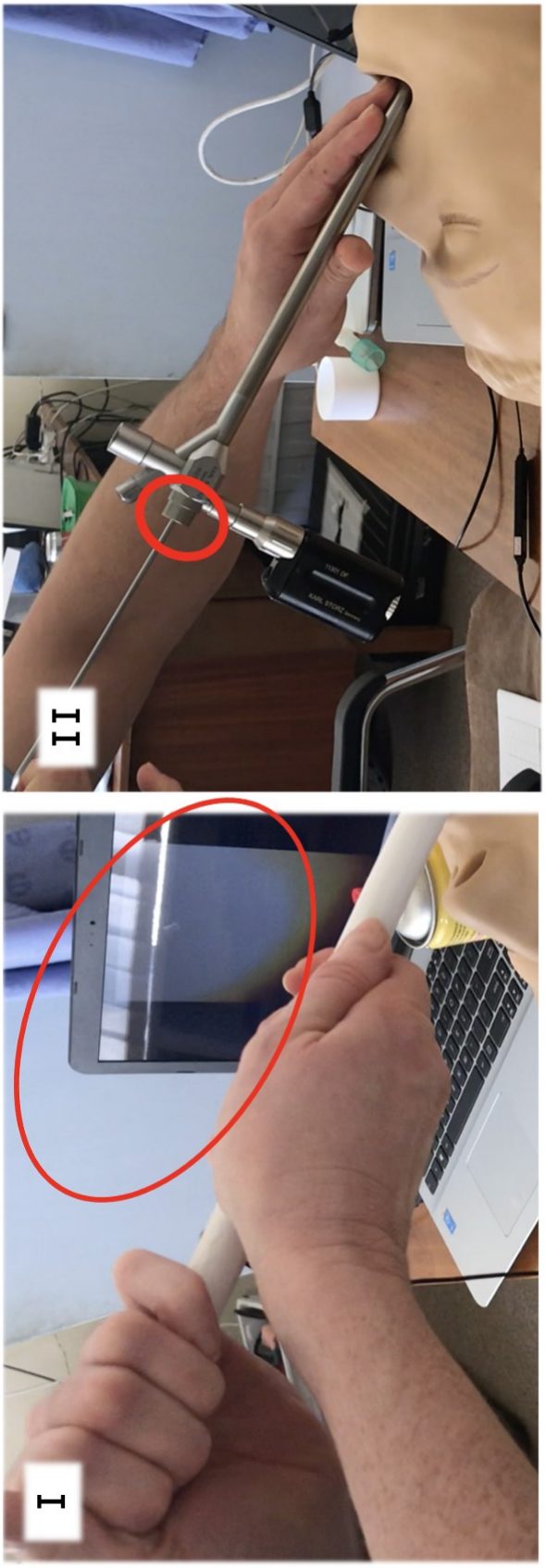

Figure 6.7: Visualisation for Re-Aspire device

Figure 6.8: Images captured by the Re-Aspire device testing: I) bronchoscope sliding over the ETT and being inserted into the airways, II) bronchoscope about to pass the vocal cords into the airways, III) FB identified, IV) teeth of the forceps opened, V) FB retrieved by the forceps

The functionality score was determined from each participant's opinion after testing each device, as displayed in Figure 6.9. The functionality score was calculated by averaging each subsystem's score for both devices. For the Re-Aspire device, these subsystems included the uncuffed endotracheal tube, ventilation connector tube (VCT), camera, bronchoscope and forceps. The rigid bronchoscope's subsystems included the bronchoscope, viewing port, and the same set of forceps used for the Re-Aspire device.

Bearing the results of one participant, the Re-Aspire device's functionality scored significantly higher than the rigid bronchoscope. These results confirmed that a higher usability and functionality was achieved with the design.

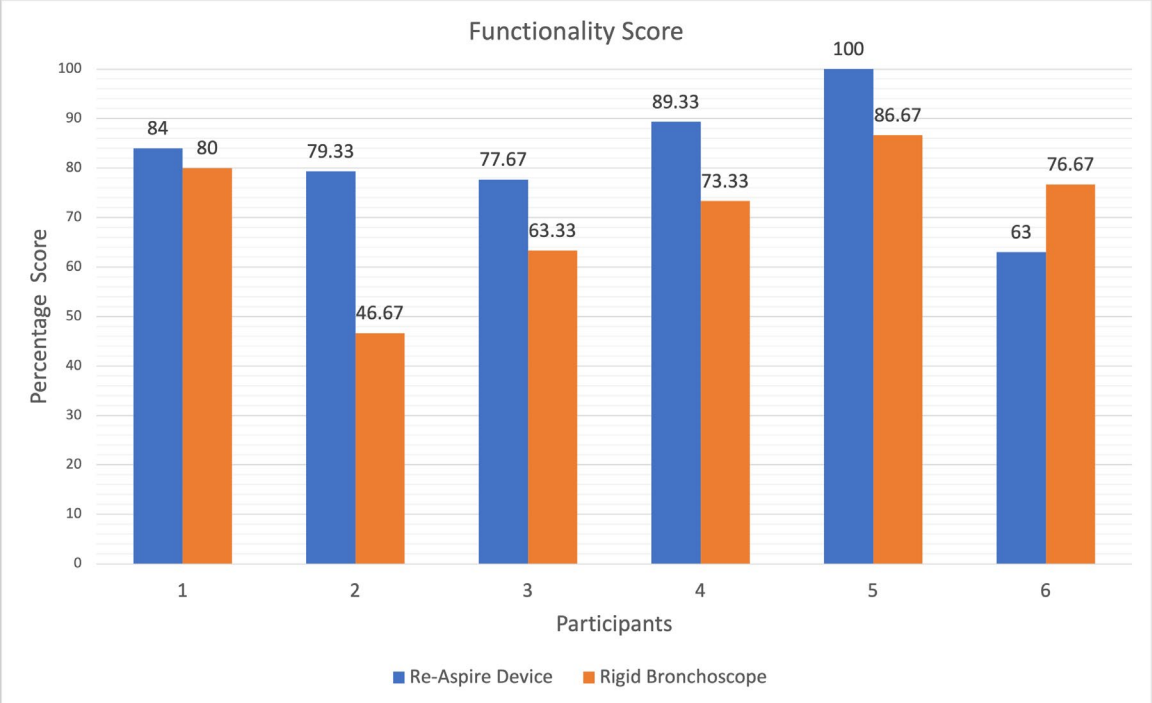

Figure 6.9: Average functionality score for each testing participant

6.3.2 System Usability Score (SUS)

Following testing, each participant completed the system usability scale as shown in Appendix G. The system usability score for the Re-Aspire device and rigid bronchoscope was calculated and is shown in Table 6.8 and Table 6.9 respectively. These SUS are graphed and displayed in Figure 6.10.

Table 6.8
System usability score (Re-Aspire device)

Usability score (Re-Aspire device)						
Question	**Testing participant**					
	1	**2**	**3**	**4**	**5**	**6**
1	3	2	3	1	4	1
2	3	2	4	4	4	1
3	3	2	4	3	4	1
4	4	2	1	2	4	3
5	3	0	4	3	4	2
6	3	1	4	2	4	1
7	3	2	3	4	4	3
8	3	2	3	3	4	0
9	3	1	2	2	4	1
10	3	2	4	1	4	1
System usability score	77.5	40	80	62.5	100	35
Average system usability score	65.83					

Table 6.9
System usability score (Rigid bronchoscope)

System usability score (Rigid bronchoscope)						
Question	**Testing participant**					
	1	**2**	**3**	**4**	**5**	**6**
1	2	2	2	0	2	3
2	3	4	3	3	3	3
3	3	4	1	2	1	3
4	2	4	2	2	4	3
5	3	3	2	3	3	2
6	1	2	4	3	2	3
7	3	0	3	1	2	3
8	2	3	3	3	3	3
9	2	2	2	3	1	3
10	1	2	3	1	1	2
System usability score	55	65	62.5	52.5	55	70
Average system usability score	60					

Overall, the Re-Aspire device resulted in a higher average system usability score of 65.83 compared to the rigid bronchoscope which scored 60. Two of the six participants, participants 3 and 6, preferred the rigid bronchoscope over that of the Re- Aspire device. This results from previous familiarity and/or bias towards the standard rigid bronchoscope compared to the redesign.

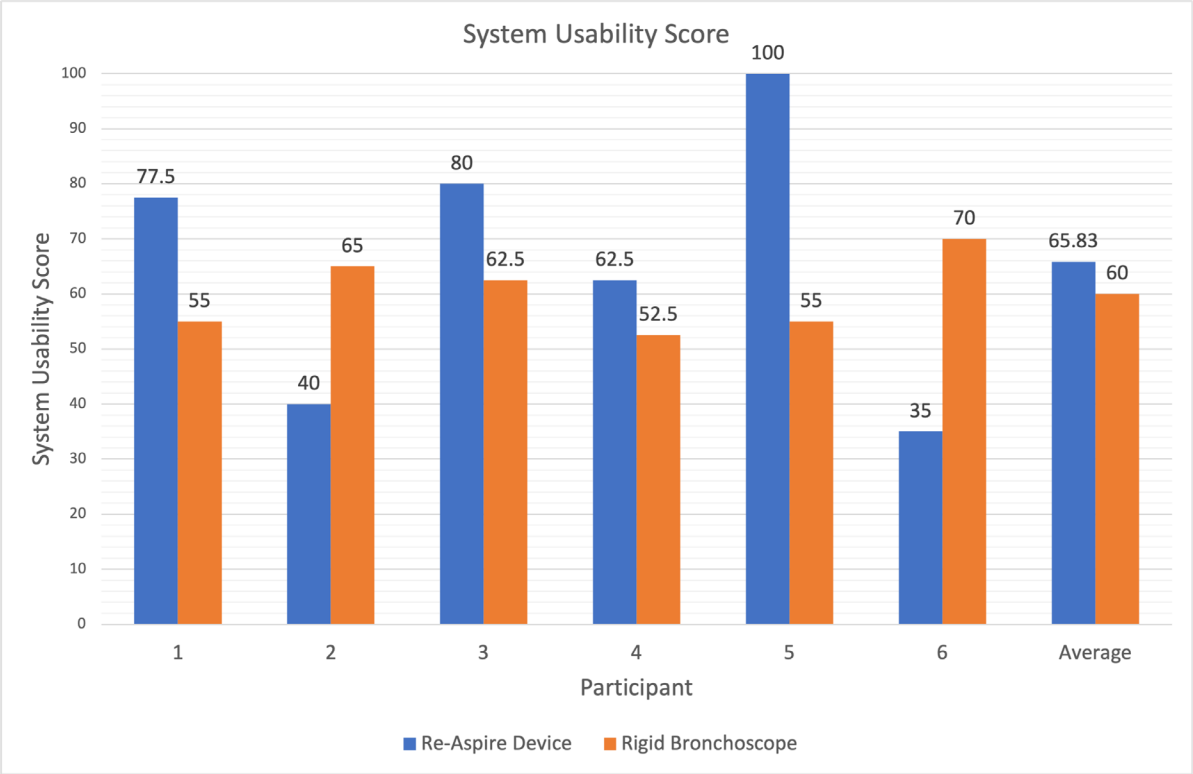

Figure 6.10: System usability score for each testing participant

The average SUS scores are plotted against the scale in Figure 6.11, where the orange and blue lines represent the rigid bronchoscope and Re-Aspire device, respectively. According to the SUS scale, both devices' SUS scores are placed within the marginal scoring region. However, the Re-Aspire device score was within the 'marginally high scoring region', whilst the rigid bronchoscope scored within the 'marginally low scoring region'. According to the user's perspective, these results demonstrated that the Re-Aspire device has a higher perceived ease of use and system satisfaction. It must be noted, that the Re-Aspire device is still within its prototyping stage. Therefore, the Re-Aspire device fared well against the rigid bronchoscope which is known as the gold standard for bronchoscopy procedures. Thus, these resulting SUS scores have confirmed that the Re-Aspire device has an increased familiarity compared to the rigid bronchoscope.

The SUS results were further analysed by studying the mean, standard deviation, and confidence intervals. For the Re-Aspire device, with 95% confidence the population mean is between 47.5 and 84.1. Whilst for the rigid bronchoscope there is a 95% confidence the population mean is between 55 and 65. Both confidence levels are based on the six participant's scoring. The unfamiliarity of the new device and the bias towards the rigid bronchoscope resulted in a wider confidence interval for the Re-Aspire device. These confidence intervals would be of a narrower range if the sample size were to be increased for future testing.

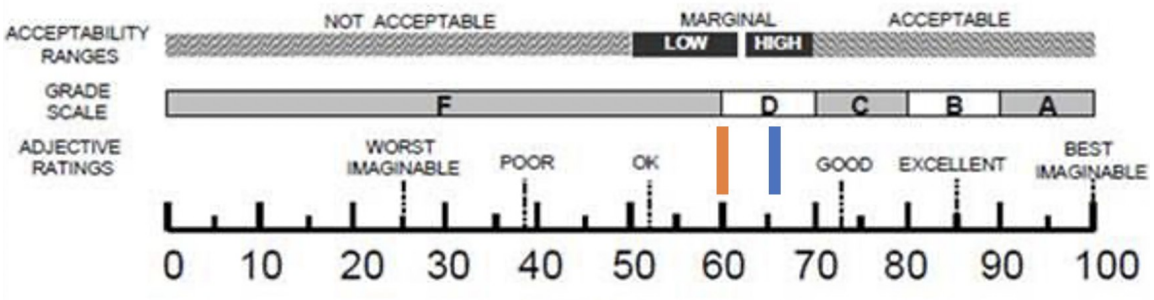

Figure 6.11: Average system usability score for the Re-Aspire (blue) and rigid bronchoscope (orange)

6.4 Summary of the Results

All hypotheses stated in the experimental method were achieved.

1. The Re-Aspire device shows improved efficacy and usability compared to rigid bronchoscope, when testing on airway mannequins.
2. Compared to the rigid bronchoscope, the Re-Aspire device results in little to no hypoxic time during the procedure.

Even though the Re-Aspire device's working prototype achieved all the stated hypotheses, subsequent design iterations are required to improve the usability and efficacy. These recommendations are detailed in the following section.

7 Future Recommendations

The testing outcomes proved that the 'Re-Aspire' device was a safer, more reliable alternative than that of the rigid bronchoscope. However, the system usability of the device should be improved. As a result, several design recommendations were determined for future design iterations to continue the research presented.

7.1 Overall Size of Re-Aspire Device

The initial working prototype was developed for a teenage/adult female population due to the budget and time constraints of the research. However, the Re-Aspire device must be downsized to fit both the paediatric and adult populations. The clearance between the Bronchoscope Subsystem (BS) and Ventilation Connector Subsystem (VCS) shouldbe minimised to ensure that the device can be downscaled appropriately.

Before commencing with clinical trials, future testing scenarios must involve testing the subsequent design iteration on paediatric respiratory models.

7.2 Ventilation Connector Subsystem Design

A screw locking method for the ventilation connector tube to be firmly secured within the proximal opening of the endotracheal tube should be incorporated into the following design iteration, without increasing the diameter thereof. This will ensure that the endotracheal tube does not disconnect from the ventilation connector tube and persist further down the airway when the bronchoscope slides over it.

7.3 Bronchoscope Design

The bronchoscope design should explore incorporating grooves situated on the distal end to ensure easy insertion of the bronchoscope into the airway. This will be achieved by including the grooves into the negative mould used to cast the bronchoscope. Different thickness levels of the bronchoscope subsystem should be explored to determine the optimal thickness of the bronchoscope. Finally, a hydrophilic coating should cover the external surface of the bronchoscope to contribute to the effortless insertion of the bronchoscope.

7.4 Visualisation Subsystem Design

The subsequent design iteration should consider a wireless endoscope camera that connects to a smart device via Bluetooth or a WIFI connection. After that, a phone/smart device application design can be developed to aid the user in identifying the FB within the airway.

8 Conclusion

This study aimed to design and develop a novel video-assisted tube-over-tube rigid bronchoscope to remove foreign bodies from the bronchi following aspiration, whilst providing constant ventilation and visualisation of the airway. For this aim to be achieved, the following list of primary objectives was to be met:

1. Design and integrate the novel video-assisted tube-over-tube rigid bronchoscope and its subsystems.
2. Validate the design of the novel video-assisted tube-over-tube rigid bronchoscope through testing the subsystems.
3. Perform pre-clinical bench testing (on a respiratory mannequin) and cadaver testing.

All objectives were met, thus achieving the research aim of the project. This chapter summarises the outcomes of the research objectives and how they were achieved.

The 'Re-Aspire device' design was broken down into several subsystems namely the visualisation, ventilation connector, bronchoscope and foreign body extraction subsystem. The components of each subsystem were successfully designed and manufactured. Thereafter, each component and subsystem were successfully integrated to form one complete system used to retrieve FBs.

The subsystems were validated and tested through preliminary testing on cadavers. This was done to ensure that the device was anatomically correct, the subsystems were integrated successfully during the operation of the device and that the material selected for each component was appropriate for its intended use.

An experimental methodology to determine the device's usability was developed based on the extensive literature review of bronchoscopy procedures. After that, the experimental testing protocol was performed on the Laerdal ® Airway Management Trainer. This airway management trainer is the current method of training surgeons to perform a rigid bronchoscopy procedure. The testing was performed by the design device and its competitor, the Karl Storz rigid bronchoscope. The Karl Storz rigid bronchoscope is considered the gold standard for bronchoscopy, therefore providing an effective benchmark for comparing the usability of the two devices. The testing participants were anaesthesiologists who have had prior bronchoscopy training during their previous studies but do not practise the procedure.

A common FB (a green lid pen) was placed in the right main bronchus of the airway trainer. The participants first practised the procedure using the airway demonstration model. Thereafter, the participants retrieved the FB from the airway of the trainer, whilst the facilitator timed the procedure and noted all observations and comments of the participants per each task. Post testing, each participant was interviewed about the functionality of each device and asked to complete a system usability scale for each device.

The experimental outcomes from the testing demonstrated that the 'Re-Aspire' device performed better against the Karl Storz rigid bronchoscope. A total of 34 attempts of FB removal was recorded for the rigid bronchoscope compared to 14 attempts for the Re-Aspire device. This was due to the better visualisation of the FB and the distal end of the forceps provided by the camera of the Re-Aspire device. It is important to note, that the testing participants who wear glasses struggled with retrieving the FB using the rigid bronchoscope due to the physical barrier of the glasses and the lack of depth perception when identifying the FB through the lumen of the scope.

Different testing times were recorded throughout for both devices. As hypothesised, the average hypoxic time was more than double for the rigid bronchoscope comparedto that of the Re-Aspire device measuring at 18.87s and 7.7s respectively. This is a crucial time for any bronchoscopy procedure, as it can prove to be fatal for patients who are not ventilated in an appropriate time frame. However, the total procedure timeof the Re-Aspire device was longer measuring at 100.55s compared to 68.08s for therigid bronchoscope. This was as a result of the participants being unfamiliar with the new device and that the diameter of the Re-Aspire bronchoscope had a tighter fit when passing through the vocal cords of the models.

According to the system usability scale, the Re-Aspire device resulted in a higher average system usability score of 65.83 compared than the rigid bronchoscope which scored 60. According to the SUS scale, both devices' SUS scores are placed within the marginal scoring region. However, the Re-Aspire device score was within the 'marginally high scoring region', whilst the rigid bronchoscope scored within the 'marginally low scoring region'.

These results demonstrated that the Re-Aspire device has a higher perceived ease of use and system satisfaction according to the user's perspective. It must be noted, thatthe Re-Aspire device is still within its prototyping stage. Therefore, the Re-Aspire device fared well against that of the rigid bronchoscope which is known as the gold standard for bronchoscopy procedures.

The Re-Aspire device achieved all the stated testing hypotheses. However, the design of the device can be improved with minor changes to further increase the usability and efficacy. Therefore, the dissertation was concluded with several design recommendations to continue the research. These include, downsizing the Re-Aspire device to fit both the paediatric and adult population, screw locking method in the ventilator connector subsystem design, incorporating distal longitudinal grooves in the bronchoscope design and investigating ways to achieve wireless imaging methods.

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A Mechanical Manufacturers Drawings

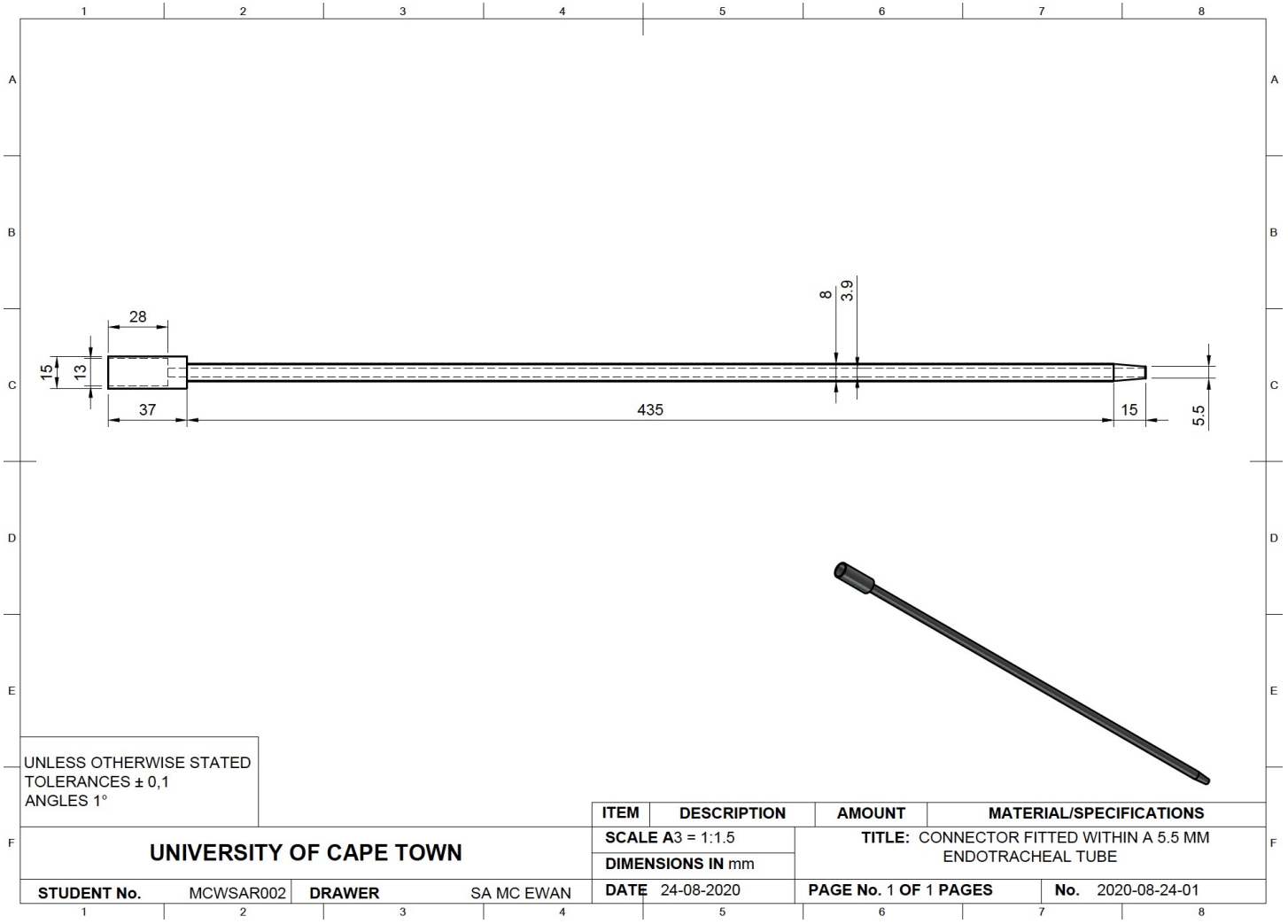

Figure A.1: Mechanical manufacturers drawings of the ventilation connector tube

B Ethics Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

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10 March 2021

HREC REF: 836/2020

A/Prof S Sivarasu
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Student: mcwsar002@myuct.ac.za

Dear A/Prof Sivarasu

PROJECT TITLE: CADAVER TESTING USING A VIDEO ASSISTED TUBE OVER RIGID BRONCHOSCOPE-MSC CANDIDATE-MISS SARAH McEWAN

Thank you for your response letter, addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 30 March 2022.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: - Miss Sarah McEwan will also be involved in this study.

Please quote the HREC REF 836/2020 in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

PBurgess

PP **PROFESSOR M BLOCKMAN**
CHAIRPERSON, FACULTY OF HEALTH SCIENCES HUMAN RESEARCH ETHICS COMMITTEE

HREC/REF 836/2020sa

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC/REF 836/2020sa

C Informed Consent Form

UNIVERSITY OF CAPE TOWN
IYUNIVESITHI YASEKAPA • UNIVERSITEIT VAN KAAPSTAD

Informed Consent Form

Background to the Study

Aspiration of foreign bodies is a prevalent occurrence in the paediatric population. The general age range of the population affected, ranges from 6 months to 14 years old; with 70% of foreign body aspiration (FBA) occurring in children younger than 3 years old (Figueiredo et al., 2012; Lowe, Vasquez, & Maniaci, 2015). If the foreign body (FB) is not removed within an appropriate timeframe; the obstruction could lead to fatality or other serious long term complications such as bleeding, reoccurring pneumonia, hypoxia or a collapsed lung (Nicolai, 2001). FBA is the `sixth most common cause of accidental death in children' (Sahin, Meteroglu, Eren, & Celik, 2013-02).

Discovery of a FB can occur within a few hours or several years after initial aspiration. Currently, FBs are removed with a bronchoscope in conjunction with a pair of forceps (Rodriguez et al., 2016). A bronchoscope is the instrumentation used to visualise the airway and provide a working channel for the forceps (Cutrone et al., 2011).

There are two instrumentations types used, namely the rigid and the flexible bronchoscope. The rigid bronchoscope is the preferred method for obstruction removal due to better control and clear visuals of the airway, in conjunction with the availability of different forceps (Singh & Parakh, 2014). A flexible bronchoscope is used if there is suspected FBA and the radiological findings of a FB are inconclusive (Hitter, Hullo, Durand, & Righini, 2011). Introduction of the current scopes into the airways of a patient puts the patient at high risk of becoming hypoxic, due to the lack of oxygen being supplied to the patient during insertion of the scope (Sharma, 2014).

Both instruments require extensive training, limiting the procedure to specialised clinicians, such as thoracic surgeons and pulmonologists. Presently in South Africa, paediatric bronchoscopies are only performed in tertiary and central hospitals and taught in academic institutions where cardiac and thoracic surgeries are performed. Consequently, there is limited access to paediatric bronchoscopy procedures in developing countries due to the lack of specialists and the socio-economic status thereof (Boufersaoui et al., 2013).

The difficulty experienced when handling the current instrument and the high risk of hypoxia are the motivations for a product redesign. This research aims to make this life saving procedure more accessible, by redesigning the paediatric bronchoscope. The project will prioritise the need for a bronchoscope that does not require a specialised surgeon to operate, whilst remaining affordable for hospitals and clinics across Africa. The proposed study will determine the usability, safety and efficacy of the designed device through testing on cadavers. The results from the testing will determine recommendations for further iterations of the medical device, which will be implemented for future clinical testing.

Purpose of the Study

Researchers at the University of Cape Town's Medical Devices Laboratory have designed and developed a novel video assisted tube over tube rigid bronchoscope which can be used to remove aspirated foreign bodies, whilst providing constant ventilation and visuals of the airway. This entire device can be seen in Figure 1 with all its subsystems.

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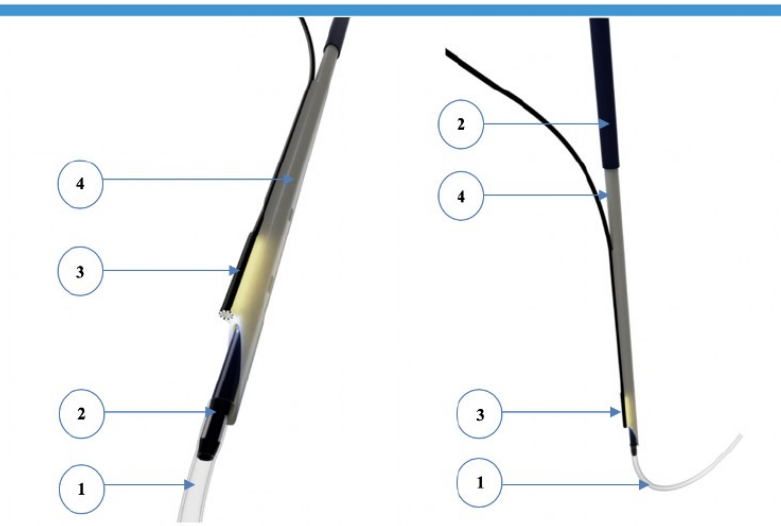

Figure 1: Video assisted tube over tube rigid bronchoscope and its subsystems: 1) Endotracheal tube, Ventilator connector, 3) Endoscope camera and 4) Bronchoscope

The purpose of the study is to determine the usability, safety and efficacy of a novel video assisted tube over tube rigid bronchoscope for the removal of foreign bodies from the left or right main bronchus following aspiration. The testing will be performed on cadavers only and take place in the dissection in the Anatomy Building, at the University of Cape Town's Faculty of Health Sciences. A foreign body (e.g. a lego piece) would be placed in the cadaver's airways and thereafter retrieved by means of the device and forceps. The testing is non-invasive and no biopsies of the cadaver will be retrieved.

The device would be inserted into the mouth, pass the pharynx, enter the trachea and finally reach the left and right main bronchi of the cadaver to retrieve the foreign body. A foreign body (e.g. a lego piece) would be placed in the cadaver's airways and thereafter retrieved by means of the device and forceps. The total testing time as well as the estimated hypoxic time will be recorded for the device. Thereafter, a usability questionnaire which will include the system usability scale will be completed by the participant. This testing procedures will be repeated on the same cadavers using the existing rigid bronchoscopy device to compare the usability of the novel device to its competitors.

Scope of the Study

The study aims to determine the usability, safety and efficacy of a novel video assisted tube over tube rigid bronchoscope for the removal of foreign bodies from the left or right main bronchus following aspiration. The usability will be determined through a questionnaire and comparing how the device performs against the rigid bronchoscope.

What is the Study Protocol?

Before the study begins you will be given a user manual of both the rigid bronchoscope and the tube over tube rigid bronchoscope. You will also be given both devices beforehand to familiarize yourself. Once you are confident in how the device works, you will perform task-based scenarios on a cadaver using the video assisted tube over tube rigid bronchoscope (Re-Aspire Device) and rigid bronchoscope as shown in Test A and Test B respectively.

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Test A: Task based scenarios for the Re-Aspire Device:

Task 1: Assembly of the Re-Aspire device

1. Listen to the explanation of the working of the device by the facilitator.
2. Ensure that all components of the device are available, if a component is missing the user must inform the facilitator.
3. Ensure that the laptop has a minimum battery level of 50% and storage of 1 Gig.
4. Connect the camera and LED light setup to the smart device.
5. Ensure that the LED lighting of the camera is on and turned to its maximum brightness.
6. Ensure that the visuals produced from the camera is displayed on the screen of the laptop.
7. Start recording on the imaging system.
8. (If there were a ventilation outlet, the patient would be ventilated by means of an oxygen mask.)
9. Place the bronchoscope over the ventilation connector tube.
10. Spray anti-fog spray on the lens of the camera.

Task 2: Preparation of patient

1. Position the patient with anterior flexion of the neck region and extension of the atlanto-occipital joint.
2. Stand directly behind the head of the patient.

Task 3: Insertion of endotracheal tube

1. Insert an uncuffed endotracheal tube into the airways of the patient by means of a laryngoscope. (The facilitator should note the time, this is the beginning of the hypoxic time and total procedure time)
2. The facilitator will confirm correct placement of endotracheal tube.

Task 4: Insertion of ventilation connector tube into the proximal opening of the endotracheal tube

1. Ensure that the bronchoscope is placed over the ventilation connector tube.
2. Insert the ventilation connector tube into the proximal port of the endotracheal tube.
3. (If there were a ventilation outlet, the proximal port of the ventilation connector tube would be connected to the ventilation source.) The facilitator will note the time as the end of the hypoxic time

Task 5: Insertion of the bronchoscope into the airway

1. Ensure that the visuals produced by the camera is shown clearly on the screen of the laptop.
2. Hold the ventilation connector tube stationary above the patient, whilst guiding the bronchoscope into the airways. (The bronchoscope will first pass over the ventilation connector tube and then the endotracheal tube. Finally, the bronchoscope will pass the vocal cords and enter the distal portions of the airway.)

Task 6: Removal of ventilator connector tube and endotracheal tube

1. Once, the bronchoscope has passed the vocal cords, slowly remove the ventilation connector tube and endotracheal tube in unison from the airways of the patient.
2. Insert the bronchoscope adaptor into the proximal port of the bronchoscope.
3. (If there were a ventilation outlet, the side port of the bronchoscope adaptor would be connected to the ventilation source.)

Task 7: Identification of the FB

1. Identify the location and type of the FB within the airway, using the visuals displayed on the screen of the laptop.

Task 8: Insertion of the forceps

1. Insert the forceps within the top port of the bronchoscope adaptor.

Task 9: Removal of the FB and Re-Aspire device from the airway
1. Capture the FB using the teeth of the forceps.
2. Remove the entire device, forceps and captured FB in unison from the patient's airways. The FB is often larger than the diameter of the bronchoscope, therefore it cannot pass through the lumen of the bronchoscope. Therefore, the forceps and attached FB must always be ahead of the distal end of bronchoscope when removing the components from the patient's airway. (The observer will note the time, this is the end of the total procedure time)

Test B: Task based scenarios for the competitor device, the rigid bronchoscope:

Task 1: Assembly of the rigid bronchoscope
1. Listen to the explanation of the working of the device by the facilitator.
2. Ensure that all components of the device are available, if a component is missing the user must inform the facilitator.
3. Connect the external light source to the side port of the rigid bronchoscope.

Task 2: Preparation of patient
1. Position the patient with anterior flexion of the neck region and extension of the atlanto-occipital joint.
2. Stand directly behind the head of the patient.

Task 3: Insertion of the rigid bronchoscope
1. Hold the rigid bronchoscope in the dominant hand. (The observer should note the time, this is the beginning of the hypoxic and total procedure time)
2. Use the middle finger of the non-dominant hand to protect the gums and upper teeth and restrict head movement.
3. Insert the rigid bronchoscope with the tip facing forward into the lateral aspect of the mouth of the patient.
4. Pass the bronchoscope through the vocal cords into the distal airways of the patient.
5. The facilitator will note the time as the end of hypoxic time. (If there were a ventilation outlet, the side port of the rigid bronchoscope would be connected to the ventilation source.)
(If the patient is in danger of becoming hypoxic during task 3, the patient would be ventilated immediately until the patient's oxygen levels have stabilised. Task 3 would then be repeated until the bronchoscope is safely inserted into the airway.)

Task 4: Identification of the FB
1. Identify the location of the foreign body within the airways through the proximal port of the rigid bronchoscope.

Task 5: Insertion of the forceps
1. Insert the forceps within the proximal port of the bronchoscope (Note this is the same port that is used to view the distal airways).

Task 6: Removal of the FB and the rigid bronchoscope
1. Capture the FB using the teeth of the forceps.
2. Remove the entire device, forceps and captured FB in unison from the patient's airways. The FB is often larger than the diameter of the bronchoscope, therefore it cannot pass through the lumen of the bronchoscope. Therefore, the forceps and attached FB must always be ahead of the distal end of bronchoscope when removing the components from the patient's airway. (The observer will note the time, this is the end of the total procedure time)

Data collection will be done through recording the total testing time and estimated hypoxic time as well as collecting feedback from the users after testing. The feedback form will include the system usability scale as well as a questionnaire relating to the functioning of the device. This testing protocol will be repeated on the same cadaver.

In alignment with the current global pandemic the following will be enforced: social distancing, hands frequently sanitised and face masks worn throughout the duration testing.

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Any Possible Risks Associated with Participation?
The task-based scenarios that you will be required to complete on the cadavers is non-invasive and completely harmless to you. There are no safety concerns related to this study and the device poses no risk at all to you. The testing is non-invasive and no biopsies of the cadaver will be retrieved.

What if I get hurt? Insurance?
The University of Cape Town provides insurance cover for research-related injuries that happen during participation in this study. If you suffer an injury or illness caused by your participation in this study, your medical expenses will be paid for by UCT based on the South African Good Clinical Practice Guidelines, based on the Association of the British Pharmaceutical Industry Guidelines. The University does not require you to prove fault (which means you will be covered, if you require it).

What about my Privacy and Confidentiality?
All personal information asked for from you during this study will remain confidential (it will not be revealed to anyone outside of the researchers involved in the study). If revealed, it will only be revealed as a number in classification analysis only (which means you will be assigned a number and that number will be used - your name or any other information about you will not be released). The information collected from this study will be stored in a password protected computer to which the researchers will only have access.

Any Potential Benefits?
There are no direct benefits linked to you taking part in this study.

Can I Withdraw Once I've Started The Study?
Your participation in this study is voluntary (it is your choice whether you would like to take part). You are free to withdraw whenever you feel you want to at any time, for any reason, throughout the period of the study.

Some Questions You May Want to Ask:
Here are some questions you can ask me before reaching a decision to take part in this study to make sure you understand everything that is involved in this study. You are welcome to ask your own questions that may not be listed below:

- Who is doing this study and what is it trying to find out?
- What could happen to me, good or bad, if I take part?
- What will I be asked to do?
- What tests or procedures will be done during the study?
- How will my treatment be decided?
- What other choices do I have if I decide not to be in this study?
- What happens if I say no to being in this study?
- If I'm hurt or get sick during the research, who will pay the costs that may result?
- Who will pay for extra costs related to the research?
- Will I be charged for anything or be paid anything for being part in this study?
- If I decide to take part in the study, how will it affect my daily life?
- Will I have to visit the hospital/clinic more often? If so, how much more often?
- How long will the study last?
- What will happen to my personal information?
- What will happen if I change my mind and want to leave the study?
- What must I do if I want to stop being in this study?
- Will I be told the results of the study?
- Who will see my study results and medical records?
- If I have any questions, who should I call?
- Who reviewed and approved this study?
- What is the Research Ethics Committee?

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Contact Information:
If you have any other questions regarding this study and/or require further information, please don't hesitate to contact:

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- Human Ethics Research Committee

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D Non-Disclosure Agreement (NDA)

Non-Disclosure Agreement

I agree to participate in the study conducted by the University of Cape Town's Medical Devices Laboratory.

I understand that participation in this usability study is voluntary and I agree to immediately raise any concerns or areas of discomfort during the session with the study administrator.

I agree to honour the confidential nature of this trial. I acknowledge and confirm that I will not divulge to any party any confidential information including and not limited to the workings of the device used in this trial and the results obtained within the trial. I agree to keep confidential information confidential and to protect the confidentiality of such confidential information with the same degree of care with which I protect the confidentiality of my own information.

I consent to be photographed/videoed and further authorise that the photographs/videos may be used or published for any project-related purpose.

Please sign below to indicate that you have read and you understand the information on this form and that any questions you might have about the session have been answered.

Date: _____

Printed Name: _____

Signed Name: _____

Thank you!

We appreciate your participation.

E Objective Data Collection

Table E.1
Objective data collection key

Outcome	Abbreviation
Success (correct use)	S
Success with Observed Difficulty	SOD
Close Call (error occurred but was recovered)	CC
Not Applicable (blocked by a previous task)	NA

Table E.2
Objective data collection form for the Re-Aspire device

Participant Details		
Name		
Profession		
Experience		
Test number		
Task	**Outcome**	**Comments/Issues**
1		
2		
3		
4		
5		
6		
7		
8		
9		

Table E.3
Objective data collection form for the rigid bronchoscope

Participant Details		
Name		
Profession		
Experience		
Test number		
Task	**Outcome**	**Comments/Issues**
1		
2		
3		
4		
5		
6		

Table E.4
Time measurements for each test

Test number	
Description	Total time (s)
Assembly	
Disassembly	
Hypoxic time	
Total procedure time	

F Post-Testing Questionnaires

Table F.1

Post-testing questionnaire for the Re-Aspire device

Strongly Agree (5) – Agree (4) – Neutral (3) – Disagree (2) – Strongly Disagree (1)							**Comments /Issues**
General Usability	**5**	**4**	**3**	**2**	**1**	**N/A**	
1. I can quickly get the equipment ready for use.	0	0	0	0	0	0	
2. I can successfully get the equipment ready for use without assistance.	0	0	0	0	0	0	
3. I know when the equipment is working properly.	0	0	0	0	0	0	
4. I can quickly remove the equipment from the patient.	0	0	0	0	0	0	
Endotracheal Tube	0	0	0	0	0	0	
5. I can quickly insert the endotracheal tube by means of laryngoscope without assistance.	0	0	0	0	0	0	
6. I am satisfied with what it takes to insert the endotracheal tube and check the correct placement thereof.	0	0	0	0	0	0	
Ventilation Connector Tube	0	0	0	0	0	0	
7. I can connect the ventilation connector tube into the endotracheal tube with ease.	0	0	0	0	0	0	
8. I can hold the ventilation connector tube stationary whilst sliding the bronchoscope over the connector and endotracheal tube.	0	0	0	0	0	0	
9. The ventilation connector tube does not move out of the endotracheal tube when the bronchoscope slides over.	0	0	0	0	0	0	
10. I can remove the ventilation connector tube and endotracheal tube in unison with ease, once the bronchoscope has been inserted.	0	0	0	0	0	0	
Camera	0	0	0	0	0	0	
11. I can easily connect the camera to the smart device.	0	0	0	0	0	0	

Table F.1 continued from previous page

12. I can easily see the real-time video produced from the video.	0	0	0	0	0	0	
13. I know how to adjust the video's LED.	0	0	0	0	0	0	
14. The video does not fog when in use.	0	0	0	0	0	0	
15. The video does not cut out when in use.	0	0	0	0	0	0	
Bronchoscope	0	0	0	0	0	0	
16. I can easily slide the bronchoscope over the ventilation connector and endotracheal tube.	0	0	0	0	0	0	
17. The bronchoscope provides adequate ventilation through its ventilation slots.	0	0	0	0	0	0	
Forceps	0	0	0	0	0	0	
18. The forceps can reach the distal portion of the bronchoscope with ease.	0	0	0	0	0	0	
19. The forceps can remove the entire foreign body with ease.	0	0	0	0	0	0	
General Difficulties	0	0	0	0	0	0	
20. I had difficulty getting the equipment ready for use.	0	0	0	0	0	0	

Table F.2
Post-testing questionnaire for the rigid bronchoscope

Strongly Agree (5) – Agree (4) – Neutral (3) – Disagree (2) – Strongly Disagree (1)							**Comments/Issues**
General Usability	**5**	**4**	**3**	**2**	**1**	**N/A**	
1. I can quickly get the equipment ready for use.	0	0	0	0	0	0	
2. I can successfully get the equipment ready for use without assistance.	0	0	0	0	0	0	
3. I know when the equipment is working properly.	0	0	0	0	0	0	
4. I can quickly remove the equipment from the patient.	0	0	0	0	0	0	
Viewing of airways	0	0	0	0	0	0	
5. I can easily connect light source to the bronchoscope	0	0	0	0	0	0	
6. I can easily see the through the bronchoscope	0	0	0	0	0	0	
Bronchoscope	0	0	0	0	0	0	
7. I can easily insert the bronchoscope into the airways.	0	0	0	0	0	0	
8. The bronchoscope provides adequate ventilation through its ventilation slots.	0	0	0	0	0	0	
Forceps	0	0	0	0	0	0	
9. The forceps can be easily inserted into the port of the bronchoscope.	0	0	0	0	0	0	
10. The forceps can reach the distal portion of the bronchoscope with ease.	0	0	0	0	0	0	
11. The forceps can remove the entire foreign body with ease.	0	0	0	0	0	0	
General Difficulties	0	0	0	0	0	0	
12. I had difficulty getting the equipment ready for use.	0	0	0	0	0	0	

G System Usability Scale (SUS)

	Strongly Disagree				Strongly Agree
	1	**2**	**3**	**4**	**5**
1. I think that I would like to use this system frequently.	o	o	o	o	o
2. I found the system unnecessarily complex.	o	o	o	o	o
3. I thought the system was easy to use.	o	o	o	o	o
4. I think that I would need the support of a technical person to be able to use this system.	o	o	o	o	o
5. I found the various functions in this system were well integrated.	o	o	o	o	o
6. I thought there was too much inconsistency in this system.	o	o	o	o	o
7. I would imagine that most people would learn to use this system very quickly.	o	o	o	o	o
8. I found the system very cumbersome to use.	o	o	o	o	o
9. I felt very confident using the system.	o	o	o	o	o
10. I needed to learn a lot of things before I could get going with this system.	o	o	o	o	o