Master Thesis

Design and development of a medical device for diagnosis of COPD

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Division of Machine Design • Department of Design Sciences

Faculty of Engineering LTH • Lund University • 2015

LUND UNIVERSITY

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Preface

This master thesis presents the final work of our education within Mechanical Engineering and Industrial Design at Lund University. The work was done on behalf of the division of Ergonomics and Aerosol Technology at the Faculty of Engineering at Lund University and concerns the design and development of a medical device for diagnosis of chronic obstructive pulmonary disease, based on a new pulmonary function measurement method developed in a joint research project between above mentioned division and the division of Clinical Physiology at Lund University.

We would like to direct our special thanks to our main supervisor Jakob Löndahl and our assisting supervisor Karl-Axel Andersson for all their valuable input. Furthermore, we would like to thank Jonas Jakobsson and Hanna Nicklasson for always being helpful and being additional sounding boards throughout the project.

The months spent working with this thesis has been intense and challenging. The holistic and multidisciplinary character of the project has been truly inspiring. We deeply hope that the work we have put into finding a path forward will be helpful in further development of the device and research related to the AiDA method.

Lund, June 2015

Sanna Eriksson and Sofia Isaksson

Abstract

This thesis presents design and development of a medical device for diagnosis of emphysema or COPD by controlled lung deposition of nanoparticles. After purging the lungs with particle free air the subject inhales a controlled aerosol mixture and holds his breath for a determined period of time, before exhaling. The degree of lung disease is calculated by measuring and comparing the concentration of nanoparticles in the inhaled and exhaled breath, giving a value of the fraction of deposited nanoparticles in the subject.

With the starting point of the thesis project being a functional prototype, the work has focused around understanding the problems and challenges of the method as well as the current setup and what needs to be improved to take the device to the next level, and thereby make way for a future small size serial production.

To do so, the first step of the process was to make a literature study to understand the basics of medical devices, clinical physiology as well as aerosol technology and all the specific components used in the instrument. A substantial survey was carried out to collect data from users and stakeholders and interpret them in terms of customer needs. Product specifications were adapted from customer needs as well as from a literature search and discussions with the research group.

When generating concepts, prototyping has been the main tool. By creating a real size cardboard model of the main functional units in the device, concepts for placement of modules were generated. Prototypes have been used throughout the project at multiple levels and have been a basis for communication with the research team and other people involved in the project. Concept selection has been made both by means of trying the prototypes as well as structured methods derived from the generic product development process by Ulrich and Eppinger.

The selected concepts were further developed with emphasis on what is possible to produce. The final design is presented by means of 3D renderings as well as a prototype together with guidelines for further development. Renderings and prototypes show the overall design structure and creates a foundation for further detailed product development, in order to manufacture a reproducible device to a reasonable cost in near future.

Keywords: Medical device, pulmonary function measurement, product development, ergonomics, prototyping.

Sammanfattning

Denna rapport redogör för design och utveckling av ett medicintekniskt instrument för diagnos av kronisk obstruktiv lungsjukdom (KOL) eller emfysem. Arbetet utgår ifrån en ny diagnosmetod och ett instrument i form av en funktionell prototyp som används för att testa den nya diagnosmetoden.

Med utgångspunkt i den funktionella prototypen har arbetet fokuserats kring att förstå vilka problem och utmaningar som finns för att kunna ta den funktionella prototypen till nästa nivå och för att bana väg för en framtida kortserieproduktion.

Det första steget i processen var att göra en litteraturstudie för att få en grundläggande förståelse för klinisk fysiologi samt aerosolteknologi och de specifika delinstrument som används i prototypen, följt av insamling av rådata från användare och intressenter och tolkning av denna data i form av kundbehov. Produktspecifikationer skapades utifrån identifierade kundbehov så väl som utifrån litteratursökning och diskussioner med forskargruppen.

Vid konceptgenerering har prototyper varit ett mycket värdefullt verktyg. Genom att skapa fullskaliga pappmodeller av de viktigaste enheterna i den funktionella prototypen har konceptgenerering för placering av de olika enheterna gjorts. Prototyper har använts under hela projektet på flera nivåer och har varit en utgångspunkt för kommunikation med forskargruppen och andra personer som varit inblandade i projektet. Val av koncept har gjorts både genom test av prototyper samt strukturerade metoder från Ulrich och Eppingers generiska produktutvecklingsmetodik.

Valda koncept har vidareutvecklats med hänsyn till vad som är möjligt att producera i liten skala. För att främja reproducerbarheten har tillämpliga förändringar vad gäller ingående komponenter undersökts. En övergripande produktarkitektur har definierats och en helhetsdesign av instrumentet har tagits fram.

Den slutgiltiga utformningen av instrumentet som helhet presenteras med hjälp av 3D-renderingar i kombination med en fysisk prototyp som visar den övergripande designstrukturen. Det resultat som presenteras skapar en grund för detaljerad vidareutveckling för att kunna tillverka ett reproducerbart instrument inom en snar framtid.

Table of Contents

1 Introduction

This chapter gives a brief introduction to a method and instrument for pulmonary function measurement developed in a research project at Lund University. The purpose of the present invention and the need for further development through this degree project are presented as well as the aims and delimitations of the degree project.

1.1 Background

Chronic obstructive pulmonary disease (COPD) is generally under-diagnosed and under-treated, even in high income countries [1]. On a global scale over 100 million people suffer from COPD, most of them smokers. According to the World Health Organization (WHO) COPD is projected to be the third most common cause of death by 2030 [2]. The progress of the disease can be slowed down by change in lifestyle, usually cessation of smoking, but without a diagnosis the patient is unlikely to change [3]. More effective methods for diagnosis are therefore needed to be able to diagnose patients suffering from COPD in early stages.

In a collaborative research project between the Faculty of Engineering at Lund University and the Department of Clinical Sciences at Skåne University Hospital a new method for diagnosis of COPD has been developed. The method is called Airspace Dimension Assessment (AiDA) and is especially effective when it comes to early stage diagnosis of emphysema or COPD.

An instrument in form of a functional prototype using the method is currently in use, but is in need of further development to meet the variety of requirements of a reproducible medical device. Both the technical setup and the overall design of the device need to be evaluated and further developed.

1.2 Objectives

The aim of this master thesis is to develop and improve the design of a medical device for diagnosis of emphysema or COPD by controlled lung deposition of nanoparticles. The thesis work includes the following:

- Identifying problems and challenges in the current setup.
- Identifying requirements for the instrument based on customer needs, ergonomics, technical limitations, target environment and safety aspects.
- Providing solutions for placement and redesign of modules critical to the patient and operator interaction with the device, without risking the functionality of the technology the method is based on.
- Presenting an overall design solution for the medical device by means of 3D renderings and a prototype.

1.3 Delimitations

After identifying user needs and problems of the current setup, the work will focus on aspects critical at the current stage of development. Remaining problems will be highlighted as recommendations for further development.

No cost analysis will be made, however roughly predicted costs will be considered to make sure that the thesis focuses on what is reproducible and financially viable.

Planning of electronics will be excluded from the degree project. Furthermore, the particle generator is being redesigned in a parallel degree project and will therefore not be considered for further development in this degree project.

2 Background

This chapter presents a brief introduction to medical and technical aspects of human physiology, pulmonary disease as well as the current setup of the diagnosis instrument. Furthermore, regulation and standards as well as design guidelines of importance for further development of the instrument are described.

2.1 **The respiratory system**

2.1.1 Anatomy and physiology

The respiratory system includes the oral and the nasal cavities, the airways, the lungs and the chest structure. The airways are a series of tubes leading to the lungs. The chest structure provides the function of moving air into and out of the lungs.

The main functions for the respiratory system are to transfer oxygen to the bloodstream and to release carbon dioxide, a waste product of metabolism, in the opposite direction. While breathing through the nose and mouth oxygen enters the respiratory system. The oxygen passes through the pharynx, which is a passage for both air and food. The pharynx is split up into two tubes: the esophagus, used for food passage, and the larynx, also known as the organ of voice, which is part of the airways.

The larynx is connected to the trachea, also known as the windpipe, a long tube through which the air is pulled down into the lungs. The trachea branches off into two primary bronchi which carries oxygen further into each lung. Thousands of small tubes, the bronchioles branches out from the two primary bronchi. The bronchioles, which are surrounded by smooth muscle, carry oxygen deep into the lungs.

The alveoli are air sacs situated at the end of each bronchiole. The alveoli lies in clusters called alveolar sacs which have extremely thin walls through which oxygen is diffused into the blood and carbon dioxide is taken out of the blood. The lungs of an adult contain a total of approximately 300 million alveoli.

The airways can be divided into the conducting and the respiratory zone. No gas exchange with the blood and no alveoli appear at the conducting zone unlike the respiratory zone which includes alveoli and gas exchange with the blood [4, pp. 434-437].

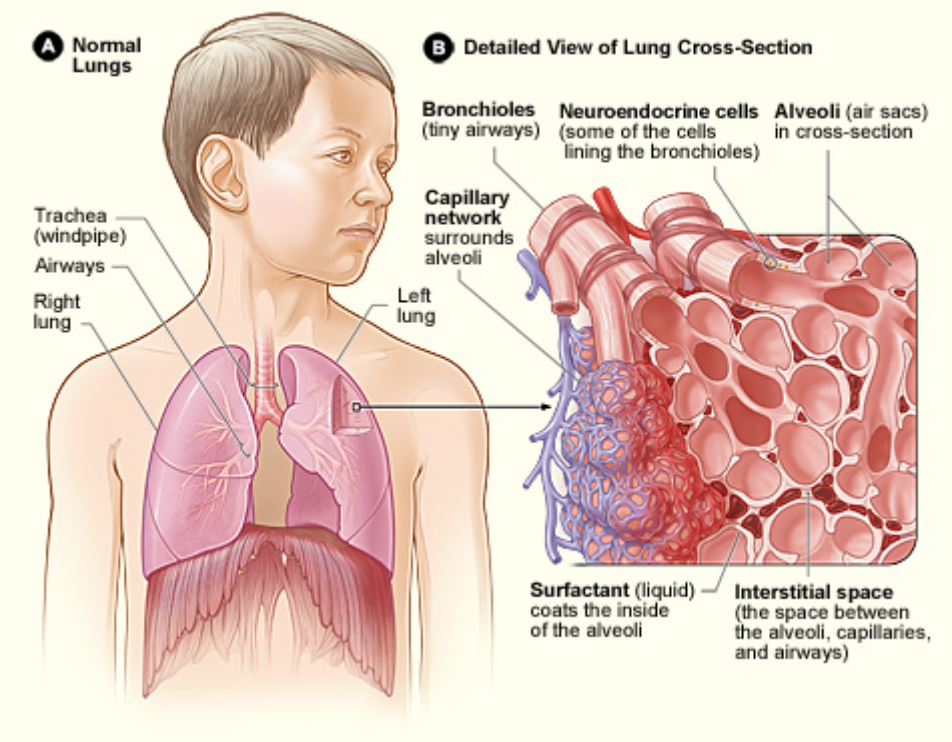

Figure 2.1. An overview of the respiratory system and a detailed view of a lung cross-section.

The surface of the alveolus is surrounded by a capillary network of small blood capillaries and during the passage of blood in the capillaries gases are exchanged by diffusion.

The right side lung is divided into three main areas whereas the left side lung is divided into two main areas or lobes which are independently functioning. The right side lung is slightly larger than the left hand side, which shares space with the heart.

The principal muscle of respiration, the diaphragm, is a skeletal muscle sheet attached to the lower part of the thorax, also called the chest. When the diaphragm expands and contracts the lungs inflates and deflates and oxygen is pulled into the lungs and carbon dioxide is pumped out of the lungs.

A respiratory cycle includes inspiration, the movement of air from the external environment to the alveoli, and expiration, movement in the opposite way.

2.1.2 *Lung mechanics and ventilation*

One of the fundamental processes included in the respiratory system is the ventilation, which takes place in the lungs. The prime function of the lungs is to transfer oxygen from the atmosphere to the bloodstream and to release carbon dioxide in the reverse direction. To enable such an exchange a large surface area is needed.

2.1.3 *Elastic recoil*

The elastic recoil of the lungs works to contract the lungs. This elastic force is mainly generated by the elasticity of the lung tissue, which exists throughout the lung. Also the surface tension of the fluid coating covering the inside walls of the alveoli conduce to the elastic recoil of the lungs. The lungs are situated in the thorax and the elasticity force of the thorax works, in contrary to the elastic force of the lungs, to expand the volume of the lungs.

A substance called surfactant covers the inside of the alveoli. This substance decreases the surface tension and thereby the elastic recoil inside the alveoli. Furthermore the surfactant prevents the alveoli from collapsing since the substance keeps the elastic recoil inside the alveoli at a low level and facilitates lung expansion [4, pp. 443-444].

The space between the lungs and the thorax is called the pleura, the lung sac. The pressure in the pleura is lower than the pressure in the alveoli which helps to balance the elastic recoil of the lungs. The difference in pressure between the pleura and the alveoli is called the elastic recoil of the lungs. The difference in pressure varies with the volume of the lungs [5, pp. 57-58].

2.1.4 *Compliance*

The compliance is a measurement of the elastic characteristics of the lungs. The compliance is measured as the change in volume divided by the change in pleural pressure. [5, p. 58].

2.1.5 *Lung volume*

Lung volume, or lung capacity is the volume of air in the lungs. The total lung capacity, or inspiratory capacity is the volume of gas in the lungs after maximal inspiration. The total lung capacity of an adult human male is about 6 L. The volume of gas left in the lungs after maximal expiration is called the residual volume, RV. The residual volume is about 1.2 L for an adult human male. The difference in volume between the total lung capacity and the residual volume is called the vital capacity, VC. The volume of air left in the lungs after a normal expiration is called functional residual capacity, FRC. Figure 2.2 (below) shows a time-volume diagram with a graph presenting the lung volumes in relation to each other [4, p. 446].

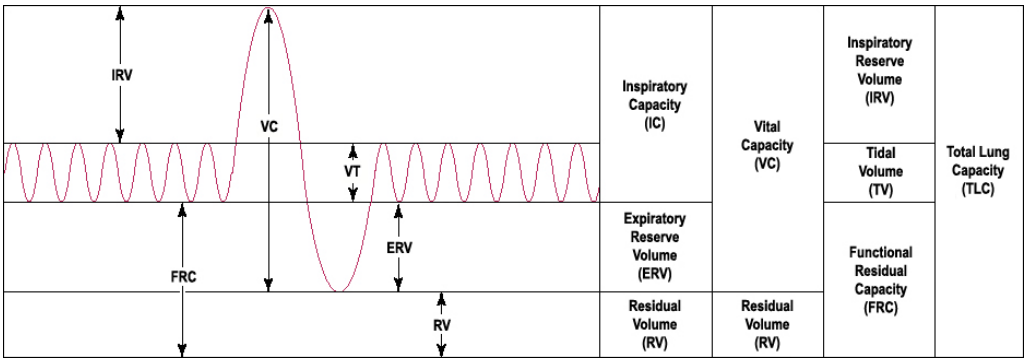

Figure 2.2. The lung volumes in relation to each other presented in a time-volume diagram.

2.2 **Chronic Obstructive Pulmonary Disease, COPD**

The term chronic obstructive pulmonary disease (COPD) is used to describe chronic respiratory diseases characterized by airway obstruction, meaning long time blockage of respiration in the airway. COPD can arise from genetic reasons or environmental exposures, usually smoking. The genetic reason of COPD is that of α1-antitrypsin deficiency[1] while environmental exposures which might lead to COPD includes smoking, biomass burning and occupational exposure.

2.2.1 *Pathophysiology*

COPD is progressive and includes an irreversible decline in lung function. An increased airway resistance leads to lung diseases classified as obstructive, while decreased lung compliance leads to lung diseases classifies as restrictive. Common conditions for COPD are emphysema and chronic bronchitis [6]. These conditions can appear separately but most often coexist, meaning that the discomfort of both should be considered when designing a lung function testing device.

2.2.2 *Emphysema*

Destruction of alveolar walls causes fewer but larger alveoli, as can be seen in figure 2.3. Abnormal enlargement emerges which reduces the lungs' surface area. Another effect of emphysema is a reduction of the natural elasticity within the lungs which means low elastic recoil of the lungs (i.e. high compliance). As emphysema progresses the vital capacity decreases and the airway resistance increases.

Emphysema leads to problems with the exchange of oxygen and carbon dioxide since the decrease in elasticity means that the carbon dioxide remains in the alveoli, causing

[1] A disorder causing deficiency of protective protein critical to lung tissue remodeling

the lungs to become and remain over inflated. In the long term this leads to changing shape of the rib cage as well as the lung tissue. This causes discomfort and a feeling which can be likened to constantly carrying a barrel around the chest. Paired with this comes less efficient breathing and a feeling of inadequate ventilation which leads to patients feeling the need to breathe faster or hyperventilate. [7]

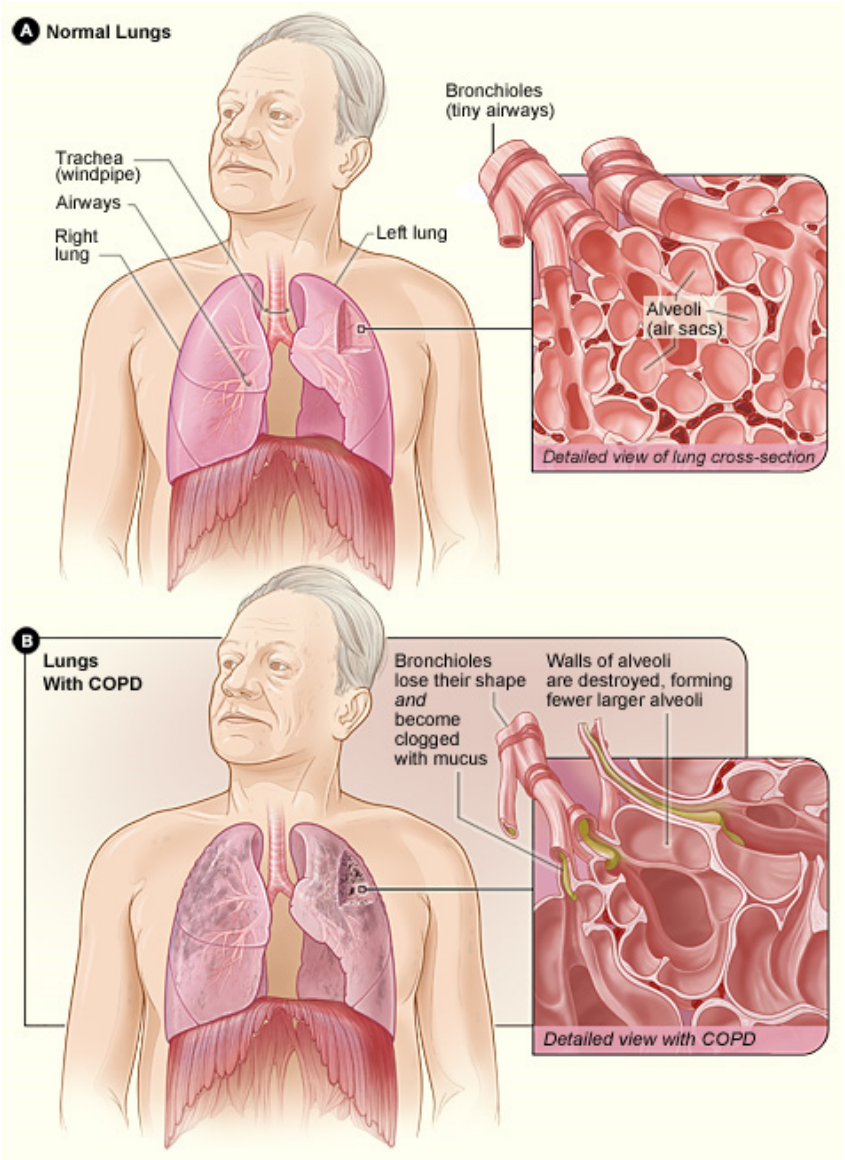

Figure 2.3. The upper picture gives a detailed view of the alveoli sacs of a person with normal lungs while the lower picture presents alveoli sacs of a person with COPD.

2.2.3 *Chronic Bronchitis*

Chronic Bronchitis is characterized by chronic inflammatory changes in the small airways or bronchial tubes and an excessive production of mucus in the bronchi, as displayed in figure 2.3. This condition aggravates the passage of oxygen in the airways and alveoli, leading to deficit of oxygen exchange [4, p. 446]. When diagnosing a patient it is a prerequisite that the patient has had a bad cough for at least three months per year for two years in a row [8, p. 241]. A common feeling of a person with chronic bronchitis is that it feels like breathing through a straw and often feeling short of breath. Such a person typically tries to compensate for the breathing problems by breathing more heavily. Furthermore, people with chronic bronchitis are more susceptible to chest infections [5, p. 243].

2.3 **Diagnostic methods**

An investigation often includes a series of diagnostic methods since each diagnostic method provides different kind of information about the disease state. The reason of investigation and applicable diagnostic methods during investigation is dependent on the background of the patient.

All patients with chronic cough, recurrent lower respiratory tract infections and lung function impairment suspected on anamnestic[2] grounds should be examined through dynamic spirometry. In other words, the first steps of diagnosing emphysema or COPD is anamnesis and dynamic spirometry [8, pp. 244-245] .

Other methods used such as physical examination, echo-doppler, lung diffusion tests as well as X-ray of the lungs, computed tomography and magnetic resonance imaging are used for more specific diagnosis.

2.3.1 *Lung volume measurement*

While some of the diagnostic methods for measurement of lung volume often is combined during an investigation, it is now common to use the same device.

2.3.2 *Spirometry*

Spirometry as a method is often used to evaluate if the patient has some reduced ventilation capacity caused by a disease. Spirometry is also a method commonly used to trace the effects of the treatment of an already know disease. The measured lung volume of a person is dependent of age, body size and sex.

While breathing through a nozzle measurement of the flow rate is made, often by a pneumotachograph which the air flows through. Volumes of the lungs are then

[2] the medical history of a patient

calculated by integration of the flow rate over time. Measurement of the different lung volumes, for example VC, is made after a maximum inhalation, TLC, after a maximum exhalation, RV, or after a normal exhalation, FRC. From TLC, forced expiratory volume during one second, FEV1, is known. Using the measured VC and FEV1 a value FEV% is calculated. Spirometry measurements are repeated three times or until the results are considered reliable.

After inhalation of a bronchial-dilating agent further measurements are done to control if the agent enhances the breathing. This is done to determine COPD from asthma. [5, pp. 281-282].

2.3.3 *Gas dilution*

To measure TLC, RV and FRC the lung volume inside the lungs different types of gas dilution methods can be used.

Nitrogen gas is an example of a gas which can be used for gas dilution test. Inhalation is made through a nozzle connected to separate ways for inhalation and exhalation of air. After a normal exhalation, at the FRC, the way is opened up to a tank with pure oxygen which can be inhaled. Breathing continues until the concentration of nitrogen in the exhaled air has decreased from about 80% to 2%. The amount of nitrogen which has been exhaled is measured and FRC can thereby be calculated.

The gas dilution methods can be performed with some variety depending on which gas is used, although a common restriction involves only measuring the part of active gas dilution volume. Volume measurements of lungs including sections with low ventilation ability carry a risk of giving a result which underestimates the volume [5, p. 282].

2.3.4 *Body plethysmograph*

A body plethysmograph measures the difference in body volume when breathing in and out. A so called “body box”, is used to measure the difference in pressure which is proportional the difference is volume. While sitting in the body box, which has a fixed volume, the gas volume within the lungs is measured. The patient breathes towards a valve. When the valve is closed the gas in the lungs is compressed or expanded. The change in pressure in the lungs is monitored by a manometer connected to the nozzle.

The difference in volume within the box is registered by comparison of the lung volume difference. Difference in pressure can be measured with a pneumotachograph connected to the nozzle. According to Boyle’s law the product of pressure and volume remains constant for a gas if the temperature remains constant. Based on this, FRC can be calculated when the values for the barometric pressure and the water vapour pressure at a temperature of 37 ºC are known values [5, pp. 282-283].

2.3.5 *Lung Diffusion test with carbon monoxide, $D_{L,CO}$*

Lung diffusion test with carbon monoxide ($D_{L,CO}$) is used to study the gas exchange between the alveoli and the blood. A test gas mixture which includes carbon monoxide and an intractable gas is used. The carbon dioxide is used because it has the ability to easily bond to the haemoglobin in the blood.

The test gas is inhaled by the patient during a maximal inhalation followed by a period of time, approximately ten seconds, when the patient is holding its breath. During the following exhalation the concentration of intractable gas in the exhaled air can be measured and compared to the concentrations of the intractable gas in test gas before it enters the patient.

The value of the lung diffusion capacity of a person is dependent of age, body size and sex. The $D_{L,CO}$ value is decreased by obstructiveness for diffusion for example caused by decreased alveolar area or capillary area, extended way of diffusion or a low concentration of haemoglobin in the blood [5, p. 284].

2.3.6 *Imaging techniques*

Imaging techniques commonly used for diagnosis of COPD includes x-ray, computed tomography and magnetic resonance imaging.

The conventional x-ray technique includes two pictures, one front projection and one side projection, taken while the patient is in a standing position. Further projections in different angles can be taken if more details are wanted. Air functions as a contrasting medium and in that way the air existing within the lungs, regional and global, can be investigated. The conventional x-ray has the advantage of having a high spatial resolution but a disadvantage having a bad resolution of soft tissue. Therefore early stage emphysema is hard to observe.

Computed tomography, CT is an imaging technique where a series of two-dimensional images are taken in the same plane but in different angels. Three-dimensional images are produced by combining the cross-sectional images.

Using magnetic resonance imaging (MRI) images are produced by use of the nuclear magnetic of the molecules that make up a substance. The signals is especially used to the soft tissues of the human body. Magnetic resonance imaging can be used to make observations of disorder of body structure which could not be seen well on x-rays [8, pp. 202-206].

2.4 **Properties and behaviour of nano sized particles**

An aerosol is defined as a mixture of gas and particles. Particles included in the aerosol have to be small, with a particle diameter size smaller than about 100μm. This requirement is a consequence of the gravitational force dragging the particles downwards. The particles must have a low falling velocity to remain as a part of the gas, which means the particles have to be small. However the particles should not be

smaller than around 1 nm because smaller particles have a tendency not to remain in a stable molecule structure.

Furthermore the particles can be solids or they can have a liquid character. An aerosol can be formed in different ways, both by the nature and humans. By the definition of an aerosol almost every gas system can be seen as an aerosol.

The particles are surrounded by gas and the motion of the particles in relation to the gas can appear differently and be a consequence of different phenomena which is also connected to how they will be deposited in a human body.

Other external forces, in addition to gravity, are affecting the aerosol particles. Particles having a high charge are attached to surfaces in the airways [9, p. 5].

2.4.1 *Deposition of aerosols*

Deposition of aerosol particles in airways can occur by three different mechanisms, impaction, sedimentation or diffusion, mainly depending on aerosol particle size and the flow rate of the air. The particles with a particle diameter >2μm are deposited in the nasal cavity and the big airways by impaction. When the airway branches or turbulence occur the particles do not follow the changed airflow direction. Instead, because of the large momentum of the particles, they keep the previous direction and collide with the airway wall where they get stuck. The deposition by impaction has an increased probability with a higher flow rate.

Particles with a particle diameter of 0.5-2 μm are deposited in the smaller airways and in the alveoli by sedimentation. The particles are affected by the gravity and some are falling downwards and get stuck at the airway wall. The smallest particles having a particle diameter < 0.5 μm are affected by collisions with gas molecules. Like the gas molecules they are deposited by diffusion. The small particles have a random motion and most of these small particles are deposited in the alveoli [9, pp. 45-47].

2.5 **AiDA Method**

The AiDA method measures the dimensions of the distal airspaces based on recovery of inhaled nanoparticles. The method is based on the fact that nanoparticles in the size range <300 nm are mostly deposited in the respiratory tract by diffusion. The process of diffusion depends both on the distance to nearby surfaces and the residence time.

By controlling the residence time the researchers behind the method concluded that it should be possible to measure dimensions of the airspaces in the lungs by letting a subject[3] perform a controlled breathing procedure where an aerosol containing

[3] here, subject refers to the person participating in measurements relating to current research and testing of the AiDA method.

controlled model particles is introduced. To determine the recovery of inhaled model particles the concentration of model particles within the aerosol is measured from an aerosol reservoir before the sample is inhaled and from a sample collector after the subject has exhaled.

2.6 **Instrument and procedure description**

2.6.1 *Overview of functions*

Polystyrene-latex nanosphere particles with a specific size are generated. The particles are transferred through an electric field to remove a background of smaller sized particles that are also produced by the generator. The selected, monodisperse particles are then mixed with particle free air. The concentration of particles is measured. When a steady concentration of particles within correct size interval has been reached the mix is ready to enter the lungs.

The subject breathes in particle free air to purge the lungs. After breathing normally through the nozzle for a short while the subject exhale maximally and then inhale the aerosol mixture. The subject holds its breath for a set time and then exhales again when instructed to do so. The exhaled air is collected in a sample collector. The concentration of aerosol particles in the sample collector is measured. The aerosol concentration in the inhaled and exhaled aerosol mixture are compared. The quota of the two can then be analysed in relation to a reference value and emphysema or COPD can be detected.

The different parts of the instrument can be divided into main functions or modules and are further explained below and displayed schematically in figure 2.4. The following modules are present in the instrument.

Aerosol generation

- Electrospray Aerosol Generator
- Differential Mobility Analyser
- Aerosol reservoir

Inhalation system

- Mouthpiece
- Valve system
- Sample collector

Particle detection and analysis

- Condensation particle counter
- Nafion air-dryer

Additional instrument equipment

- Personal computer
- Nose clip
- Breathing protocol
- Minor instruments
- Electronics box
- Air system
- Vacuum system
- Nose clip
- Breathing protocol
- Adjustable chairs for subject and operator

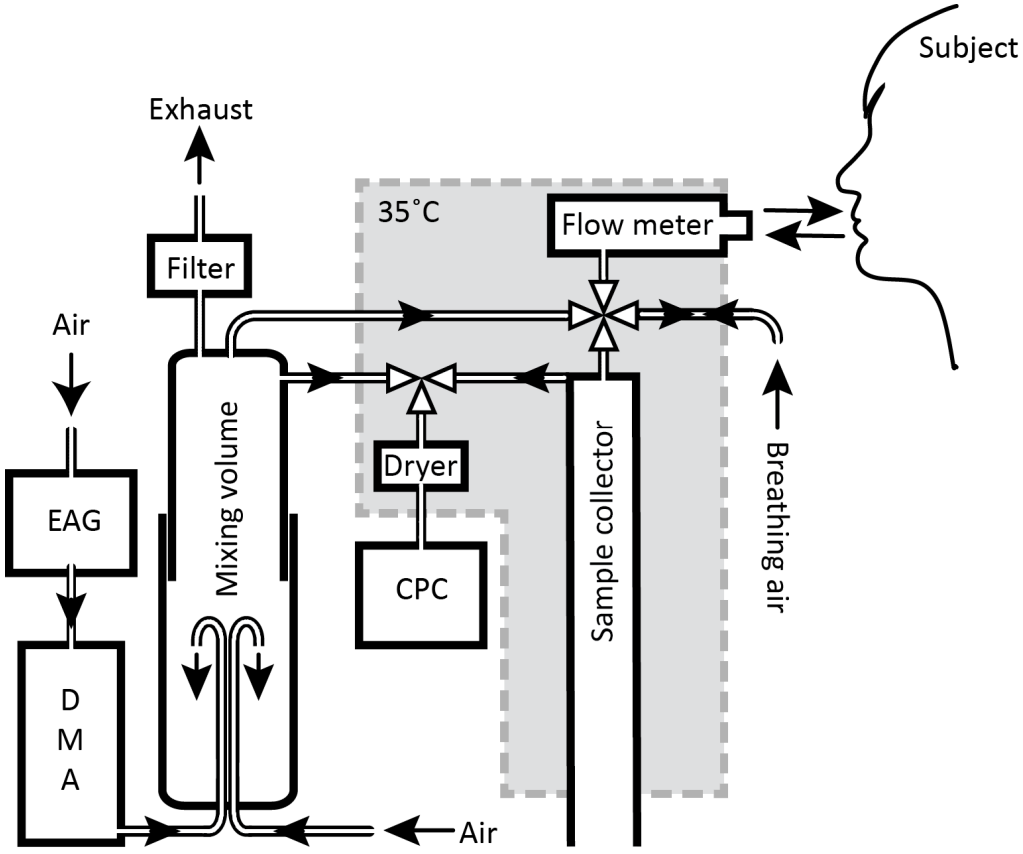

Figure 2.4. Schematic picture describing the functional setup of the instrument at the start of the present degree project.

2.6.2 *Electrospray Aerosol Generator*

The electrospray aerosol generator (EAG) generates spherical polystyrene nanoparticles in the nominal size of 50 to 100 nm through electrohydrodynamic atomization. In the current setup of the instrument an EAG from TSI Incorporated is used (TSI Inc, model 3480, DE). This type of aerosol generator is typically used in nano-aerosol studies and research within laboratory environments. The instrument can generate particles from 2 to 200 nm in diameter.

In the current setup of the instrument the EAG is placed to the far left of the instrument where it can be approached by the operator. During start up the EAG is manually turned on. Before the EAG can generate particles a centrifuge vial containing a sample solution needs to be placed in its pressure vessel. A capillary tube and a high-voltage platinum wire which will move the particles and induce an electric charge on them is then immersed in the solution by the operator. Finally the settings, such as input voltage, airflow and pressure, are fine-tuned using adjusting control levers on the side of the EAG. The droplet at the tip of the capillary is monitored by the operator through a magnifying glass built into the upper side of the EAG and fine tuning continues until desired, continuous spraying mode known as the Taylor cone-jet mode is reached.

The droplets from the spray are mixed with clean air and CO_2 and the gas flow within the EAG transports the droplets to a neutralization chamber where the charged droplets are neutralized by a radioactive source. The liquid evaporates before the aerosol exits the instrument. The EAG is correctly fine-tuned when the output signal gives a steady particle concentration in the range between 5000 and 10 000 particles/cm^3. This complete manoeuvre of starting and fine tuning the EAG takes from 15 minutes up to an hour to perform by the current operator.

2.6.3 *Differential Mobility Analyser*

The size selection of particles is done in a Differential Mobility Analyser (DMA) which sorts the aerosol particles by their electrical mobility. The mobility of the particles are dependent on particle size and charge. The DMA is connected to the EAG and the aerosol leaving the EAG enters the DMA. The DMA is calibrated to sort out a specific size of particles which are then transferred to an aerosol reservoir.

The DMA consists of two concentric metal cylinders. The inner cylinder is negatively charged and the outer cylinder is electrically grounded, creating an electric field. Separate connections near the top of the DMA introduce particle free sheath air and aerosol to the DMA. The aerosol particles drift in the DMA according to their electrical mobility and particle of preferred size can then be selected on the basis of their mobility distribution. At the end of the inner cylinder is an exit slit through which monodisperse particles of the given mobility (and thereby size) exits, while particles with different mobility exits the DMA through an exhaust flow or are deposited on the inner cylinder. The DMA used in the current setup is part of an Electrostatic classifier supplied by TSI with model no. TSI 3071A.

The operator does not interact directly with the DMA module but controls it though the computer software where parameters such as DMA Voltage and DMA sheath flow are set.

2.6.4 *Aerosol reservoir*

After exiting the DMA the monodisperse aerosol particles enters a semi-flexible reservoir built from a rigid stainless steel tank and an antistatic re-breathing bag which inflates and deflates during operation of the instrument. The total volume of the semi-flexible reservoir is around 15 L where the flexible part constitutes more than half of the total volume when fully expanded. In the reservoir the aerosol is mixed with particle free air at a flow rate of 5-7 L/min to a concentration of 2000-3500 particles/cm^3.

Both the aerosol and the particle free air enter the tank through separate pipes entering at the bottom of the antistatic bag. The length of the pipes was chosen to be long enough to assure stability of the flexible bag when deflated and the end of the pipes are designed in a way to assure they will not damage the bag when deflated. The aerosol mixture in the reservoir is continuously exchanged to assure a fresh, stable and controlled concentration of particles.

Aerosol mixture leaves the reservoir and enters the lungs of the subject via the inhalation system. At the same time aerosol mixture from the reservoir tank is drawn into the CPC and its concentration is measured. The excess aerosol mixture leaves the reservoir through a filtered exhaust placed on the top of the reservoir, which also has the function of avoiding overpressure in the reservoir.

2.6.5 *Inhalation system*

The inhalation system can be further divided into sub-modules representing a valve system, flow meter, mouthpiece and a sample collector. The inhalation system is built into a box in the current setup for two reasons. One of the reasons being to present the subject with a more welcoming design and the other reason being the need to keep the exhalation air warm enough to avoid condensation of exhaled air in tubing system, which might cause the CPC to measure also the condensed breath. The box in which the inhalation system is placed also contains the aerosol reservoir. Figure 2.5 shows the inhalation system and covering box in the current setup of the instrument.

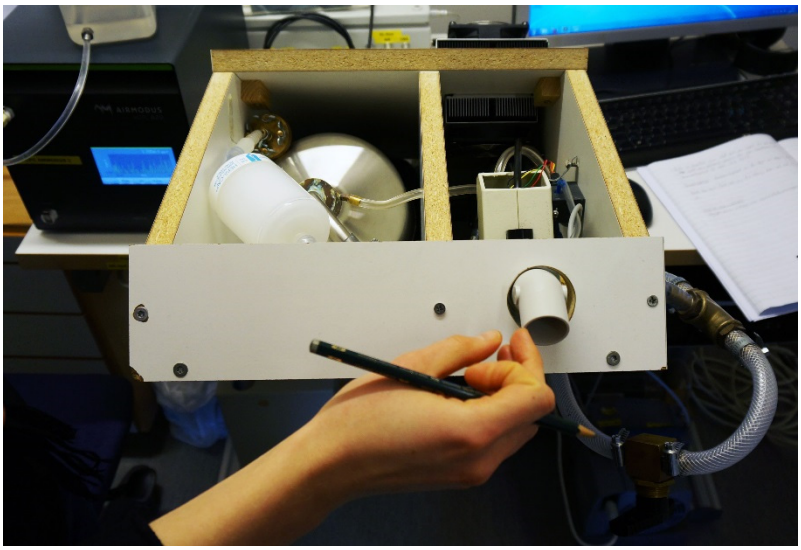

Figure 2.5. Picture of the inhalation system and covering box.

2.6.6 *Mouthpiece*

The subject breathes through a mouthpiece connected to the valve system via the plastic tube and the pneumotachograph. The mouthpiece used is a standard mouthpiece used for example in spirometry tests. A new mouthpiece is used for every subject. There are two different standard mouthpieces used depending on subject preference. The design and material differs between the two. The position of the mouthpiece can, together with the whole workstation be adjusted to accommodate a variety in length of the subject.

2.6.7 *Valve system*

The four-way computer controlled valve switches between particle free air, the aerosol reservoir and the sample collector for exhaled particles. A pneumotachograph is placed between the valve system and plastic elbow connection to which the mouthpiece is connected. The purpose of the pneumotachograph is to measure magnitude of the flow and make sure that the airflow from and towards the subject is laminar.

2.6.8 *Sample collector*

The main function of the sample collector for exhaled particles is to collect the air exhaled by the subject. The sample collected is intermediately stored in the collector before its concentration is measured during 20 seconds and with a flow of 1 L/min by the CPC. The sample collector is an open ended brass tube with a constant, narrow inner diameter of 36 mm and a length of 1000 mm. The dimensions of the collector tube helps in keeping the flow laminar. The tube collects a volume of 1 L. The exhaled breath is 1.3 L which means that the exhaled breath flushes the ambient air

and residues in the collector as well as the volume between the airways opening to the gas exchanging region of the lungs, leaving the last litre of air which has reached the deeper parts of the lungs in the collector.

The sample collector is heated to a temperature of 35 °C to avoid condensation of the exhaled air on the walls of the collector. If the exhaled air condenses before it enters the CPC the water particles would also be counted which would disfigure the measurements.

2.6.9 *Condensation Particle Counter*

The particle detector used in the current setup is a Condensation Particle Counter (CPC, Airmodus, model A20bCPC, Finland). The particle counter measures the concentration of particles in the gas samples of both the aerosol mixture in the aerosol reservoir and the exhaled air in the sample collector. Samples of both gases are led to the CPC through tubes of same dimensions to assure measurement accuracy. Magnification of particles is needed to enable counting. This is done in the condensation particle counter by encapsulation of particles in a working fluid. The working fluid used for this CPC is n-butanol. The CPC holds a butanol bath which needs to be refilled regularly. To lower the need of manual handling, a butanol container is connected to the CPC keeping the bath filled. To avoid dissipation of butanol vapour a carbon filter covers the ventilation hole on the lid of the container and two carbon filter traps are connected to the CPC exhaust. The CPC is driven by an external vacuum >0.4 bar under pressure at normal temperature and pressure.

In current setup the operator is required to turn the CPC on and off manually by pressing its power switch, placed on its rear side. Required parameters for control and usage of the CPC are set through the program AerosolCAL in the PC. The CPC has a display on which concentration reading is done by the operator during measurements.

2.6.10 *Nafion air dryer*

The relative humidity of both gases entering the CPC is reduced below 20% by a Nafion air dryer

2.6.11 *Personal computer (PC)*

A stationary personal computer combined with a screen, keyboard and mouse is used for control of the instrument and for collecting data from tests. Two programs, called AerosolCAL and KOLtest are used during operation of the instrument. The personal computer applies a controlling voltage to the instruments via LabVIEW and two data acquisition devices (DAQ) which are coupled to the PC through USB connections.

LabVIEW

Via the controlling program named AerosolCAL (written in LabVIEW) the instrument can be monitored and controlled. Some of the parameters can be manually controlled in the program, these are the opening and closing of the valves, the DMA voltage, the DMA sheath flow and the dilution air. The CPC count, the EAG voltage and the EAG is monitored in AerosolCAL and saved to a file. The data is collected with sampling frequency of 1 Hz and displayed on the interface of the program AerosolCAL.

During the actual measurement procedure another program named KOLtest is used. Also in this program the valves, the DMA voltage, the DMA sheath flow and the dilution air to the aerosol reservoir can be controlled. If values are changed in KOLtest, they are not automatically changed in AerosolCAL and the two programs cannot run simultaneously. The CPC concentration and the breathing data from the pneumotachograph, the temperatures, the relative humidity, and the valve positions are monitored and saved to a file.

2.6.12 *Minor instruments*

A number of minor instruments are used within the AiDA instrument to acquire required data and to control and monitor the performance of the instrument. Two data acquisition (DAQ) devices are used to convert analogue signals to digital values and four voltage amplifier circuits are used to amplify the signals from the DAQ before entering the personal computer and LabVIEW. Pressure sensors are used to measure air pressure from the pneumotachograph and pressure of gas samples entering the CPC. The temperature and relative humidity (T/RH) of the aerosol is monitored at different positions in the instrument through standard T/RH sensors called HydroClips.

2.6.13 *Electronics box*

The parts of the instrument are connected to an electronics box through LEMO connectors. The electronics box contains two LabVIEW chips which acquires all the data needed for successful measurements on subjects.

2.6.14 *Air system*

Pressurized air is used both as dilution air for creation of the aerosol mixture in the aerosol reservoir, as sheath flow in the DMA and for creation of particle free air for purging of lungs before measurements. Pressurized air is supplied by a central hospital air system connected to the instrument.

2.6.15 *Vacuum system*

Vacuum is required to drive the DMA sheet flow and create the suction needed for the CPC flow and dryer, hence a vacuum pump is used in the setup.

2.6.16 *Nose clip*

A standard nose clip is used to prevent subjects from inhaling or exhaling through the nose during measurements of particle deposition in the lungs. It is very important for the results of the test that the subject does not inhale or exhale through the nose since this most likely would introduce a source of error to the measurements in form potential particle loss in nasal cavities or introduction of ambient air.

2.6.17 *Breathing protocol*

A simple breathing protocol printed on an A4 paper is used to explain the test procedure to the subject.

2.6.18 *Adjustable chairs for subject and operator*

Adjustable chairs are used, both for the operator and for the subject. In combination with the height adjustability of the mouthpiece an adjustable chair is used to make sure the instrument accommodates a variety in length of subjects.

2.7 **EU Directive**

When developing a product existing directives relating to the specific product field, in this case medical devices, needs to be followed. Since the present medical device is eventually going to be launched and used internationally, starting with the European market, a basic study of directive and standards for concerned areas was done. Launching a product on the American market places different requirements on the device, which have not been considered for this project.

CE marking of the product is a way to state that the product meets EU safety, health and environmental requirements, present in the EU Directives. Rules for CE marking of products are presented in the European Union Council Directive 93/68/EEG of 14 June 1993 concerning medical devices.

The European Harmonized standards are connected to the EU Directive and present more detailed requirements and technical solutions. Following the requirements presented in the harmonized standards will guarantee compliance of the EU Directives [10, pp. 18-20].

According to above mentioned directive a ‘medical device’ is defined as [11]:

“any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*

- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means…"

Furthermore, the present device is a 'device intended for clinical investigation'. To clarify which directives needs to be considered the first step is to classify the device. Classification is done on the basis of intended use, intended performance and product safety [10, pp. 66-73]. The present device is of class IIa.

Below follows a list of general requirements and requirements regarding design and construction, found to be of specific importance to the present device, adopted from the EU Directive 93/68/EEG [11]:

- The device should be designed for patient safety, i.e. the risk of error due to the environment in which the device is intended to be used as well as the ergonomic features of the device should be reduced as far as possible.
- Technical knowledge as well as medical and physical conditions of the variety of intended users should be considered. The device should be designed with this variety in mind.
- Any possible risk related to the device should be eliminated as far as possible. For risks that cannot be eliminated protection measures, such as alarms should be employed. The user should be well informed of any shortcomings of the adopted protection measures.
- The device must be designed in a way to avoid accidental electric shocks during normal use.
- Devices supplying the patient with substances must be designed in a way that the flow rate of the substance can be set and maintained accurately enough to guarantee the safety of all users.

2.8 Ergonomics and human factors

It is a known fact that health, wellbeing and safety are affected adversely if workplaces and objects are not designed with human dimensions and properties in mind.

2.8.1 *Guidelines relating to operator*

When designing a device with which an operator should interact it is important to consider guidelines for work postures to make sure that the operator is not subject to work-related damages. A variation in working posture is in general desirable whereas static working postures should be avoided. Both for standing and seated work in front of a computer arms should be hanging loosely along the body and with the elbows in a 90° position.

Another guideline seen as important in relation this specific project is the guideline to avoid twisted or asymmetrical postures. This guideline has to be taken into consideration both when designing the workspace of the operator in relation to the patient as well as placement of parts which needs to be accessed for cleaning, maintenance and repair.

Since the work tasks of the operator are partly screen based, consideration has to be taken to the desirable position of the operator's head. Studies show that the most restful line of sight is 15° under the horizontal line of sight, whereas 0-30° below the horizontal line of sight is the recommended range and the range between 30-45° is acceptable (see figure 2.6). Minimum distance from eyes to screen should be 500 mm [12].

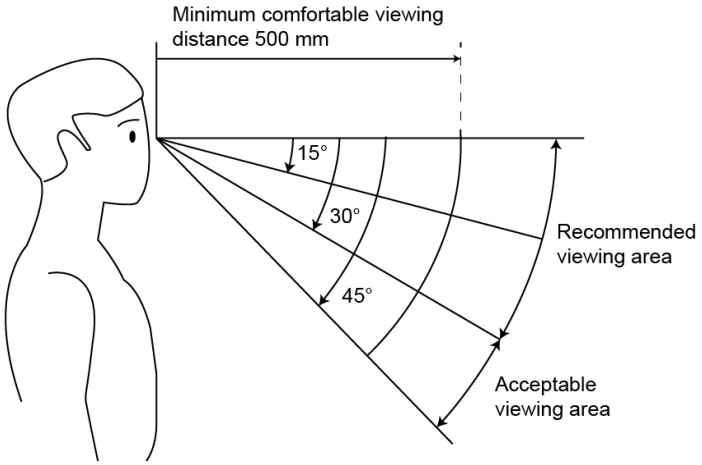

Figure 2.6. Recommended viewing area for screen based work.

2.8.2 *Guidelines relating to patient*

It is of high importance that the patient can sit in an upright position during measurements, since posture can affect the overall performance during measurement.

2.8.3 *Anthropometrics*

Body measurements vary within the target population and to accommodate a variation in body measurements a “design for all” approach is preferable, meaning that the design should be adjustable to fit people from the 5th to the 95th percentile within the population. Anthropometric values provide statistical data which can be used as guidelines and target specifications when designing a product with the physical properties, such as body dimensions and proportions of its users in mind.

Figure 2.7 shows the most important body dimensions to be considered for this project. The anthropometric estimates for these dimensions are presented in table 2.1 with values for the 5th, 50th and 95th percentile for men and women respectively. All measurements are based on statistics of British adults aged 19 to 65 [13, p. 54], which can be seen as equivalent to the target group. All dimensions are given in millimetres.

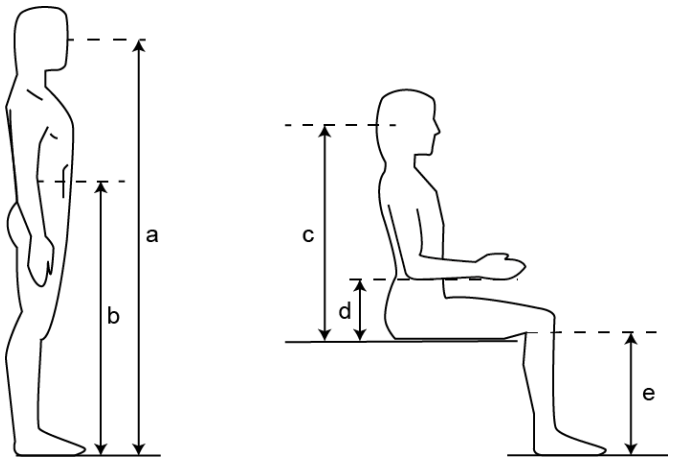

Figure 2.7. Body dimensions.

Table 2.1. Anthropometric values.

	Men			*Women*		
Dimension	5%	50%	95%	5%	50%	95%
Eye height (a)	1515	1630	1745	1405	1505	1610
Elbow height (b)	1005	1090	1180	930	1005	1085
Sitting eye height (c)	735	790	845	685	740	795
Sitting elbow height (d)	195	245	295	185	235	280
Popliteal height (e)	395	440	490	355	400	445

In addition to the above values, the sitting mouth height of the patient is of specific importance for the project. No such values can be found in reviewed literature. A small empirical study was therefore done to determine an average distance between eye height and mouth height. The average value for this dimension was determined as 65 mm. When subtracted from the sitting eye height an approximation of the sitting mouth height is obtained.

The working environment does not only concern physical properties. It is of importance to also take noise nuisance into consideration as well as exposure to chemical substances and electrical current.

2.9 **Universal design and Usability**

2.9.1 *Principles for Universal Design*

The principles of universal design can be used as guidelines to ensure that products and spaces are designed in a way that allows for human diversity, meaning that a wide range of people can use them, regardless of the user's set of abilities. The possibility to be examined through a medical test is something that should be of equal accessibility for all. Therefore it is of high importance to make sure that the specific medical device follows applicable principles for universal design. Below follows a brief account of principles and guidelines for universal design seen as substantial for the present device [14]:

- Equitable use

  Following the principles of universal design it is first of all of importance to make sure that the design offers equitable use, which means that it provides the same or equivalent means of use for all users with diverse abilities and thereby do not segregate or stigmatize any user.

- Flexibility in use

  The design should provide a choice in methods of use and be equally accessible for right- or left-handed people. It is preferable that the design helps the patient to maintain accuracy and precision throughout the test and if possible adapts to the user's pace.

- Simple and intuitive use

  The design should also adhere to the principle of simple and intuitive use. This principle has the purpose of making sure that the device is designed in a way that makes it easy to understand independently of the user's previous experience, knowledge, current concentration level or language skills.

- Perceptible information

  It is of high importance that necessary information is communicated effectively to the user. Taking into account that different people have different sensory abilities it is preferable that the patient is presented with information of high importance in different modes, for example both pictorial and verbal. Furthermore, it can be beneficial to differentiate important elements within the physical design or the user interface to make it easier to refer to them when giving instructions.

- Tolerance for error

  Keeping in mind to create a design that tolerates error is important for many reasons. To design for a good patient experience it is of high importance that elements of both the physical design and the user interface on the computer screen is arranged in a way that minimizes accidental or unintended actions. Keeping important elements accessible while shielding, isolating or eliminating hazardous elements is a good guideline to follow to make sure the design has tolerance for error.

- Low physical effort

  The design principle of low physical effort has clear connections with the previous chapter of ergonomics in relation to physical load, as previously described it is of high importance that the device can be used in a way that is both comfortable and efficient, to use reasonable operating forces, allow the user to maintain a neutral body position and minimize repetitive actions.

- Size and space for approach and use

  The principle of size and space for approach and use highlights the importance of making sure that the design can be used regardless of mobility, posture or body size of the user. A more specific example is that the design should be usable in combination with assistive devices such as wheelchairs.

2.9.2 *Usability principles*

In “The Design of everyday things” Donald Norman discusses a few principles which should be considered as guidelines in any human-centred design project. These principles are to some extent overlapping with the principles of universal design. The six usability principles are:

- Visibility

  The visibility of a product helps in clarifying basic functions. The visible functions should help the user to understand how something works and what action should be done next. Visibility is also about making the information needed by the user visible, while hiding redundant information which might lead to confusing the user [15, pp. 99-100].

- Feedback

  Feedback implies giving information back to the user after action. Through the feedback provided the user is informed about what action has been performed and the result yielded [15, p. 27].

- Constraints

  By using constrains the possible ways of usage can be minimized. It can be used to help the user to not make a wrong choice by using constraints to make it impossible to do them at all [15, pp. 81-82].

- Consistency

  The principle of consistency is about giving the user the possibility to get used to the system or product. Consistency in a product can be provided by using design elements that are commonly used in the target environment, but also using the same means of use throughout the product. If a user receives consistent results every time the same or similar action is performed it is easier for the user to create a mental model of how the product operates.

- Affordance

  Affordance is a term that refers to attributes allowing users to understand the means of use of a product or design element. The design should give clues of usage to provide the user of the correct mental model of how something should be used or is operated [15, pp. 9-11].

- Mapping

  The term mapping means a technique where a relationship between controls and their effect on the world. Mapping can appear in different ways. One type of mapping, called natural mapping, refers to relations which is built up from physical analogies and cultural standards. If natural mappings are used correctly, the user will directly understand how to use the product [15, p. 23].

3 Method

The structure of the development process used in this degree project is based on the generic product development process as described by Ulrich and Eppinger [16]*. The generic development process was modified and complemented with specific methods related to user-centred design where needed.*

3.1 **The development process**

Since the degree project is based on a functional prototype and diagnosis method which is still under development, it has throughout the process been of great importance to always keep an open mind and adapt the process in relation to parallel technical development. The way of working was iterative and characterized by learning along the way. Insights have been transformed into prototypes or concepts which were reflected upon and modified throughout the project. The structure of the work carried out during the degree project is presented in figure 3.1.

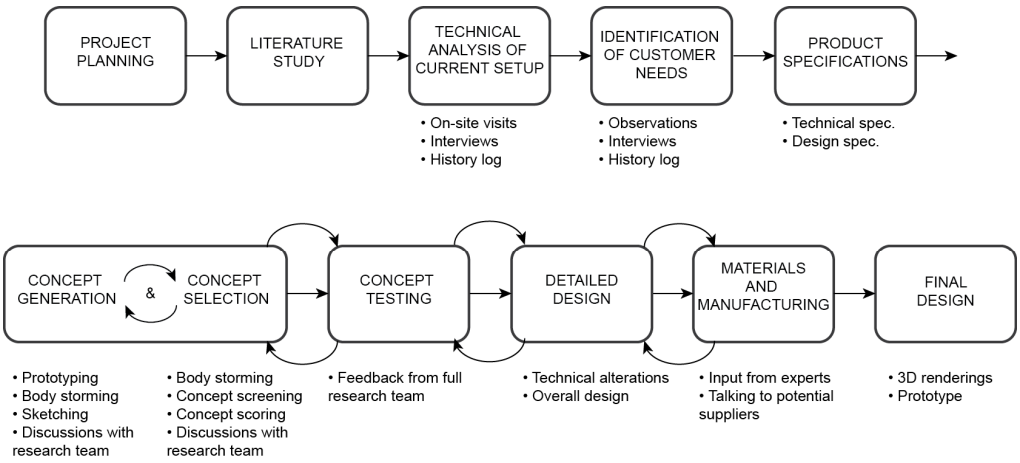

Figure 3.1. Flow chart describing the structure of the work carried out in this degree project.

An initial literature study was conducted to build on previous understanding of product development with deeper knowledge within specific fields of importance for

the present project. The most important findings from the initial literature study as well as an explanation of the present instrument and the measurement procedure is given account for in the background chapter of this report.

After gaining a basic understanding of the AiDA-method the first step of the development process was identification of customer needs followed by establishment of target specification for the product. After these two steps were finished the problems related to the present development project were clarified and divided into sub problems. Concepts were generated to solve each of the sub problems and the best concepts were selected for further development paired with iterative testing of the concepts. In the final step of the development, detailed design was considered and the overall design solution was finalized.

3.2 Analysis of current setup

Understanding the technical aspects of the current functional prototype was seen as crucial in order to get an understanding of the device to be developed, as well as understanding the technical requirements, in order to design the overall device while not missing out on critical factors of the function. Observations, a review of the measurement history reports, multiple interviews and discussions with the inventors and the operator as well as on-site visits resulted in the creation of a list of problems, with emphasis on the technical aspects of the current setup.

3.3 Identification of Customer Needs

The current design of the instrument is technology based and was constructed only to prove the functionality of the technique. To assure that further development would focus on the users and their interactions with the device the identification of customer needs aimed to identify both explicit and latent needs.

To assure structure and credibility a step-by-step method of identifying customer needs was used. The steps included gathering raw data from customers, interpreting the raw data in terms of customer needs, organizing the needs into a hierarchy, establishing the relative importance of the needs followed by a sum-up and reflection of the process and the results yielded.

3.3.1 *Identification of Customers*

Before identifying customer needs, potential customers were identified as there are many stakeholders involved in the life-cycle of a medical device. Patients and physicians are very important to consider when identifying customer needs since they are directly interacting with the product. However, any device is in need of preventive maintenance and repair and must therefore be designed with this in mind, meaning medical maintenance technicians should also be considered to be customers.

The research team behind the current instrument has in-depth knowledge about the current setup. The members of the research team are well aware of current challenges from a technological point of view and were therefore also consulted.

3.3.2 *Choice of data gathering methods*

The methods used for data gathering were selected to assure that the problems related to the current setup and the needs related to the future device were understood from multiple perspectives.

To assure identification of both latent and explicit needs of the customers a combination of data gathering methods, also called method triangulation, was used. A method triangulation is specifically effective for making sure that the contradiction of what people say and do is not overlooked.

To create a high-quality information base for further development of the instrument, the gathering of data involved direct contact with patients as well as subjects and the operator of the instrument. The data gathering and the analysis of data led to increased understanding of the problem scope and the formulation of product specifications for further development of the instrument.

The methods used for data gathering were chosen on the basis of the goals of the data gathering for identification of customer needs. Applicable methods were found to be interviews and observations as well as looking in to the device history log.

Interviews and observations were used to map out tasks performed by real users related to the specific, physical, instrument. The main part of the data collected through observations can be considered relatively objective whereas the data collected through interviews should be considered as subjective.

Participation in research team meetings has been an important factor to keep up to date to related work and gain knowledge about the technology and the needs of the research group from a technical perspective.

3.3.3 *Participant selection*

The research project is currently involved in the Swedish national scientific study Swedish CardioPulmonary bioImage Study (SCAPIS). As part of this study the AiDA method will be tested on 700 subjects at Skånes universitetssjukhus in Malmö. The tests are carried out in parallel to this degree project, giving a good base of subjects to observe and interview in relation to the AiDA method and instrument.

The demography of the subjects participating in SCAPIS represents the target patient fairly well, however some participants are older and/or are at a more advanced stage of disease than the target patient. The “operators” chosen as participants in the study represent a variety in age and anthropometrics. A medical engineer was consulted for insights regarding the needs of secondary users, mainly those responsible for maintenance.

3.3.4 *Measurement history reports*

Prior to the start of the degree project approximately 200 tests of the AiDA method and instrument had been carried out within SCAPIS. The member of the research team responsible for carrying out these tests had documented all tests in terms of success level and problems arising during each test. The measurement history reports gives a quantitative base for the collection of customer needs and the full picture of which problems are recurring.

3.3.5 *Interviews*

A structured interview was conducted with the current operator of the instrument to collect raw data of the problems the operator has experienced with the current setup, both in terms of interaction (working position, movement pattern etc.), the technology used, maintenance needed as well as what the operator has noticed and heard from the subjects’ perspective.

Apart from the thorough interview with the current operator of the AiDA instrument, unstructured interviews were conducted with biomedical scientists working with pulmonary function testing at the department of clinical physiology as well as medical laboratory scientists involved in SCAPIS.

3.3.6 *Observations*

The overall goal of the observations was to study and analyse how the users, in this case the operator and the subject or patient, performed their tasks, the interaction between the two users as well as the interaction between the users and the machine.

Multiple observations were done of the AiDA instrument in use and paired with observations of other pulmonary function testing methods such as spirometry, gas diffusion, body plethysmography and echo-doppler assessment.

The observations were followed by supplementary questions being asked to the subject or patient to clear out any question marks from the observations and to avoid false conclusions.

3.4 Product specifications

Data collected from interviews, observations and discussions with the inventors and other experts together with data from the measurement history reports and literature was interpreted into customer needs, a list of identified problems and technical target specifications. Complete target specifications are presented in Appendix B, each component is presented separately with a short description of its main function followed by a list of specifications including maintenance and supply required.

3.5 Target environment

To gain an understanding of the target environment and the design of similar devices, visits were done to multiple departments at the University hospital in Malmö. These visits included a one day in-depth observation at the departments of clinical physiology and clinical research where pulmonary function devices were observed in use. This was combined with an external search to map out the design elements as well as visual and functional attributes of products within the same product range.

To visualize the feeling of the environment in which the product is to be used an image board was created. The image board works as an inspiration in terms of what is suitable in the target environment and of what the device should communicate to its users by its shape and expression. A sector diagram was created to decide on a target placement of the device to be developed [17] in relation to similar pulmonary function measurement systems already at the market. For the sector diagram, two words of value were chosen for the x and y axis to form the basis of the sector diagram into which products within the area of pulmonary function testing was placed.

3.6 Concept generation and concept selection

3.6.1 *Concept generation*

The concept generation phase was started by creating a scale 1:1 prototype representing all main modules of the current setup of the instrument. The choice to create a scale 1:1 prototype was based on the importance of usability and ergonomics of the device and to get a common understanding of the real size of the modules within the team.

A body storming session was done with focus on patient-operator interaction to explore different possibilities of overall placement and to get a deeper and realistic understanding of the modules and sizes while having tangible 3D models to base the discussion around.

3.6.1.1 Body storming

Body storming is a method used to derive new ideas through physically experiencing a specific situation. By becoming aware of the physical space ideas and insights can be gained which are not easily gained through talking and sketching. [18]

3.6.2 *Concept selection*

Two types of structured selection processes, “Concept screening” and “Concept scoring” [16] were used to choose among the initial concepts generated. As the project progressed and attention was focused around the inhalation system generation and selection of concepts was done based on prototyping paired with body storming and discussions with the research team.

3.6.2.1 Concept screening

The concept screening method, often called Pugh concept selection was used to narrow down the number of concepts quickly and decide on which concepts should be considered for further development. The screening was done on the basis of selection criteria derived from customer needs and discussions with the research team. One of the concepts was set as a reference and the other concepts were rated in relation to the reference concept.

For all selection criteria it is important to keep in mind that the first placement concepts are on a high level and rating of concept is partly based on a prediction of how the final product would be.

3.6.2.2 Concept scoring

The basics of the methods Concept Screening and Concept scoring are similar, however there is one major difference. In concept screening, all selection criteria are weighted equally, whereas in concept scoring a specific weight factor is used for each selection criteria.

3.7 **Concept testing**

Concept testing was done to gather information concerning how the selected concept could be improved as well as highlighting if any critical aspect has not been given enough attention during the development of the device. The basic rules followed during concept testing was to listen more and talk less and to take the feedback without arguing in order to create an open discussion where criticism would not be refrained.

3.8 **Conceptual design**

Conceptual design includes a summary of the concepts selected for further development as well as the most important dimensions to be implemented in the final design.

3.9 Detailed design

Detailed design includes more specific solutions to fulfil the conceptual design. Technical alterations done during the development process is also handled in the detailed design chapter.

3.10 Materials and manufacturing

Materials and manufacturing was considered an important part of the project, since it was desirable to create a design solution which could be realizable, both technically and financially, and since the choice of material constrains the design to some extent. Finding suitable materials and manufacturing methods was done by looking at existing, similar medical devices as well as building on the basic knowledge within material and manufacturing methods acquired during previous courses in combination with consulting experts, both at the department of design sciences as well as external experts from the manufacturing industry.

3.11 Final design

Based on the work carried out in the project, the final design was created and is presented by means of 3D renderings and a prototype.

4 Analysis of current setup

Understanding the technical aspects of the current prototype has been of high importance in order to create a whole while not missing out on critical factors of the function. Through observations, review of measurement history reports and multiple interviews and discussions with the inventors and the operator a list of problems, with emphasis on the technical aspects of the current setup was created.

4.1 Identified problems and areas of improvement

The functional prototype analysed is shown in figure 4.1. It should be noted that the method is still in its early development phase and continuous development is conducted in parallel to this degree project. The functional parts of the instrument are also highly interrelated, meaning that a change in one function may have substantial impact on another or on the overall system.

Figure 4.1. The current setup of the instrument used for research purposes at Malmö University hospital.

Below follows a list of important problems and areas of improvement related to the current setup.

Aerosol generation

Electrospray Aerosol Generator

- The aerosol generator is versatile but not reliable enough.
- Time required for startup and finetuning to reach a stable particle concentration level is too long, at least 15 minutes and often much longer.
- Calibration, finetuning and maintenance requires specialist knowledge in combination with a special sense of touch which cannot be required from a nurse.
- The amount of work needed to get the EAG running is considered to be too much for the application.
- The EAG has a broader application area than required for the application and can therefore be seen as overly qualified.
- The sample solution ages and close attention has to be paid to best-before-date.

Differential Mobility Analyser

- The flow for the DMA is supplied by a vacuum pump which is considerably loud.
- Settings for the DMA are manually entered in the software when starting up the instrument.

Aerosol reservoir

- The volume is suspected to be over dimensioned.
- The connection between rigid and flexible volume is not done in a professional way and is not suitable for reproduction and easy maintenance.

Inhalation system

Mouthpiece (single-use)

- Risk of leakage if not connected properly to the instrument and subject.
- Mounting on instrument has caused damage to the mounting tube.
- Uncertainty in relation to particle loss when mouthpieces of different designs are used.
- Forces the subject to an unnatural mouth position.

Valve system

- Includes an unknown dead volume causing uncertainty in magnitude of particle loss.
- Cannot easily be removed for cleaning.

Sample collector

- The volume is suspected to be over dimensioned.
- Open end poses a risk of mixture with ambient air.
- The current length of tube constrains the solution space for the overall design.
- Is heated by a fan creating a high-pitch noise.
- The heating fan is producing heat for a larger volume than required

Particle detection and analysis

Condensation particle counter (CPC)

- Has a broader application area than required for the application and can therefore be seen as overly qualified.
- The concentration levels from measurements are not conveniently displayed for the operator.
- Working fluid (n-butanol) constitutes both a health risk and a risk for unpleasant smell in the examining room.
- Placement of CPC in relation to the other parts is not optimal since the operator has to walk past the subject to check its display during measurements.

Additional instrument equipment

Personal computer

- The desk space provided for the personal computer including screen, keyboard and mouse is much too small, causing an unnatural working position for the operator.

User interface

- The software contains of two conflicting programs.
- Training is needed to understand how to use the interface.
- Information intended for operator and for subject is mixed in an unclear way.
- The user interface is only created in Swedish.
- Naming of functions etc. is not consequent nor logic.
- The user interface does not display all needed data.
- The user interface is not attractive.
- Can be developed in terms of usability.
- Creation of data files for measurement is done manually.

Electronics box

- Detailed overall planning of electronics is needed.
- Cable structure needs evaluation and can be clarified.

Air system
- Pressurized air flow of particle free air supplied for tidal breathing is perceived as uncomfortable by many subjects.
- Risk of exposing subject to air of too high pressure.
- It is not standard to have central systems for pressurized air at health centres, which means that the current setup of the air system is not optimal in the target environment.

Vacuum system
- The vacuum pump is considerably loud.
- The vacuum pump is not suitable for the target environment.

Nose clip
- On rare occasions the nose clip falls of the nose of the subject.
- On rare occasions the nose clip doesn't sit tight on the subject, causing air-leakage through the nose.
- A few subjects feel that the nose clip is uncomfortable to use.

Breathing protocol
- The curve of the breathing protocol is not entirely accurate.
- Current solution of display of breathing protocol might not be optimal for its purpose, since some subjects tend to forget how to breathe.

Adjustable chairs for subject and operator
- A comfortable position for the operator is often in conflict with a comfortable position for the subject.
- Subjects sometimes have trouble adjusting the chair to correct height.

Work desk
- The operators work desk is much too small.
- The work desk cannot be adjusted in a way that makes it fit both the operator and the subject.
- Part of the instrument equipment is placed directly under the work desk giving the consequence that the operator has to lean towards the work bench.

Overall design

- The current overall setup and hanging of modules is a consequence of trying to build a functional prototype to test the AiDA method and is not suitable for other use.
- The overall design does not look like a whole.
- The current design is hard to adjust, is not flexible enough and cannot easily be moved.
- The overall design does not fit the hospital environment.
- The overall design does not give clear indications of which space is for the subject and which space is for the operator.
- Many solutions for the overall design are not professionally constructed.

5 Identification of customer needs

A deep understanding of customer needs is needed to set up the specifications around which the development project should be based. Engaging with customers at multiple levels through interviews with the current operator and a medical engineer, observations of the current setup of the instrument in use as well as observations of the usage of similar instruments at the University hospital led to a common understanding of the target environment as well as an understanding of the various needs that should be thought of in the development of the instrument. This section summarizes the needs which were identified.

5.1 Customer needs

The raw data gathered through interviews, observations and analysis of the measurement history reports was interpreted in terms of customer needs and then organized by their importance. The identified customer needs are mainly focused on the human-machine interaction but cover some more specific functional and technical aspects as well. A list of the main groups of customer needs follows below. A more detailed list can be found in Appendix A.

It is of importance that the patient easily understands how to perform the procedure and that the medical device:

- is comfortable to use for the patient.
- supports patient timing.
- supports a pleasant working environment.
- is easy to turn on and off.
- has a high level of performance reliability.
- can easily be cleaned and repaired.
- offers storage of additional equipment such as nose clips, medical gloves etc.
- is well dimensioned.
- supports a variety in operator anthropometry and posture.
- supports a variety in patient anthropometry and posture.
- is safe to use.
- looks reliable.
- is easy to manoeuvre.
- supports use by patients with difference in abilities.
- offers a user interface which is easy to use.

- provides the operator with necessary information throughout measurements.
- has a leakage free connection with the patient.
- is mobile.

Since the data gathering included engaging with a broad range of stakeholders the identified needs covers aspects relating to human machine interaction, both from the operator's and patient's perspective as well as from a maintenance perspective and overall safety requirements. Fundamental technological needs related to the specific technology used were also identified during this step of the process.

The needs of the operator covers aspects of work environment and physical ergonomics, such as providing sufficient space for the operator to perform the tasks, an adjustability of work height to accommodate seated and standing users and performance reliability of the device to assure that measurements can be carried out smoothly.

The data gathering gave clear indications that the needs of the patient both concerns physical and cognitive aspects. First of all it could be concluded that it is essential that the overall diagnosis procedure is comfortable for the patient. This covers many aspects, such as providing means of adjusting the device to fit the anthropometry of the patient.

Easy access for maintenance and troubleshooting of the device was highlighted as a critical aspect of what was desired for the development of the device.

The needs of safety relates directly to creating a pleasant working environment for the operator as well as for the patient.

6 Product specifications

The product specifications are interpretation of the customer needs in more specific and metric terms, combined with important guidelines identified through literature search. For clarity, the product specifications are below divided into technical specifications and design specifications. Although the first target specifications are established quite early on in the development process, the specifications develops over time and might be subject to change as new insights are gained. A detailed list of the technical specifications can be found in Appendix B.

6.1 Technical specifications

The technical specifications provide important information about functional and physical factors to consider during design and development of the device.

An overall important factor for the design of the device is to keep distances of tubing short to avoid unnecessarily big dead volume and thereby particle loss. It is also important that surfaces in contact with the model aerosols are antistatic, since static surfaces would attract the charged particles.

A more specific specification according to the distance of tubing is to keep the distance to the particle counter from the aerosol reservoir equal to the distance from the sample collector to the particle counter. The need of minimizing dead volume to avoid sources of error or uncertainty constrains the placement of the aerosol reservoir, mouthpiece and sample collector in relation to the 4-way valve system. Specific metrics for acceptable tubing length and diameter has not been possible to obtain, since this cannot be easily calculated. Keeping length and diameters of tubing as similar to the current solution as possible is therefore desirable.

It is of high importance to make sure that no leakage appears in the system. Flexibility in being able to separate parts is wanted to receive a robust construction and create good conditions for troubleshooting. Furthermore it is desirable to use easily accessible standard parts, or in the case where customized solutions are needed, making sure that its parts can be produced in a small scale.

The hospital environment places high demands on cleanliness. To meet this demand it is of high importance that any parts, and specifically any surfaces which are in contact with the patient or the operator is easily cleaned. In general, all such surfaces should be resistant to cleaning agents including at least 45% alcohol.

In current setup accessibility to the EAG, more specifically the accessibility to the magnifying lens through which the capillary tip can be seen, is of specific importance. Preferably even during measurements.

The device should be mobile since the possibility of moving the device around the hospital is required on occasion. Making the device mobile is also of high importance to facilitate cleaning of the space where the device is placed.

Adjustability of components which should be in contact with patient and operator has to be easy and intuitive to handle. It is desirable that the patient can adjust the mouthpiece and inhalation system to a comfortable height.

6.2 **Design specifications**

No detailed design specifications has been given for the project other than that the new version should look like a whole rather than an experimental setup. As all other equipment at a hospital the device should be easy to clean.

Based on experience from the field and discussions with medical doctors it was decided that the design should not stand out too much since its main function is to support the function in the best way and making sure that focus is on the patient, the patient-operator communication and the measurement function of the device. A simple, yet welcoming aesthetical design, with a light colour scheme and slightly soft shapes is therefore required. This is reflected in the image board presented in figure 6.1.

The space at the target environment where the medical device should be placed is often limited and space efficient equipment is therefore wanted. Since the technology employed for the device is rather bulky, it is desirable to find aesthetical means of designing the device to make it look as small as possible and thereby be perceived as less threatening.

Since both the operator and the patient should interact with the device it is desirable that it is clear for the patient which parts of the device is meant for the patient and which parts are for the operator.

6.2.1 *Target environment*

The environment in which the product is to be used is visualized in below image board. The image board works as an inspiration in terms of what is suitable in the target environment and of what the device should communicate to its users by its shape and expression.

Figure 6.1. Image board created as design inspiration

6.2.2 *Similar devices*

A sector diagram (figure 6.2) represents the findings from an external search of similar devices. A target position was decided for the device to be developed. As can be seen from the sector diagram, the appearance of similar devices varies a lot. In general, function seems to have a much higher priority than aesthetic values.

The word oneness, meaning the quality of the different parts being united into one consistent product was chosen for the x-axis since it has been stated from start that creating a consistent overall design was an important objective for the project. Finish was chosen for the y-axis to map out the finish of this kind of devices in relation to their target environment.

The cross in the sector diagram represents the target placement of the device to be developed within this degree project.

Figure 6.2. Sector diagram with the target placement of the device to be developed marked with a red cross.

7 Concept generation and selection

The concept generation and selection includes generating concepts followed by selecting the best concepts for further development. The process of generating and selecting concepts is divided into different parts solving specific sub problems.

7.1 Placement of modules

A first round of body storming was done to understand the size of the modules and to experience the device by trying different placement of modules. After this first round a few conclusions could be made. For example, it was determined that the sample collector cannot be placed vertically since that would not allow for a comfortable seating position for the patient without introducing a source of error in increasing the length of the mouthpiece. Based on function and the importance of good interaction between the patient and the operator the following list of relative importance of the modules was established:

1. Mouthpiece, 4-way valve and sample collector as well as aerosol reservoir, nafion dryer and particle counter
2. Screen, keyboard and mouse
3. Particle generator
4. Differential mobility analyser
5. Remaining parts

Based on the relative importance of the modules a second round of body storming, shown in figure 7.1, was done to experience different positions of the patient and operator in relation to the mouthpiece position and the operator workstation as well as in the interaction between patient and operator.

Due to functional requirements of the AiDA method the mouthpiece, 4-way valve, sample collector and aerosol reservoir were attached to each other to form a unit. This unit was mounted on an adjustable table lamp to simulate adjustability. Keeping the particle counter and its dryer close to the sample lines of the sample collector and aerosol reservoir is crucial so it was placed close to the above mentioned unit. The table used for the computer screen as well as the keyboard and mouse was fixed.

Figure 7.1. Second round of body storming

Through trying out different placements of these modules an understanding of size and how to make the interaction between patient and operator as good as possible was gained. The different positions tried are shown in figure 7.2 and 7.3 and described in detail below.

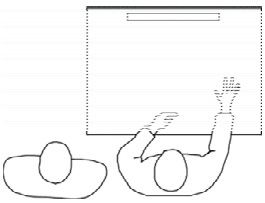

Figure 7.2. Initial position of patient and operator tried out during body storming.

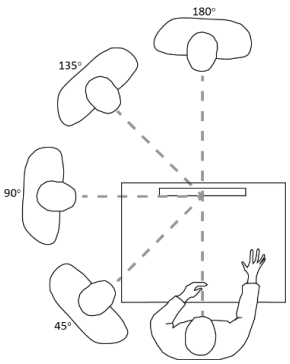

Figure 7.3. Positions tested during the first body storming session. The person representing the operator sat by a desk with a full scale model of a computer screen. The person representing the patient is moved around the table.

Position 1: The first placement which was tested was very similar to the current solution, placing the patient next to the operator. It felt unclear for the patient whether she should look at the screen or not. The operator is forced to turn her neck 90 degrees to be able to fully see the patient.

Position 2 (45°): The second position tested was similar to the first placement option, but was perceived as a little better regarding how much the operator had to turn her neck in order to get eye-contact with the patient.

Position 3 (90°): In comparison to the previous positions this is the best one so far. The operator can easily get eye contact with the patient while still having full control of the computer screen and the possibility to decide when to show the patient the screen and when not to.

Position 4 (135°): This position was perceived as equally good as position 3. The patient and operator can easily communicate during measurements and the operator can fully control when the patient sees the screen and when not.

Position 5 (180°): In this placement the screen is perceived as a barrier between the operator and the patient. If the screen is to be used for instructing the procedure it is not at all suitable.

7.2 Clarification of the problem

Following the initial body storming workshop and with the product specifications in mind the problem was further clarified and divided into simpler sub problems. Many sub problems were identified and could be divided into three main focus areas; the machine body, an easily adjustable inhalation system to which the mouthpiece is connected and a workstation for the operator. The initial effort was then put on the most critical sub problems for these three focus areas. Specific requirements in relation to each focus area can be found in Appendix B.

Machine body

- Placement of main modules within the machine body

Adjustable inhalation system

- Solutions for adjustment of the inhalation system to accommodate a variety in anthropometry of the patient
- Placement of main modules within the inhalation system

Operator’s workstation

- Solutions for adjusting the workstation to accommodate both seated and standing users

7.3 Machine body module placement

For the module placement within the machine body, a simple prototype for a machine body was built, see figure 7.4. The dimensions of the machine body prototype were 600x450x650 mm. The machine body was built in medium density fibreboard (MDF) and placed on wheels, giving it a total height of 760 mm.

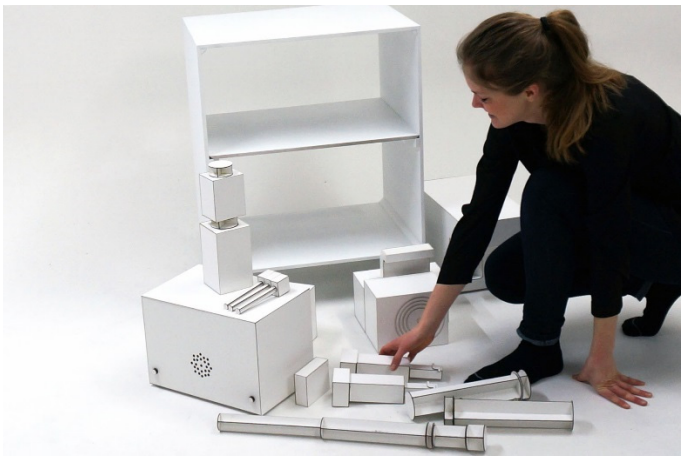

Figure 7.4. The prototype of the machine body and the main modules to be placed within it.

The real sized model of the machine body together with modules were used to generate and try different concepts for the placement of modules within the machine body. Each main concept included two variants, one with a fixed middle shelf (a) and one with a sliding middle shelf (b). The different module placement options are shown in figure 7.5. For the concepts with a fixed middle shelf it was imagined that the top of the box could be partially opened to give accessibility to setup and fine-tune the EAG. For the concepts with the sliding middle shelf the same accessibility would be obtained by pulling out the sliding middle shelf where the EAG is placed

Before starting the placement, a few design decisions were taken. To adhere to the customer needs, in terms of accessibility for maintenance and cleaning it was decided that it should be possible to access the parts from two opposite sides. In addition, technical product specifications were taken into consideration for all placements, for example the vacuum pump should be placed where it had access to air intake.

All concepts have the same placement for a few of the parts, such as the DMA, damper volume, air filters, and electronics box, however these parts do not require a specific placement and their placement can be subject to change later on in the process.

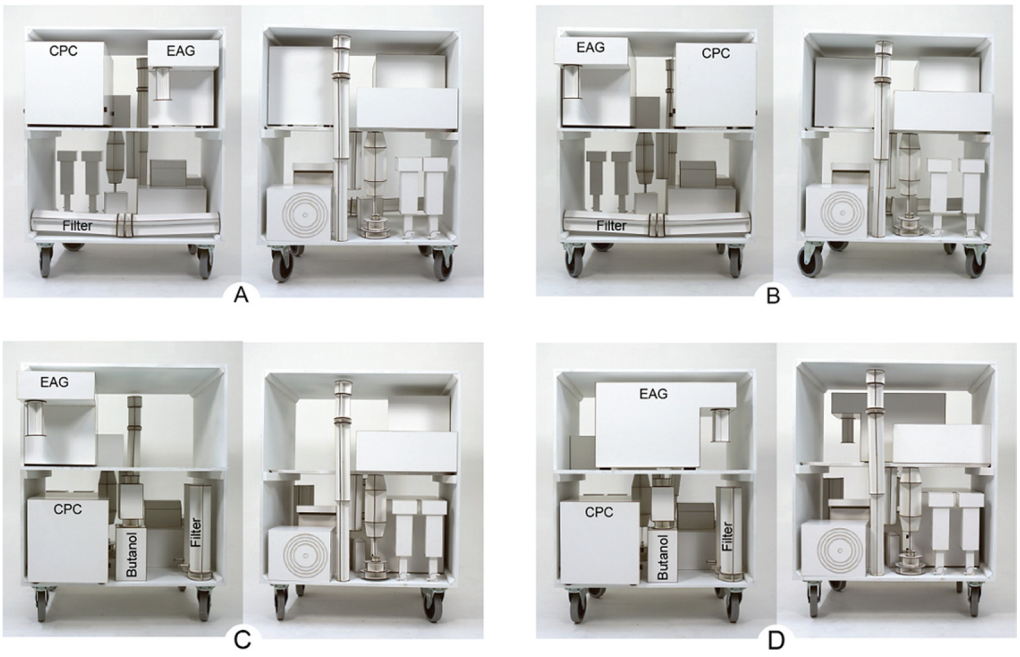

Figure 7.5. Concepts of placement of the modules within the machine body. The left hand picture of each concept represents the front of the device and the right hand picture represents the back.

Concept A: The first concept has both the EAG and the CPC placed at the middle shelf. The butanol tank and filter, which should be placed near the CPC was too big to fit into the concept and is therefore excluded from the pictures.

Concept B: The second concept is similar to the first, except the placement of the EAG and the CPC had been interchanged.

Concept C: In the third concept the CPC has been moved to the lower level, accompanied by the butanol tank and filter. Due to space limitations, the carbon filters have been placed in an upright position.

Concept D: In the last concept placement, the CPC is placed on the lower level, just like in concept C and the EAG has been turned 90º.

7.3.1 *Machine body module placement selection*

The concept module placements for the machine body were evaluated through concept scoring according the following selection criteria.

- Access and reach for operation
- Access for troubleshooting and maintenance
- Favours function
- Good distribution of weight

The selection criteria “Access and reach for operation” is about placing the modules in a way that favours the task of the operator and the task of the patient, it is about placing modules in a way that makes it easy for the users to perform the measurement.

The selection criteria “Access for troubleshooting and maintenance” is of high importance at this stage of development since unnecessary complexity could be avoided by taking this into consideration at an early stage. It is further expected that a module placement which has a high ranking when it comes to access for troubleshooting and maintenance would provide means for high safety in usage of the device.

It is of high importance to make sure that the placement of parts favours the AiDA-method. Therefore “Favours function” was also set as a selection criteria. A module placement that favours function typically means that flow distances between critical modules are kept to a minimum and so that particle loss can be minimized as well as assuring the function of each separate module by minimizing external factors where needed. Even though this first evaluation of concepts focused on the machine body itself, other parts, specifically the modules related to the inhalation system and connecting tubes between the machine body and inhalation system was thought of, even though put outside of the body.

The selection criteria “Good distribution of weight” is about the allocation of parts to make sure that the device is stable in terms of low risk of falling over and in terms of keeping the centre of gravity low.

The selection matrix can be found in Appendix C. Based on the evaluation of concepts, Concept D with a sliding middle shelf was chosen for further development.

7.4 **Flexibility of arm and working station**

The concept generation for height adjustment of the flexible arm and the working station were initially done separately but the same method was used, described below.

7.4.1 *External search*

By searching externally for solutions of similar products, existing solutions to get inspiration from were found. A concept combination table (table 7.1) related to the adjustability of the arm and work desk, based on benchmarked products, was created and used to explore possible solutions in a systematic way. Based on the combination table concept solutions were generated both individually and in group.

Table 7.1. Concept combination table for adjustability.

Energy source for vertical movement	Movement and/or stabiliy assisting force	Adjustment of position
Electrical	Mechanical spring	Parallellogram movement
Mechanical	Pneumatic gas spring	Swivel
	Moving mass	Horizontal
	Friction	Vertical
		Non

When creating the concept combination table potential energy sources for vertical movement as well as movement and stability assisting forces and how to adjust the position was considered.

The table was then used for combination and creation of different ways to receive the wanted adjustability according to the specific requirements for the flexible arm respectively the flexible work desk.

7.5 Flexible arm

Based on the concept combination table five different concepts, as shown in figure 7.6, were generated for the adjustability function of the arm.

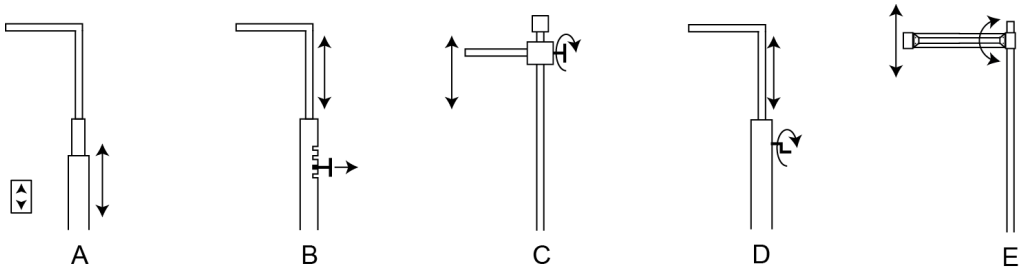

Figure 7.6 Five concepts of how to adjust the flexible arm. The arrows gives information of how the parts is intended to be moved.

Concept A. Step less electrical adjustment of a telescopic leg. Adjustment is done by using a remote control.

Concept B. Stepwise adjustment done by removing the locking pin and changing the height of the arm manually.

Concept C. Step less adjustment by screwing the knob to release or to attach the horizontal part of the arm to the vertical part and thereby adjusting the friction force holding the arm in place.

Concept D. Step less adjustment with the use of a crank mechanism. The crank is turned to adjust the vertical position of the arm.

Concept E. Step less adjustment by using a parallelogram mechanism as the horizontal part of the arm. Gas springs used to assist adjustment and balance the arm.

7.5.1 *Flexible arm concept selection*

The concepts generated for the arm function were evaluated through a concept screening matrix with regard to its flexibility, safeness and ergonomic aspects. The following selection criteria were used:

- Ease of height adjustment
- Level of precision (of height adjustment)
- Stability
- Proven to work in similar applications
- Durability
- Low physical effort

The concept selection criteria “Ease of height adjustment” is related to the complexity of the task of adjusting the height of the mouthpiece in relation to the normal working positions of the users. “Level of precision” concerns how easy it to place the mouthpiece in a level that is as correct and comfortable as possible for the patient.

The selection criteria “Stability” relates to how stable the position of the mouthpiece will be during measurements, whereas durability concerns safety aspects in the longer run, and from a maintenance perspective. Whether or not the concept is proven to work in similar applications is also used as a selection criteria. This specific criteria is important in order for the final solution to fit to the hospital environment and usage as well as enabling standardized sourcing of components.

From an ergonomic perspective it is of importance that the solution requires low physical effort to avoid repeated heavy lifting and minimize the risk of safety issues relating to the height adjustment, hence the selection criteria of “Low physical effort” was chosen.

Based on the concept screening matrix (see Appendix C) concept E with the gas spring assisted step less adjustment was chosen.

7.6 Work desk

Many different solutions for the work desk was considered, both in terms of the design of it and the height adjustability, and time was spent looking at how computer equipment is used within the medical setting.

Since a gas spring assisted solution had been chosen for the height adjustability of the arm it was decided on the grounds of consistency that the height adjustability of the work desk should be gas spring assisted as well. Combining the height adjustability with a swivel function for horizontal adjustment of the work desk would provide means for both an ergonomic sitting and standing position.

7.7 Inhalation system module placement

Placement of modules within the inhalation system was done based on prototyping, where module placement and overall design was done and changed iteratively. The exterior and the modules to be placed within the inhalation system is very closely linked.

The first prototype created was a simple box with enough room to accommodate the parts that need to be included within the inhalation system. It was directly understood that the box was unnecessarily big and could be perceived as threatening to the user. It was therefore decided to look at how to reduce the size as much as possible and keep the line of sight during measurements as free as possible for the patient while at the same time making sure there would be enough room between the patient's legs and the inhalation box.

Multiple working sessions were carried out to get a feeling for the look and feel of different shapes of the inhalation box, see figure 7.7. A re-design of the aerosol reservoir, as well as the shortening of the sample collector, later described under 'detailed design' has been seen as very important change of technical solutions to which the concept generation for the design of the inhalation box was based.

Figure 7.7. Working with prototypes to try different module placement solutions.

When working with the module placement of the inhalation box multiple factors had to be considered. The valve system and sample collector had to be able to be heated to 35° while the aerosol reservoir should be kept at room temperature. The breathing air needed to be connected to the valve system as did the aerosol reservoir, the pneumotachograph and mouthpiece as well as the sample collector.

It is of very high importance to keep the aerosol reservoir close to the valve system in order to assure that no unnecessary sources of errors are introduced. This has been a limiting factor for the module placement, as it has been desirable to maintain the same or very similar distances between the aerosol reservoir and the valve system as the setup has today.

While considering all these technical factors, usability needed to be considered as well, specifically when it comes to facilitating height adjustment as well as the customer need of somewhere to place hands during measurements. From a maintenance perspective, it was important to keep in mind that the inhalation system should be easily opened.

7.7.1 *Inhalation system module placement selection*

The selection of module placement within the inhalation system was done through testing different ways of module placement through body storming as well as discussing different ways of placing the modules based on quick sketches.

Initially, it was considered to keep the module placement within the inhalation system as it is today with the aerosol reservoir placed left of the sample collector. Through working with prototypes of the different parts it was realized that by placing the aerosol reservoir above the sample collector it would be possible to reduce both the actual and perceived size of the inhalation box, since the reservoir can be hidden from the patient during measurements and allows for a free line of sight.

It was further considered to place the air tubes inside the box to increase the oneness of the whole device. However, this led to a box much bigger than it would have to be. It was therefore decided to place the air tubes under the box, which can be seen as a good choice since supply of breathing air is not seen as something frightening.

The final module placement selected was found to be superior to the alternative module placements both in terms of size, facilitation of height adjustment and access to its internal parts, and is shown in figure 7.8. The lower (grey) part of the inhalation box is heated and separated from the top part with an insulating layer. Possible manufacturing methods and materials were considered simultaneously and are described in more detail later on in the report.

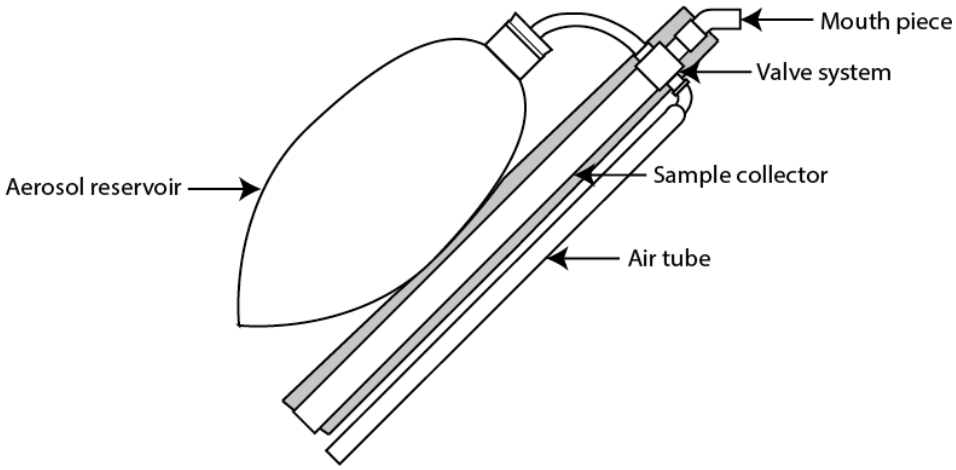

Figure 7.8. Final module placement for the inhalation system.

7.8 Design of the inhalation box

After deciding about the module placement within the inhalation box, the shape of it was considered in order to create a shape and design that would be both functional and pleasing to look at, for the patient as well as for other stakeholders. It was decided that the bottom part of the inhalation box should be as simple and strict as possible, to fulfil its function and be easy to manufacture. The top part of the inhalation box, covering the aerosol reservoir was of more interest in terms of shape and expression. Following the design specifications it was of importance to give a soft feel while keeping the line of sight free.

In creating the shape of the top part of the inhalation box a mock-up was used. In the first step a half cylindrical volume was created to encapsulate the aerosol reservoir which was manipulated into different shapes, as shown in figure 7.9. It was discovered that a cylindrical volume was space efficient but was perceived as unpleasing aesthetically and non-coherent with the rest of the device. The cylindrical volume was manipulated until a more defined, strict, shape was reached while maintaining a soft feel to the overall impression.

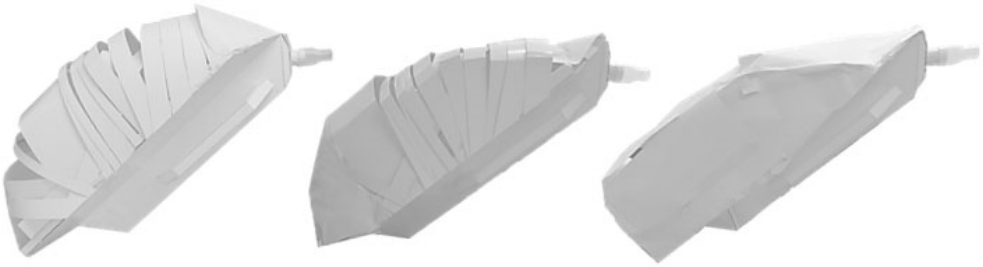

Figure 7.9. The shape of the upper part of the inhalation box evolving from rounded to more strict.

A more refined prototype, as shown in figure 7.10 was then built based on the findings and its angles and shapes were modified until a coherent expression had been reached.

Figure 7.10. Refined prototype of the inhalation box.

8 Concept testing

Testing of the basic concepts of module placement and overall design was done by presenting the prototype to the full research team and facilitating a discussion around the placement of modules as well as the interaction between the patient, operator and device. Due to the interdisciplinary composition of the team, including both physicists, medical doctors and the current operator of the device the discussion brought up many interesting and important points taken into consideration for further development.

8.1 Interaction

Discussion regarding the overall design covered aspects of the interaction between the patient and the operator. One of the medical doctors brought up an important aspect which confirmed a thought employed when designing the device, namely that the focus should not be on the machine, but rather on the interaction with the operator, who has the role of coaching the patient through the measurements. Furthermore, the medical doctor explained that if the patient is too aware of the measurements it will cause trouble. If the patient can follow the breathing curve that means that the tidal breathing won't be normal. This confirmed the idea that the screen should be placed so that the computer can be easily used by the operator during measurements, but that it should not necessarily be within sight for the patient.

The patient need of having somewhere to place their hands was highlighted. Although being an important need identified during identification of customer needs this had not yet been implemented in the prototype.

It was also questioned whether or not the proposed placement of modules would allow for easy access to the EAG in order to control the Taylor cone-jet mode of the droplet at the tip of the capillary. Due to the fact that a newer version of the EAG provides the possibility to making the same information available at the computer screen, and the newer aerosol generator being developed won't require the same monitoring, the current concept was found to be sufficient.

Positive feedback was given to the fact that the design offered easy access for maintenance by placing doors on both the front and back of the device body.

8.2 Dimensions

During the concept testing session one of the medical doctors brought up the fact that the presented prototype is too big to be used in primary healthcare. However, at this stage of development the size of the device is a consequence of the technology employed to perform its function.

8.3 Operator workstation

The workstation for the operator was brought up as an important aspect to be discussed during the concept testing. During the concept generation phase it had been questioned whether or not a workstation for the operator should be incorporated in the device or if the device should be placed next to an adjustable desk.

Following the discussions it was decided to pursue designing a possibility of incorporating a workstation into the device.

During the concept testing session an idea to be able to remote control the starting and stopping of measurements arouse. The idea immediately gained positive feedback from the rest of the team and will be looked into in more detail outside this degree project.

9 Conceptual design

This chapter describes the selected concepts from the concept selection process in more detail, with specific dimensions.

9.1 Device dimensions

The device will be divided into a machine body or cabinet with an inhalation system placed on a parallel arm and a height adjustable swivel table. The design of the inhalation box gives the patient a free line of sight during measurements, as shown in figure 9.1.

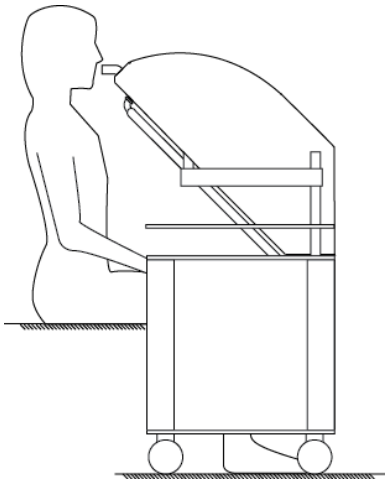

Figure 9.1. Patient sitting by device. As can be seen from the figure the line of sight is free.

When the adjustable arm for the inhalation system is in its normal position, fully parallel to the floor, the centre of the mouthpiece (a) should be 1179 mm from the floor (see figure 9.2).

The height of the desk (b) in its lowest position is 740 mm and it should be adjustable in height up to 1180 mm.

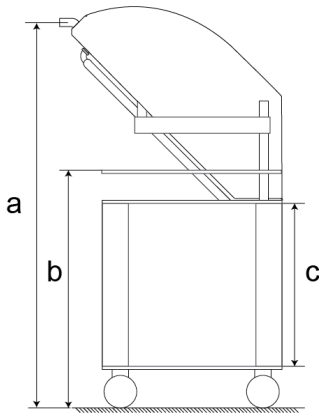

Figure 9.2. Schematic picture of the front of the device with some of its most important dimensions.

The equipment to be placed inside the machine body determines its size. Based on the module placement as described below the interior height (c) needed to accommodate all the equipment for the device is 500 mm. The depth of the interior of the device has to be at least 550 mm to accommodate all the equipment and its width has to be at least 620 mm, to provide enough room to place the DMA horizontally.

9.2 **Placement of modules**

9.2.1 *Machine body*

During the development of the device an alternative solution was found for particle detection and analysis. This meant that the rather advanced and bulky condensation particle counter was replaced by a much simpler electrometer. Apart from being beneficial for the cost of components for the AiDA method in itself it was also seen as very beneficial for the overall design since pre-requisite for the module placements were changed and the solution space was broadened. Based on this, some changes were done to the module placement selected earlier.

The main modules included in the final setup of the machine body are shown in figure 9.3, followed by a schematic picture (figure 9.4) of their placement within the machine body, where the left picture shows the lower shelf while the picture to the right shows the top shelf and the dashed rectangle represents space reserved for additional parts such as the electronics central.

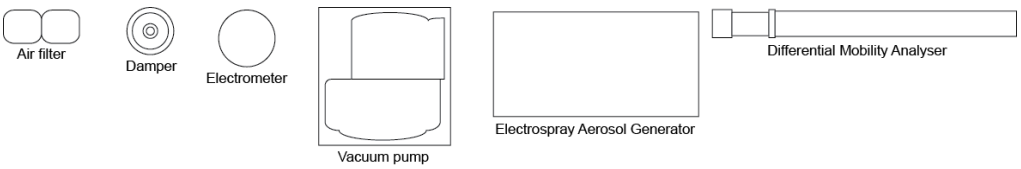

Figure 9.3. Main modules included in the final setup of the machine body.

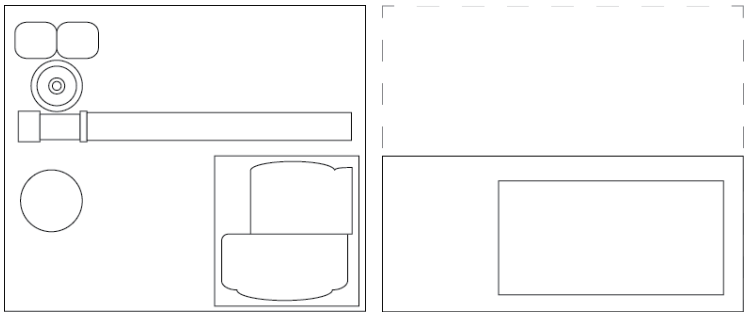

Figure 9.4. Final placement of the main modules inside the machine body.

9.2.2 *Inhalation system*

The inhalation system is collaterally adjustable as well as adjustable in height while keeping the mouthpiece horizontally. The inhalation system is connected to the machine body on an adjustable arm placed on the rear left corner of the device.

Inside the inhalation system the sample collector as well as valve system and flow meter are placed in an isolated volume. The aerosol reservoir is placed above the isolated volume. Figure 9.5 shows the main modules included in the inhalation system and figure 9.6 shows the module placement for the final design.

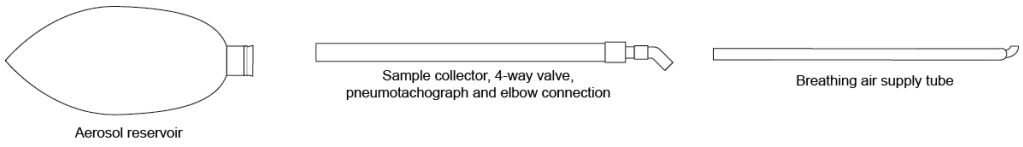

Figure 9.5. Main modules included in the inhalation system.

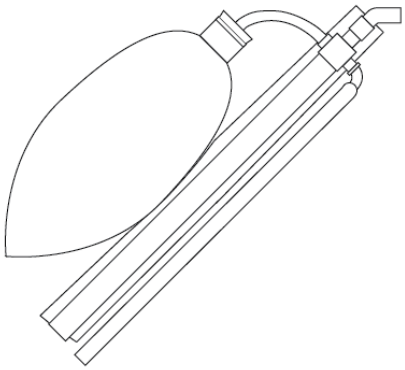

Figure 9.6. Final placement of the main modules included in the inhalation system.

10 Materials and manufacturing

Potential materials and manufacturing methods were considered to make sure that important considerations were done for the overall design in order to design a device which could be manufactured in a way that would be financially viable.

10.1 Choice of materials and manufacturing

When choosing among materials and manufacturing methods some of the most important factors to consider is the purpose of the product as well as the target environment and lot size. The target lot size at this stage of development is 10-20 instruments, which limits the range of applicable manufacturing methods as well as materials.

Most of the surfaces of the exterior of respiratory medical devices such as this one is not in direct contact with the patient, which means that choosing materials for the exterior of the device is not subject to the same biocompatibility constraints as for example with implantable devices.

10.2 Machine body

Choice of material for the machine body is divided into the profile system and top, bottom and side panels as well as doors.

10.2.1 *Profile system*

To create a stable structure for the machine body aluminium profiles where found to be a suitable option. Using aluminium profiles will give the device a stable structure while still keeping the weight low and being suitable for the hospital environment.

Due to the low predicted lot size standard profiles were found suitable, since tooling and manufacturing cost for producing custom made profiles would be much too high.

10.2.2 *Panels*

To be suitable and durable in the hospital and healthcare environment the material for the top, bottom and side panels as well as the doors of the cabinet must be scratch and impact resistant as well as being solvent resistant to adhere to the need of keeping surfaces clean.

A material fulfilling all of these criteria is high-pressure laminates (HPL), which have been proven to work in similar applications. High-pressure laminates are commonly available in thicknesses ranging from 2-20 mm and in a variety of colors. Panels can be custom processed in numerically controlled machines which will facilitate the assembly process [19].

10.3 Inhalation system

For the design of the exterior of the inhalation system it was decided for aesthetic, shape and cleaning reasons that the casing should be manufactured in plastic, whereas the bottom part of the inhalation system should be manufactured in metal, due to its load bearing function.

10.3.1 *Plastic casing for the inhalation system*

When constructing in plastic the lot size is a very important factor for determining what is financially viable, since costs for development of tooling and machine size is of great importance [20, p. 143]. For such a small lot size the viable alternatives are vacuum forming or 3D-printing. However, due to the size of the inhalation system 3D-priniting is not seen as an option, leaving vacuum forming as the most suitable option at this stage of development [21].

Using vacuum forming as a manufacturing method has both advantages and disadvantages [20, p. 138], presented in table 10.1.

Table 10.1. Advantages and disadvantages of using vacuum forming as a manufacturing method.

Advantages	**Disadvantages**
Economically viable for small series	Relatively long cycle time
Short development time	Limitations in choice of materials
Low cost of tooling, since the tool can be made of wood	

The advantages outweigh the disadvantages listed for using vacuum forming as a manufacturing method since as the cycle time, which is in the size range of minutes is not seen as a limiting factor. Although there are limitations in choice of materials for vacuum forming, the most important specification to be met when it comes to the material used is that it should be possible to use cleaning agents on the surface to keep it clean.

A local manufacturer was consulted to gain insight about suitable materials for the application and suggested ABS or PETG as suitable materials for the cover of the inhalation box.

10.3.2 *Bottom part of the inhalation box*

The bottom part of the inhalation box can potentially be manufactured in sheet metal and be formed into correct shape by bending, or alternatively by vacuum forming of plastic, similar to the plastic casing as described above. Due to time limitations this has not been investigated in detail.

11 Detailed design

Detailed design of the design concept is here presented, both in terms of technical alterations of the current setup as well as specific solutions that will be of importance to realize the conceptual design.

11.1 **Technical alterations**

11.1.1 *Redesign of Aerosol reservoir*

A redesign of the aerosol reservoir was considered for many reasons. The most important reason being that the current solution was custom built and not suitable for reproduction. An easier solution, both in terms of complexity and weight was desirable. It was realized that the rigid part was not needed to fulfil the purpose of the reservoir. Therefore a redesign of the way the aerosol and dilution air enters and leaves the aerosol reservoir is suggested, which makes assembly and maintenance easier and also lowers the amount of separate parts needed in the device.

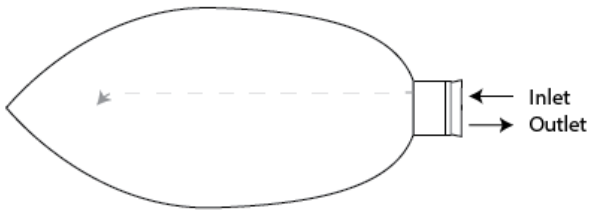

Figure 11.1. Schematic figure describing the redesign of the flexible aerosol reservoir to which particle free air and aerosol is introduced through the neck and led to the bottom of the bag. The aerosol mixture leaves the reservoir through a pipe connected to the neck.

In the redesign, as shown in figure 11.1 a 15 L re-breathing bag is used as is and the aerosol and dilution air enters the bag through the 2” neck through steel pipes leading the same to the bottom of the bag. The pipe openings of the aerosol and dilution air pipes should be introduced into the bag far from the neck to assure the two are

properly mixed before leaving the bag. The aerosol mixture then leaves the re-breathing bag through a pipe connected to the neck and the valve system.

11.1.2 *Dimensioning of sample collector*

As previously described, the current sample container is over dimensioned. It was desired to keep the diameter of the tube at its current size to avoid changing the flow behaviour. Therefore, the only parameter which could be subject to change was the length of the tube. In an experiment previously carried out by a member of the research group it was found out that the mixing of ambient air at tube end appeared after approximately 1 minute which corresponds to 1 L of sample and thereby to the total length of the tube in current design.

Based on the volume required for measuring the particle concentration in an exhaled sample, in combination with experimental values of mixture with ambient air at tube end, the length of the tube should be at least 330 mm and preferably a bit longer. To introduce a margin of safety it was decided that the length of the sample collector tube should be at minimum 500 mm.

11.1.3 *Heating of sample collector and valve system*

The fan used in the device at the beginning of the degree project was causing a high-pitch noise and was heating a volume much bigger than needed. During the degree project the fan was replaced with a heating coil which solved the problem of the high pitch noise and also directed the heat more specifically to the sample collector.

Using a heating coil instead of a fan is beneficial for the design of the device, not only in that it creates a more pleasant working environment, but also that it is smaller and doesn't require air intake from the ambient room, which also is beneficial when it comes to keeping outer surfaces of the device clean.

The replacement of the heating fan with a heating coil had led to unexpected consequences since patients started complaining about warm air with a smell from the latex bag, flowing towards them from the device, highlighting even more the need for good insulation, both in terms of providing means for comfortable usage as well as making sure that the latex bag is kept at room temperature to avoid premature aging. The box for the inhalation system is designed in a way so that the sides of the lower part can easily be insulated and combined with a dividing wall separating the aerosol reservoir from the heated zone.

11.1.4 *Adjustment of resistance in breathing air*

One of the most important points highlighted when identifying customer needs was that in the current setup the patient needs to breathe more forcefully than normal to overcome a resistance within the instrument. Upon deeper investigation conducted by the research team it was found out that a smaller tubing section had been built into the air passage way in the current setup. The smaller section was removed which solved the problem entirely.

11.1.5 *Electrometer replaces the condensation particle counter*

The condensation particle counter used in the machine is considered not to be a sustainable solution for the device in the long run, due to that it is relatively expensive, too advanced in relation to what is needed and requires supply of butanol which is not considered desirable in such a device, since it constitutes both a health risk and at times an unpleasant smell in the examining room. During the thesis project the research group found and tested an electrometer to be able to measure the particle concentration by electric charge instead of first magnifying the particles and later counting them with laser. The accuracy of this method was previously considered not to be specific enough, but recent technical development has changed this, making an electrometer well suited for the task. There are many advantages in replacing the condensation particle counter with the electrometer, the most important advantages being the cost of the module and the fact that no butanol is required.

The replacement of the condensation particle counter gave a bit more freedom in placement of the module than before, but in general it can replace the CPC without any other changes to the device. Replacing the CPC with an electrometer simplifies the device considerably. Since it can measure the concentration without magnifying the particles no butanol is needed which also means that the two active carbon filters installed to trap the butanol vapour can be replaced with simpler particle filters considerably smaller in size.

11.2 **Overall design**

For the design of the machine body the main rule has been to keep the design simple and functional. One of the main goals of the degree project has been to create an overall design which is appealing, both for the patient and for the operator. The lot size of around ten devices limits the design space of financially feasible options. Materials as well as manufacturing methods were therefore explored while working with the detailed design of the device and created a knowledge base upon which the device was designed.

11.2.1 *Design of machine body*

Profiles were chosen to form the basis of the machine body, both for structural and aesthetical reasons. Furthermore, it was decided for aesthetic reasons that that the choice of profiles should be made among profiles with a radiused outside surface. This narrowed the design space even more and two possible cross-sections were found suitable, as shown in figure 11.2.

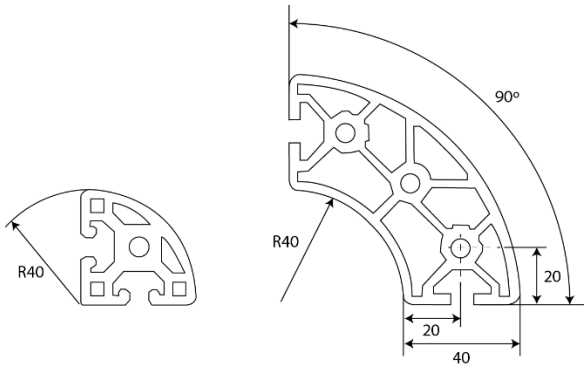

Figure 11.2. Cross-section of the two profiles with outer radius 40 (left) and outer radius 80 (right) found suitable for the application.

The choice between these two profiles was made after creating quick mock-ups of the cross section and placing them in relation to the machine body. It was decided to go with the second cross section, with the larger radius as it gave a softer feel to the overall design.

The panels of the machine body are mounted into the profiles and kept in place with a lip seal, see figure 11.3.

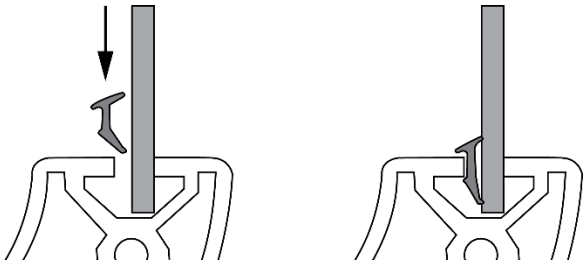

Figure 11.3. Panels are mounted into the profile with lip seals.

The doors are mounted to the machine body with hinges mounted into the profiles and fastened on the doors.

The bottom and top panel of the device should be assembled with countersunk screws. The panels should preferably be NC processed by a subcontractor to facilitate assembly.

11.2.2 *Adjustable arm*

Multiple adjustable arms for medical applications, conforming to the Directive 93/42 EEC are available on the market and it was therefore decided that a readily available arm suitable for the application should be used rather than planning the development of a specific arm for the application. When choosing a readily available arm decisions need to be taken where compromises need to be done. Specific lengths and tilt ranges are available. For this project is was decided to choose an arm with arm length 400 mm and tilt range ±20º, which makes it a slightly under dimensioned to fit the "design for all approach" from the 5th percentile woman to the 95th percentile man. The discrepancy is in the size range of a few millimetres and therefore considered to be sufficient.

With an arm with the length of 400 mm and the tilt range ±20º the centre of the mouthpiece is at 1179 mm from the floor when the arm is in its normal position and it is adjustable to the minimum height of 1042 mm and a maximum height of 1316 mm. The arm is mounted on a pole and should be mounted to reach the required height. The length of the pole is chosen to be a bit higher than required, making the design robust by giving the possibility to install the arm on a different level to fit the difference in anthropometrics of the specific market where it is being used without need for special configurations.

The arm for the application is easily adjusted by the patient and is locked into place by the operator to assure it is in a fixed position during measurements.

11.2.3 *Adjustable table*

The adjustability of the table is solved by a using a telescopic gas spring in combination with a swivel function.

Should the anthropometric values have been followed blindly the lowest position of the table should have been 540 mm, which would be impossible. It was therefore decided that the lowest position of the table should follow the standardized height of non-adjustable tables of around 730-740 mm.

11.2.4 *Wheels*

When choosing wheels for a medical device multiple aspects needs to be taken into consideration. Firstly, the size of the wheels should be chosen so that the device can transverse obstacles when moved. Such obstacles can include thresholds between rooms, cables and gaps between floors and elevators. Choosing the correct size of wheels is also important to be able to smoothly move the device over the floor or other surface. The heavier the equipment is, the wider the wheels should be to allow for a smooth movement [22, pp. 738-739].

Although the device will occasionally be moved longer distances it will most often be stationary. Wheels chosen for the device should be as silent as possible and minimize vibration when rotating on smooth surfaces. Wheels specifically developed for use in

medical settings are chosen for the application since they are designed to be silent and vibration free.

Two wheels with brakes and two wheels without brakes are needed for the device. Wheels are available with different colours of the brakes. Since the wheels should be locked by the operator or other hospital staff who are well aware of the function it is not necessary to signal its function with a distinct color. By choosing wheels with a non-distinct color the function remains hidden from the patient who is not aimed to use that function. Choosing a color that matches the rest of the device is also preferable for the overall look of the device.

To assure stability, wheels with a threaded pin are chosen and mounted into the center hole of the profiles.

11.2.5 *Handles*

By placing two handles on the inhalation system the height adjustment of the mouthpiece and inhalation system is facilitated, while also providing a place for the patient to place his hands during measurements. Using handles which are considerably longer than the width of an average hand makes it possible for the user to choose to position his hands where most comfortable.

Making the handles of the inhalation system stand out and being differentiated from the rest of the device is important to minimize accidental or unintended actions and to clearly communicate to the patient how to interact with the device. Choosing a color which is different from the inhalation box on which they are placed will both increase their visibility and make the adjustment and measurement procedure easier, where the nurse can refer to, for example the “grey handles”.

11.2.6 *Counterweights*

Due to the fact that the inhalation system is placed outside the machine body, counterweights can be needed to counterbalance the load. This has to be evaluated upon further development.

11.2.7 *Design of inhalation box*

The basic design of the inhalation box is that the top part is constructed as a cover to be placed over the bottom part. This way of thinking is well suited for constructing a vacuum formed casing.

12 Final design

The final design is presented in figure 12.1-12.4 as rendered pictures. The final prototype is displayed in figure 12.5 and 12.6. This chapter also includes a short description of how the design fulfils the most important requirements and demands.

12.1 **3D renderings**

The final design is presented in figure 12.1-12.4 as rendered pictures.

Figure 12.1. The final design of the device.

Figure 12.2. The final design of the device seen from the front side.

Figure 12.3. The final design of the device seen from the side.

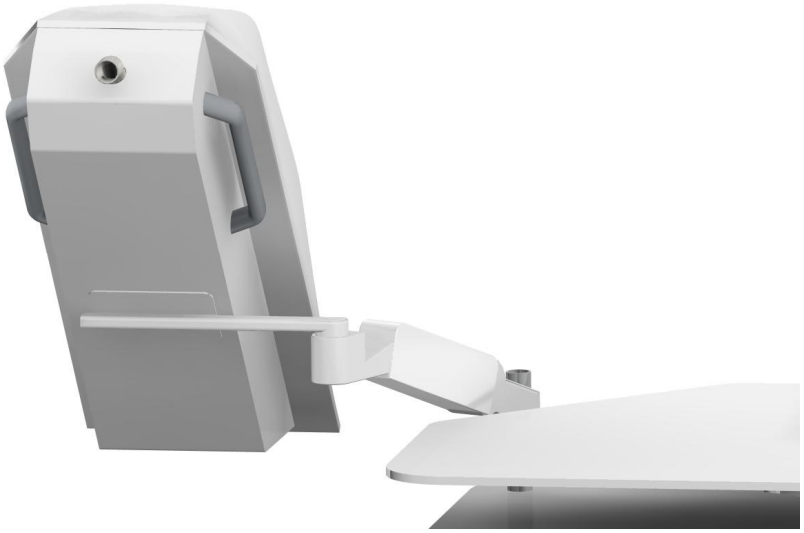

Figure 12.4. The final design of the inhalation box seen from the front. A mouthpiece is mounted on the device before use.

12.2 **Prototype**

A final prototype was built to represent a real size approximation of the final design. The body was built using the chosen aluminium profiles, chosen medical wheels and medium density board panels. The prototype has a swivel function for the work desk which allows horizontal movement. The inhalation box was built using foam board and is mounted on a gas-spring assisted parallel arm. The final prototype is shown in figure 12.5 and 12.6.

Figure 12.5. The final prototype as seen from the front side.

Figure 12.6. The final prototype.

12.3 Final design evaluation

The overall design solution is more space efficient than the current setup and differentiates the space of the patient from the space of the operator. Adjustability of the height of the mouthpiece and of the work desk can be done independently. Sideways adjustability can be done, both for the patient and for the operator to support good interaction between them during measurements, to obtain the optimal placement of patient in relation to operator as identified in the initial body storming sessions.

The design expresses the quality of oneness and its shapes are moderately soft. Surfaces are easy to clean and most components are shielded within the machine body and inhalation box. Tubes for breathing air are not shown in the pictures but will be placed on the exterior of the bottom of the inhalation box.

The device is mobile, which facilitates cleaning of the room where it is placed and the parts inside are easily accessible for maintenance and cleaning, both through removing the top cover of the inhalation box or opening the machine body from the front or rear side.

The setup of the final design is suited for small lot size production.

13 Conclusion and recommendations

This chapter covers conclusions and recommendations based on the work carried out during the degree project.

13.1 Summary and conclusion

The aim of this degree project has been to design and develop a medical device for diagnosis of emphysema or COPD. The work has included identification of problems and challenges in the current setup, identification of requirements for the instrument based on customer needs, the vision of the research team, ergonomics, and physical properties of employed nano-aerosol technology, as well as the target environment and safety aspects.

Building on a broad understanding gained about all of these aspects the work was then focused on providing solutions for placement and redesign of modules critical to the patient and operator interaction with the device, without risking the functionality of the technology the method is based on. Apart from this, the final product to be delivered was an overall design solution for the medical device by means of 3D renderings and prototypes.

The work carried out within this degree project has been a continuous learning process, mixing divergent and convergent thinking while always staying open to changing conditions and new insights. The level of uncertainty characterizing research related to new medical technologies has been very present also in this degree project. Even if the measurement method has not changed, the procedure to obtain the functions needed has changed, and is still subject to change. An example of how this has affected the work is that it has been a requirement to keep the size of the device as small as possible. The outer dimensions of the device are of course directly related to the parts inside it as well as the requirement and specifications of each specific module. As some of the parts or modules have been changed in parallel to the project this has affected the progress. It could be an option to look into purchasing and adapting an existing machine body instead of manufacturing a custom made machine body. If doing so, the work presented in this report can give important guidelines in choosing a suitable readily available machine body with the required properties and dimensions.

The technology and physics of the technique employed for the AiDA-method has constrained the design solution space to a large extent. When showing the prototype

for people without knowledge about the technical constraints of the project the size of the inhalation system has been questioned. If the properties of aerosols had not been such a limiting factor for the placement of modules, placing the reservoir within the machine body could have been a good solution in order to create a more simple design.

A major challenge throughout the project has been to transform the present setup of the instrument in to something closer to the vision of how it could be constructed more easily in the future. This has been of importance in order not to build in unnecessary complexity into the device, however, since the time for the project has been limited it has not been possible to solve all such issues, since in some cases years of research has to be carried out. In the same time it is important to try to push the idea forward, and work both with the function and the overall requirements and design to reduce the time from idea to market introduction. The width of the project in combination with the limited time and the uncertainty related to research has given the consequence that the final design is on a relatively general level and needs further detail development.

The generic product development process, with focus on concept development, by Ulrich and Eppinger, has been important in creating the basic structure of the work carried out. It has however been of importance not to follow the process in detail at all times since each project is unique and a generic development process needs to be supplemented with intuition and taking in advice from people with experience within all different fields included.

When gathering raw data from customers and stakeholders it is of high importance to employ source criticism. It was firstly decided to do longer interviews with participants of the SCAPIS project after they had been tested with the AiDA method. After doing two pilot interviews it was understood that there was a selection bias in the group, since many of the participants were not in fact ill and had volunteered for the SCAPIS project and were very pleased to be part of this important health mapping, including trying the new diagnosis method (AiDA method). The answers to the interview questions were therefore not at all representative of what a ‘real’ patient would experience and a change in strategy was therefore done for gathering of raw data, leading to more reliable input to the development process.

The fact that the functional prototype is currently in use has been beneficial when identifying customer needs as well as the challenges with the current setup, but has been a disadvantage when working with the design of the device. Having a functional prototype close at hand when working with the design could help speeding up the process since the sanity check between design and reality could have been done both easier and more often.

One particularly interesting conclusion made during the work is that many of the customer needs can be reached through creating the right conditions for the operator or nurse to perform the measurements and to guide the patient through it. This is not limited to the design of the device but also the training the operator or nurse receives in order to be able to perform the measurements. It has also been concluded that a

medical device should not ‘steal the show’, however it should be comfortable and easy to use both for the nurse and for the patient.

13.2 Recommendations for further development

The work has mapped out an overall product architecture and therefore detailed design needs to be carried out for each separate part in order to reach the stage where the device can be produced. Smaller technical solutions to look into to make the device reproducible in the way suggested is introducing the redesign of the aerosol reservoir by designing a new part that functions as a stopper for the 2” neck as well as a connection for the input to and output from the reservoir. The hanging of hoses and cables needs to be adapted to the movement of the arm as well as the movement of the sliding shelf for the aerosol generator.

When it comes to more advanced technical solutions, further development is needed, both short-term and long-term.

- Short term

  Technical solutions which need to be solved as soon as possible is replacing the EAG with a simpler solution. A replacing instrument is, as previously described being developed and is promising both in terms of reducing the costs, size and improving safety for the overall device. The instrument will offer an alternative to the PSL particles currently used, since the technology employed can generate particles of a substance commonly used as a drug excipient.

- Medium term

  To customize the device for use in medical settings the vacuum pump and pressurized air supply needs to be removed from the system. In addition to that, CE marking has to be assured for each separate part in the device and the user interface needs to be updated.

- Long term

  To be suitable for primary care use the overall size of the device needs to be reduced. To do so, alternatives for some of the modules have to be found or developed which are more specific for the device.

13.3 Division of labour

All work has been carried out in close collaboration between the two thesis students throughout the project. Besides Sofia taking the main responsibility for the report while Sanna took the main responsibility for CAD modelling, no further division of labour is seen necessary to report.

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Figures

Figure 2.1. National Heart Lung and Blood Institute (National Heart Lung and Blood Institute) [Public domain], via Wikimedia Commons http://commons.wikimedia.org/wiki/File%3ALung_structure_normal.jpg

Figure 2.2. Vihsadas at en.wikipedia [Public domain], via Wikimedia Commons http://commons.wikimedia.org/wiki/File%3ALungVolume.jpg

Figure 2.3. National Heart Lung and Blood Institute [Public domain], via Wikimedia Commons http://upload.wikimedia.org/wikipedia/commons/9/93/Copd_2010.jpg

Figure 2.6. Adopted from [12]

Figure 2.7. Adopted from [13]

Figure 11.2. and 11.3. Adopted from Item's online catalogue, http://www.item24.de/en/products/product-catalogue.html

Appendix A: Customer needs

In below table MD is used as an abbreviation for medical device. The customer needs are rated in terms of relative importance where one star represents needs of moderate importance and three stars represents high importance.

	The MD is comfortable to use for the patient
*	The overall procedure feels comfortable for the patient
*	The resistance when breathing in the device is minimized
**	Tidal breathing in the device can be performed as similar as possible to normal breathing
**	The MD prevents the patient feeling of discomfort when breathing into the instrument
***	The patient can easily breathe according to the desired breathing curve
	The patient easily understands how to perform the procedure
*	It is clear to the patient when to disconnect from the mouthpiece
***	It is clear to the patient how to perform the maximal exhalation
***	It is clear to the patient how to perform the maximal inhalation
**	It is clear to the patient how to perform the final exhalation
***	The patient can easily breathe according to the desired breathing curve
	The MD is safe to use
***	The operator can diagnose in a safe way
***	The patient can be investigated in a safe way
***	The MD prevents electrical shock
***	The design minimizes exposure to chemical substances
	The MD supports a variety in patient anthropometry and posture
***	The patient is offered an upright and comfortable position during measurements
**	The MD accommodates a variety in mobility of the patient
***	The MD accommodates a variety in anthropometry of the patient
	The MD is easy to turn on and off
**	The MD can easily be started
**	The MD can easily be shut down

The MD supports patient timing

** It is clear to the patient when to perform the maximal exhalation

*** It is clear to the patient when to perform the final exhalation

** The procedure accommodates a variation in patient reaction time

** The patient is continuously reminded about how to perform the procedure

*** The risk of patient hesitation during measurements is minimized

** The patient is being supported in a way that helps assure correct procedure

The MD supports a pleasant working environment

*** Noise created by the device is at acceptable levels

* The design minimizes the risk for exposure to unpleasant smell

*** The level and intensity of the noise from the device is at an acceptable level

The MD has a high level of performance reliability

*** The particle supply is steady and reliable

** The particle supply requires low maintenance

*** The design minimizes particle loss

*** Connections between machine parts through which the flow goes is constructed and assembled in a way that assures tightness

*** The mouthpiece is attached in a way that assures tightness

** The mouthpiece is mounted without risk of damaging the device

The MD supports use by patient with difference in abilities

** Instructions are given in a way suitable for the patients diverse abilities

** Successful participation is assured for patients with hearing loss

*** Successful participation is assured independently of patients language skills

*** Information about the measurement procedure is presented to the patient in an accessible way

The MD offers a user interface which is easy to use

*** The user interface displays necessary information

* The user interface does not display redundant information

** The computer software is tolerant for error

** The user interface is fail-safe

The MD provides the operator with necessary information throughout measurements

** Concentration levels can easily be monitored during measurements

*** All information needed to assure measurement accuracy is easily available to the operator

The MD supports a variety in operator anthropometry and posture

** The design accommodates a variety in anthropometry of the operator

** The device offers an ergonomic work position for the operator

	The MD can easily be cleaned and repaired
**	Parts of the MD are easily accessible for repair and maintenance
**	Parts of the MD are easily accessible for cleaning
***	The valve system can be sterilized
*	**The MD offers storage of additional equipment such as nose clips, medical gloves etc.**
**	**The MD is easy to manoeuvre**
**	**The MD looks reliable**
**	**The MD is mobile**
**	**The MD has a leakage free connection to the patient**
	The MD provides means of analysing data
***	Data from successful and unsuccessful measurements can easily be differentiated
**	Measurements can be compared and checked during the patient visit and/or measurement procedure
*	It can be determined if the patient has breathed in maximally (i.e. know how big the lung volume is)
	The MD is well dimensioned
**	The MD provides sufficient space for the operator to perform tasks
**	The MD offers sufficient work space for the operator
*	The instrument offers a variation in working position for the operator
**	The MD does not compromise the physical ergonomics for the operator

Appendix B: Product specifications

Product specifications seen as particularly important in the design of the device are presented. Please refer to previous Lund University master thesis work of Hedlund, Kumlin as well as Jakobsson for further detailed information of the different modules.

Overall design

- All exterior surfaces should be easily cleaned.
- The design should be robust, easy to change and modify as internal parts are changed or updated.
- No leakage.
- Low dead volume where the aerosol travels.
- Surfaces must be solvent, impact and scratch resistant.
- Matte surfaces are desirable.
- Frequency of use expected to be six persons measured per day.
- The device is expected to be started up once a day and be running for about eight hours a day.

Aerosol generator

Function: Generate spherical model particles in the size of 50 to 100 nm of a material suitable for inhalation.

- Easily accessible for startup procedure and finetuning.
- Particle sample is easily accessible for exchange.
- Daily cleaning needed.
- Time required for startup and finetuning: 5-15 minutes.

Product used: TSI Electrospray Aerosol Generator EAG 3480

- Dimension: 404x203x257 mm.
- Weight: 6.8 kg.
- Supply of particle sample, 50 μl solution of Polystyrene Latex (PSL) nanospheres diluted in 1 ml of 20 mM ammonium acetate buffer.
- Input air pressure: 1.0-1.7 bar.

- Output flow: 1.0-2.5 L/min.
- Electric supply: 230 V AC.

Differential Mobility Analyser

Function: Purifies the aerosol by sorting aerosol particles by size and only letting the particles of correct size pass through.

- Input: Aerosol particles.
- Output: Monodisperse aerosol particles.

Product used: Differential Mobility Analyser TSI 3071A

- Largest outer diameter: 56 mm.
- Length: 600 mm.
- Electrical supply: 24 V DC.
- Output flow inherited from EAG.
- Sheath flow: 9.6 l/min.

Aerosol reservoir tank

Function: Provides space for the aerosol particles to be evenly mixed with particle free air.

- Volume: 15 L (approximately).
- Antistatic material.
- Input: Particle free air and monodisperse aerosol.
- Kept at room temperature.

Product used: Re-breathing Bag 8815-020, CMVI Ltd

- Volume 15 L.
- Length: 500 mm.
- Weight: 330 g.
- Material: Black antistatic latex.
- Ferrule neck: 2”.
- Particle free air and aerosol enters through neck and is led to bottom.
- Need to be kept at room temperature to avoid premature aging of latex.
- Input and output flow inherited from EAG.
- Aerosol mixture led to valve system from opening in ferrule neck.

Inhalation system

- Weight to be kept as low as possible to avoid instability of the device as a whole.

- Adjustable in height independently of the adjustability of the operator's desk.

Inhalation box

Function: Cover the main parts of the inhalation system.

- Contain the sample collector, valve systems and aerosol reservoir
- Keep valve system and sample collector at 35°C.
- Keep the latex bag around room temperature.
- Allow mounting on arm.
- Provide space to place hands for vertical adjustment of inhalation system
- Be solvent resistant to common cleaning agents.
- Enough space provided for the patient to maintain a comfortable position while seated.

Mouthpiece (single-use)

Function: Point of connection between the patient and the inhalation system.

- New mouthpiece to be used for each patient.
- The position of the mouthpiece should remain horizontal when adjusting the inhalation system vertically.
- Connected to a 45° elbow with inner diameter 30 mm.

Product used: Standard single-use mouthpiece.

Valve system

Function: Enables only the flow, which is currently wanted, to pass and leads it to wanted direction.

- Easily accessible and/or easily removed for cleaning.
- Heating required to keep temperature at 35°C.

Product Used: 4-way balloon valve Jaeger 706131

- Inner diameter: 30 mm.
- Connected to the 45° elbow with diameter 30 mm.

Sample collector for exhaled particles

Function: Collects exhaled air and provides intermediate storage before particle concentration measurement.

- End of tube should be open towards the ambient room
- Inner diameter: 36 mm
- Outer diameter: 40 mm
- Length: 500 mm (minimum)
- Material: Metal (of choice)
- Weight to be kept as low as possible
- Heated to keep temperature at 35°C
- Heat supplied by a heating coil

Particle detection and analysis

Function: Measures the concentration of aerosol particles in a sample of gas

Product to be used: Faraday Cup Electrometer (FCE)

- Electrical input: 230 V AC
- Flow through electrometer: 1 l/minute
- Cleaning approximately once every second year
- Test of zero level between every measurement

Additional device equipment

Work desk

Function: Gives space for the operator to work in an appropriate way

- Provide variation in working posture
- Vertically adjustable from lowest desk height 740 mm to highest desk height 1180 mm
- Horizontally adjustable to accommodate seated operators
- Work desk rotatable in relation to inhalation system to facilitate good interaction between operator and patient during measurements

Personal computer

Function: Provides the user interface through which measurements are performed and saved.

- Electrical supply 230 V AC.
- Screen adjustable in height.
- Screen tiltable to enable perpendicular placement in relation to the line of sight.
- Distance from eyes to screen should be ≥ 500 mm.
- Screen placement: Line of sight 0-30° below horizontal line of sight (preferable) or down to 45° below horizontal line of sight (acceptable).

Air system

Function: Supplies the system with pressurized air.

Electronics box

Function: Contains central control system of the device. Acquires all the data needed for successful measurements on subjects and translates the signals to the personal computer.

Vacuum system

Function: Supplies vacuum to specific parts in the instrument

- Noise to be kept low

Appendix C: Selection matrixes

Selection matrix, machine body module placement

		A		B		C		D	
	Weight	a (ref)	b	a	b	a	b	a	b
Access and reach for operation	30,00%	2	2	1	4	1	4	4	5
Access for trouble shooting and maintenance	30,00%	2	4	2	4	2	3	2	3
Favours function	25,00%	4	3	4	3	4	4	4	4
Good distribution of weight	15,00%	3	3	3	3	2	2	4	4
Total Score		**2,65**	**3**	**2,35**	**3,6**	**2,2**	**3,4**	**3,4**	**4**
Rank		**5**	**4**	**6**	**2**	**7**	**3**	**3**	1

Selection matrix, adjustability of arm

	A	B	C	D	E
Flexible Use					
Ease of height adjustment	**0**	-	-	-	+
Level of precision	**0**	-	0	0	+
Safe to use					
Stability	+	+	-	+	+
Proven to work in similar applications	+	-	0	0	+
Durability	+	0	-	+	+
Ergonomics					
Low physical effort	+	-	-	0	**0**
Sum +'s	4	1	0	2	5
Sum 0's	2	1	2	3	1
Sum -'s	0	4	4	1	0
Net score	4	-3	-4	1	5
Rank	2	5	6	4	**1**
Continue?	**Yes***	**No**	**No**	**No**	**Yes**

* Concept A was initially considered as a possible option for further development but upon further investigation it was concluded that it is very important that the patient can set the correct height of the mouthpiece and this option was therefore not considered for further development