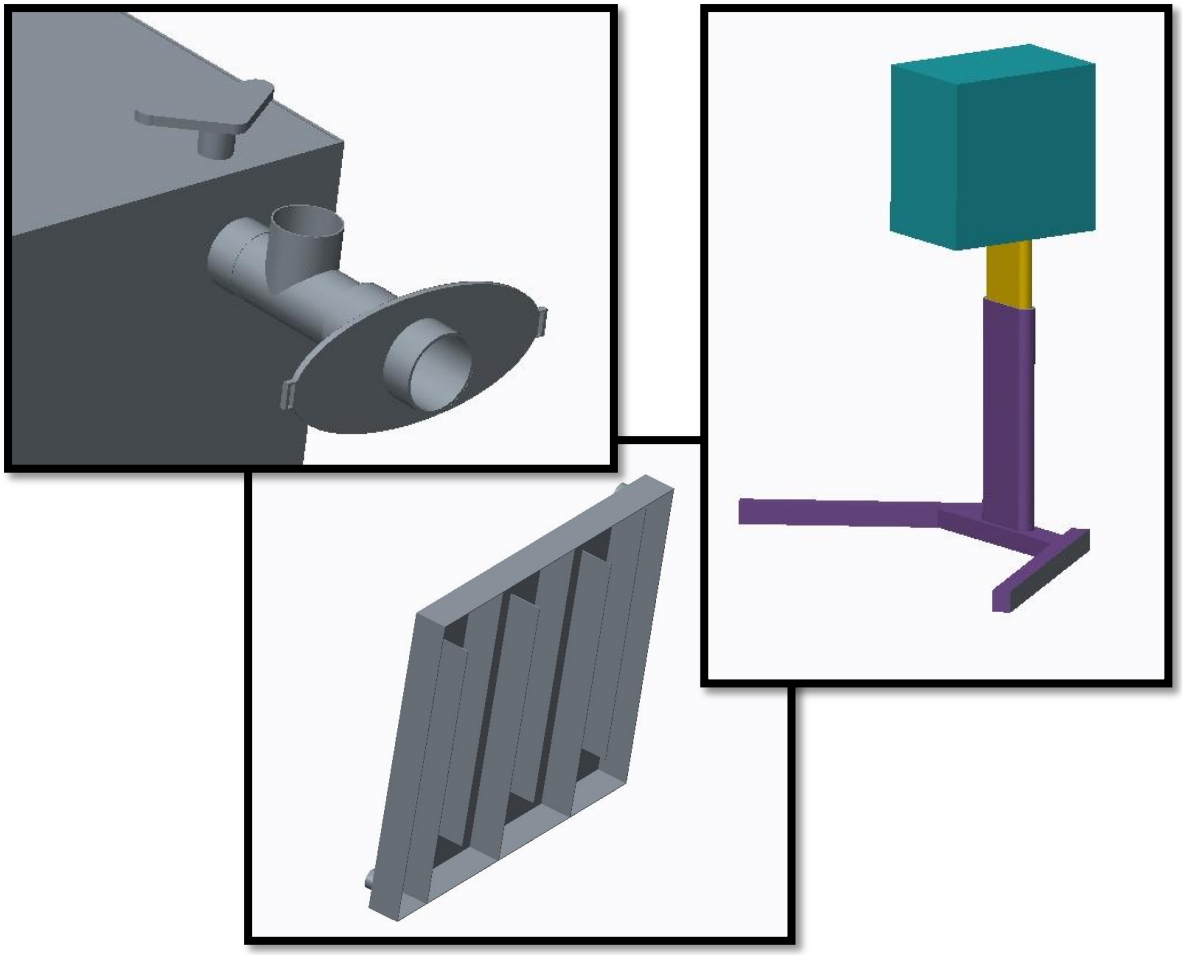
CHALMERS



PRODUCT DEVELOPMENT OF PExA

The future diagnostic instrument for lung diseases

MASTER OF SCIENCE THESIS IN PRODUCT DEVELOPMENT

ÅSA HOLMBERG & JOHAN JONSSON

Department of Product and Production Development
CHALMERS UNIVERSITY OF TECHNOLOGY
Göteborg, Sweden 2015

MASTER THESIS

PRODUCT DEVELOPMENT OF PExA

The future diagnostic instrument for lung diseases

Å. HOLMBERG
J. JONSSON

Department of Product and Production Development
CHALMERS UNIVERCITY OF TECHNOLOGY
Göteborg, Sweden, 2015

PRODUCT DEVELOPMENT OF PExA
The future diagnostic instrument for lung diseases
ÅSA HOLMBERG
JOHAN JONSSON

Department of Product and Production Development
Chalmers University of technology
SE – 412 96 Göteborg
Sweden
Telephone +46 (0) 31 – 772 1000

Examiner and supervisor: Lars Almefelt

Abstract

One of the most common causes of death in the world today is different lung diseases and to determine which disease the patient is suffering from can be difficult. Spirometry is the basic way to measure lung function in a patient but several diseases could implicate a reduced lung function. Doctor sometimes needs to use invasive methods, in which they "go into the patient" to watch the lung tubes and take samples from the tissue, in order to make more accurate diagnoses. Invasive methods are often extremely unpleasant and painful and the patient often needs to be provided with sedation or a general anesthetic during such surgery. To make more reliable diagnoses health care requires more gentle methods.

This thesis is about further development of a non-invasive instrument based on identifying different lung diseases. PExA, which stands for Particles Exhaled in Air, was founded by Evert Ljungström (Professor at Chalmers University of technology) and Anna-Carin Ohlin (doctor/researchers at the Sahlgrenska) who together discovered the ability to in a systematic way capture and retain particles from the lungs. In principle, the method is to let the patient exhale air in a nozzle, the exhaled air is then filtered on particles through a membrane in an impactor. The particles on the membrane are then analyzed and the hope is to, in this way, be able to identify biomarkers through various stages of the diseases.

Today's instruments work but are in great need of further development. In order to use the time as well as possible the first step was to identify which parts of PExA that caused the biggest problems. To solve the problems that are considered to be the greatest will mean most value for the company. This was done mostly by interviewing various stakeholders and then identifying the source to the problem.

Two parts were considered to be very under-developed and these could also be linked to many problems that stakeholders had. These were the reservoir and the nozzle/arm. It was also decided that a suggestion of how PExA could be presented as a total solution should be developed.

Scientific methods taught at Chalmers University of Technology have been used. The methods have been adapted slightly to fit this particular case but seeks essentially to generate all possible solutions for the nozzle/arm, reservoir and the total solution and then evaluate and compare all solutions and thus eventually find the best solution to the problem. The evaluation and comparison of the different concepts is based on the requirement specification that was made after the interviews. Demands and wishes of all stakeholders has been included and these demands and wishes must then be met as well as possible in the final solution. The idea is that the final solution should reflect all the demands and wishes that stakeholders had.

Finally materials and manufacturing methods was discussed for the best concepts, this was done in order to get some kind of cost estimate. The cost must then be weighed against other benefits in order to decide which solution that will be the final one.

Sammanfattning

Lungsjukdomar är en av de vanligaste dödsorsakerna i världen och att fastställa vilken lungsjukdom patienten är drabbad av kan vara svårt. Spirometri är det grundläggande sättet för att mäta lungfunktionen hos en patient men en lång rad olika sjukdomar kan innebära nedsatt lungfunktion. För att kunna ställa en säkrare diagnos behöver läkarna vissa gången använda sig av invasiva metoder där man ”går in i patienten” för att titta i lungrören och ta prover från vävnaden. Invasiva metoder är ofta väldigt obehagliga och smärtsamma och patienten behöver ofta förses med lugnande medicin eller bli sövd under ett sådant ingrepp. Sjukvården är därför i behov av fler skonsamma metoder för att kunna ställa säkra diagnoser.

Det här examensarbetet handlar om att vidareutveckla ett icke-invasiv instrument som bygger på att identifiera olika lungsjukdomar. PExA, som står för Particles Exhaled in Air, utvecklades ursprungligen av Evert Ljungström (professor på CTH) and Anna-Carin Ohlin (läkare/forskare på Sahlgrenska) som tillsammans upptäckte möjligheten att på ett systematiskt sätt fånga och samla upp partiklar från lungorna. Ett Företag med samma namn grundades senare. Principiellt går metoden ut på att patienten andas ut luft i ett munstycke, utandningsluften filtreras sedan på partiklar genom ett membran i en impaktor. Partiklarna på membranet analyseras sedan och förhoppningen är att man på detta sätt ska kunna identifiera olika biomarkörer genom olika stadier av sjukdomarna.

Dagens instrument fungerar men är i stort behov av en vidareutveckling. För att utnyttja tiden så bra som möjligt var första steget att identifiera vilka delar av PExA som orsakade de största problemen. Att lösa de problem som anses vara störst, innebär också mest nytta för företaget. En väsentlig del av arbetet har gått ut på att intervjua olika intressenter för att därefter kartlägga källan till problemen.

Två delar ansågs vara särskilt underutvecklade och dessa kunde också kopplas till många av de problem användarna/intressenterna erfor vid användning av metoden. En av de problematiska komponenterna var systemets reservoar. En annan komponent som vållade stora problem var instrumentets munstycke/arm. Det ingick även i vår uppgift att ta fram ett skarpt förslag för hur PExA skulle kunna presenteras så att en väl fungerande lösning skulle kunna tas fram.

Vetenskapliga metoder som undervisas i vid Chalmers Tekniska Högskola har använts. Metoderna har anpassats något för att passa just detta fall men går i huvudsak ut på att försöka generera alla tänkbara lösningar för munstycke/arm, reservoaren och den totala lösningen för att vi därefter ska kunna utvärdera och jämföra alla lösningar. Genom succesiv utgallring kan den bästa tänkbara lösningen sedan hittas. Utvärderingen och jämförelsen av de olika koncepten bygger på en kravspecifikation som gjordes efter intervjuerna. Krav och önskemål från alla intressenter tas med och dessa krav och önskemål skall sedan uppfyllas så bra som möjligt i den slutgiltiga lösningen. Tanken är att den slutgiltiga lösningen skall spegla alla de krav och önskemål som intressenterna hade.

Avslutningsvis diskuterades materialval och tillverkningsmetoder för de bästa koncepten, detta gjordes för att få någon form av kostnadsuppskattning. Kostnaden måste sedan vägas mot andra fördelar för att kunna avgöra vilken lösning som blir den slutgiltiga.

Acknowledgement

Finally have we arrived at the finish line, hopefully a bit wiser but definitely more experienced, where our time at Chalmers University of Technology has come to an end. Let this master thesis be a guiding light in the dark for our comrades who are about to enter the long and dreadful journey of the master thesis. Let this master thesis be a proof of hard labour and passion for technology and may it inspire the world to greatness. It is both with a sense of relief and sadness we put the life as a student behind us. But not everything will be missed, things that we now gladly leave behind are exams, Monday morning lectures, Monday lectures, Friday afternoon lectures, Saturday afternoon exams (evil), café Linsen's coffee, queuing at café Linsen, queuing at the union restaurant, queuing at the pubcrawl, queuing at Bulten or never finding an available group room. But all our amazing friends and many people we have encountered will truly be missed. We would like to specially thank our supervisors Lars Almefelt from Chalmers and Svante Höjer and from PExA AB for making this possible, also special thanks to Claes Holmberg also from PExA AB and Emilia Viklund with personal from AMM Sahlgrenska. We would also like to thank our friends and lovers for endless support and patience, we will promise to be more fun now as life slowly returns. As Aristoteles once said "The roots of education is bitter, but the fruit is sweet".

Table of Contents

1 INTRODUCTION

This chapter will introduce the purpose of this master thesis, why it was a need to conduct this product development. This includes describing the background of the company and their current situation. It will also describe the problem, the objectives and the limitations that frame the report.

1.1 Background

This master thesis is a product development project within the medical research community conducted for a company named PExA. PExA, which stands for Particles Exhaled in Air, is a recently founded company that has discovered the possibility of capturing particles from the lungs. PExA is the one and only company that provide a non-invasive method for diagnosing different lung diseases. The background section will present the company and describe their current situation, which will explain their need for a product development.

1.1.1 The company

PExA was founded by Evert Ljungstöm (Professor at Chalmers University of Technology) and Anna-Carin Ohlin (Professor/Scientist at Sahlgrenska university hospital) when they together discovered the possibility to, in a systematic way, capture and sample particles from the lungs. The business is built on this new idea that aims to produce a new medical instrument that could be used in diagnosing and monitoring respiratory diseases such as COPD and asthma [1]. The underlying research for the new method comes from the Department of Occupational and Environmental Medicine at Sahlgrenska Academy and is based on a new and unique method to gather particle samples from exhaled air [1]. By performing a subsequent analyzes of the particles in the gather sample, this provides a rather simple way to identify different biomarkers through different stages of the diseases.

The new PExA device can replace old methods such as lung lavage that is both very painful and extremely uncomfortable for the patient [2]. The procedure uses a patent-pending new technology that uses a non-invasive method that is simple and painless [1]. The potential of the research area is huge and the method can be applied in a very wide area where it can be used to develop new medical instruments within the area of diagnosis [1]. The aim with PExA is to revolutionize the monitoring, diagnosis and treatment of chronic obstructive pulmonary disease [1]. The goal with the PExA instrument is that it will exist in every hospital in the future but as a first step it will target different research groups around the world that works on connecting biomarkers with diseases [2].

1.1.2 Description of current solution

The following information was gathered by performing unstructured interviews with operators, system designers and inventors combined with tryouts of the device and the sampling procedure.

Today the existing solution, see figure 1, consists of a number of parts that has not been developed for this particular reason. The solution is functional but far from optimal. Many of the parts can be relocated and/or replaced by new parts that are more developed for this specific purpose. The placement and size of the different parts contributes to a design that is hard to handle and offers very little freedom in movement for the patient during the sampling procedure.

Figure 1: Current solution

Before performing a sampling procedure, the device requires a long startup. The startup includes an instructions manual with a large number of pages including many numbers of steps and taking around 40 minutes before it can be used. The operator has to turn on several different sub-devices in a specific order and check the operational status to confirm that right pressure, temperature and humidity are set and reached. It is of importance that the pressure, temperature and humidity in the device correspond to the environment in the patient's lungs. If they were to be compromised the exhaled air could start condensate and change the structure and composition of the particles leading to an invalid sample.

During the procedure the patient only breathes through the mouth and into an air hose connected to the device. The nose ventilation is prevented by using a plastic clamp, which closes the nose drills, see figure 2. In the beginning of the procedure the patient first needs to breathe clean air, assuring the removal of contaminating particles from the surrounding environment. This is done by a manual valve, see figure 2, in the breathing tube that is connected to air filters. During the sampling period the operator manually switches the valve allowing the exhaled air entering the PExA system for processing. The patient is then guided through a specific breathing schedule that is developed for generating as many particles as possible. The valve need to be switched several times during the sampling and the timing of the switching is crucial to assure a good quality sample and a quick painless procedure.

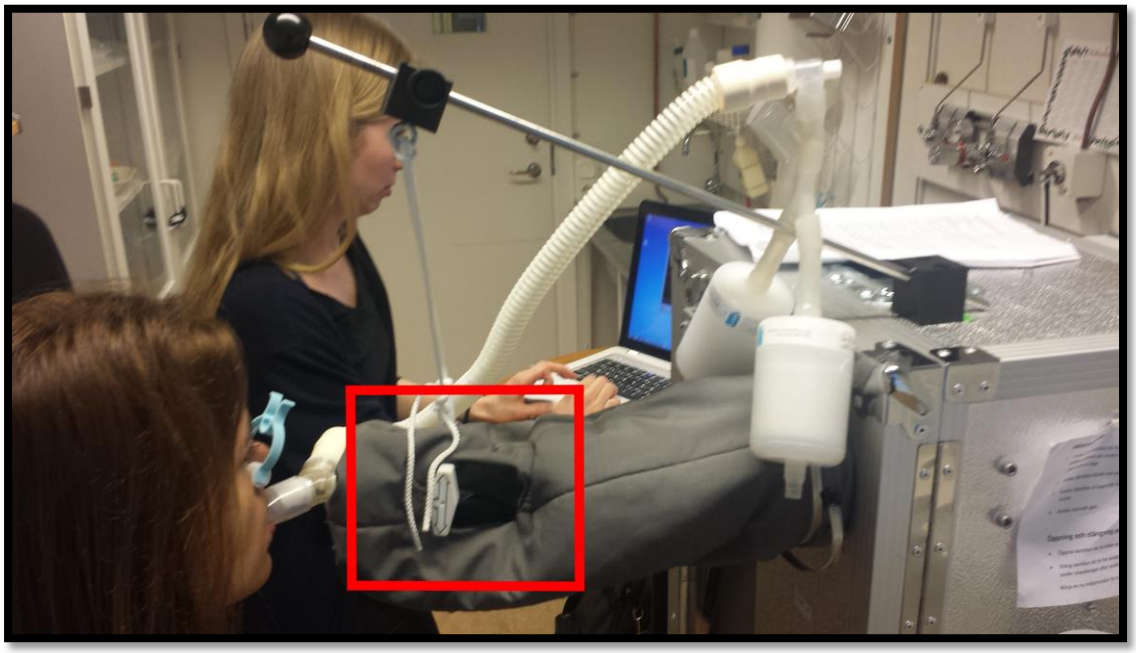


Figure 2: Testing of current solution

The particles are gathered by allowing a constant airflow through a metal container called impactor that includes a special membrane that catches the particles. The system is designed so that the airflow is divided. One amount of the airflow goes to a particle counter which makes sure that enough particles is sampled, the other part goes through the impactor and excess air goes in to a clean air reservoir. The purpose of the reservoir is to store the overflow of exhaled air and provide a constant flow and pressure through the impactor. This means that when a patient breathes in the air reservoir kicks in and supplies the impactor with an airflow assuring a constant flow through the system. This is also realized by connecting filtered compressed air in the other end of the reservoir in case of an insufficient amount of exhaled air.

When the desired amount of particles is gathered the operator has to open the PExA device and retrieve the impactor containing the membrane sample. The sample is then taken to a lab for further analyzing.

1.1.3 Current design proposal

PExA has performed an earlier design study which resulted in a new proposed visual design see figure 3. This design is only conceptual and takes little consideration to functionality of the system and placement/function of parts. It is therefore important to investigate if the design proposal could be a possible design solution as an end product.

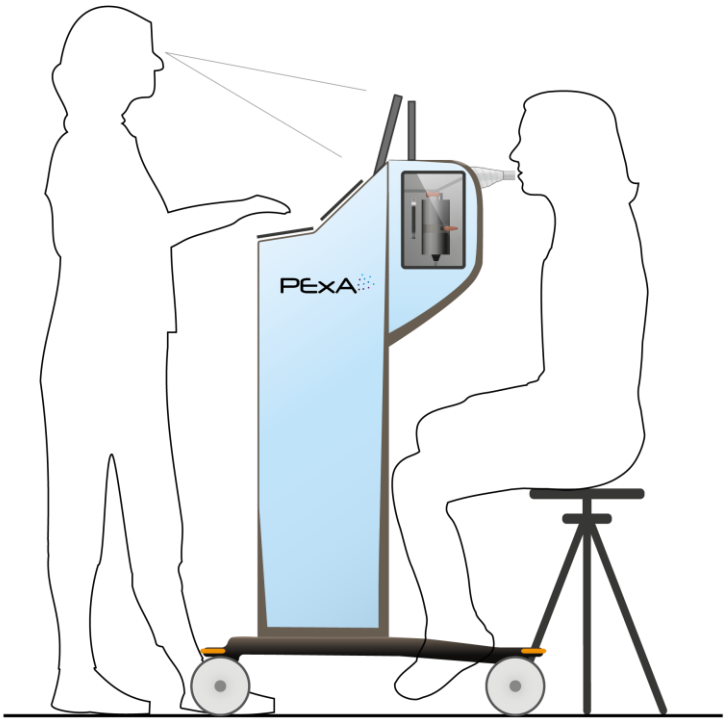


Figure 3: Design proposal

1.2 Purpose

The purpose with this study is to develop a new version of the PExA device that enables a more attractive and effective solution than the already existing version. The existing solution will be broken down into each consisting part for a thorough investigation of function, shape, placement, technical principle, material and its necessity. Combined with customer studies, this will result in a detailed requirement specification that is based on good product performance and customer needs. The current design proposal will, through customer studies, be investigated and evaluated to see if it could be a possible design solution. The end result of the study should result in a commercially viable product proposal that will simplify the sampling procedure, making it more comfortable for both patient and the operator in a more efficient design. The procedure should in theory be the same but the new solution should enable a more effective and automatic solution.

1.3 Objective

The following points are the resulting objectives for a new version of the PExA device:

- Simplified startup of device and process
- A safer and more easier data collection during sampling
- More flexible and operating stable way to lead exhaled air from patient to the PExA instrument.
- A more safer and automatic solution that controls the in and out direction of the exhaled air
- Design for a more ergonomic procedure for both the patient and the operator during the sampling procedure
- A more modularized product with less components
- Develop a more mobile product that is less bulky.
- Supply disposable components of smart packaging, such as nozzles and sample substrates, for the convenience of customers
- Simpler and more effective maintenance and procedures for good hygiene.

1.4 Problem definition

As stated before, the existing device is functional but far from optimal. It is known that a solution including the same parts as in the existing version will provide a trustworthy sample. What is not known is that if the same result could be achieved using fewer parts i.e. the necessity of the part for the system solution.

The long startup time is mostly due to the heating of the number of parts and the inside of the device but also because of many manual starting steps in the starting procedure.

The manual handling of the ventilation valve in the breathing tube creates a laborious task for the operator during the sampling procedure and can complicate the sampling if performed poorly. There is also a chance when the valve is removed and cleaned that it can be misassembled and create a malfunction during the procedure.

The total size of the device and the length and position of the breathing tube creates a limitation in the movement and positioning for the patient during sampling. The limitations for the length of the breathing tube is due the fact that is needs to keep a constant temperature and is there for kept short and wrapped with insulating material. There is also a problem with moving the device when it’s perceived to be immobile and very bulky.

The way that the sample is retrieved is by opening the cabinet and unlocking and removing the whole impactor containing the sample. During this procedure the sample can get damaged and the inside climate of the device can suffer unnecessary disruption.

1.5 Scope

The PExA instrument consists of a number of critical parts, which in one way or another will be considered in order to enable improvements to the total solution. Some of the components will be replaced and the placement of the parts will be reconfigured. Today the existing solution works but it comes with some flaws and problematic limitations. The procedure should in theory be the same but the new solution should enable a more effective and automatic solution.

Due to the difference in the parts complexity and difference in the earlier efforts spent on development, the amount of time spent on each of the parts will vary. The estimated time that will be spent on the different parts can be viewed in figure 4.

	PExA - total solution Optimizing volume and position in total solution with respect to the requirement specification. Dose not include the design part and the "outer shell" of it. **20 %**	
Impactor - the heart of PExA Positioning in total solution **5 %**	**Reservoir - To take advantage of exhaled air and serves the particle counter and the impactor with required flow** New total solution **20 %**	**Nozzle solution - Intake for exhaled air, provides clean particle free air and controls flow direction** New total solution **40 %**
Air volume meter (spiroson) - Register the flow and the speed. You can se if it is a leakage. It tracks how much air that is going through the impactor. **5 %**	**Pump - Determines how much air that should pass through the impactor. The existing one needs compressed air from "the wall"** Positioning in total solution **5%**	**Particle counter - Counts the particles in different sizes** Positioning in total solution **5%**
Electrical cabinet - Supply energy to all devices **0%**	**Fan heater, Air heater - Heats the air in the cabin** **0%**	**Computer** **0%**

Figure 4: Illustration of Project workload

1.6 Limitation

As stated in the scope some parts are more developed than others. This means that some parts will just be looked at in the purpose of getting a optimize position of the parts in the total solution.

In the beginning of the project one of the goals was to find a suitable heating solution. This goal was later in the process abandoned and reassigned to outside contractors, but some amount of time were spent on developing concepts for this specific purpose and these will be displayed but not evaluated. The reason for excluding the development of the heating solution was due to the unexpected complexity and the lack of knowledge and experience with these systems.

Parts whose development won't be covered by this thesis are the particle counter, the impactor, the air volume meter, the air moisturizer the electrical cabinet, the computer and the pump. As mentioned earlier however, the placement of some of these parts will be considered and evaluated and some of these parts might be excluded in a final solution.

1.7 Short explanation of methods used

This chapter describes in short the methods that have been selected in order to approach the problem in an objective and scientifically way. All of them are engineering methods that students, taking courses in product development, studies at Chalmers University of Technology. All method has been selected under consideration of which method that will be suitable for the particular problem. Some method has also been reconstructed in order to suit the specific situation better.

Figure 5: The development process

Figure 5 visualizes the development process used in this master thesis and every chapter will begin with this picture highlighting where the process are. The pre-phase were about understanding the problem. This meant getting a deeper understanding of how the current solution functioned and establishing the problems that existed, known or unknown. Different data collection method where used. Interviews with different stakeholders/users gave a lot of valuable information and also important contacts that was used during the development. The collected data laid the foundation for both the requirement specification and the functional description.

The needs mapping process together with the realization, which was made in the other ongoing project, identified what problem areas this project had to cover in first hand. Both a new nozzle/arm solution and a reservoir needed to be developed. An optimal position for all different parts needed to be found and an idea of how the end product could look like should be suggested.

It is obvious that the arm/nozzle solution has to be placed outside the instrument, so the development of it would not affect the placement of other, already developed,

parts. The first step was therefor to find the optimal position for the other parts. This had to be decided before developing a new reservoir since the reservoir could be formed with respect to how the other parts had been placed.

The methods used for developing a new nozzle/arm solution and a new reservoir followed the same procedure. The concept development phase can be seen in figure 6. It started with generating as many solutions as possible and then based on the requirement specification, made for each of them, screen and score the different solutions. The principle is to cover all kinds of different solutions and then end up with the best one see figure 7. The fact that the screening and scoring of different solutions is based on the requirement specifications and that the requirement specification is based on needs described by the different stakeholders makes the end product the solution desired from the stakeholders.

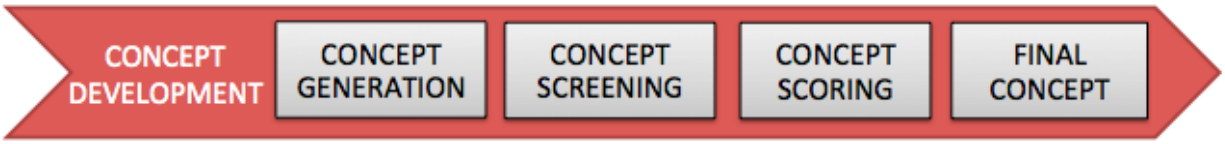


Figure 6: The concept development process

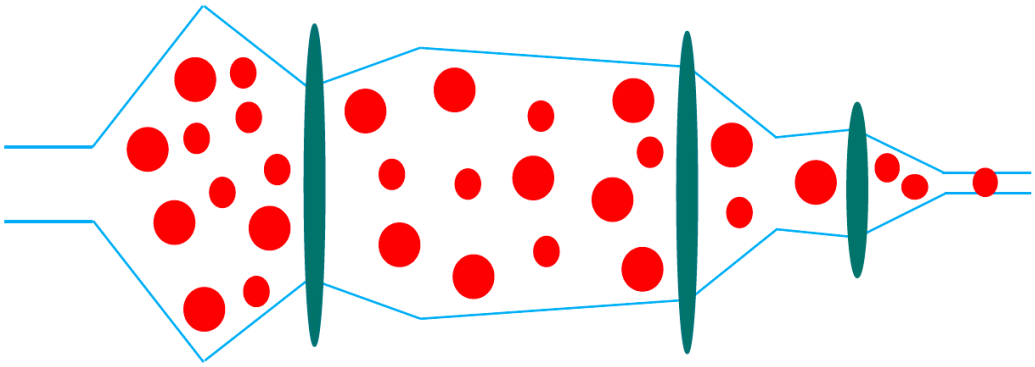


Figure 7: The process starts with many concepts and are trough different methods screened and scored in order to find the best one.

The development process became an iterative process where simple prototypes where built early on to enable testing, evaluation and early learning. This is called lean product development where testing, building and designing prototypes is and iterative process, see figure 8. The main strength for using this process in this project was to detect problems as early as possible without spending too much effort on complex and expensive prototypes.

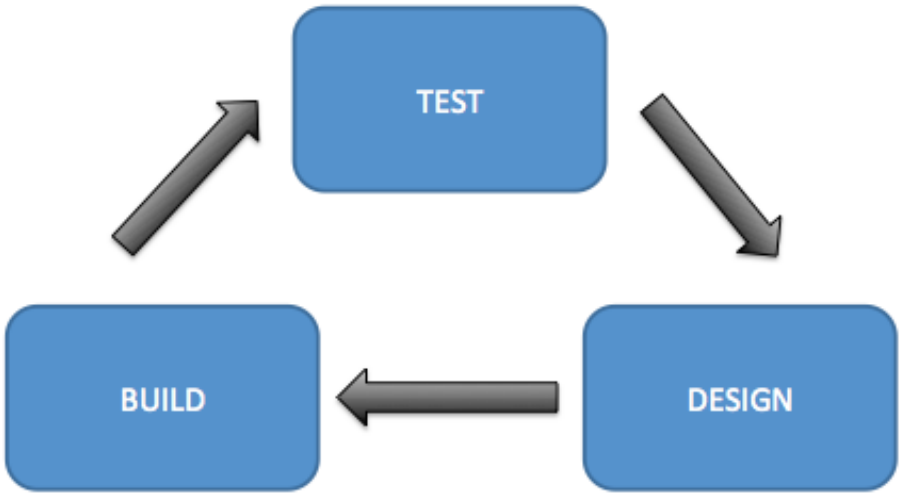


Figure 8: Test, build and design is an iterative process

The final concepts for the arm/nozzle solution and reservoir where realized in the CAD-Software Creo together with the other components. This made it possible to estimate what size PExA could have as a final product. This step was important when finding solutions for how the entire product could look like.

With help of the material selection software CES and combined with consulting specialized manufacturers, information of suitable material and manufacturing process has been gathered. CES offers the possibility to determine suitable material choices for the final concepts by using screening and limitation functions. Based on the material choices CES offers analytical calculations model of manufacturing processes where rough cost estimation has been obtained. To better get a holistic and realistic view of the result, close work with subcontractors within the industry has been maintained during this project.

1.8 Outline

The outline of the report will be presented in a chronological order. This means that the chapters will be presented in the same order as it was conducted to give the reader an easy way to follow the process and to understand how the product development works.

Chapter 2 is about identifying the needs and requirement of the target groups. Stakeholders are identified and different data collection methods are chosen in order to identify the needs. The chapter ends with analyzing different problems and connecting those problems to its source.

Chapter 3 is the theory chapter and describes how PExA works in detail. The chapter starts with a description of all the main parts and how they work individually, later it describes the start-up process and how to perform a test with PExA. This knowledge is good for understand the entire process. The chapter end with some theory about how to analyze the amount of particles produced during tests. This was used when evaluating different concepts.

Chapter 4 will explain which restrictions PExA operates under. This is done with the help of a requirement specification. The chapter starts with how to the requirement specification was made and ends with a functional description that was made to get an overview of what the system is supposed to do and how it should do it.

Chapter 5 evaluated the current system. What parts are necessary and what parts are not. It describes the product architecture in the evaluated system that is going to be developed. The chapter ends with an optimization of location on the different parts. Some parts needs to be placed at certain places in relationship to others. All required locations are identified and the entire system is then optimized in order to take as little space as possible.

Chapter 6 is the main chapter. This is where the development process is described. Three different areas was chosen to be developed and where developed one at a time. They follow the same process, which starts with concept generation, followed by concept screening, concept scoring and ends with concept selection.

Chapter 7 is a chapter that analysis the final concept. This included identifying how different components could be manufactured and to estimate cost of selected components.

Chapter 8 includes discussion, conclusion and final recommendations for continued work with PExA.

2. NEEDS MAPPING

This chapter will aim at identifying needs from different stakeholders, which in turn will frame the whole product development process. Different used data collection methods are described and a KJ-analysis is performed. The result from the KJ-analysis is then summarized in different problem areas.

2.1 Identifying customer needs

In order to evaluate the needs and requirements of the target group, several different kinds of "data collection methods" will be applied. In this case the target group has been identified as on one hand "the users" those who are going to operate with PExA and on the other hand "the test persons" those who are going to be tested with PExA. The final result of this work has to meet all requirements of the users and all needs of the test persons, if this should give at hand and attractive method and product.

Four different types of data collections methods will be used to gather as much knowledge as possible. *Secondary researches*, consisting of already made interviews, are going to be included in the work. Those interviews were conducted at an earlier stage, for almost the same purpose. *Customer visits*, which consists of both face-to-face interviews and observations at the PExA researchers own environment. These methods enable rich communications between the target group and the product developers [3].

Both *participatory observations*, where one observe and at the same time participating, and *direct observations*, where one study something that happens, should be conducted in order to gain as much knowledge as possible [4]. Interviews are the primary method for the collection of information. A detailed interview guide is therefore going to be made, can be found in appendix A, before performing the interviews. Interviews will be performed in a semi structured way with open-ended questions. The reason is that this method allows the customer to think and express him or herself freely [3].

A method called KJ (after Jiro Kawakita) analysis is going to be used in order to analyze what was collected during the observation and the interviews. The Japanese Jiro Kawakita founded it in order to organize uncertain facts and thoughts [3]. By writing down statements from the interviews, collected both first hand and second hand, on papers and placing each statements in different groups the KJ analysis method enable one to find important areas to consider during development.

In order to establish the requirement specification the needs of different stakeholders must be identified. To know how to solve the needs might not be necessary but in the end it is those identified needs together with what is technically and economically feasible that will make the specification for the final product [4]. In order to make the right trade-off, find the innovative solutions and develop a deep understanding of the target group it was substantial to interact with the different stakeholders in their user environment [4].

2.2 Participants

There are a number of different stakeholders that are relevant for participation in order to collect data. There are the founders of PExA, Anna-Carin Olin and Evert Ljungstöm. They have important knowledge about the medical and technical requirements, which needs to be considered when establishing the requirement specification. There are the people who work and use the PExA device on a daily basis, the operators. They are the most important group at the moment. Their needs are essential for the end result. There are the people who have been tested with PExA, the patients and their needs must be fulfilled in order to get a successful result. Researchers that have not come in contact with PExA can also have relevant input on what demands and needs that exists on other instruments used within the same research area. Other stakeholders such as doctors or nurses within the medical care system could also provide relevant information on what is expected of medical equipment used in today's hospitals.

During consultation with the PExA company there was decided that some of the categories could be neglected. The company based this on previous knowledge from similar research. It was decided that it would be interesting to contact three of the categories.

The interviews were finally performed with stakeholders representing the categories, founders, operators and patients. All participants can be seen in appendix B.

2.3 Data Collection Methods

In order to collect data from customers' four different collecting methods were used.
The first method that was used for collecting data was the use of already made interviews, so called internal secondary research. This method could be used because of the fact that the interviews where gathered for almost the same purpose. The interviews where performed by Svante Höjer, who is the project manager for PExA. Secondary research is quick and cheap but it does not address all the key issues and it doesn't provide you with the same knowledge as first-hand information [3].

To collect data from the operators customer visits where used. This method enabled rich communication due to the fact that both face-to-face interviews and observations were executed in the researchers own environment [3].
Interviews were the primary method, used for collecting information from the founders, the operators and the patients. A semi structured interview format was used, which consisted of a broad variety of questions being prepared in advance. This was chosen to allow the interviewee to talk freely, but also to make sure that all major topics were covered. In addition to this, notes were created beneath the main questions as a reminder of what information that was desired to collect. Probing was used when extra explanations or additional confirmations were needed [3].
The interview consisted mainly of open- ended questions with some additional close-ended questions to receive a detailed and described answer and to develop a dialogue for confirmation or disapproval of the stated. The interviews were performed in Swedish and the transcript of the question guide can be seen in appendix B [3].

Interviews with the researches took place at the laboratory, at Sahlgrenska University Hospital during customer visits. A number of, one to two hours long, in-depth

interviews, with the operators, were executed. This was preferred due to the amount of information that could be gathered at each individual occasion.
Another method that was used in order to collect information was based on observations. Three of these where of the form participatory observation, where you observe meanwhile you participate [4]. The first one, see appendix C, was to test PExA to get a better view and a deeper understanding of what patient experiences when they participate in the tests. The second one, see appendix C, was to prepare PExA for a patient and operate PExA during a test. It is easier to understand what the operators mean if you have experienced it yourself. The third one, see appendix C, was to review the machine, in order to understand what happens in PExA at a technical level. Understanding the functions of the different parts is crucial for finding better-suited solutions for the different functions.

Apart from the participatory observations, direct observations were executed while visiting researchers. The primary reason for this was to increase understanding of how the different operators used PExA. These kinds of observations can be a good complement to the interviews. All problems may not arise during the interviews due to, for example, lack of language and ”compensating behaviours” [4]. All the different observations are gathered in appendix C.

2.4 Context

The environment in which the observations were executed was at the laboratory, at Sahlgrenska University Hospital, where they usually perform tests on patients. In this way one can observe in which kind of environment the product is used and how it interacts with other apparatus. This will provide information about if the operation of the instrument needs access to water and clean air connections or if the personnel move around the device.

2.5 Mediating Tools

Mediating tools help the customers to imagine and understand different perspectives of the product. It reminds and illustrates how things have been earlier and how it could be in the future. It enables and helps the participants to imagine how the final solution could be [3].

In the earlier stages of the project PExA performed a study that resulted in a new design suggestion, the purpose was to create a productification of the device to better communicate future vision as a viable product. As mentioned in the introduction this suggestion should be considered as a possible solution for the design of the entire PExA machine. In order to get the operators opinion, on the suggestion, they were showed a picture during the interview and they were asked to talk freely about their thoughts.

2.6 Analysis and result of data collection

The KJ started by writing down all statements from the interviews on a post-it. The first post-it were then placed on a whiteboard and created the first group. Another note was picked and placed. The statement picked could be placed in the same group if there were related, if not it created a new group. This was repeated until all notes were placed on the whiteboard. Many quotas were repeated and got removed. The result with the final groups can be viewed in Appendix D.

In the following section the result from the interviews and observation will be displayed. Through a KJ-Analysis, six different areas of improvement has been identified which will be further explained.

2.6.1 A Big and bulky solution

During the interviews, it emerged that the PExA instrument perceived as very large which gives rise to several ergonomic problems. Since the instrument is fairly high it requires an adjustable chair that could leave some shorter patients dangling with their legs.

"One wants to be able to sit as comfortable as possible and since the device is as high as it is and since the length of the patients varies a lot, a quite adjustable chair, is required"

“Some patients might end up dangling with their legs.”

One of the interviewed stakeholders mentioned that it is important for the patient to have support for their feet and to be able to stretch their legs during the procedure since it can be time consuming and tiresome. If the instrument were to be smaller it could be placed on a table which would facilitate a lot for the patient. The patient can be placed closer to the instrument and therefore enable a more comfortable and freely placement of the legs. This would also make it easier to use a chair that provides support for the neck and back, all to make the sampling as comfortable as possible. This goes as well for the operator as for the patient. The interviewees placed great importance of being placed next to the patient during the sampling for having a good view of the patient's status and at the same time control the computer and operate the air valve.

"You want to sit next to the patient so that you are in level with them. It would be easier to ensure the status of the patient and easier to instruct them”

Also by making the instrument smaller and less bulky it will be easier to move it to other places or to store it, when not needed, which was also a concern that emerged under the interviews.
The reason for the PExA instrument’s big size is related to the great number of parts and their sizes. These quite bulky parts demand a big cabinet where all of them can be placed in a controlled environment. During interviews with inventors, designers and individuals at the company, responsible for the PExA instrument, it became known that some of the parts might be excluded or replaced and/or redesigned in order to enable a more space efficient solution.

2.6.2 Poor solution of breathing tube/arm with air valve and nozzle

The arm that extends from the PExA instrument and includes the breathing tube, air valve and nozzle is something that the interviewees have many complaints about.
Because of the high requirement on keeping the right temperature of the air in the breathing tube, this leads to a solution that is relatively short and that is wrapped in a big and thick heat insulating fabric. As a result the arm becomes very restricted in flexibility and movement. According to the interviewees this requires for a more precise positioning of the chair's height and placement so the patient can obtain a comfortable position for the neck during the procedure. Even though a fairly good positioning can be obtained, the lack of flexibility and movement in the arm will create tension in the patient's neck after while due to its fairly fixated positioning.
During the sampling the operator must control the direction of the airflow in the breathing tube by manually switch an air valve located on the arm. This is according to the interviewees a laborious task that becomes tiresome for shoulders, wrists and hands. To have to stand and turn the valve every time the patient exhales out in the instrument is one of the biggest problems according to several of the interviewees. There is also an underlying risk that when the valve has been disassembled and cleaned, it can be wrongly reassembled and cause malfunction in the sampling.

"Absolutely, I want to have an automatic switch. Today, one must have a two-handed grip. One that holds the arm and one that twists on vault. The nozzle strikes the teeth of the subject, which is very unpleasant. "

One other problematic part of the arm is the rubber nozzle that the patient breathes through. The nozzle is similar to a snorkel and works combined with a plastic clamp that prevents nose ventilation. The nozzle is held in place by positioning it between the teeth and cheek and by biting the rubber. The interviewees says that many patients finds it tiresome after a while to bite on to the rubber nozzle and that it creates a saliva overflow due to the difficulties of swallowing properly with the nozzle in the mouth

2.6.3 Easy hygienic handling

When receiving a new patient that is unfamiliar with the PExA instrument it is, according to the interviewees, important to do the installation and unpacking of new fresh nozzles and clamps in front of them so that they feel that it is safe to use.

"Then there is this thing with the cleaning. I tend to always be very careful that they'll see that they have not breathed in the same nozzle as others. I always put on a new in front of the patient so that they know that the nozzle is clean. "

So far there have not been any signs of possible contamination between patients. Since the exhaled air only flows into the instrument that means that the patient will never come in contact with air that's been inside the instrument. But some concerns have been raised about the heat insulating fabric that is wrapped around the arm. It is, according to one of the inventors, a possible source for bacterial formation that could need cleaning or replacement between patients.
Even though that the chances of contamination between patients are very minimal there has emerged a demand from both operators and responsible stakeholders that the parts in the device easily can be detached and cleaned. It is basically a safety measure when dealing with patients who has highly contagious diseases. Therefore

there is a demand of obtaining a solution that is highly modularized so that different parts easily can be replaced/removed and cleaned.

2.6.4 Loss of particles

One other complaint that emerged from the interviews was that the sampling time was too long and that some patient didn't have the stamina to endure a procedure of 30-40 minutes. Many of the interviewees pointed out a suspicion of particle loss in the instrument and that this was an underlying cause for the long sampling time. If this particle loss were to be reduced, this could in turn result in a quicker sample time and therefore less painstaking for the patient.

2.6.5 Noise

To circulate and heat air in the PExA instrument, an air pump and heating fans are used. These parts create a buzzing noise, especially the air pump which many of the interviewees have complaint about. They mentioned that after working a whole day with the instrument the sound gets you very tiring.

"When you stand and work with it as much as we do, the sound is very tiring "

This is primarily a problem for the operators and not really an issue for the patients. It is a low frequency noise that is not directly damaging for the hearing but after a while it gets annoying and makes the operators lose focus.

2.6.6 Many tiresome manual operating steps

The operating procedure of the PExA instrument today includes several manual steps, both during the sampling procedure and especially during the start-up and preparation phase. Many of the interviewees complained about the complex starting procedure and that it involves too many manual steps such as manually starting each of all the different sub-devices in a specific order or choosing right USB-connection etc.

"The operator needs to choose which USB port to use. This does not happen automatically and the starting procedure needs to become more self going and should not need as much support as it does today"

"To improve PExA you could reduce the number of manual steps"

As explained before, the sampling procedure requires manual regulation of the air valve that controls the flow direction of the exhaled air. This is also an example of a part that the interviewee's feel could be made more automatized or easier to operate by e.g. just pressing a button. Overall there is a clear consensus from the operators that the instrument is perceived to be very technically complicated and that the different sub-functions require too much focus, both during start-up and during sampling. This ultimately affects the patient because the operator can't offer their full attention and tend to their needs fully.

3 PRE-STUDY: THEORY

The theory chapter describes how PExA works in detail and how tests and data programs that are used works. The chapter starts with a description of all the main parts and how they work individually, later it describes how the start-up process and a test procedure are performed. In order to understand the entire process it is essential to understand these things. The chapter ends with some theory about different data programs and how to analyze the amount of particles produced during tests. This was used when evaluating different concepts.

3.1 The PExA device 1.0

This section will describe which main parts PExA consists of and their function. It will also go through how the operator prepares PExA before a test and how a test is executed.

3.1.1 Different parts

This section will describe the different parts and how they work. Most of the information is gathered though interviews and observations with experts see appendix B and C.

The impactor

The impactor is the heart of PExA. This is where the sampling of different particles takes place. The exhaled air from the patient enters through a tube at the top of the impactor see figure 9. The technology is based on the fact that different particles have different velocity. The impactor catches particles in two different size intervals. These intervals represent the biggest particles, the smaller ones follows the airflow out again. A pump that draws a continuous sample of 230 ml/s serves the impactor.

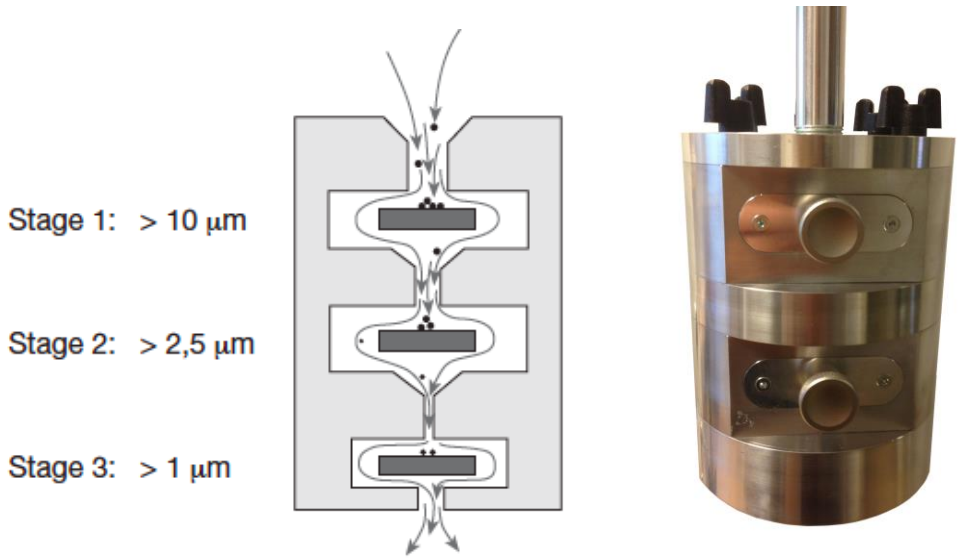


Figure 9: The impactor

The nozzle solution/arm

The nozzle solution/arm consists of many different parts, see figure 10, in order to filter inhaled air and direct exhaled air.

B: The exhaled air enters through the mouthpiece. There are today two different kinds of *mouthpieces.* One, called the pipe, where the test person needs to keep its lips firmly around the mouthpiece so that no unfiltered air is inhaled through the mouth and one, called the snorkel, which is placed under the lips.

A: The inhaled air enters through a filter in order clean it from particles, to make sure that particles from the surrounding don't contaminate the sample.

C: There are two check valves to make sure that the in- and exhaled air goes in the right directions. It is of great importance to make sure that the test person cannot inhale air from PExA.

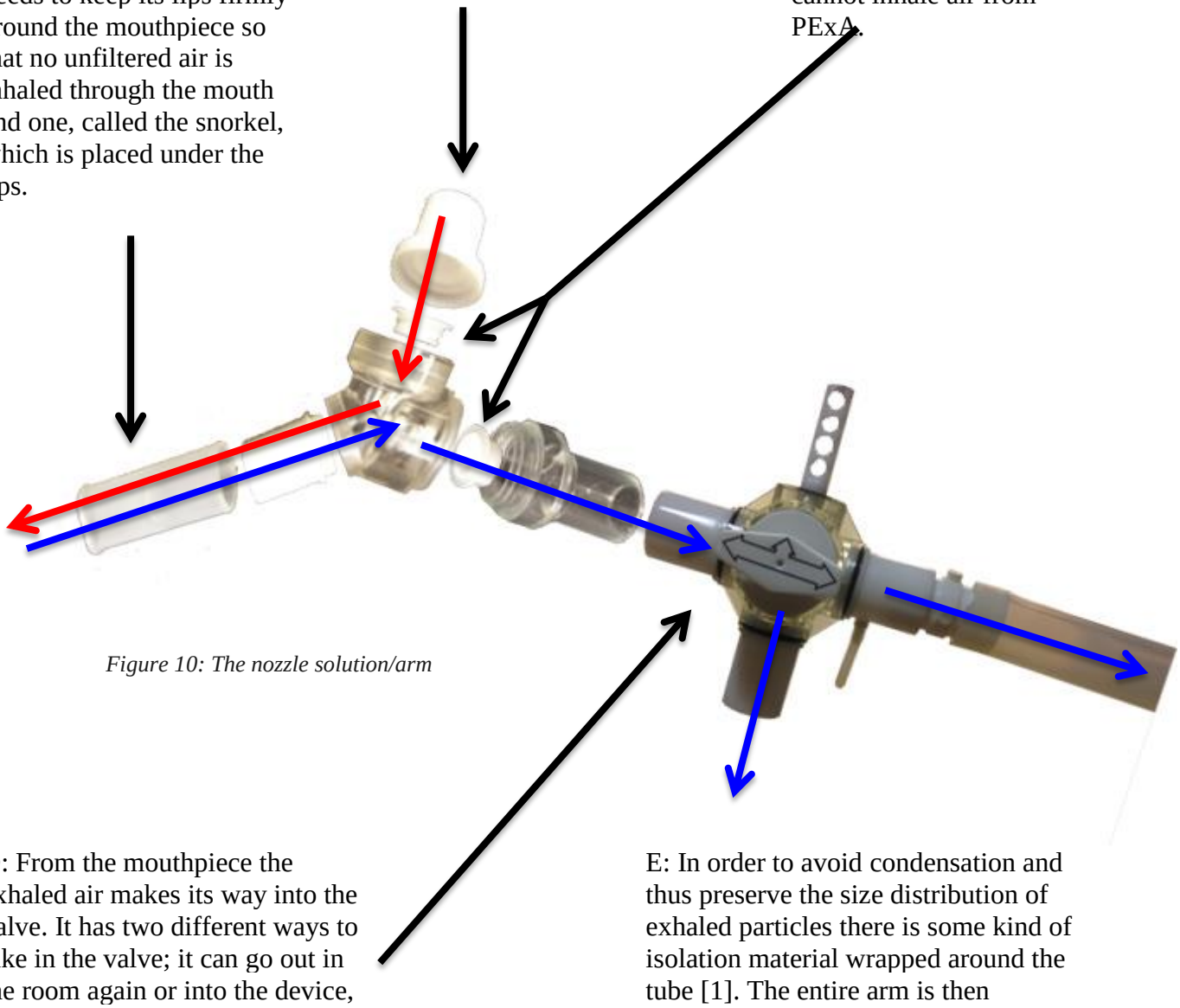


Figure 10: The nozzle solution/arm

D: From the mouthpiece the exhaled air makes its way into the valve. It has two different ways to take in the valve; it can go out in the room again or into the device, which way it takes is decided by the operator who manually switches the valve.

E: In order to avoid condensation and thus preserve the size distribution of exhaled particles there is some kind of isolation material wrapped around the tube [1]. The entire arm is then suspended from a string. Tying the string into different lengths regulates the arm.

The reservoir

The reservoir is a metal canister, see figure 11. It is tubular and can accommodate over 5 L.

It has two tasks, it serves as storage for some of the exhaled air and it ensures that the impactor always gets a constant flow of air. The impactor cannot handle the entire volume of a breath and it is of great importance to capture all the particles from the whole breath, the reservoir is there to storage some of the air until the impactor is ready for new air. The impactor needs a constant flow even when no air is exhaled in to PExA. In order to do that the reservoir gets compressed air from a stationary air connection in the room. To make sure that the compressed air does not contaminate the sample it needs to have the same properties as the exhaled air. The compressed air gets saturated with water vapour by a *humidifier*, the air gets cleaned from particle by a filter and *fan heaters* heat it before entering the reservoir.

Figure 11: The reservoir

The particle counter

The existing *particle counter*, called Grimm (Grimm model 1.108, Grimm Aerosol Technik GmbH, Ainring, Germany), is a very advanced instrument with many functions. PExA uses it to measure particle number concentration in eight size intervals, formally from 0.3 to greater than 2.0 μm in diameter, as 1 s averages. The particle counter operates on the principle of light scattering and is size calibrated using polystyrene latex spheres traceable to the US National Institute of Standards
And Technology [13]. This is done to ensure that enough particles have been collected. Grimm offers many other functions that PExA does not require. This means that PExA pays for a very advanced instrument when they only use a fraction of it.

Grimm supplies itself with approximately 10% of the exhaled air by an integrated pump.

Figure 12: The particle counter

3.1.2 Start-up procedure in short

The procedure starts with assembling the impactor, with a new sampling membrane, and starting the fan heaters. The start-up procedure takes about 30 minutes and this is due to that "the box" and especially the impactor needs to reach 36 °C. This is done to avoid that the exhaled air doesn't condense. When the box has reached its desired temperature the operator turn Grimm on and start to set the fluxes. There are two outlets for the air and they need to be plugged when 0-calibrating the fluxes.
After the calibration the compressed air is turned on. It can be regulated with a needle valve in order to get the right flow. PExA has a flow meter (OEM flow sensor, Spiroson-AS, Medical Technologies, Zürich, Switzerland). The flow meter makes it possible to record and visualize the in- and exhalation flows in real time and is connected to a computer. The computer has two important programs. The one described that is connected to the flow meter and can control how the test person breathe during the test and one program that is connected to Grimm to see how many particles that has been sampled. When all programs and instrument are turned on and when the airflow is right, it is time to assemble the mouthpiece and the valve. This is done according to figure 12. After this, the operator can start to instruct the test person and the test can start.

Figure 13: The valve

3.1.3 Sampling

The operator starts with adjusting the chair and the nozzle in order to get it as comfortable as possible for the test person. The operator then instructs the test person of how to breathe during the test:

1. Exhale as much as you can from one ordinary breathe, when you cannot exhale anymore (when your lungs are empty) you give a sign. You should now hold your breath in 3 seconds, we count the seconds for you.
2. Inhale as much and as fast as you can
3. Exhale slowly until almost all air is out, but you should not force the air out in the end
4. Breathe normally

The test person can start to breath normally into the instrument for 2 minutes, when the nose clip is placed. The 2 minutes of breathing is performed in order to filter the inhaled air, to avoid contamination by the ambient air. The operator stands beside the test person during the test to help recall the breathing maneuver. The test person breaths normally between the manoeuvre and these are repeated until the necessary amount of particles are sampled.

The operator does not only instruct during the test. They also need to control how the test persons breathe in order to regulate the valve and how much particles that have been sampled in order to calculate how long time the test will take. This is done via the flow meter and the Grimm that is connected to the computer. The operators have their own instruction when operating the valve:

1. Open the valve when the patient holds their breath in 3 seconds, or when the patient inhales a deep breath.
2. Close the valve when the patient have exhaled almost all the air, at the help line of 50 ml (it is only during exhaling after breath holding that we collect the particles)

3.1.4 Description of how the air flows

The test person inhales air through the filter and exhales the air through a mouthpiece to the valve, see figure 13. With the valve the operator decides if the air should enter into PExA or out in the room. If the air continues into PExA it divides in three different directions. The particle counter takes 20 ml/s, the impactor takes 230 ml/s and the rest goes into the reservoir and waits until the impactor process it. The impactor needs a constant flow so when the test person does not exhale into PExA it gets its air from the reservoir. The reservoir in turn gets its compressed air, with the same properties as the exhaled air, from a stationary air connection in the room.
The valve under the reservoir, see figure 14, emits the air that doesn’t fit in the reservoir.

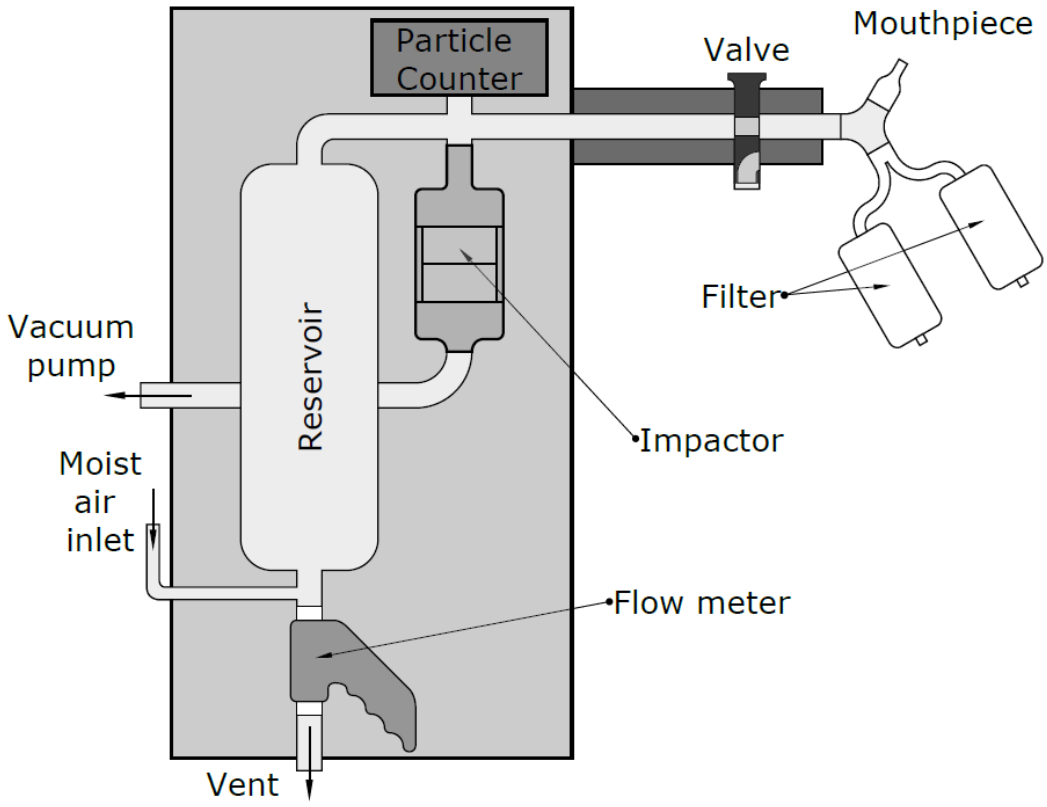


Figure 14: PExA 1.0 [12]

3.2 Particle measurement

One main aspect when developing PExA is to assure that as many particles as possible are sampled during the test. The needs mapping process clearly showed that the long test time in comparison to other tests was a big issue with PExA. It takes approximately 30-45 minutes to collect an analysable amount of particles. There are strong suspicions that some particles disappears before they reach the impactor in the current solution. Because of this, it is imperative to examine how the collection of the particles changes with different solutions. This was done with the particle counter and the flow meter. The particle counter counts the amount of particles and the flow meter measures the airflow. These two in combination can describe how many particles that where sampled and where in the breath they were collected.

The following two sections will explain the two software´s that is to be used during the testing and measuring of the sample procedure. It will explain what it does and for what purpose it is used.

3.2.1 Spiroson v.1.4.2

This software registers and monitors the amount of exhaled air in the system. The actual measuring is performed by a Spiroson, which is connected to the air channel inside the PExA device. There it is connected by an USB-connection to a computer where the measurement is displayed. It helps visualize the breathing pattern of the patient so that the operator can monitor the breathing and make sure that everything works and is performed accordingly, see figure 15.

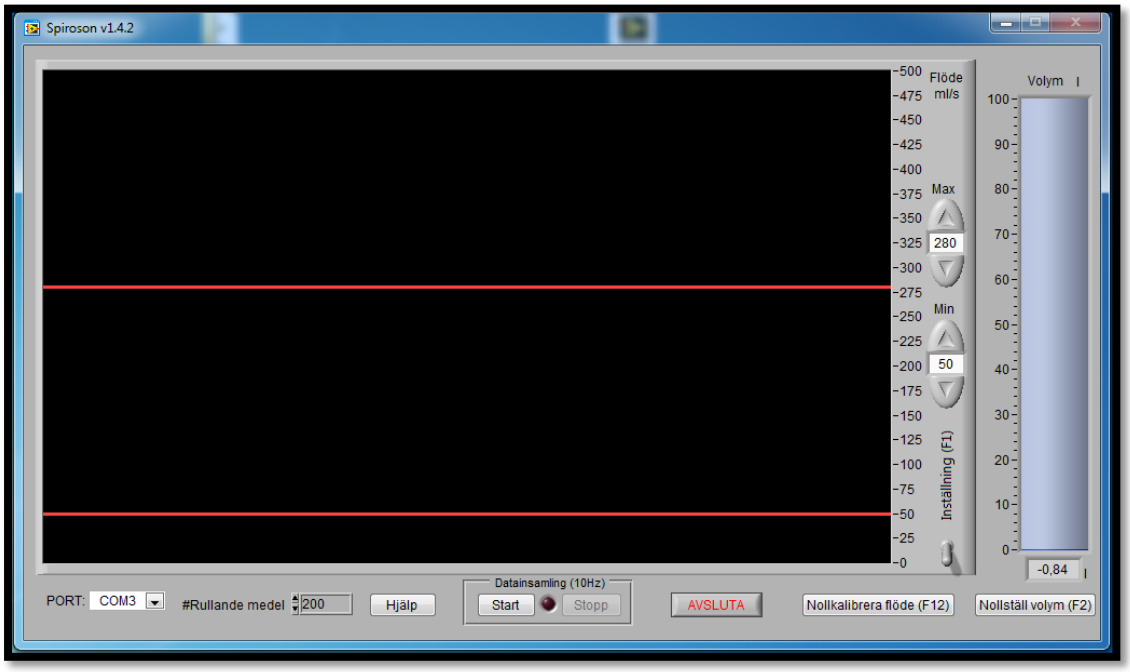


Figure 15: Interface of measurement and flow graph

With help of the software the operator can easily see where in the breathing movement the patient is which is very useful for the ability to give good guidance during the test. The collected data is after the procedure saved and translated in a preprogramed excel-document combined with data from the particle measuring.

3.2.2 GRIMM 3

To be able to know how much of the particles that been sampled the PExA instrument uses a special device called GRIMM which measures and registers very small particles in various sizes. The GRIMM is connected to a computer were it sends the registration and data of the particles to an appurtenant software. The software then translates the received data and visualizes the monitoring of the mass particles sampled, the size of the particle, the number of particular sized particles and may deliver a number of other data and information, see figure 15.

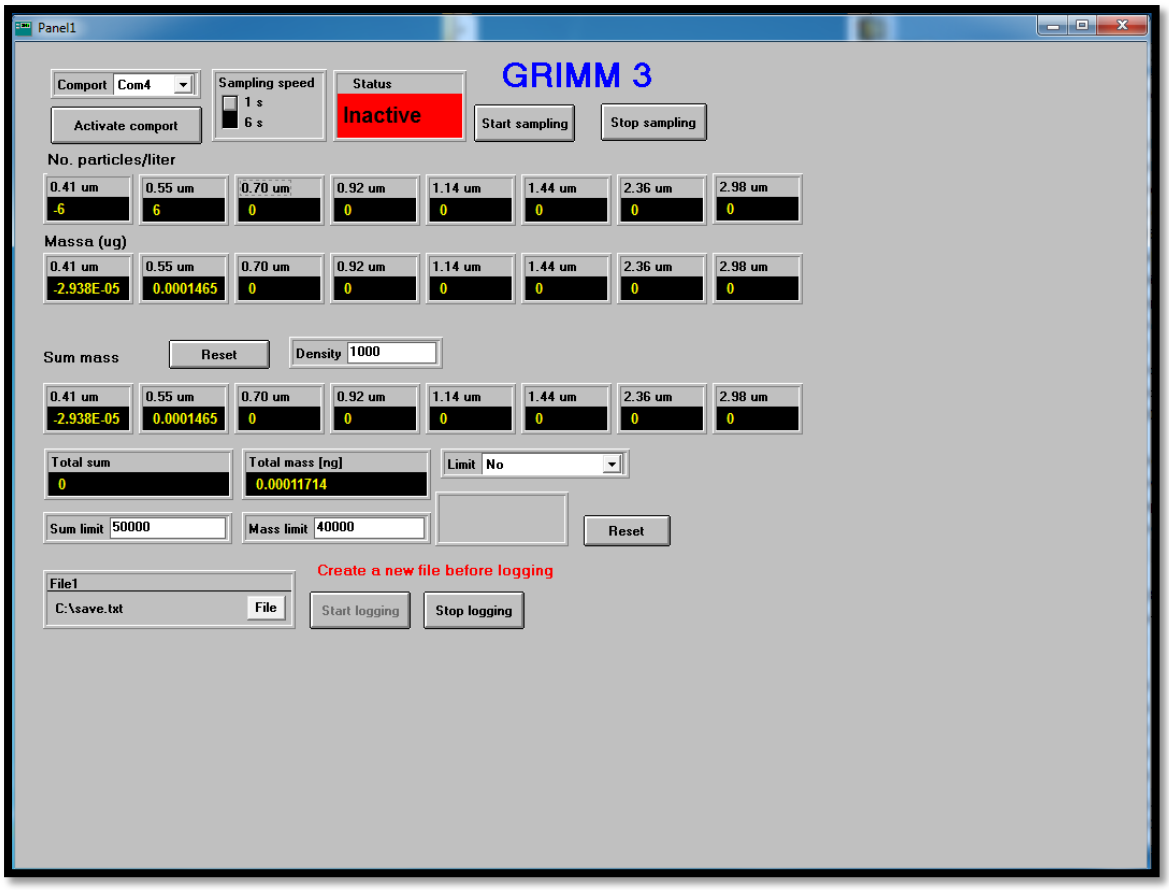


Figure 16: Table of measurement control

This software is very crucial for the whole procedure because without this the operator is completely blind. This software tells how much that has been sampled and if there is still particles in the system left to be sampled before next exhalation. The software tells the operator when the desired amount of particles been sampled and then saves the file. The saved file is then transferred to a preprogramed excel document where combined with data from the Spiroson v.1.4.2 are translated into graphs and desired tables.

3.2.3 The testing procedure

By using the mentioned software above several measurements of particle generation were performed. With the help of the GRIMM 3 the particle generation was quickly revealed in real time and the effects could be revealed almost instant. The test were performed in such a fashion that test persons with a good experience of breathing into the instrument and good knowledge of the system were used for most of testing. This was because of the desire to obtain an identical breathing pattern as possible to avoid deviation in particle generation and breathing patterns between different persons during repeated tests. By having knowledge about the Spiroson software and have it visually displayed in front of them during the test, the test person could themselves monitor and control their breathing in a resembling way. By using the same persons it was also easier to identify deviation and exclude corrupt tests.

3.3 Software to use

This section contains description of the software that has been used in the project. The reason and viability of the software will also be explained and for what purpose it's been designated for will be provided.

3.2.1 CES

CES offer a systematic selection process of material. The selection of material is an important step during development and CES is a good aiding tool in this process. Not only is it an enormous database for different material, it also offers information on suitable manufacturing process and typical using areas. It also offers analytical models to estimate manufacturing cost.

At the mechanical program at Chalmers University of technology CES is a widely used and accepted software tool for aiding different steps in engineering processes. Designed by the professor Michael Ashby of Cambridge University this goes hand in hand with his course literature that also is used at Chalmers University.

3.3.2 CAD

CAD technique will be used in order to realize the concepts that have passed through the concept scoring process. In this way one can visualize the solutions to get an even better understanding of how your sub-concepts will fit into the whole product. It also makes the communications with the company easier. You will be able to compare the different concepts to each other and you might discover problems or opportunities that where impossible to see before.

4 PRODUCT SPECIFICATION AND FUNCTIONAL DESCRIPTION

This chapter will explain under what restrictions PExA can work. This is done with the help of a requirement specification. The chapter starts with how the requirement specification was made and it ends with a functional description that was made in order to get an overview of what the system is supposed to do and how it should do it.

4.1 Product specification

Needs are not specific. They are not objective and quantitative but rather qualitative wishes. They may be identified without knowing if or how they will be addressed [5]. In simple words "the specifications" are the needs translated into engineering language. These are precise descriptions of what the product has to do and how it must perform in order to satisfy all the needs.

The requirement specifications consist of two different types of requirements; "demands = must have", and "wishes = should have". Wishes are requirements that will affect the product in a positive way, if the product will fulfill them but it will be safe to use and function as well, without them. They can however be what distinguish between a product that is just working and a product that everyone within the target group desires. Wishes should be weighted in the specification, in order to establish how important the wish is for the outcome of the product.

The requirement specifications will consist of five different columns. These are; "requirement", "justification", "requirement/desire weight" and "measurement/evaluation". Weights are the weight on the desires/wishes. With measurement/evaluation means, how you will verify your target value.

Two requirements specifications are going to be made. "The first specification", the target specification, will be established early in the product development process. This represents hopes and aspirations [5]. But the requirements cannot be totally static during the process, due the fact that all knowledge that has to be gained during the process, will not be gathered during the first phases of the project.

It might turn out that some requirements are in conflict with each other. It could be difficult to meet the requirement with the existing technology. Other unexpected things, that are impossible to predict beforehand, might happen [5].

The second specification, "the final specification", will be established when the choice of a concept is finalized. The requirements in the target specification are going to be revisited in order to express the target values more precise [5].

The requirement specifications are going to be divided into different sections. There are going to be requirements on the total solution. These requirements have to be fulfilled for all the different sub-systems. Special requirement that will affect only the

sub-parts will have an own section, see figure 17 for an explanation of the structure

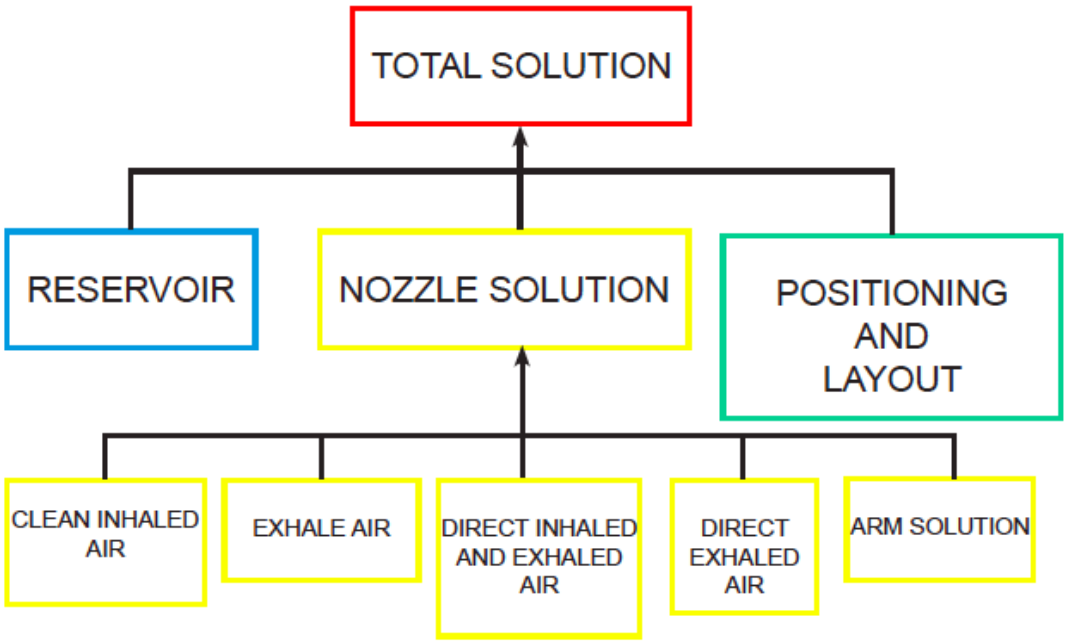


Figure 17: The design of the requirement specification

The whole requirement specification can be found in appendix E. Figure 18 presents an excerpt of it.

Requirement specification

#	R/W	Requirement	Justification	Measurement/Evaluation
Total solution				
Performance				
1.1	R	The solution should be able to sustain 37 °C (the same as exhaled air)	Allow for the particles to stay the same	YES/NO
1.2	R	The total solution should be able to sustain the same moist as exhaled air	Allow for the particles to stay the same	YES/NO
1.3	R	Be able to collect 160 nano gram particles within 45 min	Allow to collect the sample as fast as possible	Particle test
1.4	W	Be able to collect 160 nano gram particles within less then 45 min	Allow to collect the sample as fast as possible	Particle test
1.6	R	Be able to performe a test within 30 minutes after a test	Allow to perform the test many times in a row	YES/NO
1.7	W	Be able to performe a test within less then 3 minutes after a test	Allow to perform the test many times in a row	YES/NO
Ergonomics				
2.1	R	The operator should be able to be placed beside test person during test	Allow the operator to instruct during test	Physical test
2.2	W	The operator should be able to stand in one place during test	Allow the operator to concentrate on the patient during test	Physical test
2.3	W	The operator should be able to sit in one place during test	Allow the operator to be comfortable beside patient during test	Physical test
2.4	R	The computer should be placed at a reaching distance from the operator	Allow the operator to be at one place during test	Physical test
2.5	R	The operator should not require breaks	The test should not be longer than it already is	Physical test
2.6	R	The total solution should enable support for the feets	The test person should sit as comfortable as possible	Physical test
2.7	W	The test person should be able to see the computer	Gives the test person better understandning	Physical test
2.8		should take no more t... to adjust	Streamline test time	...cal test

Figure 18: An excerpt of the requirement specification

4.2 Functional description

To get an overview of what the system is supposed to do and how it should be done, the system needs to be broken down into manageable pieces = “modules”. Each of them should be managed individually but put together they should form the desired system. This can be done with different methods. Design solution independent modeling [6], also called black box, where selected in this case since the system was easy to divide into different subsystems and it was clear what each subsystem needed to solve.

There are two main parts that needs to be included to solve the problem and to clarify: the objective is to sample particles from the lungs so that they can be analyzed. These main parts are the respiratory system and the impactor. The other components are just parts that are added in order for them to work.

The sample of particles is going to be collected from the lungs. In order to not detect the wrong particles the inhaled air needs to be cleaned and the exhaled air are supposed to be directed either into the device or out in the surrounding again. In order to prevent condensation of the exhaled air, heat is added to it, se figure 19.

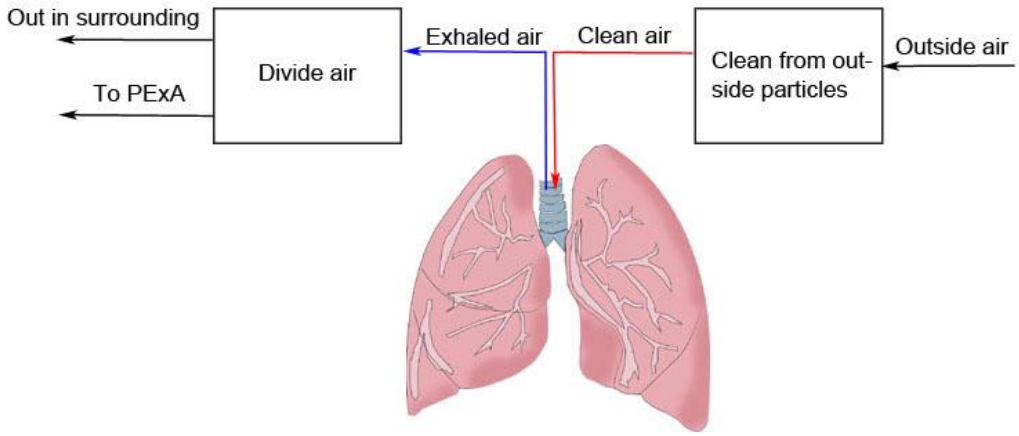


Figure 19: Back box of the current nozzle solution

The impactor has been developed in order to collect the sample. It needs exhaled air, something to catch the particles on and heat in order for the air to not condense, see figure 20.

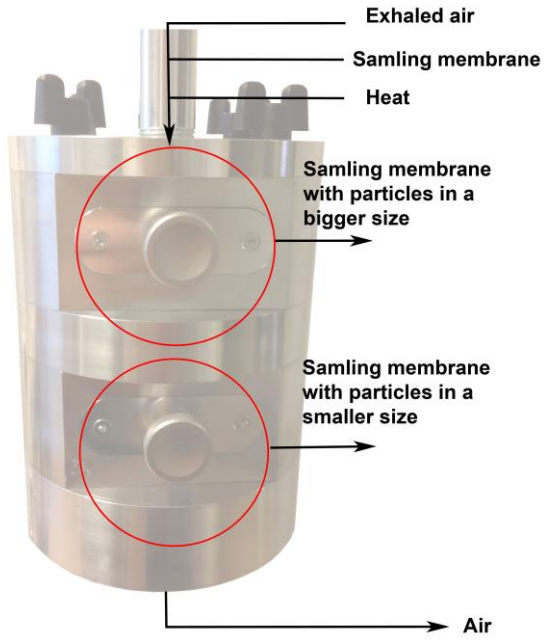


Figure 20: Black box of the impactor

In a best-case scenario PExA would consist of only the impactor and a solution for the first black box. The current solution consists of many more and the reason for that is mainly because the impactor cannot handle all exhaled air at once. It is important to get to the conclusion that the other parts are needed as well without having them in the functional description. Because of this an evaluation chapter was performed and a new functional description will be made when the necessity of parts has been evaluated.

5. EVALUATION OF EXISTING (CURRENT) SOLUTION

This chapter will provide an explanation of the evaluation and elimination of certain parts that was used in the current version of the PExA instrument. It will then provide a suggestion of a new system layout and point out benefits with a new updated version.

5.1 Evaluating the existing parts necessity

Somewhere in the middle of the project the conditions for the instrument were changed. Along the side of this project it became known that there was another on-going project which goal was to offer a version of PExA that could be used for patients that was seduced and intubated for artificial breathing. This could be realized by connecting PExA between the patient and the ventilator system and by so perform the breathing manoeuvre with the help of the ventilator system. This means that there is no need for a humidifier since the ventilator reuses the moist from the exhaled air. It also means that the need of compressed air is eliminated because the desired breathing manoeuvre can be performed the whole time since the patient breathing is controlled by the ventilator system.

The way the ventilator version of PExA would work inspired to investigate if something similar could be done for the current PExA instrument. What was really interesting were if there was a possibility reuse the exhaled air and the moist in it because doing so would eliminate a lot of parts from the current version. This concept was so promising so that a decision was taken for further development to be towards this new idea for the current version of PExA. The new updated version will be explained in the following section.

5.2 Updated version of PExA

Just as in the ventilation version of PExA this new version also reuses the moist that already exists in the exhaled breath. Instead of applying new pressurized air from the outside, which needs to be moisturized by a moisturizer, one let’s the exhaled air with correct moisture level and temperature loop back into the reservoir. When a new breath is exhaled into the system the overpressure opens a small check valve placed before the re-entrance of the reservoir and excess air is let out. If no breath is exhaled into the system, the already existing air can theoretically be looped in infinity and always make sure that there is a constant flow through the impactor without external supply of air. The new system model can be viewed in (figure 21) where the flow path is better explained and easier understood.

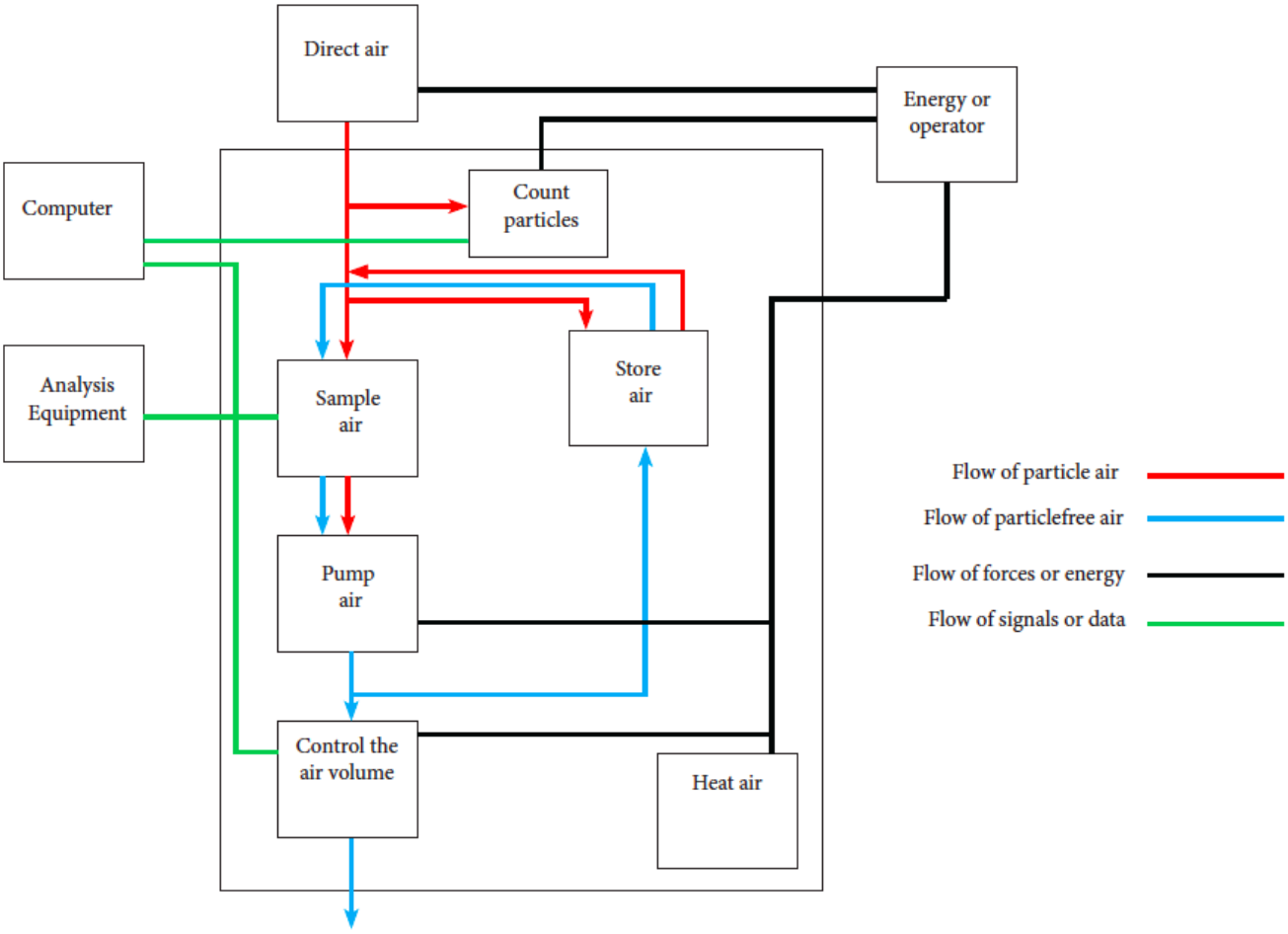


Figure 21: New system model of PExA where different flow paths are illustrated

This new system solution means that the moisturizer can be eliminated and removed and so the need of pressurized air. The current moisturizer was quite big and expensive and need to be supplied with water at regular intervals, all of which now are removed. The current need of pressurized air created a limitation of where the instrument could be used, since it had be connected to a source of clean pressurized air the instrument could only be used in rooms equip with these outlets. The new version only needs to be connected to an electric socket that makes it possible to place in almost any room. The current solutions vacuum pump can also be replaced by a simpler and smaller air pump that task only is to circulate a given flow of air. The elimination of these unnecessary parts creates a system that is less complex and has fewer parameters to control. This gives a product that is easier to operate than the current because it's less to keep track on (see figure 22). The lowered number of parts decreases the total size of the instrument decreased, also adding to and easier handling of the instrument making it easier to place and store. Maybe the most important thing of all; the cost is decreased for producing the instrument and ability to improve the profit margin is increased.

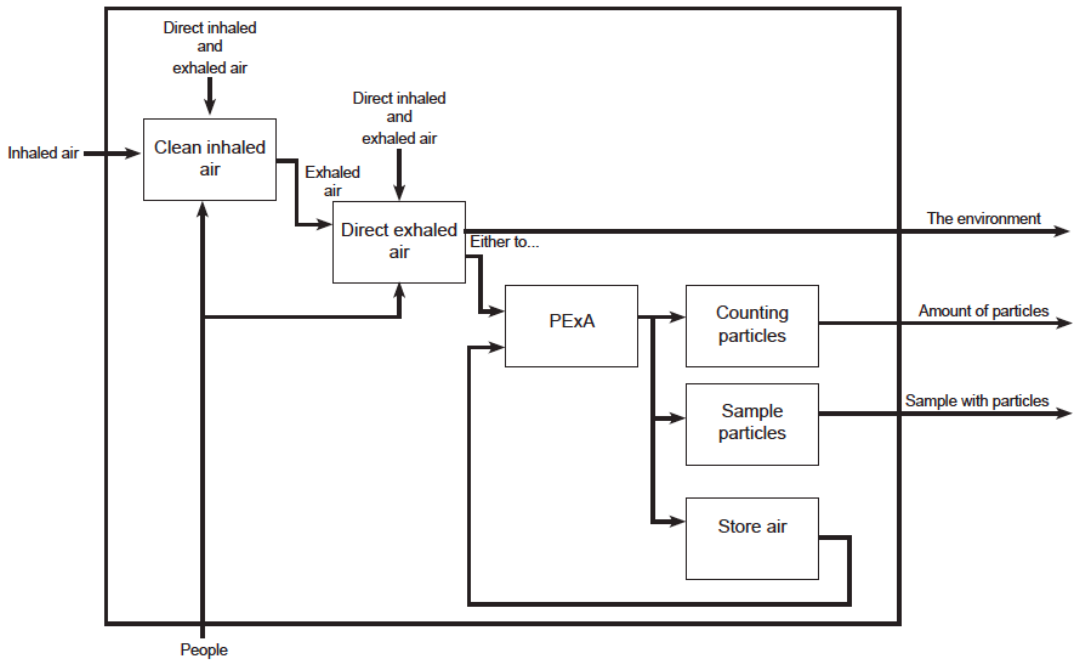


Figure 22: IDEF0 of a new simplified version of PExA,

5.3 Optimization for the placement of parts

When deciding the placement of the different parts it is important to bear in mind what the functions are for each part and what the function is for the whole system. It is also crucial to identify the mechanism between the different parts that is needed to achieve the desirable functions. Since the main function of the instrument is to collect particles, it is therefore highly relevant to achieve a design that minimizes the loss of particles to maximum extent. The aim with the following section is to investigate how the different parts in the system can be place with respect to minimize particle losses and minimize the total size of the instrument. By pointing out each parts functions and constraints a recommended placement of each part will be provided. This will lead to an estimated perception of the size for the final solution and how a future reservoir can be formed and place to affect the size to a minimal.

5.3.1 Placement of impactor

An important factor when placing the impactor is that its location should be easy accessible for a quick and effortless handling when installing and collecting the samples. This means that an ideal solution would be to place it close to an outer wall where it can be accessed by a hatch. Another very important factor to take account is to minimize the risk of disturbing the particle's physical composition and lose them. The longer the particle travels the greater is the chance of more losses which means that it is desirable to place the impactor close to the intake so that a quick sampling is feasible. The impactor is shaped as a cylinder and has to have an upright position to enable a correct sampling and because of this it becomes taller than if placed in a lying position. The height makes it desirable to place as low as possible to minimize the height of the total solution but the need of connections in both ends makes it impossible to be placed at the bottom. Therefore a placement somewhere in the middle (height wise speaking) and close to a wall is necessary.

5.3.2 Placement of GRIMM

The GRIMM's function is to count particles and need therefore access to the exhaled air before it reaches the impactor where the particles are collected. To enable a correct particle reading it is important that the intake for the GRIMM is placed between the reservoir and impactor so that only the particle's that actually reaches the impactor is being counted. The GRIMM should also be placed so that the operator can see the monitor display and access it in order to turn it on/off and to be able to change different settings. Today's solution uses a transparent hatch on the upper front side of the outer shell and something similar would also be needed in this case. The form of the GRIMM is like a small digital box where the display is placed on the long side, see figure 23. This form makes it easy to place on top of other parts.

Figure 23: The particle counter (GRIMM)

5.3.3 Placement of reservoir

The function of the reservoir is to temporary store excess contaminated air so that the whole breath can be processed over time. The reservoir needs therefore to be connected to the intake, GRIMM and reservoir. The reservoir has two connections; one where it receives the exhaled air alternately provides sampled air for to the impactor and a second connection from where the old sampled air is reintroduced into the system. The most important connection is the first one because it is there a loss of particles can occur. It is therefore crucial for the reservoir's first connection to have a short distance between the intake and the impactor to minimize the risk of losing to many particles. The second connection can be placed more freely because it receives used air that filtered and therefore has no requirement of contributing to minimize a particle loss. The reservoir itself is the most spacious part in the system that means that it will add much to the width and depth of the total solution. It is likely that the reservoir will have a design similar to a shoebox standing upright with the first connection at the top close to the intake and impactor and the second one in the bottom close to the bottom see figure 24.

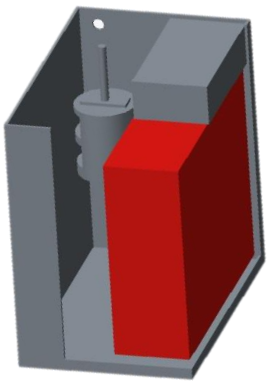


Figure 24: The red box illustrates the position of the reservoir and how much space it would be desirable that the reservoir took

5.3.4 Placement of intake

The intake is where the nozzle solution will be connected to the PExA instrument. Since the previous placement of parts concludes that they need to be placed closed to the intake, the actual placement of the intake will decide where the other parts end up. There is though one placement of the intake that is better than the other. If one were to choose to place the intake in the middle of the top front side one would end up with a total solution that has one side packed with part and one empty side, hence very inefficient use of space. This is because the reservoir needs to be placed on either left inside or the right side of the impactor. This leads to the conclusion that the intake should be placed close to the front corner and somewhere between the middle and the top to both allow a straight flow to the impactor and a space efficient layout. In the picture, see figure 24, one can see that the parts can be placed close together and still meet their requirements and the red space is an estimation of available space where a reservoir can be design and placed.

5.3.5 Placement of the other parts

There are of course more parts than just the impactor, GRIMM and the reservoir. Part such as flow meter, pump and filter are necessary for the system to work but does not restrict the placement of the other parts in the same way as the impactor, GRIMM and the reservoir does. These parts can be place with respect to the available space and desired form and can be performed in the very last.

6. CONCEPT DEVELOPMENT

In this chapter the development process is described. Three different areas where chosen to be developed one at a time. The development of the three different parts follows the same process, which starts with concept generation, followed by concept screening, concept scoring and ends with concept selection.

6.1 Selection of which parts to develop

When it was established that PExA 2.0 could consist of less parts then the current version, see chapter 5, it was time to select which parts that would be most beneficial to develop further. The outcome from the needs mapping process served as a basis for this selection. Problems that where identified could be addressed to particular parts and those parts that contributed the most where selected. The size of PExA was one big issue. The reservoir is the main contributory factor to what size PExA has. So the reservoir has to become smaller if any reduction in size should be possible. The part that contributed to most problems was the nozzle solution, which consists of handpicked parts. This is also the part that is considered to be most underdeveloped. The third "part" that was selected was positioning and layout, which considers how PExA 2.0 should look without any design aspect. Design aspect in this sense is form and color. This part was not addressed through the needs mapping process but was instead considered as a part that would add a lot of value for the company. Figure 25 shows what parts and in which order parts will be developed.

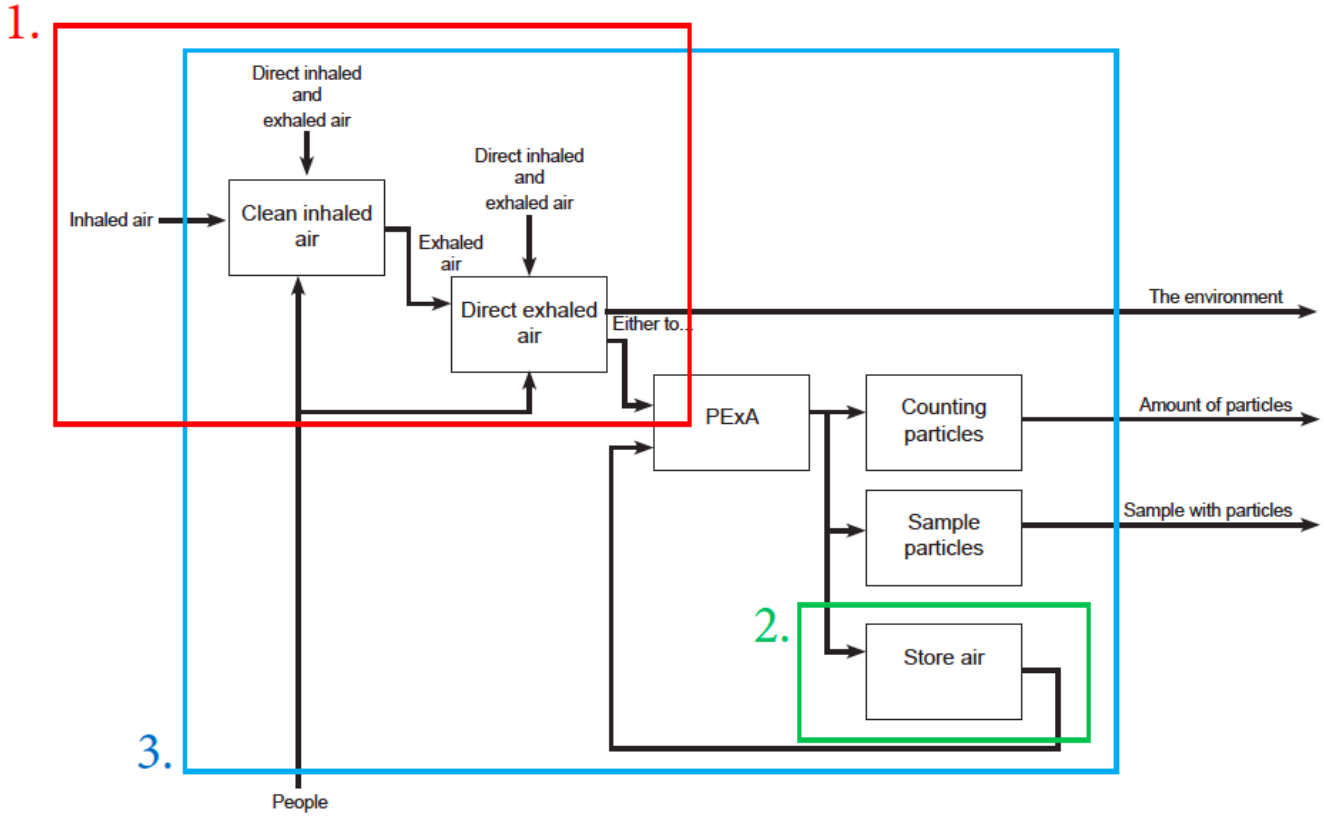


Figure 25: What parts and in which order they will be developed

6.2 Nozzle solution

The nozzle solution is the solution of the entire arm including the mouthpiece, see figure 26. This will be the first part to develop since it is thought to be the source to many of the problems mentioned by the operators.

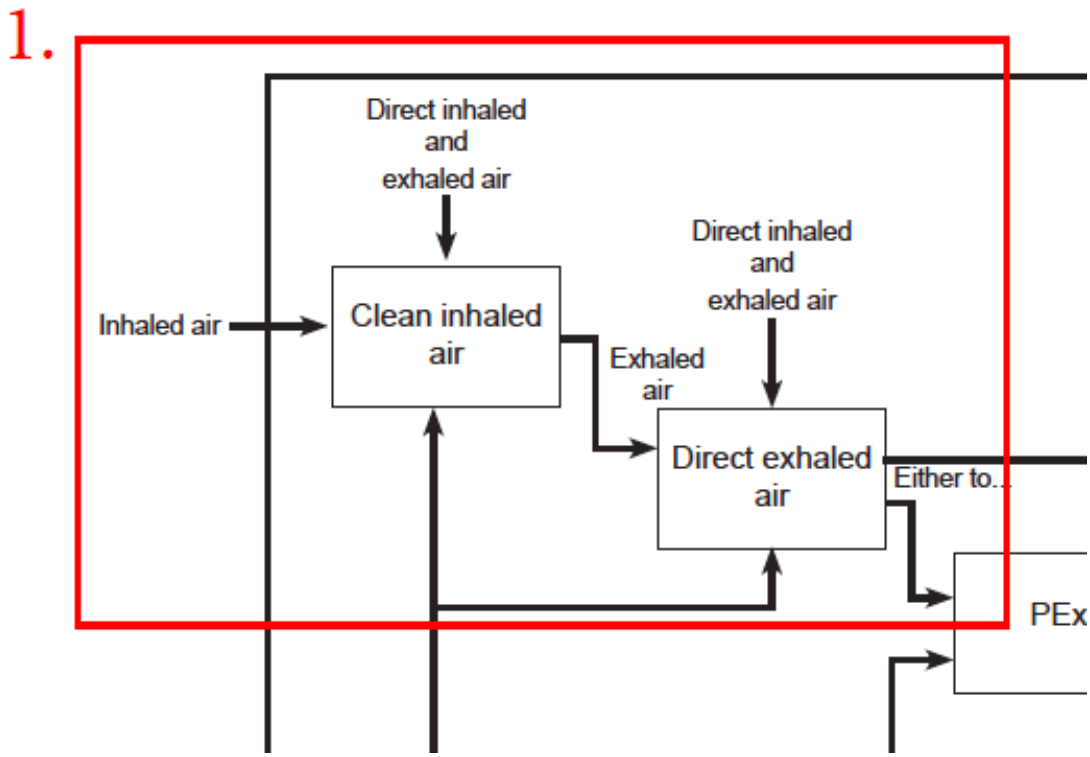


Figure 26: Different functions that the nozzle solution should be able to solve

6.2.1 Concept generation

The generation of concept is based on the functional description made in chapter 4 and 5. The generation of solutions is made for each function concerning the nozzle solution. The functions concerning the nozzle solution are clean inhaled air, direct inhaled and exhaled air, exhale air, direct exhaled air and arm solution.

There are two methods when generating solutions. These are on one hand "creative methods" and on the other hand "systematic/rational methods" [8]. In this case "Brainstorming" was used as a creative method and in order to generate as many solutions as possible and to get as many different ideas as possible the group together with PExA management was invited to the Company Etteplan in Halmstad. Etteplan, which is a company that develops technical solutions within different industrial areas, contacted the project manager of PExA and offered a free consultation meeting that included guided brainstorming session and workshop for simple prototyping. The aim of the meeting was mostly to focus on a solution for the arm part but other inputs concerning other parts was also welcome. The participants in the meeting, besides the group and PExA management were three employees from Etteplan, two engineers and one designer. The whole meeting was guided by one of the employees.

Before the brainstorming a brief introduction of PExA was presented to Etteplan and a mind mapping session was performed which intent is to stimulate creativity and help participants think outside of the box. After the mind mapping a 45 minutes long brainstorming session was started where problems and ideas were discussed among the participants. To help visualize the ideas and concepts the participants had access to a great variety of workshop materials. In the end of the first brainstorming session, participants were gathered and asked to display their concepts with a brief explanation. In this stage of the concept process, participants were given a short break to help clear their mind before entering a second phase of brainstorming. The purpose of the second phase was to help each other for further development of the generated concepts by supplying new feedback, fresh ideas and a different view. When the second brainstorming session was over the participants once again were asked to display their concepts with a brief explanation. The different concepts were discussed and participants had a chance to ask questions concerning the different concepts.

The consultation session resulted in several concepts which all were photographed and documented with belonging description see example in figure 27. The documentation of the concepts can be viewed in appendix F.

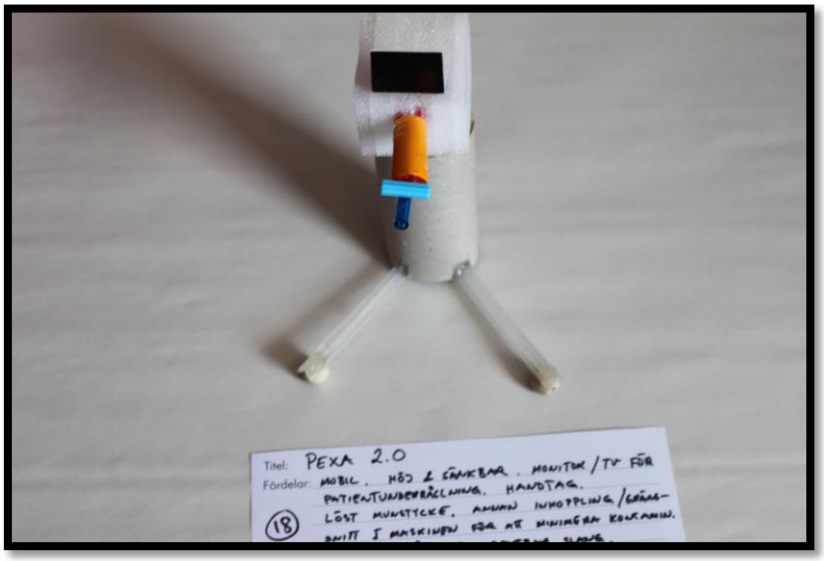


Figure 27: One example of a concept whit an explanation under

The systematic/rational methods where to; “search in literature”, “search in databases”, “analysis of competitor’s products”, “interviews with experts” and “interviews with lead users” [8]. This resulted in a couple of different sub-concepts.

Description of sub-concepts

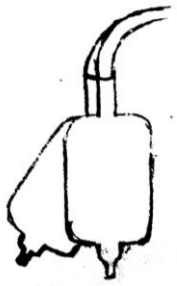
This section describes sub-concepts that were generated during brainstorming, through systematic search and analyze of other products. There are five main problems to solve in order to make a new solution for the arm. These are clean inhaled air, direct inhaled and exhaled air, exhale air, direct exhaled air and leading air/arm solution. Before all new sub-concepts are described each category starts with an explanation of what problem that needs to be solved and how it is solved in the current solution.

Clean inhaled air:

To make sure that the samples does not get contaminated the inhaled air needs to be cleaned from particles that exist in the surrounding environment before entering the device. One suitable solution for this is to have some sort of filter before inhalation. In the current solution solves this by having a big filter, which is used many times, and a nose clip. The nose clip is used in order to prevent patient from inhaling particles from the surrounding through the nose. The nose clip solution needs to be combined with those mouthpiece solutions that do not cover the nose. The big filter is a cheap idea but makes the arm solution even bigger than it already is.
Filters in other sizes and forms were thought of as different sub-concepts. Except for the current solution there where three sub-concepts chosen for further investigation:

Big filter

In those cases were the mouthpiece covers both mouth and nose a big filter can be used without a nose clip. The main thing with the big filter is that it can be used several times before it needs to be replaced. It can be made less visible by integrating it in the cupboard and then made easy for access for routine changing. The filter can be of different forms depending on what other sub-concepts that is selected.



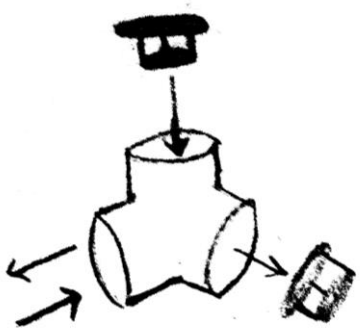
Mini filter + nose clip

The function is the same as for the big filters but the idea is to make a smaller arm solution with filters that can be replaced after each patient. A filter that is design for single use will allow for a less bulky solution because of the significant smaller size. There is also a good possibility that the filters can be integrated with the chosen mouthpiece. The nose clip is used for the same reason as in the previous described sub-concepts.

Mini filter

In solutions where the mouthpiece covers both mouth and nose there is no need for nose clip. An example of a solution like this is a facemask, which could be design to have a separate inhalation with an integrated mini filter. This also creates a less bulky arm solution.
Only a mini filter can be selected in those cases where the mouthpiece also covers the nose.

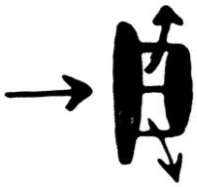
Directing the inhaled and exhaled air (Control the flow direction and prevent backflow):



It is important to not inhale the air that comes from the device so there has to be a function that makes sure that the inhaled air goes through the filter and the exhaled air goes into the device. The current solution consists of a 3-way channel with two check valves. These two check valves make sure that the inhalation and exhalation only goes in desirable directions. The complexity of different check valves can vary for many reasons, example how many times they should be used, if they should be cleanable, the flow rate or the pressure.

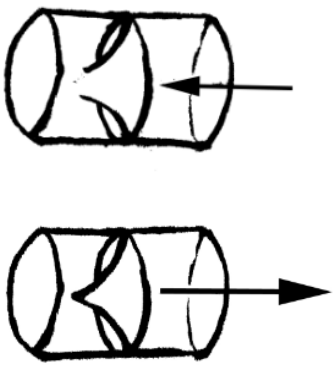
Besides the solution that is used today two different sub-concepts where chosen for further investigation. All consist of check valves since it is a cheap and easy way to direct air during in- and exhalation. In the following section different types of check valves will be presented and also examples of whole solutions where the valves will be integrated in will be presented.

Current check valve



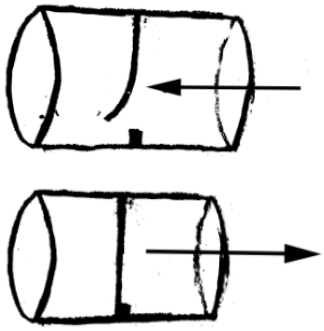
This valve type has a rubber lid that is attached by four rubber strings. The valve is placed so that it extends and opens with a positive airflow and closes for negative flow. When the valve is open the air flows out between the stretched rubber strings and around the rubber lid. This type of valve closes and opens effectively and can be washed and reused. One suspected reason to particle loss is believed to be caused by the valves rather obstructive flow path. Another problem with these valves is that they can easily be placed incorrectly during installation and create a risk for inhalation from PExA. The cause for this is more related to the design of the casing of the surrounding 3-way valve rather than the check valve itself.

Lip valve



The centered lips on this check valve consist of a thin rubber material. The rubber lips are placed in direction of the desired flow path which means that the lips will point in the same direction as the air flows. When exposed of a positive pressure the lips will open, creating a centralized circular opening and allowing air to flow freely without obstruction. When exposed to negative pressure the lips are pinched together creating an air tight seal that prevents backflow. This type of check valve will be simple and cheap to produce and can be used as a single use product.

Hatch valve



This check valve has a hatch/lid that swings open when experience positive pressure. A very simple version of a valve like this is one that is made in thin a thin rubber sheet where a circular hole has been punched out in the middle. A rubber lid, slightly bigger than the hole, is then attached over the opening in one end to be able to swing open. This is a very cheap and simple solution and requires very little pressure to open that is good for a non-obstructive exhalation. The flow path is acceptable but not as open and free as the Lip valve.

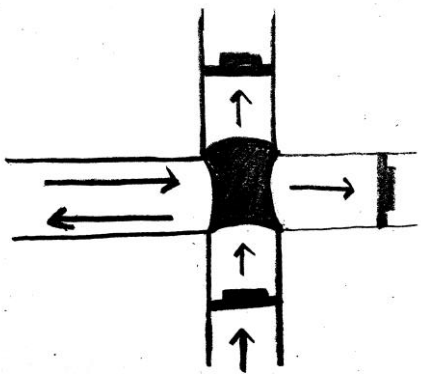
Check valve (Integrated check valve)

One sub-concept is to skip the 3-way channel and instead integrate check valves in the mouthpiece. This would make the arm solution smaller and maybe enable some sort of disconnection from the arm during the test.

Improve the current 3-way valve

This concept aims to keep a 3-way valve but design one that is cheaper and simpler than the previous. By replacing the old check valves with new improved types, one can have a solution that is far cheaper and better in performance. Another advantage with this concept is that it can be design to have a replaceable mini filter for single use. By doing so, one will end up with a smaller total arm solution when the big filter that's currently being used is eliminated. One can also see an economical value in selling single use products to customers.

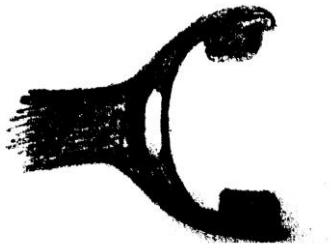
4-way channel (Multi valve)



One idea was to integrate the two valve solutions that exist in the arm in the current solution, see figure 10 in the theory chapter. This would lead to using a 4-way channel with three check valves instead of two 3-way channels that is used today. The 4-way channel would have one channel for connecting the mouthpiece, one channel for supply of clean air and the two channels with a switch for the exhaled air. This solution would also make the arm smaller but it could make it harder to clean and assembly hence less modular.

Exhale air (Connecting the patient to PExA):

The exhaled air needs to be exhaled through something. The most important part is that it should be comfortable for the patient and easy to replace between each patient. It is also of great importance that it allows for a good flow to enable a good particle generation. The two solutions that exist today are the pipe and the snorkel. Both solutions works but can be uncomfortable in the long run. It can be hard to press the lips around the pipe during a whole test. This may lead to spasm of the lips or that the patient inhales some air through the mouth.

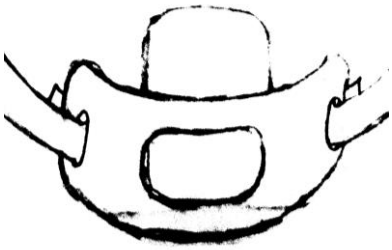


The snorkel solution solves this problems but it has its own flaws. It makes the patient produce a lot of saliva.

Besides these solutions two other sub-concepts where selected:

Bronchoscopy

This solution consist of a short pipe with silicone skirts that seals tight against the skin around the lips with the help of rubber stripes attached around the head. The stripes around the head will not only keep the mouthpiece airtight but also offer support so that the patient won't have to pinch with their lips or bite with their teeth to keep it on place. This helps the patient to relax the lips and enables the patient to just focus on the breathing maneuver.



Mask

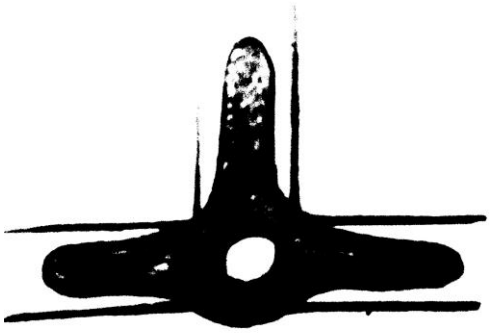
This solution covers both the nose and the mouth. The idea is to have a mask strapped around the patient's head. This solution can make it possible to integrate many of the other functions. Integrated check valves and filters would replace the first 3-way channel and the fact that the mask will cover the nose would replace the nose clip. Two main problems that needs to be considered in this case is how much it would cost and how to clean it after each test.

Mask with pipe

This mask has an integrated filter and inserted pipe for mouth ventilation. This allows the patient to breathe clean air through the nose and exhale by mouth through the inserted pipe that is connected with the breathing hose. The main advantages with this solution is that it eliminates the expensive check valve that's being used today and with an integrated check valve in the pipe the patient can continue breathing filtered air when disconnected.

Direct (the) exhaled air:

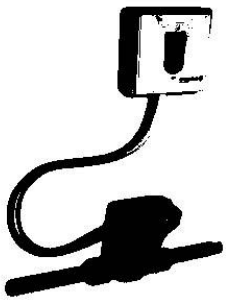
In order to direct the exhaled air in the current solution, either out in the room or into the instrument, the operator has to manually turn a 3-way valve.



The turning maneuver is performed in every breathing exercise. The operator direct the air into PExA when the patient empty the lungs by a big exhalation and when the lungs are empty the operator switches direction and the patient can return to normal breathing and the air flows out into the surroundings. Depending on how much particles each patient generates this maneuver has to be repeated between 15-30 times or even more. For an operator, that has several of patients during a day, this can create a lot of strain on wrist and fingers.

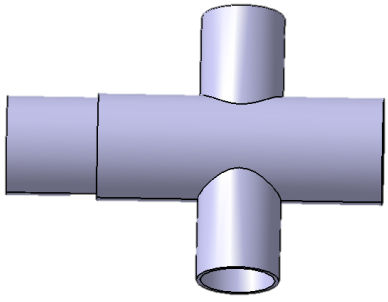
During concept generation the necessity of the valve was questioned in the purpose of turning it between each breathing maneuver. Instead of switching the valve after each maneuver one idea was to let the test persons keep exhale into the device during the whole test. The turning maneuver would then only take place when starting or stopping the test, which would make today's manual solution quite suitable. With this in mind following solutions where selected for further investigation:

An automatic valve



By having an automatic valve this would eliminate the turning maneuver for the operator and by so relieve a lot of stress from wrists and fingers. There are many valves on the market that offers this by example the use of solenoids. The downside of the available solenoid valves is that they have a very obstructive flow path through the valve which probably would affect the particle generation negatively. The majorities of solenoid valves are design for higher temperatures and pressures which makes them quite bulky and unnecessary robust. The same goes for a valve that uses actuators.

Self-designed valve

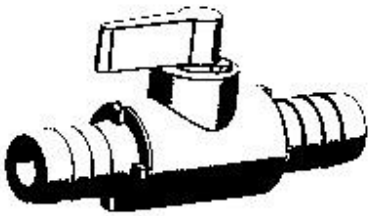


By using the technique of solenoids or actuators to create movement one can design a valve that is better suited for this application, a valve that is smaller, simpler and biocompatible. The desire is to design a new valve that could be combined with either solenoid or actuators or the ability to be manipulated by pressure fluctuations. The signal for switching the direction could be given by a press of a button or it could be controlled by software that monitors the breathing of the patient and automatically sends a signal when the time is right. One can also make the valve work manually so that is could work with different breathing solutions. One downside is that developing a new

valve will be very costly and often require a big starting investment.

2-way valve connection – manual

This solution can also be used if it turns out that the test person can keep exhaling into the device. The switching maneuver is handled manually which makes it cheaper and less complex. One possibility with this solution is to have an easy connection between the previous solution for filtering the exhaled air, direct inhaled and exhaled air, exhale air and this one. That would make it more comfortable for the test person when filtering the lungs in the beginning or taking a break in the middle of the test. The test person could keep breath through the mouthpiece with the filter solution and with an easy connection connect to PExA when ready for the test.

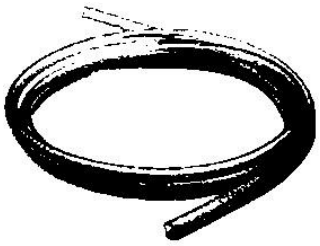


4-way channel (Multi valve)

See 4-way channel (Multi valve) under directing the inhaled and exhaled air (Control the flow direction and prevent backflow).

Leading air/arm solution:

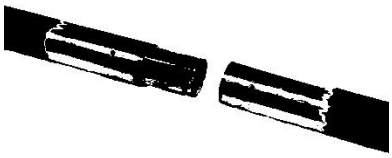
The arm solution is what´s holds every function together; it is what leads the air into the device and it is supposed to offer stability during testing and flexibility for adjusting it to suit different persons.
The current solution consists of a silicone tube and is upheld by a string attached in a rod placed over the arm solution. It is neither stable nor flexible.
Three other sub-concepts where selected for further investigation:



Flexible tube 1 (The goose neck)

This solution is a hybrid between a pipe and a hose that means that it both has flexible properties but still rather stiff. This solution can be bent in to a desirable position or form to improve the comfort for the patient. The solution can be bended in every direction and can take forms such as s-curves. This solution makes it easy to adjust to patient of various sizes and the breathing hose is integrated within the solution making it less bulky and more space efficient. It is easy combined with several of hose-connections which make it quick and easy to connect and disconnect from the PExA instrument.

Stiff tube with joints



By combining a stiff tube with joints one can achieve a good and stable maneuverability. This is a technique well used in other medical areas such as at the dentist office where the dentist has the instrument attached in an arm to provide stability and maximum precision. These are so called gas arms and uses gas cylinders combined with joints to create a stable and smooth movement but still offer support. These types of arms can also function by using inertia in the joints combined with springs such as you're average desk lamp. Downside with these solutions is that the breathing hose can't be integrated and must be attached on the outside. The gas arm version provides the best functionality but is also significantly more expensive.

Morphological matrix

When all different kinds of sub-concepts where generated these where combined into different alternatives, fulfilling different sub-solutions [8]. This procedure where done in a morphological matrix [9,6] that can be seen in figure 28.

All different sub-concepts were not included in the morphological matrix. Check valve represent all different kinds of check valves and the same applies for the different valves. The mask solution represents the integrated solution, where check valves and a filter is integrated, and the mask with pip where check valves and a filter is not integrated. Which one it is depends on which sub-concepts that are chosen.

	Sub-concept 1	Sub-concept 2	Sub-concept 3	Sub-concept 4
Clean inhaled air	Bigfilter	Big filter + noseclip	Mini-filter	Mini-filter + noseclip
Direct inhaled and exhaled air	Check valve	3-way with ckeck valve	4-way with check valve	
Exhale air	Mask	Bronchoscopy	Pipe	Snorkel
Direct exhaled air	3-way valve manuell or automatic	2-way valve manuell or automatic	4-way valve manuell or automatic	
Arm solution	Flexible tube	Plastic tube	Stiff tube + joint	

Figure 28: The morphological matrix. Illustrates all the different concepts

The sub-concepts where combined in order to fulfill all requirements in the requirement specification. Many more could have been combined but that would have made the concept screening very bothersome. This should instead be an iterative process where solutions can be combined after the first evaluation. If some solutions get low scores due to some sub-concept they can be combined with solutions that gets higher scores.
Choosing one concept from each row constructs a whole solution. Seven concepts where constructed see figure 29.

	Clean inhaled air	Direct inhaled and exhaled air	Exhale air	Direct exhaled air	Arm solution
Solution 1					
Solution 2					
Solution 3					
Solution 4 Current					
Solution 5					
Solution 6					
Solution 7					

Figure 29: Seven different solutions was combined

Testing concepts

As was mentioned in the first chapter under the short explanation of the methods used, this development process should be an iterative one where easy prototypes where built early on to enable testing. Testing is an essential part of the development process where it enables a qualitative evaluation of different sub concepts. This evaluation is a major part during concept screening.

Three tests where made to evaluate the nozzle solution. One was made to compare different mouthpiece solutions in terms of comfort and particle generation. One to evaluate if different lengths of the arm would affect the amount of captured particles. The necessity of switching the directions of the exhaled air was also tested to see how a constant inhalation into PExA would affect the particle generation. The execution of the particle test is described in the theory chapter under particle measurement.

Testing of breathing pattern:

In the early stages of the project the breathing pattern of the patient was questioned. The question was if it was necessary to switch the direction of the exhaled air between the breathing maneuvers or if the generation of particles was so small during normal breathing that it could be ignored. The underlying reason for changing the breathing pattern is that the need for a new and improved valve solution is eliminated because the switching of the valve would only be a few times. The possibility for making a less complex solution would increase and the strain on the operator would decrease. Therefore was several tests performed to try to compare the particle generation between the two breathing patterns.

Result of changed breathing pattern:

The testing of new breathing pattern revealed that the amount of particles that were produced during normal breathing was very small compared to the current breathing-pattern. One could assume that in terms of particle generation the difference is negligible. This result is very interesting but there is a very important thing to keep in mind before drawing too large conclusion; the test that was performed only counted and measured the exhaled particles and did not analyze what type of particles that were produce. This means that even if a changed breathing pattern doesn't have a significant effect on the amount of particles generated it doesn't guarantee that the "right" sorts of particles is generated. The particles of interest are generated in a specific part of the lungs for which the existing breathing pattern is developed for. If there would be a change in the breathing pattern there is a risk, according to medical experts, that this will stimulate the generation of particles from other places such as e.g. the throat or other parts of the lungs. This could lead to samples being contaminated with undesirable particles and aggravate the medical research of connecting illness with particles.

To fully determine the effects of a slightly changed breathing pattern a large clinical study has to be performed on several persons which is both costly and time consuming.

Evaluation of nozzle solutions:

In the following section an evaluation of the test for the different mask/mouthpiece will be performed. The tests were performed with respect to comfort and particle generation, both for the existing breathing pattern and the changed one. The test revealed that there was very little or no difference between the different nozzle solutions in terms of particle generation. Therefore will the analysis focus on the comfort for the different solutions. The result can be viewed below.

Pipe solution

This solution is one out of two of the already existing solution that is currently being used. It works by breathing through a small plastic pipe, combined with a nose clip to prevent nose ventilation. Here the patient has to secure the pipe and keep it air-tight by pinching their lips around the pipe. By doing so it gets quite tiresome for the lips in the long run. Having a pipe in the mouth creates big difficulties in swallowing saliva and rehydrating the upper palate, leading to lot of saliva is gathered in the lower parts of the mouth and dryness in the upper parts of the mouth. The positive properties of this solution are that it is very cheap and one size fits many different people. This solution has been tested and used many times before and is therefore verified to work as a suitable solution that means that it succeeds in generating the desirable particles.

Snorkel solution

This solution is one out of two already existing solution that is currently being used. This rubber nozzle looks just like a snorkel that is used for underwater diving and works combined with a nose clip. Here the lips can slide over the rubber molding, making it air-tight and the nozzle is secured by biting on the two rubber blocks. This solution makes it a bit easier to swallow compared with the pipe but in the other hand it does generate more saliva which does create a drooling problem but still not the same mouth dryness. There is no experienced lip fatigue as in the pipe solution but biting on the rubber blocks does create pain and discomfort in the teeth after a while. This solution is very cheap but is more suited for people with bigger mouths. People with smaller mouth might struggle with getting their lips properly over the rubber molding which could create soreness for the lips. This solution is verified and approved.

Mask solution

This solution is a facemask that has a silicone mold around the edges that creates an airtight seal against the skin. The mask is secured by using stretch belts, one each side and one on the top of the mask, all which intertwine on the back of the head creating good support for the mask. With this solution the patient has a big freedom of lips and mouth, making it easy to swallow and rehydrate the mouth, leading to very little mouth dryness and no drooling. The silicone molding creates a soft and comforting seal around the nose and mouth. The uncomfortable nose clip is no longer an issue. The mask is produce in three different sizes S, M and L that covers various face sizes. One downside with this solution is that it is expensive compared to Pipe and Snorkel which currently being used. This solution is by far the most comforting solution and no negative aspects of the particle generation could be identified from the test results even though there was some small condensation in the mask.

Mask-pipe solution

This mask has an integrated filter and inserted pipe for mouth ventilation. This allows the patient to breathe clean air through the nose and exhale by mouth through the inserted pipe that is connected with the breathing hose. The main advantages with this solution is that it eliminates the expensive check valve that's being used today and with an integrated check valve in the pipe the patient can continue breathing filtered air when disconnected. The testing of the mask revealed downsides such as; nose ventilation is quite strenuous compared to mouth ventilation when ventilating high volumes of air. For a patient with a reduced respiratory function this could be very exhausting. One even bigger disadvantage is that nose ventilation is not a verified method for generating the right sorts of particles so it would require a clinical study before it can be used. When breathing through a pipe the problems with mouth dryness and saliva still exist. Compared to existing solutions it is viewed as expensive.

Bronchoscopy solution

The idea for this solution came from a bronchoscopy mouthpiece that has a small pipe inserted in the mouth but with surrounding plastic moldings to support lips. The solution that was tested was a modified bronchoscopy mouthpiece that had been made air tight around the lips. The planned solution will consist of a short pipe with silicone skirts that seals tight against the skin around the lips with the help of rubber stripes attached around the head. The stripes around the head will not only keep the mouthpiece airtight but also offer support so that the patient won't have to pinch with their lips or bite with their teeth to keep it on place. Beside the mask, this is the most comfortable solution of the simpler concepts. Because of the silicone skirts and the rubber stripes, the patient can more easily swallow and therefore not have the same mouth dryness and drooling problems. This is due to the fact that it both seals and keeps it on place without help of the lips. The design is fairly simple so it has good possibilities to be a once-use-only product that can be produced to a low cost. The disadvantages with the solution is that it needs the uncomfortable nose clip to prevent nose ventilation and that the patient would have to have a pipe in the mouth which is viewed as fairly uncomfortable. It might be a good idea for further development of the solution to integrate some kind of nose clip in the solution. Another disadvantage is that it is expensive to produce plastic/rubber molds for production but the revenue from selling self-produced mouthpieces might help covering expenses and also give profit.

Nose clip

This had to be used during the breathing with pipe and snorkel to prevent nose-inhalation. It consists of a plastic clip with foam pads that pinches the nose drills to prevent ventilation through the nose. The pinch is quite hard and is perceived as very uncomfortable and even painful after a while. The clip is for single use and is thrown away after the procedure. This is due to simple design and low cost of the clip.

Evaluation of arm length:

One important thing to investigate was to see how the distance traveled for the exhaled air could influence the amount of sampled particles. It is important to see how much effect an increased or decreased arm length would affect the particles to be able to identify length constraints for the solution. The test was performed by trying

both longer and shorter versions of the existing silicone tube combined with existing solution and snorkel.

Arm length

The result from the testing revealed that the length of the breathing tube did affect the amount of particles. The test showed that the particle losses did increase when the length of the tube was increased. The opposite goes for the shorter tube where a shorter tube seems to enhance the particle generation slightly. A longer tube did have more negative effects on the particle generation than a shorter tubes positive effect on the particle generation. The reason for this phenomenon is not determined but likely causes could be that the risk for the particle getting caught or destroyed along the way to the impactor is increased with the distance traveled. One other cause could be that a longer tube is less straight then a short tube which could create a more turbulent flow. Another less likely reason is that it is more difficult to control the temperature for a longer tube. Even if the whole tube was covered with isolating material, one can assume that the flow of warm air was decreased on the outer parts of the tube which could have led to a temperature difference. To prevent this a longer up-warmer period was taken and the temperature on the outer parts was measured. But if there is a temperature fluctuation it will take longer to reach correct temperature again with existing heating solution that could have an impact on the particle generation. Most likely out of these reasons is that the risk for the particles getting caught or destroyed is increased with increased distance traveled.

.

6.2.2 Concept screening

When the sub-concepts have been combined the next step is to narrow it down to the best one. This will be done during; "concept screening" and "concept scoring".

There are some difficulties to consider during the process of screening and scoring the solutions. Different stakeholders can value different things; it is almost impossible to please all stakeholders [9]. Stakeholder managements have to be taken into account. Different stakeholders need to be managed differently. There are also difficulties when solutions shall be judged. Some properties can be measured quantitative while others cannot and has to be judges qualitative. In order to make the right decisions there are some different standard methods to apply.

The method that has been chosen for the decision making in this case, is based on using different kinds of "decision matrices". This is due to the fact that this process has several advantages; It is easy to document, different perspectives are well integrated, it allows the decisions to be based on the requirement specification and it provides a good overview [8].

During combination of different sub-concept many solutions that where unable to meet all the demands, where eliminated [6].

All concepts that solve the "main problem", fulfill all demands, can be realized within cost and technology and are safe where to be further investigated in a second matrix called Pugh [7].

All wishes and demands, which are beneficial to fulfill to an even larger extent, than what has been required, are considered in this matrix. Select one of the alternatives as

a referent and then compare the other alternatives with that one. "+" stands for fulfilling the demand or the wish better than the reference, "0" the same as the referent whereas "-" stands for worse than the referent. To be sure that are the best ones are taken further and that the right ones are eliminated this process can be done several times, with different references [7].

Before continuing to the next phase there is the possibility to combine different good alternatives to eliminate the "minus-values" and perform a new screening in order to get the absolute best possible solutions to the next phase.

The first Pugh matrix, that can be seen in appendix G, clearly showed that some concept got higher scores than others. It was also quite clear that many wishes depended on the mouthpiece solution and that this was one main explanation for the disseminate results. In order to see if any mouthpiece solution could be eliminated a separate Pugh was made with only the mouthpiece concepts, see figure 30.

	Solution 1 Mask	Solution Bronchoscopy	Solution 3 Pip	Solution 4 Snokel
Manufacturing cost	-	-	0	0
Should not require nose clip	+	0	0	0
Enable support for mouth	+	+	-	0
Minimize salivation	+	+	0	0
Prevent dryness	+	+	-	0
Suit different persons	+	+	+	0
Not afflict pain	+	+	0	0
Time to sterilize	+	+	0	0
sum +	7	6	1	0
sum -	1	1	2	0
sum 0	0	1	5	8
Total score	6	5	-1	0
Rank	1	2	4	3

Figure 30: Pugh matrix of different mouthpiece concepts

Eliminated
Should be further investigated

Solution pip and snorkel, both of which are in the current solution, was compared to solution 1 and 2 quite bad options and got very low scores. Because of this they got eliminated and a new Pugh, where pip and snorkel was replaced with mask and bronchoscopy, was made see figure *31*. An exemption is made for the current solution.

The seven concepts that where included in Pugh where:

Solution 1 – Integrated mask connected to a 2-way valve that works as an on off. The arm consists of a flexible tube. Depends on whether or not the second 3-way valve is unnecessary.

Solution 2 – Mask with pip connected to a 3-way valve with a big filter. The 3-way valve is then connected to another 3-way valve that can be switched manually or automatic. The arm solution consists of a plastic tube.

Solution 3 – Mask with pipe connected to a 4-way valve with a mini-filter. The 4-way valve has two functions and does not have to be connected to anything else. The arm solution consists of a flexible tube.

Solution 4 (current) – A snorkel connected to a 3-way valve with a big filter. The 3-way valve is connected to another 3-way valve that is switched manually. The arm consists of a plastic tube.

Solution 5 – A bronchoscopy connected to a 4-way valve with a mini-filter. The 4-way valve has two functions and does not have to be connected to anything else. The arm solution consists of joints and a stiff tube.

Solution 6 - A bronchoscopy connected to a 4-way valve with a big filter. The 4-way valve has two functions and does not have to be connected to anything else. The arm solution consists of a flexible tube.

Solution 7 - A bronchoscopy connected to a 3-way valve with a mini-filter. The 3-way valve is then connected to another 3-way valve that can be switched manually or automatic. The arm solution consists of joints and a stiff tube.

	Solution 1	Solution 2	Solution 3	Solution 4 Current	Solution 5	Solution 6	Solution 7
Minimize the loss of particles	+	0	+	0	+	+	0
Manufacturing cost	-	0	+	+	+	0	-
Length	+	0	+	0	+	0	0
Appearance	+	0	0	-	0	0	0
Number of parts	+	0	+	-	0	-	-
Easy to direct exhaled air	+	0	-	-	-	-	0
Enable support for head	+	0	+	0	+	+	+
Time to adjust	+	0	+	0	+	+	+
Ability to take a break	+	0	0	0	0	0	0
Should not require the nose clip	0	0	0	-	-	-	-
Should enable support for mouth	0	0	0	-	-	-	-
Minimize salivation	0	0	0	-	-	-	-
Prevent dryness	0	0	0	-	-	-	-
Suitable for different persons	0	0	0	+	+	+	+
Afflict as little pain as possible	0	0	0	-	0	0	0
Amount of times to direct the valve	+	0	0	0	0	0	0
Time to sterilize	+	0	-	0	-	-	+
Amount of steps when assembling	+	0	-	0	-	-	+
Time to assemble	+	0	-	0	-	-	+
Minimize the ability for human errors	+	0	-	0	-	-	+
sum +	13	0	6	2	6	4	7
sum -	1	0	5	8	9	10	6
sum 0	6	20	9	10	5	6	7
Total score	12	0	1	-6	-3	-6	1
Rank	1	3	2	5	4	5	2

Figure 31: Pugh matrix of the nozzle solution

After three iterations it was clear that the current solution and solution 6 was the worst ones and could be eliminated in the next phase. Some interesting conclusions could also be drawned. It was obvious that some sub-solutions performed much worse than others sub-solutions. These should be eliminated before concept scoring and some other solutions might be combined as replacements. The first one was plastic tube sense it is hard to adjust and gives no support. The second one is the 4-way valve that takes more time to sterilize, requires more steps and time when assembling and has a greater risk for human errors. The third one is the mask with a pip, which will cost too much in relation to it is benefits. The integrated mask will probably cost more but it also has more advantages.

After eliminating these sub-concepts there where only solution 1 and solution 7 remained. Two more promising solutions could be combined with all new knowledge in mind.

Solution 8 – Integrated mask connected to a 3-way valve that can be switched manually or automatic. The arm solution consists of joints and a stiff tube.

Solution 9 - A bronchoscopy connected to a 3-way valve with a big filter. The 3-way valve is then connected to a 2-way valve that works as an on off. The arm consists of a flexible tube.

6.2.3 Concept scoring

There are supposed to be only a handful of concepts left in this phase. Two of the original concepts made it through concept screening and two new ones were constructed. All of these concepts meet the demands and due to this only the wishes are considered in this phase. During concept scoring you have to decide which of the remaining concepts that fulfill the wishes best. This can be done using a method called Kesselring, where you rank and weight the different criteria's. Different criteria's might be more important to consider than others [10]. This can be done together with "the customer = the user" to assure that the weighting reflect the value of the wishes. This will result in a weight factors from 1-10 that can be see as an "important factor". Each solution is also valued from 1-5 in how well the solution fulfills the different criteria´s. These two are then multiplied for each criterion in order to get an overall performance factor for the solution. This process gave a systematic way to end up with the best solution depending on the requirement specification and the generated concepts, see figure *32*.

	Weight	Solution 1		Solution 7		Solution 8		Solution 9	
Minimize the loss of particles	9	7	63	5	45	6	54	6	54
Manufacturing cost	7	3	21	5	35	1	7	6	42
Length	4	7	28	3	12	5	20	5	20
Appearance	4	4	16	4	16	4	16	4	16
Number of parts	3	5	15	3	9	4	12	3	9
Easy to direct exhaled air	7	4	28	7	49	7	49	3	21
Enable support for head	5	7	35	10	50	10	50	7	35
Time to adjust	5	5	25	5	25	5	25	5	25
Ability to take a break	5	7	35	3	15	7	35	3	15
Should not require the nose clip	4	10	40	0	0	10	40	0	0
Should enable support for mouth	6	8	48	5	30	8	48	5	30
Minimize salivation	7	8	56	5	35	8	56	5	35
Prevent dryness	4	7	28	3	12	7	28	3	12
Suitable for different persons	4	2	8	6	24	2	8	6	24
Afflict as little pain as possible	7	4	28	4	28	4	28	4	28
Amount of times to direct the valve	5	4	20	1	5	1	5	4	20
Time to sterilize	5	6	30	4	20	6	30	4	20
Amount of steps when assembling	3	6	18	5	15	6	18	5	15
Time to assemble	3	6	18	5	15	6	18	5	15
Minimize the ability for human errors	10	9	90	8	80	9	90	8	80
sum									
			650		520		292		516

Figure 32: Kesselring matrix of the nozzle solution

6.2.4 Final concept – Nozzle solution

The solution that scored best was the solution 1, which consists of a mask with integrated filters and check valves and a flexible tube. The strength in this solution lies with use of the mask and that it's designed to work with a simpler breathing pattern. The mask allows for a more comfortable breathing for the patient and reduces the risk significantly of getting saliva into the system. The use of a simplified breathing pattern leads to that the solution can be kept simpler which helps cutting costs. There is though one problem, which is that these strengths are also the weaknesses of the solution. As mentioned in previous chapters, the use of a mask solution will require a clinical study before it can be validated as a suitable solution which can't be performed within the given time frame for this project. The same goes for the change of breathing pattern. It is also important to point out that the goal for this project is to create a research instrument, which means that it is very important to be able to have a good and precise control over the process. This is because of that the connection of particles and specific diseases has not been done, hence the purpose of PExA. But when these connections have been made there won't be the same high demand of precision and control because one will know what to look for. So for an implementation in the medical industry this can be a suitable solution that is less complex, cheaper and more oriented towards patient comfort. This will be more explained in recommendation but this solution will be excluded from further development.

Since the highest scoring solution has to be eliminated the selection falls on next in line, which is solution 7. Solution 7 consists of the bronchoscopy mouthpiece, a 3-way check valve, a 3-way valve for direction of flow which all is attached on a joint stiff tube. After the solution was selected it was realized that some more improvements could be made. By making the controlling of the 3-way valve automatic led to that the valve could be placed inside the device. This lowers the need for a rigid arm solution since the arm can be kept much shorter. By just adding a short rubber hose as a connection between the device and the other parts one can have a solution that is both fairly rigid and flexible for good comfort. One other major advantage for this is that the arm is so short that is does not need external heating which creates a less complex heating solution and to a lower cost. This solution has improved the tiresome movement for the operating personnel and contributes to obtain a less bulky and attractive design. It is also important to point out the solution modular design. Since it is expected that a small company as PExA AB won't be able to handle the investment cost of developing everything at the beginning it is important that this can be done step by step. By making it modular and compatible with previous valves and connections the development transition can happen step by step as finance is covered. Then slowly as it enters the market piece by piece can be refined and improved or replaced without need for major changes on other interfaces. The modularity also creates possibilities to combine other parts such as e.g. mouthpieces or other types of valves allowing customers to have a degree of customization. Some other strengths in this solution is that consists of several single use components designed for a simpler, safer and more efficient use which also creates an aftermarket for the company. One of the goals for the project was to try to develop single use component to be able to continue make earnings on sold instruments and good candidates for this has been identified and will be explained in sections below.

The bronchoscopy mouthpiece is casted as a whole piece in silicone that make it suitable for mass production and as a single use component. The aim with the design

of the bronchoscopy mouthpiece is to create an airtight seal around the mouth so that the lips can be offered some support during the procedure. By using a shorter integrated pipe, a stable and similar flow as previous mouthpieces can be obtained. The whole mouthpiece is attached with a rubber band around the neck for good support see figure 33. All these improvements will create a mouthpiece that is more comfortable and makes it easier to swallow for the patient. It has a good possibility to be used as a single use component that both gives a more sterilized solution but also helps improve earnings on an aftermarket.

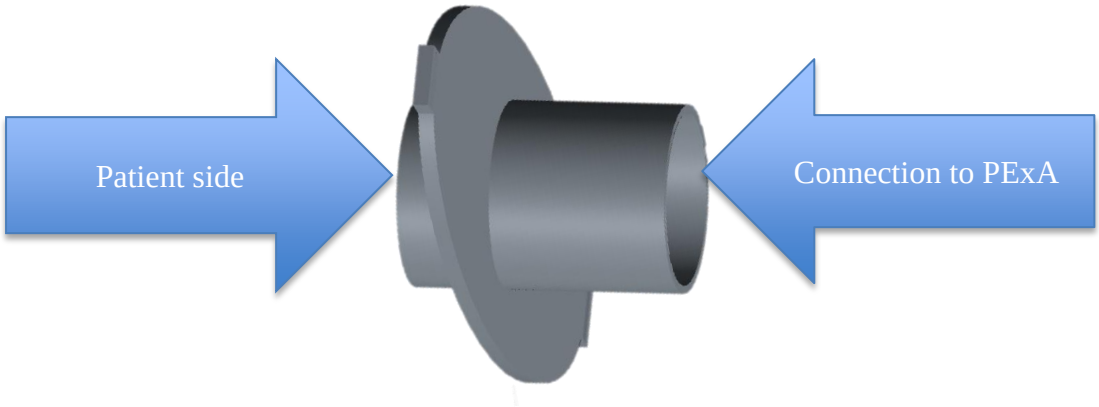


Figure 33: Final concept of the mouthpiece

The self-designed 3-way check valve is designed as a t-junction that can be casted in a suitable plastic for mass production and single use see figure 34. The t-junction will have flanges inside at each opening so that check valves can be attached to enable a correct flow. The design is also made so that a small single use mini-filter can be attached instead of the bigger one used today though it is still possible to use it with the bigger. This part helps create a less expensive solution, which can cut cost and improve earnings. Since the part is preassembled it will also reduce the risk of a wrong assembly by operating personnel, which is a current problem.

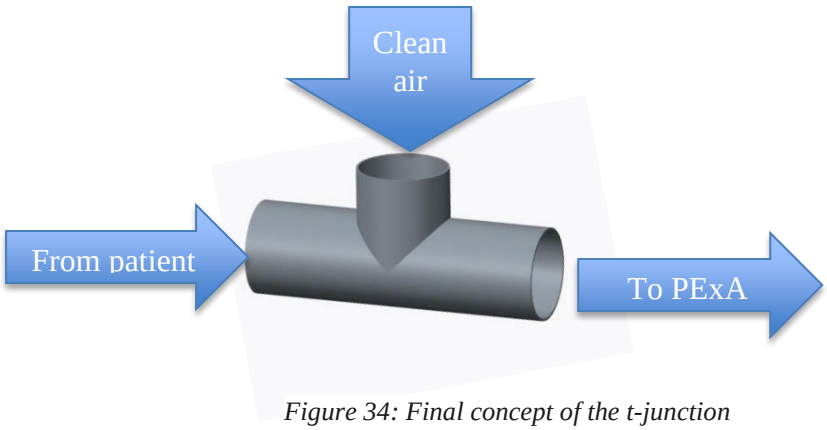


Figure 34: Final concept of the t-junction

Many operators complained about the previous 3-way valve where the flow direction was controlled and switched. It included tiresome twisting movement several times during the procedure in an uncomfortable position. By placing an automatic valve on

the inside this problem can now be eliminated. This new placement has many benefits for the total solution such as an easier heating solution as mention before and a shorter arm solution but also facilitates the ability to make an automatic solution. Having it on the inside gives the ability to hide the extra electrical components that is needed for the new valve and helps to improve the visual appearance. Through the development process, three different suitable candidates of valves for this automatic solution have been identified. Two of these valves are valves that already exist on the market and one of them is currently being used in the existing version of PExA. The third one is a self-developed valve specially design for an automatic solution and placement inside the instrument. The existing valve can be controlled by an actuator that rotates the position of the valves openings and by so change the direction of the flow. The two other valves use a sideways movement for a change of flow direction unlike the existing valve that has a rotating movement. Figure 35 below shows the function for the self-designed valve demounted for easier understanding the principle for the other existing side-way valve is similar.

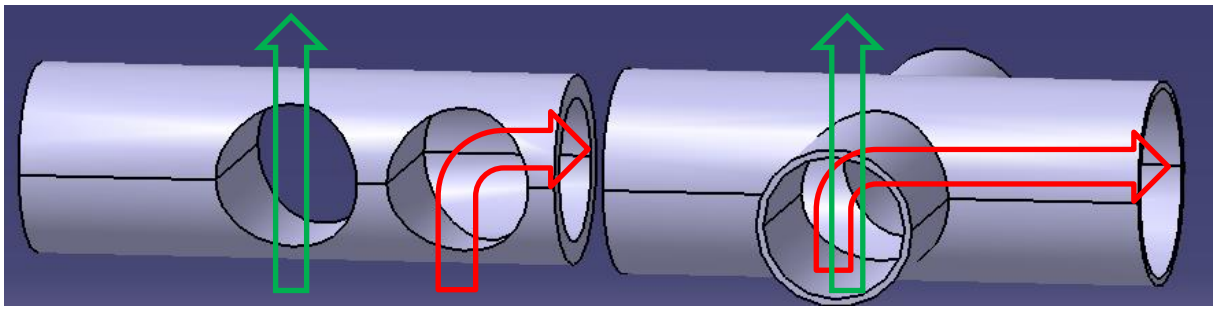


Figure 35: Centre-piston to the left. Green and red arrow shows two different flow paths when aligned.

These valves can be controlled by a solenoid that slides it sideways in order to change the direction of the flow. The sideways movement can be done very effortless and don't require a high force or advance controlling. The solenoid piston is held in place by a metal spring and when power is applied in the solenoid piston moves sideways compressing the spring and the flow switches direction. When the power is cut the spring expands again and moves the piston and valve to original position. A turning movement will require a bit higher force and might be a bit slower but it is common to use actuators in the industry for these applications. In general a solenoid is smaller than an actuator that creates the same output force. The three valves are very similar in performance so a final choice of a 3-way valve for flow direction will be based on a cost evaluation performed in following chapter 7.

6.3 Reservoir

The reservoir will be developed in this section. The method for developing the reservoir will be the same as for the nozzle solution. The function of the reservoir is to temporary store excess contaminated air so that the whole breath can be processed over time, see figure 36.

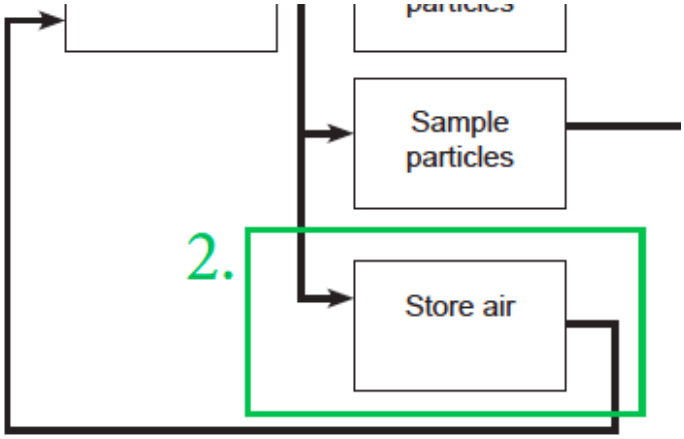


Figure 36: The function that the reservoir solution should be able to solve

6.3.1. Concept generation

There are a couple of things to consider when generating concepts for the reservoir. It has to have a volume of at least 5 liter and it has to have two connections; one where it receives the exhaled air alternately provides sampled air for to the impactor and a second connection from where the old sampled air is reintroduced into the system. The path between the two connections is also important to consider, the air shouldn't be able to go directly from the inlet to outlet.

The placement of the reservoir was explained in Chapter 5 and will work as a guide when generating concepts. The deposition site of the reservoir can be seen in figure 37. With this in mind a couple of different alternatives where chosen to be investigated further.

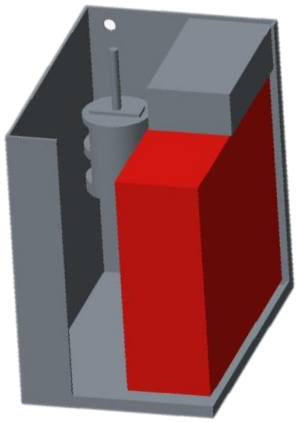


Figure 37: The red box illustrates the position of the reservoir

Description of sub-concepts

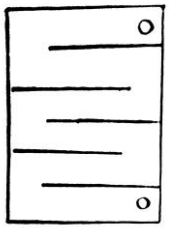
This section describes sub-concepts that were generated during brainstorming, through systematic search and analyze of other products.

Tube

This solution consists of a long tube that can be formed in different ways in order to suit the total solution. The air gets a natural and easy way from the inlet to the outlet. The solution is cheep so instead of cleaning the tube it can be replaced with a new one.

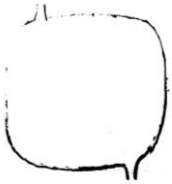
Box

This solution has the form of a box and contains walls that direct the air inside in order to make it impossible for the air to go directly from the inlet to the outlet. The box takes little space relative to the volume it can contain.



Bag

This solution consists of a bag that varies in size depending on how much air that is blown into it.



Cylinder

This is what is used in the current solution. Instead of walls the cylinder is made quite long in order to make the air travel a longer way. This is the main reason for the long height of PExA today.

Free form

This solution can be of any form depending on how the total solution looks like. This can make the reservoir very space effective but it can also make the reservoir very complicated to clean.

Elimination matrix

An elimination matrix, see figure 38, was made in order to eliminate some of the solutions, see figure 38. In this matrix, only the demands in the requirement specification are considered. If a solution doesn't meet a demand it gets eliminated.

	Solution 1 Tube	Solution 2 Box	Solution 3 Current	Solution 4 Bag	Solution 5 Free form
The solution should prevent stagnation and create an even flow	YES	YES	YES	YES	YES
X m distance between inlet and outlet	YES	YES	YES	NO	YES
The reservoir should not leak	YES	YES	YES		YES
Ability to change or clean the reservoir 2 times a year	YES	YES	YES		YES
The reservoir should have the volume of at least 5 L	YES	YES	YES		YES
The reservoir should not be longer then x m	YES	YES	NO		YES
The reservoir should not be wider then x m	YES	YES			YES
The reservoir should not be higher then x m	YES	YES			YES
Produce 50 per/year	YES	YES			YES
The material of the reservoir should tolerate 37 °C	YES	YES			YES
The material of the reservoir should tolerate moist	YES	YES			YES

Figure 38: An elimination matrix of the different concepts for the reservoir

The current solution got eliminated due to it is length and the bag solution got eliminated due to it is to short inside distance between inlet and outlet.

6.3.2 Concept screening

Three solutions was investigated in the Pugh matrix, see figure 39. When it comes to the reservoir the requirement specification contain mostly requirements, which made the Pugh matrix, that contain wishes, quite sparse.

	Solution 1 Tube	Solution 2 Box	Solution 5 Free form
Size	-	0	+
Manufacturing cost	+	0	-
Time to sterilize	+	0	-
Easy to connect	0	0	-
sum +	2	0	1
sum -	1	0	3
sum 0	0	6	0
Total score	1	0	-2
Rank	1	2	3

Figure 39: Pugh matrix of the reservoir

Solution 5 got eliminated in the Pugh matrix and the reason was because of it is complex form. The complex form has the advantage of making the reservoir very space efficient cause it will only take the space that would have been empty anyway but the form will also make the solution expensive to manufacture and hard to sterilize and connect.

6.3.3 Concept scoring

Solution 1 and solution 2 had to be compared in a Kesselring matrix in order to make sure that the best solution is selected as a final choice.

	Weight		Solution 1 Tube		Solution 2 Box
Size	7	6	42	9	63
Manufacturing cost	7	9	63	7	49
Time to sterilize	5	5	25	5	25
Easy to connect	5	4	20	9	45
sum			150		182
Rank			2		1

Figure 40: Kesselring matrix of the reservoir

Even though the tube solution is a very cheap solution, which also makes it easy to sterilize since it can be replaced with a new one it got eliminated in the Kesselring matrix, see figure 40. This was due to the size of it and the connection possibilities. The optimal situation, from a connection sight, would be to have a tube with the same diameter as the other tubes. The reservoir would then be easy to connect with the other tubes but as can be seen from the calculations it would have to be almost 16 meter long to be able to contain 5 liter if it where to have the same diameter as the other tubes.

$$V = \pi * r^2 * l$$

$$l = \frac{V}{\pi * r^2}$$

$V = Volume = 0{,}005 m^3$
$l = length$
$r = radius$

$$r = 0{,}01 \rightarrow \ l = \frac{0{,}005}{\pi * 0{,}001^2} = 15{,}92\ m$$

$$r = 0{,}03 \rightarrow \ l = \frac{0{,}005}{\pi * 0{,}003^2} = 1{,}77\ m$$

The length can be reduced a lot by increasing the radius but special connection will then have to be made which will increase the price. A tube with a diameter of 6 cm will have to be 1,77 m long. This tube will take a lot more space then the box.

6.3.4 Final concept – reservoir

The box solution became the final solution for the reservoir. This solution had many advantages such as how little space it required, how the connection could be placed anywhere and how the connections could be made to allow an easy connection between other elements.

The best placement of the reservoir was decided in chapter 5 and that placement guided which length, width and height it should have and how the connections should be placed. From figure 41 it can be seen that the reservoir is placed under the particle counter so the height of the reservoir is decided from which height PExA has to have due to other component, such as the impactor, minus the height of the particle counter. The length of the reservoir is the same as the length of PExA and the width is then decided from the 5 liters it should contain. Figure 41 explains the different parameters.

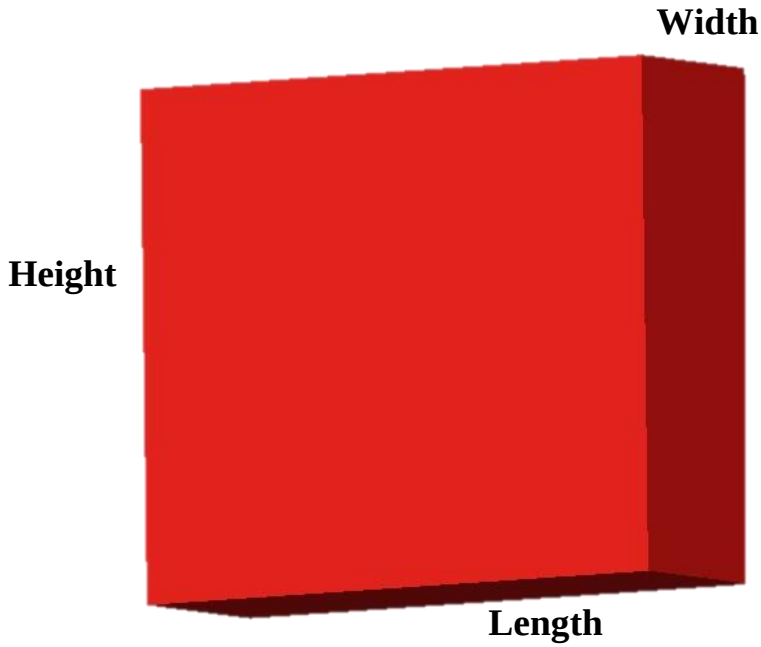


Figure 41: Explanation of the different parameters referenced

Two different connections should be placed and that placement is also based on chapter 5. Since the first connection requires a short distance from the intake the first connection will be placed to minimize this distance, which is in the upper right corner.

The second connection can be placed more freely and will therefore be placed near the outlet where all leftover air disappears. That outlet will be placed at the bottom of PExA and the shortest distance is obtained if the connection is placed in the lower left corner.

The two connections is formed as cylinders with the same diameter as the standard tube that will be used inside PExA. This enables an easy connection between the tube and the reservoir.
There will also be walls inside the reservoir, which controls which and how long way the air takes between the connections. The final reservoir can be seen in figure 42.

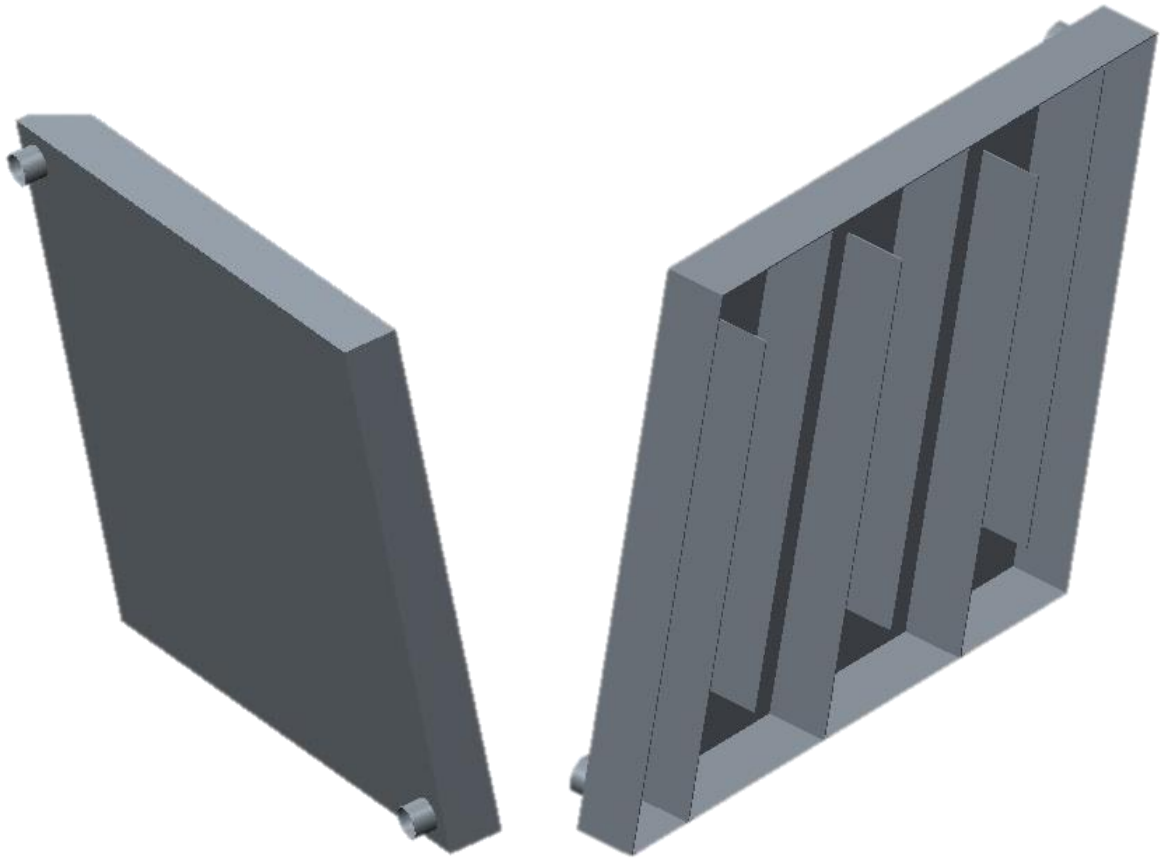


Figure 42: Final concept of the reservoir

6.4 Presentation of total solution

To add value for the company a suggestion of how PExA could look like, as a total solution will be presented. This means how PExA should look when it comes to size, movability and handling off it as a whole device. The total solution will not describe how it will look like when it comes to forms, bottoms and colours. There are some reasons for way this is included in the report. One of them was that an investigation of the design proposal, described in the first chapter had to be made. If that design proposal would work it would save PExA some time. Another reason was that a lot of knowledge concerning this was gathered during the interviews and it would be as well to include it the report. Figure 43 displays the concern system.

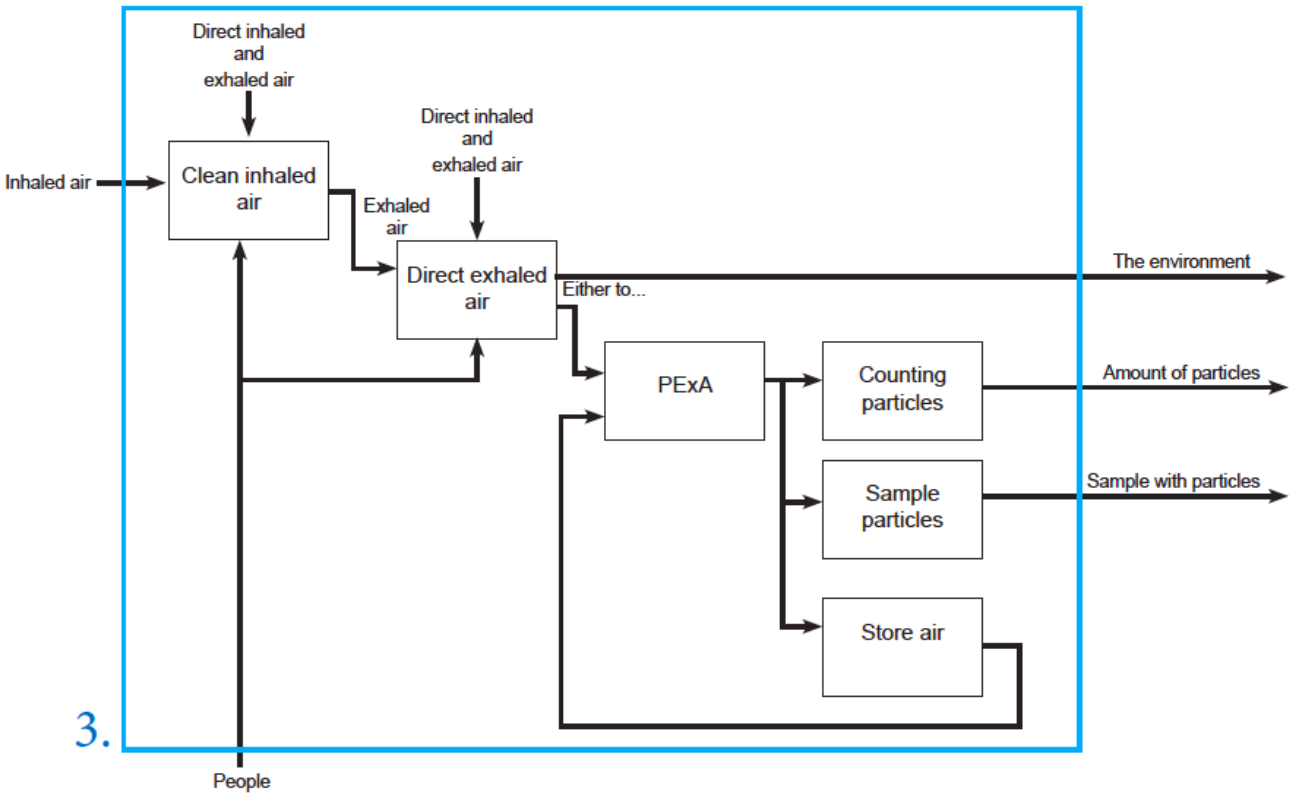


Figure 43: The total solution is the shell that contains the different functions

6.4.1 Concept generation

During Chapter 5 all parts where positioned which made it possible to estimate a realistic size. This was used as a guide when generating concepts.
During brainstorming eight different concepts was chosen to be investigated further, apart from the current solution and the design proposal, see figure 44.

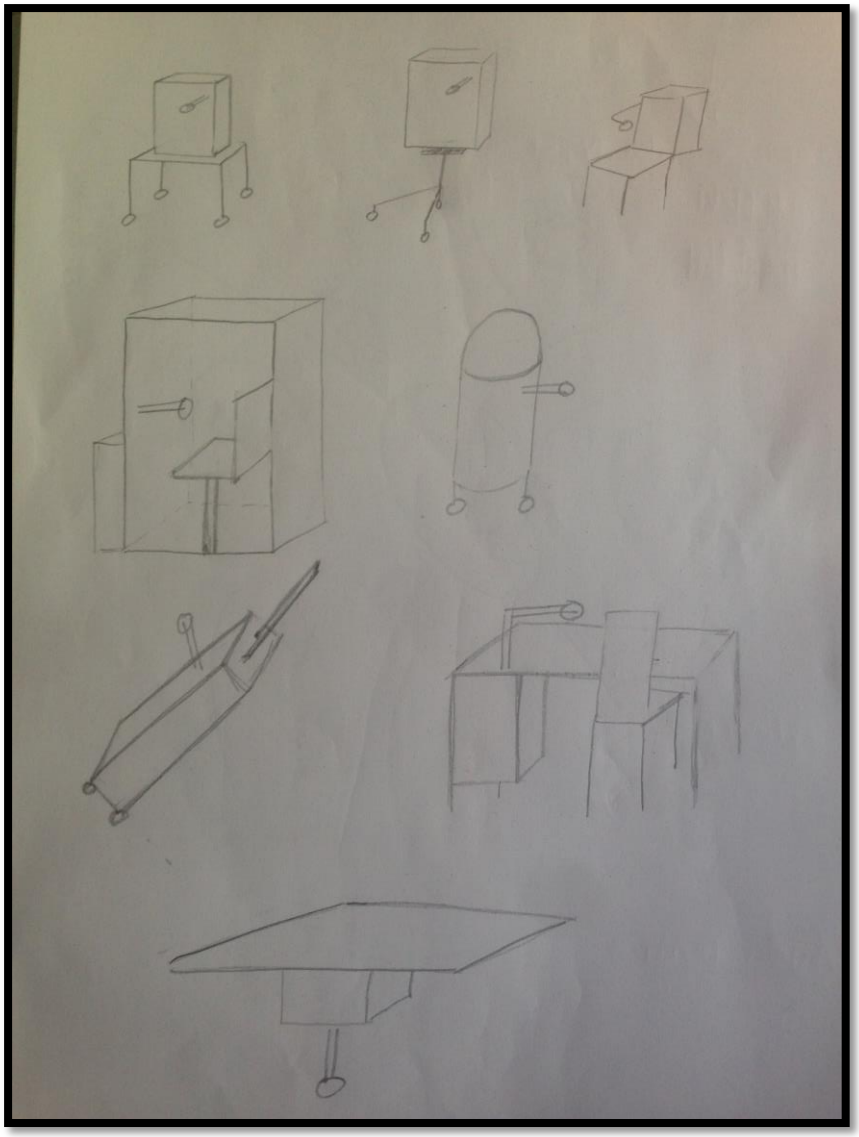


Figure 44: Sketches from the brainstorming

An elimination matrix was made in order to eliminate some of the solutions, see figure *45*. In this matrix, only the demands in the requirement specification are considered. All demands that where included in the requirement specification of the total solution where included in the matrix even though every demand would not affect the described total solution that will be developed as a concept in this chapter. For example, the start-up time will not be affected by how this concept will look like. In this phase however it dose not matter if they are included or not what matters are which concepts that are unable to meet all the demands.

	Table	Chair	Stand	Room	Cleaner	Writing desk	Roof	Design	Current	Suitcase
Sustain 37 degrees	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Sustain moist	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Collect x g particles	YES	YES	YES	YES	YES	YES	YES	YES	YES	YES
Movable	YES	YES	YES	YES	YES	NO	NO	YES	YES	YES
Lifetime 5 years	YES	YES	YES	YES	YES			YES	YES	YES
10 min to change parts	YES	YES	YES	YES	YES			YES	YES	YES
Produce 50 per/year	YES	YES	YES	YES	YES			YES	YES	YES
300 000 kr to manufacture	YES	YES	YES	YES	YES			YES	YES	YES
Not be bigger then 370x420x1300 mm	YES	YES	YES	NO	YES			YES	YES	YES
Operate at 37 degrees	YES	YES	YES		YES			YES	YES	YES
Rust and corrosion resistant	YES	YES	YES		YES			YES	YES	YES
Operator can be placed beside test person	YES	YES	YES		YES			NO	YES	YES
Computer at a reaching distance	YES	YES	YES		YES				YES	YES
No breaks for operators	YES	YES	YES		YES				YES	YES
Enable support for feet's	YES	YES	YES		YES				YES	YES
No more then x min to adjust	YES	YES	YES		YES				YES	YES
No break for test person before x min	YES	YES	YES		YES				YES	YES
Start-up in x min	YES	YES	YES		YES				YES	YES
Not in danger anyone	YES	YES	YES		YES				YES	YES

Figure 45: An elimination matrix of the different concepts for the total solution

The four solutions that was eliminated was the room that where to big, the writing desk that would be hard to move, the roof solution that also would be hard to move to other rooms and the design proposal where the operators have to stand in front of the patients. So according to the elimination matrix the design proposal will not work for PExA, which also became quite clear after interviewing the operators. The operators required a solution where they could stand beside the patients in order to instruct and help them, which is not the case with the design proposal.

Description of concepts

Solution on table

PExA is placed on a movable table. This enables the test person to have their legs under the table and in that way get closer to the device. If wishful this solution would have the possibility of a shorter arm.

Solution on a stand

PExA is placed on a stand with wheels that is height adjustable. If placing the legs smart this solution would also enables the test person to get closer to the devise.

Chair solution

PExA is placed on the backside of a movable chair. Requires a longer arm but one can sit very comfortable during test.

Solution vacuum cleaner

PExA is integrated with only wheels and is a low solution that enables a long arm.

Solution suitcase

This solution is quite similar to the vacuum cleaner solution but instead PExA is integrated with two wheels and a handle. This solution is very movable but requires a longer arm.

Current solution

(Has been described in previous chapters)

Testing concepts

When it came to the total solution it was hard to make any prototypes except for digital ones. This meant that the evaluation had to consist mainly of qualitative assessments, which made the concept testing of the total solution very sparse. However, it was quite easy to make good evaluations based on only the concepts that were simply sketched. How big it would become compared to the other concepts, how movable the solution would be and so on was quite easy to predict and compare.

Some wishes where predicted to be the same for the different concepts. One example is the operator's position during test. In the current solution the valve, located on the arm, is placed on the opposite side of where it is optimal to have the computer placed. This makes it hard for the operator to get an optimal position. They have to direct the valve on one side while the computer is on the other. This mistake will be corrected in all other concepts and an optimal position will be possible in each case, which will make the scoring for this wish the same for all concepts. Similar considerations have been made with other wishes.

To evaluate if there was any differences between the different concepts when it came to the amount of sampled particles a test needed to be performed. The only thing that would make the generation of particles different in the different concepts is the arm solution. Some solutions will require the arm to be longer and the test had the purpose of investigating if the length of the arm had any implications on the amount of sampled particles. This test can be read about in section 6.2.1.3 testing concepts.

6.4.2 Concept screening

All concepts that solved the "main problem", fulfilled all demands, can be realized within cost and technology and are safe where to be further investigated in Pugh, see figure 46. All whishes that were included in the requirement specifications were not included in this matrix. This was because of the fact that some wishes would be the same for all solutions and this is because they won't be affected of how the total solution would look like.

	Solution 1 Table	Solution 2 Stand	Solution 3 Chair	Solution 4 Cleaner	Solution 5 Suitcase	Solution 6 Current
Minimize the loss of particles	+	+	+	0	0	+
Manufacturing cost	+	-	-	0	+	-
Movable	-	0	0	0	0	-
Appearance	0	0	0	0	0	-
Size	-	0	-	0	0	-
Weight	-	0	-	0	0	-
Operator position during test	0	0	0	0	0	-
Time to adjust	0	0	0	0	0	-
Computer position	0	0	0	0	0	-
Length of arm	+	+	+	0	0	+
sum +	3	2	2	0	1	2
sum -	3	1	3	0	0	8
sum 0	4	7	5	10	9	0
Total score	0	1	-1	0	1	-6
Rank	**2**	**1**	**3**	**2**	**1**	**4**

Figure 46: Pugh matrix of the total solution

The only solution that could be removed with certainty was the current solution. The five others had to be evaluated in a Kesselring matrix.

6.4.3 Concept scoring

The two best solutions according to the Kesselring matrix, see figure 47, was the table and stand solution.

	Weight	Solution 1 Table		Solution 2 Stand		Solution 3 Chair		Solution 4 Cleaner		Solution 5 Suitcase	
Minimize the loss of particles	9	4	36	5	45	3	27	2	18	2	18
Manufacturing cost	7	4	28	2	14	2	14	2	14	3	21
Movable	7	3	21	5	35	3	21	5	35	5	35
Appearance	4	4	16	4	16	4	16	4	16	4	16
Size	6	2	12	3	18	3	18	4	24	4	24
Weight	3	2	6	3	9	2	6	4	12	4	12
Operator position during test	7	5	35	5	35	5	35	5	35	5	35
Time to adjust	5	4	20	4	20	4	20	4	20	4	20
Computer position	7	5	35	5	35	5	35	5	35	5	35
Length of arm	5	4	20	5	25	3	15	1	5	1	5
sum											
			229		252		207		214		221

Figure 47: Kesselring matrix for the total solution

Both the table solution and the stand solution are good potential solutions for PExA. The stand solution performs a little bit better in most respects but the possibility to place PExA on a desk together with the computer is a big advantage described by the operators as well. This led to the realization that the best solution would be a combination of them. This would not risk that any positive benefits are lost for the solution, rather only add to it instead.

6.4.4 Final concept – total solution

The final solution is a combination of the stand solution and the table solution. The combination is a solution that is supposed to be placed on a stand but has the possibility to be moved from the stand to a table. The table can be of any kind and will not be described or developed, the idea is to have the possibility to place it on whatever table that is available if it would suit the operator better.

If designing the stand in a correct way it will have a lot of advantages compared to the current solution. During the test it could be seen that a shorter arm resulted in more sampled particles, which is quite logic since they will have a longer way to travel with a lot of obstacles in the way. The current solution needs to have a quite long arm due to the current size and shape of PExA, see figure 48. The stand on the other hand can be formed in a way that enables the patients to have their legs under PExA which leads to a shorter arm and in turn to more sampled particles, see figure 48.

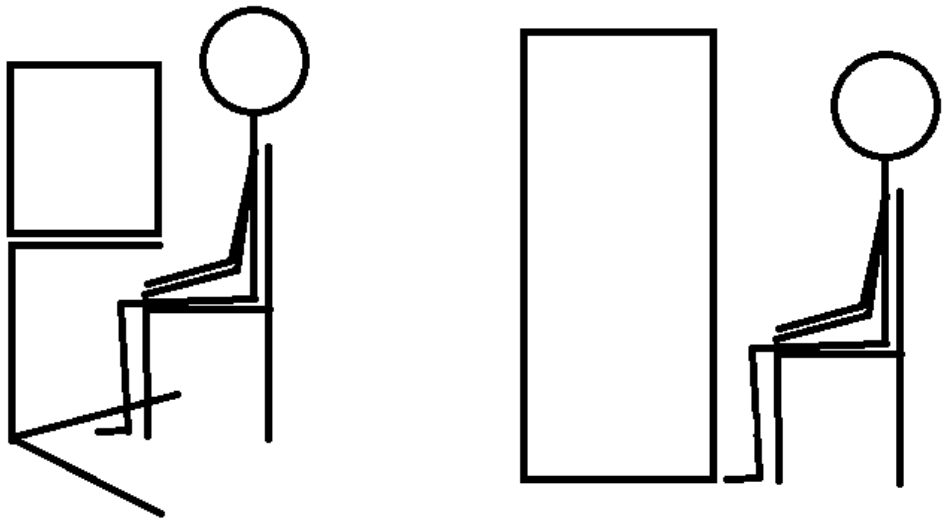


Figure 48: Illustration of how much shorter the arm could be if PExA had another design

The stand solution will be easy to move between rooms and it can be disassembled into two parts which is a big advantage if it would be necessary to move it to another building. The idea is also that the stand should be height adjustable, which will simplify the adjustment and increase the comfort between different patients.
There are a number of ways to design the stand especially when it comes to designing the "legs" of it. Two important aspects need to be considered in this case. The first one is the previous mentioned one where the patient needs to have their legs under PExA to allow a short arm and the second one is the stability. The stand needs to be stable during test and during transport.

There are some things to consider when positioning the legs and the wheels due to stability and degrees of freedom. When it comes robust design one should in most cases lock all degrees of freedom without overdoing it. Six points are needed to lock a part in space see figure 49.

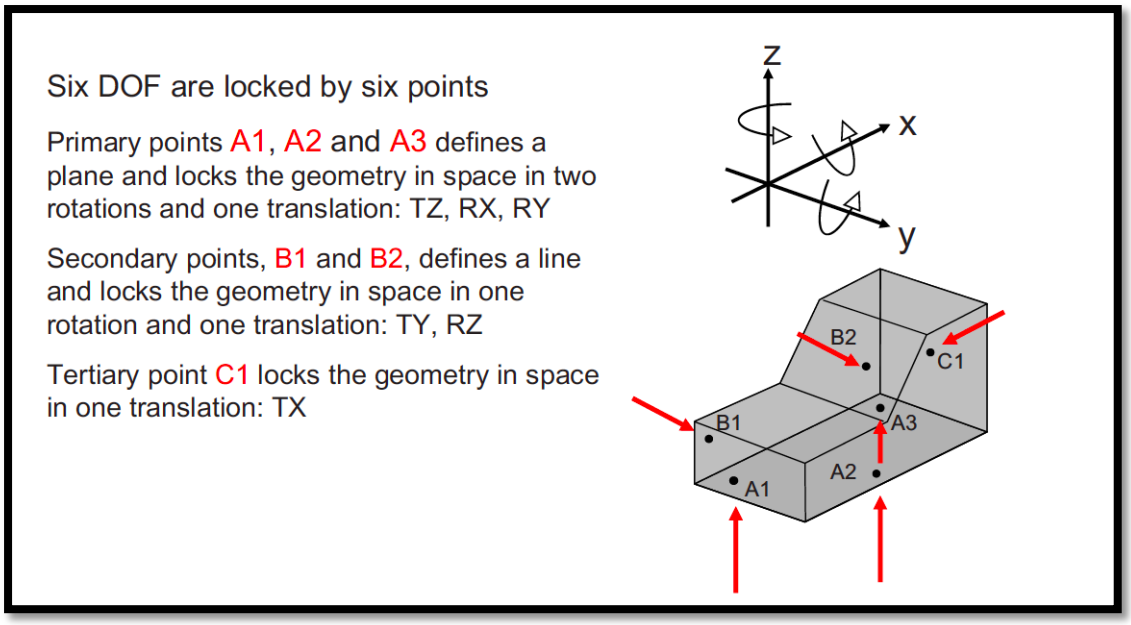


Figure 49: The concept of locking a part in space in order to make a robust design

The stand should be able to rotate in Z and move in Y and X so in this case only three degrees of freedom needs to be locked, these are translation in Z and rotation in X and Y. This can be done with A1, A2 and A3, see *figure 49*.
With the aspects on stability, degrees of freedom and where the patients need to place their legs the shape of the stand could be designed, see figure 50.

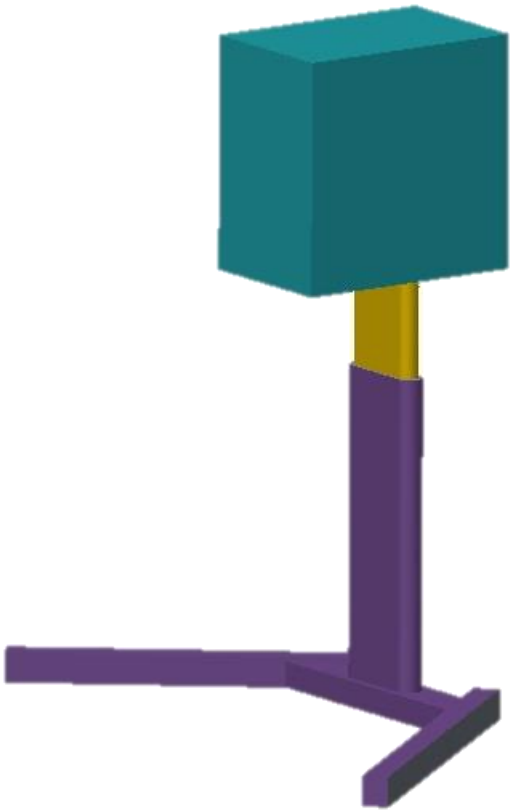


Figure 50: The final concept of the total solution

7. MANUFACTURING

The purpose of this chapter is to identify suitable manufacturing process for each selected concept such as the 3-way valves, mouthpiece, reservoir and the 3-way check valve so that an estimation of cost can be obtained. The chosen manufacturing process combined with a suitable material choice will result in guidance in cost for each concept. The information for the manufacturing and cost analysis has been acquired by the use of CES software and by consulting the sub-contractor Hagall Group that has been involved with prototype manufacturing in current project with PExA AB. The batch sizes are based on the companies estimated sales in the beginning of product launch. As mentioned before, the cost estimation will only work as guidance and will not represent a final absolute cost.

7.1 Mouthpiece and 3-way check valve- choice of material/ manufacturing process

Since the mouthpiece and the 3-way check valve are designed for single use a large batch size is expected. An estimation of sold pieces of each product per year is around 160 000 units. That figure is based on supplying 100 PExA instruments that is used 200 days per year with 8 patients per day. The typical choice of manufacturing process to use for mass-producing semi-complex geometries in polymer material is injection molding. The principle of injection molding is that molten polymers are injected into a cold steel form under high pressure. The injected polymer solidifies under pressure and is than ejected and the cycle repeats. Due to the high capital and tooling cost the process is almost exclusively used for large volume productions. Not all polymer materials are suited for injection molding so to identify a good material to use for the process is essential for good result. By using the material selection software CES one promising material candidates for each part were identified. The selection of material was mainly based on cost and the capability for injection molding by using graphs and limit functions, an example of the graph of the material selection for the 3-way check valve can be viewed in *figure 50*.

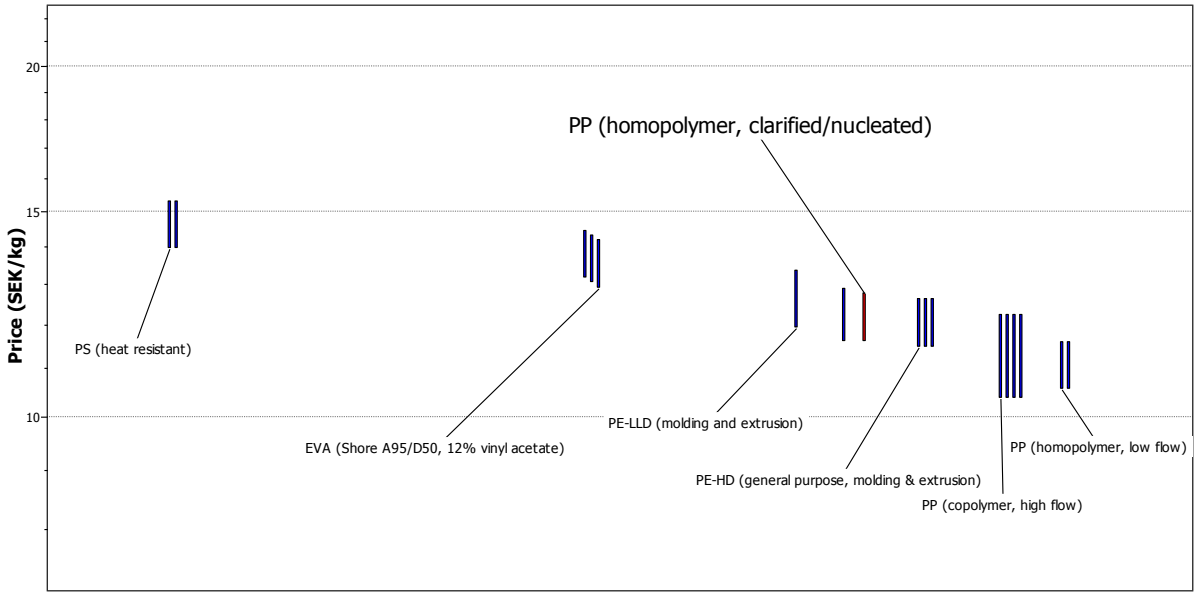


Figure 50: Material table from CES Edupack 2014 displaying material candidates for 3-way check valve

By studying the generated candidates, material that already has a typical application area within the medical area could be identified. The existing use of these materials within the medical system indicates that they are safe, approved and tested for such a use. With aid of the software CES a roughly cost estimation has been made for injection molding for both materials and can be viewed below in *figure 51* and *figure 52*.

Part:	Mouthpiece
Material:	Silicone(VMQ, heat cured, low hardness)
Price:	76,3-90,8 sek/kg
Density:	1050-1070 kg/m^3
Typical use:	Medical applications

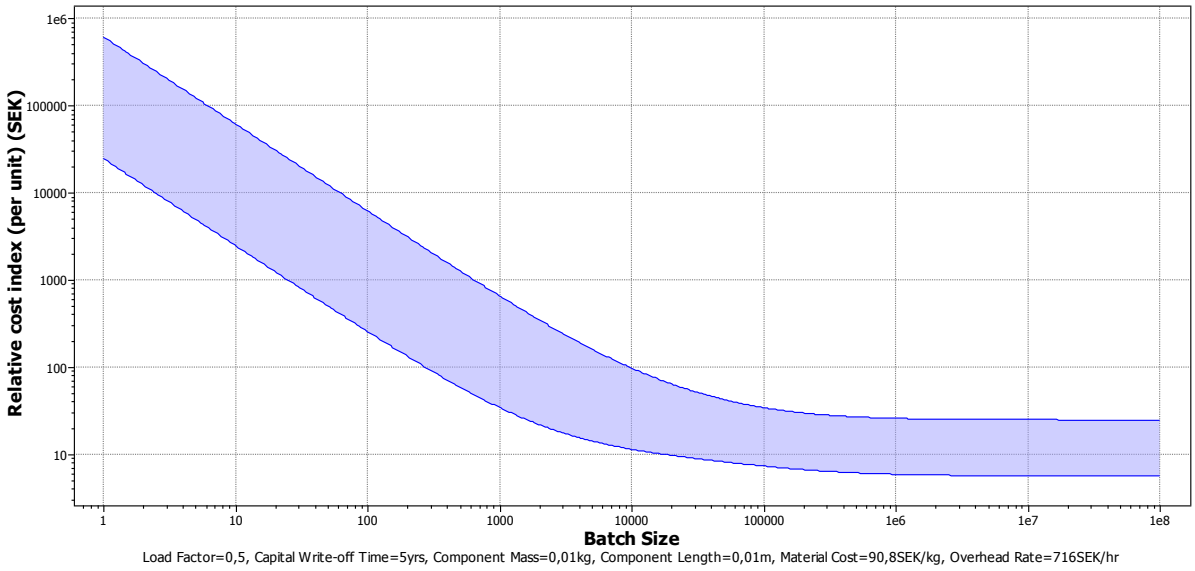


Figure 51: Cost/Batch size Graph from CES over injection molding for mouthpiece

Part:	3-way check valve
Material:	PP(Homopolymer, clarified, nucleated)
Price:	11,6-12,8 sek/kg
Density:	900-909 kg/m^3
Typical use:	Very wide, medical applications

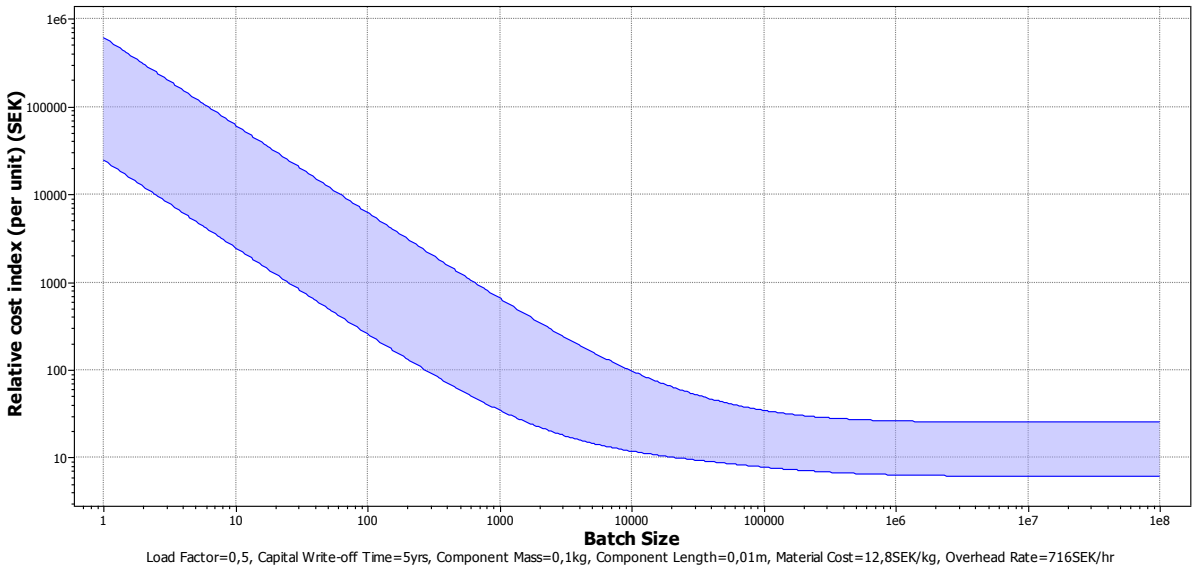


Figure 52: Cost/Batch size Graph from CES over injection molding for 3-way check valve

The result from the the analysis clearly shows that the cost decreasis as the batch size increases. An exact cost is impossible to give and as seen in both tables the cost-span is quite wide. The analysis does not consider the correct geometry and capital write of and load factor are only rough estimations. When viewing both tables the lower value closes in to 10 sek/unit for a batch size around 160 000. A batch size on 160 000 units is probably a too low size to obtain a really good profit margin but as sales will improve it is highly likely that a lower cost can be obtained and so a higher profit margin.

7.2 Self-designed 3-way valve and reservoir

The self-designed 3-way valve and the reservoir are parts that are designed and positioned for a more permanent installation. This means that they will be used for a longer period and therefore will be made in relatively small batch sizes around 150-200 units. Because of the high capital cost and high tooling cost for injection molding, manufacturing cost for such a small batch would be unnecessary high. According to experts, at the material/manufacturing science department at Chalmers University of Technology and Hagall Group, only the molds for each component could cost as much as one million SEK which only by that would create a cost of 5000 SEK/unit and that without any other cost included. Manufacturing of parts with complex geometry in smaller batches, like the reservoir and the valve, can be manufactured with more labor-intensive methods like machining, cutting and

welding. These methods are still fairly expensive but more suited for smaller series and does not require the same high investment cost as injection molding since no special tools needs to be developed.
The cost of the current used 3-way valve is around 2000 SEK and the price for the other premade side-sliding valve is around 5000 SEK. It is likely that a better price can be obtained when the purchased batch size is increased but the sliding valve will still be expensive compared to the existing. An estimation of the cost, according to Hagall Group, for the self-made valve will likely be around 5000-6000 SEK per unit that also is more expensive than current valve. The uniqueness and the expected performance of self-made valve are not superior enough to motivate a cost increase of that amount. And since the part is meant to be a permanent installation and specifically design for this purpose it is hard for the company to create an aftermarket for the product. Based in these obtained price information the final recommendation of valve will fall on the current 3-way valve. This valve should be installed with a turning actuator so that the direction can be changed automatically. This solution might be a bit harder to place and require a bit more space but this trade-off is still not sufficient to motivate another more expensive choice. The market price for actuators varies depending on size, effect and durability but for this application the cost is estimated to around 1000-2000 SEK, the cost is based on looking on different models and consulting Hagall Group.

In order to significantly reduce the size of the device, a new reservoir had to be designed. The function of the reservoir is unique and similar products that could replace it don't exist, at least not to the extent that the research has revealed. One possible solution was to replace the reservoir with a hose but which revealed to be both less space efficient and more expensive than a "box". As a step towards developing a new prototype, PExA AB decided that a prototype of the new reservoir should be manufactured. The reservoir was manufacture by Hagall Group to a price of 6000 SEK and will be manufactured in stainless sheet metal parts that are welded together. Since it was the first time it was manufactured and it was a prototype, the price is viewed to be more expensive than for a commercial version. This means that it is likely that the price will drop both due to "learning by doing" and to a quantity discount. But 6000 SEK is still, compared to the previous reservoir that cost around 10 000 SEK, a significant cost decrease and the new reservoir is viewed a key factor for the decreased volume which is crucial performance wise.

8. REVIEW

This chapter contains discussion, recommendations and conclusions. The discussion section will provide the authors view of the project and discuss different aspects that have affected the outcome. The recommendation section will contain recommended further action for the company and the product that hasn't been covered by the project. The final section will link the goal against the outcome and provide conclusions of what has been achieved.

8.1 Discussion

The methods that has been used in this project are methods that a fairly common and taught at Product Development department in Chalmers University of Technology. But even if the method on paper look pretty straightforward there lays many challenges in translate it on a particular project.

In almost every project, whether it is a product development project or a completely different project, it's impossible to fully address all stakeholders' needs. This especially is the case in an interdisciplinary area where engineering science meets medical science. Doctors and medical staff naturally tend to turn their focus on the wellbeing of the patients. For them it is important that the procedure is quick, comfortable and afflicts no pain for the patient. In engineering the focus tends to be more towards the functionality and performance of the product and things such as comfort for patients and users tends to be secondary. On top off this there is always a management that has a more economical interest and a budget to follow. There has been a challenge to balance performance and functionality combined with the patient and user needs with respect to an economic feasibility of the solutions in this project. There has been a struggle dealing with contradictive requirements from stakeholders. Specially the demands of reduce the losses of particle and increase patient comfort where a comfortable mask or a longer arm solution could affect the particle generation negative. Since the PExA instrument is planned to first be used as a research instrument one can argue that performance and functionality might weigh heavier than patient and user comfort.

It is often challenging to set a reasonable scope in beginnings of projects and estimate necessary efforts to meet targets. In retrospective the scope for this project might have been too optimistic and the scale of the project underestimated. As the project preceded the complexity and the scale of the project was revealed. This resulted in a revision by removing the heating solution of the device from the scope. Even with a revised version the scope the size of the project was too big to fit in a 30 credit master thesis. This led to a lack of probing in the different solutions and difficulties in developing detailed solutions. For example, solutions for connecting all the parts have been poorly investigated. A more reasonable scope of the project would have been to only focus on a single function or part of the device such as the arm-solution. This area itself would have been challenging enough to be a master thesis with its different parts and functions, not to mention all the perceived problems that are related to it. Even though we believe that the project was a success on many levels and many good and useful results was obtained even if there is a sense of incompleteness of the recommended solutions.

Relating to this feeling of incompleteness is the fact that many of the test and investigations that were performed could not be fully understood due to a lack of knowledge in the medical area. The test that was made looked on particle generation and not on what type of particle that was generated which is equally interesting. Maybe this thesis could have been an interdisciplinary project consisting of an engineer and a bio-analyst and by so be able to achieve a deeper understanding of the results. To be able to deal in some way with this uncertainty a constant dialog with scientist and bio-analysts has been kept in order to check the validity of the results and methods. There have been meetings when concepts have been discussed with every possible stakeholder so that things that are totally inconsiderably can be identified and feedback on progress obtained.

Another challenge for this thesis was the fact that most of the work was performed during the summer. During summer a lot of people leave for longer vacations and cannot be reached and if stand-ins exist they have insufficient knowledge to be able to offer support. This led to long response times from subcontractors and difficulties in obtaining help from knowledgeable people when needed. To not lose too much time some decisions had to be made on a very little knowledge base. But to do the thesis during the summer was the premises and the difficulties with this were also expected. To deal with this, the time plan was designed so that process steps which requires a lot of contact or that was dependent on certain people was carefully placed to minimize the impact of peoples vacations. Good communication and planning has been crucial for the success in this project.

8.2 Recommendation

As in many projects, especially in academically projects the studies ends with recommendation of further studies, which is the case also the this time. The PExA instrument still has a long journey before it can be used in different hospitals around the world, making a difference in people's life. The aim is now to produce a research instrument that can help scientist around the globe identify markers for specific deceases. We believe that this master thesis has helped PExA instrument to get closer to that goal but we also believe that there is still some issues that needs to be further addressed and investigated. Therefore will a few recommendations be proposed.

For further development of the chosen concept it is recommended for the company to work closely with a detail manufacturer that can help produce some more prototypes that can be tested and evaluated. The implementation of new components will probably require some time in validating the functionality before it is fully safe to use.

The stand is something that has to be developed in consideration to external design together with the finishing look of the PExA instrument. This study has only provided a functional concept for this solution. The external design is viewed as important for the whole visual impression of the product and is therefore recommended to have a coherent design with the rest of the product.

The development of special interfaces between parts is also something that is recommended. This means that in order to prevent the buyer from usage of other

parts not supplied by PExA such as mouthpiece or 3-way check valves, it is important to develop non-standardized dimensioned interfaces so that only parts supplied by PExA would fit. This is important partly because the use of other parts could lower the profitability but also risk improper function of the instrument that could affect the result.

We believe that it is highly interesting to further try to investigate the possibilities to implement a changed breathing pattern. This creates the possibility for the test-subject to continue breathing into the instrument during the whole sessions without closing and opening the valve between manoeuvres. This could lower the complexity of the instrument and simplify the procedure.

The next task for the PExA instrument is to try to identify particle markers that can be connected with different diseases. Therefore is it recommended to have a more performance-oriented view of the instrument. The ability to control parameters and to have a high precision is important in a research stage so that results can be trustworthy and obtained quick. As a future role within the medical industry when most parameters are known, the focus should shift from performance view to a more patient oriented view.

The development of the test substrate-membrane couldn't be covered within the given time frame of the master thesis. But it is believed that this substrate-membrane holds great possibilities to be developed into a single-use component that is easier to handle for operators. This would also help improve the possibility to increase the profitability on an aftermarket.

8.3 Conclusions

Looking back to the previous version of PExA a lot has improved. The implementation of the new system led to the elimination of big, bulky and expensive parts, resulting in a device that weighs less, require less space and costs less. This is an achievement by itself that really opens the possibilities for a new PExA device that is smaller and easier to handle. One of the goals with the project was to identify and develop parts for single use so that PExA AB could be profitable on an aftermarket. Both the mouthpiece and the 3-way check valve are believed to be two suitable products for this use and not only can they contribute to an increased profit but also to a safer sampling procedure for the patient. By having single use products one can better assure that the parts are clean and correctly assembled.

The project has also resulted in a detailed requirement specification. These requirements are based on data that has been collected through many different interviews with stakeholders and through many hours of testing. This requirement specification can be used as a support for further development and research where many important aspect of product performance has been identified.

Around the method and the way the particles are generated lies a degree of uncertainty. Scientists can't really give a clear answer on what's affecting the particle generation, only that the current method works with current equipment. Since the connection between certain particle patterns and diseases haven't been determined, the scientist are eager that as much as possible of particles are generated so that no

pattern can remain undetected. This means that bigger changes to parts such as the mouthpiece could affect the types of particles that are generated and lead to that some particles could be lost during sampling. Though with that said, keep in mind that this can neither be confirmed nor denied. These uncertainties have affected the development. If these uncertainties could be eliminated, the use of facial mask could be implemented which significantly would improve the comfort for the patient. The same goes for the ability of eliminating unnecessary parts. The need for a 3-way valve to control the flow direction between breathing manoeuvres could be removed or significantly simplified. This new method of diagnosing diseases has great potential but one could question its readiness. Investment in new technical solutions should maybe be put too side until key factors for the generation and performance are identified. It might be a good idea to keep it simple in the beginning since an increased product complexity could obstruct the analysing of the results.

Since PExA AB is a very small company in an early stage of its business the resources are limited. The first version of the PExA device looks like a typical prototype and doesn't give a very professional impression. This is a problem when the resources are scarce and one has to rely on already existing parts on the market. When taking different parts from different manufacturers and suppliers it is hard to achieve a cohesive design and impression of the device. To avoid this, it's believed that PExA AB should put a lot of focus on the finishing outer shell to achieve a design that is appealing for customers.

During this development little aspects has been paid to environmental aspects. But relating to the fact that number of parts has been reduced and the size been reduced, the use of energy consumption for heating of the instrument is lowered. But one can question the use of single-use components as environmental friendly when it leads to an increased consumption of material and production energy, but this is something that the company themselves has to consider and compare to their policies.

REFERENCES

[1] GU Holding, 2012-05-21, PExA-Affärsprojekt http://holding.gu.se/V%C3%A5ra+bolag/pexa/, Retrieved 2014-06-03.

[2] GU Holding, 2012-05-21, PExA-Business Project, http://holding.gu.se/english/Portfolio/pexa/, Retrieved 2014-06-03.

[3] McQuarrie, E. 2005. The market research toolbox. 2. Edition. London. SAGE Publications, Inc.

[4] Karlsson, MariAnne; professor at Product and Production Development, Chalmers University of Technology. Lecture 131129 (data collection methods)

[5] Ulrich, K. T., Eppinger, S. D. (2000) *Product Design and Development*, 2nd edition, McGraw-Hill, Boston

[6] Pahl, G., Beitz, W. (1995) *Engineering Design*, 2nd edition, Springer-Verlag, London

[7] Pugh, S. (1990) *Total Design*, Addison-Wesley, Wokingham, England

[8] Johannesson, Hans; Professor Production Development, Chalmers University of Technology. Lecture 140120 – SysDesOverwiew

[9] Zwicky, F. (1966-1971) *Entdecken, Erfinden, Forschen im Morphologischen Weltbild*, Droemer-Knaur, München

(9] Maylor, Harvey, Project management, Pearson Education Limited 1996, 4th Edition, 2010

[10] Kesselring, F. (1951) *Bewertung von Konstruktionen, ein Mittel zur Steuerung von Konstruktionsarbeit*, VDI-Verlag, Düsseldorf

[11] Ashby, Michael,. Shercliff, Hugh and Cebon, David. Materials – engineering, science, processing and design, Butterworth-Heinemann 2010, 2nd edition

[12] Anna Bredberg, figure of PExA 1.0

[13] Grimm Catalog – Indore air monitoring (2011)

APPENDIX

APPENDIX A. INTERVIEW GUIDE

Intervjuguide
Största användarna

- En presentation om oss
- Varför vi gör en intervju – Examensarbete, Chalmers
- Vårt mål, kravspecifikation

[ ]Vad har du för bakgrund?
… [ ]

Jämförelse med andra produkter

[ ] Kan du jämföra PExA instrumentet med andra instrument som du använder dig av?
{ testtid, ergonomi under testtagingen,}

Erfarenheter med PExA som produkt

[ ] Hur längre har du jobbat med PExA?

[ ] Hur ofta använder du den?

[ ] Vad gillar du med den nuvarande produkten?

[ ] Vad gillar du inte med den nuvarande produkten?

[ ] Vilka förbättringar skulle du göra på produkten?

[ ] Kan du demonstrera när du använder den?
… [ ] Vad är din roll vid testtagningen?

PExA i framtiden

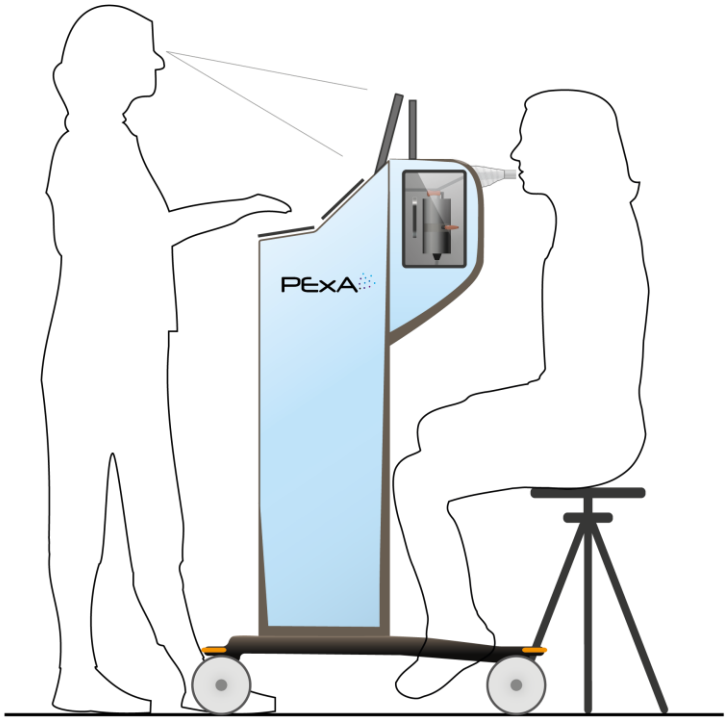
[ ] Hur ser PExA instrumentet ut i framtiden i bästa fall?
… [ ] Storlek, höjd – bredd
… [ ] Förflyttningsbarhet
… [ ] Integrerad data, extern data
… [ ] Munstycke
… [ ] Ergonomi

[ ] Kan du rangordna förbättringarna? Vad är viktigast för dig?

[ ] Vad är din roll vid testtagningen i framtiden?

[ ] Vad är dina förhoppningar på PExA i framtiden?

[ ] Vad tycker du om detta design förslaget? Vad gillar du/ Vad gillar du inte?



Epilog
Vi kommer använda datan för att indikera viktiga faktorer med Venturs produkter och sedan applicera detta för att utveckla produkten
Det här är slutet på intervjun

APPENDIX B. INTERVIEWS

Intervju med Annika – 23/5-2014

Vad har du för bakgrund?
Jag är sjuksköterska. Innan dess har jag jobbat inom företagshälsovården och på Sahlgrenska med hjärtinfarkter i en herrans massa år.

Hur läge har du jobbat med PExA?
Kanske i 4 år.

Hur ofta använder du PExA?
Det sista året har jag inte använt den så himla mycket faktiskt. För mig går det lite i shok när vi har olika projekt. Nu var det nästan ett år sedan som jag körde mycket. Nu ska jag köra ganska mycket efter den här intervjun.

Du kör den när det är något projekt?
Yes, det gör jag.

Vad gillar du med den nuvarande produkten?
Men själva den. Vad gillar jag med den… Den är lugnare nu efter pumpen och lite mer behändig nu än den förra men allt går att utveckla.

Vad gillar du inte med den?
Då är det ju den här ventilen som man ska vrida. När man blir lite äldre och får lite besvär i fingrarna som jag har kan det vara lite besvärligt med den ibland. Då tänker jag att det måste man ju kunna lösa på något bättre sätt genom att kanske trycka på någon knapp så rör sig ventilen.
Sedan är det ju den där armen som är rätt besvärlig. Den hänger konstigt. Måste ju gå att göra något bättre med den. Sedan hade det varit bra om den var höj och sänkbar men jag tror inte att det går faktiskt. Vi är ju olika långa….

Vilka förbättringar skulle du vilja göra?
Man vill ju helst att den inte ska låta så mycket. Man blir trött av allt buller.
Sedan är programmet rörigt men det håller dem ju på att förbättra. Och sedan är det du ventilen som är jobbig ibland.

Storleken?
Om den kunde bli lite mindre. Men man vet ju hur det är. Vi hade en annan maskin som hette kväveoxid som var stor innan och är mycket mindre nu. Man förstår ju att det är såhär det måste gå till.

Hur ser du instrumentet om två år i bästa fall?
Ja, då tror jag att det är lite mindre och mera lätthanterligt så att man lätt kan flytta den. När man kommer in med sina försökspersoner måste man nästan uräkta apparaten. Den ser ju ut som ett ”hemmabygge”. Man hoppas ju att den ska se lite proffsigare ut. ”Det här är en metodutveckling” får man säga för att dom inte ska bli rädda.

Sedan är det ju det här med rengöringen. Jag brukar alltid vara väldigt noga med att de ska se att dem inte har andats i samma munstycke som andra. Jag sätter alltid på nytt inför försökspersonen så att dem vet att munstycket är rent.
Sedan är jag tydlig med att man bara andas ut i instrumentet och inte in. Vissa kan ju undra vad dom andas in annars…
Vissa kollegor monterar munstycket fel och därför vill jag alltid montera munstycket när jag håller i testet.
Även om det är en metodutveckling så vill man ju inte att hanteringen ska vara oproffsig och det är oproffsigt att montera ett valv fel.

Man skulle ju vilja att det var ett engångsmunstycke som man fick slänga. För det är ju rätt mycket pyssel med munstyckena.

Hur ser du på om datorn skulle vara integrerad?
Ja, det skulle ju vara bra. Det viktiga är att vi och försökspersonen kan se datorn. Försökspersonen kan ofta tycka att det är roligt att se.

Vad tycker du om detta designförslag?
Det ser… jag tänker på andra apparater jag har och då vill jag vara bredvid patienten. Man vill inte stå framför när dom blåser ut och få allt på sig. Men här släpper dom ju inte munstycket…

Om jag ser ordentligt så kanske. Försökspersonen kanske får ha en hög pall så att man kan se.

Jag kanske jag gå runt och instruera och sedan gå tillbaka. Man kollar ju på om dem andas ut tillräckligt. Jag undrar om jag inte tycker att det är mer behagligt att stå bredvid ändå. Man ser bättre. Känns trevligare att stå bredvid.

Intervju med Emilia – 7/4-2014

Hur läge har du jobbat med PExA?
Våren 2011 började jag. Så sedan dess med ett uppehåll på ett halvår.
Håller på med mer än bara PExA?
Ja, med lite andra lungfunktionsstudier också men det är mycket PExA som man utgår ifrån.
Och du var biomedicinskanalytiker?
Ja precis!
Hur ofta jobbar du med PExA om dagen? Eller i veckan?
Varje dag mer eller minde och olika angrepps sett.
Har du konstant patientkontakt?
Nej, jag har inte konstant patientkontakt. Några dagar i veckan. Jag tar hand om allt material. Analyserar allt material utifrån den mjukvaran som kommer ut. Med det är mycket pill, mer än vad man tänker sig. Hålla koll på alla apparater som är här och där.
Har du din dator inkopplad?
Nej, den är stationär också tar man med sig filerna och sätter sig någon annan stans och arbetar analysen sedan.
Vad gillar du med den nuvarande produkten?
Det är ett nytänkt. Längre insamlings tid men det är en patientvänlig metod. Inget invasivt ingrepp, de är det som är hela tanken. Att hitta ett alternativ till de invasiva metoderna.
Finns det något som du gillar att instrument har? Något som inte skall tas bort?
Det är ett öppet system så man kan felsöka själv. Man kan hjälpa andra att felsöka andra PExA utrustningar på andra orter. Man kan följa hela flödet.
Vad är inte lika bra?
Insamlingstiden som den har men det hänger ju ihop med så mycket annat. Den kemiska analysen som är svår att styra över. Man kan tänka sig att om man skulle optimera insamlingen genom att inte förlora så mycket material på vägen så skulle det vara väldigt bra.
Ni misstänker att det försvinner massa material på vägen?
Ja, det vet man egentligen inte men man kan tänka sig att det gör det. Den kanske är optimal. Man är inte säker på att man kan samla in så mycket mer material men en ny lösning heller.
Men i och med detta är det ju väldigt mycket ergonomi också. Man vill ju kunna sitta så bekvämt som möjligt och i och med att apparaten är så hög som den är kräver det ju att man behöver ha en stol som man kan justera väldigt mycket beroende på person.
Något mer med ergonomin?
Vissa kanske behöver sitta och dingla med benen.

Vi har hört att munstycket är en stor nackdel (hela armen).
Nä precis, detta beror på att man är långt ifrån munstycket. Så man kan tänka sig att man skulle kunna skippa en bra bit av munstycket om man kom närmre insamlingsplatsen.

Inget annat som är jobbigt?

På samma sätt som det är bra med att allt är manuellt så är det också jobbigt. Den tänker ingenting själv alls. Man vill inte att allt ska skötas av sig själv. När maskiner gör det så kan det också ofta bli fel. Utan att man automatiserar vissa delar i alla fall. Det är jobbigt att vara uppe i ansikte på folk när man ska vrida på ventilen.

Kan man jämföra PExA med något annat instrument?

Skillnaden från PExA och andra är att man oftast bara gör en manöver och då är det inte lika viktigt med ergonomin. Oftast så sitter man vid ett bord och gör testet då. Sitter man lägre så är det oftast att man gör vanliga andetag. Andra maskiner kräver inte lika mycket ergonomitänkt helt enkelt.

Det finns ingen läsning som något annat instrument har som du tror skulle passa för PExA?

Nä, jag tror att man skulle behöva plocka lite här och där.

Kan du ge exempel?

Det är ju de här automatiserade lösningarna som att man har en sensor som känner av ett vist flöde och då öppnas eller stängs en ventil. Det finns säkert flera.

Hur ser PExA instrumentet ut i framtiden i bästa fall?

Ja, då tänker jag att det är en liten apparat. I storleken att man bara håller den i handen och att det räcker med ett utandningsprov. Antingen att det kan analyseras i den eller att man enkelt kan ta den och analysera senare. Men att man gör allt i en utandning. Väldigt lite apparatur.

Hur ser du PExA om 2 år i bästa fall?

Då tänker jag att det är en apparat som står på ett bord. Så att man sitter vid ett bord och att det är ett mer rörligt munstycke som man andas i.

Vad tror du behöver hända om man använder den i en sjukhusmiljö?

Allting måste vara mycket mer automatiserat för att i en sjukhusmiljö så vill man inte ha alla dessa manuella delarna. Allt ska vara väldigt mycket smidigare. Den måste ur en hygiensynpunkt vara idiotsäker. Den får inte heller vara för otymplig. Den måste vara på hjul men man kan också ha en på ett bord som är på hjul. Att den kan vara flytt bar

För er är inte det flyttbara något problem?

Alla är ju på hjul och alla är ju flyttbara.

Med bord tänker du att det är viktigt att komma under?

Ja, att man har markkontakt.

Vad är viktigt när man interagerar med laptopen?

Att den är i en ergonomisk höjd. Alla flyttar runt den. Den kan lika gärna vara integrerar. Men skärmen måste ju sitta på rätt ställe.

Ser du några fördelar med att ha den integrerad?

Färre lösa delar

Man vill inte kunna koppla in sin egen dator?

Det är lätt att flytta över sina egna filer. Man analyserar gärna på ett annat ställe.

Om du får välja en förbättring?

Storleken, den behöver hamna på ett bord.

Vad tycker du om detta design förslaget?

Jag tänker att man gärna sitt bredvid personen och att man inte har markkontakt. Den skulle vara vid ett bord egentligen. Har inte hänt så mycket, den har bara blivit snyggare.

Varför vill man sitta bredvid?
Man jobbar ofta så. Man är i höjd med dem så att man fysisk kan vara med och instruera. Inte bara att man stå på varsin sida. Den är för hög. Alla är vlidigt olika och det blir väldigt olika när man ska ställa in en stol.

Ska man emot sjukvården så ska man siktat på att göra så små och smidiga apparater som möjligt.

Intervju med Helen – 23/5-2014

Vad har du för bakgrund?
Jag är biomedicinsk analytiker och har gått den här inriktning på utbildning som är fysiologi då. Det finns två inriktningar på utbildningen och jag har gått fysiologi inriktning och då pluggar man mycket om diagnostiska instrument och så. Jag har jobbat i fem år och höll på med lite andra grejer innan jag utbildade mig till detta. När jag var färdig hamnade jag på en annan arbetsplats och där jobbade jag jättemycket med olika lungfunktionstester av olika slag och då bli man ju lite bekant med alla apparater man använder inom det här yrket och så. Sedan har jag varit här i nästan 1,5 år på arbets- och miljömedicin..

Hur läge har du jobbat med PExA?
1,5 år, februari 2013. Innan dess hade jag inte hör talat om detta alls.

Hur ofta använder du PExA?
Fyra dagar i veckan sedan jag började.

Håller du på med PExA hela dagarna då?
Nej utan det är en del i den undersökningsstudien som jag håller på med nu. Vi kör en jättestor befolkningsstudie på Östra sjukhuset. PEx är en del i många undersökningar som vi gör.

Vad gillar du med den nuvarande produkten?
Tyckte att det var väldigt svårt att lära sig i början men det tror jag alla tycker. Vad ska jag säja att jag gillar med instrumentet nu när jag kan det?
Jättesvårt, det finns mycket som jag inte gillar mad instrumentet om man säger så

Är det någonting som du inte vill ska tas bort?
Nej, det kan jag ärlig säga att det är de inte. Jag har massa förslag på vad man kan gör istället.
När man står och kör deltagare i studien så tänker man ju på att det hade varit bättre om datorn var placerad så eller om armen…
Jag har ingenting som jag tycker måste finnas kvar. Jag tycker att det är rätt obekvämt att köra PExA insamling faktiskt.

Vilka förbättringar skulle du då vilja göra?
Jag skulle vilja förbättra det här med datorns placering t.ex. och den här armen.

Man står ju på höger sida och vrider vredet på armen och så skulle jag helst vilja ha datorn på samma sida så att säga. Jag har prövat att ganska mycket nu men då blir de en konstig vridning på nacken. Så nu har jag fått sätta tillbaka datorn på andra sidan men så tycker hag att det är ganska jobbigt att se, datorn kommer för långt bort. Jag skulle vilja ha datorn på samma sida och då har jag tänkt mig att man kanske kan ha något slags bord som går ut ifrån instrumentet och att bordet kanske också kunde vara höj och sänkbart.

Om man inte hade behövt att göra manövern med valvet så hade det inte blivit lika jobbigt kanske?!
Då hade det inte alls blivit lika jobbigt för då får man ju inte den vridningen av nacken.

H

Datorn är egentligen placerad bra om man inte hade behövt att vrida valvet på armen?!
Ja, om man bara kan stå och hålla koll.

Förbättringarna på armen?
Jag tänker på att det skulle vara bra om man lättare kunde höja och sänka armen. Nu kan man höja och sänka stolen om man säger så men det är ett väldigt bökande när man ska ställa in så att deltagaren sitter bra. Det är ju superviktigt att deltagaren sitter bra.
När man har ställt in stolen 4-5 gånger så ska man ställa in armen som sitter i ett snöre. Snöret trillar ner m.m. – jag önskar att det hade varit en mycket enklare konstruktion.

Hur skulle du vilja att PExA ser ut om två år?
Dela att man kanske slapp vredet men framförallt att det hade varit ett mera portabelt instrument. Nu är det ganska bökigt.
Ljudvolymen också, när man står och jobbar med det mycket som man gör så är ljudet väldigt tröttande.

Storleken?
Att den blir mindre hade varit bra och vredet hade underlättat jättemycket. Väldigt jobbigt för armarna.
För att summera: Ett mindre instrument, slippa vredet och att det inte brusar så mycket.

Vad menar du med att den ska vara portabel? Hur ofta flyttas den?
Om någon säger att dom behöver ett instrument så ska den vara lätt att flytta till en annan avdelning.

Vad tycker du om att datorn skulle vara integrerad?
Det kan lika gärna bli en nackdel som en fördel. Det viktigaste är att man får en bekväm arbetsställning.

Vad tycker du om detta designförslag?
Det ser väldigt smidigt ut med hjulen. Det som jag tänker på direkt när jag ser det är att man kanske inte har riktigt koll på försökspersonen. För försökspersonen sitter på andra sidan. Man måste ju hålla koll på försökspersonen så att den har munstycket rätt i munnen och att man gör andningsmanövern rätt. Det kan man ju inte hålla lika bra koll på om man står på andra sidan.
Man behöver däremot inte hålla koll på datorn hela tiden så man skulle ju kunna gå runt och kolla till försökspersonen emellanåt.

Storleksmässigt då?
Då ser den ju jättebra ut. Den ser ju smidig ut.
Den ser lätt och smidig ut men jag tycker att man behöver ha kontakt med försökspersonen och så är inte förslaget så bra.

Intervju med Marianne – 23/5-2014

Vad har du för bakgrund?
Jag är biomedicinskanalytiker. Sedan har jag jobbat som mät ingenjör här i väldigt många år.

Hur länge har du jobbat med PExA?
Jag har varit med från början…

Hur ofta använde du PExA idag?
Det varierar ju. Dels jobbar jag med studier och samlar in och sedan jobbar jag ju med att utveckla och testa olika saker på instrumentet. Så det varierar mycket över tid. Men jag använder ju den i snitt flera dagar i veckan.

Vad gillar du med den nuvarande produkten?
Jag tycker det är ganska kul att kunna se hur den fungerar…

Vilka förbättringar skulle du vilja göra på PExA?
Absolut så vill jag ha ett automatisk vred. Idag måste man ha ett tvåhandsgrepp. Ett som håller i armen och ett som vrider på valvet. Munstycket slår emot tänderna på försökspersonen, vilket är väldigt otrevligt.
Man skulle kunna vilja sitta vid instrumentet när man är den som sköter instrumentet. Det är jobbigt för försökspersonen att sitta så låst.

Jag är väldigt positiv till den här lådan som Svante och Evert håller på att utveckla. Jag tänker mig en låda som man kan ha på ett skrivbord och sitta framför, båda två. Man jag sitta jämte varandra.

Sedan pratar man om förluster i tre-vägsventilerna som vi måste titta på. Det måste också utvecklas. Kan man få bort källan till förlusterna så behöver inte försökspersonen sitta så länge. Det ska ju gå och använda för sjuka personer också och så är det väldigt viktigt att man inte ska behöva sitta så länge.

Hur ser PExA instrumentet ut om två år?
Om två år har vi en låda som står på ett skrivbord och försökspersonen och handledaren sitter jämte varandra. Båda ska kunna se skärmen. Låter väldigt tjusigt att ha en låda som är helt tät och man behöver inte ha tryckluft och befuktning. Vilket innebär att det blir många färre steg. Temperaturen är ju väldigt viktigt för att inte få kondens. Vissa har haft problem med att befruktaren piper vilket gör en tokig.

Hur flyttbar behöver den vara?
Väldigt flyttbar

Hur ofta flyttas den?
Jättejobbigt att flytta den till Sahlgrenska. Hjulen skramlar sönder.
Nere på andningsfys flyttas dom dagligen men den är jobbig att flytta.
Hade det varit en låda som står på ett rullbord och att man inte behöver tryckluft så hade man kunnat flytta den från olika rum. Den skulle vara mycket mer flexibel.

J

På sjukhus har man ju problem med att hitta lediga rum. Hade den då varit flexibel och om man inte hade behövt använda tryckluft så hade man ju kunnat flytta den till olika rum där det var ledigt. Så ser ju tillvaron ut på sjukhus.

Vad tycker du om att datorn skulle kunna vara integrerad?
Jag vet inte… Kanske är en fördel…

Vad tycker du om detta design förslaget?
Jag tror egentligen att jag tycker att det är mycket bättre att man sitter sida vid sida än att man står framför så. Hellre att man har en burk på en bänk på en rullvagn. Hellre de än i den formen.

APPENDIX C. OBSERVATIONS

Participating observations

Test PExA
Address:
What type of observation: Participating in a test
Description: We tested PExA in order to get a better view and a deeper understanding of what patients experience when they participates in the tests. First you need to adjust the chair. The machine is quit long and the nozzle is placed at the top of the machine. Second you get instructions of how you are supposed to breath:

1. Exhale as much as you can from one ordinary breath, when you cannot exhale anymore (when your lungs are empty) you give a sign. You should now hold your breath in 3 seconds, we count the seconds for you.
2. Inhale as much and as fast as you can
3. Exhale slowly until almost al air is out, but you not force the air out in the end
4. Breath normally

You are ready to star when you have a nose clip on your nose and when you have placed the nozzle in your mouth. You can get different nozzles. We got the ones that look like those you have when snorkeling. We where told that those are good for older patient that may have problem with holding the other nozzles tight enough. You start with normal breathing for 2 minutes. The air you inhale goes through a filter in order to "clean" you lungs before starting.
Meanwhile you perform the procedure described above, the operator stands next beside you and reminds and instructs you of how to breath. Their job is to analyze how much particles they are getting from each patient and calculate how long time each patient needs to sit. It is usually between 20-30 minutes. They also need to open and close a valve in the nozzle in order to direct the air. Their instructions are:

1. Open the valve when the patient holds their breath in 3 seconds, or when the patient inhales a deep breath.
2. Close the valve when the patient have exhaled almost al the air, at the help line of 50 ml (it is only during exhaling after breath holding that we collect the particles)

You repeat the procedure until the operator has got the right amount of particles. Each patient has different amounts of particles and therefore.

Our observations: To start with the air that you inhaled was quite dry. There was no resistant when breathing but it was a bit uncomfortable for your throat with the dry air. The nozzle we got made you produce quite a lot of saliva and it was quite bothersome the jaws after a while. We sat for like 5 minutes each and it was quite nice to get a break at that point. It is not the most comfortable test and it requires a lot of effort from the patient, especially if they have to do it for 30 minutes. But compared to the invasive methods you would choose PExA easily.

Direct observations

Observe when an operator operates with PExA during a test
Address:
What type of observation: Observe the operations during a test
Description: Meanwhile one of us tested PExA the other one observed how the operator performed the test. Their job during the test is described in observation 1. As an operator of PExA you constantly need to inform the patients of how to breath. Even if it was possible you would not be able to just give the patient instructions and then leave them to it, the procedure is to complex. The operator stands beside the patient, in order to instruct and to be able to close and open the valve on the nozzle, and beside the computer, in order to observe how much particles they get. With other world they are quite active during tests.

Direct observations – customer visits

After the interview we asked everyone if they could show us how they start PExA and if they could describe the difficult parts when preparing for a patient and where it could go wrong. Everyone had an instruction paper of how to start it and how to prepare for a patient. These instructions can be found in appendix X.

Emilia Viklund
You need to turn on PExA 30 minutes before the test. This is due to the fact that it needs to reach 37 degrees inside. The first thing to do is to prepare the impactor with a new filter that should capture the particles. It is important that you do this carefully, you do not want to strap other things. Place the imapactor inside and turn on every unit inside. When you set the fluxes you are able to see it something is wrong. There are some things that can fuss from time to time but with the open system you can usually find the problem yourself. For example you can follow the flow and discover if there is a leakage anywhere.
When you assemble the nozzle you can do a number of mistakes. For example it Is possible to mount the valves it the opposite direction or mount the nozzle on the arm in the wrong directions. There are arrows that describe the directions but they are quite hard to se.
After the test it is time to prick out the filter from the impactor. You need to handle the test carefully, if something goes wrong the test needs to be retaken.

APPENDIX D. KJ

Size	Breathing tube/arm with air valve
Man vill ju kunna sitta så bekvämt som möjligt och i och med att apparaten är så hög som den är kräver det ju att man behöver ha en stol som man kan justera väldigt mycket beroende på person.	Man är långt ifrån munstycket. Man kan tänka sig att man skulle kunna skippa en bra bit av munstycket om man kom närmre insamlingsplatsen.
Vissa kanske behöver sitta och dingla med benen.	Det är jobbigt att vara uppe i ansikte på folk när man ska vrida på ventilen.
The most important thing is the size, it needs to be placed on a table.	
It is to high	
Jag tänker att man gärna sitter bredvid personen	
Man står ju på höger sida och vrider vredet på armen och då skulle jag helst vilja ha datorn på samma sida så att säga.	
	Jag tänker på att det skulle vara bra om man lättare kunde höja och sänka armen.
Att den blir mindre hade varit bra och att slippa vredet hade underlättat jättemycket. Väldigt jobbigt för armarna.	
Man behöver ha kontakt med försökspersonen	
	Absolut så vill jag ha ett automatisk vred. Idag måste man ha ett tvåhandsgrepp. Ett som håller i armen och ett som vrider på valvet. Munstycket slår emot tänderna på försökspersonen, vilket är väldigt otrevligt.
Man skulle kunna vilja sitta vid instrumentet när man är den som sköter instrumentet.	Den här ventilen som man ska vrida. När man blir lite äldre och får lite besvär i fingrarna som jag har kan det vara lite besvärligt med den ibland. Då tänker jag att det måste man ju kunna lösa på något bättre sätt genom att kanske trycka på någon knapp så rör sig ventilen. Sedan är det ju den där armen som är rätt besvärlig. Den hänger konstigt. Måste ju gå att göra något bättre med den.
Jag tänker mig en låda som man kan ha på ett skrivbord och sitta framför, båda två. Man jag sitta jämte varandra.	Vissa kollegor monterar munstycket fel och därför vill jag alltid montera munstycket själv när jag håller i testet.
Den skulle behöva bli lite mindre	The instrument is to big and the ergonomic aspect for both the patient and the operator is not the best one.
	You need to have easy access to the computer and the valve at the same time

Hygiene (Modularization)	Loss of particles	Sound
Sedan är det ju det här med rengöringen. Jag brukar alltid vara väldigt noga med att de ska se att dom inte har andats i samma munstycke som andra. Jag sätter alltid på nytt inför försökspersonen så att dem vet att munstycket är rent.	Man kan tänka sig att om man skulle optimera insamlingen genom att inte förlora så mycket material på vägen så skulle det vara väldigt bra.	Man vill ju helst att den inte ska låta så mycket. Man blir trött av allt buller.
	Sedan pratar man om förluster i tre-vägsventilerna som vi måste titta på. Det måste också utvecklas. Kan man få bort källan till förlusterna så behöver inte försökspersonen sitta så länge. Det ska ju gå och användas för sjuka personer också och så är det väldigt viktigt att man inte ska behöva sitta så länge.	Ljudvolymen också, när man står och jobbar med det mycket som man gör så är ljudet väldigt tröttande.
	It is the ergonomic aspect and the time is what the patients think is the hardest.	
	The arm is rickety and you must screw on a valve located near the patient's mouth, risk of disturbing the sampling	
	It should be good to try to increase the amount of material you get	
	The method is time consuming, you might get tired	
	It takes long time to sample a particular amount of particles	
	The disadvantage is that it takes time to sample and some people might think that this is a hassle	

Low degree of Automatization	(Placering)
Den tänker ingenting själv alls. Man vill inte att allt ska skötas av sig själv. När maskiner gör det så kan det också ofta bli fel. Utan att man automatiserar vissa delar i alla fall.	Thing are placed on different sides, the operator needs to reach here and there, there is know logistic flow
The operator needs to choose which USB port to use, this doesn't happen automatically	The patient is instructed to look at a screen that isn't placed straight forward but a little a side; they have to turn their heads.
The method needs to become more self going and should not need as much support as it dose today	Man står ju på höger sida och vrider vredet på armen och så skulle jag helst vilja ha datorn på samma sida så att säga. Jag har prövat att ganska mycket nu men då blir de en konstig vridning på nacken
The process needs to be improved. It could be more automatized	Jag tänker att man gärna sitt bredvid personen
	Om två år har vi en låda som står på ett skrivbord och försökspersonen och handledaren sitter jämte varandra. Båda ska kunna se skärmen.
	Jag undrar om jag inte tycker att det är mer behagligt att stå bredvid ändå. Man ser bättre. Känns trevligare att stå bredvid.

	Interviews gathered first hand
	Interviews gathered second hand

APPENDIX E. REQUIREMENT SPECIFICATION

Requirement specification

#	R/W	Requirement	Justification	Measurement/Evaluation
Total solution				
Performance				
1.1	R	The solution should be able to sustain 37 °C (the same as exhaled air)	Allow for the particles to stay the same	YES/NO
1.2	R	The total solution should be able to sustain the same moist as exhaled air	Allow for the particles to stay the same	YES/NO
1.3	R	Be able to collect 160 nano-gram particles within 45 min	Allow to collect the sample as fast as possible	Particle test
1.4	W	Be able to collect 160 nano-gram particles within less than 45 min	Allow to collect the sample as fast as possible	Particle test
1.5	R	Be able to perform a test within 30 minutes after a test	Allow to perform the test many times in a row	YES/NO
1.6	W	Be able to perform a test within less than 3 minutes after a test	Allow to perform the test many times in a row	YES/NO
Ergonomics				
2.1	R	The operator should be able to be placed beside test person during test	Allow the operator to instruct during test	Physical test
2.2	W	The operator should be able to stand in one place during test	Allow the operator to concentrate on the patient during test	Physical test
2.3	W	The operator should be able to sit in one place during test	Allow the operator to be comfortable beside patient during test	Physical test
2.4	R	The computer should be placed at a reaching distance from the operator	Allow the operator to be at one place during test	Physical test
2.5	R	The operator should not require breaks	The test should not be longer than it already is	Physical test
2.6	R	The total solution should enable support for the feet	The test person should sit as comfortable as possible	Physical test
2.7	W	The test person should be able to see the computer	Gives the test person better understanding	Physical test
2.8	R	It should take no more than 4 minutes to adjust	Streamline test time	Physical test
2.9	W	It should take less than 2 minutes to adjust	Streamline test time	Physical test
2.10	R	The test person should not require a break within 4 min	Streamline test time	Physical test
2.11	W	Lower noise then current solution	The test should not be disturbed by the noise	Sound test
2.12	W	The test person should sit as close as possible to the nozzle	The arm-solution should be as short as possible	YES/NO
2.13	R	The total solution should be movable	Allow for one person to move it	YES/NO
Maintenance				
3.1	R	The total solution should work for at least 5 years	Ensure good quality	Quality evaluation
3.2	W	The total solution should work for more than 5 years	Ensure good quality	Quality evaluation
Cost				
4.1	R	Should be able to produce 50 per/year	Estimated sales per year	Manufacturing analysis
4.2	R	Should not cost more than 300 000 SEK to manufacture	Make a profit of 50 %	Cost analysis

4.3	W	Should not consist of more than current number of parts	Consist of as few parts as possible	Summarize
		Automatized		
5.1	R	Should not take longer than 30 min to start	Streamline test time	Physical test
5.2	W	Should take less than 30 min to start	Streamline test time	Physical test
5.3	W	Fewer steps during startup	Streamline test time	Physical test
		Reliability		
6.1	R	The procedure shouldn't endanger the test person safety	should be a very safe procedure	Test and verification
6.2	R	The procedure shouldn't endanger the operators safety	should be a very safe procedure	Test and verification
		Size		
7.1	R	The total solution should not be bigger than 370x420x1300 mm	The solution should be as small as possible	YES/NO
7.2	W	The total solution should be smaller than 370x420x1300 mm	The solution should be as small as possible	YES/NO
7.3	W	The total solution should not weigh more than 20 kg	Allow to carry the device	YES/NO
		Material		
8.1	R	The material of the total solution should be able to operate at 50 °C	It must work within the desired environment	Material evaluation
		Nozzle solution - Intake for exhaled air, provides clean particle free air and controls flow direction		
		Performance		
9.1	R	The inspired air should contain zero particles	No particles from the surrounding should be sampled	Physical test
9.2	W	Minimize the loss of particles	As few particles as possible should get caught on the way	Particle test
		Maintenance		
10.1	R	All parts should be changeable	Prevent others to get sick	Assembly analysis
10.2	W	All parts that could be contaminated should be changeable within 1 min	Prevent others to get sick, they have to be changed for every test	Assembly analysis
10.3	R	Should take 4 min to sterilize all parts that could be contaminated	They have to be changed for every test	Physical test
10.4	W	Should take no time to sterilize all parts that could be contaminated	They have to be changed for every test	Physical test
		Cost		
11.1	W	All parts that are contaminated should be able to be produced > 200t per/year	Ability to use only one time	Process evaluation
11.2	W	All parts that are contaminate should not cost more than 8 SEK to manufacture	Ability to use only one time	Process evaluation
		Size		
12.1	R	The nozzle solution should not be longer than 0.4 m	The nozzle solution should not be longer than the current	Physical test
12.2	W	The nozzle solution should be less than 0.3 m	Easier to sustain heat and moist	Physical test
		Ergonomic		
13.1	R	The test person should be able to take a break	Gives the test person the ability to rest	Physical test
13.2	W	The test person should be able to disconnect from PExA and still breath filtered air	Gives the test person the ability to rest the neck	Physical test

R

13.3	W	The test person should not require the nose clip	Make it as comfortable as possible for the test person	YES/NO
		Material		
14.1		The material of the nozzle solution should tolerate 37 °C	The sample should only contain particles from the lungs	Material evaluation
		Reliability		
15.1	R	The nozzle solution should prevent contamination from other test persons	Prevent others to get sick	Test and verification
15.2	R	Minimize the ability for human errors	Prevent others to get sick	Test and verification
		Assembly		
16.1	R	All parts that could be contaminate should take < 4 min to assemble	They have to be changed for every test	Physical test
16.2	W	All parts that could be contaminate should take less then < 2 min to assemble	They have to be changed for every test	Physical test
16.3	R	All parts that could be contaminate should be assembled in 7 number of steps	They have to be changed for every test	Physical test
16.4	W	All parts that could be contaminate should be assembled in less than 4 number of steps	They have to be changed for every test	Physical test
		Position in total solution		
17.1	R	The nozzle solution should be placed outside the total solution	Allow test person to easy reach the mouthpiece	YES/NO
17.2	R	The nozzle solution should be placed close to the impactor	Allow for the particles to stay the same	YES/NO
17.3	R	The nozzle solution should be placed close to the reservoir	Allow for the particles to stay the same	YES/NO
		Clean inhaled air (filter)		
		Performance		
18.1	R	Remove alien particles from inhaled air	Prevent outside particles to enter	Physical test
		Material		
19.1	R	The material should tolerate moist	It must work within the desired environment	Material evaluation
19.2	R	The inside material should release 0 g particles	No particles from the material should be sampled	Material evaluation
		Direct inhaled and exhaled air (3-way check valve)		
		Performance		
20.1	R	All particles should enter the second valve during exhalation	No air should leak out through the entrance of the first vault	Physical test
20.2	R	0 g particles should come from the valve during inhalation	No inhalation of air from PExA	Physical test
		Material		
21.1	R	The material should tolerate moist	It must work within the desired environment	Material evaluation
21.2	R	The inside material should release 0 g particles	No particles from the material should be sampled	Material evaluation

21.3	R	The material should be biocompatible	The sample should only contain particles from the lungs	Material evaluation
21.4	R	The material should tolerate 140 °C if not single use	Possibility to clean with heat	Material evaluation
		Exhale air (mouthpiece)		
		Ergonomic		
22.1	W	Should enable support for lips	Make it as comfortable as possible for the test person	Physical test
22.2	W	Minimize saliva	Prevent others to get sick	Physical test
22.3	W	Prevent dryness	Make it as comfortable as possible for the test person	Physical test
22.4	R	Should be suitable for different persons	Leak proof	Physical test
22.5	R	Should afflict as little pain as possible	Make it as comfortable as possible for the test person	Physical test
		Material		
23.1	R	The material should tolerate moist	It must work within the desired environment	Material evaluation
23.2	R	The inside material should release 0 g particles	No particles from the material should be sampled	Material evaluation
23.3	R	The material should tolerate 140 °C if not single use	Possibility to clean with heat (autoclave)	Material evaluation
23.4	R	The material must be approved for oral use	The nozzle should not be dangerous to have in your mouth	Material evaluation
		Direct exhaled air (3-way valve)		
		Performance		
24.1	R	Able to change the direction of exhaled air manually	Allow for exhaled air to be directed	Physical test
24.2	W	Able to change the direction of exhaled air automatically	Allow for exhaled air to be directed	Physical test
		Ergonomic		
25.1	W	Minimize operation with valve	Facilitate for the operator during test	Physical test
		Material		
26.1	R	The material should tolerate moist	It must work within the desired environment	Material evaluation
26.2	R	The inside material should release 0 g particles	No particles from the material should be sampled	Material evaluation
26.3	R	The material should be impact resistance	It must handling durability for the desired environment	Material evaluation
26.4	R	The smaller cylinder should be able to slide in the bigger one	Possibility to clean the reservoir with heat	Physical test
		Arm solution		
		Performance		
27.1	R	The arm should be flexible	Allow for easy adjustment	Physical test
27.2	W	The arm should be stable	Make it as comfortable as possible for the test person	Physical test

T

		Ergonomic		
28.1	R	It should take no more than 5 minutes to adjust	Streamline test time	Physical test
28.2	W	It should take less than 2 minutes to adjust	Streamline test time	Physical test
		Material		
29.1	R	The material should withstand moist	It must work within the desired environment	Material evaluation
29.2	R	The material should not contaminate sample	No particles from the material should be sampled	Material evaluation
		Reservoir - Storage for air		
		Performance		
30.1	R	The solution should prevent stagnation and create an even flow	Allow for the particles to stay the same	Physical test
30.2	R	The reservoir should not leak	No exhaled air may not disappear	Physical test
30.3	R	3 m< distance between inlet and outlet	Air from the inlet should not be mixed with air from the outlet	Physical test
		Maintenance		
31.1	R	Ability to change or clean the reservoir 2 times a year	To assure good hygiene	Assembly evaluation
		Cost		
32.1	R	The reservoir should be able to be produced > 50 per/year	One for each device plus one to replace if destroyed	Process evaluation
32.2	W	The reservoir should not cost more than 3000 SEK	The company needs to go with profit	Cost calculation
		Size		
33.1	R	The reservoir should have the volume of at least 5 L	It should be able to contain a big breath	Measure dimension
33.2	R	The reservoir should not be longer than 0.4 m	It should take as little space as possible	Measure dimension
33.3	R	The reservoir should not be wider than 0.005 m	It should take as little space as possible	Measure dimension
33.4	R	The reservoir should not be higher than 0.35 m	It should take as little space as possible	Measure dimension
		Material		
34.1	R	The material of the reservoir should not release particles	The sample should only contain particles from the lungs	Material evaluation
34.2	R	The material of the reservoir should tolerate 37 °C	It must work within the desired environment	Material evaluation
34.3	R	The material of the reservoir should tolerate moist	It must work within the desired environment	Material evaluation
34.4	R	The material should be rust and corrosion resistant	It must work within the desired environment	Material evaluation
34.5	R	The reservoir should tolerate 40 °C if not single use	Possibility to clean the reservoir with heat	Material evaluation

		Position in total solution		
35.1	R	Minimize distance to the impactor <0.10	Allow the particles to stay the same	Measure dimension
35.2	R	Should be placed close to one side of the shell	Easy access when cleaning or replacing it	Physical test
		Positioning and layout		
		Performance		
36.1	R	The total solution should be movable	Allow for one person to move it	YES/NO
		Size		
37.1	R	The total solution should not be bigger than 370x420x1300 mm	The solution should be as small as possible	YES/NO
37.2	W	The total solution should be smaller than 370x420x1300 mm	The solution should be as small as possible	YES/NO
37.3	W	The total solution should not weigh more than 20 kg	Allow to carry the device	YES/NO
		Material		
38.1	R	The material of the total solution should be able to operate at 37 °C	It must work within the desired environment	Material evaluation
38.2	R	The material should corrosion resistant	It must work within the desired environment	Material evaluation

APPENDIX F. ETTEPLAN

Summery

A workshop day was held in Halmstad 2014-06-10 with PEXA and Etteplan. The objective was to find new solutions & possible improvements for the PEXA machine and its interface to the user/care giver.
The result was considerable ideas/models/sketches that possibly could contribute to improving features on the machine.

Participants

- PEXA. Svante, Claes, Åsa, Johan.
- Etteplan. Magnus L & Tomas & Mattias.

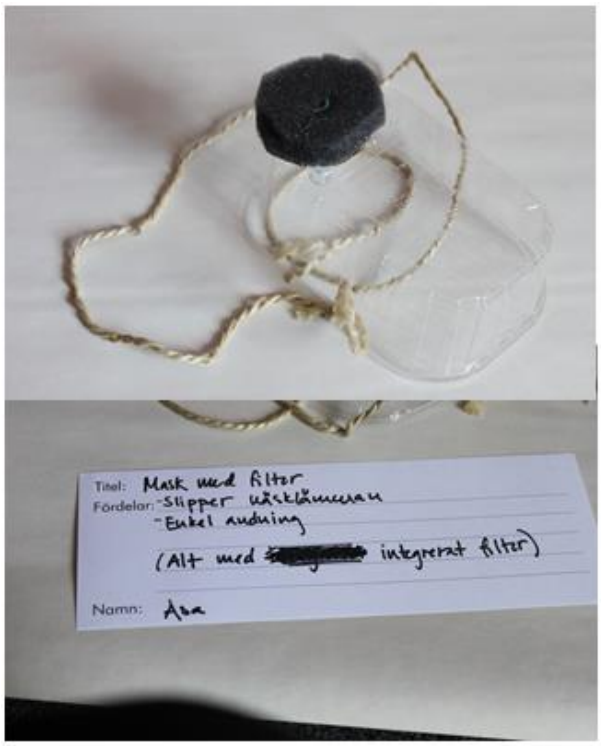
Agenda

- 09.00 Ankomst
- 09.30 Information om dagen, deltagarpresentation
- 09.45 Pexa håller en kort briefing om produkten och uppdraget
- 10.00 Brainstorming-regler, mind-mapping
- 10.20 Idégenerering
- 11.00 Kort presentation av idéer
- 11.15 Fika
- 11.30 Idégenerering fortsätter
- 12.30 Presentation och summering av idéer
- 13.00 Lunch och avslutning på dagens workshop

Ideas – Sketches & models

- 1. Automatiskt valv

- 2. Korklösning



- 3. Mask med filter

- 4. Damask

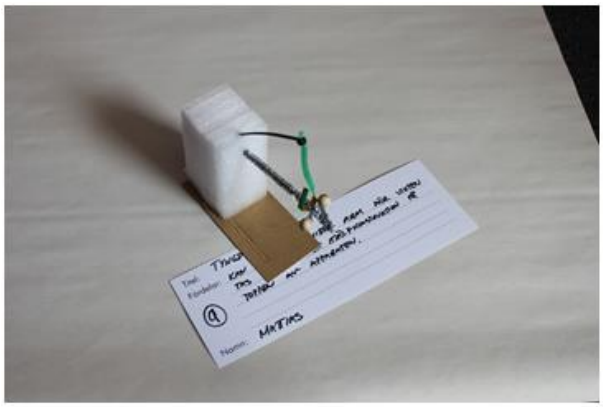
- 5 ?

- 6. Metal wire joint

- 7. Arm med böjlig och ledade delar

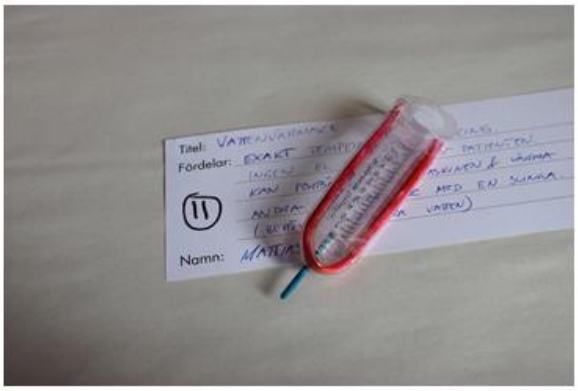
- 8. Dubbel kulled

X

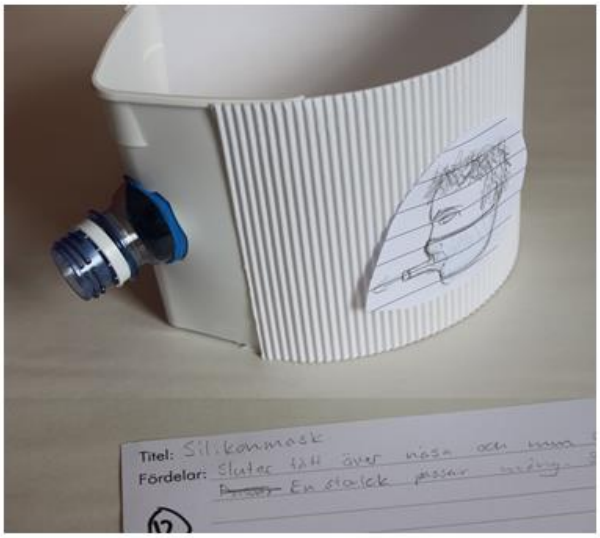


- 9. Tyngd xx..

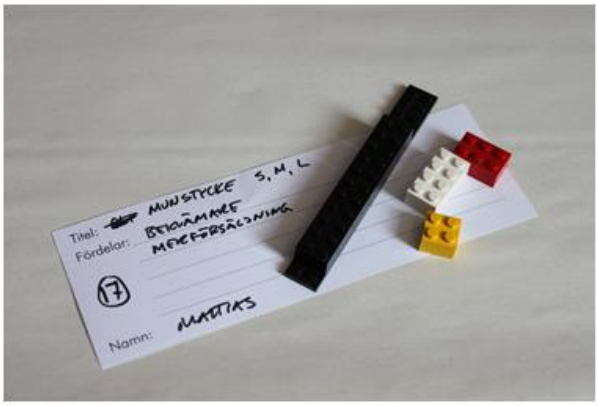
- 10. Led



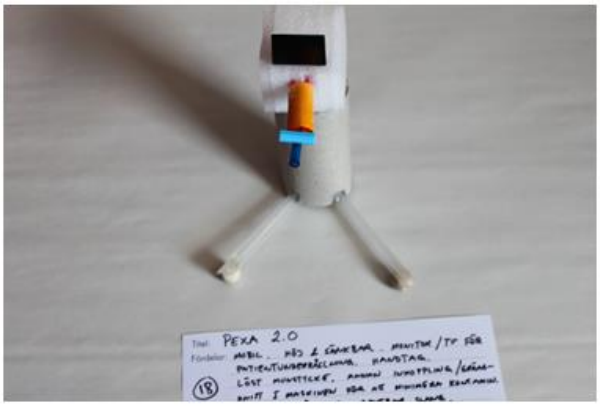
- 11.Vattenvärmare



- 12. Silikonmask

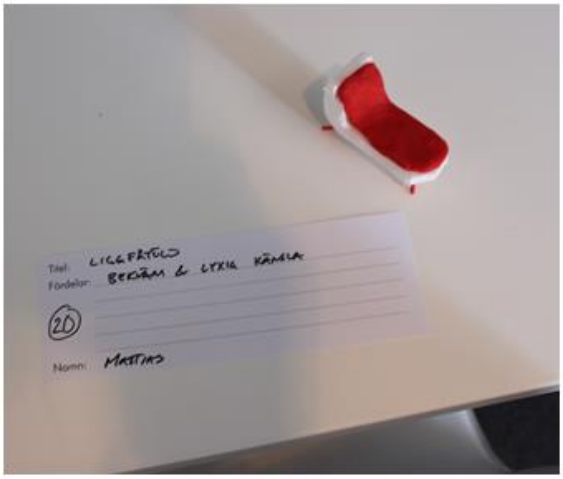


- 17. Munstycke S-M-L



- 18. Pexa 2.0

- 19. Stollösning



- 20. Liggfåtölj

Text on notes

Titel: TYNGDAVLASTARE
Fördelar: KAN GE EN FLEXIBEL ARM DÄR VIKTEN TAS UPP AV EN MÅRLPKONSTRUKTION PÅ TOPPEN AV APPARATEN.
(9)
Namn: MATTIAS

Titel: VATTENVÄRMARE
Fördelar: EXAKT TEMPERATURREGLERING. INGEN EL I NÄRHETEN AV PATIENTEN. KAN FÖRBÄTTRA UV I MASKINEN & VÄRMA ANDRA KOMPONENTER MED EN SLINGA. (BEHÖVER INTE VARA VATTEN)
(11)
Namn: MATTIAS

Titel: PEXA 2.0
Fördelar: MOBIL. HÖJ & SÄNKBAR. MONITOR/TV FÖR PATIENTUNDERHÅLLNING. HANDTAG. LÖST MUNSTYCKE. ANNAN INKOPPLING/GRÄNSSNITT I MASKINEN FÖR ATT MINIMERA KONTAMIN. FAST VÄRMEMÅTTNING, UTBYTBAR SLANG.
(18)
Namn: MATTIAS

Title: Orientation
Benefit: • flexibilitet
• alternativ positionering
(5)
Name: Tomas

Titel: Danmark
Fördelar: Flexibel [illegible]
Enkel justerbarhet
Enkel rengöring
(4)
Namn: Magnus & Susanne

Title: DUBBEL KULLED
Benefit: ENKEL ATT JUSTERA. MUNSTYCKET GÅR ATT STÄLLA HORISONTELLT OBEROENDE AV MÖJD. ARMEN KAN VARA STYV.
(8)
Name: MATTIAS

Titel: Stollösning
Fördelar: Bekväm för patienten
(19)
Namn: Johan

Titel: Arm med böjlig och ledade delar
Fördelar: Det är egentligen en ganska liten rörelsefrihet som krävs för att anpassa munstyckets position efter alla tänkbara patienter → Enklare att lösa temperaturstabiliteten
(7)
Namn: Claes Holmberg

Z

Text on notes

Title: METAL WIRE JOINT (DOUBLE)
Benefit: FLEXIBEL & STÄLLBAR. BEHÅLLER SIN POSITION EFTER REGLERING. LÖST ENGÅNGSMUNSTYCKE.
(6)
Name: MATTIAS

Titel: ~~DET~~ MUNSTYCKE S, M, L
Fördelar: BEGRÄNSARE
MEKFÖRSÄLJNING
(17)
Namn: MATTIAS

Title: Led
Benefit: ledad arm för nyckel flexibel positionering
(10)
Name: Tomas

Title: Automatiskt valv
Benefit: Slipper att ställa och reglera ventilen
(1)
Name: Åsa

Titel: Silikonmask
Fördelar: Sluter tätt över näsa och mun skyddigt
~~Passar~~ En storlek passar [illegible]. Billig.
(12)
Namn: Johan

Titel: Korklösning
Fördelar: - slipper ventilen
- slipper att sitta fast under hela testet
(2)
Namn: Åsa

Titel: Mask med filter
Fördelar: -Slipper näsklämmaren
-Enkel andning
(3)
(Alt med [redacted] integrerat filter)
Namn: Åsa

APPENDIX G. PUGH MATRIX

	Solution 1	Solution 2	Solution 3	Solution 4 Current	Solution 5	Solution 6	Solution 7
Minimize the loss of particles							
Manufacturing cost	-	-	-	0	-	-	-
Length	+	0	+	0	+	+	0
Appearance	+	+	+	0	+	+	+
Number of parts	+	+	+	0	+	0	0
Easy to direct exhaled air	0	+	0	0	0	0	+
Enable support for head	0	0	0	0	+	0	+
Time to adjust	+	-	+	0	+	+	+
Ability to take a break	+	0	0	0	0	0	0
Should not require the nose clip	+	+	+	0	0	0	0
Should enable support for mouth	+	+	+	0	0	+	+
Minimize salivation	+	+	+	0	0	+	+
Prevent dryness	+	+	+	0	0	0	0
Suitable for different persons	-	-	-	0	+	+	+
Afflict as little pain as possible	+	+	+	0	0	+	+
Amount of times to direct the valve	+	0	0	0	0	0	0
Time to sterilize	+	-	-	0	0	0	+
Amount of steps when assembling	+	0	-	0	-	-	+
Time to assemble	+	0	-	0	-	-	+
Minimize the ability for human errors	+	0	-	0	-	-	+
sum +	15	8	9	0	6	7	12
sum -	2	4	6	0	4	4	1
sum 0	2	7	4	20	9	8	6
Total score	13	4	3	0	2	3	11
Rank	**1**	**3**	**4**	**6**	**5**	**4**	**2**

	Solution 1	Solution 2	Solution 3	Solution 4 Current	Solution 5	Solution 6	Solution 7
Minimize the loss of particles							
Manufacturing cost	-	-	-	0	0	-	-
Length	0	-	0	-	0	-	-
Appearance	0	0	0	0	0	0	0
Number of parts	+	-	+	-	0	-	-
Easy to direct exhaled air	0	+	0	0	0	0	+
Enable support for head	-	0	-	-	0	-	0
Time to adjust	0	0	0	0	0	0	0
Ability to take a break	+	0	0	0	0	+	0
Should not require the nose clip	+	+	+	0	0	0	0
Should enable support for mouth	0	0	0	0	0	0	0
Minimize salivation	+	+	+	0	0	0	0
Prevent dryness	+	+	+	0	0	0	0
Suitable for different persons	-	-	-	0	0	0	0
Afflict as little pain as possible	0	0	0	0	0	0	0
Amount of times to direct the valve	+	0	0	0	0	+	0
Time to sterilize	+	-	-	0	0	+	+
Amount of steps when assembling	+	+	0	+	0	+	+
Time to assemble	+	+	0	+	0	+	+
Minimize the ability for human errors	+	+	0	+	0	+	+
sum +	10	7	6	3	0	6	5
sum -	3	5	4	3	0	4	3
sum 0	6	7	11	13	20	9	11
Total score	7	2	3	0	0	2	2
Rank	**1**	**3**	**2**	**4**	**4**	**3**	**3**

CC

DD