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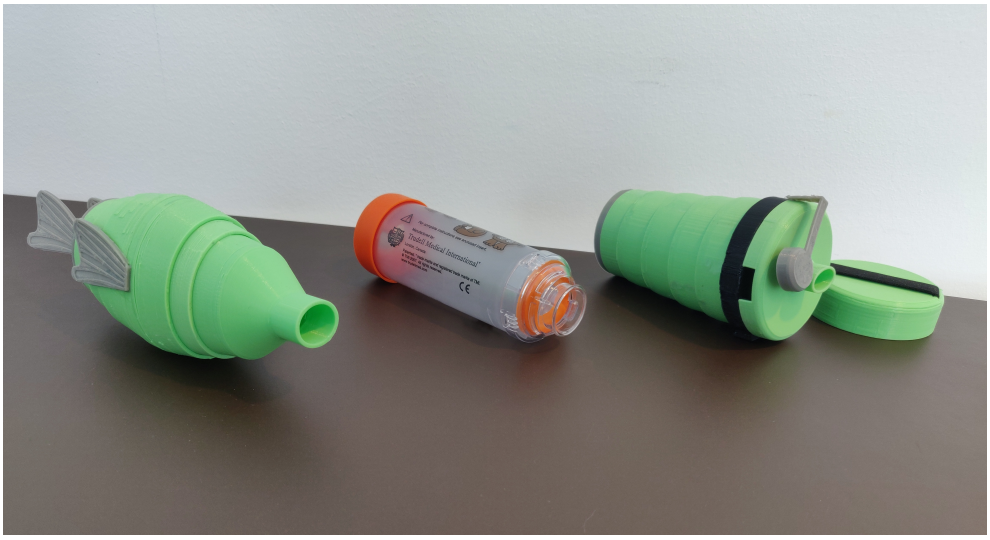

A Novel Inhalation Chamber Design

Improving the User-Friendliness of Asthma Medication for Children of the Age 3-6 years

Master's thesis in Product Development

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Cover: The two 3D printed spacer concepts together with a commercial product.

Abstract

Asthma is a common pulmonary disease, often medicated with the help of inhalers, one type of inhalers is the *Pressured Metered Dose Inhaler* (pMDI). To improve the medicine to lung deposition for pMDIs, an inhalation aid called a *Spacer* or *Valved Holding Chamber* is used. With use of the spacer the medication can be inhaled in controlled and slow manner. The purpose of this thesis is to develop a new children spacer design which is more portable and encouraging than the four currently available spacers recommended by the "West Sweden Region health authorities".

The thesis went through the entire product development process: *gathering of customer needs, concept generation, concept selection, detailed development, prototyping, physical testing and evaluation.*

Ultimately, two physical prototypes were made through 3D-printing with corresponding CAD models. Prototypes were evaluated through delivered dose testing, design- and patient risk assessment and evaluation against the four spacers on the market and their product specifications.

The two prototyped concepts, **The Pike** and **Bear 2.0**, were considered more portable than the four already established products because of their ability to be reduced to a length of 25% and 61% shorter than the smallest established product *AeroChamber Plus Flow-Wu*, when not in use. This was achieved through their innovative telescopic design. Both concepts were considered to have a more encouraging design for children, but at the cost of an increased amount of parts and complexity. Both prototypes during the *Delivered dose testing* performed equally well as the *AeroChamber Flow Vu* in regards to 0s hold time, and 25%/20% higher delivered dose during 5s hold time, for **Bear 2.0** respectively **The Pike**. From the Design- and Patient Risk assessment it was concluded that even though the telescopic design worked largely as intended, it is yet to be optimized with regards to durability, easy-of-use and dust protection. Both solutions run the risk of pinching the user during extension and compression of the telescopic parts, a risk that needs to be reduced in future iterations.

Acknowledgements

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A Novel Inhalation Chamber Design

1 Introduction

Asthma is a pulmonary disease that affects people globally, at a total number of 300 million individuals. The disease can be developed through a genetic mutation, or either as a result of being exposed to high amounts of tobacco smoke or by living in highly air polluted areas. Patients with the asthma disease receive continuous inflammation within the airways and as a result have problems receiving enough oxygen to the lungs which might result in severe breathing difficulties and coughing. If not treated properly, patients with critical asthma conditions can end up dying (Cukic et al., 2012).

1.1 Background

With proper treatment, children suffering from asthma have the possibility to live an active life. As of now, the delivery of asthma medication to young children is generally more tricky than to adults. Current portable inhalation devices are difficult to use and bring their own set of instructions that can be hard to follow as a new patient. Common difficulties are coordination issues between the actuation (pressing down the pressurized canister to release the drug) and inhalation, as well as the inhalation being too strong or too weak, resulting in an incorrect treatment. However, with the help of an inhalation chamber between the device and the patient, called a spacer, the usage is simplified. The spacer helps children that have problems coordinating the actuation of the medical device while at the same time inhaling, promoting the chances that the correct amount of drug is delivered to the lungs. Without a spacer, the user has to actuate, while at the same time taking a deep breath. With a spacer the user can take several smaller breaths instead of one deep breath and thereby minimize the need to coordinate the actuation and inhalation.

Today, the majority of children living in Sweden that are diagnosed with asthma are prescribed with a spray inhaler in combination with a spacer, and not solely an inhaler. Even though spacers are commonly known to be beneficial for drug to lung deposition, they are still in need for optimization (Vincken et al., 2018).

1.2 AstraZeneca - Pharmaceutical Company

AstraZeneca is a company that was created through the fusion between the Swedish pharmaceutical company Astra AB and the British company Zeneca in 1999 and they have their head office located in Cambridge, United Kingdom. AstraZeneca operates in over 100 countries and their medicines help and are consumed by millions of individuals all over the world (Johnson, 2015)(Linkedin, 2019). AstraZeneca's vision as a company is to develop products with a primary focus on patients health and at a low environmental impact for all their products throughout their entire life cycle (AstraZeneca, 2019).

As a pharmaceutical company, AstraZeneca mainly focuses their business on three different therapy areas: Cardiovascular and Metabolic Disease, Oncology and Respiratory. During the years the company have had several commercially successful medicines, such as the *Symbiocort* formulation together with the *Brilinta* tablets. *Symbiocort* is a medicine that combines budesonide which is an inhaled corticosteriod together with formoterol which acts as an bronchodilator to treat patients with problematic asthma conditions. *Symbiocort* was first launched in Sweden in 2000 and has since then been approved in around 120 countries and is sold either as the product *Symbicort Turbohaler* or *Symbicort pMDI*(AstraZeneca, 2017). *Brilinta* also called *Ticagreloron*is on the other hand is used together with aspirin to reduce the risk of patients having serious heart problems, stroke or end up dead after having severe chest pains or heart attacks. As a medicine it prevent clots from developing in the blood, and was approved by the FDA (Federal Drug Administration) in 2011 (Drugs, 2019)(Durbin, 2019).

When it comes to spacer development, AstraZeneca have not been operating extensively in the area. However, they have previously developed one product called the *Nebuchamber*. The *Nebuchamber* was a pear-shaped spacer made out of metal, and compared to most of today's versions that are made out of plastic, the Nebuchamber were very resistant towards static charge, which was also one of its benefits (Lavorini and Fontana, 2009).

1.3 Project aim

The aim of this thesis is to develop a new spacer that promotes children of the ages 3-6 years to use it both at home and in a public environment, ensuring that the children receive the correct dosage of medicine at a lower effort at all times. Effort in this case means the ease of which it can be transported and willingness to be used because of its encouraging design.

1.4 Project goals

- Develop a spacer that is more portable in the sense that it takes up less space when not used than today's versions by a different design and material selection.
- Create a design solution that promotes the use of the spacer giving it an advantageous aesthetic design for the user.

1.5 Delimitations

- The project will only focus on developing a spacer and not any existing corresponding inhalers.
- The spacer is to be developed for kids between the ages of 3-6.
- Customers needs are based on individuals currently living in Sweden.
- Project is limited to 20 weeks of work.

- A maximum of two 3D-printed functional prototypes will be made.
- Prototypes will be kept at a user experience prototype level.
- Only mechanical parts of the concepts will be physically prototyped.
- Validation of the models will be made internally.
- Not all requirements in the requirements list will be verified during this thesis.

1.6 Deliverables

- Customer needs list
- Requirements list
- Hand-sketched concepts
- Final concepts
- Two developed CAD-designs
- Two 3D-printed prototypes

1.7 Outline of thesis

Throughout the thesis the following chapters will be presented:

- **Chapter 2: Theoretical Framework** - The chapter will describe theories and information that lay as a base for the thesis.
- **Chapter 3: Method** - During this chapter each method used during the thesis will be described and how they were applied.
- **Chapter 4: Results** - The results chapter will present based on the methods used, results of each method together with their final outcome.
- **Chapter 5: Discussion** - This chapter will discuss the results obtained from the methods and connect them with the theories given in the theoretical framework.
- **Chapter 6: Conclusion** - During this chapter the discussion is summarized and the main discoveries achieved throughout the thesis, presented and compared with the project goals to evaluate the degree of goal fulfillment.
- **Chapter 7: Future recommendations** This chapter will present, based on the result achieved, what the future developer needs to focus on in order to further improve the final product.
- **Appendices:** Will present tables and results that was not included within the original report.

2 Theoretical Framework

In this chapter, theories and information will be presented that have been taken into consideration during the whole project and used prior to developing the final product prototype. The topics included are *Treatment of asthma, pMDI, DPI, Similarities and differences of pMDI and DPI, Spacer, pMDI- spacer interaction, Benefits with the use of spacer, Problems with current spacers, Design guidelines, The development history of the spacer, adherence and compliance with spacer usage, Effects of crying on delivered dose, Effects of flow rate and inhalation delay on emitted dose.*

2.1 Treatment of asthma

For patients that are given the diagnosis of asthma pulmonary disease, there are several treatments available, one more suitable for a specific person and their needs than another. The two most common types of inhalers to treat pulmonary diseases are with help of either a dry-powder inhaler (DPI) or a pressurized Metered Dose Inhaler (pMDI). (Tidy, 2018)

2.1.1 Pressurized Metered Dose Inhaler (pMDI)

A pMDI is a kind of inhaler that uses a propellant to deliver the active substance to the patient. The typical pMDI consists of a metal canister which includes a liquefied propellant and active medicine. The medicine comes in either a suspension or a solution form. The canister is connected through a valve to the casing with a mouthpiece. The canister is pressed down towards the casing and actuates a plume of propellant and medicine from the mouthpiece. A schematic picture of a pMDI can be seen in Figure 1 below. The current trend in the industry is to include sensors and electronics together with the pMDI to give feedback to the user regarding usage. This can show, among other things, how many doses are left, on which days the dose have been taken and if the inhalation is done with an appropriate inhalation flow and coordination between actuation and onset of inhalation.

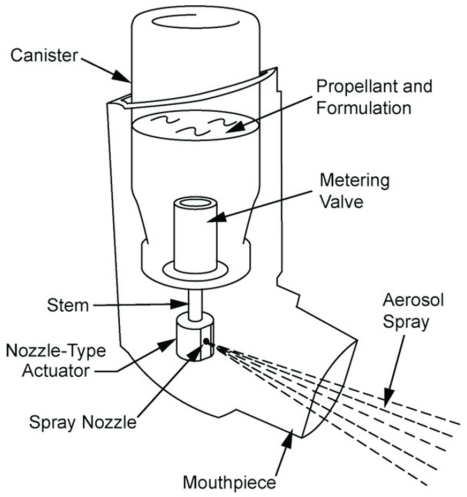


Figure 1: Schematic picture of a typical pMDI device. Image source: (King, 2013)

2.1.2 Dry Powder Inhaler (DPI)

Is a device, just like the pMDI, that has the sole goal to deliver pulmonary medication in a convenient way. The difference between the devices lays within how the drug is composed and delivered. The medicine in a DPI is made out of dry powder and instead of pressing down a canister to actuate the device as with the pMDIs, the DPIs are breath activated. The DPIs also has a certain threshold when it comes to flow-rate which the patient has to exceed using their own lungs in order for the medicine to be released from the device (AAAAI, 2019). This flow rate threshold can, for some patients, be difficult to reach, specifically for older individuals and young children, making it sub-optimal for them.

Figure 2: Dry-powder inhaler. Image source: (Times Of Market, 2019)

2.1.3 Similarities and differences of pMDI and DPI

With the DPI, patients need to use a higher inhalation effort than with the pMDI-solution, as they are not driven by propellant but by the patient's lung capacity. PMDI is thus more commonly used by children whose lung capacity in general is not as great as for young adults (UseInhalers, 2012). However, with the pMDI device, common problems are failures in coordinating the actuation of the canister together with inhalation resulting in low amount of drug deposition (Sheth et al., 2017). Studies have shown that 33 % of astma patients using a pMDI have bad coordination when using the product (Giraud and Roche, 2002). To mitigate coordination problems and aid in medication, the inhalation chamber called "spacer" is used as an add-on to the pMDI (Sheth et al., 2017).

2.2 Spacer

A spacer see Figure 3, or a valved holding chamber, is an air chamber that the patient place between the pMDI product and the mouth in order to aid in the medication procedure. The typical spacer consists of a mouth piece where the patient inhales the medicine from, an air chamber where the inhaler plume is collected and an inlet where the pMDI product can be connected. Today's spacers also often are delivered with different feedback systems such as a visual breath indicator in form of a moving membrane or a whistle to give feedback on how well the user performs the inhalation. A spacer used by a patient can be seen in Figure 4 below.

Figure 3: Philips OptiChamber spacer. 1: Mouthpiece, 2: Air chamber, 3: Inhaler inlet. Image source: (Med24.dk)

Figure 4: Patient using pMDI with spacer. Image source: (Ebay)

Swedish guidelines in "West Sweden Region health authorities", for prescription of spacer and pMDI devices, say that all spray-based inhalers should be prescribed with a spacer. Children under four years of age should be prescribed a mask together with the spacer. However, children older than four years can use the spacer on its own since most of them are considered able to place their lips tight enough around the mouth piece making a mask unnecessary. When children grow as old as six to seven years a

large percentage of them can transition to using a DPI instead (Allergi-Andning-ÖNH, 2016).

2.2.1 pMDI - Spacer interaction

The procedure for using the pMDI together with the spacer is described in the Figure 5 below together with the following steps:

1. First the patient need to straighten up both torso and head and then remove the pMDI's cap. Then the pMDI is shaken for at least five times in order to prevent the risk of the pMDI delivering a severely diminished dose into the spacer.
2. Secondly, the user has to hold the pMDI upright and insert it into the spacer's inhaler inlet on the backside while the spacer is kept horizontal.
3. As the third step the patient has to exhale and to empty the lungs of any pre-existing air.
4. Fourth, the user wraps their lips tightly around the spacers mouthpiece, pressing down the canister within the pMDI while inhaling in a slow manner.
5. Fifthly the user is recommended to hold the breath for as long as comfortably possible
6. Lastly, the user has to exhale and repeat the steps if additional doses are required.

(Vincken et al., 2018)

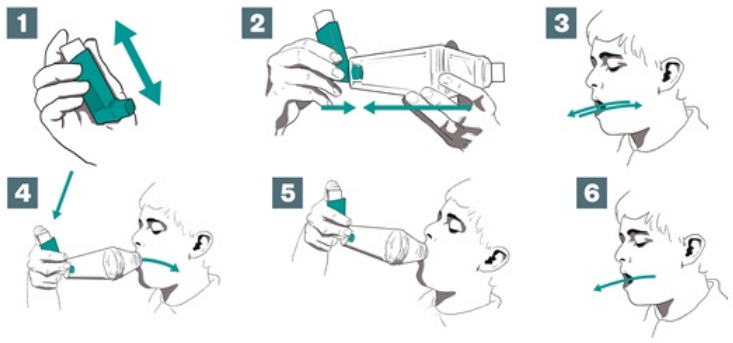


Figure 5: Using the spacer together with a pMDI. Image source: (Trigo, 2016)

2.2.2 Benefits from the use of a spacer

Using a spacer as an add-on to the pMDI is beneficial in several ways for the asthma medication procedure. One benefit is that it reduces the risk of coordination issues between the user's inhalation and pMDI actuation as the plume from the inhaler is slowed down and contained within the chamber. This allows the user to breathe normally, several times, out from and into the spacer rather than one large breathe like when using solely the pMDI. With the spacer the propellants evaporation time is increased resulting in a smaller particle size which leads to improved medicine deposition

in the lungs. The spacer also reduces the risk of the medicine partly being swallowed (Vincken et al., 2018).

2.2.3 Problems with current spacers

As mentioned in the section *Benefits from the use of a spacer*, there are several benefits with the spacers when its comes to the medicine delivery itself. However, adding a spacer to your medicine routine can in some scenarios be troublesome. The routine itself includes taking care of the chamber and cleaning it regularly. During regular use, the spacer needs to be cleaned once a month to prevent medicine build up inside the spacer which can be exhausting for some patients (Marshall, 2010). Also additionally, some spacers can be large in size making them bulky and difficult to transport and therefore less portable (Vincken et al., 2018).

2.2.4 Design guidelines

Spacers are available in different shapes and volumes, where there are recommendations about the volume of the spacer chamber given by "Swedish Medical Products Agency". Their guidelines says that a spacer volume of 250-350 mL is enough for most sprays (Läkemedelsverket - Swedish Medical Products Agency, 2017). One in vitro study compared pear-shaped and roller-shaped spacers measuring medicine deposition in the throat as well as in the spacer container. This study showed no significant difference in performance between the pear-shape spacer and the roller-shaped type (see Figure 6 below for the shapes) (Momeni et al., 2016). However, in general, less medicine is stuck on the internal walls in large volume chambers (Nikander et al., 2014).

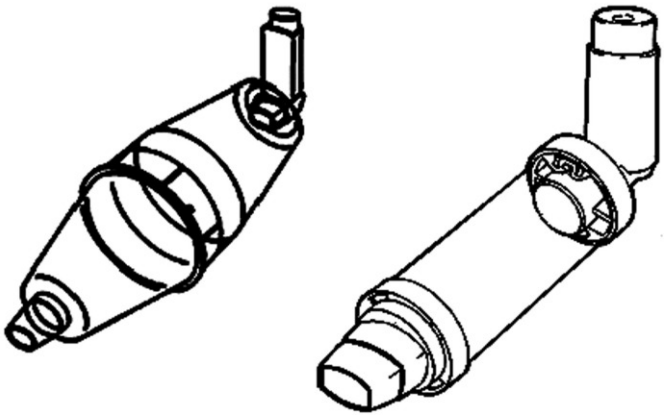


Figure 6: Pear and roller shaped spacer. Image source: (Momeni et al., 2016)

Spacer's chamber should also be made with anti-static material. Materials that are not anti-static have a negative impact on spacer performance, because electrostatic charge has been shown to attract aerosol particles which can lead to reduced medicine left to inhale. Up to 50 % of the dose can be reduced due to electrostatic charge. Electrostatic

charge can be reduced by priming the spacer with several doses of medicine, coating the walls in medicine. However this results in unnecessary waste of medicine and can be costly in the long haul. Spacers that are made out of anti-static material negates this problem (Vincken et al., 2018).

2.2.5 The development history of the spacer

As a response to the problem of coordinating both the actuation of the pMDI and the user's inhalation becoming more apparent, the first spacer device was developed. Since then, the spacer has been an unrivaled product that in an inexpensive, reliable and convenient way can deliver pulmonary medicine together with the pMDI. But, it was not until 1956 that the first one was developed and patented. During the late 1960s as the general awareness of dangers that can occur during excessive use of bronchodilators got better, so did the need for accurate and controlled medication, pushing the development of spacers forward in a rapid pace. Some of the more common occuring side-effects during excessive use of bronchodilators are depression and asthma-specific anxiety(Gerald et al., 2015). One of the central pillars in the spacer development was the integration of indicators which could measure how well the inhalation had been performed. One of the first indicators developed was integrated into a plastic container-spacer that during the inhalation process, was collapsing and reducing in size, hence, giving the user the feedback that the container with medicine had been emptied. This does not only, to some extent, improve the drug deposition but also improve user adherence. This product was released during 1982 under the name **InspirEase** (Nikander et al., 2014). Another large milestone in the development of spacers was the implementation of anti-static material or coating with anti-static spray inside the container, preventing the medication to get stuck inside the container walls as a result of static charge. This further ensured an accurate dosage and was implemented into a spacer and patented as a solution by the year of 1991 (Nikander et al., 2014).

2.2.6 Adherence and compliance within spacer usage

There are several factors that can disrupt the inhalation technique and become a major issue for children struggling with asthma. It can either be because of ignorance, fear or boredom which in return are reducing the chance to breathe in a slow and controlled manner, making the medication procedure worse. Education surrounding the spacer usage itself can help users improve adherence in general, but does have a lower effect on younger children compared to grown up patients (Watt et al., 2003). Education given in person or via recordings also improves compliance compared to only written instructions (Nikander et al., 2014). As a result, a spacer device called the **Funhaler** was developed (see Figure 7) that incorporated a toy-ball into the design to improve compliance for children and parents. It was shown that 38 % more parents were successful in medicating their child with the **Funhaler** compared to the previous day where an "ordinary" small spacer was used. At the same time 60 % more children were willing to take the right

number of recommended aerosol cycles with the new device (Watt et al., 2003). Studies show however that the **Funhaler**, and other novel devices that incorporate incentive toys does not improve long-term adherence, but rather short-term (Nikander et al., 2014).

Figure 7: Funhaler spacer device. Image source: (The Allergy Shop, 2010)

Other research has showed that particularly young children (younger than 24 months) who are prominent to cry during inhalation, significantly increase their adherence while being distracted by cartoons in the short-term (see Figure 8). However is it still unknown how these effects remain during long-term use. While the research were conducted mainly on children outside of the interesting age group, it might still be applicable for the younger users within the observed scope (Frémont et al., 2018).

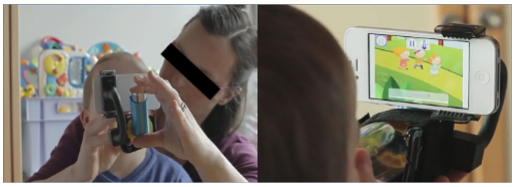


Figure 8: Cartoon study. Image source: (Frémont et al., 2018)

2.2.7 Effects of crying on delivered dose

A study was done studying infants and how crying and distress can affect the delivered dose to the lungs negatively because of an abnormal breathing pattern. The study showed that it would be beneficial to give medication to a quiet or sleeping child instead of one being crying and distressed, this was also agreed for preschool children (Iles et al., 1999).

2.2.8 Effects of flow rate and inhalation delay on emitted dose

With the use of pMDIs and spacers there are several factors affecting the final medicine deposition to the lungs. Two factors of high importance are at which flow rate the medicine is inhaled, together with how long time the delay has been from the pMDI actuation to the inhalation through the spacer. With an increased flow rate, the amount of medicine retained within the spacer is lowered and more medicine leaving the chamber. With an increased time delay between the actuation of the pMDI and the inhalation through the spacer, the amount of particles depositing within the spacer is significantly increased (Liu et al., 2017).

3 Method

In this section the methods used throughout the project are described. Topics covered are *Identification of customer needs, Concept generation, Concept selection, Detailed development - Computer Aided Design, Prototyping, Physical testing* and finally *Evaluation*. A flow-chart showing all the methods used can be seen in Figure 9.

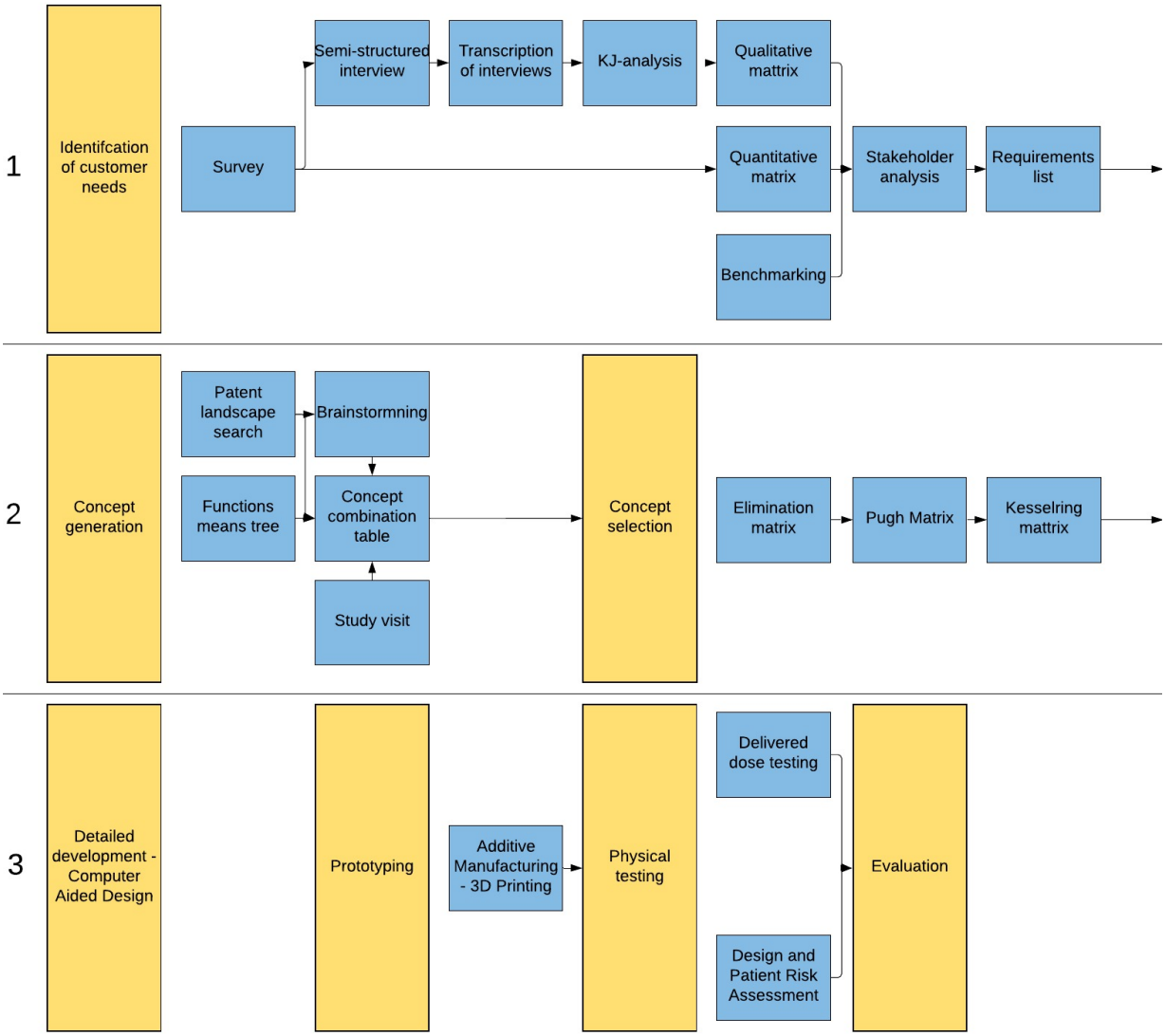


Figure 9: Flow-chart of methods used through out the thesis.

3.1 Identification of customer needs

To be able to gather a majority of the customer needs of a product, developers needs to be in direct contact with customers and experience the user's struggles in a realistic en-

vironment. The work procedure was mainly based on the structure of "Product Design and Development" by K. Ulrich (Ulrich and Eppinger, 2012). This chapter will include the following headings; *Survey, Semi-structured interviews, Transcription of interviews, KJ-analysis, Quantitative matrix, Qualitative matrix, Benchmarking, Stakeholder analysis and Requirements list.*

3.1.1 Survey

Surveys can be done to collect quantitative data from a selected target group and is typically used to confirm hypotheses. Depending on the kind of information wanted from the survey, different kinds of questions can be used such as demographic questions, descriptive questions and rating scales (Malmqvist, 2018).

To be able to get answers from the right target group and reach as many people as possible, two Facebook groups for parents with children living with asthma was contacted. The survey was answered by the parents and the survey was made using "Google Forms" at https://www.google.com/forms/about/. The survey was conducted first, before interviews, so that survey answers could be collected while searching for people to interview. The survey was made to confirm the assumptions about the use of the spacer and to ask the respondents of the survey if they were willing to be interviewed. In this way, both quantitative and qualitative data were collected at an early stage to confirm some assumptions and, at the same time, additional people were asked to participate in interviews. Some qualitative open ended questions were also included in hope to get some ideas that might be left out in the interviews. The information received from the surveys was used during both planning and conducting of the interviews.The survey was the first step made to get in contact with the target group. The survey was structured to first include demographic questions to make sure that the parents child was in the correct age group and to know what gender the child is. Secondly, descriptive questions were included so that the most common type of spacer could be identified as well as other important aspects regarding usage. Later also rating scale questions were included to understand how important different aspects are. The purpose of the survey was to get quantitative data of what functions or features the user values most in a spacer. Some qualitative questions were added to the survey as well where the respondent had the opportunity to write answers not mentioned in the form, see Appendix *A - Survey.*

3.1.2 Semi-structured interviews

Semi-structured interviews is a method where a single customer is interviewed about potential customer needs surrounding a certain product. The questions asked are to cover certain topics but at which order and how they are formulated are not pre-decided. It is recommended to have between 10 to 50 interviews to be able to realistically capture all of the customer needs. Interviews with customers can be documented in different

ways, for example by audio recording or by one team member taking notes. Audio recordings is an easy way to record the interview but transcribing them takes a lot of time. Taking notes is the most common way to document the content of interviews and the notes can be used as a base to form customer needs if directly transcribed after the interview (Ulrich and Eppinger, 2012).

Semi-structured interviews were chosen as a way to get qualitative data both from parents with children at the ages three to eight years but also from health care professionals who use the product as a part of their job. The target group for the product is children at the age of three to six years but children up to eight years were considered for interviews. This decision was made because of the struggle to get enough people for interviews and it was thought that even though the child may have stopped using the spacer for two years, both the parent and the child could still have a clear memory of that time and provide valuable input for the project. Kids that were more than two years over the age limit were not included as a result. Health care professionals that worked directly with youth asthma patients were chosen for interviews. Doctors, nurses as well as physiotherapists were considered. The interviews were semi-structured and therefore an interview guide was written in preparation for the interviews. One guide for the parents and one for health care professionals. The interview guides can be seen in Appendix *B - Interview guide*. For each interview one person was responsible for asking the questions and the other for taking notes and, if felt necessary, ask any missed questions or follow-up questions. Audio recordings were also used for each interview.

3.1.3 Transcription of interviews

Transcribing of audio recordings are done by listening to the audio recording and writing it down word by word. This is a very time consuming process. Another way is taking written notes during the interview by a note taker. These should be transcribed as soon as possible after the interview have been conducted so that the transcription is as accurate as possible. Transcribing the notes together with the person conducting the interview right away also adds an extra chance to share thoughts between the note taker and the interviewer. Transcribing in this way gives an accurate representation of the interview that is very close to an actual transcript (Ulrich and Eppinger, 2012).

After each interview the notes were transcribed by the note taker and the interviewer together. To get an even more detailed and accurate transcript, the audio recordings were listened to as well as the notes adjusted if anything was missing or misinterpreted before. The transcript was recorded statement by statement on post-it notes where each note was given a number, where the number represented which interview the statement as taken from, which was also helpful when analyzing customer needs in the next step. This was thought to be the best possible scenario using hand written notes together with listening and examining the audio recording.

3.1.4 KJ-analysis

KJ-analysis is a method where customer statements are written down on post-it notes. The post-it notes are then analyzed and the ones representing the same criterion are grouped into the same pile (Wallgren, 2017).

After all statements were collected from the semi-structured interviews, each of them were separately analyzed with regards to what they actually meant resulting in customer needs. The post-it notes were categorized and the ones representing the same need as another previously analyzed, were put under the same need. Whether the statement supported the customer need or were directly contradicting the need were given a plus or a minus respectively. Needs could only receive a maximum of one plus point for each interview as the sum of statements could be skewed if a person would mention something several times during the interview. Finally, the needs were given a value based on the sum of all "+" and "-" taken from all the interviews.

3.1.5 Quantitative matrix

With the quantitative matrix customer needs gathered from the survey can be documented, categorized, and their relative importance score received. With this information, the final importance of each need within the *Requirements List* can be more accurately presented, taking the survey into consideration.

The quantitative matrix was an analysis of the data taken from the survey. The initial part of the survey was purely demographic data so the information was only used to decide the individual fits the inclusion criteria or not. Some questions were qualitative and the answers from these were used to get extra customer needs, while the rest of the questions were quantitative in nature and the result was used and compiled in the spreadsheet. If 90% of the respondents wanted a specific need then that was given a rating of nine out of ten for example. From the quantitative matrix, the results from the survey was directly converted into needs with importance at the scale of 1-10. Questions from the survey that represented a specific need in the matrix was documented, to allow for easier backtracking of information.

3.1.6 Qualitative matrix

The qualitative matrix compiles all customer needs from the interviews. The needs are grouped into categories based on common themes of the needs. The matrix also states how many times each need is mentioned giving them a relative importance rating.

The qualitative matrix was made using the customer needs that was discovered through the KJ-analysis. Those needs were organized into groups depending on their specific nature. For example the two customer needs *"Boilable"* and *"Easy to clean"* was structured under a category named *"Cleaning"*. The spreadsheet also includes scores of all

customer needs and in which interview each need is mentioned. All customer needs are also illustrated through a quote from the interviews. The final score was achieved using the number of interviewees that mentioned the need, and since the number of interviews was equal to 10, this resulted in a scoring range from one to ten.

3.1.7 Benchmarking

The benchmarking method is used to position where the developed product should head in terms of gaining a competitive edge relative to its competitors products. Within the method, product metrics are documented in a chart for the competitor products to support future positioning decisions and give target values for the upcoming design (Ulrich and Eppinger, 2012).

Prior to the concept generation and selection phase a benchmarking study was performed on established spacer products on the market in order to find relevant specifications and limits comparable for the future developed product. The four spacers chosen for the comparison were based on what *"West Sweden Region health authorities"* health centers are able to prescribe currently together with information received from the results of the quantitative analysis regarding actual models used by patients. In each metric of interest, the best performing value for the four products were taken as a reference to act as a guideline when determining acceptable and target values for the developed concepts. Some metrics of interest were: weight, size, whether they were boilable or not and if they included toxic materials. The information was either directly taken from *Apotea*'s website or from personally measuring the actual products (Allergi-Andning-ÖNH, 2016). With the help of the benchmarking study, a sense of importance for each function was gathered prior to the knowledge-based analysis scoring, but also to create the best possible reference product comparable in the selection matrices.

3.1.8 Stakeholder analysis

One last spreadsheet was created where additional customer needs were added based on product research besides the ones received within the Quantitive-, and Qualtivie matrix. For example, the chamber should be made of an anti-static material so that it does not affect the spray cloud in a negative way when it enters the chamber. This need was added and ranked as a requirement. Other criteria were evaluated if they were to be considered as a requirement or wish/need whereas this decision was based on personal preference and literature. Needs were given a rating between one and ten where one was considered to be of low value and ten very important. The reason for having an additional spreadsheet for knowledge of the team was to make sure that all needs of the product are covered, not only the ones mentioned by customers but also important findings from the *Theoretical Framework*.

3.1.9 Requirements list

Requirements list, also called *requirements specification*, is a method to collect experience, data and information received from different stakeholders and customers to form a list of specifications that can ensure a successful product. The list distinguishes criterion from either demands or requirements.

The requirement list was created by combining the three previous spreadsheets: *Quantitative matrix* , *Qualitative matrix* and *Stakeholder analysis* in both the categories as well as scores. The combined score would be the mean value of the scores of the three previous matrices if it was a need, and an "R" if it was decided that it was a requirement.

3.2 Concept generation

This part will describe all methods used to help get more knowledge and more inspiration during the concept generation phase. The topics covered are *Patent landscape search, Functions means tree, Brainstorming, Concept combination table and Study visit.*

3.2.1 Patent landscape search

The patent landscape search is a method to find trends within the current market, find leading actors, as well as a tool to gather intelligence and aid in the decision making process. The patent search can be a part of the concept generation stage and is one step of the external search of information. With the search it is important to look at patents that are newer than 20 years from the patent application as they can still be protected and thereby not usable or have to be licensed in order to be used (Ulrich and Eppinger, 2012). The upside is that much of the information contained in patents is only available here and nowhere else, meaning that it is still possible to gain inspiration for concepts even though a specific part of the solutions is protected (Haldorson, 2016).

Several patent landscape searches were made using the results from the literature review as well as the requirements list as a base. First, a patent landscape search generally about spacers and valved holding chambers was made in order to locate all patents that could be of interest in this area. The search was conducted at www.derwentinnovation.com using the following search terms "((MDI OR (metered ADJ dose ADJ inhaler) OR PMDI OR (pressur* ADJ metered ADJ dose ADJ inhaler)) AND (spacer* OR chamber* OR tidal))". After doing the requirements list an additional patent search was made using https://worldwide.espacenet.com/. By doing the requirements list first, the requirements that were valued high, and required more inspiration, could be researched more thoroughly through a separate patent search. The requirements that were decided to be included in the patent search were “adjustable size” and “indicators”. These searches were not related only to spacers but also other products in other

fields. Some search terms was "flexible", "foldable", "collapsible" and "meter" among others. From the patent search patent information and pictures were collected.

3.2.2 Functions means tree

There are several possible ways to do a functional model for a product and the function means tree is one that divides the product in two different dimensions; a functional dimension and a means dimension. A function is formed by a verb plus a noun, whereas the means represent a sub-solution that solves a specific function. The tree can be divided in different of levels but each level contains both dimensions (Almefelt, 2018).

The input to the function means tree was the most commonly used spacer according to the conducted survey, which in this case was the *Philips Optichamber* (see Figure 14). The spacer was examined and taken apart whereas each part was examined and grouped with its corresponding function in the spacer system. Each of the functions were given at least one means solving that specific function.

3.2.3 Brainstorming

Brainstorming is a way to take advantage of the internal knowledge from all people involved in the project. The aim is to take the knowledge that the people already have and apply it to the problem at hand. To receive the maximum amount of ideas it is recommended to brainstorm individually at first. After that, brainstorming in group can be conducted in order to feed off of each others ideas as well as improve other people's concepts. During the brainstorming sessions, four different guidelines are taken into account; no judgement towards other people's ideas, value quantity of ideas over fully developed ideas, ideas that are not really feasible are accepted and, finally, use drawings or other media to illustrate the ideas (Ulrich and Eppinger, 2012).

The brainstorming activity was divided into several different sessions and the functions means tree and the concept combination table worked as a base. Each of the brainstorming sessions included initially individual brainstorming and after that a short presentation of the ideas. Here the ideas that could be further developed were presented and feedback given by the other person. Brainstorming sessions were conducted for each row of the concept combination table with more thorough sessions for the most important functions. Brainstorming sessions were conducted to generate some complete concepts as well and not only solutions to specific sub-functions. All of the concepts for the specific sub-functions as well as the full concepts were realized with drawings. Some ideas were removed prior to starting the Concept combination table because they were thought to be unfeasible.

3.2.4 Concept combination table

The concept combination table is used as a way to get more creative when developing concepts but also used as a tool to obtain completely new concepts directly from the combinations in the table. The table is made up of a bracket, where the rows are made out of functions, essential for a successful concept according to the requirements list and where the columns represent a specific solution to that function (Ulrich and Eppinger, 2012).

Based on the function means tree, a concept combination table was made with the addition of functions based on requirements taken from the requirements list. The first concept combination table was a matrix that contained solution fragments which were more abstract in how they could solve a specific function as a way to generate more ideas for each separate function. The solutions gained in the first matrix contained all the possible ways a function could be solved, not taking into account how realizable the solution would be in that specific issue. Solution fragments that were not realizable were then removed prior to the following table. A second table was made which contained detailed fragmented solutions for a specific function, which had been gained through the numerous brainstorming sessions made previously. With the specific fragments, solutions gained from each of the function rows, complete solutions could be obtained when combining one fragment from each row with another on the next one in the second combination table. When creating the new concepts, a new empty table was made where the new concepts and the respective numbers were stated in the top column, and column by column (see Appendix *E - Concept combination table 2 results*). The required functions taken from the second combination table were then documented vertically in the left column. The next step was to start with the first concept column and fill in the rows with a fragmented solution taken directly from the second table for each function. Each person within the team was responsible for creating five concepts and their combinations each, where the choices for each fragmented solution in the respective function was chosen by personal preference. These concepts were after being documented in the table directly sketched to match the prior concepts degree of realization before the concept selection phase.

3.2.5 Study visit

A study visit was conducted in order to gain further inspiration when developing the concepts during the concept generation-phase. The main goal of the study visit was to gain further inspiration within the spacer criteria of "can be reduced in size when not used" and "encouraging design" since inspiration within these areas were lacking. The study visit targeted mainly two different types of stores, camping stores and toy stores. Camping stores were visited because of the impression of their equipment being extremely functional but at the same time easy to bring with you and thus contributing to inspiration within the "can be reduced in size when not used" criteria. Toy stores were visited because of the initial impression of them having designs that encourage

kids to use them frequently and catch their attention. Interesting products that had functions or appearance of interest were photographed and documented to be easier used for upcoming idea generation sessions.

3.3 Concept selection

To be able to select the best two concepts among all other contenders three different selection matrices were made and will be described in the three following headings; *Elimination matrix, Pugh matrix and Kesselring matrix.*

3.3.1 Elimination matrix

The elimination matrix is a method that can help filter a high amount of concepts that are not suitable for further development. Concepts that do not fulfill all the set requirements, solve the main problems nor fulfill other vital chosen demands are eliminated (Almefelt, 2018).

When creating the elimination matrix, the concepts generated from several brainstorming sessions together with concepts created from the concept combination table were used. The criteria used for eliminating concepts were based on the requirements directly taken from the requirements list together with the one highest valued need from the same list. To eliminate even more concepts one final criterion was added, *Realizable* with the aim to filter out the concepts that are not thought to be realistic enough to actually execute. Concepts were evaluated separately and if they fulfilled all the criteria, were taken into further consideration and development. Concepts that had attributes that were unclear whether they fulfilled a specific criterion were still accepted through the matrix. If more information regarding a specific criterion and concept was needed, this was investigated prior to evaluating the concept in the Pugh matrix. Lastly, concepts that were accepted through the elimination matrix with sketches that were not up to pair with some of the others, were then re-sketched to match the degree of realization as the rest prior to the Pugh Matrix.

3.3.2 Pugh Matrix

With the Pugh matrix, more successful concepts can be evaluated and compared against a reference product. In the matrix concepts will be compared against a reference product in a specific set of desires. The reference product is often a product that is either the best product on the set market, or a combination of the best performing products. The best product in each desirable category is used as reference in that regard. If the concept perform better in the specific category than its reference product it is given a (+), and if worse a (-). However if the concept performs equally as well as the reference in any regard it is given a (0). These values are then added to a total sum for each concept, and if the total sum is positive, then the concept was considered to be better than its reference product and should be kept for further development. With the Pugh

matrix it is common to perform a second iteration using another reference concept to validate that the result from the first one converges with the result of the second one (Almefelt, 2018).

The reference product for the first Pugh matrix was a combination of the products prescribed by doctors in the "West Sweden Region health authorities": *L'espace, Vortex, Optichamber and Aerochamber*. According to the survey, *Philips Optichamber* was the most commonly used spacer and was therefore chosen as the main reference. If one of the other prescribed spacers were performing better in a specific function, then they acted as a reference instead. This was documented by either "0" or "0*Model", depending on the model acting as the reference for that specific function. After the first iteration of the Pugh matrix a second Pugh matrix was made. With the new iteration of the Pugh matrix, the reference product changed, which in this case was one of the winners from round one. The concept **Bear 2.0** was chosen as a reference concept because of its high score. All concepts except the reference product from the first iteration was then compared individually against "Bear 2.0", and whether they were better or worse at each specific criteria. All the successful concepts from the Pugh matrix went through a development face where they were improved using different options from the concept combination table as well as new sketches done with more exact scale as well as number and placement of components etcetera. When all concepts had equally developed drawings and specifications they were inserted into the Kesselring matrix.

3.3.3 Kesselring Matrix

The Kesselring matrix is a more precise way of evaluating concepts compared to the Pugh and also require more thoroughly developed concepts. The Kesselring matrix requires weight factors for each criterion that gives each criterion a different relative importance. It also requires creating of a scale of fulfillment to be able to grade what level the criterion has been fulfilled for each concept (Almefelt, 2018).

The weight factor of each criterion within the Kesselring matrix was directly converted from the importance in the requirements list, whereas the performance was graded from a scale of 1-5 for each concept's respective function. Where a 5 meant that the concept was performing much better than its reference and if given a 1, much worse. One criterion was evaluated for all concepts before the succeeding criteria was evaluated to get as fair scoring as possible between the different concepts. All the concepts scores were later calculated by multiplying the weight factor with the grading scale score and there after adding the values to one total sum for each concept. Finally all concepts were given a rank from one to five and the two best ones were taken into further development. As a reference product it was decided to use a "best of the best" reference based on the four prescribed spacer products, in the same way as mentioned in the Pugh Matrix.

3.4 Detailed development - Computer Aided Design

This section will explain the Computer Aided Design, also called CAD, process for the detailed development of both concepts; **The Pike** and **Bear 2.0**. The process will describe the procedure from early sketches to finished 3D models in true scale and rendered images to show the designs in as high quality as possible. *CAD* is a method that includes the ability to, in a simple way, design concepts made in three dimensions making it easier to asses concepts and their potential, ability to be manufactured and their fundamental properties (Ulrich and Eppinger, 2012).

The program used for CAD was Catia V5 from Dassault Systèmes. As the telescope was one of the main features of both designs, an iterative process was used and several shapes of telescopes were made as well as with different angles and length of overlap. For the 3D renders Catia V5 from Dassault Systèmes was used once again and a post touch up was done using Adobe Photoshop. The 3D renders were made to have pictures which can be used to better evaluate the actual aesthetics of the spacers seeing as any colour can be chosen as well as transparent materials with good optical properties among other things. This, together with the physical prototypes, gives a more realistic comprehension of how the spacers will look once they are done. When both concepts were finished in CAD they were measured to verify volume as well as length and width.

3.5 Prototyping

In this section all steps towards the prototype process is described as well as guidelines followed to make the process easier. The prototypes are not intended to be fully functioning models and do not have the correct materials. They are made to show the functionality of the telescope design and to be used in physical tests of medicine deposition in the chamber. This chapter describes the methods used regarding *Additive manufacturing - 3D printing and Post touch-up.*

3.5.1 Additive manufacturing, 3D printing

3D printing is a type of additive manufacturing that takes a model from a CAD system and builds it by adding layer on top of layer. Each layer is a cross section of the part in question and layer thickness can be adjusted depending on how close to the original the part must be. A smaller layer thickness gives a more exact model. 3D printing is mainly used when wanting to create something fast and to create a prototype which can work as a model for further development (Gibson et al., 2015).

The prototypes were based on the CAD models and printed with "ZYYX+ 3D Printer" from ZYYX Labs AB. Two different materials for filaments were used, "ZYYX PLA" filament which is made out of a PLA blend which is a biodegradable thermoplastic and "ZYYX Pro-flex" filament which is a softer and more flexible material. When doing

the CAD models, some guidelines were followed in order to make the printing process as easy and time efficient as possible. Some things that were taken into account were thickness of supported, as well as unsupported walls, which should not have a thickness less than 0.8 mm. Overhangs are required to be at maximum 45 degrees or less in order to be able to be printed without support material (Brockotter, 2019).

3.5.2 Post touch-up

After 3D printing, additional adjustments were made to make all pieces fit together. Among other things, all the support material had to be cut away. On some places of the prototypes, minor flaws in the shape of extra material had to be cut or grinded to get a smooth surface and in order to get the parts ready to be assembled.

3.6 Physical testing

This chapter describes the process involved in the physical testing which were *Delivered dose testing, and Design- and Patient Risk Assessment.*

3.6.1 Delivered dose testing

In order to assess the characteristics of the spacer prototypes, the delivered dose leaving the spacer was analyzed. The setup of the tests can be seen in Figure 10 below. The delivered dose from the spacer prototypes was collected on "AirLife Bacterial/Viral Filter" by "CareFusion" using 30 l/min airflow for 15 seconds. This results in 7,5 l of air pulled through the spacer, more than 20 times the volume of each spacer prototype making sure it was properly emptied. The lab setup was arranged in two different configurations, the first consisted of a pMDI product connected to a filter and via a hose to an in-house vacuum system via a trig-box consisting of a regulating valve and a timer. This setup was done to get reference values of the pMDI product without the influence of a spacer. The second setup was identical, with the only difference being that the spacer prototypes was placed between the filter and the pMDI product see Table 10 below. To make sure that spacer prototypes remained fully expanded, duct tape was used on the outside of the spacer chambers. One observandum was that the spacer prototypes were not constructed in anti-static material, to minimize the effect of this each prototype was primed with five doses of pMDI product to coat the chamber walls. This was done before the actual characterization test was initiated, in order to asses the spacer geometries and not the material properties.

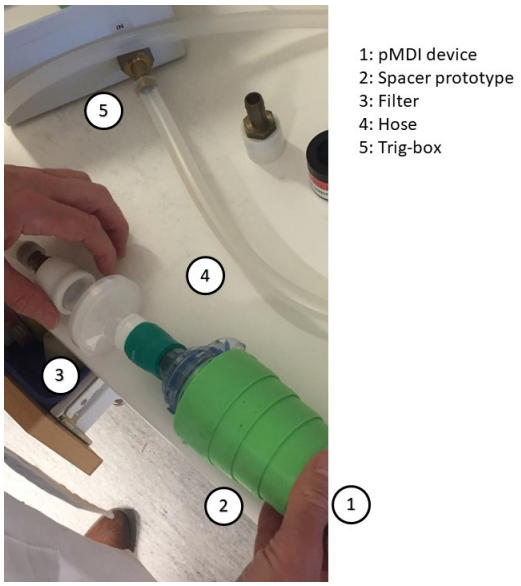


Figure 10: Setup with spacer prototype Bear 2.0.

For the tests, the hold time was varied using either zero seconds or five seconds. The hold time was defined as the time between the actuation of the pMDI product in to the spacer until the airflow was activated to draw air out of the spacer. For the test, two different hold times were used since it can be a delay between actuation of the pMDI and until the patient start inhaling from the spacer. For the reference tests the data were collected using flow-on instead of using a hold time, meaning the airflow was already activated when the pMDI was actuated. To get a proper set of reference data a testing protocol was structured the following way, see Table 1 below. Two actuations of the pMDI product constituted one dose and hold time was used for each actuation.

Table 1: Testing protocol.

Testing protocol											
Test #		Test #	Hold time:		Test #		Test #	Hold time:		Test #	
1	Reference	6	5 sec	Bear 2.0	16	Reference	21	0 sec	The Pike	31	Reference
2	Reference	7	0 sec	Bear 2.0	17	Reference	22	5 sec	The Pike	32	Reference
3	Reference	8	5 sec	Bear 2.0	18	Reference	23	0 sec	The Pike	33	Reference
4	Reference	9	0 sec	Bear 2.0	19	Reference	24	5 sec	The Pike	34	Reference
5	Reference	10	5 sec	Bear 2.0	20	Reference	25	0 sec	The Pike	35	Reference
		11	0 sec	Bear 2.0			26	5 sec	The Pike		
		12	5 sec	Bear 2.0			27	0 sec	The Pike		
		13	0 sec	Bear 2.0			28	5 sec	The Pike		
		14	5 sec	Bear 2.0			29	0 sec	The Pike		
		15	0 sec	Bear 2.0			30	5 sec	The Pike		

The reason every other test was done using zero second hold time and every other using five second hold time was to get a fair comparison between the two by negating

the effects of the spacer chamber walls being saturated by medicine which could have affected the delivered dose ex-spacer. As can be seen in Table 1, the reference tests were taken at three different times. This was to take in to account the variability in the dose that can occur. For all tests the pMDI product was shaken before each actuation as per the handling instructions for the product. This testing protocol resulted in five samples collected per hold time and spacer model. All in all 20 samples were collected from the two spacer prototypes on 20 different filters and 15 reference samples collected on 15 different filters. Because one way valves had not been designed for each prototype, an attachment (see Figure 11 below) was made that made it possible to connect the inhaler mouth piece and a one-way valve of *AeroChamber Plus Flow-Wu* to each prototype.

Figure 11: Attachment shown in use with **Bear 2.0** telescope.

In order to assess the dose on the filter, and by doing so determining the retention coating of the spacer walls, an analysis was made using liquid chromatography. A "Waters Acquity UPLC" pump was used with an "Acquity BEH C18 2.1x50 mm, 1.7 μm" column, 0,6 ml/min flow rate and 40 degrees celsius column compartment temperature. The injection volume was 2 μl and the detector wavelength 254 nm.

3.6.2 Design- and Patient Risk Assessment

In order to evaluate the concepts and in which areas there is need for improvements a design and patient risk assessment was made. This was done together with members from the company that had expertise within the specific area. First the **The Pike** was evaluated with its potential risks from a design perspective, then the **Bear 2.0**. After this, the same process was performed but in order to locate the patients risk involved.

3.7 Evaluation

To evaluate the two prototypes and how they compare against the four prescribable spacer products in the West Sweden Region, a matrix was made based on the benchmarking study. **The Pike** and **Bear 2.0** were added to the matrix together with how they performed in each criteria. *Maximum length when expanded, Encouraging design, Keep devices organized, Intuitive design* as well as *Delivered dose* were also added as criteria to the pre-existing ones from the benchmarking study.

4 Results

In this section the results will be presented. The topics covered are *Identification of customer needs, Concept generation, Concept selection, Detailed development - Computer Aided Design, Prototyping, Physical testing and finally Evaluation*

4.1 Identification of customer needs

All the information collected from users are presented below as well as the analyses that are used to form the requirements list. The results are divided in to the following topics; *Survey, Semi-structured interviews, Transcription of interviews, KJ-analysis, Quantitative matrix, Qualitative matrix, Benchmarking, Stakeholder analysis and Requirements list.*

4.1.1 Survey

It was decided to include children of the ages three to nine years old within the survey. The reason the six to nine years of age category was included in the survey analysis even though they were not part of the target group for the product, was because they were thought to still have valuable feedback from the time the child were the correct age. Parents with children of the ages of newly born to two years old were not included since they were thought to not have the experience yet of using the product while their child were within the range of age out of interest.

The survey was answered by 97 people of which 90 individuals' whose children use or have used a pMDI, and seven individuals' whose children who never used a pMDI which were excluded from the study. Children were also excluded from the survey if they were not currently using or never had used a spacer. The age group included in the survey were children of three to nine years of age leaving a total of 55%, or 53 people, to finally be analyzed. The demographics for the included population can be seen in Figure 12 and Figure 13 below.

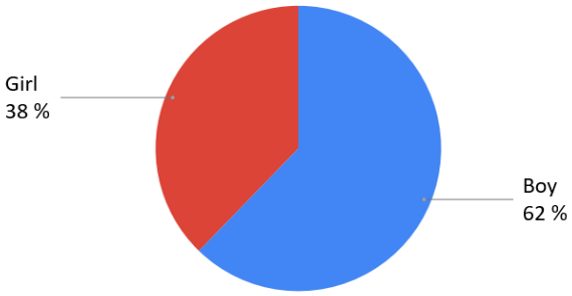


Figure 12: Distribution of girls and boys.

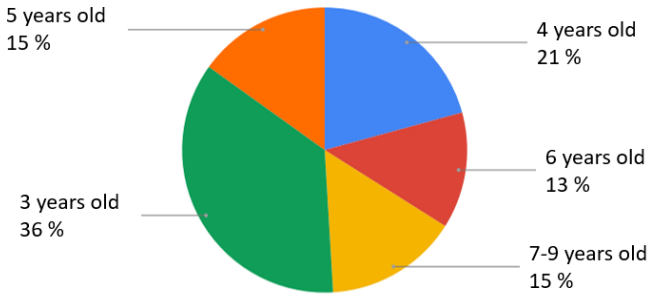


Figure 13: Distribution of age.

Statistics regarding what spacer different individuals used is presented below in Figure 14. Some users had used several different kinds of spacers which is why the total number were higher than 53.

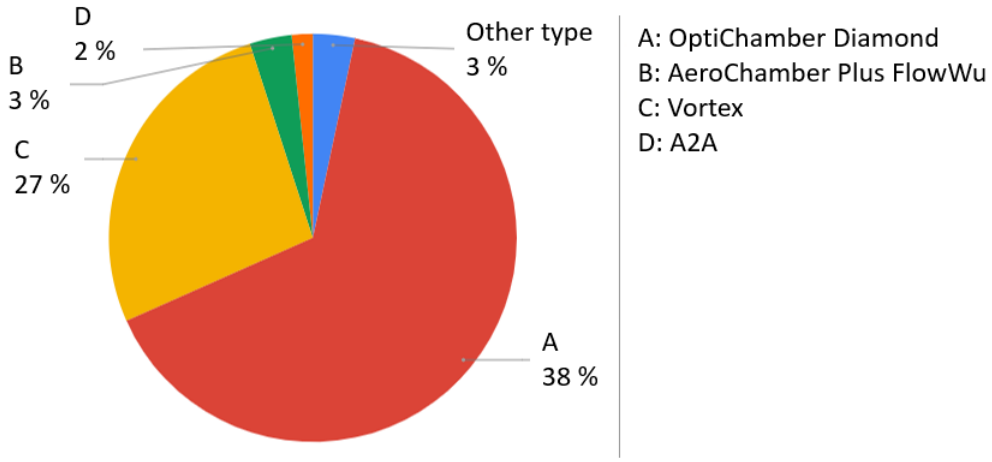


Figure 14: Distribution of what spacer the individuals use.

To get statistics on how often the spacer was used together with the pMDI, a rating scale from one (never), to five (always), asking how often the pMDI is used together with a spacer was asked. The results can be seen in Figure 15. To get a sense of if the portability of the spacer was a problem, a question if the user ever intentionally did not bring the spacer with them because of its size, was asked. Which resulted in 24,5 percent of respondents answering yes to that question.

To get a sense of how important different functions in the spacer actually was rating scales of the following functions included in the survey; ability to reduce spacer in size when not in use, additional feedback system that measures how well the user inhales, a more aesthetically pleasing design and a dose reminder function. The functions were rated on a scale from one, which is not important, to four, which is very important. The amount of answers on each question was multiplied with the corresponding level on the four grade scale. These values were divided by the max possible score of each feature giving them an absolute percentage which can be seen in Figure 16.

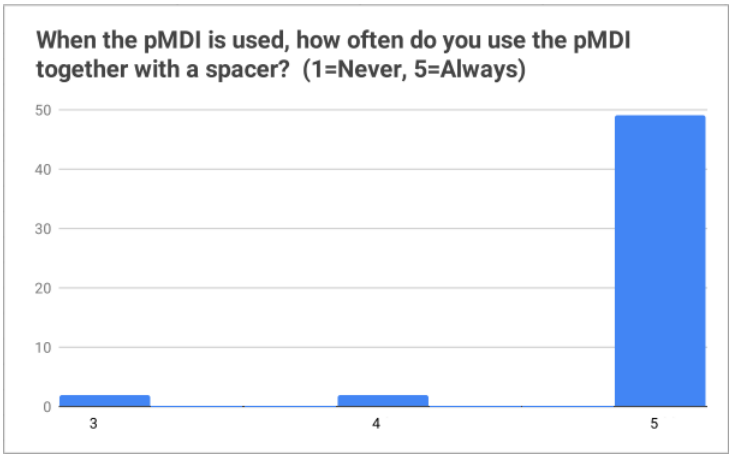


Figure 15: Distribution of the degree of use of the spacer.

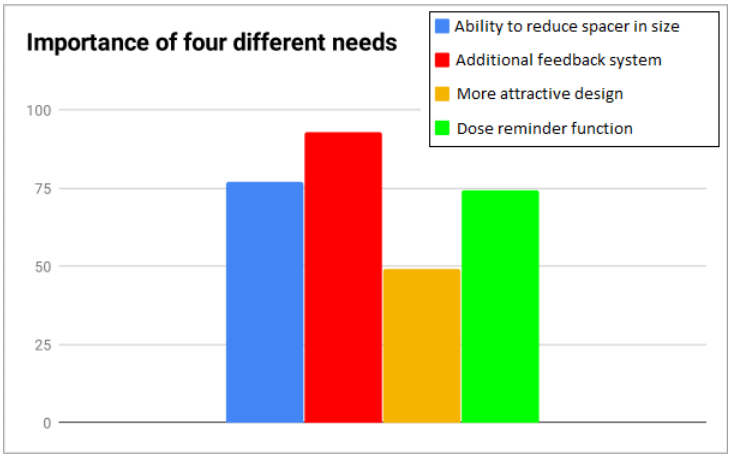


Figure 16: Ranking of how important different features are.

When asked "Under what circumstances has your child experienced discomfort during usage of the spacer?" 34% said they had experienced "no discomfort" and 45% answered they "Found the spacer "scary" or they "Felt embarrassed around their friends/people outside the family". The remaining individuals answered that the child had "Felt uncomfortable during inhalation" or problems related to the mask and other miscellaneous problems.

4.1.2 Semi-structured interviews

Eight parents were interviewed and the duration of each interview were ranging from 20-60 minutes. The interviews were conducted either in conjunction with their child's day care facility or at a conference room at the Chalmers University of Technology. In addition to the parents, one nurse, one physiotherapist and one doctor were interviewed. All of them were currently working with, or had previous experience with children suffering from asthma. Eleven interviews were conducted, where only ten of them were analyzed. The eleventh interview was excluded as their child was outside of the focused age span (18 months old instead of in between three to six years old).

4.1.3 Transcription of interviews

The results of the transcription of the interviews were ten piles of post-it notes with statements. The full results of the transcription of the interviews can be seen in Table 3.

4.1.4 KJ-analysis

The results of the KJ-analysis can be seen in Table 3.

4.1.5 Quantitative matrix

The resulting quantitative matrix can be seen in Table 2. The different needs were put in to categories depending on their theme and to get a better structure. As can be seen two categories, *Portability* and *Physical attributes* got a high ranking on all needs indicating these needs were important for the users. *Aesthetics* on the other hand got quite a low ranking on each need.

Table 2: Quantitative matrix.

Quantitive Survey Analysis				
Spacer - Inhalation chamber device				
Category	**Interpreted need**	**Percentage supporting the need (%)**	**Grading conversion (100% = 10)**	**Questions where its mentioned**
Portability				
	Keep devices organized	97,4 %	97,4% = **10**	1
	Can be reduced in size when not used	(97,4 % + 76,9 %)/2 = 87,2	87,2% = **9**	1,3
Aestethics				
	Encouraging design	(45,3% + 49,1%)/2 = 47,2%	47,2% = **5**	2,5
	Colourful	49,1%	49,1% = **5**	5
	Customizable	49,1%	49,1%= **5**	5
Physical attributes				
	Visible breath-indicator	(92,9% + 74,5%)/2 = 83,7%	83,7% = **8**	4,6

4.1.6 Qualitative matrix

The qualitative matrix can be seen in Table 3 below. All interpreted customer needs were grouped in categories to get a clear structure. Compared to the quantitative matrix were many more categories and needs discovered. The values that stood out to be the most important ones were *Can be reduced in size when not used*, *Visual breath-indicator*, *Durable design* and *Encouraging design*. A majority of the interviewees mentioned these in a positive manner. On the lower scale of the spectrum *Keep devices organized*, *Non-toxic material*, *Low amount of separate parts* and *Low manufacturing cost* were valued low. The reason for these criteria being rated low could be because the interviewees did not see them as a problem or that the current products fulfill these criteria well already.

Table 3: Qualitative matrix.

Qualtitive Interview Analysis		
Spacer - Inhalation chamber device		
CATEGORY	**Interpreted need**	**Number of times mentioned + (Which interview)**
Aestethics		
	Customizable	3 (1,3,8)
	Encouraging design	8 (1,2,3,5,6,8,9)
	Colourful	4 (1,2,5,8)
Ergonomics		
	Physical ergonomics (child)	4 (2,3,4,9)
	Physical ergonomics (Parent)	3 (1,2,4)
	Promotes concentration	7 (1,2,3,5,6,7,8)
Portability		
	Can be reduced in size when not used	10 (1,2,3,4,5,6,7,8,9,11)
	Keep devices organized	2 (8,9)
Cleaning		
	Easy to clean	5 (2,3,4,5,9)
	Boilable	3 (2,3,5)
Safety		
	Non-toxic material	2 (5,11)
	Resistant towards dust and contamination	7 (1,2,3,4,5,9,11)
User friendly		
	Low amount of seperate parts	2 (7,8)
	Flexible spacer inlet	6 (2,3,4,7,9,11)
	Intuitive design	7 (1,3,4,5,6,9,11)
	Durable design	8 (1,3,4,5,6,7,9,11)
	Visible breath-indicator	9 (1,2,3,4,5,6,7,8,11)
Manufacuring		
	Low Manufacturing Cost	2 (3,9)
Material		
	Transparent material	4 (1,4,5,8)

4.1.7 Benchmarking

The result of the benchmarking study can be seen in Table 4. The study clearly shows that every product includes transparent, non-toxic, anti-static and recyclable material which indicates that they were important characteristics that a spacer should have. From the benchmarking study it is also clear that none of the existing products were customizable in the sense of being able to be personalized and at the same time did not provide an opportunity to be able to be reduced in size when not in use, making them increasingly difficult to transport between locations. Simultaneously, through the information given about the four products, it was notable to see that all products

and their volume were below the recommendations given by the *West Sweden Region health authorities*(Allergi-Andning-ÖNH, 2016) guidelines. Hence, indicating that there is room for further development with respect to volume.

Table 4: Benchmarking of the four prescribable spacer products in the West Sweden Region.

CATEGORY	Interpreted need	Metric	Optichamber Diamond	L'espace	Aerochamber Plus	Vortex
Aestethics						
	Customizable	Sold in different variations **(Yes/No)**	No	No	No	No
Ergonomics						
	Physical ergonomics (Child)	Subjective **(1-5)**	3	2	5	3
	Physical ergonomics (Parent)	Subjective **(1-5)**	3	3	3	3
Portability						
	Can be reduced in size when not used	**(Yes/No)**	No	No	No	No
Cleaning						
	Dishwashable	**(Yes/No)**	No	Yes	Yes (<70 degrees)	Yes
	Boilable	**(Yes/No)**	No	Yes	No	Yes
Safety						
	Non-toxic material	**(Yes/No)**	Yes	Yes	Yes	Yes
	Resistant towards dust and contamination	Dust protected in both ends ? **(Yes/No)**	No	No	No	No
User friendly						
	Low amount of seperate parts	Number of seperate pieces **(#)**	2	3	3	2
	Flexible spacer inlet	Compatible with different inhalers **(1-3)**	2	2	2	3
	Breath-indicator	**(Yes/No)**	Yes	No	Yes	No
Performance						
	Low spacer medicine deposition	Amount of drug leaving the spacer (Without mask*) **(Ug/L)**	202	68	221	110
Physical Attributes						
	Small size (Maximum Length, diameter)	**mm**	142x52	135x62	133x45	160x50
	Lightweight construction	**g**	57	66	45	62
	Approriate chamber volume (Litres)	**mL**	140	204	145	200
Manufacturing						
	Sales cost (includes mask)	**SEK/unit**	414	339	499	459
	Contains recyclable material	**(Yes/No)**	Yes	Yes	Yes	Yes
Material						
	Anti-static material	**(Yes/No)**	Yes	Yes	Yes	Yes
	Transparent material	**(Yes/No)**	Yes	Yes	Yes	No

4.1.8 Stakeholder analysis

The result of the stakeholder analysis can be seen in Table 5. Some needs were graded as requirements such as *Non-toxic material*, even though it was graded low in the qualitative matrix. The reasoning behind this was because it is considered nowdays a must for medical devices to be approved for the market (Amaral, 2014). Other requirements such as *Anti-static material* was considered a requirement because of the studied literature supporting it. The two last requirements, *Boilable* and *Visible breath-indicator*, was chosen to give a competitive edge over the other products currently on the market and are considered a must to be implemented in the new spacer (see Table 4). The lowest ranking requirement, *Keep devices organized*, was ranked low because a lot of individuals had an own separate bag to keep all the inhalers and the spacer in one place which was something they were satisfied with. *Lightweight construction* was one of the other criterion that was given a low ranking. This was because all four established spacer products on the market already were lightweight, even exceeding their weight with 50 % would not result in a much heavier or less functional product. Hence, because of this, not thought to be a big competitive edge.

Table 5: Stakeholder analysis.

Stakeholder based analysis		
Spacer - Inhalation chamber device		
CATEGORY	**Interpreted need**	**Grade (1-10, 10 = very important, R = Requirement)**
Aestethics		
	Customizable	3
	Encouraging design	6
	Colourful	5
Ergonomics		
	Physical ergonomics (Child)	7
	Physical ergonomics (Parent)	4
	Promotes concentration	8
Portability		
	Can be reduced in size when not used	10
	Keep devices organized	2
Cleaning		
	Easy to clean	8
	Boilable	R
Safety		
	Non-toxic material	R
	Resistant towards dust and contamination	7
User friendly		
	Low amount of seperate parts	4
	Flexible spacer inlet	8
	Intuitive design	9
	Durable design	6
	Visible breath-indicator	R
Performance		
	Low spacer medicine deposition	8
Physical Attributes		
	Lightweight construction	3
	Approriate chamber volume	5
Manufacturing		
	Easy to assemble	4
	Low Manufacturing Cost	6
	Non-complex design	6
	Contains recyclable material	3
Material		
	Anti-static material	R
	Transparent material	3

4.1.9 Requirements list

The full requirements list is presented in Table 6. The criteria presented in the requirements list are explained in the following list, D means it is a desire and R that it is a requirement:

- **(D) Customizable** - To make the product feel more personal, the design should allow the user to be able to change the spacer appearance in a simplistic way fitting their personal need.
- **(D) Encouraging design** - The design itself is funny or entertaining to use, promoting willingness to use the spacer.
- **(D) Colourful** - The design contains intense rich colours in large parts of its design.
- **(D) Physical ergonomics (Child)** - As a child, the spacer mouthpiece should fit the child's mouth and the spacer should be easy to hold.
- **(D) Physical ergonomics (Parent)** - As a parent, the spacer should be easy to hold while assisting the child during inhalation.
- **(D) Promotes concentration** - The design should be constructed in such way that its appearance, function and feedback system to encourage use and reduce the risk of the child crying and not being focused on the task at hand.
- **(D) Can be reduced in size when not used** - When the spacer is not used, the spacer should able to be folded/compressed etc. in such way that it is smaller than during use, making it easier to transport between locations.
- **(D) Keep devices organized** - Since there is more than one device included in the medication routine for asthma than just the spacer, it can be beneficial to have a solution that can promote the idea of keeping the devices at the same location in a simple way.
- **(D) Easy to clean** - The design should be easy to clean in the sense that the designs internal parts are easily detachable, making it easy to clean by hand.
- **(R) Boilable** - Parts of the spacer should be boilable, reducing the need for being hand washed.
- **(R) Non-toxic material** - Components should made out of materials that are classified as food grade.
- **(D) Resistant towards dust and contamination** - The solution should able to prevent dust from entering the chamber from both the frontside but also from the backside of the spacer.
- **(D) Low amount of separate parts** - The goal is to have a solution that does not involve high amount of parts to reduce need for low tolerances between several moving parts.
- **(D) Flexible spacer inlet** - The inlet design should be designed in such a way that allow the most inhalers to be inserted into the spacer, not limiting the spacer to specific inhaler design.

- **(D) Intuitive design** - The solution should be designed in such way that it is easy to understand how its used during use and cleaning.
- **(D) Durable design** - The solution should be constructed in such way that it can withstand daily occurring wear and tear on the spacer, increasing the product life span.
- **(R) Visible breath-indicator** - The solution should include an indicator that communicates to the user whether its performing the medication in a correct way, giving them feedback on their inhalation technique.
- **(D) Low spacer medicine deposition** - The constructed spacer should be developed in such way that limit the amount of particles that gets stuck within the chamber.
- **(D) Lightweight construction** - This measures the total weight of the design.
- **(D) Appropriate chamber volume** - The volume of the chamber ideally to be made according to the recommendations given by the "West Sweden Region health authorities" healthcare.
- **(D) Easy to assemble** - The spacer should include parts that are designed in such way that they are easy to assemble and disassemble as an user.
- **(D) Low Manufacturing Cost** - The total cost of the manufacturing process should be kept low as a result design and materials selected.
- **(D) Non-complex design** - Parts needs to be designed in such way that they are easy to manufacture and minimizes the need for separate assembling tools to fit together.
- **(D) Contains recyclable material** - Components should be made out of recyclable material.
- **(R) Anti-static material** - The inside of the spacer chamber should be made out of material that are anti-static, preventing particles getting stuck inside the spacer as a result of static charge.
- **(D) Transparent material** - The optical quality and how big part of the chamber that is composed of transparent material , allowing the user to know whether the chamber needs to be cleaned or not.

Table 6: Requirements list.

Requirements list						
Spacer - Inhaltion chamber device						
CATEGORY	**Interpreted need**	**Grades (Qual, Quant, KB)**			**Total Grade**	**Verification method**
Aestethics						
	Customizable	3	5	3	**4**	Physical testing
	Encouraging design	8	5	6	**6**	Survey/Follow-up interview
	Colourful	4	5	5	**5**	Survey/Follow-up interview
Ergonomics						
	Physical ergonomics (Child)	4	N/A	7	**6**	Anthropometry + RULA (Rapid Upper Limb Assessment)
	Physical ergonomics (Parent)	3	N/A	4	**4**	RULA (Rapid Upper Limb Assessment)
	Promotes concentration	7	N/A	8	**8**	Internal evaluation
Portability						
	Can be reduced in size when not used	10	9	10	**10**	Physical measuring
	Keep devices organized	2	10	2	**5**	Physical testing
Cleaning						
	Easy to clean	5	N/A	8	**7**	Physical testing
	Boilable	3	N/A	R	**R**	Material selection
Safety						
	Non-toxic material	2	N/A	R	**R**	CES Edupack - Material evalution
	Resistant towards dust and contamination	7	N/A	7	**7**	Internal evaluation
User friendly						
	Low amount of seperate parts	2	N/A	4	**3**	CAD model evaulation
	Flexible spacer inlet	6	N/A	8	**7**	Physical testing
	Intuitive design	7	N/A	9	**8**	Survey/Follow-up interview
	Durable design	8	N/A	6	**7**	Physical testing
	Visible breath-indicator	9	8	R	**R**	Internal evaluation
Performance						
	Low spacer medicine deposition	N/A	N/A	8	**8**	Physical testing
Physical Attributes						
	Lightweight construction	N/A	N/A	3	**3**	CAD model evaulation
	Approriate chamber volume	N/A	N/A	5	**5**	CAD model evaulation
Manufacturing						
	Easy to assemble	N/A	N/A	4	**4**	DFA
	Low Manufacturing Cost	2	N/A	6	**4**	Cost analysis
	Non-complex design	N/A	N/A	6	**6**	Internal evaluation
	Contains recyclable material	N/A	N/A	3	**3**	CES Edupack - Material evalution
Material						
	Anti-static material	N/A	N/A	R	**R**	CES Edupack - Material evalution
	Transparent material	4	N/A	3	**4**	CES Edupack - Material evalution

All the criteria that were rated as requirements in the *Stakeholder analysis* were ranked as requirements in the requirements list. The most important need was *Can be reduced in size when not used* since this was ranked high in all previous matrices. *Promotes concentration*, *Intuitive design*, and *Low spacer medicine deposition* were all ranked among the top because of their importance from the previous matrices.

4.2 Concept generation

Results from the concept generation step are presented in the following topics; *Patent landscape search, Functions means tree, Brainstorming, Concept combination table and Study visit.*

4.2.1 Patent landscape search

The first patent landscape search regarding spacers resulted in 318 different patents which were screened one by one to see which one was relevant for the project. 51 patents were connected to spacers or valved holding chambers and descriptions as well as pictures taken to be used as aid when generating concepts (see Appendix *C - General Patent Landscape Search*).

The rest of the patent landscape searches regarding specific requirements resulted in five different patents which were photographed to be used as inspiration (See Appendix *D - Functional Patent Search*).

4.2.2 Functions means tree

The function means tree is based on *Philips OptiChamber diamond* and is presented in Figure 17. The blue boxes represents functions and the white ovals represent means or components. As can be seen two functions merges in to the same component which means they can either be integrated in one, or separated into two parts. The five functions created that were included in the *Philips OptiChamber*, were: *Hold inhaler, Prevent contamination, Give feedback, Contain medication* and *Minimize static electric charge*.

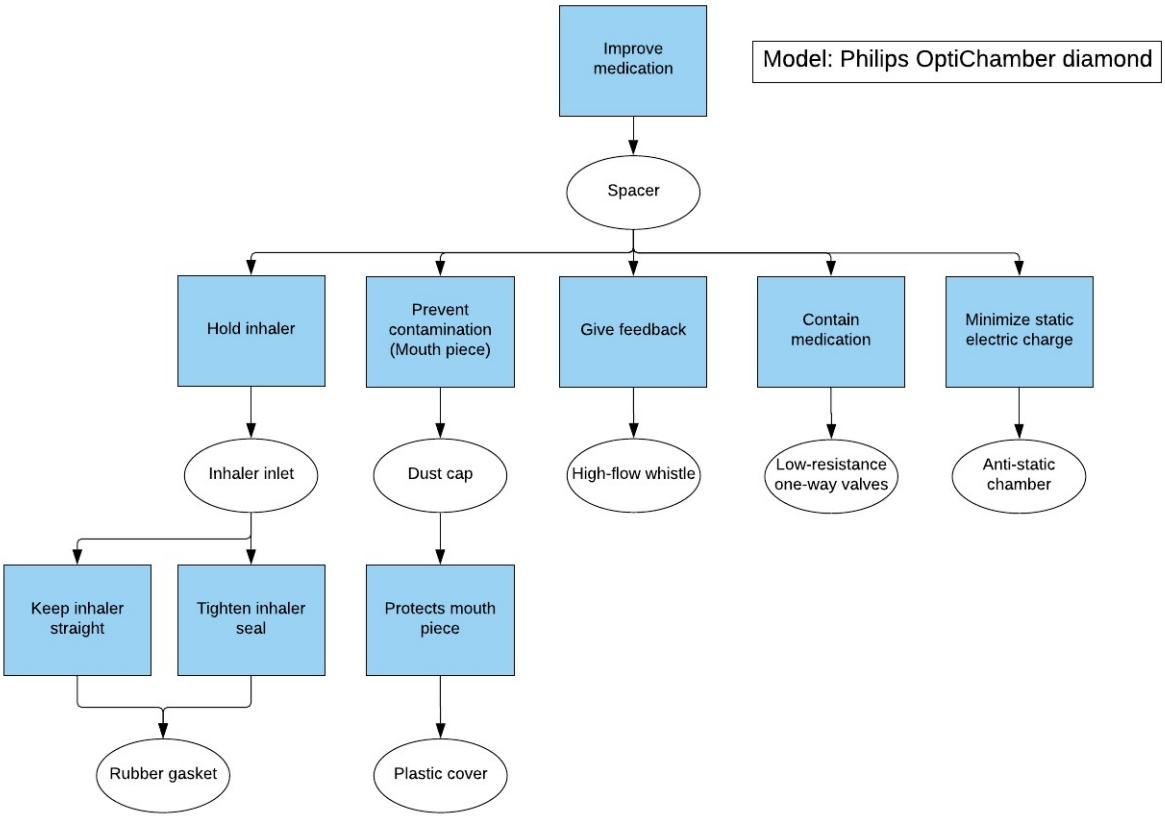


Figure 17: Function means tree of *Philips OptiChamber diamond*

4.2.3 Brainstorming

From the different brainstorming sessions a total number of 28 complete concepts were generated, 15 different feedback systems, 12 different ways to reduce something in size, five concepts for how to prevent contamination, 23 variants around encouraging design, and 12 miscellaneous other fragmented solutions. Each of these were documented in one or several drawings.

4.2.4 Concept combination table

The result of the second concept combination table can be seen in Table 7. From a second combination table, ten new concepts were generated, that were unique compared to previous acquired concepts from the brainstorming sessions. Ten new sketches were developed, representing each of the new concepts (see Appendix *E - Concept combination table 2 results*).

Table 7: Concept combination table

Function	Concept number													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Hold inhaler	"Rubber" inlet	Baloon ring	Inhaler shaped backside	Tightening cords										
Hold inhaler extra	Foldable flaps	None												
Prevent contamination (Inhaler inlet)	Closed membrane	Integrated bag	Dust-cap	Hinged dustcap	Integrated "box"	Orange inlet	None							
Prevent contamination (Mouthpiece)	Integrated bag	Dust-cap	Hinged dust-cap	Integrated "box"										
Give feedback	Ball with colour	Water wheel counter	Rubber membrane + colour	Vibrating membrane	Figure shaped baloon	Human + rot. membrane	Clicker + membrane	Inflatable outer shell	Pressure sensor + diode	Mechanic whistle + cellphone	Pressure sensor + app			
Contain medication	One-way valve													
Minimize static electric charge	Anti-static material													
Adjustable size	Compressible, 1 piece	Telescope with bag	Telescope	Plastic +magnets	Foldable direction	Bag square	Inflatable valved walls	Origami	Retraction system	Slideable crutchpin	Hinged tubes	Rollable + Valved	2- Piece divided	None
Easy cleaning	Hinged tubes	None												
Customisable apperance	Outer "lego" shell	Theme rolls	Changable theme	Interchangable parts	None									
Keep organized	Integrated dustcap and elastic bands	Elastic bands	Integrated bag	Foldable flaps	Outside holders	Retractable bag	Store inside	Integrated "box"	None					
Mouth piece	"Mouth"-shaped	Circle Shaped												
Encouraging design	Extractor/compac.	Animal print	Car	Treasure chest	Crocodile	Elefant	Fish	Lemur	Turtle	Ufo	Train	Baloon	Snake	

4.2.5 Study visit

The result of the visit to *Naturkompaniet* and *Fjällsport* is presented in this chapter. One product specifically interesting found at *Naturkompaniet* was the compressible cup shown in the Figure 18. The solution is a portable and foldable cup. The idea for different compressible telescope spacer concepts was inspired by this concept.

Figure 18: Camping cup

Figure 19: Stuffed fish

At *Naturkompaniet* they also had a few stuffed animals, one that was in particularly interesting was a fish, which is shown in Figure 19. The fish's shape being long and having a relatively thin diameter resembled the shape of a traditional spacer and raised the idea of a fish-shaped spacer. Ultimately, two concepts were based on this specific idea.

In order to look at specifically encouraging elements in designs for children the toy store *Lekia* was explored. At *Lekia*, several toys were analyzed regarding elements in the design making them appealing for young children and how these elements could be incorporated into spacer solutions. In Figure 18 and Figure 19 two products are shown that were considered promising, which were one treasure chest and a baby.

Figure 20: Treasure Chest

Figure 21: Interactive baby

The treasure chest was judged interesting due to the pirate theme. The baby toy did not only have a theme that was directly connected to the movie franchise "the incredible", but also allowed the user to be interactive with it, an element that could be used within spacers in hopes to encourage use and improve the inhalation pattern overall.

4.3 Concept selection

The concept selection phase was covered by the following topics; *Elimination matrix, Pugh matrix and Kesselring matrix.*

4.3.1 Elimination matrix

After the elimination matrix evaluation was performed, 17 concepts of the total 28 concepts were taken into further development. Out of the 17 accepted concepts, six concepts were still in need of further investigation before they could be taken directly into the Pugh matrix. As can be seen in the elimination matrix Table 8, eight concepts were eliminated because they failed to fulfill the *Can be reduced in size when not used* criterion. The three last eliminated concepts failed on the criterion *Realizable* for being too uncertain if they would be realistic to design or not. The ones that were given a *(?)* in some criteria, meaning that more info was needed in that aspect. They were finally decided to go through to the Pugh matrix in order to be further developed prior to the matrix itself and the unsure criterion investigated.

Table 8: Elimination matrix.

Elimination matrix for:								**Criteria fulfilment:** (+) Yes (-) No (?) More info needed **Decision:** (+) Continue (-) Remove (?) More info needed	
Solution alternative	**Boilable**	**Non-toxic material**	**Breath-indicator**	**Anti-static**	**Can be reduced in size when not used**	**Realizable**	**Low manufacturing cost**	**Comment**	**Decision**
Finding Nemo	+	+	+	+	-				**-**
Nalle	+	+	+	+	+	+	+		**+**
Jack Sparrow	?	+	+	+	-				**-**
The Camping Rug	?	+	+	+	+	+	+		**?**
The friendly croco	+	+	+	+	-				**-**
The plastic bag telescope	?	+	+	+	+	+	+		**?**
Gracious Elefant	+	+	+	+	-				**-**
MTR Express	+	+	+	+	-				**-**
Lambo SUV	+	+	+	+	-				**-**
Alien Attack	+	+	+	+	-				**-**
Donatello	+	+	+	+	+	+	+		**+**
Terminator	+	+	+	+	+	-			**-**
King Julien	?	+	+	+	+	+	+		**?**
Twister	+	+	+	+	+	+	+		**+**
Origamic Lifeguard	?	+	+	+	+	-			**-**
Square bag	?	+	+	+	+	+	+		**?**
The Pencilholder	+	+	+	+	+	+	+		**+**
The silicon cup	+	+	+	+	+	+	+		**+**
The gamer	+	+	+	+	-				**-**
The easy gamer	?	+	+	+	+	+	+		**?**
Bear 2.0	+	+	+	+	+	+	+		**+**
Mr Obvious	+	+	+	+	+	+	+		**+**
The pencil purse	?	+	+	+	+	+	+		**?**
Baloon Fever	+	+	+	+	+	-			**-**
Sad Croco	+	+	+	+	+	+	+		**+**
The pike	+	+	+	+	+	+	+		**+**
The happy mouse	+	+	+	+	+	+	+		**+**
Space Snake	?	+	+	+	+	+	+		**+**

4.3.2 Pugh Matrix

The reference product within the matrix was a combination of the four currently prescribable spacer devices within the "West Sweden Region health authorities", whereas a majority of the reference was constructed based on the *Aerochamber Plus Flow-Wu*. The first iteration of the Pugh matrix can be seen in Table 9. Seen in the Pugh 1 matrix all of the concepts were worse than the reference in terms of *Intuitive design*, which was because all of the concepts were reducible in size meaning they had at least one additional step before they could be used than the current established products. All of the concepts were performing the same as the reference in *Easy to clean* as the reference already was boilable and to clean it, the user just let it rest in boiling water or put it in a dish washer. All the concepts in development were assumed to be made out of boilable material and were therefore considered to be equal in this regard. Another criterion where the developed concept could not exceed the reference either was the *Flexible spacer inlet* as the *Vortex* had a flexible inlet which allows for a tight seal around all pMDI products that it was tested with. Some criteria where the developed concepts gained advantage were *Can be reduced in size when not used, Encouraging design* and *Keep devices organized* among other things. It was decided to keep the concepts that scored a total net score of three or higher to go through to the next stage. All in all, six concepts made it through to the next iteration of the matrix called Pugh matrix 2 in Table 9 shown in Figure. The concepts with their names in highlighted in green are the ones that scored the highest and that are scored again in Pugh 2.

Using **Bear 2.0** as a reference concept in Pugh 2, resulted in a similar outcome when it came to which concepts were standing out from the crowd, which in this case were **King Julien**, **Mr Obvious**, **Sad Croco** and **The Pike**. The difference between the itterations was that the concept called **The Pencilholder** got significant worse score with the switch in reference concepts and as a result, got eliminated prior to the Kesselring matrix. The reason **The Pencilholder** got rejected at this stage was that even the positive aspects gained in the first iteration were worse than **Bear 2.0** when comparing their performance in the same aspects.

Table 9: Pugh Matrix 1 and 2

Pugh 1

	Alternative												
Criterion	Naile	The Camping Rug	The plastic bag telescope	Donatello	King Julien	Twister	Square bag	The Pencilholder	**Reference**	The silicon cup	The easy gamer	Bear 2.0	Mr Obvious	The pencil purse	Sad Croco	The pike
Customizable	0	0	0	0	+	0	0	+	0	0	0	+	+	0	0	0
Encouraging design	+	0	+	+	+	0	-	0	0	0	+	+	+	0	+	+
Physical ergonomics (Child)	0	-	0	-	0	0	-	0	0	0	0	0	0	0	0	0
Physical ergonomics (Parent)	0	-	0	-	0	0	-	0	0	0	0	0	0	0	0	0
Promotes concentration	0	0	0	+	0	+	0	+	0	+	0	+	0	0	+	+
Can be reduced in size when not used	+	+	+	+	+	+	+	+	0	+	+	+	+	0	+	+
Keep devices organized	+	+	0	0	+	0	0	+	0	0	+	0	0	0	+	+
Easy to clean	0	0	0	0	0	0	0	0	0* L'espace/Vortex	0	0	0	0	0	0	0
Resistant towards dust and contamination	0	0	0	0	+	+	0	+	0	+	0	0	+	0	+	+
Flexible spacer inlet	0	0	0	0	+	0	0	0	0* Vortex	0	0	0	0	0	0	0
Intuitive design	-	-	-	-	-	-	-	-	0	-	-	-	-	-	-	-
Durable design	0	-	-	-	-	0	-	0	0	0	0	0	0	0	0	0
Lightweight construction	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Appropriate Chamber Volume	0	0	+	0	+	0	0	+	0* L'espace	0	0	+	+	0	0	0
Transparent material	0	0	0	-	0	-	0	+	0* Optichamber	-	0	0	0	0	0	-
Sum +	3	2	3	3	6	3	1	6	0	3	3	6	5	3	7	5
Sum -	1	4	2	5	2	2	4	1	0	2	1	1	1	1	2	2
Sum 0	11	9	10	7	7	10	10	8	15	9	10	8	9	10	6	7
Net value	2	-2	1	-2	4	1	-3	5	0	1	2	5	4	2	5	3
Placing	7	11	10	11	4	8	14	1	N/A	8	7	1	4	7	1	4
Furter developement	No	No	No	No	Yes	No	No	Yes	N/A	No	No	Yes	Yes	No	Yes	Yes

Pugh 2

	Alternative												
Criterion	Naile	The Camping Rug	The plastic bag telescope	Donatello	King Julien	Twister	Square bag	The Pencilholder	Bear 2.0	The silicon cup	The easy gamer	Mr Obvious	The pencil purse	Sad Croco	The pike	The happy mouse
Customizable	-	-	0	-	-	-	0	-	0	0	-	-	-	0	0	-
Encouraging design	+	0	-	+	+	-	-	-	0	0	0	0	0	+	+	+
Physical ergonomics (Child)	0	-	0	-	0	0	-	0	0	-	0	0	0	-	0	0
Physical ergonomics (Parent)	0	-	0	-	0	0	-	0	0	0	0	0	0	-	0	0
Promotes concentration	0	+	0	+	0	+	0	0	0	0	0	0	0	+	0	0
Can be reduced in size when not used	0	-	0	0	0	0	-	-	0	0	0	0	0	0	0	0
Keep devices organized	-	0	-	-	0	0	0	0	0	-	0	0	0	0	0	-
Easy to clean	0	0	0	0	-	0	-	0	0	0	0	0	0	-	0	-
Resistant towards dust and contamination	-	-	-	-	0	0	-	0	0	0	0	0	0	0	0	0
Flexible spacer inlet	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Intuitive design	0	-	-	0	0	0	0	-	0	0	0	0	0	0	0	0
Durable design	0	-	-	0	-	0	-	0	0	0	0	0	0	-	0	0
Lightweight construction	-	0	0	0	0	0	0	0	0	0	0	0	0	+	0	0
Appropriate chamber volume	0	-	-	-	-	-	-	0	0	-	-	0	-	-	-	-
Transparent material	0	0	-	-	0	-	0	0	0	-	0	+	0	0	-	-
Sum +	1	1	0	2	1	1	0	0	0	0	0	1	0	3	1	1
Sum -	4	7	7	8	3	5	7	6	0	5	4	3	3	5	2	5
Sum 0	10	7	8	5	11	9	8	9	15	10	11	11	12	7	12	9
Net value	-3	-6	-7	-6	-2	-4	-7	-6	0	-5	-4	-2	-3	-2	-1	-4
Placing	5	12	14	12	2	7	14	11	N/A	11	7	2	5	2	1	7
Furter developement	No	No	No	No	Yes	No	No	Yes	N/A	No	No	Yes	No	Yes	Yes	No

4.3.3 Kesselring Matrix

The best performing concepts within the Kesselring matrix were **Bear 2.0** together with the concept **The Pike**, as can be seen in Table 10. The Kesselring matrix relative performance scale can be seen in Table 11. **Bear 2.0** received 409 points as a total score mainly because of its ability to be reduced in size when it was not used. It is supposedly becoming reduced in size to such an extent that it received the maximum score in that regard and since this need was graded the highest in the list, it became a major factor for its success. The solution also performed great in criteria such as "Resistant towards dust and contamination" and "promotes concentration". With the orange inlet, dust particles can be kept outside of the spacer when the pMDI is not connected giving the solution a high score in this regard. The pressure sensor with diod gives the user a sense of feedback when performing the procedure correctly and by giving out light signals it can help the user keeping their concentration on the spacer during the inhalation. **The Pike**, like **Bear 2.0**, did perform exceptional in the aspect "can be reduced in size when not used" and thus received a high score because of its two-sided telescope and received a total of 384 points. **The Pike**'s biggest advantage compared to other concepts was its encouraging design as it is designed and painted as a fish, assumed appealing to young children. Another benefit with the solution is its capability to hold extra devices under its fins and was performing well in the "Keep devices organized" aspect.

Table 10: Kesselring matrix

Criteria	Weight factor (0-10)	Solution alternative											
		Reference		King Julien		Bear 2.0		Mr. Obvious		Sad croco		The pike	
		v	t	v	t	v	t	v	t	v	t	v	t
Customizable	**4**	3	12	4	16	5	20	4	16	4	16	3	12
Encouraging design	**6**	3	18	4	24	4	24	3	18	4	24	5	30
Colourful	**5**	3*Aerochamber	15	4	20	4	20	4	20	4	20	5	25
Physical ergonomics (Child)	**6**	3	18	2	12	2	12	3	18	2	12	3	18
Physical ergonomics (Parent)	**4**	3	12	2	8	2	8	3	12	2	8	3	12
Promotes concentration	**8**	3	24	2	16	4	32	4	32	4	32	4	32
Can be reduced in size when not used	**10**	3	30	3	30	5	50	5	50	5	50	5	50
Keep devices organized	**5**	3	15	3	15	5	25	3	15	4	20	5	25
Easy to clean	**7**	3* L'espace/vortex	21	2	14	3	21	3	21	2	14	3	21
Resistant towards dust and contamination	**7**	3*Vortex	21	4	28	5	35	4	28	4	28	4	28
Low amount of seperate parts	**3**	3	9	3	9	3	9	2	6	2	6	2	6
Flexible spacer inlet	**7**	3*Vortex	21	3	21	3	21	3	21	3	21	3	21
Intuitive design	**8**	3	24	1	8	3	24	3	24	2	16	3	24
Durable design	**7**	3	21	1	7	3	21	3	21	2	14	3	21
Lightweight construction	**3**	3	9	4	12	2	6	2	6	4	12	2	6
Appropriate chamber volume	**5**	3* L'espace	15	4	20	5	25	5	25	3	15	3	15
Easy to assemble	**4**	3	12	1	4	3	12	2	8	2	8	2	8
Low Manufacturing Cost	**4**	3	12	2	8	2	8	2	8	2	8	2	8
Non-complex design	**6**	3	18	2	12	3	18	2	12	2	12	2	12
Contains recyclable material	**3**	3	9	3	9	2	6	2	6	2	6	2	6
Transparent material	**4**	3*Optichamber	12	3	12	3	12	3	12	3	12	1	4
Sum		348		**305**		409		**379**		**354**		384	
Rank		N/A		5		**1**		3		4		**2**	
Decision		N/A		No		Yes		No		No		Yes	

Table 11: Kesselring matrix - Relative performance scale

Relative performance	
Much worse than reference	1
Worse than reference	2
Same as reference	3
Better than reference	4
Much better than reference	5

4.3.4 Final concepts

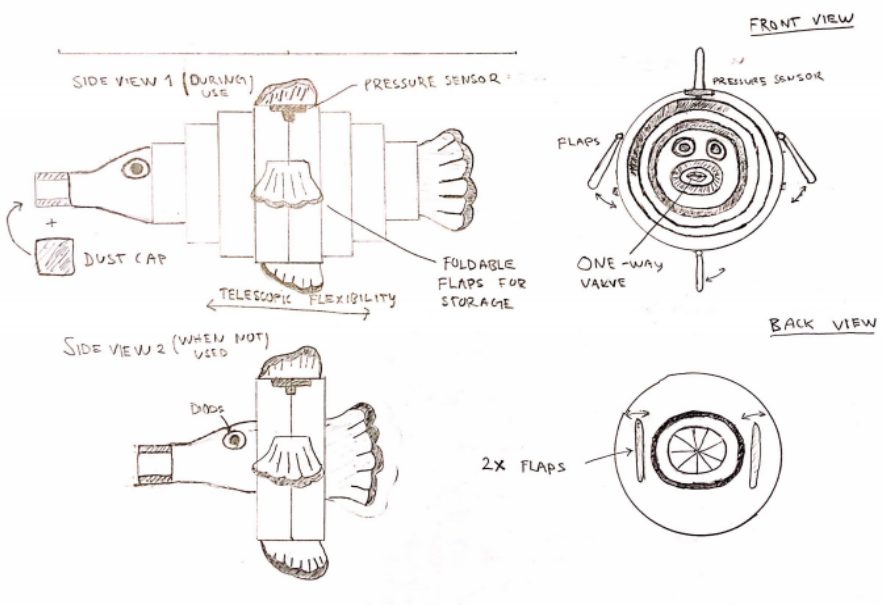


Figure 22: The pike - Concept

The Pike is a fish inspired concept constructed of 2-sided telescopic anti-static chamber, foldable flaps, pressure sensor connected to two light diodes, rubber inlet, orange inspired contamination protection, one-way valve and a dust cap (see Figure 22).

As the solution is constructed as two telescopes connected to each other the solution can be compressed to a fraction of its original size while not in use. With the help of the flaps, the solution allows for external storage where the flaps are folded over a pMDI connecting the ends of the flaps to a sticky surface on the fish-body, retaining it. The pressure sensor is sending out signals when the desired flow-rate is applied, signaling the diodes located in the eyes of the fish to send out a specific light whether the flow-rate is within or over the ideal flow-rate range. Green signals for a flow rate that is within the accepted range whereas red signals that the inhalation has been performed with a excessive flow-rate. With the orange contamination protection shown in Figure 22 under "Back View", together with the dust-cap the solution is resistant towards dust particles entering the spacer when it is not in use. The concept will also include a QR-code that brings the user to an instruction video to improve user experience and ensure correct technique.

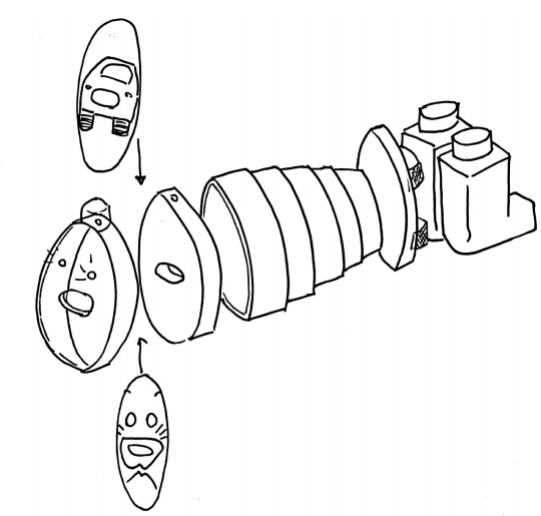


Figure 23: Schematic drawing of the **Bear 2.0** concept.

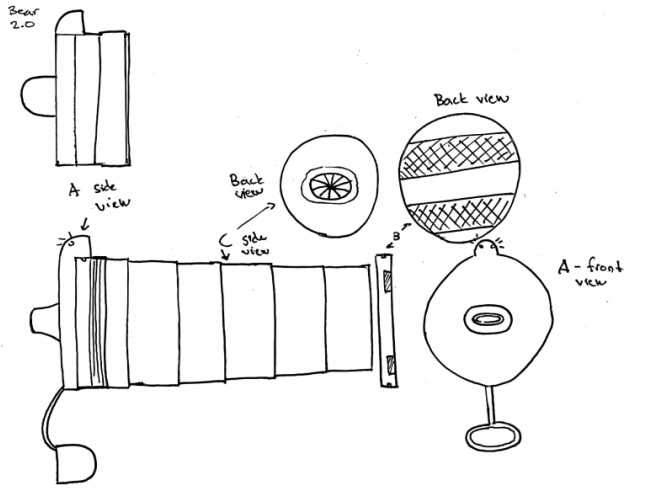


Figure 24: Drawing showing involved parts as well as folded and un-folded position.

Two conceptual pictures of **Bear 2.0** can be seen in Figure 23 and Figure 24. The concept consists of a transparent telescope with an anti-static chamber, a transparent customizable front, a back piece with elastic bands to hold two inhalers, pressure sensor connected to two light diodes, rubber inlet with orange shaped contamination protection, one-way valve and a dust cap to protect the mouthpiece.

This concept was developed with the purpose of making the most portable design possible. The front is transparent with a compartment where the user can put their own desired theme, either printed from a computer or hand drawn, to make it customizable and also more encouraging for the user. For a concept sketch of this see Figure 23. The front piece has a hole for the mouthpiece and is also connected to the telescope. The mouthpiece is protected with a dust cap that is attached to the front cover. At the other end of the telescope there is a soft inlet to allow any shape of inhaler and with an integrated membrane, kind of resembling an orange peel pattern (see Figure 24) to protect against dust and other types of contamination from the environment. Like **The Pike** this concept also has a pressure sensor, which measures the inhalation flow, is connected to two light diodes. When inhaling with the the correct flow rate the green light turns on and when inhaling with a too high or too low of airflow the red light turns on and in that way gives feedback to the user. The lights can be seen both from the front by the user and from the side by for example a parent. Bright colours will be added by having all none transparent parts coloured in bright colours. To make it more intuitive, visual instructions in the shape of four pictures describing the using procedure will be printed on the side of the case as well as a QR-code being present. The QR code will be connected to an online video with instructions on how to use the product.

4.4 Detailed development - Computer Aided Design

In this section all the results from detailed development will be presented with some calculations as well as images from the CAD software as well as rendered images with the right colours.

Bear 2.0 as shown in Figure 25, has a chamber volume of 273 ml and in expanded mode it measures 130 mm long with a max diameter of 67 mm. When pushed together for max portability is measures 52 mm long and a diameter of 67 mm. An exploded view of **Bear 2.0** can be seen in Figure 25. It consists of one back piece (1), one flexible inlet (2), five telescope parts (3-7), three front pieces to allow for the customizable front picture (8-10), one mouth piece (11) and one dust cap for the mouthpiece (12).

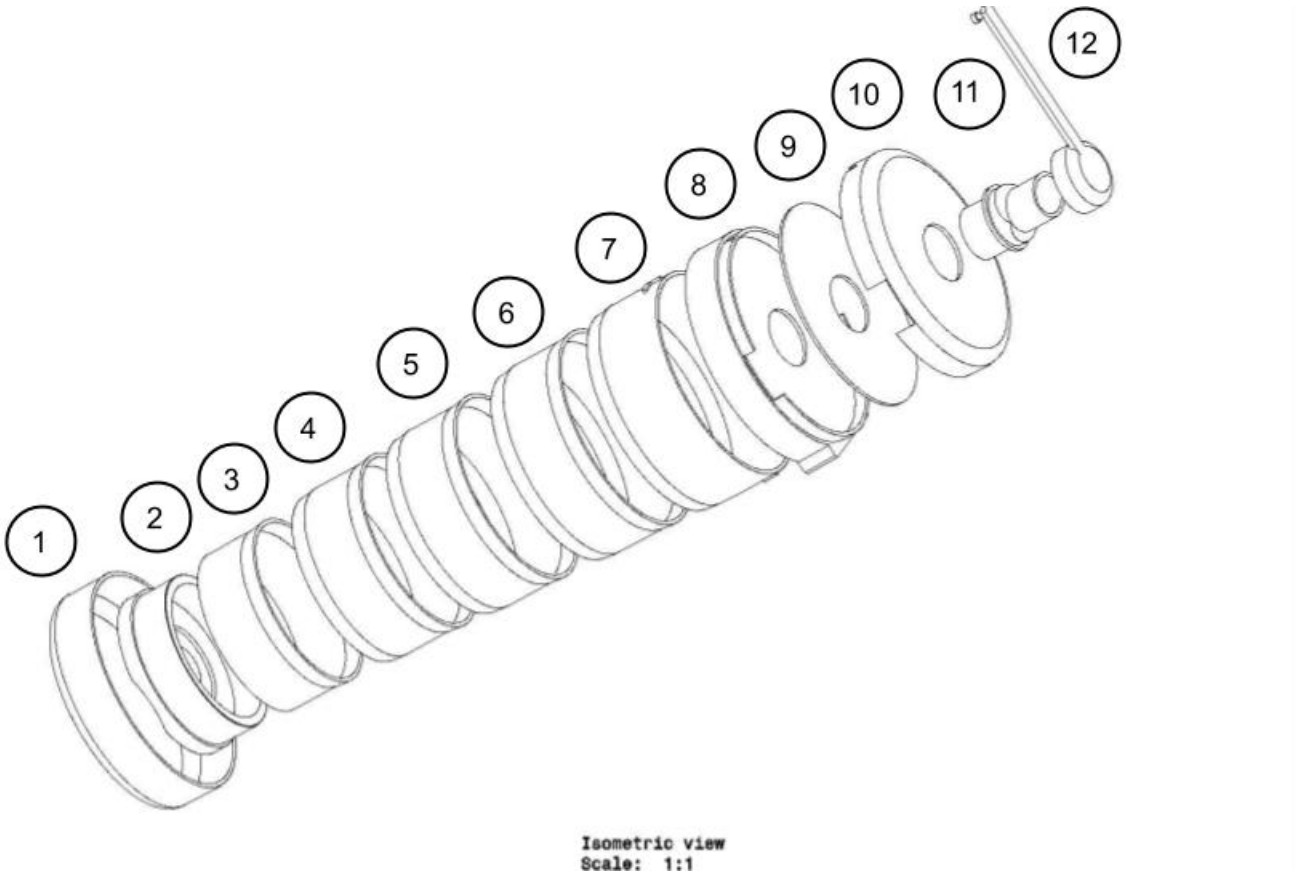


Figure 25: Exploded view of **Bear 2.0**

Figure 26 shows the concept when the telescope is expanded and is ready for use.

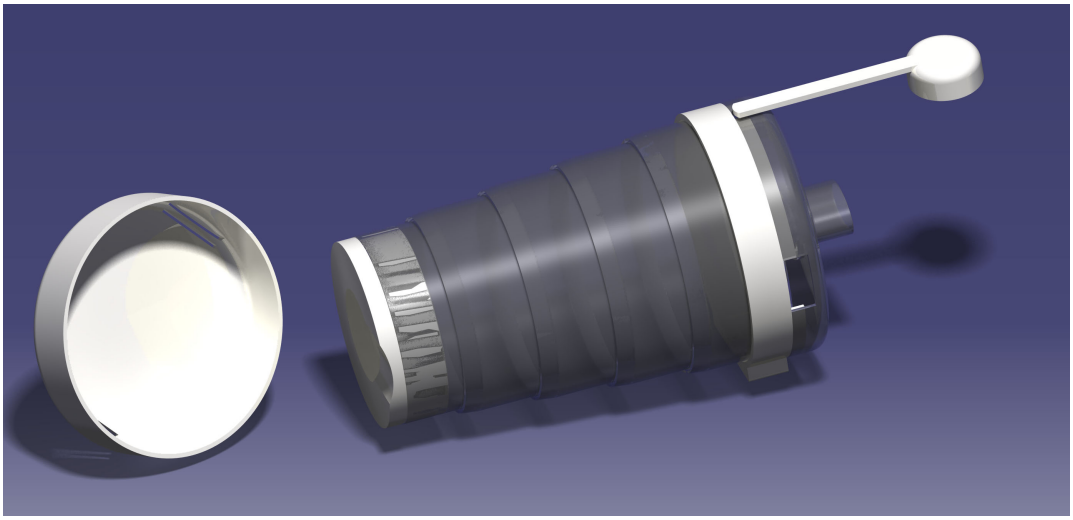


Figure 26: Bear 2.0 expanded and ready for use.

Figure 27 shows **Bear 2.0.** when the telescope is pushed together and the back piece is attached. In the figure a sample of instructions to be included on the back piece is shown to better illustrate the entire concept.

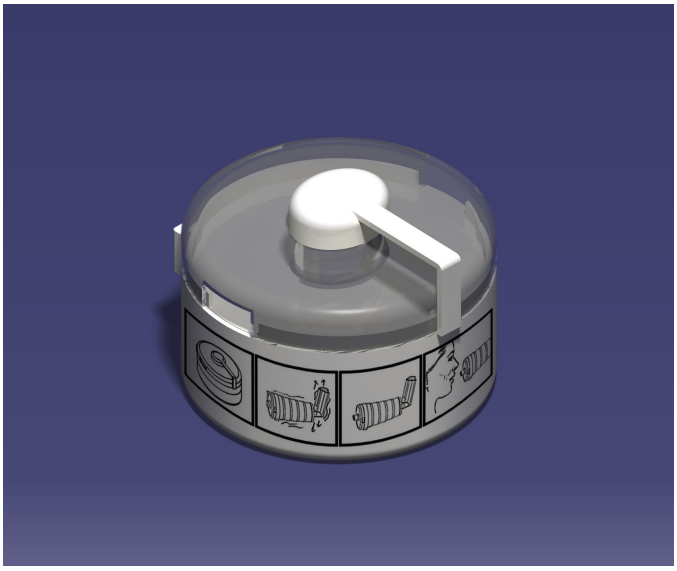


Figure 27: Bear 2.0 when it is not in use.

The Pike in a exploded view is shown in Figure 28. The solution includes a total number of 12 components. (1) is showing the mouthpiece shaped as a fish and (2,3,5,6,7) are presenting each of the telescoping parts. Number (4) in the figure is showing the telescopic stop that prevents the telescopic parts to move past the middle point of the

fish whereas (8) is visualizing the flexible inhaler inlet and (9) are showing the four fish fins (9). The total volume of **The Pike** is measured to 192 ml and at a total length of 137 mm during use, and 100 mm when compressed and not in use. The largest part in diameter and width are the telescopic stop at a diameter of 69 mm and a width of 50 mm and the total weight of **The Pike** is 64 grams.

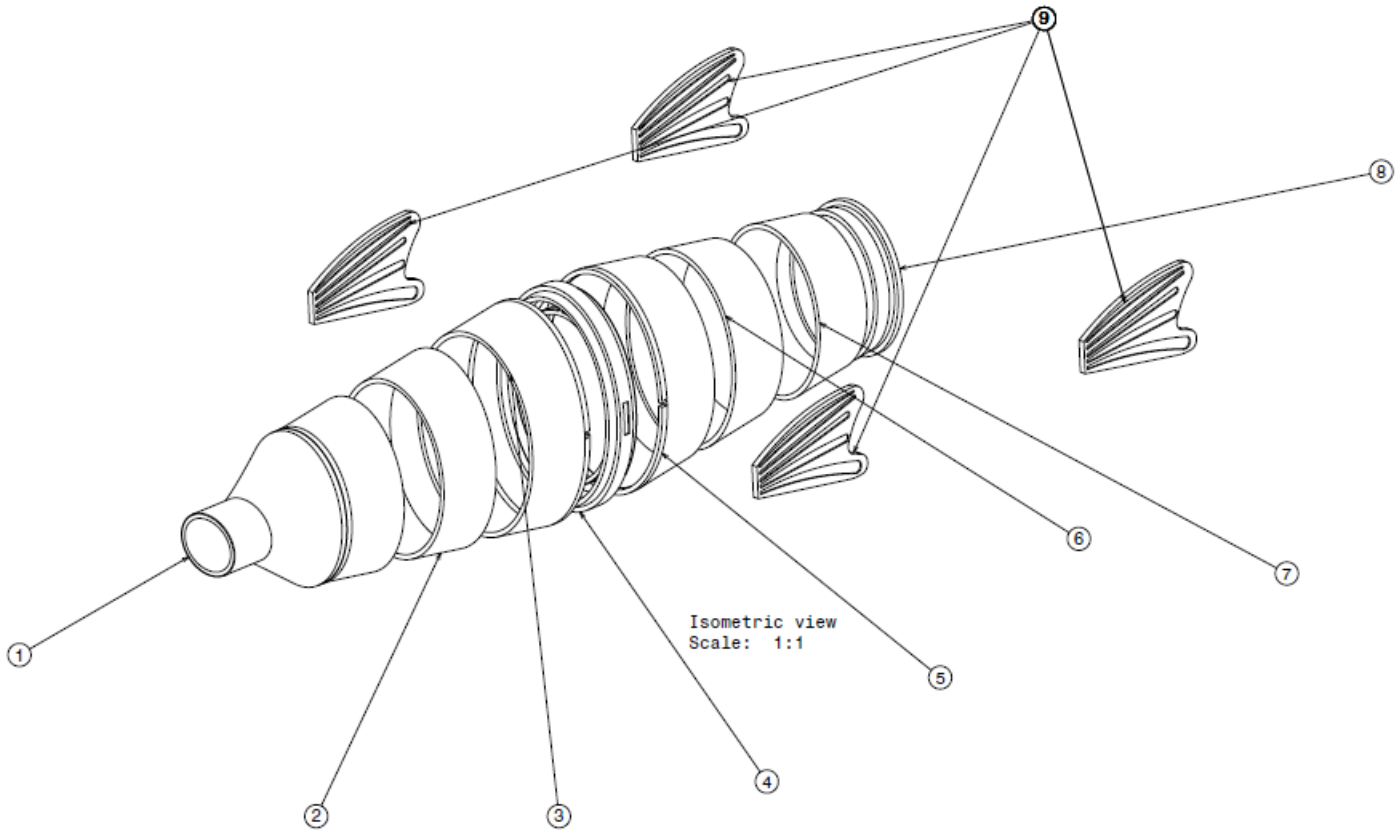


Figure 28: Exploded view of **The Pike**

The children spacer is shown in Figure 29 with the intended colours and fish eyes. The model is with its theme aimed to be encouraging for children to use and bring to public places without feeling embarrassed. Within Figure 30 **The Pike** is shown when its compressed and not in use, together with a inhaler received from the *GrabCad library*.

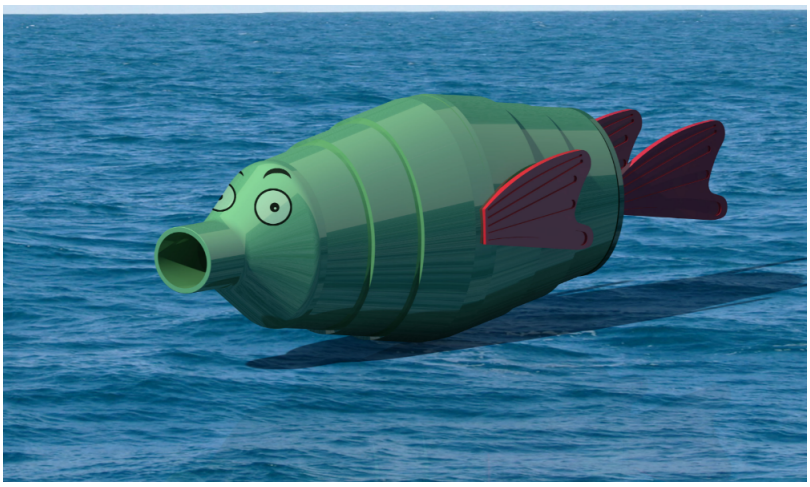


Figure 29: The Pike expanded and ready for use.

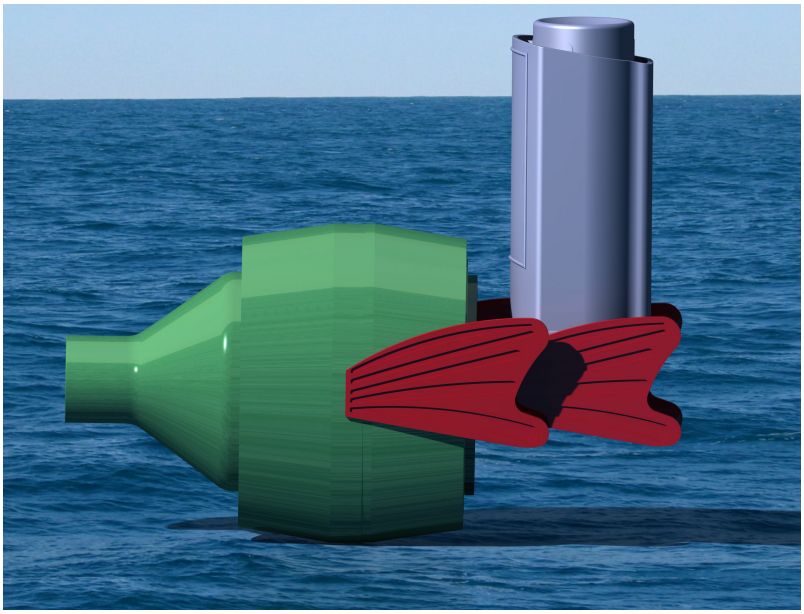


Figure 30: The Pike when it is not in use. Image Source: (GrabCad Community, 2015)

4.5 Prototyping

The results from prototyping were two 3D printed prototypes. All physical attributes as well as pictures are presented in *Additive manufacturing, 3D printing* - ***The Pike*** *and Additive manufacturing, 3D printing* - ***Bear 2.0***.

4.5.1 Additive manufacturing, 3D printing - The Pike

With the 3D printing of the CAD-model using the "ZYYX+ 3D Printer", some things did not end up completely as initially expected. Several parts had shrunken to a degree which meant that some parts could not be connected to each other. For example, the connection slot on the backside of the spacer made to fit the back fins. Instead some manual processing was needed, allowing the parts to be connected. With the quality and material from the printer, details that had large curving surfaces in some cases received large amounts of support material. This was specially obvious for the telescopic parts (2),(3),(5),(6) and (7) shown in Figure 28. With the extra support material on the telescopic parts, they had problems moving in relation to each other and had to receive some post touch-up to be smoothed up and function properly.

Figure 31: The Pike - 1 of 2

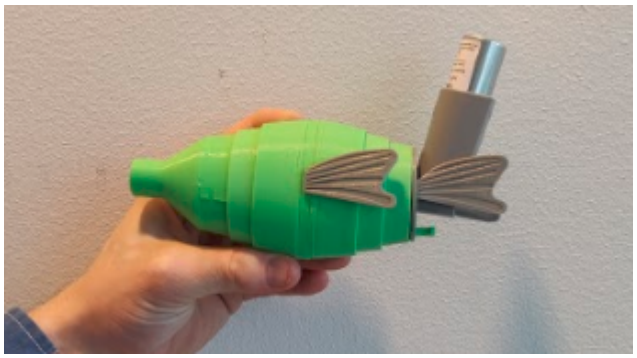


Figure 32: The Pike - 2 of 2

Lastly parts that had elements thinner or smaller than 2 mm together with the quality of the printer in some cases became non-existent or deformed to a degree that removed its main function. This was extra obvious for the telescopic stop part (4), Figure 28, where its inner circle got shrunken to such a degree that it got severely thinner compared to its CAD-model and almost broke during its initial functional testing. As a result a new iteration of the same part was made, where the inner ring was thickened by 150% from 2 mm to 5 mm.

4.5.2 Additive manufacturing, 3D printing - Bear 2.0

The **Bear 2.0** 3d printed prototype has a functioning telescope but the surface is too rough and needs to be corrected in order to get a smooth interaction between the pieces when the telescope is expanded. The inlet worked well but the material that the 3D printer used was too hard which made inserting the inhaler difficult. The dust cap should be made more durable in the connection to the front piece by increasing the dimensions of the material used. In Figure 33, the prototype is shown expanded and with a pMDI connected. The rough surface of the 3D print is visual in some areas. As can be seen the prototype is not transparent as it is intended to be and it should not be in two different colours as it is now neither.

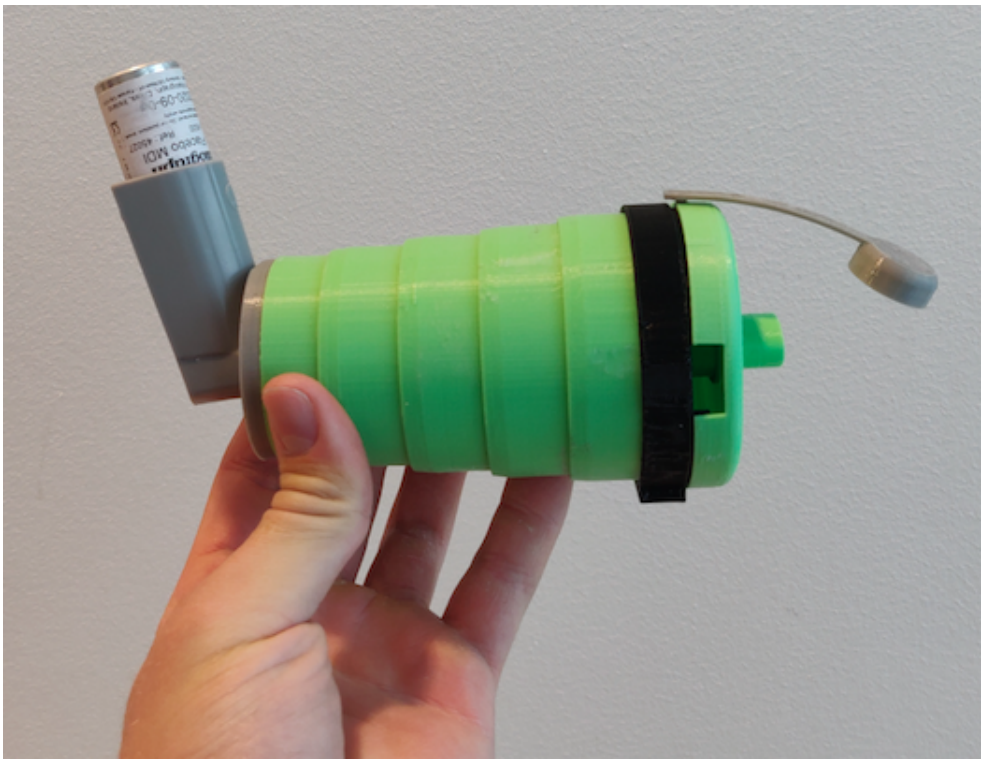


Figure 33: Bear 2.0 prototype expanded with inhaler.

In Figure 34 below the prototype is shown pushed together so that it can be transported but without any inhaler attached. Figure 35 shows the same prototype but with two inhalers attached to the backside via the elastic band attached to the back side.

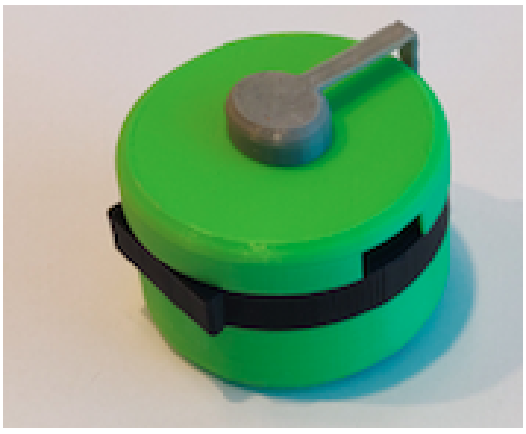


Figure 34: Bear 2.0 prototype in travel mode.

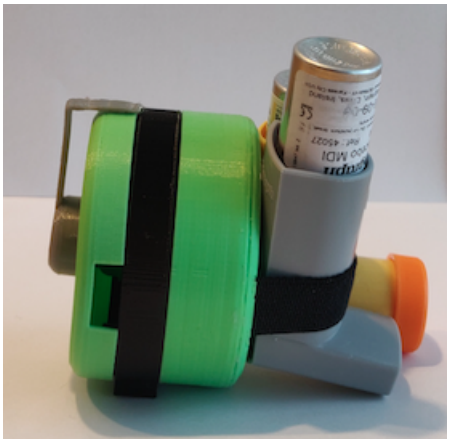


Figure 35: Bear 2.0 with two inhalers attached.

4.6 Physical testing

All test values and results of the prototypes are presented in *Delivered dose testing and Design- and Patient Risk Assessment.*

4.6.1 Delivered dose testing

In Table 12 below, the delivered dose from the spacer prototypes as well as a reference can be seen. All values were measured using the same pMDI product.

Table 12: Delivered dose from the two prototypes measured in percent of label claim.

Test device	% of label claim	Test device	Hold time	% of label claim	Test device	% of label claim	Test device	Hold time	% of label claim	Test device	% of label claim
pMdi product	99.4	"Bear 2.0"	0 sec	64.9	pMdi product	98	"The Pike"	0 sec	54.7	pMdi product	96.7
pMdi product	97.6	"Bear 2.0"	0 sec	65.5	pMdi product	98.4	"The Pike"	0 sec	46.8	pMdi product	97.3
pMdi product	99.8	"Bear 2.0"	0 sec	58.7	pMdi product	96.8	"The Pike"	0 sec	52.7	pMdi product	99.1
pMdi product	98.5	"Bear 2.0"	0 sec	57.4	pMdi product	97.4	"The Pike"	0 sec	45.1	pMdi product	95.6
pMdi product	99.5	"Bear 2.0"	0 sec	56.9	pMdi product	100.3	"The Pike"	0 sec	48.9	pMdi product	100.9
		"Bear 2.0"	5 sec	53.2			"The Pike"	5 sec	66.7		
		"Bear 2.0"	5 sec	55.3			"The Pike"	5 sec	50.6		
		"Bear 2.0"	5 sec	49.2			"The Pike"	5 sec	62.2		
		"Bear 2.0"	5 sec	54.1			"The Pike"	5 sec	56.1		
		"Bear 2.0"	5 sec	50.6			"The Pike"	5 sec	58.1		

Figure 36 below shows the mean values of the delivered dose for both prototypes and for both hold times. The reference was also included and all values are presented in percent of label claim for the given pMDI product. Figure 37 below shows the same data but normalized to reference data regarding *AeroChamber Plus Flow-Wu.*

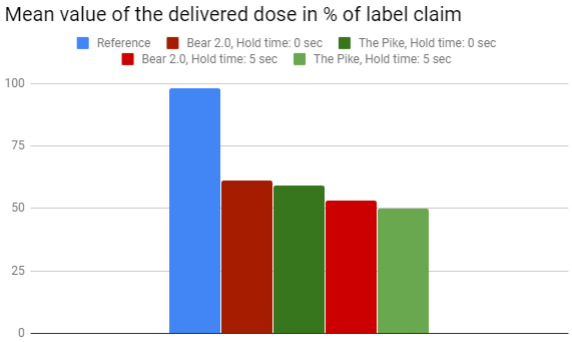


Figure 36: Mean of the test values of both prototypes as well as the reference.

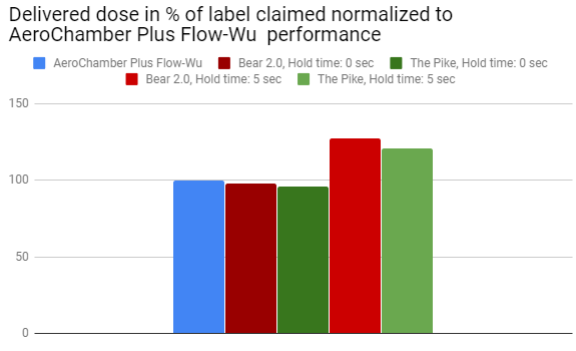


Figure 37: Test values normalized to performance of the *AeroChamber Plus Flow-Wu.*

The results in Figure 37 indicates that both spacer prototypes **Bear 2.0** and **The Pike** performed approximately the same as the reference data with zero seconds holding time. Using five second hold time resulted in a 27 (**Bear 2.0**) and 21 (**The Pike**) percentage

points increased delivered dose from the spacer prototypes compared to the reference data. Potentially explained by the larger volume or by the choice of 3D-printed material.

4.6.2 Design- and Patient Risk Assessment

A few areas for design improvements were located for **The Pike** and **Bear 2.0** concepts during the design risk assessment:

- With a telescope solution it is considered a risk that particles and dust can get stuck on the outer side of the telescope, and when these parts are squeezed together the particles might fall down into the chamber itself, contaminating it. These particles can also in the same way, if stacked upon each other, make it harder to press the parts together during excessive use. - *Applicable to both* ***The Pike*** *and* ***Bear 2.0***
- The inhaler inlet (8) (see Figure 28) was considered to be too "hard" making it difficult with the current material to remove the inhaler without damaging the inlet itself. - *Applicable to both* ***The Pike*** *and* ***Bear 2.0***
- The use of the telescope involves parts, made out of hard plastic, that moves in relation to each other. The daily use was assumed to put wear on the product.- *Applicable to both* ***The Pike*** *and* ***Bear 2.0***
- Even though both solutions were designed to be cleaned in boiling water and be machine-washable (see Figure 13), dirt that might get stuck in between the telescopic parts can be hard to remove.- *Applicable to both* ***The Pike*** *and* ***Bear 2.0***
- **The Pike**'s telescopic parts were considered to have too large of a gap, making it sound clattering, which might give it a toy like impression. - *Applicable for* ***The Pike***
- With the shape of the spacer it was not able to stand on its own when put on a flat surface, which can be inconvenient when stored and not in use. - *Applicable for* ***The Pike***
- There was a possible problem for the **Bear 2.0** that when the telescopic parts were pressed in separately, they could be flipped around, making it hard to get each of them out again without tilting the telescope upside down. - *Applicable for* ***Bear 2.0***
- The mouthpiece connected to the front of the **Bear 2.0** had a telescopic function in order to save even more space when not in use, which was considered unnecessary compared to having it more durable and stiff - *Applicable for* ***Bear 2.0***

The concepts were then evaluated from a patient risk standpoint, where risks regarding how the concepts could affect the patient's health in a negative way during normal use was described. The risks identified were:

- With a telescope design, children with small fingers might be able to stick their

fingers in between the moving parts and accidentally get pinched. - *Applicable to both* ***The Pike*** *and* ***Bear 2.0***

- Secondly, with the current design for both concepts, there were no indicators that show the user whether the telescope is fully extended or not, which in return can mean that the user actuates the pMDI and inhale while the spacer is not fully expanded. - *Applicable to both* ***The Pike*** *and* ***Bear 2.0***
- Lastly, both solutions had at least one part that were smaller than the recommended smallest size for components in children toys (3.2cm in width and 5,7cm long) (United States - Consumer product safety commision, 2019), which in a worst case scenario, means that a kid could get a part stuck in their airways. These recommendations is worth considering even though these are set for children under the age of 3. - *Applicable to both* ***The Pike*** *and* ***Bear 2.0***

4.7 Evaluation

In Table 13, all relevant values presented in previous result chapters are included. Values not applicable for a set model or not being able to be efficiently evaluated was documented by: *N/A* in Figure 13. The *Encouraging design* criteria is evaluated internally by the authors. **The Pike** was given the highest rating based on its design being like a fish. Through having both the shape of a fish, fins, eyes, and encouraging colours, the design was thought to be fun for children to use. The ergonomics of the spacer prototypes were not evaluated because the telescope function with the current prototypes needed further optimization. As can be seen in the *Low amount of separate parts* criterion in the table, both prototypes have more parts than the four established spacer products on the market. The telescope parts adds many pieces which was a big contributing factor to this. The *Visible breath-indicator* was not evaluated in the current concept. The size was comparable between all four established spacer products as well as the two prototypes when the telescopes were expanded. When the telescopes are pushed together **The Pike** was 33 mm shorter than the smallest of the four established spacer products on the market and **Bear 2.0** 81 mm shorter. The weight of both prototypes were weighed with the 3D printed materials which means the weight can differ when using the intended material. None of the prototypes have any valves included yet, which will add weight as well to the finished products.

Table 13: Evaluation matrix.

Interpreted need	Metric	Optichamber Diamond	L'espace	Aerochamber Plus	Vortex	*The Pike*	*Bear 2.0*
Aestethics							
Customizable	Customizable out of the box **(Yes/No)**	No	No	No	No	No	Yes
Encouraging design	Subjective **(1-5)**	2	3	3	2	5	4
Ergonomics							
Physical ergonomics (Child)	Subjective **(1-5)**	3	2	5	3	N/A	N/A
Physical ergonomics (Parent)	Subjective **(1-5)**	3	3	3	3	N/A	N/A
Portability							
Can be reduced in size when not used	**(Yes/No)**	No	No	No	No	Yes	Yes
Keep devices organized	Ability to attach inhalers **(0-2)**	0	0	0	0	2	2
Cleaning							
Dishwashable	**(Yes/No)**	No	Yes	Yes (<70 degrees)	Yes	Yes	Yes
Boilable	**(Yes/No)**	No	Yes	No	Yes	Yes	Yes
Safety							
Non-toxic material	**(Yes/No)**	Yes	Yes	Yes	Yes	Yes	Tes
Resistant towards dust and contamination	Dust protected in both ends ? **(Yes/No)**	No	No	No	No	Yes	Yes
User friendly							
Low amount of seperate parts	Number of seperate pieces **(#)**	4	3	5	5	13	12
Flexible spacer inlet	Compatible with different inhalers **(1-3)**	2	2	2	3	3	3
Intuitive design	Subjective **(1-5)**	5	4	5	5	3	4
Visible breath-indicator	**(Yes/No)**	Yes	No	Yes	No	N/A	N/A
Performance							
Delivered dose	Amount of drug leaving the spacer **(% of Aerochamber performance at 0 sec hold time and at 5 sec hold time)**	N/A	N/A	100 and 100	N/A	96 and 121	98 and 127
Physical Attributes							
Small size (Maximum Length, diameter/largest width)	**mm**	142x52	135x62	133x45	160x50	100x69,5	52x67
Maximum length when expanded, diameter/ largest width	**mm**	142x52	135x62	133x45	160x50	137x69,5	130x67
Lightweight construction	**g**	57	66	45	62	64 *	91 *
Approriate chamber volume (Litres)	**mL**	140	204	145	200	192	273
Manufacturing							
Sales cost (includes mask)	**SEK/unit**	414	339	499	459	N/A	N/A
Contains recyclable material	**(Yes/No)**	Yes	Yes	Yes	Yes	Yes	Yes
Material							
Anti-static material	**(Yes/No)**	Yes	Yes	Yes	Yes	Yes	Yes
Transparent material	**(Yes/No)**	Yes	Yes	Yes	No	No	Yes

5 Discussion

Both the **The Pike** and the **Bear 2.0** compared to the four prescribable products in the West Sweden Region ended up with more separate parts as a result of having a telescopic design which in return can be a design risk when it comes to durability. However, by having more parts in a telescopic solution means that a spacer is able to be compressed to a bigger extent making them even more portable. With a spacer being compressible it is easier to follow the guidelines given by "West Sweden Region health authorities" (Allergi-Andning-ÖNH, 2016) when it comes to an increased recommended volume without having to create a bulky spacer.

Bear 2.0 was the heaviest of the products compared to **The Pike** and the four commercial products (see Figure 13). But at a difference of 25 grams compared to the second heaviest product, was considered negligible from a user's ergonomic perspective. The **Bear 2.0**'s increased weight is directly connected to its increased volume and fulfillment of the recommended volume (Allergi-Andning-ÖNH, 2016). **The Pike**'s volume was in the end still below the recommended one, which had its reasons. With the solution being made out of two telescopes instead of one, meant it had less potential of being as compressible as the **Bear 2.0**, unless adding additional separate telescopic parts to the concept and reducing each telescopic parts length. The concept was also planned to not be longer during use than the four established products (see Table 13) and had a desired shape which in the end resulted in a volume of 192ml for **The Pike**, comparable to today's products.

The encouraging design aspect was evaluated by the authors using knowledge gathered from the pre-study. With continued work the aim is to evaluate the designs through customer feedback to know what the customers like and dislike about them. The designs can later be improved based on the feedback. Preferably feedback should be collected from both parents as well as children in the right age span. The first step could be interviews conducted with parents together with their children. Even more feedback could be collected through surveys to get feedback from a larger group of individuals. The literature shows that novel designs such as the Funhaler (see Figure 7) improves the willingness of children to use the spacer but only for a limited amount of time (Nikander et al., 2014). This raises the risk that a design such as **The Pike** may be really exciting at first but later lose the long-term appeal. Future work could revolve around electronic apps which can give the user the possibility to change the encouraging part of the spacer when he or she loses interest in it. One way we tried to take in to account the fact that children lose their interest over time was with the **Bear 2.0** design. With the **Bear 2.0** design, the user can change the theme as the child lose interest. The visual effect of a picture compared to the whole spacer being in the shape of an animal is however thought to not be as encouraging for the child but this too is something to be evaluated by customer feedback in the future.

Adding extra steps in order to use a product, such as in the case of adding a telescope, puts extra emphasis that the product is as intuitive as possible. As was highlighted in the design and patient risk assessment, it is not obvious when the telescope is fully expanded making it possible that users get confused. One discussed solution was to add markings or a pattern that clearly indicates when the telescope is fully deployed. Other solutions such as adding mechanical stops similar as used in crutch pins is also possible but must be examined further. One way used to make the designs as intuitive as possible was to include a QR-code on both designs, this was however kept at a concept level. The **Bear 2.0** also includes an instruction on the back piece. To finally evaluate how the users perceive the design, and how intuitive it is, a human factors studies could be performed to show areas of improvement.

The telescope function requires other optimization and testing that are not directly related to intuitive design. Some sort of mechanism that locks the parts in-to place when it is expanded but that also makes sure it can be pushed together easily when inhalation is finished is needed. The effect of the parts sliding relative to each other over and over again should also be examined. As highlighted in the design and patient risk assessment, the friction could potentially lead to wear on the material. This wear can affect the visual look, the function of the telescope making it less prone to stay in expanded position and finally also cause particles from the plastic material to end up within the spacer. Spacer prototypes should be made with the right material and be tested for wear during a typical life cycle by calculating how many times a day the typical patient uses it and multiplying that with at least one years worth of use.

When it came to different feedback systems to measure how well the medication had been performed and help the user's concentration, it was kept at a concept phase. A conceptual solution was developed which included a pressure sensor connected to light diodes, but where the concept was not fully developed to suit each concept and thus not included into CAD-drawings. Next step is to further test the functionality within each prototype and the concept itself, but as this was delimitation this was not investigated further within this thesis.

With the concepts current telescopic solutions that were made in hard plastics, they ran the risk of the chambers being contaminated during use as it is still a little bit of space in between each part to allow for movement. Solutions mimicking the plastic cup, see Figure 18, would remove this issue and would be interesting to investigate further. It would, however, have to be made out of a somewhat stiffer material to be able to keep the structure when being used. However this solution was not chosen to be included in the finals concepts because of the many uncertainties like how well the structure would hold during use and its perceived bad optical capabilities.

During this thesis a few things could have been done different in retrospect. When it came to the patent landscape search, a high number of useful patents was gathered to

use as inspiration prior to the brainstorming sessions. However, with the initial patent search resulting in a total of 318 patents and with the limited time meant that each patent could not be examined to the same extent as if the search would have been more specific in its choice of keywords and reduced amount of patent results. With a more restrictive search, time could have been saved and each patent more thoroughly examined and documented. The drawback would be the risk missing out on important patents not discovered in a potential limited search.

During the concept selection phase a high amount of concepts were gathered resulting in the 28 complete concepts described in the elimination matrix, see Table 8. With the high amount of complete concepts entering the elimination matrix the filter had to be very strong, which with the set requirements the matrix showed not to be. In retrospect more concepts could have been eliminated prior to the eliminations matrix with the addition of using the multi-voting technique (Ulrich and Eppinger, 2012). The multi-voting technique involves that each person in the team get to vote for a set amount of concepts by giving out dots to the once preferred and later proceed with the set amount of concepts given the most dots and ideally result in a maximum of 12 concepts entering the elimination matrix.

To generate even more ideas from the concept generation phase, a visit to an inhalation chamber fair showing off newly developed spacer solutions could have been useful. Not only to gain inspiration but also to through own testing figure out things to avoid integrating into the spacer itself.

6 Conclusion

Two physically prototyped spacers have been developed that includes a telescope solution in order to be reducible in size when not in use and elements that encourages the children to use them, as these aspects are not taken into consideration by products currently on the market.

To make the two concepts in to commercially viable products the telescope must be optimized. There are still some question marks regarding both how intuitive the designs are but also how the concepts will hold up over time. Further evaluation is required. To develop the two concepts into complete products that can compete with the four already established products, the sensor system has to be developed from a concept phase to a functioning system.

Both concepts show promise and have different strengths compared to the requirements list. **The Pike** potentially has a more encouraging design than **Bear 2.0**, which is more optimized when considering the volume and size for transport. With extra feedback from customers, an informed decision can be made to decide which concept shows the most promise for future development.

Through the testing phase it was concluded that both **The Pike** and **Bear 2.0** are in one measurement performing better, and in other similarly well compared to one main commercial options, which in this case was the *AeroChamber Flow-Wu* in regards to delivered dose.

With a total length of 52 mm for the **Bear 2.0** and 100 mm for **The Pike** means that they are 61% respectively 25% smaller than the smallest of the four established product, which is *AeroChamber Flow-Wu*, when they are not in use.

Both solutions provide a novel way to store additional devices on their body, improving the spacer's user-friendliness, as many users have several devices, which was shown in the interviews. These solutions however need to be further optimized prior to commercialization. The designs of both spacer concepts have the potential to have a more encouraging design than the four already established products but this has to be verified through additional interviews and surveys.

7 Future Recommendations

- Conduct additional interviews and surveys with customers to get feedback regarding encouraging design.
- Evaluate how the designs are perceived in a human factors studies to be able to ensure an intuitive design.
- Develop the telescope functionality in terms of usability and make an assessment of the wear during a life cycle.
- Develop a pressure sensor system that is specially designed for both prototypes and to verify its ability to measure the quality of the inhalation flow.
- Investigate optimal materials and manufacturing processes for both concepts to ensure quality at a competitive price.
- Determine which of the two concepts are the one to push towards commercialisation based above recommendations.

References

AAAAI (2019). Dry powder inhalers definition. https://www.aaaai.org/conditions-and-treatments/conditions-dictionary/Dry-Powder-Inhalers. Accessed: 2019-02-15.

Allergi-Andning-ÖNH, R. T. (2016). Regional terapigrupp allergi-andning-Önh. https://alfresco.vgregion.se/alfresco/service/vgr/storage/node/content/workspace/SpacesStore/8080e751-6b3f-42aa-8849-3402a72849b3/Val%20av%20spacer%20vid%20f%C3%B6rskrivning%20av%20sprayinhalator%20-%20utvidgat%20terapir%C3%A5d%20170124.pdf?a=false&guest=true. Accessed: 2019-03-02.

Almefelt, L. (2018). Systematic design - overwiew. https://pingpong.chalmers.se/courseId/8803/node.do?id=4353422&ts=1516018979816&u=-908341140. Accessed: 2019-02-19.

Amaral, M. J. (2014). HCWH Europe report - Non-Toxic Healthcare. (English) [On pediatric pulmonology]. *Pediatric Pulmonology*, 1(1):1–25.

AstraZeneca (2017). Us fda approves symbicort (budesonide/-formoterol) for the treatment of asthma in paediatric patients. https://www.astrazeneca.com/media-centre/medical-releases/US-FDA-approves-Symbicort-budesonide-formoterol-for-the-treatment-of-asthma-in-paed.html. Accessed: 2019-05-11.

AstraZeneca (2019). Our purpose and values. https://www.astrazeneca.com/our-company.html. Accessed: 2019-05-11.

Brockotter, R. (2019). Design rules for 3d printing. https://downloads.3dhubs.com/3D_Printing_Design_Rules.pdf. Accessed: 2019-03-28.

Cukic, V., Lovre, V., Dragisic, D., and Ustamujic, A. (2012). Asthma and Chronic Obstructive Pulmonary Disease (COPD) – Differences and Similarities. (English) [On journal of the academy of medical sciences of bosnia and herzegovina]. *Journal of the Academy of Medical Sciences of Bosnia and Herzegovina*, pages 100–105.

Drugs (2019). Brilinta approval history. https://www.drugs.com/history/brilinta.html?fbclid=IwAR1glkx8pQHAQbXii41jLcsRbJgLbikY92vLALmhMdB43PG5JWXLAde-Dlg. Accessed: 2019-05-11.

Durbin, K. (2019). Brilinta. https://www.drugs.com/brilinta.html. Accessed: 2019-05-11.

Ebay. Ebay. https://i.ebayimg.com/images/g/cnoAAOSwzlRck5VQ/s-l300.jpg. Accessed: 2019-04-02.

Frémont, A., Taam, R., Wanin, S., Lebras, M.-N., Ollier, V., Nathanson, S., Hadchouel, A., and Drummond, D. (2018). Cartoons to improve young children's cooperation with inhaled corticosteroids: A preliminary study. (English) [On pediatric pulmonology]. *Pediatric Pulmonology*, 53(9):1193–1199.

Gerald, J. K., Carr, T. F., Wei, C. Y., Holbrook, J. T., and Gerald, L. B. (2015). Albuterol Overuse: A Marker of Psychological Distress?. (English) [On pediatric pulmonology]. *Pediatric Pulmonology*, 3(6):957–962.

Gibson, I., Rosen, D., and Stucker, B. (2015). *Additive Manufacturing Technologies 3D Printing, Rapid Prototyping, and Direct Digital Manufacturing Second edition*. Springer New York Heidelberg Dordrecht London.

Giraud, V. and Roche, N. (2002). Misuse of corticosteroid metered-dose inhaler is associated with asthma stability. (English) [On research gate]. *European Respiratory Journal*, 19(2):246–51.

GrabCad Community (2015). Generic inhaler. `https://grabcad.com/library/generic-inhaler`. Accessed: 2019-05-11.

Haldorson, E. (2016). Patent searching and analysis: I searching for patents. `https://pingpong.chalmers.se/courseId/8779/node.do?id=4186549&ts=1511370568379&u=-908341140`. Accessed: 2019-04-02.

Iles, R., Lister, P., and Edmunds, A. T. (1999). Crying signicantly reduces absorption of aerosolised drug in infants. (English) [On expert opinion on drug delivery]. *Arch Dis Child*, 81:163–165.

Johnson, A. (2015). Astrazeneca. `https://www.foretagskallan.se/foretagskallan-nyheter/lektionsmaterial/astrazeneca/?fbclid=IwAR0JyNrHXNq_EXPhaK2vz0An0Jt4saJLkNle6wc0bB0Lyr63TGtD9SMLvWo`. Accessed: 2019-05-11.

King, M. D. (2013). A pressurized-medical-metered-dose inhaler pmdi the device comprised of the canister. `https://www.researchgate.net/profile/Maria_King4/publication/259592933/figure/fig11/AS:317196661215258@1452636985392/A-pressurized-medical-metered-dose-inhaler-pMDI-The-device-comprised-of-the-caniste` `png`. Accessed: 2019-04-02.

Lavorini, F. and Fontana, G. A. (2009). Targeting drugs to the airways: the role of spacer devices.. (English) [On expert opinion on drug delivery]. *Expert Opinion on Drug Delivery*, 6(12):91–102.

Linkedin (2019). Astrazeneca. `https://se.linkedin.com/company/astrazeneca`. Accessed: 2019-05-11.

Liu, X., Guo, C., Chowdhury, B., Starke, P., Limb, S., Peri, P., Schroeder, A., and Doub, W. (2017). Valved Holding Chambers and In Vitro Metered Dose Inhaler Performance: Effects of Flow Rate and Inhalation Delay.. (English) [On pubmed]. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*, 30(6):1–12.

Läkemedelsverket - Swedish Medical Products Agency (2017). Information från läkemedelsverket (swedish medical products agency). https://lakemedelsverket.se/upload/om-lakemedelsverket/publikationer/information-fran-lakemedelsverket/Info_fr_LV_2007-1_astma-suppl.pdf. Accessed: 2019-02-15.

Malmqvist, J. (2018). Lecture 9: Quantitative data collection. https://pingpong.chalmers.se/courseId/8779/node.do?id=4186560&ts=1511370568508&u=-908341140. Accessed: 2019-03-15.

Marshall, H. (2010). How to use your spacer device. https://www.netdoctor.co.uk/conditions/allergy-and-asthma/a6114/how-to-use-your-spacer-device. Accessed: 2019-05-02.

Med24.dk. Med24.dk. https://www.med24.dk/images/large_optichamber-diamond-philips.jpg. Accessed: 2019-03-02.

Momeni, S., Nokhodchi, A., Ghanbarzadeh, S., and Hamishehkar, H. (2016). The Effect of Spacer Morphology on the Aerosolization Performance of Metered-Dose Inhalers. (English) [On advanced pharmaceutical bulletin]. *Advanced Pharmaceutical Bulletin*, pages 257–260.

Nikander, K., Nicholls, C., Denyer, J., and Pritchard, J. (2014). The evolution of spacers and valved holding chambers.. (English) [On journal of aerosol medicine and pulmonary drug delivery]. *Journal of Aerosol Medicine and Pulmonary Drug Delivery*, 27:4–23.

Sheth, P., Grimes, M. R., Stein, S. W., and B.Myrdal, P. (2017). Impact of droplet evaporation rate on resulting in vitro performance parameters of pressurized metered dose inhalers.. (English) [On science direct]. *International Journal of Pharmaceutics*, 528(1-2):360–371.

The Allergy Shop (2010). Funhaler mask. https://www.theallergyshop.com.au/funhaler-mask/2019-05-21. Accessed: 2019-05-21.

Tidy, D. C. (2018). Asthma inhalers. https://patient.info/chest-lungs/asthma-leaflet/asthma-inhalers. Accessed: 2019-03-15.

Times Of Market (2019). Global dry powder inhalers market analysis 2019 – 3m, aerovance, boehringer ingelheim, chiesi, cipla, civitas/alkermes. http://timesofmarket.com/81148/

global-dry-powder-inhalers-market-analysis-2019-3m-aerovance-boehringer-ingelheim-c Accessed: 2019-05-21.

Trigo, J. (2016). How to use a metered dose inhaler (mdi) with spacer. https://www.pharmaceutical-journal.com/learning/learning-article/how-to-help-patients-optimise-their-inhaler-technique/20201442.article?firstPass=false. Accessed: 2019-05-02.

Ulrich, K. T. and Eppinger, S. D. (2012). *Product Design and Deveopment: 5th edition.* McGraw-Hill.

United States - Consumer product safety commision (2019). Small parts for toys and children's products business guidance. https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Small-Parts-for-Toys-and-Childrens-Products. Accessed: 2019-05-27.

UseInhalers (2012). Comparative studies on metered dose inhalers and dry powder inhalers. http://use-inhalers.com/comparative-studies-on-mdi-and-dpi. Accessed: 2019-03-02.

Vincken, W., Levy, M. L., Scullion, J., Usmani, O. S., Dekhuijzen, P. R., and Corrigan, C. J. (2018). Spacer devices for inhaled therapy: why use them, and how?. (English) [On erj open research]. *ERJ Open Research*, 4(2):1–10.

Wallgren, P. (2017). Methods to support analysis from data to requirements. https://pingpong.chalmers.se/courseId/8779/node.do?id=4211277&ts=1511966450610&u=151611464. Accessed: 2019-04-23.

Watt, P. M., Clements, B., Devadason, S. G., and Chaney, G. M. (2003). Funhaler spacer: Improving adherence without compromising delivery.. (English) [On research gate]. *Archives of Disease in Childhood*, pages 579–581.

Appendices

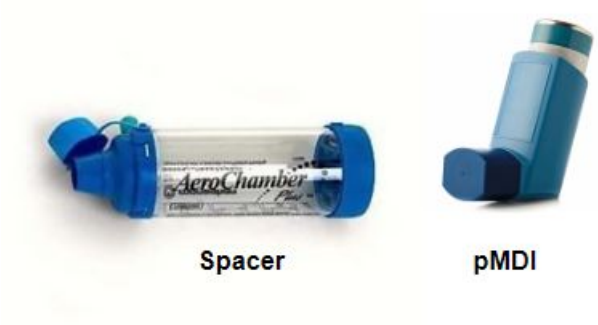
A Survey

Inhalation spacer for children

This questionnaire is about the usage of the inhalation chamber, also called a "spacer", together with a pMDI (pressurized metered dose inhaler) device.

*Required

1. **Does your child currently use or has used a pMDI?** *



Mark only one oval.

- ◯ Yes
- ◯ No *After the last question in this section, stop filling in this form.*

2. **Gender of your child?** *

Mark only one oval.

- ◯ Boy
- ◯ Girl
- ◯ Other

3. **What is the age of your child?** *

Mark only one oval.

- ◯ 0-2 years old
- ◯ 3 years old
- ◯ 4 years old
- ◯ 5 years old
- ◯ 6 years old
- ◯ 7-9 years old
- ◯ 9+ *After the last question in this section, stop filling in this form.*

4. **Does your child currently use or has used any kind of spacer?** *

Mark only one oval.

- ◯ Yes *Skip to question 6.*
- ◯ No *Skip to question 5.*

Usage

5. **Why does your child not use a spacer? Please fill in all correct answers.** *
   Tick all that apply.

   - ☐ Not aware of its benefits
   - ☐ Difficult to use
   - ☐ Unpractical (Hard to bring outside of home etc.)
   - ☐ Feels uncomfortable with the design
   - ☐ Other: _____

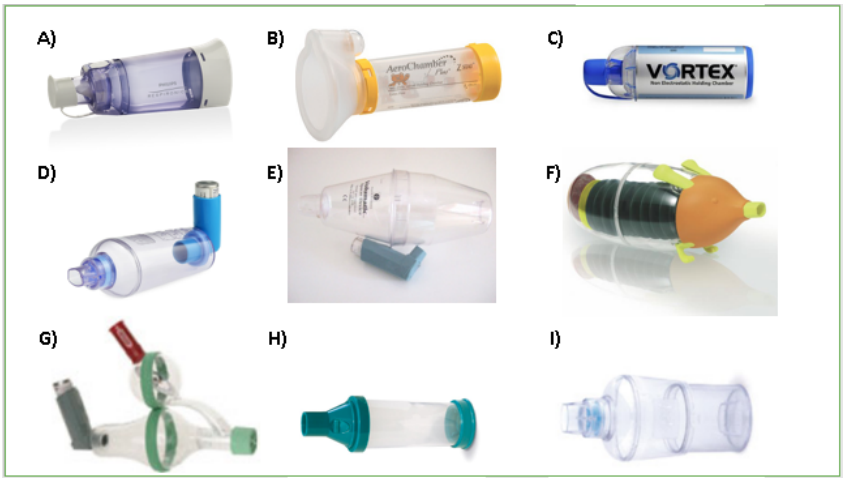
Stop filling out this form.

Usage

6. **When the pMDI is used, how often do you use the pMDI together with a spacer?** *
   Mark only one oval.

	1	2	3	4	5	
Never	◯	◯	◯	◯	◯	Always

7. **What spacer model is your child currently using? If more than one type, please mention all models.** *



Tick all that apply.

- [ ] A
- [ ] B
- [ ] C
- [ ] D
- [ ] E
- [ ] F
- [ ] G
- [ ] H
- [ ] I
- [ ] Other type

8. **Under what circumstances has your child experienced discomfort during usage of the spacer? Please fill in all correct answers. Your child has** *

Tick all that apply.

- [ ] Felt embarrassed around their friends/people outside the familly
- [ ] Found the spacer "scary"
- [ ] Felt uncomfortable during inhalation
- [ ] Not experienced any discomfort
- [ ] Other: _____

9. **Where have you and your child medicated with the help of a spacer in the last month? Please fill in all correct answers.** *
   Tick all that apply.

   - [ ] At home
   - [ ] At kindergarden
   - [ ] Connected to sports/recreational activeties
   - [ ] At social events (friends, parties, relatives and public transport e.g.)
   - [ ] Other: _____

10. **Has it ever happend that you intentionally did not bring the spacer with you beacause of its size?** *
    Mark only one oval.

    - ◯ Yes
    - ◯ No

11. **Would you be open to have integrated electrical components with the spacer if it improves its user performance, e.g. getting a correct dose facilitated??** *
    Mark only one oval.

    - ◯ Yes
    - ◯ No
    - ◯ No opinion

12. **Does your child like the aesthetics of your current spacer?** *
    Mark only one oval.

    - ◯ Yes
    - ◯ No
    - ◯ No opinion

13. **Does your child find the spacer ergonomically friendly to hold while using it?** *
    Mark only one oval.

    - ◯ Yes
    - ◯ No
    - ◯ No opinion

14. **As a parent, do you find the spacer ergonomically friendly to hold when assisting your child?** *
    Mark only one oval.

    - ◯ Yes
    - ◯ No
    - ◯ No opinion

15. **How important are the following features to you in a new spacer? Grade them separately (1=not important, 4 = very important)** *

Mark only one oval per row.

	1	2	3	4
Ability to reduce spacer size, when not in use, without any decrease in performance.	◯	◯	◯	◯
Additional feedback system that measures how well your child inhales.	◯	◯	◯	◯
More attractive design.	◯	◯	◯	◯
Dose reminder function	◯	◯	◯	◯

16. **Please, mention below any improvements/functions that you would like to see included in the next generation's spacer:**

B Interview guide

Parents

Structure - What do we need to understand?	Questions	Comments
Introduction		
	How old is your child? - And how long have they been using the spacer system?	
	What type of spacer do your currently use (Show picture of spacers)? - Why did you buy this specific one? - Have you used any other model prior to this? Why did you decide to change?	
Daily routines		
Medication habits	How does your medication routines look like? - Only at emergency situations or? - What times do you usually take it? - How long does it take? - In what context? - How often (daily, several times, in emergency etc.)	
Usage	Can you describe the usage procedure of the spacer system? - Is the pMDI inserted within the spacer while shaking the inhaler?	
	How did you learn how to use the spacer system? - Did you read the instructions before usage? - Was the instructions hard to follow? - Why/why not? - How would you have liked the learning process to be? - Have you seen any instructional videos?----- - When you changed spacer, did you look at the new spacers instructions?	X
	Is there any time during the day where you or your child is resistant in using the spacer system? - If yes, why is that?	To understand how resistant people are in using it dependent on social environment.

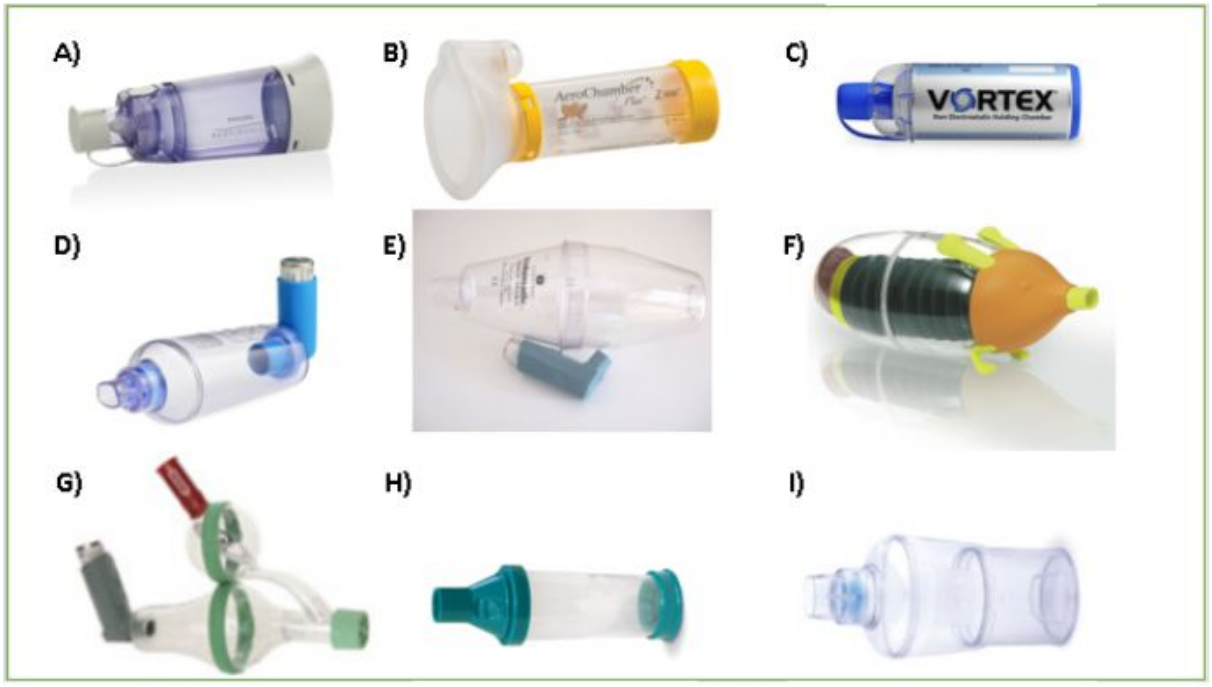
	If your child cries*/protest* during usage, what do usually do to make them calm down and improve the inhalation?	
Portability	Do you always bring the spacer with you when travelling with your child? - How do you usually pack it?	
Cleaning of system	How do you usually clean the spacer system? - How long does it usually take? - How often do you clean it?	
Design		
Functionality	What do you think about your current spacer's design? - What makes it a good solution? - What do you dislike about it? - What can be improved? -	
Aesthetic	What do you think about your current spacer's design? - What makes it a good solution? - What do you dislike about it? - What can be improved?	
Toys	What toys does your child mostly use at home and why do they enjoy playing with them?	X
	Do your child have a own smartphone? - What games do they play?	
Areas of improvement	Is there any additional functions you would like to see in a future product?	
Sensor /feedback system	Today's inhalers does in some cases have integrated feedback system, e.g. dose counter, inhalation confirmation and if dose has been taken.	
	- What do you think about having integrated electronics in the spacer system? - What, else than the previously mentioned metrics, would be of interest for you as a parent?	

Medical personnel

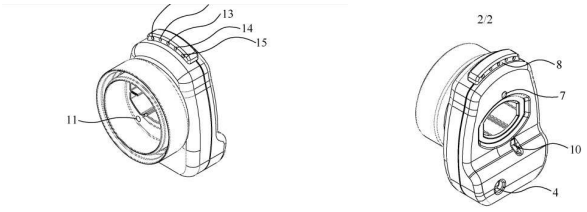
Structure - What do we need to understand?	Questions	Comments
Introduction		
	What is the typical age for children that are using a spacer? - When do they typically stop using it? - At what age would you recommend for a child to stop using facemask?	
	What type of spacer is most commonly used/recommended (Show picture)? - Why would you recommend this specific one? - Is there a spacer type from the picture above you are trying to convince patients to avoid or any other type, if so, why is that?	
Daily routines		
Medication habits	At what times do they usually take their medicine? - How long does it usually take? - How often (daily, several times, in emergency etc.) - In what context? - What is the main hurdles and concerns patient usually have using the pMDI and spacer system? - What is the balance between pMDI and nebulizer treatment in the age of 3-6 years? - In what cases would you recommend nebulizer treatment instead of pMDI together with spacer?	
Usage	Can you describe the usage procedure of the spacer system? - In what way do you teach your patients? - Do you give links to videos etc.? - Do you usually have a follow-up meeting regarding usage? And in that case why is that? - What is the most common mistake patients do with the spacer system?	

	How did you learn how to use the spacer system? - Did you read the instructions? - Was the instructions hard to follow? - Why/why not? - Is there any follow up education for you regarding usage? - How would you have liked the learning process to be?	
	Do you know any times or situations when children or their parents is resistant while using the spacer system? - If yes, why is that?	To understand how resistant people are in using it dependent on social environment.
	If the child cries*/protest* during usage, what would you recommend for a parent to usually do in order to make them calm down their child and improve the inhalation?	
Portability	Do you have any recommendation regarding the transportation of the spacer? - Do you recommend having external protection for the spacer when travelling?	
Cleaning of system	How do you usually recommend cleaning the spacer system? - How long does it usually take? - How often should they clean it?	
Design		
Functionality	What do you think about the current spacer design (the one she most commonly recommends)? - What makes it a good solution? - What do you dislike about it? - What can be improved? - Is there any additional functions you would like to see in a future product?	
Aesthetic	What do you think about your current spacer design(the one she most commonly recommends)? - What makes it a good solution? - What do you dislike about it? - What can be improved?	
Areas of improvement	If you could choose freely to improve or integrate any function into the spacer, what would that be?	
Sensor	Today's inhalers does in some cases have	

/feedback system	integrated feedback system, e.g. dose counter, inhalation confirmation and if dose has been taken.	
	- What do you think about having integrated electronics in the spacer system?	

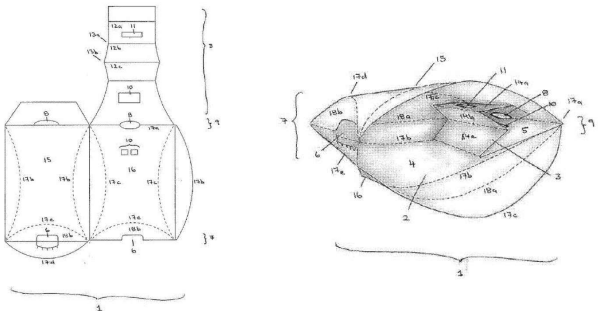

A)
B)
C)
VORTEX
D)
E)
F)
G)
H)
I)

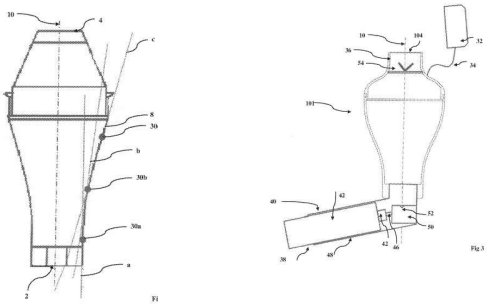
C General patent search



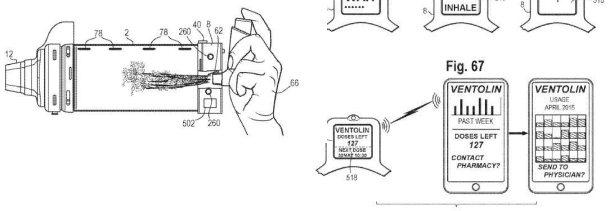
The solution is mountable between the spacer and pMDI and includes a pressure sensor that detects the dispensing of medication between pMDI into the spacer at which rate and volume of air when being used.

Collapsible disposable spacer for metered dose inhalers - AU2016902049A



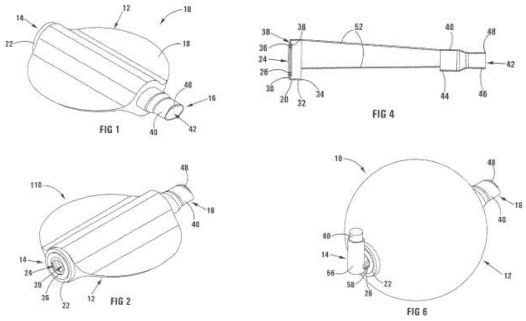


Smart valved holding chamber - US62338798P/US62366327P



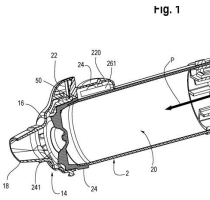
The spacer solution include a activation detector, display and flow indication detector.

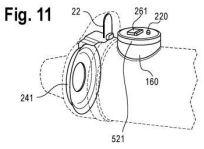
Spacer device for an inhaler - AU2016901448A/WO2017AU50347A



A partly inflatable valveless spacer solution.

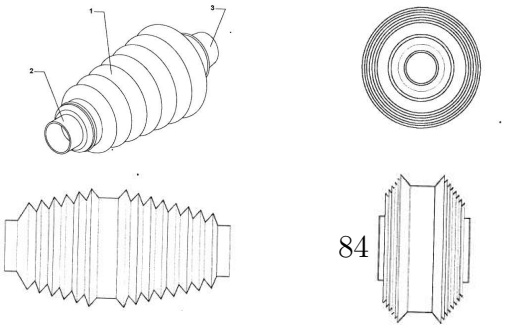
Respiratory care system with electronic indicator - US62312830P





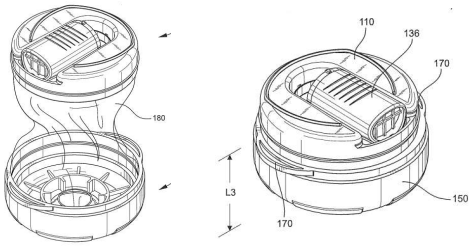
Electronic indication that sends signal in response to the movement of mechanical flow indicator.

Spacer chamber - ARP20150102875A



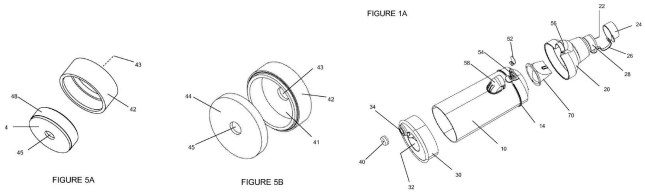
A compressible spacer solution based on zig zag folds.

Inhalation devices and systems and methods including the same - US2012636320P/US2013771406P



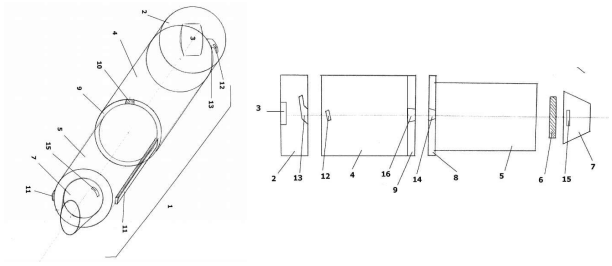
Collapsible spacer solution, with "plastic sleeves" as shell.

Valved Holding Chamber With Whistle for the Administration of Inhalable Drug - US2011498483P



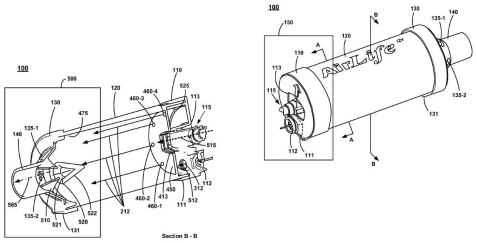
Solution includes a whistle (figure 5A/B above) that makes a sound when the flow is not sufficient .

Asthma spacer - GB20118910A



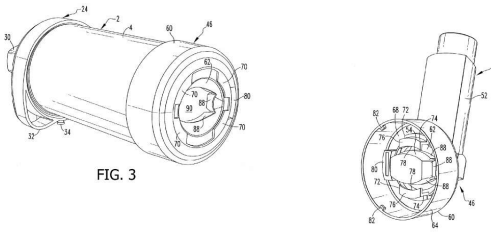
Telescope collapsible spacer solution

Metered dose inhaler spacer - US13077849A



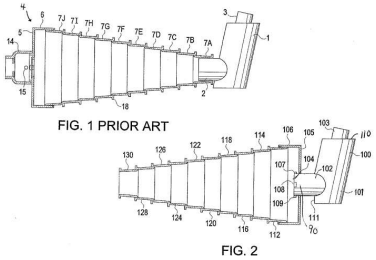
A spacer that includes one-way flow control valve that permits external airflow.

Vavled holding chamber and mask therefor - US2008138541P/WO2009IB55257A



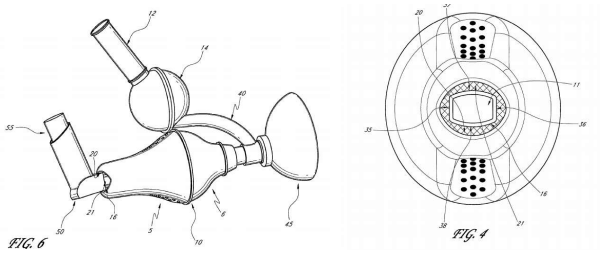
Valved holding chamber with MDI adapter inlet that is hard on the outside and more flexible on the outside. The inlet is shaped in a way that "locks" the inhaler from moving too freely in all degrees.

Extendable spacer device and metered dose inhaler - US2001904701A



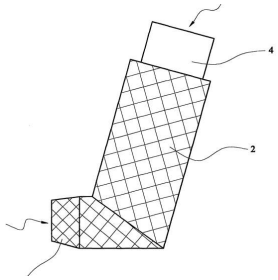
Telescopic spacer solution that can be compressible.

Spacer device - AU20013877A/WO2002AU332A



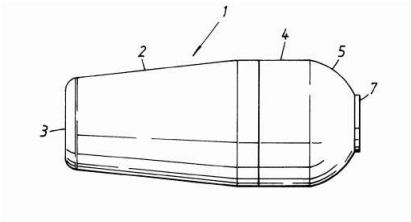
Spacer device with a correlating whistle and playball to increase compliance with kids during inhalation.

Respiratory aid - GB200010995A



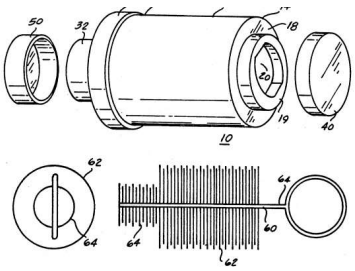
Solution that implements "glow-in dark" element onto the pMDI as aid to easier locate the pMDI in darkness. Can be useful for small solutions.

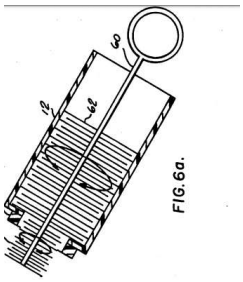
Spacer for use with a metered dose inhaler - SE1994257A



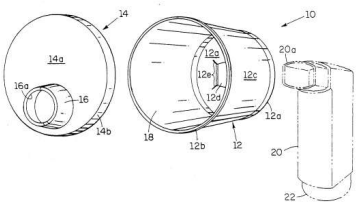
Inhalation chamber that is anti-static and developed for kids.

Metered dose inhaler spacer device and associated cleaning brush - US1991724761A

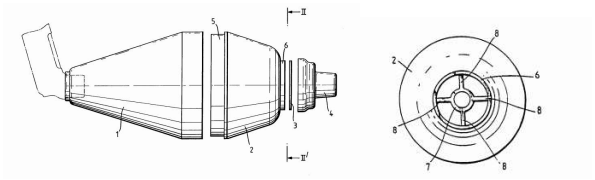




Disposable respiratory medication dispersion chamber - US1989423352A

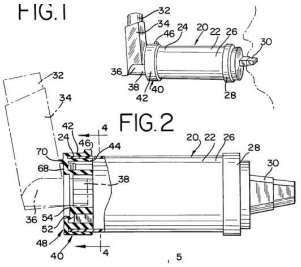


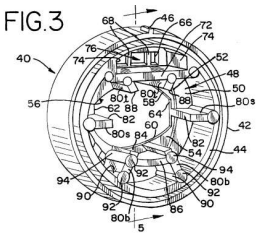
Aerosol holding chamber - GB198915420A



Spacer with a one-way valve that improves the inhalation.

Backpiece for receiving an MDI adapter in an aerosolization spacer - US1994248716A

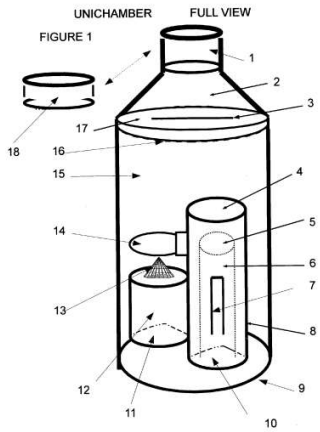




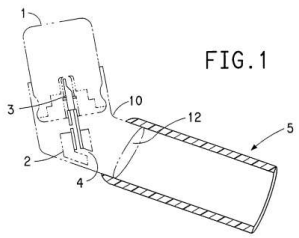
A flexible inlet (figure 3 above) that are supposed to be universally for function for every inhaler.

Add-on that reduce the amount of drug getting stuck in the walls of the interior surface of the spacer.

Unichamber - US2008217490A

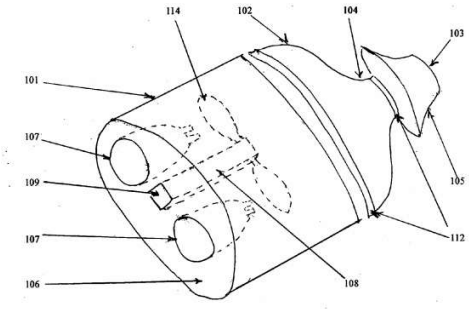


Build-up resistant spacers for metered dose inhalers - US199630152P



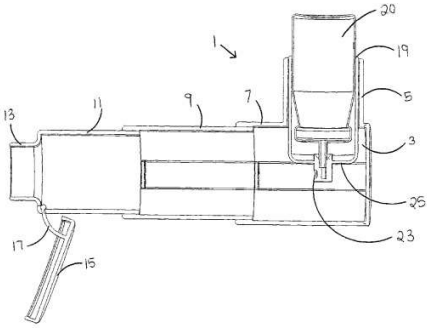
Description: Spacer with a MDI within the first chamber and a flexible latex-free rubber diaphragm seperating to the second chamber (2).

Duo chamber - US2007900020A



Description: The Duo chamber have two connections (107) for pressurized canisters so no need for an additional MDI device.

Spacer/holding chamber for pressurized metered dose inhaler - US2007825086A



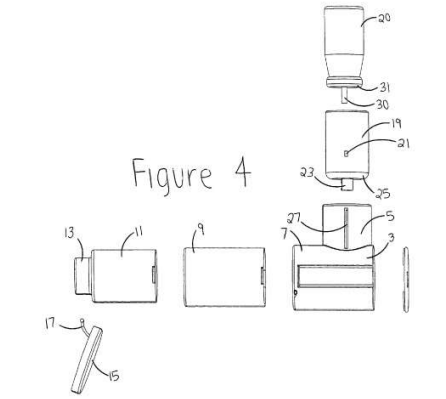
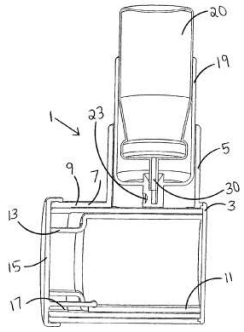
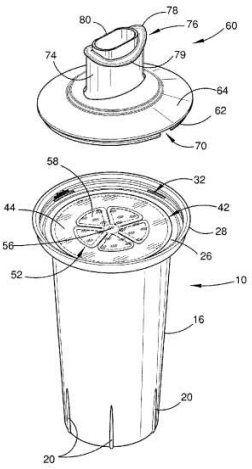


Figure 4

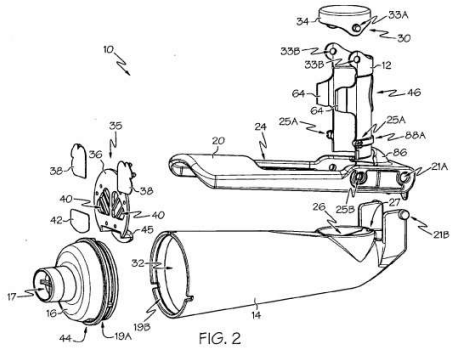


Description: Combined MDI and spacer device which is collapsible.

Inhalation Device - AU2007903524A

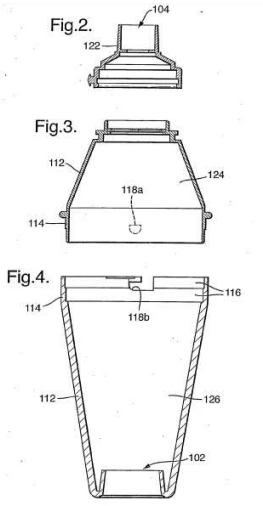


Metered dose inhaler having spacing device - US2005723500P

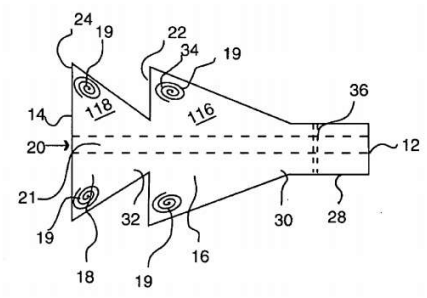


Description: Integrated MDI and spacer device.

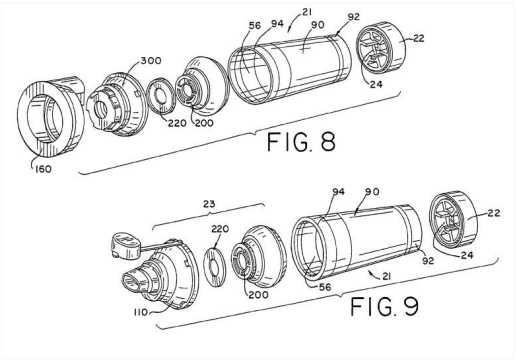
Spacer - IN2004MU1113A, WO2005GB3984A



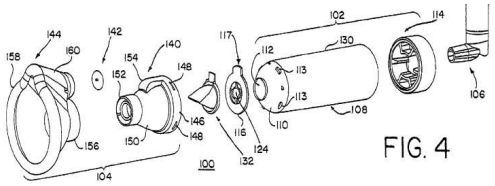
Spacer for delivery of medications from an inhaler to children and breathing impaired patients - US2004775465A



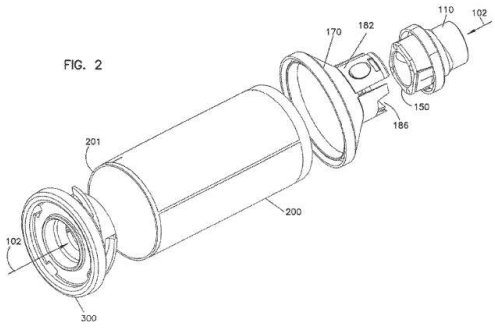
Antistatic medication delivery apparatus - US2003463288P



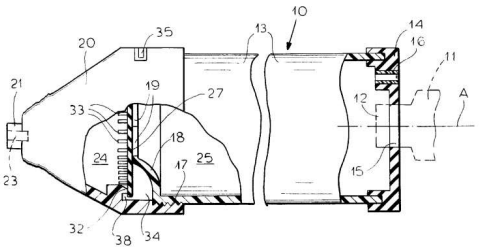
Visual indicator for an aerosol medication delivery apparatus and system - US2002382227P



Aerosol medication inhalation system - US2002137007A



Aerosol holding chamber for a metered-dose inhaler - US1999468381A



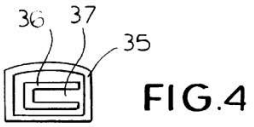
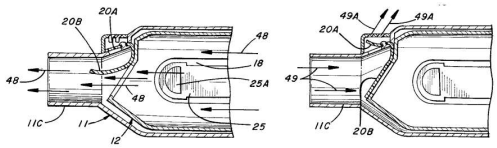


FIG.4

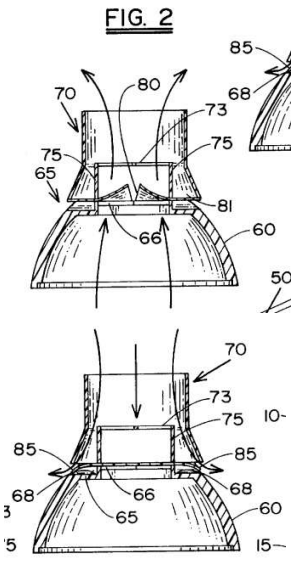
Description: A noisemaker (Fig.4) that makes noise when the user exhales to make sure the lungs are as empty as possible before actuating the medicine and inhaling.

Portable chamber for metered dose inhaler dispensers - US199828260A



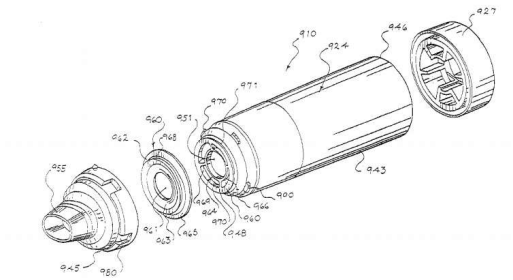
Description: Inhalation and exhalation valve.

Aerosol medication delivery apparatus and system - US1997938686A, US1999287997A



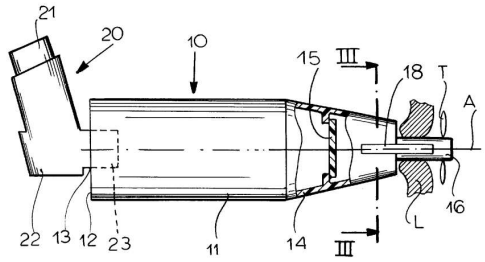
Description: Inhalation and exhalation vent in the same part.

Aerosol holding chamber for a metered-dose inhaler - US1997946985A



Description: Valve that permits medication to come out of the spacer but at the same time prevents backflow into the chamber.

Metered dose inhaler cloud chamber - US199831867A



Description: Another type of mouthpiece.

D Functional patent search

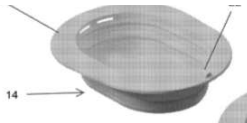


FIG. 6

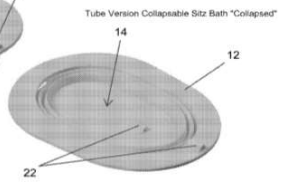


FIG. 7

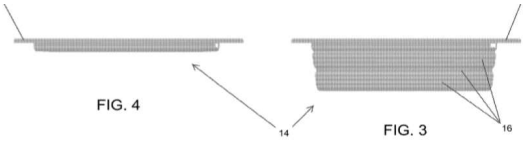
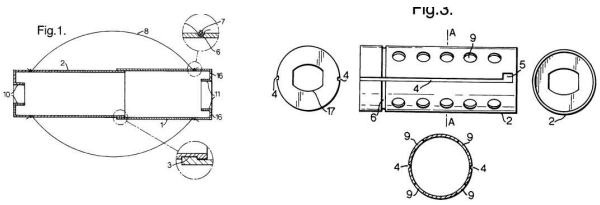


FIG. 4 FIG. 3

Description: Bath tub for sitz baths that is placed inside the toilet bowl. It can be folded and is made out of silicone or something similar.
GB2412325

A portable spacer for use with inhalers - GB2412326



A telescope solution allowing the two tubes parts to be inserted into each other making it more portable. The solution also includes a inflatable neoprene "bag" around it.

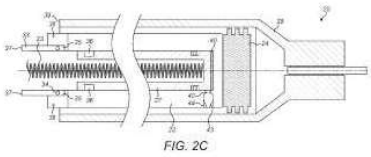


FIG. 2C

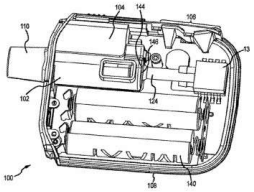


FIG.1A

Feedback mechanism for an injection device - WO2018082891

The solution provides indicator that provides feedback when a specific set of volume of fluid has passed the chamber. The syringe solution includes a squared outlet that proves a sound after the specific set of volume have passed through syringe.

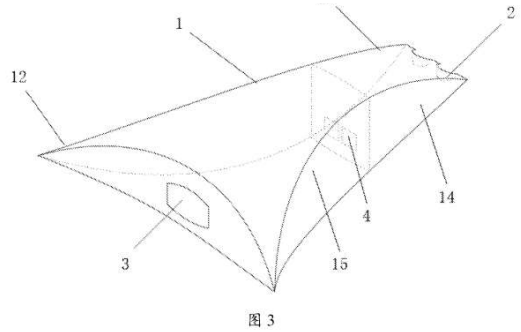


图 3

Description: Foldable spacer.
Feedback system (physical)/indikaton

Aerosolization system with flow restrictor and feedback device - US2018021530

The solution inside the dry-powder inhaler includes a feedback system that vibrates when the person inhales with enough flow rate within a set range. If the patient inhales to strong, a second indication is shown.

E Concept combination table 2 results